To the Minister for the Environment

By a decision at the Government meeting of 15 October 1998, the Government authorized the Minister for the Environment to commission a special investigator to submit proposals for the implementation of new guidelines on chemicals policy (Dir. 1998:91).

The Committee has adopted the name of the Committee on New Guidelines on Chemicals Policy (M1998:09).

With the support of the authorization of 15 October 1998, former Director-General Arne Kardell was appointed on 18 December 1998 as special investigator. The following persons were appointed as specialists: Director-General Gunnar Bengtsson (from 18 December 1998), Director and Associate Professor Cynthia de Wit (from 18 December 1998) and Director Environmental Affairs Lena Gevert (from 22 February 1999).

The following persons were appointed as experts to assist the Committee: Legal adviser Egon Abresparr (from 19 March 1999), Associate Professor Håkan Björndal (from 19 March 1999), Scientific adviser Dr. Sten Flodström (from 19 March 1999), Associate Professor Sven Ove Hansson (from 26 April 1999), Director Mikael Karlsson (from 15 June 1999) Principal Administrative Officer Birgitta Melin (from 29 September 1999) Executive Vice President Anita Ringström (from 19 March 1999), Deputy Director Eva Sandberg (from 19 March 1999), Desk Officer Maria Sandqvist (from 1 November 1999), Professor Mats Tysklind (from 19 March 1999) and Desk Officer Gia Wickbom (from 19 April 1999).

Desk Officer Mona Blomdin Persson was appointed Principal Secretary (from 8 February 1999). Associate Professor Peter Sundin (from 1 May 1999) and Senior Technical Officer Ingela Andersson (from 1 June 1999) were appointed secretaries. Desk Officer Kristian Seth (from 1 June through 29 October 1999), Student Jennie Jansson (from 7 February 2000 through 30 April 2000) and Legal Adviser Åsa Wiklund

Fredström (from 17 January 2000 through 19 March 2000) have also been secretaries on the Committee.

Jessica Karlsson (from March 1999 through August 1999), Eva Pettersson (from August 1999 through March 2000) and Marika Kallio-Göthlin (from March 2000) have been assistents to the Committee.

The specialists have not submitted any special statements. The Committee has decided that experts may not make special statements.

We hereby turn over our report ”Non-hazardous products – Proposals for implementation of new guidelines on chemicals policy” (SOU 2000:53).

We will continue our work to review the future direction, resources etc. of the National Chemicals Inspectorate in accordance with the additional terms of reference of 18 May 2000.

Stockholm, June 2000

Arne Kardell

/Mona Blomdin Persson
Ingela Andersson
Peter Sundin

Contents

Glossary

Abiotic degradation	Degradation of a substance due to the influence of light, heat, water etc., in contrast to biotic degradation.
Adsorption	Binding to surfaces, e.g. soil particles.
Anthropogenic emissions	Emissions caused by man.
Bioaccumulation	Accumulation of a substance in organisms in higher concentrations than in the surrounding environment or food.
Bioavailability	Availability for uptake in living organisms.
Bioconcentration	Accumulation of a substance in organisms in higher concentrations than in the surrounding environment.
Bioconcentration factor	A measure of the bioaccumulation potential of a substance that only takes into account uptake from the surrounding environment.
Biodiversity	Diversity of species, biological diversity.
Biomagnification	Increase in the concentration in organisms of a bioaccumulative substance moving upwards in the food chain, for example from prey to predator.
Biomarkers	Measurable changes in living organisms that are exposed to toxic substances. The changes do not have to be harmful in themselves.
Biotic degradation (biodegradation)	Degradation of a substance due to the influence of living organisms.
Carcinogen	Substance that can cause cancer.
CE marking	Marking of products that satisfy the requirements established in product directives in the EU.
CMRH substances	Substances which are carcinogenic, mutagenic, reproduction-toxic or endocrine-disruptive
CMR substances	Substances which are carcinogenic, mutagenic or reproduction-toxic.
Data	Here: particulars on a substance’s inherent properties (e.g. toxicity), uses, etc.
Desorption	Opposite of adsorption.

Ecotoxicology	Describes how toxic substances affect ecosystems.
Ecotoxic properties	The potential of a substance to harm the environment (plants and animals).
Emissions	Releases to air (and sometimes other media).
Endocrine effects	Hormone-disruptive effects.
Endocrine systems	Hormone systems.
Epidemiological	Referring to studies of exposed groups of people.
Eutrophication	Over-enrichment with nutrients.
Genotoxicity	Potential of a substance to cause damage to genetic material.
Glycerides	Fatty substances based on glycerol.
Green Paper	In the EU: The European Commission's documents intended to stimulate debate and launch a process of consultation at European level on a particular topic (such as social policy, the single currency, telecommunications). These consultations may then lead to the publication of a White Paper, translating the conclusions of the debate into practical proposals for Community action.
Halogens	The elements fluorine, chlorine, bromine and iodine.
In vitro study	A study performed in test tubes (as opposed to an *in vivo* study performed in a living organism).
Chemical products	Category embracing chemical substances and preparations of chemical substances. A Swedish concept.
Chemical substances	Chemical elements and their chemical compounds.
Congeners	Substances that are members of a group of organohalogens with the same basic molecular structure but different degrees of halogenation and/or different positions of the halogens. Examples of halogens are chlorine and bromine.
K_{ow}	Partition coefficient between octanol and water. A measure of the fat solubility of a substance. Sometimes called P_{ow}.
Covalent	Bond between atoms in a molecule where the electrons are shared between the nuclei. A

	covalent bond is stronger than an ionic bond.
Life cycle assessment	An assessment of the environmental impact of a product during its entire life cycle (”cradle to grave”).
Mobile substances	Substances that move readily between different parts of the environment.
Mechanistic	Mechanistic research is research that clarifies e.g. the action mechanisms of different substances on the fundamental cellular or molecular level.
Metabolize	Convert in the process of metabolism.
Metabolism	The process of chemical change by which energy is provided in living cells.
Metal speciation	Indicates in what form or forms a metal occurs where it is encountered, e.g. as an element, as an ion or as a particular chemical compound.
Microbial degradation	Degradation of a substance due to the influence of microorganisms.
Monomers	Low-molecular compounds that can be linked together by polymerization to form polymers, i.e. long molecular chains of units with the same structure. Plastics are composed of polymers.
Mutagenic substances	Substances which can cause mutations, i.e. changes in the chromosomes.
Organic substances	Chemical compounds based on compounds of carbon and hydrogen, including compounds where the hydrogen content has been completely or partially replaced by other substances such as halogens. The molecule may also contain other elements, such as oxygen, nitrogen and phosphorus. Organometallic compounds are also included here.
PB substances	Substances which are both persistent and bioaccumulative.
PBT substances	Substances which are persistent, bioaccumulative and toxic.
Persistence	Ability of a substance to resist degradation and thereby be long-lived.
Persistent	Poorly degradable, long-lived.
Polymer	See monomer.

Potency	The potential of a substance to cause a given effect. A highly potent substance causes effects even at low doses.
Precautionary principle	Principle entailing that preventive measures should be adopted as soon as there is reason to believe that a given measure or activity could harm human health or the environment.
Reactant	A substance that is transformed in a chemical reaction.
Reaction intermediate	A substance that is created as an intermediate product in a chemical reaction.
Regulatory signal systems	Chemical signal systems that regulate various functions in living organisms.
Reproduction-toxic substances	Substances that disrupt or impair reproduction, cause foetal damage or disrupt the development of the progeny (offspring).
Risk phrase	Risk phrases are included in the labelling of chemical products. They describe how a substance is dangerous.
Screening	A study where many substances are analyzed.
Subsidiarity principle	The principle in the EU intended to ensure that decisions are not taken at a higher level than necessary.
Synthesis intermediate	Substance intended to be used in a synthesis, i.e. a chemical reaction where it forms a new substance.
Teratogenicity	The ability of a substance to cause foetal damage.
Toxic	Poisonous.
Trophic levels	Levels in a food chain.
White Paper	In the EU: The European Commission's documents containing proposals for Community action in a specific area. In some cases they follow a Green Paper published to launch a consultation process at a European level.

Abbreviations

BAF	Bioaccumulation factor.
BCF	Bioconcentration factor.
BMF	Biomagnification factor.

CEFIC	European Chemical Industry Council.
CEN	Comité Européen de Normalisation. (European Committee for Standardization.)
CENELEC	European Committee for Electrotechnical Standardization. Responsible for western European standardization in the electrical field.
CFCs	Chlorofluorocarbons.
CLRTAP	Convention on Long-range Transboundary Air Pollution – also known as the Geneva Convention. The purpose of the convention is to reduce acidification and other kinds of air pollution.
CSD	Commission on Sustainable Development – a UN body.
DDT	Dichlorodiphenyltrichloroethane.
DDE	Dichlorodiphenyldichloroethylene.
DYNAMEC	OSPAR Ad Hoc Working Group on the Development of a Dynamic Selection and Prioritisation Mechanism for Hazardous Substances.
EC	European Community.
ECE (UN-ECE)	United Nations Economic Commission for Europe.
ECVAM	European Center for Validation of Alternative Methods.
EINECS	The European Inventory of Existing Commercial Chemical Substances. A European list of the substances that were considered to exist on the common market between 1 Jan. 1971 and 18 Sept. 1981.
ELINCS	European List of Notified Chemical Substances
ETSI	European Telecommunications Standards Institute. Responsible for western European standardization in the telecommunications field.
EU	European Union.
EURAM	European Union Risk Ranking Method
EUSES	European Union System for Evaluation of Substances.
GLP	Good Laboratory Practice.
HBFC	Hydrobromofluorocarbon.

HCB	Hexachlorobenzene.
HCCH	Hexachlorocyclohexane.
ICCA	International Council of Chemical Associations.
ICP MS	Inductively Coupled Plasma Mass Spectrometry.
IFCS	Intergovernmental Forum on Chemical Safety.
IOMC	Inter-organization Programme for the Sound Management of Chemicals.
IPCS	International Programme on Chemical Safety.
ISO	International Organization for Standardization.
IUCLID	International Uniform Chemical Information Database.
KemI	National Chemicals Inspectorate.
log K_{ow}	See K_{ow}.
LRTAP	Long-Range Transboundary Air Pollution.
MISTRA	Swedish Foundation for Strategic Environmental Research, a foundation that funds research in the environmental field.
NSDB	Nordic Substance Database.
OECD	Organization for Economic Cooperation and Development.
OJ	Official Journal of the European Communities.
OSPAR	The 1992 Oslo-Paris Convention for the Protection of the Marine Environment of the North-East Atlantic.
PAHs	Polyaromatic hydrocarbons.
PBDEs	Polybrominated diphenyl ethers.
PCBs	Polychlorinated biphenyls.
PCDDs	Polychlorinated dibenzo-*p*-dioxins.
PCDFs	Polychlorinated dibenzofurans.
PIC	Prior Informed Consent (UNEP).
POPs	Persistent Organic Pollutants.
P_{ow}	See $K_{ow.}$
QSAR	Quantitative Structure-Activity Relationship.
SETAC	Society of Environmental Toxicology and Chemistry.
SIDS	Screening Information Data Set (OECD).
SLU	Swedish University of Agricultural Sciences.
UNEP	United Nations Environment Programme.
WHO	World Health Organization.
VOCs	Volatile Organic Compounds.

Summary

Our commission

The objective of a non-toxic environment

In the Bill ”Swedish Environmental Quality Objectives” (Gov. Bill 1997/98:145), the Swedish Government proposed fifteen environmental quality objectives that should be reached within a generation, i.e. by around 2020. The Riksdag (Swedish Parliament) approved these objectives in April 1999 (1998/99:MJU6). One of the environmental quality objectives aims to achieving a non-toxic environment and is formulated as follows:

> *”The environment must be free from man-made substances and metals that represent a threat to health or biological diversity. This means that:*
>
> – *the levels of substances that occur naturally in the environment must be close to background levels*
> – *the levels of man-made substances in the environment must be close to zero.”*

The new guidelines on chemicals policy

To achieve the environmental quality objective of a non-toxic environment, the Government issued the following new guidelines on chemicals policy:

1. *New products introduced onto the market are largely free from:*

   - *man-made organic substances that are persistent and liable to bioaccumulate, and from substances that give rise to such substances,*

- *man-made substances that are carcinogenic, mutagenic and endocrine-disruptive – including those which have adverse effects on the reproductive system.*
- *mercury, cadmium, lead and their compounds.*

2. *Metals are used in such a way that they are not released into the environment to a degree that causes harm to the environment or human health.*
3. *Man-made organic substances that are persistent and bioaccumulative occur in production processes only if the producer can show that health and the environment will not be harmed. Permits and terms of the Environmental Code are devised in such a way as to guarantee this guideline.*

According to the Government, the above guidelines should provide guidance for companies in their product development and serve as a goal for their chemicals strategies. They shall also provide support for the work of government agencies and for implementation of the Environmental Code. The Government intends to promote that these guidelines are implemented within 10–15 years (2008–2013).

The commission

The Committee on New Guidelines on Chemicals Policy (M 1998:09), referred to as the Chemicals Committee, has been commissioned to propose how the new guidelines are to be implemented. The commission has included defining the substances that should be covered by the new guidelines, for example how persistent and bioaccumulative a substance should be for it to be banned from use in newly manufactured products. The commission has also included exploring what further measures and instruments are needed to implement the guidelines, as well as analyzing the economic and other consequences of the proposals.

It is important to emphasize that, in addition to implementation of the new guidelines, far-reaching measures are also needed against particularly dangerous substances that are already present in society – in products and on landfills – and against the continued large-scale use of chemicals, in order that the environmental quality objective of a non-toxic environment can be achieved. For an overall view with regard to interim objectives and measures to achieve the objective of a non-toxic environment, we refer to the report of the Environmental Objective Committee (SOU 2000:52).

Some starting-points (Chapter 2)

Chemicals play an important role in our society. The development of chemical substances and preparations has contributed greatly to our current material prosperity. We use chemicals in most contexts today, for example in cars, pharmaceuticals, plastics, preservatives, detergents, cleaning agents, paints, clothes, building materials and fuels.

But use of chemicals has also contributed to the back side of prosperity. Dangerous substances can cause harm to man and the environment. The number of substances on the market is large, as are the flows of products and chemicals contained in them. This makes it difficult to keep track of all the different substances and chemicals in circulation. There are currently over 11,000 chemical substances in the National Chemicals Inspectorate's products register, which covers all the chemical products manufactured in or imported to Sweden. These substances are incorporated in around 60,000 chemical products (substances and preparations), which are in turn present in an even larger number of manufactured products. No one knows exactly *how many chemical substances* exist on the Swedish market. If the chemical substances present in other products than chemical substances and preparations are also included, the total could come to around 20,000 substances.

A big problem with today's use of chemicals is *the great lack of knowledge* concerning the health and environmental properties of the substances. An EU report from 1999 shows that only 14 percent of the approximately 2,500 high-production-volume chemicals that are registered in the EU's database IUCLID have data complying with the basic requirements in the EU's dangerous substances directive (Council Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances), 65 percent have some data and 21 percent have no data whatsoever. It can be assumed that the data shortage is even more pronounced for lower-volume substances. The American EPA has also conducted a study of the knowledge situation for the chemicals that are manufactured in or imported to the USA in volumes of over 454 tonnes per year (over 1,000,000 pounds per year). This study shows that only 7 percent of the approximately 3,000 have the data considered by the OECD countries to be necessary knowledge. No data at all are available for 43 percent of the substances.

Owing to the great lack of knowledge, it is not possible today to identify all substances that are dangerous for human health or the environment, or to make risk assessments or adopt adequate risk reduction measures.

The problem with the use of substances that are persistent and bio-accumulative, as well as substances that are carcinogenic, mutagenic, toxic to reproduction and endocrine-disruptive, is that the effects of releases – both direct releases and diffuse releases via manufactured products etc. – are or may be delayed. What is released today will not have effects for another decade or two. It may also take a very long time before measures to prevent effects have results, especially if the concentration in the environment has been built up over a long time. The threat of harmful effects of chemicals on man and the environment is such that both policymakers and business leaders have to adopt a much longer view than is normal in society today.

International work in the chemicals field is of great importance, since many problems with chemicals cannot be solved at the national level. The chemicals and products that are sold are often manufactured in other countries. The substances are thus spread via trade in products. Furthermore, certain poorly degradable substances may be transported by winds to places far from where they are manufactured and used.

The Committee's conclusion is therefore that due to the international trade aspect, the stipulated guidelines cannot be implemented solely via measures on a national level, but that measures must be adopted primarily on an international level, to begin with at the EU level. It is our opinion that restrictions of chemical substances that pose particularly serious risks to human health and the environment should be realized via legislation in the EU. However, *market-driven and voluntary instruments* must also be used to achieve success. The market itself must also come up with solutions. Important mechanisms here can be ecolabelling, environmental management systems, environmental product declarations, and stipulations for public procurement.

Further efforts are needed on the part of both government and industry to augment and bolster the work of implementing the guidelines and to achieve the environmental quality objective of a non-toxic environment. Our ambition with the proposals in this report has been to lay a good foundation for continued efforts both within and outside of Sweden.

The EU needs a new chemicals strategy (Chapter 3)

The EU is the main arena in which Sweden should act to implement the new guidelines. We have submitted a number of proposals for changes in EU policies and regulations in the chemicals field.

As a basis for a new chemicals policy, Sweden should advocate the adoption of a new chemicals strategy within the EU. This strategy should be based on the same principles as those embodied in the Swedish Environmental Code, namely the *precautionary principle* and the *substitution principle*, as well as *producer responsibility* and the *polluter pays principle*. Based on these principles, the Committee proposes that a new chemicals strategy be devised along with a concrete action programme.

The precautionary principle and the substitution principle should be incorporated into some of the EC's legislation in the chemicals area. It is particularly urgent that the precautionary principle be incorporated into the restrictions directive (Directive 76/769/EEC on restrictions on the marketing and use of certain dangerous substances and preparations).

In a new chemicals strategy it is important to stress the adoption of a *long-term perspective* in assessing health and environmental effects of chemicals. It is also important that the same *documentation requirements* be made on existing substances as on new substances. Companies (manufacturers and importers of chemicals) should be clearly given responsibility for gathering data, and should also carry out initial risk assessments and adopt the necessary precautions.

A forthcoming chemicals strategy in the EU must also contain signals that *a tightening of the EU's chemicals legislation is needed*. This should be done by amendments in existing legislation to begin with. Eventually, the EU's chemicals legislation should be gathered under a framework directive or the like.

Current risk assessments need to be streamlined and augmented with a more *general approach* to the most dangerous substances. This should be accented in the EU's future chemicals strategy. This means that substances with particularly dangerous properties should be restricted due to their inherent properties. General phase-out criteria should therefore be established whereby restrictions are imposed on persistent and bioaccumulative substances as well as on carcinogenic, mutagenic, reproduction-toxic and endocrine-disruptive substances (see proposed criteria in Chapter 5). Furthermore, the future chemicals strategy should

stipulate that the use of mercury, cadmium and lead, and compounds of these metals, should in principle cease.

We also propose that *supervision* and enforcement in the chemicals field be tightened up and improved. Minimum requirements on enforcement of the chemicals rules should be introduced.

Proposal for EU system for requirements on knowledge of the health and environmental properties of chemical substances (Chapter 4)

Knowledge of the health and environmental properties of chemical substances is fundamental to all safety work in the chemicals field. Knowledge of the inherent health and safety properties of the substances is also a prerequisite for being able to identify the substances that are covered by the new guidelines. Today such knowledge is largely lacking for substances already on the market, whereas it is required for new chemical substances.

We propose that all substances that are used – regardless of whether they are new or existing – shall be subject to the same requirements regarding data on the properties of the substance, so that those substances for which data are lacking may not be placed on the market after a certain date. After that the substances will be treated as if they were new substances, which means that they are subject to existing rules on pre-market notification of new substances.

For all high-production-volume substances (1,000 tonnes per year or more), we propose that manufacturers and importers must, by not later than the end of 2005, have compiled knowledge on inherent health and environmental properties that meets the requirements made on new substances in the EC's dangerous substances directive (67/548/EEC). For medium-volume substances (10–1,000 tonnes per year), such data shall be compiled by not later than the end of 2009, and for other substances not later than the end of 2010.

Furthermore, the data requirements made in the dangerous substances directive should be extended regarding the persistent and bio-accumulative properties of the substances and, as soon as testing methods are available, their endocrine-disruptive properties.

Proposed phase-out criteria for persistent and bioaccumulative substances (section 5.1 and Annex 3)

The Committee defines an organic substance as persistent if it is stable in the environment in the sense that it degrades slowly. A persistent substance is thus highly resistant to the various processes in the environment which lead to degradation of other, less resistant substances.

A substance is bioaccumulative if it is readily available for uptake by other organisms, but is only slowly metabolized or otherwise eliminated. The substance can thereby be accumulated in organisms in higher concentrations than in their environment or food.

We have deemed it more serious that a bioavailable substance is persistent than that it is bioaccumulative, since a persistent substance can give rise to prolonged exposure, and there is a risk that unforeseen effects will manifest themselves during the exposure period. There is furthermore a risk that persistent substances will be transported to places far from where they are manufactured and used. In addition, it takes a long time for the environmental concentrations of a persistent substance to decrease, even after the use has ceased.

The Committee has considered various half-lives for when a substance should be regarded as unacceptably persistent, as well as for when a substance should be regarded as unacceptably bioaccumulative. After discussions with researchers both nationally and internationally, we propose that *new* substances may not be placed on the market from 2005, and *existing* substances from 2015, if they are so persistent and bioaccumulative:

- that their half-life is longer than 8 weeks (in a simulation test at 20ºC), and
- that their bioconcentration factor is higher than 2,000, or
- that they are deemed to fulfil these criteria on the basis of other reliable scientific studies or internationally accepted calculation methods.

We further propose that the existing substances that are most persistent and bioaccumulative may not be placed on the market from 2010 if they are so persistent and bioaccumulative:

- that their half-life is longer than 26 weeks (in a simulation test at 20ºC), and

- that their bioconcentration factor is higher than 5,000, or
- that they are deemed to fulfil these criteria on the basis of other reliable scientific studies or internationally accepted calculation methods.

Proposed phase-out criteria for carcinogenic, mutagenic and reproduction-toxic substances (sections 5.2 and Annex 4)

Today, the EU's dangerous substances directive (67/548/EEC) contains definitions of what is meant by carcinogenic, mutagenic and reproduction-toxic substances. The directive also contains special criteria for classification of chemical substances when it comes to these properties. Depending on how strong the scientific evidence is, the substances are placed in one of three categories. Substances for which it is proven that harm is caused to man are placed in category 1. Substances for which there is clear evidence of harmful effects in animal studies are placed in category 2. When the evidence is weaker a substance is placed in category 3.

According to the restrictions directive (76/769/EEC), substances in category 1 or 2 may not be present in chemical substances and preparations that are intended to be sold to the public. We propose that this ban be extended to include all kinds of products, such as computers, clothing and automotive tyres. We thus propose that the substances that have been classified as carcinogenic, mutagenic or toxic to reproduction within category 1 or 2 according to the EC's dangerous substances directive (67/548/EEC) may not be present in consumer-available products from 2007. We believe that in the next step these restrictions should be extended to products for occupational use.

Endocrine-disruptive substances (section 5.2 and Annex 5)

The Committee was also instructed to propose criteria for when a substance is to be regarded as so endocrine-disruptive that it should not be incorporated in products. Since internationally accepted testing methods and criteria for endocrine-disruptive substances do not yet exist, we have not considered it possible to propose phase-out criteria. We do, however, propose an action plan for continued work in the area.

For endocrine-disruptive substances, the testing methods within the effect area of reproduction toxicology should be made more thorough, and chemical substances should be tested using these methods. It is above all the methods on development toxicology that need to be further developed. In our judgement, it should be possible to detect most of the endocrine-disruptive substances in this manner.

In the matter of endocrine-disrupting substances, we also propose that Sweden should pursue its own activities while also acting internationally. The following areas should be prioritized in the work with endocrine-disrupting substances:

- further research on endocrine-disruptive effects,
- development of testing methods for endocrine-disruptive properties,
- requirements on testing of the endocrine-disruptive properties of chemicals,
- greater emphasis on endocrine-disruptive effects in risk assessments,
- risk-reducing measures aimed at endocrine-disruptive substances.

Metals (Chapters 5, 6 and 7 and Annex 6)

Mercury, cadmium and lead shall be phased out according to the guidelines. In view of transboundary trade in products and atmospheric transport, we believe that these substances should be phased out within the whole EU. Regarding cadmium, Sweden has a ban in place today that is more far-reaching than the EU's rules, and Sweden has an exemption from the common rules. Before the exemption expires in 2002, the Commission will review the provisions regarding cadmium in the restrictions directive (76/769/EEC). In conjunction with this, Sweden should advocate the imposition of a total ban on cadmium within the EU.

As regards mercury and lead, we believe that notification of national bans can be a way to create interest in a phase-out in the EU. For this reason, we recommend that the Swedish ban on mercury be made complete by not later than 2003. In the case of lead, two areas of application remain today that lead to direct release of lead into the environment: ammunition and fishing sinkers. We propose that lead in ammunition and fishing sinkers be banned by not later than 2008. The largest area of application for lead is, however, lead accumulators such as starter batteries in cars. Here it is difficult to find alternatives, so until a phase-out can be realized it is important that lead be recycled in closed loops.

Sweden should also promote amendments to several individual product directives in the EU. The following directives are of particular importance for metals:

- The crystal glass directive (69/493/EEC) should be amended so that use of lead is not required.
- The battery directive (91/157/EEC) should be adapted to recent technical progresses in cadmium batteries. The directive should also be tightened up so that remaining use of mercury ceases by not later than 2003.
- The fertilizer directive (76/116/EEC) should be tightened up with regard to the cadmium content of fertilizers.
- The directive on the type-approval of motor vehicles (70/156/EEC).

According to the guidelines, other metals may be used in such a way that they do not leak out and cause harm; their use must not lead to risks. Several of the higher-production-volume metals are now being risk-assessed in the EU's programme for existing substances. It is important that Sweden contributs to these assessments and ensure that effective steps are taken against whatever risks the assessments reveal.

Since risk assessments within the EU often take several years to carry out, we consider it appropriate to begin now taking measures against the uses we know give rise to widespread metal pollution. Examples are: brake linings, wood preservatives, antifouling paints and water pipes.

To prevent increasing quantities of metals from accumulating in society and on landfills, with a risk of leaking to the environment, effective recycling of metals is important. Techniques and systems for recycling need to be further improved.

Proposed tightening-up of EU rules regarding restrictions on chemical substances (Chapter 6 and Annex 2)

We submit a number of proposals for amendments to EU legislation in the field of chemicals and products which Sweden should advocate for the purpose of implementing the new guidelines in the chemicals field. As far as knowledge (data) requirements for existing substances are concerned, we deal with the amendments needed in EU legislation separately. Some of our most important proposals for amendments in the EU rules are summarized below.

Dangerous substances directive (67/548/EEG)

New classification and labelling rules should be introduced for substances in line with the Committee's proposals for phase-out criteria for persistent and bioaccumulative substances. The substances should be labelled with the symbol for danger to the environment and with new risk phrases. The new rules should be applied starting in 2005. The data requirements made in the dangerous substances directive must be extended regarding the persistent and bioaccumulative properties of the substances and, as soon as testing methods are available, their endocrine-disruptive properties.

Dangerous preparations directive (1999/45/EG)

Amendments are needed to determine the concentration at which a preparation containing persistent and bioaccumulative substances should be classified and labelled according to our new criteria.

An amendment should also be made to the rules on material safety data sheets, whereby they should be updated at least every third year, or whenever new knowledge becomes available.

Restrictions directive (76/769/EEG)

The Committee proposes that the precautionary principle be incorporated in the directive. We also propose the following amendments to phase out the substances covered by the new guidelines:

- New substances notified in accordance with the dangerous substances directive after 2004, and covered by our proposal for new classification and labelling criteria with regard to persistence and bioaccumulation, shall not be allowed to be placed on the market as from 2005. This ban should also include preparations and products containing such chemical substances.
- Existing and new substances notified prior to 2005 shall, as from 2010, be covered by the above restrictions, provided they are covered by the new classification and labelling rules and have a half-life >6 months and a bioconcentration factor >5,000.
- As from 2015, the restrictions shall apply to all substances covered by the new classification and labelling rules with regard to persistence and bioaccumulativity.
- Today's restrictions on chemical substances and preparations that are carcinogenic, mutagenic and toxic to reproduction should be extended

not later than 2007 to include other consumer-available products as well. Occupational use should be included as well in the next step.

- Certain exemptions from the bans are proposed.

Regulation on risk evaluation of existing substances

The work within the framework of Council Regulation (EEC) No. 793/93 on the evaluation and control of the risks of existing substances needs to be supplemented with a more general approach. The precautionary principle should be incorporated in this regulation. We consider that substances with particularly dangerous properties should be restricted due to their inherent properties. This entails a changed role for the work of risk assessment and risk management.

We also propose that simplifications be made in the work with risk assessments. Risk assessment methods should be changed to speed up the assessments and to better take into account important factors, such as:

– contribution made by products to emissions of a substance
– persistent and bioaccumulative properties of substances
– interaction between different substances.

Product directives and standards

The Committee's proposals when it comes to product directives and product standards are as follows:

- The relationship between rules regarding restrictions of products containing dangerous chemicals and EC directives that regulate products should be explored to reveal any rule conflicts and the need for amendments in EC legislation to facilitate the implementation and application of provisions regarding restrictions of dangerous chemicals in products.
- Environmental and health protection considerations must be taken into account in devising new product standards and directives and be incorporated in existing ones. New product directives and standards should undergo an environmental assessment.

Sweden should also promote amendments to several individual product directives within the EU, for example restrictions regarding the chemical

content of vehicles should be incorporated in the directive on the type-approval of motor vehicles (70/156/EEC).

Environmental management systems – the EMAS regulation

The Committee believes that the chemicals aspects should be clarified in e.g. the regulation on EMAS.

Market-driven instruments (section 7.3)

The use of market-driven instruments can be valuable in the work of complying with the new guidelines. We submit a number of proposals that aim at using and developing such instruments so that they take into account chemicals use to a greater extent than today.

Public procurement

Public procurement can be an important motive force for phasing out the dangerous substances that are covered by the new guidelines on chemicals policy. It should be possible to require that substances covered by the Committee's proposed criteria for phase-out should not be incorporated in chemical preparations or other products that are procured by public bodies.

Positive ecolabelling

It is urgent that more product groups be covered by positive ecolabelling. Products containing substances covered by our proposed criteria for phase-out should not be given a positive ecolabel.

National Chemicals Inspectorate's Observation List

As a special project, we have evaluated the National Chemicals Inspectorate's Observation List. The results of the evaluation are presented in Annex 9. In summary, we find that the Observation List should be modified to make it more user-friendly. Furthermore, activity-specific information on hazardous chemicals needs to be made available to a greater extent than it is today. Principal responsibility for such information should rest with industry. Furthermore, the National Chemicals Inspectorate and the different industrial sectors' own Internet-

based information on hazardous chemicals should be developed in a more user-friendly direction (search methods, databases, etc.).

Environmental product declarations

Voluntary environmental product declarations should always contain information on a product's content of hazardous chemicals. Furthermore, the life cycle analysis on which the declaration is based should include the effects on health and the environment caused by chemicals.

Environmental management systems

Chemicals aspects should be clarified in the environmental management systems that are used. Use of chemicals should always be included in the environmental report's summary of data on the organization's environmental work (a proposal for the EMAS regulation is also provided in Chapter 6).

Proposals for further commissions (section 7.4)

Within the framework of our inquiry, we have identified a number of areas that need to be explored further by means of inquiries or commissions so that the new guidelines can be fully implemented. Some of the most important areas are summarized below:

Special commission on petroleum-based fuels

The composition of petroleum-based fuels needs to be modified so that the Government's guidelines can be fully implemented. We propose that a committee be charged with the assignment of investigating how to better promote the use of vehicles with lower emissions of carcinogenic and other harmful substances. The committee should also examine ways to encourage the use of fuels with low or no content of carcinogenic substances in applications where some of the fuels can be expected to be emitted in uncombusted form (e.g. from older vehicles or non-road machinery). We submit this proposal in consultation with the Committee on Environmental Objectives (SOU 2000:52).

Special commission on health and environmental information for products

For products other than chemical products (substances and preparations), there are no rules today on health and environmental information regarding their content of chemicals. This means that today's consumers have no way of ascertaining the content of e.g. flame retardants in electronics and textiles, bactericides in clothing and scrub sponges, or plasticizers in plastics products. We propose that Sweden should promote an EU-wide system for formulation of health and environmental information for products that are not chemical products. This is a complex question. We therefore propose that a special inquiry gather facts for further EU work in this matter. We submit this proposal in consultation with the Committee on Environmental Objectives (SOU 2000:52).

Limit values for sludge

Limit values for sludge should exist for all metals used in Sweden by 2012. We propose that the Swedish Environmental Protection Agency be commissioned to propose limit values for metals that are not listed today in the Ordinance (1998:994) on prohibitions etc. in certain cases in conjunction with handling, import and export of chemical products, and review existing limit values. The limit value for cadmium in sludge should in particular be reconsidered with the aim to lower the value.

Proposal for continued international work (Chapter 8)

In addition to the measures we propose within the framework of Sweden's membership in the EU, measures also need to be taken within the framework of other international bodies. The committee has gone through the international work that is of importance for the new guidelines on chemicals policy. As international trade in chemicals and products increases, international cooperation in chemicals control is becoming increasingly urgent. We would particularly like to highlight the following in the international work of the years to come:

The upcoming convention with global restrictions on the most harmful substances (POPs)

Sweden should work for the extension of the convention to include those persistent and bioaccumulative substances that are covered by the new

guidelines on chemicals policy. Sweden should advocate the prompt nomination of a number of prioritized substances that should be covered by global restrictions within the framework of the convention.

Intergovernmental Forum on Chemical Safety (IFCS)

Within the Intergovernmental Forum on Chemical Safety, Sweden should work to bring about application of the fundamental principles (mainly the precautionary principle, the substitution principle and the principle of corporate responsibility) that exist in Swedish chemicals control on a global level as well. A special priority question should be to begin discussing a global phase-out of substances covered by the new guidelines.

Convention on Long-Range Transboundary Air Pollution (CLRTAP)

The convention should incorporate the objective that emissions – both direct emissions from point sources and diffuse emissions from products – shall cease by 2020. More substances should be covered by restrictions in the convention. General criteria should be used to extend the convention to include more substances, for example those covered by the new guidelines. The Protocol on Heavy Metals should be broadened as soon as possible to further reduce the long-range atmospheric transport of cadmium and mercury.

Organization for Economic Cooperation and Development (OECD)

The OECD has long pursued important work in the chemicals field, for example when it comes to hazard and risk analysis, guidelines for testing, documentation requirements, harmonization of classification and labelling systems, etc. Within the OECD, Sweden should advocate the development of testing methods for endocrine-disruptive properties and the refinement of existing testing methods so that they are more sensitive to endocrine-disruptive effects. New testing methods should be developed for half-lives in a terrestrial environment and for bioaccumulation in a terrestrial environment. In addition, further harmonized criteria should be formulated for classification and labelling. The work of finding new testing methods that do not require animal experiments should be prioritized within the OECD.

The North Sea Conference, OSPAR and HELCOM

Chemicals issues and the substances covered by the objectives of the Esbjerg Declaration should be further elaborated by the next North Sea Conference in 2002. In advance of this meeting, Sweden should formulate a Swedish strategy with proposals for which questions should be discussed at the meeting for the purpose of eventually bringing about binding decisions within e.g. OSPAR and HELCOM. The substances covered by the new guidelines on chemicals policy should be the point of departure for the continued work within the framework of the North Sea Conference, OSPAR and HELCOM. In preparation for OSPAR's next ministerial meeting in 2003, Sweden should prioritize the chemicals issues for the purpose of obtaining decisions on the new approach in chemicals policy, which includes phasing out those substances covered by our phase-out criteria. Persistent and bioaccumulative substances should be prioritized in this work.

Proposal on research, environmental monitoring and follow-up (Chapter 9)

Companies shall bear responsibility for furnishing knowledge on the health and environmental properties of substances and their presence in manufactured products. Still, research, environmental monitoring and other forms of follow-up are of utmost importance here. Research is needed as a basis for refinement of testing methods. Environmental monitoring is also needed to keep track of the occurrence of the substances in society and the natural environment.

The need for research in the environmental field is increasing as new chemicals are produced and used. Research is also needed when new harmful effects on health and the environment are discovered or suspected. However, the greatest research need probably concerns existing substances, since in most cases very little is known about their properties and effects, and how they are spread in the environment. Efforts towards the environmental objective of a non-toxic environment and the implementation of new guidelines on chemicals policy require a broadened scope of environmental research. A vigorous national programme of fundamental ecochemical, ecotoxicological and toxicological research is furthermore a prerequisite for Sweden's ability to pursue chemicals issues in international fora in a knowledgeable, well-founded and thereby convincing manner.

The Committee also deems the need for method development to be urgent, along with the need to validate, standardize and implement testing and analysis methods. This is above all true when it comes to the development of testing methods, where there is a particularly great need to develop tests for endocrine-disruptive effects, and the development of methods for routine analysis where such are lacking.

Measuring the environmental occurrence of chemical substances is one way to learn more about which substances could pose environmental problems. Such chemicals monitoring is an important part in the follow-up of the measures adopted to achieve the environmental objective of a non-toxic environment.

Among the additions to the current environmental monitoring programme which we recommend are monitoring of certain *phase-out substances*, monitoring of *pesticide residues* in agricultural areas, increased *health-related* environmental monitoring, and an expanded programme for regular *screening* of pollutants in the environment and in organisms. Future environmental monitoring in the *metals area* should be expanded to include as many metals as possible. In addition to traditional environmental monitoring, environmental monitoring of *products* should be developed and implemented. It is important that environmental specimens be collected in a ”specimen bank” so that new toxic pollutant problems discovered in the future can be traced back in time. The Committee considers it necessary that chemicals monitoring be supplemented with models on how substances are transported.

For overall follow-up purposes, ongoing reporting of different forms of follow-up and evaluation is needed in the form of both detailed reports and simple key statistics, which should also reflect the research and environmental monitoring activities that are being conducted. The Swedish Environmental Protection Agency has, in consultation with the National Chemicals Inspectorate and others, developed a system of indicators for follow-up of the environmental quality objective of a non-toxic environment, which has been further dealt with by the Committee on Environmental Objectives (SOU 2000:52). The Chemicals Committee considers the work on indicators to be an important part of the follow-up work.

Consequences of our proposals (Chapter 10)

Consequences of the requirement on data for all substances

Calculating the costs of furnishing data on all substances manufactured in or imported to the EU is very difficult, since many unknown factors are involved. It is, for example, not known how many substances exist on the European market. Common guesses are that around 20,000 substances are used, other guesses lie around 40,000–60,000 substances. The Swedish products register contains around 11,000 substances that are used in chemical products on the Swedish market today.

We have carried out three sample calculations where we assume that there are 11,000, 20,000 or 40,000 substances on the market. The costs of furnishing data are based on figures from the US EPA and stem from slightly less far-reaching requirements than ours. However, the calculations give some idea of the order of magnitude of the costs. The calculations show that the costs to Swedish industry can be estimated at around SEK 73 million for 11,000 substances, SEK 130 million for 20,000 substances and SEK 270 million for 40,000 substances. Spread out over the number of years the Committee proposes for implementation, i.e. 9 years, the cost is SEK 8, 15 and 30 million per year, respectively. This can be compared with the annual revenues of Swedish chemicals industry: around SEK 71,000 million.

Consequences of the Committee's phase-out criteria

The consequences of banning the use of substances with certain properties cannot be estimated, since we do not know exactly which substances will be subject to the requirements until we have more knowledge of the properties of the substances. Based on today's insufficient knowledge, approximately 1,000 substances will be subject to our phase-out criteria. This figure only includes those substances on which such data exist today that it is possible to determine whether they are subject to the criteria or not. Approximately 200 of these 1,000 substances are persistent and bioaccumulative, and approximately 800 are carcinogenic, mutagenic or toxic to reproduction. The latter group is dominated by complex petroleum-based "substances". However, it is important to note that further substances will be added to this group of approximately 1,000 when the requirement on knowledge of the properties of the substances is met.

Despite the difficulties, we have tried to shed light on the consequences for industry and commerce by talking to representatives of certain

economic sectors. The sectors have been selected based on the information in the product register on which sectors use substances which, based on current knowledge, can be assumed to meet the proposed phase-out criteria.

Most of the representatives claim that the proposals are in line with the company's or the sector's own objectives and visions. The representatives of the building sector believe that the consequences will be moderate, although they will be greater for the producers of building materials than for the building contractors.

The building contractors have said that they will of course be able to construct buildings 10–15 years from now even without the substances in question. The materials industry claims that 10–15 years is not a long period of adjustment if big process plants have to be replaced.

The need for increased chemicals expertise and better provision of information is also emphasized by the concerned economic sectors. Representatives of the base chemicals industry, the paint industry and the building plastics, plastic packaging and plastic products industry have stated that it is very difficult to project the consequences of the proposals. But they thought that 10–15 years would be a reasonable period of adjustment.

1 Commission, delimitations, definitions and execution

1.1 Commission

Information on the background to the Committee's commission is provided below, along with a summary of the commission. The Government's terms of reference to the Committee are found in Annex 1.

In the Bill "Swedish Environmental Quality Objectives" (Gov. Bill 1997/98:145, 1998/99:MJU6), the Swedish Government proposed fifteen overall environmental quality objectives for the future environmental work, and the Riksdag decided on 29 April 1999 to approve these objectives (1998/99:MJU6). The objectives are described in Chapter 2. One of the fifteen environmental quality objectives is aimed at achieving a non-toxic environment, requiring that the environment must be free from man-made substances and metals that represent a threat to health or biological diversity.

The aim is that this environmental objective, along with the others, should be achieved within a generation, i.e. by around 2020.

To enable the objective to be achieved, the Government found in the Bill "Swedish Environmental Quality Objectives" that the chemicals policy should be supplemented with the following new guidelines:

1. *New products introduced on the market are largely free from:*
   - *man-made organic substances that are persistent and liable to bioaccumulate, and from substances that give rise to such substances,*
   - *man-made substances that are carcinogenic, mutagenic and endocrine-disruptive – including those which have adverse effects on the reproductive system.*
   - *mercury, cadmium, lead and their compounds.*

2. *Metals are used in such a way that they are not released into the environment to a degree that causes harm to the environment or human health.*
3. *Man-made organic substances that are persistent and bioaccumulative occur in production processes only if the producer can show that health and the environment will not be harmed. Permits and terms of the Swedish Environmental Code are devised in such a way as to guarantee this guideline.*

According to the Government, the guidelines should provide guidance for manufacturers in their product development and serve as a goal for their chemicals strategies. They shall also provide support for the work of public agencies and for implementation of the Environmental Code. The Government intends to work to ensure the implementation of these guidelines within 10–15 years.

According to the Bill ”Swedish Environmental Quality Objectives”, the Government’s general view is that all chemical safety work should be based on risk assessments. However, the Government considers that today’s work methods should be augmented with a more general approach aimed at chemical substances with documented dangerous properties and at man-made organic substances that are bioaccumulative and persistent.

The Bill also emphasizes the need for a new approach in the chemical work aimed at hastening the work of, *inter alia*, achieving the goals in the Esbjerg Declaration – i.e. that the concentrations of substances that occur naturally in the environment shall be close to background levels, while the concentrations of man-made synthetic substances shall be close to zero. The present-day risk assessment process, as it is applied in the EU’s programme for existing substances, is proceeding too slowly. The work can be pursued faster if action is taken against such substances that should not normally occur in products and in production processes due to the inherent dangerous properties of the substances.

The current way of working, which is based on evaluations of one chemical substance at a time, is thus inadequate and far too slow. Moreover, certain substances are very difficult to risk-assess. This is particularly the case with man-made organic substances that are persistent and liable to bioaccumulate.

Summary of the commission

The Chemicals Committee's commission entails concretizing and submitting proposals for the implementation of the Government's new guidelines on chemicals policy. In summary, the Chemicals Committee shall:

- propose more precise definitions in the form of limits, criteria etc. for the properties and effects of the substances referred to in the Government's new guidelines on chemicals policy. For example, limits should be proposed that indicate when a substance is so persistent and bioaccumulative that it shall be subject to the phase-out requirement in accordance with the stipulated guidelines.
- clarify how the guidelines for carcinogenic, mutagenic and endocrine-disruptive or otherwise reproductive-toxic substances can be related to existing classification systems.
- review current legislation and analyze whether tighter control is needed of the substances covered by the Government's new guidelines. Among other things, the Committee shall report on the need for a system of permits for marketing chemical products containing the substances covered by the guidelines.
- analyze other instruments than legislation and whether proposals need to be submitted for additional instruments/tools. Examples of such instruments are labelling, environmental product declarations, the National Chemicals Inspectorate's Observation List, and various voluntary instruments used in industry such as environmental management systems and voluntarily prepared observation lists.
- analyze the consequences of the proposals – both on public finances and on private companies and individuals.

According to the terms of reference furnished by the Government, the Committee's proposals shall be scientifically substantiated, utilize internationally accepted definitions (where such exist), and be based as far as possible on a consensus between regulatory agencies, the business community and the research community.

The terms of reference state that Sweden should work for the adoption of a more general approach in the international chemical safety work. An important point of departure for the Chemicals Committee is therefore the general approach embodied in the Government's proposed guidelines.

The results of the Committee's work shall be reported to the Government by not later than 1 June 2000.

1.2 Limits of the commission

A central task for the Committee has been to propose more precise definitions for the properties and effects referred to in the Government's new guidelines on chemicals policy and to analyze and present proposals for additional instruments to achieve the guidelines. This means that the commission is focused on *how* the guidelines should be defined concretely and *how* they should be implemented. We have, for example, not considered it our principal task to describe the problem, this has already been done by the Chemicals Policy Committee (SOU 1997:84). Detailed problem descriptions are also found in the Bill "Swedish Environmental Quality Objectives" (Gov. Bill 1997/98:145) and in the National Chemicals Inspectorate's report "Giftfri miljö" ("Non-toxic environment", available in Swedish only, National Chemicals Inspectorate, 1999). Instead, we have worked to prepare and present concrete and action-oriented proposals for the implementation of the new guidelines.

The Government's guidelines pertain to substances with certain particularly dangerous properties – carcinogenic, mutagenic, reproduction-toxic (including endocrine-disruptive) substances, and substances that are persistent and liable to bioaccumulate above a certain level. A general approach shall be used for substances with such properties. It should be noted that besides these dangerous properties there are also other dangerous properties (neurotoxic, immunotoxic, sensitizing, ecotoxic, etc.), but that these properties are not covered by the Government's guidelines (see Chapter 2). No general approach is stipulated in the guidelines for substances with such other toxic properties. There are, on the other hand, wordings stating that humans and the environment shall not be harmed as a result of use of metals or use of persistent and bioaccumulative substances in production processes. In order to be able to judge this, all types of toxicity must be taken into consideration. Thus, toxicity is included in the guidelines on metals and production processes, but not in the other guidelines.

The scope of the guidelines is illustrated schematically in Figure 1.1 for different categories of substances – organic substances, metals and metal compounds, and inorganic substances that do not contain metals.

Figure 1.1 Scope of the guidelines.

The shaded squares show the scope of the guidelines for different groups of substances. For example, the guidelines include general phase-out criteria for

man-made organic substances, but not risk assessment for organic substances that may have other dangerous properties than those covered by the general criteria.

	Organic substances	Metals and metal compounds	Inorganic non-metals
Phase-out on general criteria regarding PB			
Phase-out on general criteria regarding CMRE			
Phase-out of mercury, cadmium and lead			
Restrictions based on risk assessment			

PB = persistent and bioaccumulative
CMRE = carcinogenic, mutagenic, reproduction-toxic and endocrine-disruptive
Inorganic non-metals = elements that are not metals and inorganic compounds of these elements. Examples of non-metallic elements are oxygen and sulphur. Examples of compounds of such elements are carbon monoxide and sulphuric acid.

In summary, we have chosen to delimit our commission so that e.g. the following areas, which may cause health and environmental problems associated with chemical substances and preparations, have not been dealt with or focused on in the work:

- existing products and materials in society
- historical contaminants in soil and water
- landfills
- occupational safety issues linked to chemicals use
- climate issues
- radioactivity and radiation protection
- foods
- pharmaceuticals
- narcotic preparations
- veterinary preparations
- petrol and petroleum-based fuels

– chemical weapons
– chemical accidents

We offer comments on the limits of our commission, and our views regarding it, below.

Delimitation vis-à-vis the Committee on Environmental Objectives

An important general point of departure for the Chemicals Committee has been to focus on identifying and proposing measures for certain particularly dangerous substances, i.e. substances which, according to the new guidelines, should not exist at all in products in 10–15 years. It is important to point out that a number of additional risk-limiting measures are needed beyond those we propose in order to reduce the risks of all chemical use overall. For a total picture, we refer to the report of the Committee on Environmental Objectives (SOU 2000:52).

Further action may need to be taken against substances not covered by the guidelines. Moreover, the new guidelines only apply to *new* products. In order to achieve the environmental quality objective, measures are also needed to reduce leaching of substances from *existing* products in society, from landfills and from contaminated sites.

This leaching amounts to large quantities overall, will continue for a long time and requires special remedial action. It is therefore important to note that the Committee's commission pertains solely to policy instruments and measures aimed at new products. Accordingly, the commission does not include measures aimed at dangerous substances in products that are already out on the market or have been discarded, or measures to prevent leaching from landfills.

We would like to call to mind the Environmental Objective Committee's commission to propose interim targets, action strategies and policy instruments to realize all environmental quality objectives, including the objective of a non-toxic environment. The Environmental Objective Committee's commission is a broad one, but does not primarily include the implementation of the new guidelines on chemicals control. There are of course nonetheless many points of overlap between setting interim targets for achieving a non-toxic environment and the new guidelines on chemicals control. We have therefore had close contact with the Committee on Environmental Objectives during the course of our work, particularly with regard to the interim target for knowledge of the health

and environmental properties of chemical substances (interim target 1, see Table 1.1) and the interim target for particularly dangerous substances (interim target 3, see Table 1.1). The points of overlap and division of labour are illustrated in the following table.

Table 1.1 Points of overlap and division of labour between the Chemicals Committee and the Committee on Environmental Objectives, based on the Committee on Environmental Objectives' interim targets for the objective of a non-toxic environment.

Interim target regarding	**Committee on Environmental Objectives**	**Chemicals Committee**
1. knowledge of inherent properties of chemical substances	(X)	X
2. health and environmental information for products	X	(X)
3. chemical substances with particularly dangerous properties	(X)	X
4. general risk reduction goal	X	-
5. target values for environmental quality	X	-
6. contaminated sites	X	-

X = main responsibility for proposing measures

(X) = responsibility, but not main responsibility for proposing measures

– = not covered by the new guidelines on chemicals policy

The Committee on Environmental Objectives proposes formulations for the interim targets in its report (SOU 2000:52). Their proposals for interim targets 1, 2 and 3 are based on the proposals we present in this report and on the National Chemicals Inspectorate's proposed subgoals. We have therefore consulted with the Committee on Environmental Objectives regarding the formulations of their proposals for interim targets 1, 2 and 3. The actual formulations are presented in the Committee on Environmental Objectives' proposals.

Measures already decided on

It is likely that a number of substances or groups of substances already targeted by special phase-out measures or restrictions will be found among the substances which we propose should be covered by the new guidelines.

The Committee finds no reason to reconsider measures already decided on; instead, we see it as our task to consider whether additional policy instruments are required to meet the guidelines for these substances.

Occupational safety

In our work we have not dealt with measures needed to protect employees against harmful chemicals in the working environment. As long as the substances are handled in manufacturing processes without any risk of escaping to the environment, via releases or in products, we assume that the persons who handle the substances are afforded adequate protection by the occupational safety legislation.

Petrol and other petroleum-based fuels

As is evident from Annex 4, carcinogenic substances are present in petrol and other petroleum-based fuels. These account for most of the volume of substances used in Sweden that can cause cancer. It is also likely that a number of persistent and bioaccumulative substances are contained in these products.

From the Committee's perspective, measures are thus needed against fuels and propellants as well. However, there are several reasons why our terms of reference should not be interpreted as directing the Committee to propose policy instruments for phasing out petrol and other fuels within 10–15 years. In this case the fuels would have to be modified or removed from the market, which is a matter of concern for Sweden's energy and transport policy. For the most part, other instruments are required for such a change than those normally used in the chemicals field.

One of the Swedish environmental quality objectives, clean air, entails that the concentrations of air pollutants shall not exceed established low-risk levels for cancer. The Committee on Environmental Objectives was commissioned to present measures to achieve this objective, and we have

had close contact with the Committee on Environmental Objectives in these matters. Owing to the special nature of the question, we have not proposed measures for its implementation. A number of the proposals presented by the Committee on Environmental Objectives will contribute to reducing the emission of these substances from petroleum-based fuels. In addition, we propose further investigations aimed at reducing the risks associated with petrol and other petroleum-based fuels. Such further investigations should be included as an important issue within the framework of the investigations proposed by the Committee on Environmental Objectives (the reader is referred to the report of the Committee on Environmental Objectives, SOU 2000:52, in the section ”Clean Air”).

Naturally occurring toxic pollutants

In view of the fact that the new guidelines apply to man-made substances, we do deal with naturally occurring toxic pollutants in this report, except to the extent that they are concentrated by man, such as in the case of mercury and other metals.

1.3 Some important definitions

Following is the Committee’s interpretation of some fundamental terms in the Government’s new guidelines.

Chemical substances, chemical preparations, chemical products and products

By ”chemical substances” we mean elements and their compounds, for example organic substances, metals and metal compounds.

By ”chemical products” we mean both chemical substances and chemical preparations, where preparations are mixtures or solutions composed of two or more substances. Examples of chemical products are paints, adhesives, detergents and cleaning agents. (This category is not used internationally, for example in the EU, where a distinction is made between substances and preparations.)

By ”products” we mean both chemical products and finished products such as cars, clothes, computers and building materials.

New products introduced onto the market

We interpret the term ”new products introduced onto the market” as including all products that have come out onto the market as of a given point in time, even if products with the same function were already present on the market. A product is considered to be new even if recycled material has been used as a raw material in its production. On the other hand, reused products, such as second-hand clothes, cannot be regarded as new when they are sold a second time.

Organic substances

By ”organic substances” is meant chemical compounds that are based on the element carbon in chemical union with the element hydrogen, including compounds where the hydrogen content has been completely or partially replaced with other substances such as oxygen, nitrogen and phosphorus. This category also includes organometallic compounds.

Man-made substances

The term ”man-made substances” includes both synthesized substances and substances extracted from e.g. plants or minerals.

We mean both deliberately produced substances and other substances to which they can give rise (e.g. DDE, which is a degradation product of DDT). We do not, on the other hand, mean inadvertently produced substances such as polyaromatic hydrocarbons generated by wood burning, or chlorinated dioxins generated in composting processes. Such substances are to be regarded as falling within the sphere of the environmental objective of clean air, or within the sphere of the environmental objective of a non-toxic environment, which pertains to discharges and emissions.

Hazard and risk

A distinction is made between the inherent hazard of chemicals and their risk.

The *hazard* posed by a substance has to do with the inherent potential possessed by the substance to cause harm to health and the environment. It is based primarily on an assessment of the biological, chemical and

physical properties of the substance. These properties determine the inherent capacity of the substance to cause harm to man and the environment, as well as the inherent potential of the substance for exposure. Hazard can be divided into health hazard (danger to health) and environmental hazard (danger for the environment) (see further in Chapter 2).

There are great differences in hazard between different substances. Substances can be irritating to the eyes and skin, other substances can cause e.g. liver or kidney damage at even low levels of exposure. Certain substances are carcinogenic, toxic for reproduction, mutagenic or sensitizing. Some substances have high toxicity to fish, other substances become concentrated in the food chains and can therefore cause severe damage in nature.

The *risk* posed by a substance is the result of a weighing-together of its hazard with additional information for the purpose of assessing the probability that harm will occur and assessing the possible extent of the harm. In order to be able to assess the risk posed by a substance, an exposure assessment for the substance in question is needed. The exposure assessment requires knowledge of how and to what concentrations man and the environment are exposed.

1.4 Planning and execution of the work

An important feature of our inquiry has been our way of working openly and in dialogue with researchers, the business community, public agencies and environmental organizations.

The Committee has had three appointed specialists and eleven experts (see cover letter and Annex 8). Meetings with the Committee's specialists and experts have been held nine times during the course of the inquiry.

In addition to our appointed specialists and experts we have also worked with the following three reference groups to broaden the Committee's contacts with the research community, the business community and public agencies.

- A scientific reference group
- A reference group on policy instruments
- A reference group on consequence analyses

Following is an account of how contacts have taken place inside and outside the reference groups in order to obtain feedback on the Committee's ideas and proposals.

Contacts with the business community

The reference group on policy instruments has met twice for presentation and discussion of the Committee's commission and our proposals. The purpose of the reference group has been to broaden our contacts with the business community and public agencies and to provide an opportunity for a dialogue on how the new guidelines on chemicals policy can best be implemented. Moreover, the reference group has been given our draft report for viewpoints.

The reference group on policy instruments consists above all of representatives of the business community – both individual companies and trade organizations – but also representatives of public agencies and one environmental organization. The participants in the reference group are listed in Annex 8.

In September 1999, the Chemicals Committee, together with the Committee on Environmental Objectives (M 1998:07) and the Environmental Advisory Council (Jo 1968:A), arranged a seminar on the role of market-driven instruments in the environmental work. Around 60 participants from the business community and public agencies participated in the seminar.

In connection with our evaluation of the National Chemicals Inspectorate's Observation List, a questionnaire was sent to a large number of companies, organizations, agencies and municipalities. In addition, a large number of interviews were held. In administering the questionnaires we collaborated with the Federation of Swedish Industries, the Association of Swedish Chemical Industries, the Swedish Plastics and Chemicals Federation and the Swedish Federation of Trade. In addition, a meeting was held with representatives of both the business community and public agencies and organizations to compare the results of the evaluation with our proposals.

The Committee has also had a special reference group that has dealt with the question of what consequences our proposals have for society, public agencies and the business sector and how these consequences can be described and, in some cases, calculated. In connection with our work on

consequence analyses, we have had contacts with representatives of the construction and building materials trade, as well as with the plastics and chemicals industry. We have had contact with, among others, Skanska Sverige AB, NCC AB, the Swedish Construction Federation, the Swedish Plastics and Chemicals Federation, the Association of Swedish Chemical Industries, the Swedish Paint, Lacquer and Varnish Manufacturers' Association, the Building Industry's Recycling Council and Trelleborg AB. The group has had four meetings.

Furthermore, we have had numerous other contacts and meetings with representatives of the Swedish business community, such as the Association of Swedish Chemical Industries, the Swedish Mine-Owners' Association, the Swedish Ironmasters' Association, AB Volvo, the Swedish Institute for Standards (SIS) and the Swedish Environmental Management Council.

Contacts with the research community

To broaden our contacts with the research community and obtain feedback on our proposals from a scientific perspective, the Committee has had a scientific reference group. We have had five meetings with the scientific reference group. The chairperson has been Cynthia de Wit, director of the Institute for Applied Environmental Research at Stockholm University and specialist on the Committee. The members of the reference group are listed in Annex 8.

On 27 April 1999, at the first meeting of the scientific reference group, the Committee held a seminar on criteria for liability to bioaccumulate and persistence. Around 25 persons (researchers and representatives of public agencies and the business sector) participated in this seminar.

One of the Committee's important initiatives has been to arrange an international scientific roundtable discussion on phase-out criteria for persistent and bioaccumulative substances ("Roundtable Discussion on Criteria for Phasing Out Persistent and Bioaccumulating Organic Chemicals"). The roundtable discussion was held in Steningevik, Sweden on 10–11 December 1999. At this meeting we compared notes on our preliminary thoughts regarding phase-out criteria for persistent and bioaccumulative substances with researchers from both the European countries and the USA, Canada and Japan. Representatives of the chemicals industry and the environmental organizations also participated. A

list of the participants and a documentation with conclusions from the seminar can be found in Annex 7.

Contacts with agencies

In our day-to-day work we have had close contact with above all the National Chemicals Inspectorate and the Swedish Environmental Protection Agency (SEPA).

Both our scientific reference group and our reference groups on policy instruments and consequence analyses (see above) have included representatives from public regulatory agencies. The reference group on policy instruments has included representatives of the National Chemicals Inspectorate, the SEPA and the Swedish Consumer Agency, listed in Annex 8.

The SEPA, the National Chemicals Inspectorate, the secretariat for the Committee on Environmental Objectives and representatives from the Swedish Government Offices have participated in the reference group for consequences (see Annex 8).

In connection with our evaluation of the National Chemicals Inspectorate's Observation List, a large number of interviews were conducted, including ones with representatives of central and regional public agencies and municipalities.

Moreover, we have had further contact and meetings with, for example, representatives of the Swedish National Board for Laboratory Animals and the Swedish Consumer Agency.

Contacts with other committees of inquiry

During the course of the inquiry we have, as noted above, had regular contact with the Committee on Environmental Objectives (M 1998:07). The secretariat of the Committee on Environmental Objectives has also been represented in our reference group on consequence analyses and in our reference group on policy instruments.

During the course of the inquiry we have also had contact with the Environmental Advisory Council (Jo 1968:A) and the Committee on Resource-Effectiveness (Fi 1999:02), which has been commissioned by

the Government to examine the relationship between growth environment and the need for measures for a more effective use of natural resources, including metals.

Contacts with environmental organizations

In the inquiry work we have had contact with the Swedish Society for Nature Conservation, which has also been represented in our group of experts. International representatives from the World Wide Fund for Nature (WWF) and from Greenpeace also participated in our international scientific roundtable discussion in Steningevik.

1.5 Consensus between public agencies, the business community and the research community

As we said in section 1.1, the Committee's proposals should be based as far as possible on a consensus between public agencies, the business community and the research community. To the extent such a consensus cannot be reached, the Committee shall clearly state where the differences in opinion exist.

We can conclude that there is by and large a consensus concerning the proposals in this report. The representatives of the business community have, however, offered some dissenting viewpoints. We summarize these viewpoints in the relevant sections of the report. The viewpoints of the Association of Swedish Chemical Industries with respect to the phase-out of substances with particularly dangerous properties are taken up in section 5.4, and the Association's viewpoints regarding the economic consequences for the Swedish chemicals industry are presented in section 10.3.2. The viewpoints of the Swedish Mine-Owners' Association on the Committee's thoughts regarding metals recycling are presented in section 7.4.3.1.

2 Points of departure

2.1 Summary of points of departure

Chemicals play an important role and do a great deal of good in our society. The development of chemical substances and preparations has contributed greatly to our current material prosperity, and we use chemicals in most contexts today. Examples of such uses are pharmaceuticals, plastics, preservatives, detergents, cleaning agents and paints. Chemicals are also contained in many products, such as clothes and computers.

But use of chemicals has also contributed to the back side of prosperity. The number of substances on the market has increased sharply in the past few decades, as have the flows of products and chemicals contained in them. Small quantities of dangerous substances can cause harm to man and the environment. We are exposed to a very large number of substances from an even larger number of sources, particularly finished products. Our exposure to a single substance from a single product may be small, but altogether man and the environment are exposed to a large quantity of chemical substances, of which an unknown number may be dangerous.

It is often difficult today to determine whether observed effects are due to a given substance, and it is also difficult to link the effects to a specific exposure. Nevertheless, efforts in Sweden and the rest of the world are aimed at risk-assessing and regulating isolated substances with the aid of extensive scientific documentation. But the work goes slowly. Very few decisions on actual measures – e.g. prohibitions or restrictions on dangerous substances – have been made in practice, although it should be pointed out that considerable success has been achieved in the risk management work in recent decades, such as for example the adoption of standardized testing methods, an EU-wide system for classification and labelling of chemicals dangerous for health and the environment, national and international restrictions on a number of

substances, and not least a greater awareness among companies and public agencies of the health and environmental risks of chemicals use.

In addition to developing criteria for the substances to be identified for phasing-out in new products, we have regarded it as one of the Committee's main tasks to present thoughts and proposals for the content of the EU's future products and chemicals policy, and to come up with workable solutions to the legislative problems created by the implementation of the guidelines. These proposals are intended to serve as a platform for the Swedish Government in its EU work.

In summary, the most important points of departure for our commission are the need for:

- more knowledge of the health and environmental properties of the substances,
- a more general approach in chemicals policy, chiefly with regard to persistent and bioaccumulative substances, as well as to carcinogenic, mutagenic, reproduction-toxic and endocrine-disruptive substances,
- new approaches with regard to dangerous chemicals based on the precautionary principle and the fact that the aggregate risk posed by chemicals today is more complex and difficult-to-assess. Previously the threat was mainly from local point releases – today the main problem is releases of many substances in small quantities from a large number of products,
- stopping the chemicals problems at the source, i.e. seeing to it that substances with particularly dangerous properties are not manufactured or used in the first place,
- concrete measures to implement the new guidelines on chemicals policy and thereby contribute towards achieving the environmental quality objective of a non-toxic environment,
- a platform for the Swedish Government in its work to bring about changes in EU chemicals policy and legislation, based on common knowledge requirements, the precautionary principle and a more general approach to the most dangerous substances,
- development and utilization of the market-driven tools in the chemical safety work.

2.2 What problems exist with today's use of chemicals?

2.2.1 Many substances, many preparations and many products

Today's use of chemicals is complex and extensive. There is a large number of chemical substances, which are incorporated in an even larger number of chemical preparations, which are in turn incorporated in a very large number of finished products. This makes it difficult to keep track of all the substances, preparations and products in circulation.

The National Chemicals Inspectorate has a database in the form of a products register that was created back in the late 1970s. This register was established to keep track of the large number of chemical products in Sweden. All companies that manufacture or import chemical products must submit a notification to the National Chemicals Inspectorate's products register every year where they re-notify and de-notify products, estimate the quantity of the products and update chemical compositions. The products register also contains information on the function, uses, and health and environmental hazard classification of chemical products.

According to the information submitted to the products register, some 60,000 chemical products (i.e. substances and preparations) are currently manufactured in or imported to Sweden. The total number of substances in these products is approximately 11,400. No one knows exactly how many chemical substances exist on the Swedish market if the chemical substances present in finished products (i.e. not just in chemical products) are also included, but it is estimated that the total could come to around 20,000 substances.

A few groups of chemicals are subjected to advance testing before being placed on the market. These groups are pesticides, pharmaceuticals and food additives. No approval is required for other chemical products. Cosmetic products must, however, be registered, and new substances introduced within the EU must be notified before manufacture or importation may commence.

2.2.2 Lack of knowledge

Lack of knowledge concerning the health and environmental properties of substances

There are great knowledge gaps concerning the possible inherent dangerous properties of chemical substances. The results in a report from the European Chemicals Bureau (ECB) serve as an example of this dearth of data. The report shows that only 14 percent of the approximately 2,500 high-production-volume (HPV) chemicals that are registered in the EU's database IUCLID have data complying with the basic requirements in the EU's dangerous substances directive, 65 percent have some data and 21 percent have no data whatsoever (Allanou et al., 1999). It can be assumed that the lack of data is even greater for lower-volume substances.

Another example that illustrates the lack of knowledge is the American EPA's study of the knowledge situation for the chemicals that are manufactured in or imported to the USA in volumes of over 454 tonnes per year (over 1,000,000 pounds per year). This study shows that only seven percent of the approximately 3,000 substances that occur above the volume limit have the minimum data considered by the OECD countries to be necessary knowledge. The same study also shows that no data at all are available for 43 percent of the substances (EPA, 1998).

To permit the selection and prioritization of hazardous substances within the framework of OSPAR-DYNAMEC (see section 4.4 in Annex 3) a Nordic database has been compiled (see section 8.5). It contains data on the persistence, bioaccumulation potential and toxicity of the substances, among other things. The database currently contains approximately 18,000 substances, although there are data on e.g. persistence *and* bioaccumulation potential for only approximately 2,000 of these.

In actual fact, people are not exposed to one substance at a time, but to a complex variety of substances, which increases the uncertainty. Existing knowledge on the effects of exposure to several substances simultaneously is very scanty.

Owing to the great lack of knowledge, it is not possible today to either identify all substances that are dangerous for health or the environment, or to make the necessary risk assessments and adopt adequate risk limitation measures.

Lack of knowledge on chemicals in products

In the case of consumer products other than chemical products, foods, pharmaceuticals and cosmetics, no rules exist today concerning health and environmental information, environmental product declarations or other documentation that provides information on the chemical content of products. This means that today's consumers have no way of ascertaining the content of e.g. flame retardants in electronics and textiles, bactericidal chemicals in clothing and dishrags, or plasticizers in plastics products. This also means that there is no way to get a picture of volumes and flows of chemicals in products in today's society.

2.2.3 In what way can chemicals be dangerous?

There is in the EU a system for classification and labelling of dangerous substances and chemical products. There are also rules for risk assessments, which are accompanied by a Technical Guidance Document (TGD, 1996) which describes in great detail how the assessments are to be carried out.

Chemicals can be dangerous or hazardous in a number of different respects, and the term "hazard" refers in this context to the substance's inherent properties. It is, however, important to distinguish between the inherent properties of a substance and the risk which exposure to the substance can lead to. When the risk is assessed, the hazard of the substance is weighed together with the exposure to which man and the environment are subjected. A very toxic substance can give rise to risk even at a low exposure, while a higher exposure is required for a substance that is less toxic.

The assessment of a substance's *health hazard* is usually based on studies on laboratory animals who have been exposed to the substance via food, inhalation air or skin. A substance's health hazard is divided into different hazard classes depending on what types of effects it causes and at what dose the effects occur. Certain effects manifest themselves after a single exposure of short duration, while other effects are the results of an individual's being exposed to a substance over a long period of time.

The following hazard classes for health hazard are used today in the EU:

- very toxic
- toxic

- corrosive
- harmful
- irritant
- sensitizing
- carcinogenic
- mutagenic
- toxic for reproduction

Substances shall be classified as *dangerous for the environment* if they constitute, or may come to constitute, an immediate or delayed danger for the environment. The assessment is normally based on data on harmful effects on aquatic organisms (e.g. fish, Daphnia and algae) and data on how bioaccumulative and persistent the substances are. Other data, for example on harmful effects on terrestrial animals and plants, may also underlie an environmental hazard classification.

Substances that are toxic to animals or plants in the environment are usually called *ecotoxic*. Data on the ecotoxicological effects of substances can be compared to the data that underlie the assessment of a substance's health hazard; in both cases the data concern actual harmful effects. Persistence and bioaccumulation potential differ from toxic properties, since persistence and bioaccumulation potential are not properties which in themselves harm organisms. However, the fact that a substance has these properties can lead to prolonged and high exposure to the substance in relation to a substance that does not have these properties. Prolonged, high exposure increases the risk of injuries, including ones that are not revealed by normal toxicity tests. Reasons why such injuries are not detected in normal tests can be that the organisms in these tests are exposed for too short a time for injuries to occur, that the tests do not take biomagnification (see Annex 3) into account, or that the tests are performed on organisms that are not as sensitive to the tested substance as other organisms in the environment.

2.2.4 Large volumes of dangerous substances

The total number of chemical products manufactured in or imported to Sweden in 1997 was 60,000; the aggregate volume of these substances and preparations was nearly 77 million tonnes. A relatively large quantity of the chemical products is exported – approximately 9,500 products were exported in 1997, making up a total volume of 34 million tonnes.

A relatively small number of products accounts for most of the volumes. Approximately 2,500 products account for 95 percent of the manufactured or imported volumes. Large portions of the total volume consist of synthesis intermediates (32 %), motor fuels (28 %), fuels for heating (13 %) and other fuels (8 %).

Today approximately 2,500 substances are classified as dangerous for health and/or the environment in the EU. The classification is based on the knowledge that the substances have dangerous properties in some respect. However, data are often lacking on other properties than those that have led to the classification, even for these substances. The classified substances may be contained as a component in many different chemical products and thereby lead to a classification of the products.

Approximately half of all chemical products in Sweden are classified as dangerous for health today. These products account for 85 percent of the total volumes. The group ”products dangerous for health” is dominated in terms of volume by those products classified as toxic. The products classified as toxic accounted for 39 million tonnes in 1997 and were used to a great extent as synthesis intermediates and fuels. The largest quantity of toxic substances was found within petroleum refining.

The volumes in the hazard class ”harmful” are smaller – the figure for 1997 was about 16 million tonnes – but the largest number of products is in this class, about 10,400.

Rules on environmental hazard classification have not existed for as long as rules on health hazard classification, which means that fewer substances have undergone an assessment regarding the environmental hazard. Today, just under 300 substances are classified in the category ”dangerous for the environment”. The environmentally dangerous substances are contained in more than 9,000 chemical products.
The picture is complicated by the fact that a large quantity of products containing chemicals are imported to Sweden. These products are not

included in the statistics from the National Chemicals Inspectorate's products register. Imports of products to Sweden amount to about 60 million tonnes per year, in the same order of magnitude as the net influx of chemical products, which is around 40 million tonnes per year.

2.2.5 What do we know about risks and effects?

What we know about the risks and effects associated with the substances covered by the new guidelines is dealt with in greater detail in Annex 3 (persistent and bioaccumulative substances), Annex 5 (endocrine-disruptive substances) and Annex 6 (metals). A general picture of the problem is presented below.

Persistent substances – long-term problems

Harmful substances can be released in all stages of chemicals handling: production, consumption and waste management. A particularly great problem is the release of long-lived or persistent substances. Substances that remain in circulation in society and the environment for a long time may lead to long-term problems. This may be the case with persistent organic compounds as well as metals, which never degrade.

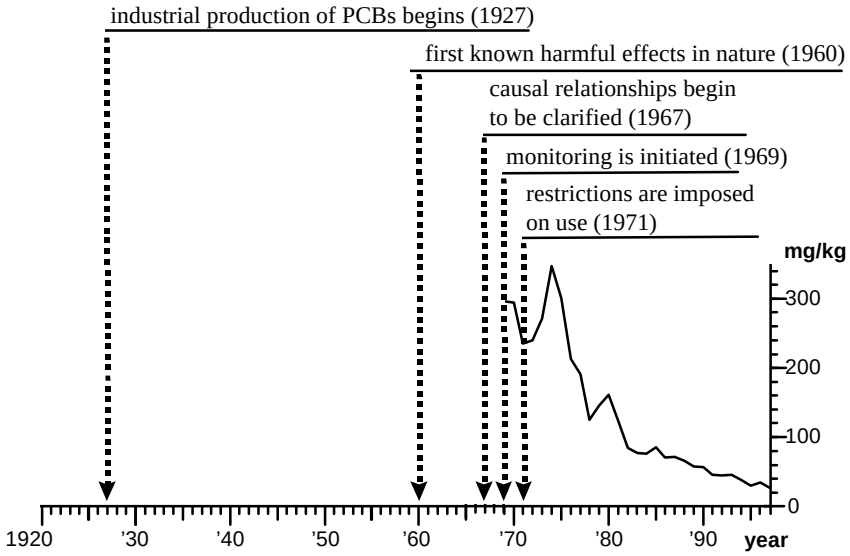
Another risk with persistent substances is that they can be transported long distances before they degrade. There are many examples of persistent substances that are spread all over the earth, including uninhabited polar regions.

We already know that many persistent substances have harmful effects. Many such substances are toxic to man and the environment. The effects of many other persistent, bioavailable substances are unknown at present, but history has taught us that harmful effects may exist that are difficult to detect, and once they are the substance may be so spread in society and the environment that it is very complicated to eliminate. An example of the latter is PCBs, which were not considered dangerous when they began to be used. It took several decades to discover the connections between PCBs and harmful environmental effects (see Figure 2.1), such as impact on the reproductive capability of seals. PCBs were banned, but despite the fact that the bans have been in effect for nearly 30 years the substance remains in the environment, and new effects are still being discovered today. As recently as the spring of

2000, it was found that PCBs can contribute to impaired development of bone tissue (Lind, 2000).

Figure 2.1 PCB concentrations in guillemot eggs 1969–1997.

Concentrations (by fat weight) of polychlorinated biphenyls (PCBs) in eggs of guillemot in the Baltic Sea. Note that, in contrast to what is shown in the figure for this seabird, since 1989 it is no longer possible to see any signs that the concentrations of PCBs are still falling in *Baltic herring*. On the contrary, there are signs of a new influx of PCBs to the Baltic Sea. (Data from Prof. Mats Olsson, Swedish Museum of Natural History).



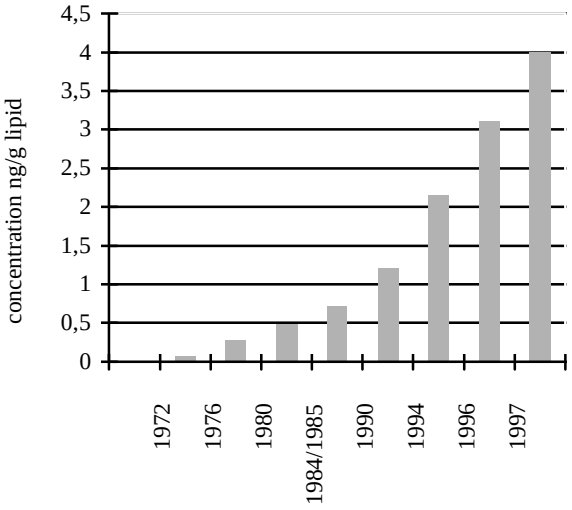
Another illustrative example of the problem with persistent organic pollutants (POPs) is the insecticide DDT. DDT was previously used in Sweden. It took several decades after the start of large-scale DDT use to discover undesirable effects, e.g. eggshell thinning in white-tailed eagles. Further decades passed before the damaged population began to recover. DDT is still found all over the world today and occurs in virtually all living organisms – from penguins in the Antarctic to polar bears in the Arctic.

Both PCBs and DDT are prohibited in Sweden today, but other groups of substances with similar properties are still used. Several brominated flame retardants have a PCB-like structure. Such substances are used in Sweden and are encountered widely in the environment. Human beings

also ingest persistent bioaccumulative substances, mainly via food. A serious and clear sign of this is the fact that many toxic pollutants are found in breast milk. The concentrations of PCB-like brominated flame retardants is increasing very rapidly in breast milk.

Figure 2.2 Brominated flame retardants in breast milk.

Temporal trend for concentrations of brominated flame retardants in breast milk. Sum of polybrominated diphenylethers, PBDEs. (Norén and Meironyt, 2000)



Use of persistent and bioaccumulative substances can lead to high and prolonged exposure in animals high up in the food chains. It is highly likely that more and more effects of such exposure will be discovered with time. This particularly applies to effects based on complex relationships, such as disruptions of the endocrine systems. Endocrine disruptions can in turn cause a number of disorders such as impaired fecundity, cancer and behavioural disturbances.

When it comes to metals, it is known that they never degrade, even though they can eventually become unavailable to living organisms, for example by being sequestered in deep sediments. Use of metals has increased sharply in recent decades. Some applications lead to a relatively rapid release of the metal to the environment (e.g. brake linings and marine antifouling paints). In many other applications,

contamination of the environment is small in the long term in relation to the quantity used. This is the case for e.g. water supply pipes and copper roofing. But the large quantity used and the long time the structures are present in society nevertheless gives rise to large metal flows over time. Thus, for example, copper water supply pipes are the predominant source of copper in sewage sludge. In a very long-range perspective, there is always a risk that the metal that was once extracted from the earth's crust may be released to the external environment.

As a consequence of man's conversion of metals, the concentrations of mercury, cadmium and lead in southern Sweden have increased considerably in relation to natural background levels. The high concentrations have an influence on the degradation of dead organic matter, and thereby on the cycling of nutrients in the forest ecosystems. Metals that end up in soil remain there for a very long time – hundreds of years – so that the problems are very long-range indeed.

Another alarming example of metal contamination of the environment is that the copper concentrations in many Swedish coastal waters are now so high that adverse effects can be expected on e.g. bladder wrack, which is a key species for the entire coastal ecosystem.

High concentrations of dangerous substances in the environment also affect man, who ingests them via food. The levels of mercury in fish are so high at some places in the country that women of fertile age should not eat fish due to the risk of foetal damage. Cadmium can cause kidney damage, and at prevailing intakes of cadmium there is a risk that sensitive individuals will suffer some adverse effects on kidney function.

Substances that cause particularly serious effects

Man and the environment can often not avoid exposure to chemical substances, which are constantly being released when products are produced, used and discarded. Each of the properties carcinogenic, mutagenic, reproduction-toxic and endocrine-disruptive is in itself very serious. Endocrine-disruptive impact can lead to a number of the major national diseases (see further Chapter 5.2). In its report, the Chemicals Policy Committee (SOU 1997:84) has given particular attention to these properties. The reasons given for this were that the properties are very serious and that substances with such properties should not be allowed to cause inadvertent exposure. A single exposure at low dose can cause

injury, and there is no way to predict how large a total dose the individual or the environment will be exposed to.

Other examples of chemical substances that have given rise to serious and irreversible harmful health effects on direct exposure are nickel (allergies), certain organic solvents (damage to the nervous system) and certain plant protection products.

2.3 Chemicals policy and chemicals control

2.3.1 Principles and legislation

For an account and analysis of the chemicals work since the mid-1980s, the reader is referred to the Chemicals Policy Committee's report "A sustainable chemicals policy" (SOU 1997:84, Annex 2, in Swedish only, summary in English). For an account and analysis of the chemicals work prior to that, the reader is referred to the Chemicals Commission's report "Chemicals control" (SOU 1984:77, in Swedish only). A summary description of chemicals control today is given in this section. In the light of the new guidelines on chemicals policy, EU and Swedish legislation in the chemicals field is dealt with in Chapters 3, 6 and 7. A brief introduction setting forth the points of departure is provided below.

The Committee notes that fifteen years have passed since the Chemical Products Act (1985:426) entered into force, and more than a year has passed since it was replaced by the Environmental Code (1998:808). The overarching purpose of Swedish chemicals policy and chemicals legislation under these two bodies of legislation has been and is to prevent injuries to human health or the environment caused by chemical substances, chemical products and finished products. Important goals of chemicals control can be summarized in the following points:

- *Knowledge goal*, i.e. that chemical substances and products shall be well-researched with respect to their effects on health and the environment.
- *Information goal*, i.e. that knowledge shall be passed on to those who use the chemical substances and products.
- *Product goal*, i.e. that as harmless products as possible shall be chosen and that harmful substances shall as far as possible be replaced with less harmful and preferably harmless ones.
- *Handling goal*, i.e. that health and environmental risks shall be eliminated by safe handling of chemical substances and products.

An important principle is that manufacturers and importers bear principal responsibility for the chemical substances and products they deliver. The task of the regulatory agencies is to ensure that the companies do what is necessary to reduce and eliminate environmental and health risks. An accepted principle, which has long existed in Sweden and is also embodied in the legislation, is the precautionary principle, which entails that anyone who handles or imports a chemical product shall adopt such measures and precautions as are needed to prevent harm to man or the environment if even a suspicion exists that such harm might arise.

Another important principle in Swedish chemicals control is the product choice principle (substitution principle), which is now also embodied in the Environmental Code's general rules of consideration. This principle entails that chemical products that can be replaced with less dangerous products shall be avoided.

Swedish chemicals policy is influenced by the country's EU membership. The EU has long had extensive legislation in this field, which has come about in an ambition to facilitate trade in finished products and chemical products between the member states. This has been accomplished by harmonization of the member states' requirements regarding e.g. classification, labelling and restrictions of dangerous chemicals. The Community has had a number of environmental action programmes, but it was the Single European Act (which entered into force in 1987) that first incorporated principles of importance for the environment in the overarching legislation – the EC Treaty.

The Single European Act entailed, among other things, that the environmental objectives of the Community were given a clearer formulation (Article 130r), where it was stated that the Community's measures with regard to the environment shall preserve, protect and improve the quality of the environment, contribute to the protection of human health, and ensure a prudent and rational utilization of natural resources. Through the Single European Act, four principles were also incorporated in the EC Treaty stating that preventive action should be taken, that pollution should be rectified at the source, that the polluter should pay, and that environmental protection requirements should be integrated in overall Community policy.

The environmental aspects have been further clarified through the Maastricht Treaty (which entered into force in 1993). Among other things, the Community shall, in addition to pursuing the previous

environmental objectives, promote measures at an international level to solve regional or global environmental problems. The precautionary principle was also introduced into the EC Treaty.

Chemicals policy in the EU consists partly of national policy and partly of decisions taken at the Community level. Legislation at the Community level may consist of harmonized rules, which leave little room for special national rules. The chemicals field is regulated to a great extent by harmonized legislation. For further description of the EU's chemicals policy and legislation, the reader is referred to Chapters 3 and 6.

2.3.2 The environmental quality objective of a non-toxic environment

An important point of departure for the work of the Committee is the environmental quality objective of a non-toxic environment. The Bill "Swedish Environmental Quality Objectives" (Gov. Bill 1997/98:145) proposes 15 national environmental quality objectives:

1. Clean air
2. High-quality groundwater
3. Sustainable lakes and watercourses
4. Flourishing wetlands
5. A balanced marine environment, sustainable coastal areas and archipelagos
6. No eutrophication
7. Natural acidification only
8. Sustainable forests
9. A varied agricultural landscape
10. A magnificent mountain landscape
11. A good urban environment
12. **A non-toxic environment**
13. A safe radiation environment
14. A protective ozone layer
15. Limited influence on climate

One of the environmental quality objectives thus entails achieving a non-toxic environment. It is formulated as follows:

”The environment must be free from man-made substances and metals that represent a threat to health or biological diversity.

This environmental quality objective means that:

– *the levels of substances that occur naturally in the environment must be close to background levels*
– *the levels of man-made substances in the environment must be close to zero.”*

In 1998 the Government commissioned the National Chemicals Inspectorate to develop subgoals and propose action strategies to realize the subgoals. Within the framework of the National Chemicals Inspectorate’s work of developing subgoals and action strategies for realizing the environmental quality objective of a non-toxic environment, the National Board of Health and Welfare, the Geological Survey of Sweden, the Swedish Environmental Protection Agency, the National Board of Occupational Safety and Health, the National Board of Housing, Building and Planning and the Swedish Board of Agriculture have also collaborated. On 1 October 1999, the National Chemicals Inspectorate presented its account of the Government commission to the Government (National Chemicals Inspectorate, 1999). The Government subsequently turned over the report to the Committee on Environmental Objectives and to our Committee. In the work towards the objective of a non-toxic environment, the National Chemicals Inspectorate has chosen to include the environment in a broad sense, i.e. everything from the natural environment to the urban environment, including the indoor environment and the working environment.

The subgoals that were proposed by the National Chemicals Inspectorate – and with which the Committee in Environmental Objectives has worked further – are the following:

- *Subgoal 1 – Properties and effects of chemical substances*

By 2010, data that satisfy established minimum requirements are available for deliberately manufactured products and extracted substances handled on the market. Knowledge regarding the occurrence and properties of unintentionally formed substances and the combined effects of different chemical substances is constantly growing.

- *Subgoal 2 – Finished products*

By 2010, finished products carry health and environmental information. Knowledge exists regarding where substances with dangerous properties occur in products and how they flow out into the environment.

- *Subgoal 3 – Systematic risk reduction*

The health and environmental risks associated with chemical substances in all types of products and processes decrease progressively, along with the occurrence and use of chemical substances that impede the recycling of materials.

- *Subgoal 4 – Particularly dangerous substances*

Exposure of man and the environment to substances with particularly dangerous properties, caused by their occurrence and use in products and production processes, has ceased by 2020.

- *Subgoal 5 – Target values for environmental quality*

In 2020, target values for environmental quality, established not later than 2015 for prioritized chemical substances, are not exceeded.

The National Chemicals Inspectorate concludes that international efforts are required to meet several of the subgoals. At the same time, they conclude that national efforts must be pursued on a broad front by the business community, non-governmental organizations, consumers and public agencies.

The National Chemicals Inspectorate's proposals for subgoals, and other assessments as regards the environmental quality objective of a non-toxic environment, have been an important point of departure for our work.

To enable the objective of a non-toxic environment to be achieved, the Government judged in the Bill "Swedish Environmental Quality Objectives" (Gov. Bill 1997/98:145) that the chemicals policy also needed to be supplemented with new guidelines. The new guidelines, which comprise the basis for our commission, were presented in Chapter 1.1. The new guidelines pertain above all to the National Chemicals Inspectorate's proposed subgoals 1, 2 and 4 above, i.e. to the properties and effects of chemical substances, finished products, and particularly dangerous substances.

2.3.3 Product perspective increasingly important

Most finished products are composed of a number of materials, which contain different kinds of chemicals as components and additives in order to provide such properties as durability, plasticity and flame retardance.

In recent years the realization has grown that many environmental problems are not primarily related to the production or use of the pure substance or preparation, but to products that contain or have been treated with chemicals. Even though the risk of exposure on contact with the product may be small, the large number of products in society entails a potential risk both during use and when the product is discarded and becomes waste. Certain product groups that contain problematical chemicals have also increased in use in recent years, e.g. computers.

The increase in the quantities of products in the past few decades has also entailed an increased input of chemicals, including dangerous chemicals, into society.

The changed problem picture – from point releases to diffuse releases from finished products – means that the chemicals work must change. A product-oriented approach should be founded on the principle of finding substitutes for dangerous chemicals added to products. Nor should dangerous substances be formed during the use of the product or when it has entered the waste stream. Greater integration of chemicals, waste and release issues should facilitate a product-oriented approach.

2.3.4 Dangerous properties of substances should be sufficient grounds for phase-out

It should be pointed out that risk assessments will continue to be needed in the chemical safety work. But today's work methods need to be supplemented with a more general approach aimed at chemical substances that have inherent properties making them dangerous for health or the environment, such as carcinogenic, mutagenic, reproduction-toxic or endocrine-disruptive properties. In other words, it is a question of taking measures against particularly dangerous substances in view of their inherent dangers, instead of waiting for a risk assessment. (See Chapter 1 for a definition of hazard and risk.)

The reasons why a new approach is needed are firstly that the current way of working with risk assessments of one substance at a time goes far too slowly, and secondly the long "braking distance" for persistent substances. With the precautionary principle as a basis, measures must be adopted in time – before effects can be seen in man and the environment.

The Chemicals Policy Committee (SOU 1997:84) made the judgement that it is not possible to manufacture or use chemicals without their eventual release into the environment. The Committee was of the opinion that the use of certain substances with particularly serious properties should cease – such properties in particular being that they are persistent and bioaccumulative, and these properties suffice for a substance to be phased out. The Esbjerg Declaration, wrote the Chemicals Policy Committee, assumes that substances must be persistent, liable to bioaccumulate *and* toxic in order to be restricted or phased out. The Chemicals Policy Committee was, however, of the view that the requirement of known toxicity is ultimately a question of whether the work with persistent substances should be preventive, or whether it should proceed substance by substance after harmful effects become known. Once a persistent and bioaccumulative substance has been shown to have harmful effects, the damage is often already done; the persistent substance is already in the environment and will continue to cause effects, since it degrades very slowly and cannot as a rule be collected. If only those substances which scientists already know are toxic are phased out, we will always be one step behind, according to the Chemicals Policy Committee. The Committee's conclusion was therefore that a preventive approach should be taken, meaning that substances shown by experience to cause long-term harmful effects should be phased out.

The Chemicals Policy Committee proposed as an objective that the use of persistent and bioaccumulative man-made organic substances should be phased out of use in finished products by 2007 and in production processes by 2012.

The current approach in the chemicals field is based on targeting one substance at a time. In the Government's judgement, this approach is far too slow. Moreover, it is extremely difficult to estimate the risks posed by certain substances, particularly those that are persistent and bioaccumulative. The guidelines defined by the Government in the Bill "Swedish Environmental Quality Objectives" (1997/98:145) entail that a more general approach be aimed at man-made organic substances that are bioaccumulative and persistent, in accordance with what was proposed by the Chemicals Policy Committee.

The Government states the following in the terms of reference for our Committee:

> *"...in order for the guidelines to be applied, more precise definitions must be given of what is meant by persistent and bioaccumulative. Among other things, limits must be defined for when these properties are unacceptable, i.e. when their use leads to an unacceptable risk for man and the environment. It is in most cases difficult to set an exact limit for persistence and bioaccumulation above which substances with such properties on exposure pose an unacceptable risk for man and the environment. Nevertheless it may in many cases be necessary to set clear-cut limits in the form of limit values. The assumption must always be that man-made organic substances always pose a potential risk for human health and the environment, that they can accumulate in organisms and that they are so persistent that they also accumulate in the ecosystem."*

The Government has thus taken yet another step with these terms of reference, which serve as points of departure for the work of our Committee.

2.3.5 Measures are needed at national and international level

International work in the chemicals field is of great importance, since many problems with chemicals cannot be solved at the national level. The chances of finding solutions to problems in Sweden depend on chemicals use and control in other countries. The chemicals and products that are sold are, for example, often manufactured in other countries. The substances are thus spread via trade in products and furthermore out into environments far from both manufacture and use, due to the fact

that many substances are poorly degradable and may be transported far away by e.g. winds.

To achieve the environmental quality objective of a non-toxic environment, national chemicals policy must to a large extent be internationally oriented. Chemicals control is already well-developed in Sweden, where the Environmental Code in particular is a good tool. But achieving the environmental quality objective will require better chemicals control in many other countries as well, both rich and poor.

A large portion of the products we use are manufactured in other countries. Global trade makes it more difficult to keep track of chemicals use in the manufacture of products, since the products have often passed through several production stages in different countries before arriving in Sweden.

As the global trade in chemicals and products has increased, the international work of chemicals control has also grown in importance. International cooperation via various bodies, as well as global and regional agreements on chemicals, are naturally extremely important in reducing the health and environmental risks associated with chemicals use.

Membership in the EU and the World Trade Organization (WTO) also entails restrictions on national freedoms and commitments to ensure that national environmental policies that may have an influence on international trade comply with certain requirements. Here again, international cooperation is of great importance.

Our conclusion is that from the perspective of finished products, it is quite apparent that the stipulated guidelines cannot be enforced solely by measures on a national level. Measures must also be adopted on an international level, to begin with in the EU.

2.3.6 Both hard and soft instruments are needed

When it comes to instruments for implementing chemicals policy, it is the opinion of the Committee that both hard (legislative) and soft (voluntary) instruments must be used to achieve success. The solutions must come both from the market – where existing voluntary tools in the form of ecolabelling, environmental management systems etc. can be used and developed – and from public decrees stipulating the highest

tolerable level of risk to citizens and the environment that society can accept in a long-term perspective.

Restrictions of substances that entail particularly great risks for health and the environment should be imposed via legislation in the EU, since there is an extensive international trade in chemical substances, preparations, and other products. A national ban on a chemical substance, for instance, will have only a limited health and environmental effect, since the substance can often occur in large quantities in the products we import from other countries. It may be difficult to impose national bans on chemicals, or on chemicals in products, when such bans are often regarded as technical trade barriers.

When it comes to national measures, however, ”soft” or market-driven instruments play an important role.

The following table (Table 2.1) provides an overview of the policy instruments that can be used in the work of implementing the new guidelines on chemicals policy. Descriptions of the policy instruments and proposals on how they should be used and developed to achieve compliance with the guidelines are provided in the Committee report.

Table 2.1 Summary of policy instruments that can be used

	National	EU	International
Market-driven and ”soft” instruments	Positive ecolabelling (Nordic Swan + Good Environmental Choice) Observation list, or Voluntary commitments Environmental product declarations Target values Other information R&D	EMAS Positive ecolabelling (EU flower) Chemicals and products policy R&D	ISO standards of various kinds Industry standards
Regulatory instruments	Licensing of environmentally dangerous activities and pesticides Restrictions of individual substances Supervision Self-inspection Environmental quality standards Restrictions of individual substances	Restrictions/prohibitions for substances that lack minimum data Restrictions/prohibitions for PB and CMR substances in chemical products and other products Expanded data requirements for new and existing substances Risk assessment of existing substances Health and environmental information for products Emission rules Producer responsibility for end-of-life products Standards, type approvals	Environmental conventions POPs CLRTAP OSPAR HELCOM OECD guidelines WTO

3 The EU needs a new chemicals strategy

3.1 Introduction

As a member of the EU, Sweden is subject to European legislation in the chemicals field. An important part of the Swedish work in the chemicals field therefore takes place today within the framework of the EU.

According to our points of departure in Chapter 2, the new guidelines should be implemented via common EU-wide rules, in view of the product perspective (trade, diffuse emissions, etc.). Common global rules are also needed in the long run. There are of course several ways to bring a matter up on the EU's agenda. When it comes to matters that are of a general character and involve many substances and products – while also representing a new strategic point of view – we believe that notification of national proposals is not a suitable method. Instead, efforts should be made to directly influence EU policies and rules. On the other hand, we believe it is possible to influence the EU by notification of national prohibitions in the case of individual substances, such as mercury (see section 7.2.1).

This chapter describes some points of departure for the EU's chemicals work and *acquis communautaire* in the chemicals and environmental field. It also presents what we, based on the new guidelines in Swedish chemicals policy, consider to be important parts of an environmentally oriented products policy and a new chemicals strategy in the EU. Later – in Chapters 4 and 6 and in Annex 2 – we present our concrete proposals for changes in the EU's different legal acts. In Annex 2 we also outline how the EU could implement our proposals within the framework of existing legislation.

3.2 Some points of departure for the EU's chemicals work

The EU has long had extensive legislation in the chemicals field. An open single market, where customs duties and other types of trade barriers between member states have been abolished, has been a fundamental objective for the Community ever since the advent of the Treaty of Rome (EC Treaty) in 1957. The common EU legislation in the chemicals field has thus come about in an effort to facilitate trade in chemical products between the member states, which has been accomplished by harmonization of the member states' requirements regarding e.g. classification, labelling and restrictions for certain chemicals.

It has often been discussed whether the internal market has prioritized economic aspects and trade at the expense of environmental and health protection, which has been regarded more as a potential obstacle than a goal in itself. But the Single European act of 1986 moved environmental issues up to the political level in the Community from a level with different kinds of Community measures and rules.

The Single European Act has also been criticized for certain shortcomings in environmental protection, decision-making rules etc. However, the Maastricht Treaty (Treaty on European Union) in 1992 solved some of these problems – especially with regard to the decision-making procedure that is applied within the environmental field. It then became possible to make decisions by a qualified majority instead of unanimously. This treaty also established the application of the precautionary principle.

The Treaty of Amsterdam[1], adopted in 1996 and amending the treaties of Maastricht and Rome, introduced *sustainable development* as an objective. The integration of environmental policy into the Community's other policies was also advocated.

With the Single European Act from 1986 and the Maastricht Treaty from 1992, concrete EU legislation has also begun to be more directly influenced by the EU's general environmental policy. Furthermore, a decision was taken at the meeting of the European Council in Cardiff in

[1] The Treaty of Amsterdam entered into force on 1 May 1999.

June 1998 to integrate environment and sustainable development into all Community policies.

EU's points of departure for the products and chemicals field

In recent years the EU's work with chemicals has been criticized due to the fact that progress on risk assessment and risk management of existing substances has been far too slow. In the spring of 1998 in Chester, the Commission announced that it was going to devise a strategy for chemicals, and at the Environment Council meeting in December 1998 the Council adopted certain conclusions underlining the need for an integrated and coherent strategy for the EU's future chemicals policy. The purpose was given as being a high degree of protection for human health and the environment in a rapidly growing market for chemicals and the efficient functioning of the internal market. According to the Council, the future chemicals policy should reflect the precautionary principle and the principle of sustainability.

The discussions of a future chemicals policy in the EU continued at the informal meeting of the environment ministers in Weimar in May 1999. Among other things, the question of a shortage of data on many chemicals was brought up. The need for a common products policy and the connection between a chemicals policy and a products policy were also discussed at the meeting.

A number of shortcomings in the existing chemicals policy were noted at the Council meeting in June 1999. The Council observed in its conclusions, among other things in view of the fact that a risk assessment had only been performed for a very small number of existing substance, that the current approach will scarcely lead to the necessary risk limitations. They further stressed the importance of establishing strategies for achieving effective risk management measures for substances that may cause threats of serious or irreversible damage to human health or the environment. Encouraging the substitution of less dangerous substances for dangerous substances was also said to be important.

Two of the most important issues in the EU's environmental work in the upcoming years are thus to reform the EU's chemicals policy by framing and adopting a new chemicals strategy and making the necessary changes in the *acquis communautaire*, and developing a strategy for products.

The European Commission will submit a proposal for a chemicals strategy during 2000. The hope of our Committee is that the proposal submitted will be vigorous and far-reaching. The Commission is also preparing a Green Paper on an environmentally oriented product policy, which will also be presented during 2000. It is our hope that the proposals we present can serve as a valuable platform for Swedish contributions to the further development of these strategies.

3.3 Environmentally oriented product policy

3.3.1 Why is an environmentally oriented product policy needed in the EU?

Awareness has gradually increased in the last few decades that it is not possible to solve environmental problems solely by focusing on production processes and emissions. A greater focus is also needed on consumption, products and waste. Emissions of substances harmful to health and the environment from products, buildings etc. are much greater than emissions from production processes. The relative importance of leaching of dangerous substances from products has increased in recent decades due in part to success in reducing point emissions of dangerous substances. Viewed over several decades, an increased flow of products is also a problem in itself. A coherent and long-term strategy is therefore needed to address the environmental impact of products in order to limit the spread of dangerous substances in the future.

The Commission's evaluation of the Fifth Environmental Action Programme[2] shows that much progress has been made in environmental legislation, but that the EU has not come very far when it comes to integrating environmental aspects in other policies. The fundamental principles that were established for the Fifth Environmental Action Programme are therefore still valid. Among other things, they entail rectifying the patterns of consumption and production that are undermining environmental quality, giving rise to health and safety problems, and wasting natural resources.

[2] The EU prepares time-limited action programmes for the environmental work. The current Fifth Environmental Action Programme applies to the period 1993–2000. The European Commission intends to present a proposal for a new environmental action programme at the end of 2000.

A coherent, unified environmental strategy for goods is currently lacking in the EU, even though many rules in the EU regulate products and the environment. But the European Commission has initiated work on an integrated product policy (IPP) and intends to present a Green Paper before the summer of 2000.

In May 2000, the Swedish Government submitted a communication to the Riksdag (Swedish Parliament) regarding an environmentally oriented product policy. The communication describes the future strategy by formulating an environmentally oriented product policy on a national basis and at the EU level. The purpose is to analyze and possibly stipulate common requirements on the products that are produced, and to describe different actors' responsibility for the products that are placed on the market during the entire life cycle of a product. Another purpose is to provide an overview to coordinate the efforts being made in the field so that they strive in the same direction within the internal market, business, finance, consumer and environmental sectors.

The ultimate goal is to obtain products that are resource- and energy-efficient and do not contain substances that can give rise to adverse effects on environment and health. The work should be characterized by a cradle-to-grave view of the products – from production and use to reuse, recycling, destruction and disposal. A holistic view must also be embodied in rules governing the entire life cycle of the products and all actors involved – from design and production to consumption and recycling.

Examples of tools with relevance for the work on an environmentally oriented product policy include e.g. producer responsibility, ecolabelling, environmental product declarations, environmental management systems, standardization, environmentally responsible procurement, taxes and charges, life cycle analyses and voluntary agreements.

The work of integrating environmental aspects in a product perspective must consider such factors as industrial competitiveness, employment, functioning competition and free cross-border trade.

Within the framework of the EU's work, the Commission has engaged consultants to produce a report and arranged a workshop (December 1998) on what a common environmental strategy for products in the EU might look like. The question of an integrated environmental product policy was also dealt with at the informal environment ministers' meeting in May 1999 in Weimar. The Swedish minister for the

environment then proposed that chemicals policy be integrated in the work on an environmental product policy.

3.3.2 What should an environmentally oriented product policy contain?

In summary, we believe that the most important parts of a future environmentally oriented product policy in the EU are as follows, with regard to chemicals:

- A system for a producer (manufacturer, importer, seller) to provide information on a product's content of dangerous chemicals should exist in the EU by not later than 2010. The question is complex and we therefore propose that the Government appoint a special committee to investigate this matter (see section 7.4.1).
- The substances that are especially dangerous for health and the environment – that according to our proposals should not be included in chemical products (substances and preparations) – should not be present in other finished products either (see Chapters 5 and 6).
- It should be considered whether producer responsibility for end-of-life products should be extended to embrace more product groups. Requirements on restrictions of dangerous chemicals in products should always be considered when devising rules regarding producer responsibility for end-of-life products. General references should be provided to the rules that restrict dangerous substances.
- Different strategies for recycling, reuse, collection and destruction of products containing substances dangerous for health and the environment are needed.
- Chemicals issues should be emphasized in Council Regulation (EEC) 1836/93 on voluntary eco-management and audit for companies, EMAS (see Chapter 6).
- The efforts of industry must be the most important part of the chemicals safety work.
- Environmental considerations must be integrated in product directives and product standards.
- In the formulation of new directives on CE marking of products (the new approach directives) and other product directives, assurance must be provided that sufficient consideration is given to environmental and health aspects. Rules restricting dangerous

substances must be taken into account. Every product standard should undergo environmental assessment (see Chapter 6).

- Existing product directives must be reviewed with regard to the environmental and health aspects of dangerous substances (see Chapter 6).

The Committee emphasizes the importance of developing a common environmental product policy in the EU, where chemical and other environmental and health aspects are integrated in the other policy areas. We particularly wish to stress the chemical aspects in such a policy, since products and handling of products largely has to do with flows of energy and chemicals. Harmful chemicals are being spread diffusely today in society above all via products.

The link between a new chemicals policy and a coherent environmental strategy for products is crucial in addressing the product problem. If the environmental product policy is truly to serve its purpose and be an effective instrument in the environmental work, chemical aspects should permeate all parts of environmental product policy.

Any conflicts between the function of chemicals and their health and environmental properties should also be elucidated. For example, the relationship between long-lived products and phase-out of persistent substances needs to be clarified. In order to increase the service life of products and materials, chemical substances with environmentally less desirable properties are sometimes added to them. It may then be necessary to weigh different goals against each other.

Certain metals should be phased out instead of being recycled. Moreover, knowledge of the health and environmental effects of many metals is inadequate today. Special analyses may therefore be needed of how a policy for reuse and recycling should be formulated.

The Committee finds that extensive work is needed over the next few years to clarify and also implement the intentions of an environmental product policy. An area that should be prioritized is integrating and highlighting the use of chemicals in products. Besides an overall common policy, the EU also needs to find new common instruments and improve existing ones.

A system for providing information on a product's content of dangerous chemicals should be developed in the EU. We believe that Sweden is very knowledgeable in the area of chemicals and products, and we

therefore propose that Sweden should actively contribute to the development of such a system by arranging for investigation of the many questions that must be elucidated before deciding how such a system should be designed (see Chapter 7).

Like the Swedish Environmental Protection Agency (SEPA, 1999d), the Committee feels that responsibility for the environmental load of products throughout their life cycle should constitute a fundamental principle of an integrated product policy (IPP) and that it is incumbent upon the producer (manufacturer, importer, seller) to be aware of the consequences for human health and the environment of the products he provides. The producer should also adopt preventive measures to reduce the total environmental load during the entire life cycle, as well as solicit and furnish environmental information on the product's content of particularly dangerous substances and the product's environmental impact during its entire life cycle.

This entails a greater responsibility than today and a broader view of producer responsibility, since diffuse emissions during use are also included. The current waste policy principle of producer responsibility is a specific instance of this broader view.

It should be possible to expand a statutory producer responsibility for end-of-life products to cover more product groups. Producer responsibility for end-of-life products may also provide an opportunity for phasing out particularly dangerous substances in products. In the first place, the rules on producer responsibility can prohibit certain dangerous substances from being used in products (cf. the Commission's draft proposal for producer responsibility for electrical and electronic products, see Chapter 6 and Annex 6), and in the second place, producers are given a general and strong incentive to remove harmful substances from their products since they are given responsibility for recycling/reuse.

The Committee shares the SEPA's view that further investigation is needed of questions pertaining to producer responsibility for the environmental impact of a product throughout its life cycle.

3.4 New chemicals strategy

3.4.1 Why is a new chemicals strategy needed?

Sustainable chemicals handling is still a long way off in the EU, even though important progress has been made in recent years. The Committee finds that an important step along the way is the work now being done to obtain a sustainable chemicals strategy in the EU. Today's chemical safety system contains a number of serious deficiencies or problems. We believe the most important problems are as follows:

- There is a great lack of knowledge concerning the health and environmental properties of substances. As a result, the vast majority of the chemical substances are not covered at all by the EU's current chemicals legislation.
- There is a lack of long-term perspective, especially when it comes to health and environmental effects, but also when it comes to economic effects. It is costly to do something about dangerous substances when they are already widespread in the technosphere and the environment. It is better to prevent and apply the precautionary principle than to clean up afterwards.
- Companies are not being given enough, or clear enough, responsibility.
- There is an inefficiency in the present-day system. For example, the work on risk assessments is proceeding far too slowly.
- A strategy is lacking for the most dangerous chemicals.
- There is an inadequate product perspective when it comes to chemicals in products; the presence of dangerous chemical substances and preparations in products is not given enough attention in the *acquis communautaire*. There are also conflicts of interest between free trade in goods on the one hand and health and environmental protection on the other. Examples of this are given in Chapter 6, e.g. with regard to product directives and product standards.

3.4.2 What should the new chemicals strategy contain?

The Committee believes that Sweden should advocate the adoption of a new chemicals strategy within the EU based on:

- the precautionary principle

- the substitution principle
- the principles of producer responsibility and the polluter pays principle

Based on these three principles, the Committee proposes that a new chemicals strategy should contain the following:

General approach (See further in Chapters 4, 5, 6 and in Annex 2)

- The chemicals strategy should be devised as a concrete action programme. The question of implementation (action programme, resources, new chemicals agency etc.) and follow-up of the strategy are important aspects that must be included in the strategy document.
- It should be stated that the precautionary principle and the substitution principle should be incorporated directly into the EC's legal acts in the chemicals area. This is particularly urgent in the case of the restrictions directive (directive 76/769/EEC). The principles should also be used concretely and actively in the application of the chemicals rules and directly by companies.
- The coupling between the chemicals strategy and an integrated product policy should be included in the strategy. The strategy for chemicals in products must be an important part of an integrated product policy.
- Global restrictions of dangerous substances and other initiatives are urgent in the chemicals field. This should be included in the chemicals strategy; among other things, the EU's role in international fora should be clarified.
- A long-term perspective should always be adopted in assessing health and environmental effects.
- Companies should be given full responsibility for data collection. Greater responsibility should also be given to companies for preliminary risk assessment and risk management.
- An important part of the chemical safety work is voluntary activities on the part of industry, such as environmental management systems and the chemical industry's work with ”Responsible Care” and ”Product Stewardship”.
- Supervision in the chemicals field needs to be improved. Minimum criteria for enforcement of the EU's chemicals rules should be formulated by not later than 2003.

- Necessary tightenings of the EU's chemicals legislation should be brought about by amendments to existing legislation to begin with. (A model with proposals for changes in rules is provided in Annex 2.)
- Eventually, the EU's chemicals legislation should be gathered under a framework directive or the like.

Knowledge – otherwise phase-out (see more detailed description in Chapter 4 and Annex 2)

- For all existing substances in the EU, the same documentation requirements shall be made as for new substances.
- Substances for which data on health and environmental properties are lacking may not be placed on the market after a certain date.
- For all high-production-volume (HPV) substances (at least 1,000 tonnes per year), knowledge on e.g. inherent health and environmental properties that meets the requirements made on new substances must be available by not later than the end of 2005.
- For medium-production-volume (MPV) substances (10–1,000 tonnes per year), such knowledge shall be available by not later than the end of 2009.
- For other substances (under 10 tonnes per year), such knowledge shall be available by not later than the end of 2010.
- Companies shall be held responsible for collecting data.
- The data requirements need to be extended in certain respects.
- Companies shall carry out initial risk assessments and adopt precautions if necessary.

Phase-out of substances with particularly dangerous properties (see more detailed description in Chapters 5, 6 and Annex 2)

- A general approach should be applied to those substances that are most dangerous for health and the environment. This means that measures should be taken against substances that are persistent and bioaccumulative and against carcinogenic, mutagenic, reproduction-toxic and endocrine-disruptive substances, as well as mercury, cadmium and lead. General phase-out criteria should be established.
- The *existing* substances that are classified as persistent and bio-accumulative according to the criteria proposed by the Committee should not be allowed as chemical substances, in preparations, and in

finished products from 2015. Certain existing substances that are particularly persistent and bioaccumulative should not be allowed from 2010. Certain exemptions may be necessary.

- The *new* substances that are classified as persistent and bio-accumulative according to the criteria proposed by the Committee should not be allowed as chemical substances, in preparations, and in finished products after the end of 2005.
- The substances that have been classified as carcinogenic, mutagenic and reproduction-toxic (categories 1 and 2) should be phased out from consumer-available products by not later than 2007.
- Use of mercury, lead and cadmium or their compounds should for the most part cease in accordance with our proposals in Chapters 6 and 7.
- The substances that are subject to restrictions in the environmental conventions that pertain to the EU should be regulated jointly in the EU.

In the opinion of the Committee, a new coherent chemicals strategy within the EU is of the utmost importance, and such a strategy should serve as a basis for changes in the *acquis communautaire* and in chemicals policy in all areas. The Committee therefore takes a very positive view of the current work in the EU on a proposal for a new chemicals strategy.

The Committee observes that there are conflicts between the goal of the single internal market and the chemicals policy that is intended to protect health and the environment. It should be possible, however, to achieve both the goal of the internal market and the goal of sustainable development within the EU. The Committee believes that there should be greater integration between the policies in these two areas – if sustainable development is to be achieved, the internal market policy should provide more leeway than it does now for supporting and promoting the purpose of the chemicals policy, which is to provide a high level of protection for health and the environment throughout the Union.

The harmonized chemical rules should embody a higher level of protection than today. If the level of protection is high enough, there will also be less need for individual member states to impose national rules. It is, for example, important that the level of protection in the EU be set according to the least favourable environmental conditions, for example

as regards the degradation of substances. An example of such conservative assumption is a cold climate.

In accordance with the principle of subsidiarity, responsibility for achieving a sustainable chemicals policy must be shared at all levels and by all actors. The EU must therefore promote and provide leeway for measures at a the national, regional and local levels. Governments, companies and citizens must be fully involved if these goals are to be met.

In the opinion of the Committee, Sweden should advocate adoption of the principles established in the Swedish Environmental Code (on which Swedish environmental policy is based) in the EU as well. Above all, the EU's new chemicals policy should be based more clearly on the precautionary principle and the principle that preventive action should be taken, the substitution principle, the principle of producer responsibility, and the polluter pays principle.

Precautionary principle etc.

The precautionary principle and the principle that preventive action should be taken are embodied in the EC Treaty and in several international environmental conventions. The principles have also been expressed in some of the EC's legal acts, for example in the directive on the use of genetically modified organisms (90/219/EEC). The implication of the principle of preventive action is that protective measures must be adopted before any damage to health or the environment has occurred even though the relationship between cause and effect may be uncertain.

The precautionary principle must therefore warrant action for preventing damage in certain cases, even if the cause-and-effect relationship cannot be proven based on available scientific facts. The purpose must therefore be to prevent not only positively foreseeable, but also possible damages and nuisances to health and the environment. The Committee believes that the principle should be applied more within the EU and that it is important that it be clear in a new chemicals strategy.

Another consequence of the precautionary principle is, according to Swedish legislation, that the burden of proof is clearly placed upon the party who wishes to manufacture or sell a chemical that can be assumed

to cause damage to health or the environment, instead of on the party who risks incurring damage or on a public agency.

The European Commission adopted a communication on the precautionary principle in February 2000. The communication, which is the Commission's interpretation of the precautionary principle, deals with the precautionary principle in general terms and makes no distinction between its application in different sectors. In the communication, the Commission comments on the application of the precautionary principle in different parts of the decision-making process, the need for risk assessment, and the reversed burden of proof. According to the Commission, one of the intentions of the communication is to contribute to the ongoing debate on this issue, both within the Community and internationally.

In Sweden, the precautionary principle has long been applied in the chemicals field in the way that was expressed in the preparatory work to the previous chemicals legislation. According to the statements there (*inter alia* Gov. Bill 1984/85:118, p. 39 ff.), even a suspicion of the risk of damage arising from good scientific grounds is a sufficient ground for intervention under the legislation. This means, for example, that a producer who wishes to market an insufficiently known product must take into account such suspicions in deciding whether the product should be marketed or not. To avoid prohibitions or other restrictions, a producer must prove as far as possible that the suspicion is unfounded. Otherwise the producer has to accept the fact that the authorities will treat the product as dangerous for health and the environment – the public should not suffer the consequences of any uncertainty regarding the risks.

Responsibility for investigating risks and adopting precautions has above all rested with manufacturers and importers. The precautionary principle is first expressed concretely in a legal text in the Swedish Environmental Code (Chap. 2 Section 3 second paragraph), where it is said that precautionary measures must be taken as soon as there is reason to assume that an activity or a measure may lead to damage or nuisance to human health or the environment.

As it is interpreted in Sweden, the precautionary principle thus has a bearing on both work methods and priorities in both scientific risk assessment and actual decision-making.

Furthermore, according to the preparatory work to the Environmental Code (Gov. Bill 1997/98:45, Part 1 p. 210), a natural consequence of the precautionary principle is said to be that the burden of proof is reversed from the party who risks being affected by a nuisance to the party who takes an action that can be assumed to lead to a nuisance. This is expressed in the legal text in Chap. 2 Section 3 of the Environmental Code.

The Committee wishes to emphasize the importance of giving greater responsibility to companies who handle chemicals in the EU. This should also be reflected in the Community's application of the precautionary principle. Sweden should therefore promote within the EU the principles that have underlain the application of the precautionary principle in the chemicals field in Sweden, and which in many respects reflect an opposing view to that which is reflected in the Commission's communication. This is particularly true with regard to the placement of the burden of proof and corporate responsibility for taking action when scientifically founded suspicion exists that the use of a chemical could cause harmful effects to human health or the environment.

Sweden should advocate adoption of this principle in EC legal acts in the chemicals field, especially in the restrictions directive (directive 76/69/EEC) and in other EC legislation where needed to bolster the application of the principle for chemicals. A proposal for adoption of the precautionary principle is presented in Chapter 6 and Annex 2.

In addition, the importance of the principle being applied both in risk assessment and in risk management is emphasized.

Substitution principle

The substitution principle (or product choice principle) entails that less harmful or harmless chemical products should be substituted for harmful products wherever possible. Within the EU, the substitution principle has been manifested in, for instance, the biocide directive (directive 98/8/EEC).

The principle should be applied to all handling of chemical substances and preparations, as well as to finished products containing such substances and preparations.

Polluter pays principle

The principle that the party responsible for pollution should pay for whatever measures are needed to prevent or remedy any nuisance is an internationally accepted one, generally known as PPP (polluter pays principle). This principle has also been established in Article 174 (formerly 130r) of the EC Treaty.

The Committee believes that it is of the utmost importance that industry be given clear responsibility within the chemicals and products field. Manufacturers, importers and other suppliers and vendors of chemical products and finished products should be given clearer responsibility for the product during its entire lifetime. This responsibility includes collecting data, assessing inherent properties, gathering and furnishing health and environmental information, and not placing chemical products and other products on the market which entail unacceptable risks in any stage of handling.

It is essential for the success of a new chemicals strategy that knowledge of all the health and environmental properties of used substances be gathered. Companies that manufacture or import chemical substances will be given responsibility for gathering data. This should be done in a step-by-step process. Requirements should first be made that data be gathered for HPV substances, then for MPV, and finally for low-production-volume (LPV) substances. (This is further dealt with in Chapter 4.)

As previously noted, the Committee would like to emphasize the importance of giving greater responsibility to companies that handle chemicals within the EU. Sweden should therefore promote within the EU the principles that have underlain the application of the precautionary principle in the chemicals field in Sweden, in particular with regard to the placement of the burden of proof and corporate responsibility for taking action when scientifically founded suspicion exists that the use of a chemical could cause harmful effects to human health or the environment.

A new approach

An important part of a chemicals strategy should be a systematic and effective risk management programme. The EU work in the chemicals field over the next few years must be characterized by a more general

approach. Based on the aforementioned principles, this should entail that chemicals or groups of chemicals should be able to be restricted within the EU if their inherent properties fulfil certain established criteria. This entails a changed role for the existing programme for risk assessment and risk management of existing substances. There are, however, a large number of substances that are not so dangerous that they should be subject to the general approach for risk management. In these cases, substance-specific risk assessments will continue to serve as a basis for risk management. There is therefore also a need to improve existing rules and models for risk assessment and risk management.

Based on the precautionary principle and the principle of preventive action, it should be possible to restrict chemicals in the EU if their inherent properties meet the criteria we propose in Chapter 5. The substances whose inherent properties should fulfil the criteria for initial restrictions are substances which are carcinogenic, mutagenic and toxic for reproduction, as well as substances which are persistent and bioaccumulative (see Chapters 5 and 6).

According to the Committee, a new chemicals strategy should focus on prohibiting the use of substances that are to be phased out.

Different approaches are possible within the EU in order to phase out the organic substances that fall under the Committee's proposed phase-out criteria for bioaccumulative and persistent substances. The simplest procedure is to use present-day systems and rules in the EU to implement the proposed criteria for phase-out of particularly dangerous substances. Another way is to propose new legislation in the EU, e.g. new directives. The proposals that we have considered and that are presented in Chapter 6 entail changes within the framework of the EU's existing regulations and directives and can be said to be changes that are needed in the short term. A framework directive for chemicals may be needed in the long term.

In Annex 2 we have sketched a model with proposals for changes within the framework of the EU's existing *acquis communautaire*.

Companies should also be given responsibility to carry out initial risk assessments based on the data that have been gathered and to take whatever precautions are necessary based on the risk assessments.

Furthermore, the new chemicals strategy must also be more clearly linked to various international environmental conventions. In order to meet these commitments, common rules should be adopted in the EU.

A special issue which we would also like to emphasize is the need for the actual implementation of a chemicals strategy. Sufficient resources are needed, for example, for the framing and implementation of new rules etc. Special initiatives for research and development, follow-up and evaluation may also be needed for implementation of the strategy. The Commission is thinking of creating a new chemicals agency within the EU. Such an agency could play an important role in the implementation of a new chemicals strategy.

In short, a concrete action plan is needed in order to actually implement a new chemicals strategy fully. We believe that both the question of implementation and the question of follow-up of a new chemicals strategy should be included and clarified in the coming strategy document.

4 Proposed EU system for requirements on knowledge concerning the health and environmental properties of chemical substances

Chemical substances and preparations should not be allowed to be used in the EU if fundamental information is lacking on their health and environmental properties. In this chapter we describe present-day testing requirements, and in section 4.4 we also present a proposal for a more complete system for ensuring that such health and environmental information is available. In Chapter 10 we describe the consequences of these proposals.

The Committee's appraisal and proposals

- Knowledge of the health and environmental properties of chemical substances is fundamental for all safety work in the chemicals field, and is thereby also an important prerequisite for protecting biological diversity and human health.
- Knowledge of the health and environmental properties of chemical substances is a prerequisite for determining which substances are covered by the Government's new guidelines.

The Committee proposes that Sweden advocate rule changes in the EU as follows:

- For all high-production-volume (HPV) substances (1,000 tonnes/year or more), manufacturers and importers must have gathered knowledge of inherent health and environmental properties that complies with the requirements made on new substances in the EC's dangerous substances directive (67/548/EEC) by not later than the end of 2005. For medium-production-volume substances (at least 10 tonnes but less than 1,000 tonnes), such data shall be available by not later than the end of 2009. For other substances, such data shall be available by not later than the end of 2010.
- After certain deadlines, substances may only be released on the market if the data requirements are met. If the required data are lacking for a substance, it shall be treated as a new substance, which means prior notification is required.
- Based on the data furnished, companies shall make an initial risk assessment and take the necessary precautions.
- Test methods that limit the number of animal tests must be developed and validated. The testing requirements according to the dangerous substances directive must be changed as new testing methods become available that require fewer animal tests (see also section 6.3 and Chapter 9).
- The testing requirements in the dangerous substances directive must be changed so that they test for the properties covered by the Government's guidelines. New requirements regarding persistence and bioaccumulation potential should be introduced. Similarly, testing requirements on endocrine-disruptive effects should be introduced as soon as standardized testing methods are available. It should be possible to cover most of the endocrine-disruptive effects by expanding the testing methods for reproduction toxicology (see section 5.2.2).

4.1 The knowledge gaps are great

As we previously noted in section 2.2.2, owing to the great lack of knowledge, it is not possible today to either identify all substances that are dangerous for health or the environment, or to make the necessary risk assessments and adopt adequate risk limitation measures.

The EU has rules governing new substances requiring that they be tested before being placed on the market. Such requirements do not exist for existing substances, however, and the knowledge gaps there are great.

In recent years reports have come from both the American EPA and the European Chemicals Bureau (ECB) showing that only about 10 percent of all substances that occur in high production volumes on the market have the necessary minimum data. Data are lacking completely for many HPV chemicals (see section 2.2.2).

The meeting of the EU's environment ministers in Weimar, Germany on 7–9 May 1999 found that a fundamental lack of knowledge exists on the toxic and ecotoxic properties of many substances.

In other words, there is broad awareness and agreement that the problem of inadequate data must be solved in international collaboration, and several initiatives have been taken to obtain more knowledge.

The Committee believes that a system is needed that generates more information than that provided by the present-day system and voluntary efforts taken together. We also wish to stress the importance of the subgoal proposed by the National Chemicals Inspectorate in the Report "Non-toxic environment" (National Chemicals Inspectorate, 1999, in Swedish only):

> "By 2010, data that satisfy established minimum requirements are available for deliberately manufactured products and extracted substances handled on the market. Knowledge regarding the occurrence and properties of unintentionally formed substances and the combined effects of different chemical substances is constantly growing."

The Committee backs the National Chemicals Inspectorate's proposal that a harmonized international system should be created to gather data for existing substances. To start with, agreement should be reached in the EU on what data requirements should be made; then the EU should work to bring about an international harmonized system.

4.2 Testing requirements in the EU today

The EU's acquis differentiates between existing and new substances, to which different testing requirements apply today.

Existing substances are defined as those included in EINECS (The European Inventory of Existing Commercial Chemical Substances), which is a European list of substances considered to exist on the Common Market between 1 January 1971 and 18 September 1981. Accordingly, substances not listed in EINECS are regarded as new.

4.2.1 Existing substances

The Council Regulation (EEC No. 793/93) on the evaluation and control of the risks of existing substances contains rules on data reporting for existing substances. The data are submitted to the European Commission and collected in a special database, IUCLID. The rules apply to manufacturers and importers who have produced or imported a substances in quantities exceeding 10 tonnes in certain years preceding the entry into force of the rules. The regulation stipulates what data are to be submitted, and the requirements are much more extensive for quantities exceeding 1,000 tonnes than for quantities in the range 10–1,000 tonnes.

According to the rules, manufacturers and importers must make all reasonable efforts to obtain existing data on the properties of the substances. In the absence of information, manufacturers and importers are not bound to carry out tests to obtain additional data.

The substances covered by the directive can be subjected to risk evaluation. Such substances are put on a priority list (the three priority lists drawn up to date include slightly more than 100 substances). Additional requirements on data reporting exist for the substances on the priority lists. If the data listed in the dangerous substances directive as comprising the base set (see Table 4.1 and Annex 2) are not available, manufacturers and importers shall carry out the testing necessary to obtain the missing data.

The substances on the priority lists thus undergo a risk evaluation. For each substance, a member state is designated as being responsible for this evaluation, and the member state in turn designates a rapporteur. If the rapporteur finds in the course of the risk evaluation that additional

data are needed on a substance, the Commission shall be informed accordingly. It can then be decided that the manufacturer or importer must submit further information.

4.2.2 New substances

The rules for notification of new substances are set forth in the dangerous substances directive (Council Directive 67/548/EEC, amended by Council Directive 92/32/EEC). Before a new substance is placed on the market, the manufacturer or importer of the substance to the EU must submit a notification to the member state in which the notifier is established. The notification shall contain general information on the substance, uses, estimated quantities, physico-chemical properties, toxicological and ecotoxicological test results, proposed classification and labelling, etc. Each member state appoints one or more competent authorities who receive the information and ensure that the submitted data comply with the requirements in the directive. The competent authority in turn sends the information to the Commission, which then forwards the information to the other member states. If there are no objections regarding the completeness of the documentation, the manufacturer is guaranteed access to the entire internal market.

The basic rule entails that the information shall be submitted in accordance with what is specified as the base set. For substances that are manufactured or imported in quantities of less than one tonne per year and company, there are rules that permit less extensive data reporting. Similarly, there are rules enabling the competent authority to stipulate further data requirements on substances placed on the market in higher quantities. In addition, data must be submitted on e.g. uses. Table 4.1 contains a summary of the testing requirements, and Annex 2 presents the full wording of the requirements in accordance with the dangerous substances directive. The notified new substances are put on a list called ELINCS, which today contains nearly 3,000 substances.

When the quantity of a previously notified substance increases, this shall be reported by the manufacturer or importer so that the competent authority can make additional data requirements.

The directive also contains provisions on criteria and methods for testing of the dangerous properties of chemical substances. These provisions are revised regularly by the Commission, which makes decisions in accordance with committee procedure. Revisions of testing methods are

based for the most part on new OECD guidelines. Assessment of a substance's dangerous properties is done on the basis of existing data. For substances where data are lacking, there is at present no way to stipulate requirements on further testing.

Table 4.1 Testing requirements for new substances in the EU.

The data required in Annex VII. A of the directive are usually referred to as the base set. Documentation in accordance with Annex VII. A is required for existing substances subject to risk evaluation. The actual requirements made according to Annex VIII vary from case to case. The documentation requirements are not only associated with annual quantities; there are also rules entailing that requirements at each level must be met when the aggregate quantity over the years amounts to certain values.

Annex	**Production volume (t/y and manufacturer)**	**Testing requirements**
VII. C	0.01 – 0.1	Acute toxicity (rat).
VII. B	0.1 – 1	Skin and eye irritation. Skin sensitization. Mutagenicity (1 in vitro study). Biodegradability study.
VII. A	≥ 1	Acute toxicity via two routes of administration in rat. Skin and eye irritation. Skin sensitization. 28 day toxicity study on rat. Mutagenicity studies (2 in vitro studies). Toxicity test (acute) for fish, Daphnia, algae, bacteria. Biodegradability and abiotic degradation. Adsorption/desorption studies.
VII, Level 1	≥100 (certain tests may be required at > 10)	Tests in addition to the above: Fertility study and teratogenicity study. Subchronic/chronic toxicity study. Additional mutagenicity studies. Information on biotransformation (rat). Prolonged toxicity test with fish and Daphnia. Toxicity studies on plants and earthworms. Bioaccumulation study in fish (BCF). Supplementary degradation studies.

Annex	Production volume (t/y and manufacturer)	Testing requirements
		Supplementary adsorption/desorption studies.
8, level 2	≥1 000	Tests in addition to the above: Chronic toxicity. Carcinogenicity study. Multi-generation fertility study. Developmental toxicity. Teratogenicity in additional species. Additional information on biotransformation. Additional tests for accumulation, degradation, mobility and adsorption/desorption. Further toxicity tests on fish. Toxicity tests on birds and other organisms.

4.2.3 Testing requirements in the EU in relation to the OECD's minimum data

The OECD countries have agreed on what minimum data should be available for high-production-volume (HPV) chemicals (> 1,000 tonnes/year and manufacturer). These data are usually called SIDS (Screening Information Data Set). There have been programmes during the 1990s within the OECD to collect such data, and several voluntary initiatives have recently been taken which will hopefully expedite this work considerably.

The requirements made in SIDS resemble the "base set" requirements for notification of new substances in the EU. A few items of information are more far-reaching in SIDS, for example environmental concentrations, which are naturally more relevant for existing HPV chemicals than for substances that have not yet been introduced on the market.

The base set requirements for substances in the EU begin to apply at quantities of one tonne per year. If comparison is made with the requirements that can be made in the EU on substances at quantities of 1,000 tonnes per year, i.e. the same quantities as SIDS was developed for, the EU's rules are much more far-reaching.

4.3 Several initiatives have already been taken

Several initiatives for increased knowledge have already been taken. The American EPA has started a programme aimed at getting industry to collect data for HPV substances. Data equivalent to SIDS data will be collected by not later than 2004 for 2,800 substances.

The International Council of Chemical Associations (ICCA) has taken an initiative whereby SIDS data will be collected for approximately 1,000 substances by 2005. In addition there is a voluntary commitment to gradually supplement collected data with an assessment of the substances. The European Chemical Industry Council (CEFIC) has undertaken to participate in this work.

The Netherlands has drafted an action plan for existing substances (Ministry of Housing, Spatial Planning and the Environment, 1999). As a part of this work, they will investigate what is needed to have complete base information on health and environmental properties for HPV chemicals within five years, and to have equivalent data for other chemicals within eight years.

4.4 Proposed system for more knowledge

4.4.1 Committee's appraisal and proposals

The Committee presents proposals here on how a system for knowledge collection in the EU can be devised. The data requirements we propose for the EU should be expanded as soon as possible to include the OECD and eventually the rest of the world. Although it is important to have a uniform system for both new and existing substances the world over, we have chosen to begin with a proposal aimed at the EU, since it is our opinion that the EU is the arena where the proposals can make the biggest impact initially.

A system for more information must be devised with clear requirements regarding both what information on health and environmental effects is to be collected and when this information is to be available. A reasonable deadline that harmonizes with industry's own commitments is the end of 2005 for HPV substances (> 1,000 tonnes/year), 2009 for MPV substances (10–1,000 tonnes/year) and 2010 for other substances. This

should be preceded by an initial stage where the manufacturers and importers who intend to furnish data on a substance submit a notification to this effect to the Commission prior to the end of 2004 (our proposals are illustrated schematically in Figure 4.1).

We believe that the data requirements for existing substances must be the same as those made on new substances. A person buying a chemical substance must be able to obtain the same information on the properties of the substance regardless of how long the substance has been on the market.

For new substances, carcinogenicity and reproduction toxicity tests are only required at medium or high production volumes. Such tests are needed in order to be able to determine which substances are covered by the Government's guidelines with regard to these properties. Due to the fact that the tests require extensive animal testing, however, we do not believe that such tests need to be required as a rule at lower volumes. It is, however, important that the same requirements be made on existing as on new substances.

The data requirements should thus be adapted to the volumes that are released on the market, in the same way as in the present-day system for new substances. Since many of the existing substances are manufactured and imported by many companies, and they cannot all be expected to find out how much of the substance is released on the market in the EU, the quantity limits shall apply for each individual company's manufacture or imports during each of certain specified years. If the quantities increase after the reporting occasion, supplementary information will be required.

According to the current rules for new substances, more extensive information requirements are made for substances in volumes of more than 100 tonnes/year (sometimes 10 tonnes/year) than for substances in lower volumes. When these data requirements are made, it is possible for the concerned company to demonstrate to the competent authority in the country where notification has been made that a given test is inappropriate or that an alternative method is preferable. The authorities can thereby modify the requirements slightly from time to time depending on what is appropriate. Furthermore, a company can, regardless of production volume, refrain from furnishing certain data if it is not technically possible or is not considered necessary on scientific grounds to furnish the information. This must, however, be approved by the competent authority. The Committee considers it reasonable that similar

options should also exist for existing substances, but such a system must be devised in a manner that does not place an undue burden on the authorities.

Even if the testing requirements are aimed at each individual manufacturer or importer, we presume that companies will find ways to collaborate so that a test only need to be done once. There are economic as well as ethical incentives for such cooperation, since it leads to fewer animal tests.

In connection with previous reporting of existing data in accordance with the regulation on existing substances, certain exemptions were specified, for example for a number of oils, fatty acids and glycerides as well as the elements carbon, hydrogen and argon. Certain exemptions also exist in the rules on notification of new substances, for example for substances that are exclusively used in foodstuffs, animal feeds and medicinal preparations (these are controlled according to other rules) and for substances that occur in quantities of less than 100 kg and are intended solely for research and development under controlled conditions. It is reasonable that the exemptions that are made for new substances should also apply to existing substances.

The system should be designed so that data on existing substances is reported to a database, e.g. the EU-wide IUCLID database, which is used today for reporting of data on existing substances. The Committee believes that the companies need an incentive to collect data on the substances. The data requirements should therefore carry a condition stating that substances that do not comply with the requirements may not be placed on the market. One way to devise a prohibition could be to use EINECS to list those substances for which the data requirements are met and prescribe that substances may only be placed on the market if they are included in EINECS, subject to whatever restrictions on quantities are stipulated in EINECS.

Substances that lack data at the above deadlines should be treated as new substances. This requires that some authority, e.g. the European Chemicals Bureau, be assigned the task of reviewing the IUCLID database to see whether the required fundamental data exist for the substance. However, we believe that this should be done in the simplest possible manner and only include checking whether data exist or not – not a judgement of the quality of the reported data. The reason for this is that a large quantity of information will be reported, and it is very time-consuming to check all this information. A system entailing that the

authorities check the quality of this information would require considerable resources and could further act as an obstacle to the application of the system. We therefore believe it is better that any possible errors are discovered and corrected as the information is used.

The data contained in the database should, wherever possible, be made available to authorities, researchers, companies, and the general public. Careful consideration must be given to what data can be given to each category, and in what form, taking into account the confidentiality wishes of the companies furnishing the data.

The Committee also deems it important that the companies take greater responsibility for risk assessment and risk limitation. The work of drawing conclusions from the new data collected should not wait until a substance is placed on a priority list. All manufacturers and importers should therefore be instructed to carry out an initial risk assessment when data on a substance have been collected, and to take the necessary precautions. These precautions include a preliminary classification and labelling. This responsibility should include not only handling of the substance in-house, but also addressing risks and protective measures further down the line. Information on such risks and protective measures should be provided in material safety data sheets.

The proposal does not entail that the companies own initial risk assessments and precautionary measures should take the place of the work of producing risk assessments and taking action for risk limitation at the Community level. But it is important that the data on the properties of the substances that are collected be used to reduce the risks during the period up until when the Community has taken a stand on the need for measures for a substance. The company's own measures will also be a complement to the more general measures that may be considered at the Community level. An example of a company's precautionary measures may be that the company does not sell its product for a given use that is deemed to involve unacceptable risks, and furnishes information on the risks of such a use, even though there are no statutory restrictions for the product.

The extended requirements on testing existing substances can be incorporated in the EU's acquis in a number of ways. One way is to use existing rules, where extended requirements on data can be made by amending the regulation on existing substances so that testing requirements are introduced for all substances lacking data equivalent to what is required for new substances. A proposal for amendments to the

regulation is presented in Annex 2; the proposal should be regarded as a rough sketch showing one of several possible ways to proceed. Another possible way is to draft a new regulation on data requirements for existing substances.

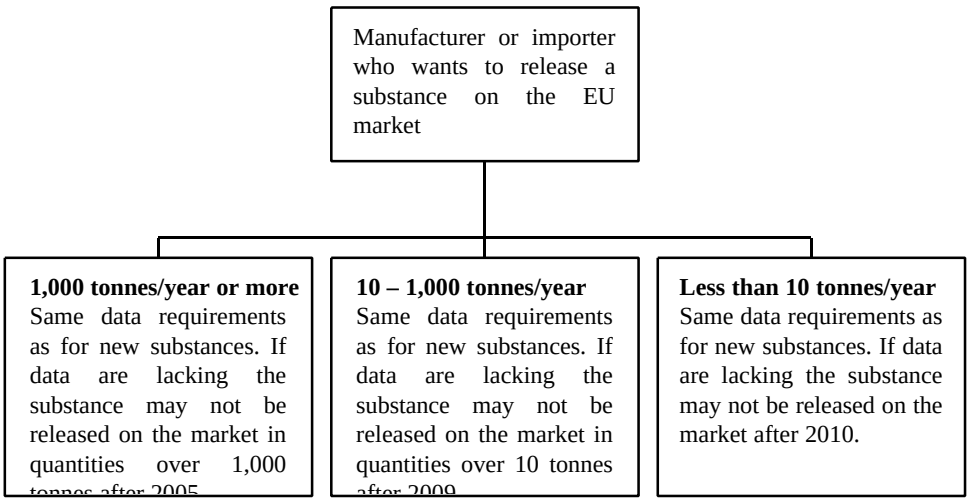
Both alternatives have their advantages and disadvantages. Using existing rules can be the fastest way to proceed, but the advantage of advocating a new regulation is that it is then possible to stress the responsibility of companies, which can be more difficult in an existing regulation, which imposes a heavy responsibility on the authorities today.

The Committee has also considered controlling the collection of data by means of changes in the system for classification and labelling. Incentives are lacking today for companies to collect data for existing substances. It can even be argued that there are incentives for them not to collect additional data, since there is then a risk that the substance will be danger-classified. With such a system there is a risk that companies will refrain from reporting additional data on their substances.

By introducing requirements that chemical products containing substances that have not been fully tested should be labelled with a question mark (symbolizing unknown properties), market forces could be enlisted to encourage a greater collection of data (Rudén & Hansson, 2000). This is based on the assumption that faced with a choice, consumers will choose to buy a chemical product whose properties are tested over one whose properties are unknown. It is, however, uncertain how great an effect such labelling would have, especially since a very large number of products would have to be labelled in this manner. Sweden should therefore preferably advocate rules stating that untested substances should not be allowed to be used after a given date.

Figure 4.1 Requirements on health and environmental information for chemical substances.

A simplified model of our proposals regarding requirements on health and environmental information for all chemical substances. Observe that the data requirements vary between the different quantity limits.



4.4.2 Viewpoints of the Association of Swedish Chemical Industries

The Association of Swedish Chemical Industries is of the viewpoint that the proposals that knowledge of chemical substances must be available are reasonable in principle. The Association feels, however, that the ambition level is too high inasmuch as the Committee proposes that existing substances in high volumes should be subject to the same data requirements as new substances, and that the time is a bit short. The Association believes that the documentation for existing substances should only have to comply with the base set requirements (i.e. Annex VII. A in the dangerous substances directive). The extended requirements (i.e. Annex VIII in the dangerous substances directive) should be judged from case to case, based on test results in the base set and other information.

Although the Association finds that the timetable is not realistic, they appreciate that a deadline has to be set for when data must be available

and that this deadline must not be too far in the future if it is to serve as an incentive (Association of Swedish Chemical Industries, 2000b).

4.5 Factors that complicate the testing

There are several factors that can complicate the testing of chemical substances as well as the interpretation of test results. These factors are not unique for existing substances, but also exist in connection with testing of new substances. Some problems have already been solved within the framework of current rules for testing of new substances, but the problems take on extra urgency when a large number of substances are to be tested.

Among the complicating factors is the fact that certain substances on EINECS are not substances in the true sense but complex mixtures of many different substances. An example is the complex groups of substances based on petroleum or coal. Despite the fact that they are not substances in the true sense, these materials have for practical reasons been treated as such when placed on EINECS.

The problem with the complex coal- and petroleum-based ”substances” (i.e. mixtures) is that their composition can vary, largely depending on the content of the coal or crude oil used in production. For one thing, they contain many substances that are not always exactly the same from one mixture to another, and for another the proportions between the quantities of constituent substances can vary within certain limits. The consequence is that tests conducted on a given sample of this ”substance” will only be representative for the tested sample. If the same test is performed with a new sample of the ”substance”, another result may be obtained, since the composition of the mixture may be different.

There are also other substances that are not consistently defined. This can be exemplified by chloroparaffins and phthalates, which are listed as individual substances on EINECS even though they are often mixtures of different closely related substances, where the same substance may be included in several of the ”substances” on EINECS.

In some cases the testing requirements in the dangerous substances directive are not fully applicable to a group of substances due to the fact that the substances possess special properties. This is true, for example, of enzymes, and the European Commission has put out a consulting assignment to determine what testing requirements should be made on

enzymes. Polymers and chemical intermediates are other groups of substances that are considered to need special (less extensive) testing requirements due to their special properties and exposure conditions. Furthermore, it should also be mentioned that substances can be difficult to test due to the fact that they have, for example, very low water solubility or high volatility.

4.6 Testing methods need to be changed

Many of the tests that are required by the dangerous substances directive involve the use of laboratory animals, and one consequence of extended requirements on data generation is that more animals will be used for testing. It is therefore important to develop systems and alternative methods where animal testing is minimized.

In many cases, developing testing methods that minimize the need for laboratory animals requires considerably improved knowledge of toxicological mechanisms. Both basic research and development and validation of testing methods are needed here (see Chapter 9). Development of alternative methods is something which in itself requires laboratory animals, but which in a longer perspective contributes towards reducing the use of animals. As soon as methods of adequate quality are available, the dangerous substances directive should be amended so that alternative methods can begin to be used to meet the data requirements.

The dangerous substances directive specifies how testing of new substances is to be done. For existing substances, data may have been obtained by means of other methods than those specified in the dangerous substances directive. There may therefore be reason to review the requirements regarding the testing methods for the purpose of making it possible to use data already obtained by means of other methods than those specified in the directive, provided they are of good quality. For substances in use for a long time, epidemiological data may be available showing whether humans are affected by the substance. In this case as well, where some of the substance's harmful properties are already known, the requirement on new animal studies should be able to be omitted.

The testing requirements in the dangerous substances directive must also be supplemented to cover the effects included in the Government's guidelines. Requirements on testing of half-lives should be introduced for

all substances that have been shown to be not readily biodegradable. Requirements should also be introduced to determine bioconcentration factors (BCFs) for substances in quantities up to 100 tonnes. We believe it is sufficient that such BCFs should be calculated by means of QSAR (see Annex 3, section 2). Testing requirements for endocrine-disruptive properties should be introduced as soon as suitable testing methods have been developed (see section 5.2.2).

Finally, certain special solutions may also need to be devised to remedy the problems described in section 4.5.

5 Proposed criteria for phase-out of substances with particularly dangerous properties

This chapter deals above all with the Committee's proposals for general phase-out criteria for particularly dangerous substances mentioned in the Government's guidelines. We have not made any judgements regarding substances that can be considered to be particularly dangerous due to other properties (see sections 1.2 and 2.2.3).

Criteria for phase-out of persistent and bioaccumulative substances are proposed in section 5.1, while criteria for phase-out of carcinogenic, mutagenic and reproduction-toxic substances are proposed in section 5.2. The Committee's proposed action plan for endocrine-disruptive substances is also presented in section 5.2. Section 5.3 contains the Committee's standpoints regarding metals, while section 5.4 presents the Association of Swedish Chemical Industries' views regarding the Committee's proposals regarding phase-out of substances with particularly dangerous properties. More exhaustive descriptions of the area of persistent and bioaccumulative substances are provided in Annex 3, endocrine-disruptive substances in Annex 5, and metals in Annex 6.

The general approach referred to in the guidelines (section 1.1) entails that organic substances that meet the Committee's criteria regarding persistence and bioaccumulation should be phased out without other data or risk assessment being required. The same applies to substances that do not meet these criteria but do meet the criteria for carcinogenic, mutagenic and reproduction-toxic properties. Organometallic compounds may fall under all guidelines, since they can be assessed on the basis of both their metal part and their organic part.

For substances that do not meet the criteria in the areas overseen by the Committee, but may need to be controlled due to other properties in other areas, risk assessments will probably continue to be the principal tool for determining what measures are called for.

5.1 Phase-out criteria for persistent and bioaccumulative organic substances

The Committee's proposals

The Committee proposes phase-out from *2005 of new substances*, and from *2015 of existing substances* that are so persistent and bioaccumulative:

- that their half-life is longer than 8 weeks (in a simulation test at 20 ºC), and
- that their bioconcentration factor is higher than 2,000, or
- that they are judged to meet these criteria based on other reliable scientific studies or international accepted calculation methods.

Furthermore, the Committee proposes phase-out from *2010 of existing substances* that are so persistent and bioaccumulative:

- that their half-life is longer than 26 weeks (in a simulation test at 20 ºC), and
- that their bioconcentration factor is higher than 5,000, or
- that they are judged to meet these criteria based on other reliable scientific studies or internationally accepted calculation methods.

The guidelines defined by the Government in the Bill "Swedish Environmental Quality Objectives" (1997/98:145) entail the following:

- New products introduced onto the market shall largely be free from man-made organic substances that are persistent and liable to bio-accumulate, and from substances that give rise to these substances.
- Man-made organic substances that are persistent and bioaccu-mulative shall occur in production processes only if the producer can show that health and the environment will not be harmed.

The guidelines entail adopting a general approach towards man-made organic substances that are persistent and liable to bioaccumulate, in accordance with the proposal of the Chemicals Policy Committee (see section 2.3.4). The Committee interprets the guidelines as implying that if a man-made organic substance has properties with respect to persistence and bioaccumulation that exceed the criteria established by the Committee, the substance may not, after a given date, be used in new products – or in production processes unless the producer can show that health and the environment will not be harmed.

The commission of the our Committee includes proposing more precise definitions in the form of limits etc. for the intended properties and effects. According to its terms of reference, the Committee shall ”for example be able to propose limits for when a substance is so persistent and bioaccumulative that it is subject to the requirement on phase-out in accordance with the stipulated guidelines.”

The following is stated in the terms of reference our Committee:

> *”...in order for the guidelines to be applied, more precise definitions must be given of what is meant by persistence and bioaccumulation. Among other things, limits must be defined for when these properties are unacceptable, i.e. when their use leads to an unacceptable risk for man and the environment. It is in most cases difficult to set an exact limit for persistence and bioaccumulation above which substances with such properties on exposure pose an unacceptable risk for man and the environment. Nevertheless, it may in many cases be necessary to set clear-cut limits in the form of limit values. The assumption must always be that man-made organic substances always pose a potential risk for human health and the environment, if they can accumulate in organisms and that they are so persistent if they also accumulate in the ecosystem.”*

The Committee interprets the guidelines in this area as meaning that it is initially sufficient that knowledge be available on the properties of substances with regard to persistence and bioaccumulation to determine whether they may, on the basis of these properties, be present or not in new products and in production processes from a given date.

5.1.1 What does it mean to say a substance is persistent?

An organic substance is defined here as persistent, i.e. long-lived, if it is stable in the environment. A persistent substance thus resists the physical, chemical and biological processes in the environment that lead to degradation of other, less resistant substances.

Degradation should be defined as decomposition to harmless end products[1]. In most cases, this involves mineralization, i.e. decomposition to carbon dioxide, mineral salts and other simple, inorganic compounds of whatever other elements, besides carbon and hydrogen, comprised the

[1] By ”harmless end products” is meant well-known substances and elements that do not have any adverse health and environmental effects in the quantities at which they are produced as a result of degradation.

parent molecule – for example oxygen, which furthermore often plays an active role in the mineralization process (for a more detailed discussion of the concept of persistence, see Annex 3).

5.1.2 What does it mean to say a substance is bioaccumulative?

A substance is bioaccumulative if it is readily available for uptake by organisms, but is metabolized or secreted only slowly. The substance can thereby accumulate in organisms at higher concentrations than in the surrounding environment or food, and bioaccumulation reflects the total uptake of a substance, both via e.g. skin and mucous membranes, and via the gastrointestinal tract.

The bioaccumulation potential of a substance is given by the bio-accumulation factor (BAF), which is obtained by dividing the equilibrium concentration in the organism by the concentration in the surrounding environment and food. The contribution made by the food to enrichment in food chains is expressed by a biomagnification factor (BMF – see section 5.1.5 and Annex 3). For practical reasons, the BAF or BMF is often replaced by the bioconcentration factor (BCF), which is easier to determine experimentally. However, the BCF only takes into account uptake via mucous membranes in organisms in the aquatic environment, such as uptake via the gill membrane in fish. This means that substances with very low water solubility may have a low BCF but be potentially bioaccumulative. Despite certain limitations, the BCF is a useful parameter for describing the uptake of substances in biological material (for a more exhaustive discussion of these terms, see Annex 3).

5.1.3 What methods are suitable for determining whether a substance fulfils the criteria?

The Committee's appraisal and proposals

Information on how persistent and bioaccumulative organic substances are should be based on:

- standardized, internationally accepted testing methods, which today are primarily based on an aquatic environment,
- other scientific studies which can be accepted as reliable on the basis of expert judgement, or
- estimated values, if the calculation methods used for the estimation are internationally accepted.

When it comes to how *persistent* substances are, the Committee proposes:

- that a substance's half-life in water, determined by currently available, standardized, internationally accepted testing methods, be used to determine whether the substance is so persistent that it should be subject to requirements on phase-out according to the Committee's criteria,
- that as a complement to, or in some cases a substitute for, these tests, other reliable scientific results may also be used to determine whether a substance is persistent,
- that when it comes to degradation of substances in air, Sweden complies with the recommendations given within the framework of international conventions such as CLRTAP,
- that values of biodegradability of the substances estimated with today's calculation models should not be regarded as acceptable information for the purpose of phase-out.

When it comes to how *bioaccumulative* substances are, the Committee proposes:

- that a substance's bioconcentration factor, determined using currently available, standardized, internationally accepted testing methods based on an aquatic environment be used to determine whether the substance is so bioaccumulative that it should be subject to requirements on phase-out according to the Committee's criteria,
- that as a complement to, or in some cases a substitute for, these tests, other reliable scientific results may also be used to determine whether a substance is bioaccumulative.

- that values estimated by means of structure-activity models also be regarded as acceptable information as to what degree fat-soluble, bioavailable substances are bioaccumulative.

In order to be able to propose limits for when man-made organic substances that are persistent and bioaccumulative should be phased out from use in new products and in production processes, information is required on the degree to which the substances exhibit these properties. Today there are three ways to obtain such information:

- standardized testing methods
- other scientific studies
- estimated values.

Standardized testing methods

Today's standardized, internationally accepted, experimental methods for measuring the biodegradability of organic substances primarily pertain to the aquatic environment (see Annex 3). This applies to both simulation tests, from which half-lives can be obtained, and simple biodegradability tests, with the exception of a testing method that measures biodegradability in soil.

Today's standardized, internationally accepted, experimental methods for determining the bioaccumulation potential of organic substances are based on the aquatic environment. These methods involve determining the bioconcentration factor for aquatic organisms, normally fish.

Standardization of tests means that the results for a substance do not always agree with the behaviour of that substance in a given environment. However, obtaining data on, for instance, the biodegradability of a substance in all possible environments and under all possible circumstances is far too great a task. Nor is such a degree of detail commensurate with the purpose of proposing general criteria for bioaccumulation and persistence. A fundamental purpose of these criteria is after all to expedite the international work of preventing releases of substances covered by the Committee's guidelines. For this reason the general criteria must be simple enough to facilitate this work.

It is noted in the terms of reference for the Committee that it is difficult in most cases to set an exact limit for e.g. persistence and bioaccumulation above which substances on exposure pose an unacceptable

risk for man and the environment. In our judgement it is therefore warranted to employ today's standardized, internationally accepted, experimental methods when these properties of substances are to be assessed.

It should, however, be stressed here that there is a great need to refine and revise testing methods for determining how persistent and bioaccumulative organic substances are, at the same time as test data are largely lacking for most substances in use and must therefore be determined (see Chapter 4). It would, for example, be desirable to be able to use an internationally accepted standardized method to experimentally determine the half-life of a substance in a certain kind of soil environment in a given climate, and likewise to be able to determine the bioaccumulation of a substance in a terrestrial environment, such as on uptake in herbivores (see section 9.1.2).

Other scientific studies

Since standardized testing methods have many limitations, there may often be reasons to weigh in results from other scientific studies as well to determine whether substances are so persistent and bioaccumulative that they should be phased out.

Field studies and other scientific studies of biodegradability often make greater allowance for the substance's partitioning between different environmental media than do standardized testing methods. It may therefore be advisable to take these kinds of studies into account when determining the behaviour of a substance in the environment.

Similarly, it may be advisable to take into account scientific studies, as well as screening studies and environmental monitoring, showing that man-made organic substances occur in animals or in man when determining whether substances are bioaccumulative.

Estimated values

As an alternative to time-consuming and costly experimental studies, it is also possible today to estimate how persistent and bioaccumulative substances are by calculations using structure-activity models.

There are calculation models whose purpose is to predict whether substances are readily biodegradable or not (see Annex 3). Within the EU (TGD, 1996), however, it is recommended that the results of such models be interpreted conservatively, i.e. that substances indicated by the models to be poorly biodegradable also be regarded as such, while the models cannot be used to identify substances to be regarded as readily biodegradable. It is also the judgement of the Committee that the calculation models for ready biodegradability that are available today should not be used to determine whether substances are so persistent that they should be phased out or not. There are no standardized calculation models today for estimation of *half-lives* as a result of microbiological degradation.

When the BCF is unknown, it can be estimated for fat-soluble substances based on the partition coefficient (K_{ow}) between the organic solvent octanol and water. For bioavailable, fat-soluble and neutral organic substances, the agreement between measured and estimated values is considered to be very good in the low K_{ow} range 1 to 7 (see Annex 3). In the judgement of the Committee, it may therefore be warranted to use estimated BCFs for such substances.

However, the Committee sees considerable need for further development and research in these areas (see section 9.1). It is desirable that future classification of chemical substances can to some extent be based on well-validated models. The need for these tools for classification is particularly great for assessment of existing substances.

5.1.3.1 Biodegradation in an aquatic environment is proposed to determine whether a substance is persistent

A fundamental complication when determining whether organic substances are persistent or not is that they can distribute themselves between several different environmental media, such as soil, water and air, where their biodegradation can furthermore vary with many different factors (see Annex 3). In the judgement of the Committee, it is difficult to combine a strategy for highly simplified risk assessment with a definition of criteria for persistence that takes full account of the distribution and biodegradability of the substances in different environmental media under different conditions. Today, standardized, internationally accepted testing methods are available that instead appear to be the most suitable point of departure for determining whether a bioaccumulative substance is so persistent that it should be phased out.

Today's internationally accepted, standardized methods for determining the biodegradability of organic substances are on the one hand simpler tests of ready biodegradability and inherent biodegradability, and on the other hand the simulation test, which determines the half-lives of substances under more natural conditions (see Annex 3). In the opinion of the Committee, it is more relevant to use half-lives to indicate the biodegradability of substances than the results given by the simpler tests alone.

A simulation test resembles the actual degradation situation in the environment more closely than the simpler tests, and is also more complicated to carry out. Several simulation tests have been implemented within the framework of the ISO system (see section 8.6.1 for information on ISO). For example, ISO 11734 measures anaerobic biodegradability, while ISO 14592 measures biodegradability in surface water. Further simulation tests, e.g. for biodegradability in sediments, are under development. The OECD's current test guidelines include a simulation test, 303A, which however simulates biodegradation under the conditions that prevail in sewage sludge, so the results of this test cannot be applied to conditions in natural waters. Nor is it considered possible to use the results of this test for classification of organic substances. The OECD is currently working on incorporating additional simulation tests in its test guidelines.

Substances that are biodegraded in an aquatic environment can be considered to be biodegraded in a similar manner in soil, provided enough water and oxygen are available and the temperature permits degradation. The US Environmental Protection Agency (EPA) takes roughly the same view when screening the properties of substances (EPA, 1999b), but claims that the degradation is slower in sediments under anaerobic conditions. The results of biodegradability tests in an aquatic environment should therefore be able to be considered to be applicable today to a terrestrial environment as well, in lieu of standardized tests for other environmental media. Nevertheless, the results of other reliable, scientific studies of the biodegradability of substances, for example in soil, can still be taken into account in assessing the persistence of substances, and this recommendation can be reconsidered as new testing methods are developed.

Present-day methods for estimating the biodegradability of substances with the aid of calculation models are, however, not sufficiently reliable

for the results of such estimates to determine whether a substance may be persistent or not (see Annex 3).

There are no standardized, internationally accepted tests available today for biodegradation in air. Estimated values are generally used instead. The Committee does not consider it meaningful to propose its own criteria for biodegradability in air, but is instead of the opinion that criteria agreed upon within the framework of international conventions such as CLRTAP (see section 8.2.3) should be applied in the EU.

In summary, we propose that standardized, internationally accepted testing methods providing information on the half-lives of substances should preferably be used to determine when a substance is so persistent that it should be subject to phase-out requirements according to the Committee's criteria. As a complement to these methods, or in lieu of the results of such tests, it should be possible to use other scientific results deemed to be reliable. Estimated values should not be regarded today as acceptable information on how persistent substances are.

5.1.3.2 Bioconcentration values for aquatic environment are proposed to determine whether a substance is bioaccumulative

The standardized, internationally accepted testing methods that are available today to obtain an experimental value of the bioaccumulation of substances are based on determining the substances' bioconcentration factors (BCFs) for aquatic organisms, normally fish (see Annex 3). The criteria that can be proposed today can thus only be based on test results from an aquatic environment. There may, however, be reason to weigh in results pertaining to bioaccumulation from other scientific studies as well, such as those for a terrestrial environment, when considering phase-out. Such results may include data collected within the framework of environmental monitoring and screening studies (see section 9.2). There are also reasons for taking a closer look at the possibility of developing testing methods that measure bioaccumulation in a terrestrial environment (see section 9.1.2).

Bioaccumulative substances are often fat-soluble and must be available for uptake in organisms. Calculation models are available today (QSAR) that can estimate the bioconcentration factor of organic substances with good precision based on data on their fat solubility and other properties, such as molecular size (Sijm et al., 1999).

Bioavailable substances can, however, be bioaccumulative due to properties other than their fat solubility. They may, for example, bind to macromolecules in organisms, such as proteins. In the opinion of the Committee, scientific studies of such factors can serve as a basis for determining whether a substance is sufficiently bioaccumulative to be subject to requirements on phase-out.

In summary, we propose that standardized, internationally accepted tests preferably be used to determine when a substance is so bioaccumulative that it should be subject to requirements on phase-out according to the Committee's criteria. As a complement, or in lieu of results from such tests, it should be possible to use other scientific results, such as from environmental monitoring and screening studies, that can be deemed reliable. Values estimated on the basis of fat solubility, in accordance with internationally accepted calculation methods, should also be regarded as acceptable information as to what degree bioavailable substances are bioaccumulative (see Annex 3). Experimentally determined BCFs shall, however, always take priority over estimated values.

5.1.4 Proposed phase-out criteria for persistent substances

The Committee's appraisal and proposals

The Committee deems it more serious that a bioavailable substance is persistent than that it is bioaccumulative, since:

- a persistent substance gives rise to prolonged exposure, and there is a risk that unforeseen effects will manifest themselves during the exposure period,
- there is a risk that persistent substances will be transported to places far from where they are produced,
- it takes a long time to bring down the environmental concentrations of a persistent substance after its release has ceased.

The Committee proposes:

- that a substance be regarded as unacceptably persistent if its half-life is longer than 8 weeks in a simulation test at 20 ºC.

The Committee further proposes in accordance with Chapter 6:

- that the stipulated phase-out criterion shall apply to new substances from 2005 and to existing substances from 2015,
- that the phase-out criterion ”a longer half-life than 26 weeks in a simulation test at 20 ºC” shall apply to existing substances from 2010.

The above criteria are proposed to apply only in combination with the phase-out criteria for bioaccumulation that are proposed in 5.1.5.

In many areas where chemicals are used, persistence is a desirable property of chemical substances. This is particularly true of chemical substances that are incorporated in materials intended to endure for a long time, such as building materials, paints and other surface coatings. But even in the case of pesticides such as DDT, it is still regarded as an advantage today, in the areas where the agent is still used[2], that the substance is persistent so that the treatment will be long-lasting and not has to be repeated so often.

However, persistence in a substance also entails a risk of prolonged exposure. This means that a persistent substance, if it is also bio-accumulative, may be available for uptake in organisms for a long period of time. This may eventually lead to unforeseen effects. Such effects may be difficult to counteract, since it takes a long time to bring down the environmental concentrations of a persistent substance after its release has ceased. Unforeseen toxic effects of persistence substances may include synergistic and additive effects in combination with other substances. There may also be effects such as chronic low-dose toxicity. Persistent substances may also be transported to locations far from the production site, for example in water, winds and products.

There may be reason in the future to consider whether persistent man-made organic substances may be undesirable in the environment even if they are not bioaccumulative. They may have other properties, besides persistence, that give rise to possible future risks even if their toxicity is not known. Such a property may be that they are highly mobile[3] in the environment, which contributes to a further increased risk of exposure.

[2] DDT is used above all in tropical regions, where there is not yet a more effective alternative for controlling certain disease-carrying insects, such as malaria mosquitoes and tsetse flies.

[3] That a substance is ”mobile” means that it can be readily transported by e.g. water and air, and that there are no mechanisms (such as adsorption in soil) that significantly retard such transport.

An example of such a substance, whose toxicity is however documented, is the herbicide atrazine, which is often found in groundwater samples despite the fact that it has not been allowed to be sold in Sweden since 1991. Such finds are also common in large parts of the rest of Europe and the United States. Atrazine can also be detected in the Arctic (Chernyak et al., 1996).

5.1.4.1 When should a substance be regarded as persistent in the environment?

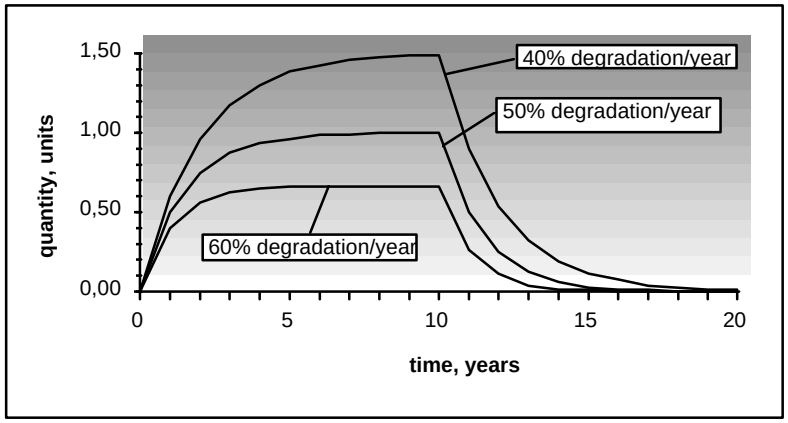
Criteria for judging persistence can be the amount in which a substance can be expected to remain in an environment in relation to the risk that the substance will cause some kind of harmful effects in the environment, and how long it takes for the substance to disappear from the environment after its release has ceased. The risk of harmful effects for a substance in the environment is, however, very difficult to estimate, particularly for a substance whose possible toxic effects are not known. But the idea behind the general approach that underlies the Committee's commission is, as previously mentioned, to take restrictive action against substances that are persistent and bioaccumulative without their possible toxic effects necessarily being known. The Committee therefore makes the judgement that the principle should be that there should not be a risk that a bioaccumulative substance that is introduced into the environment has too long a "braking distance", i.e. that the substance's retention time in the environment after its release has ceased should not be too long. A substance's half-life in the environment determines how much of the substance remains in the environment at a given release rate (Rodan et al., 1999), and how long the braking distance is after release has ceased.

It should be noted that the following method for estimating half-lives and retention times is necessarily simplified. But the line of reasoning could nevertheless be justified as a basis for the general discussion of the biodegradability of substances in the environment that is needed in order to propose a general criterion for persistence.

Figure 5.1 Accumulation in the environment and "braking distance" for substances with different biodegradation rates.

The curves show the average accumulation in a given environment of a substance that is released at the same annual rate over a period of 10 years, and that simultaneously degrades at a rate equivalent to 40 (upper curve), 50

(middle curve) and 60 (lower curve) percent per annum.[4] The release ceases after 10 years, and the substance disappears from the environment at a rate that is dependent on its half-life. The darkening field symbolizes the risk of harmful effects, which increases as the amount accumulated in the environment increases (see further discussion in text).



The average accumulation in a given environment of a substance whose release rate to this environment is the same every year for 10 years and which is degraded at a rate of 40, 50 and 60 percent during a single year is shown by the examples in Figure 5.1. These degradation figures correspond to half-lives in the environment of approximately 69, 52 and 43 weeks, respectively. In the examples, the release ceases after 10 years and the substance disappears from the environment at a varying rate, depending on the half-life.

A substance that degrades by 40 percent during a year will reach an environmental level equivalent to about 1.5 times a constant annual release. When the release ceases, it takes 5 years for the environmental level to decline by 90 percent, and 9 years for it to decline by 99 percent.

A substance that degrades by 50 percent during a year will reach an environmental level approximately equivalent to a constant annual

[4] The remainder after each year is added to the new increment. A steady state level is reached after a number of years. Depending on how release has occurred during the year, and how degradation varies during the year, the process in reality will follow a much more dynamic course that the curves show (see e.g. Rodan et al., 1999).

release. When the release ceases, it takes 4 years for the environmental level to decline by 90 percent, and 6 years for it to decline by 99 percent.

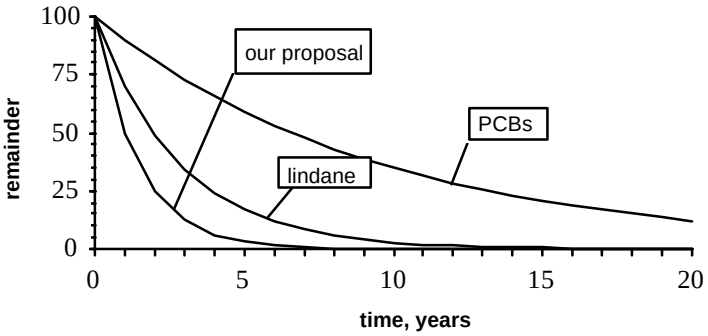
A substance that degrades by 60 percent during a year will reach an environmental level equivalent to about two-thirds of a constant annual release. When the release ceases, it takes 3 years for the environmental level to decline by 90 percent, and 5 years for it to decline by 99 percent.

It is the Committee's judgement that for a substance that degrades by at least 50 percent during the course of a year, i.e. has a half-life in the environment of no more than 52 weeks, the braking distance is sufficiently short (at least 90 percent degrades in 4 years). Substances that do *not* meet this persistence criterion (i.e. half-life of at least 52 weeks) would then be eliminated from the environment relatively quickly if their use has to be restricted, e.g. due to the discovery of serious but unforeseeable toxic effects.

The chosen criterion for persistence, that the half-life in the environment shall not exceed 52 weeks, can be compared with the calculated half-lives in an aquatic environment for lindane and PCBs, which are 107 and 327 weeks, respectively (Beyer et al., 2000). Accordingly, approximately 33 and 10 percent, respectively, of a given amount of the substances disappears from the environment in one year (see Figure 5.2).

Figure 5.2 Degradation of different substances in water

The curves show the average biodegradation with time in the aquatic environment of PCBs (upper curve), of lindane (middle curve) and of a substance that degrades at a rate that is equivalent to that proposed by the Committee to be the lowest acceptable (lower curve) in its criterion for persistent substances.



Here again, however, it may be well to note that the reasoning is based on simplified assumptions. For example, the half-life of a given substance in the environment can vary widely, which is not taken into account in the arguments given above. The degradation of PCBs can, for example, be much slower than is indicated in Figure 5.2, due to the fact that PCBs are largely distributed to parts of the environment where they are less accessible for degradation processes.

5.1.4.2 What half-life in a simulation test at 20 ºC corresponds to a half-life of one year in a northern European climate?

In the opinion of the Committee, allowance must be made for the fact that substances may have ”higher persistence”, i.e. biodegrade more slowly, in northern regions in e.g. Europe, where climatic conditions for degradation of organic substances may be unfavourable. Similar reasoning is employed in conjunction with the revision of the EC’s biocidal products directive (Braunschweiler & Koivisto, 2000, see also Annex 3).

When it comes to substances that can be dispersed with products and chemical preparations, one cannot uncritically permit substances which are readily biodegraded in one climate if they are liberated from the products they are incorporated in, but in another climate exhibit poor

biodegradability. The precautionary principle also warrants taking into account the varying biodegradability of organic substances, e.g. under different climatic conditions. Here it is a question of striking a reasonable balance between expected biodegradability under different climatic conditions, taking into consideration what climates the products can be expected to be dispersed to in such quantities that substances contained in the products can be expected to lead to exposure to man and the environment if they are persistent and bioaccumulative and if they are released from the products during use or in the waste stream.

Since the Committee proposes that it shall be possible to determine the persistence of organic substances in the environment based on experimental tests carried out under standardized conditions, it is necessary that a given requirement on a maximum half-life in a given environment can be ”translated” to an equivalent half-life in e.g. a simulation test at 20 ºC.

The half-life for microbial degradation is affected by, among other things, the temperature, which in a northerly climate can be said to be limiting. The Finnish Environment Institute has proposed that the effective temperature sum over the year should be used when discussing the biodegradability of herbicides in different climate zones (Seppälä, 1999).

The annual temperature sum is the sum of all mean daily temperatures that exceed a given threshold value during the course of a year[5]. If we start with the annual temperature sum calculated for forest growth given by the climate in the Lake Mälaren Valley (Morén & Perttu, 1994)[6], and estimate the equivalent annual temperature sum for microbial activity, we find that a substance that has a half-life of 52 weeks in this climate should have a half-life of approximately 16 weeks at 20 ºC.

Based on the annual mean temperature (5ºC in Central Sweden), the National Chemicals Inspectorate makes a similar estimate of half-lives for herbicides in agricultural soil, assuming that the half-life is halved

[5] The concept of temperature sum is established in the forest sciences, where the threshold value for growth of forest is considered to be 5ºC, and the annual growth is proportional to the annual temperature sum. For microbial activity in e.g. soil, which in a similar manner can be expected to be proportional to the annual temperature sum, a suitable threshold value should be 0ºC or just under.

[6] and unpublished material from the Finnish Meteorological Institute.

when the temperature rises 10 degrees. The two calculation methods give results that are in good agreement for this climate zone. However, the annual temperature sum probably gives a better estimate of the climate in a given area than the annual mean temperature.

It should, however, be noted that both annual mean temperatures and annual temperature sums are normally based on meteorological data where the temperatures are measured about two metres above ground level. The temperature at and below the ground surface is normally lower during the growing season than is given by meteorological data (Magnusson, 1997). Lower temperatures can also be expected in surface waters (Eklund, 1998), and much lower in sediments. Furthermore, microbial activity, and thereby biodegradation, varies greatly in the environment with other conditions as well (see Annex 3), which cannot be taken into account by simple criteria.

A persistence criterion entailing that the half-life of a substance in a simulation test at 20 ºC may not exceed 16 weeks (equivalent to a maximum half-life of 52 weeks in an environment with the climate of the Lake Mälaren Valley) assumes that the conditions for degradation in the environment are always optimal at a given temperature, and further that the temperature conditions in soil are similar to those in air. Such an assumption may to some extent be warranted in the case of e.g. biodegradation of herbicides in agricultural soil. But when it comes to substances that are more diffusely dispersed to a number of environments of differing character, it is not as justified to assume that microbial degradation will always be possible in these environments, and that it will always occur under optimal conditions. Furthermore, a more northerly climate than that in the Lake Mälaren Valley should also be considered, in view of the fact that the regions along the coast of Norrland, for example, are relatively (at least by Swedish standards) densely populated and exposed to considerable flows of products. A lower time limit for the maximum acceptable half-life in a simulation test at 20ºC should therefore be warranted, and the Committee proposes that this limit be set at 8 weeks.

With reference to Chapter 6, the Committee proposes that the above phase-out criterion shall apply to new substances from 2005 and to existing substances from 2015, provided they also meet the phase-out criterion proposed by the Committee for bioaccumulation potential (see section 5.1.5). The phase-out criterion supported unanimously at the Committee's roundtable discussion in Steningevik (see section 5.1.6), which only applies to the most persistent and bioaccumulative

substances, shall apply to existing substances from 2010. This entails phase-out of substances whose half-life, experimentally determined in a simulation test at 20 ºC, is longer than 26 weeks ($t_{½}$ > 26 weeks), provided they also meet the phase-out criterion for bioaccumulation potential proposed by the Committee (see section 5.1.5).

In summary, the Committee makes the appraisal:

- that a substance is to be regarded as unacceptably persistent if its half-life in the environment is longer than one year,
- that the limit beyond which a substance is unacceptably persistent should be set so that the half-life in the environment is also relevant for a temperate northern European climate, and
- that this limit is approximately equivalent to *a maximum half-life of 8 weeks in a simulation test at 20 ºC, which the Committee proposes as the phase-out criterion for persistence.*

5.1.5 Proposed phase-out criteria for bioaccumulative substances

The Committee's proposals

The Committee proposes:

- that a bioconcentration factor higher than 2,000 shall comprise the phase-out criterion for bioaccumulation of persistent substances.

The Committee further proposes in accordance with Chapter 6:

- that the specified phase-out criterion shall apply to new substances from 2005 and to existing substances from 2015.

that the phase-out criterion "a bioconcentration factor higher than 5,000" shall apply to existing substances from 2010.

The above criteria are proposed to apply only in combination with the phase-out criteria for bioaccumulation that are proposed in 5.1.5.

The fact that a substance is bioaccumulative entails an increased risk of exposure for organisms, since bioaccumulation means that the substance can be absorbed and accumulated in the organism at higher concentrations than in the surrounding environment or in food. Bio-available substances which, in the environment or in organisms, rapidly undergo complete degradation or are rapidly secreted run little risk of being bioaccumulated. In order to decide whether such substances are

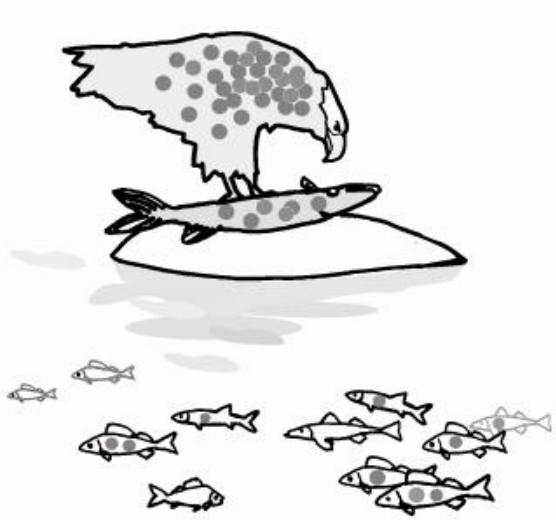
unsuitable to use, further information is required on other properties, such as toxicity, of both the substances as such and of any reaction intermediates that arise during degradation. Accordingly, it is above all persistent, bioavailable substances that can be bioaccumulative.

Bioaccumulative substances can be transferred between organisms, for example via breast milk in mammals and from prey to predator in the food chain. If bioaccumulative substances are accumulated in predators to a higher degree than in prey, i.e. can be enriched in the food chain, the substances are said to be biomagnifying (see Figure 5.3, and Annex 3). The fact that a substance is biomagnifying leads to a further increased exposure risk, particularly for organisms at the top of the food chain, with an associated risk that previously unforeseen harmful effects will manifest themselves.

It is not possible to set a limit for the bioaccumulation potential of persistent substances that provides greater protection for biological diversity at low trophic levels in the food chain solely on the basis of these properties. If a low limit for bioaccumulation potential is used, increased protection might possibly be achieved by phasing out a larger number of chemical substances. But other properties of persistent substances than bioaccumulation potential, such as mobility and various types of toxic effects, are also of importance for their effects on biological diversity.

Figure 5.3 Biomagnification

A biomagnifying substance that is absorbed from food is enriched in the food chain, i.e. accumulated in predators to a higher degree than in prey.



Allowing only the bioaccumulation potential of persistent substances to be decisive in protecting biological diversity at low trophic levels in the food chain is thereby a far too limited approach. No matter how low the limit for bioaccumulation potential is set, there will always be substances with lower bioaccumulation potential that can adversely affect biological diversity because they are toxic and e.g. mobile. The primary purpose of the bioaccumulation potential criterion should therefore be to prevent the release of substances that are highly bioaccumulative, as well as ones that can be biomagnifying and thereby pose an additional threat to organisms above all at higher trophic levels in the food chain.

As is evident from Annex 3, today it is necessary to estimate bioaccumulation potential from tests performed in an aquatic environment, usually in the form of a bioconcentration factor (BCF) for fish. In general, substances with BCFs lower than 100 are not considered to be bioaccumulative to any alarming extent. This is reflected e.g. in the provisions of the dangerous substances directive (67/548/EEC) regarding classification and labelling of chemical substances and preparations, while the equivalent limit in the harmonized classification

criteria proposed by the OECD exempts substances with BCFs lower than 500 (see section 4.1.1 and 4.3 in Annex 3).

The EPA (1999a; see also section 4.5 in Annex 3) largely concurs with the assessment in the EC's dangerous substances directive, going on to say that substances with BCFs between 100 and 1,000 are not so bio-accumulative that they give cause for any great concern (”medium concern for bioaccumulation”), while substances with BCFs in excess of 1,000 give rise to ”high concern for bioaccumulation”. The National Chemicals Inspectorate also considers substances with a BCF in excess of 1,000 to have a high bioaccumulation potential, which is manifest in the Observation List's environmental hazard (danger for the environment) criterion for bioaccumulation potential (see section 4.7.1 in Annex 3).

The EC's directives on plant protection products (91/414/EEC) and biocidal products (98/8/EC) state that a substance[7] has an undesirable bioaccumulation potential if the bioconcentration factor is higher than 1 in the case of exposure of vertebrates[8], or if the risk of such exposure does not exist, is higher than 100 for substances which are not readily biodegradable and 1,000 for substances which are readily biodegradable[9] (see section 4.1.2 in Annex 3). The EC's two pesticide directives thus take particularly great account of the risks of bioaccumulation in vertebrates, and set a much lower limit for unacceptable bioaccumulation potential for substances that are persistent than for those that are readily biodegradable.

For a substance to be biomagnifying, however, the BCF normally has to be higher than 1,000. Results from studies conducted in this field show that a substance can be biomagnifying if log K_{ow} is greater than 4.5–5 or if the BCF is higher than approximately 3,500.[10]

[7] ”active substances” for plant protection products and ”active substance or potentially harmful substance” for biocidal products

[8] ”birds and other terrestrial vertebrates” for plant protection products and ”non-target vertebrates” for biocidal products

[9] ”where there is a possibility of aquatic organisms being exposed” for plant protection products, no reservations for biocidal products.

[10] personal communications with the National Chemicals Inspectorate and information from the ICCA (www.chem.unep.ch/pops/iccapops.html, with reference to the U.S. EPA)

There are, however, several uncertainties to take into account:

- It is unclear what relevance BCFs for the aquatic environment have for bioaccumulation in e.g. the terrestrial environment.
- The studies that have been done have been focused on a limited number of substances.
- Experimentally determined BCFs underestimate to some extent the substances' bioaccumulation potential, since uptake via food is not included, but can lead to bioaccumulation on other grounds than fat solubility.

It is therefore the judgement of the Committee that the phase-out limit with respect to bioaccumulation potential should be set lower than the limit above which it is known with certainty that substances risk being biomagnifying, and the Committee's proposed phase-out criterion is BCF > 2,000.

We also propose, with reference to Chapter 6, that the above phase-out criterion shall apply to new substances from 2005 and to existing substances from 2015, provided they also meet the phase-out criterion proposed by the Committee for persistence (see section 5.1.4). The phase-out criterion supported unanimously at the Committee's round-table discussion in Steningevik (see section 5.1.6), which is only met by the most persistent and bioaccumulative substances, shall apply to existing substances from 2010. This entails phase-out of substances whose bioconcentration factor, experimentally determined for fish, is greater than 5,000 (BCF > 5,000), provided they also meet the phase-out criterion for bioaccumulation potential proposed by the Committee (see section 5.1.4).

In summary, the Committee makes the appraisal:

- that substances with a bioaccumulation factor higher than 1,000 are considered to be highly bioaccumulative,
- that a bioaccumulative substance that is persistent poses a particularly great risk if it can furthermore be biomagnifying, i.e. be enriched in the food chain,
- that biomagnifying substances are above all found among substances with bioconcentration factors higher than 3,500.

The Committee therefore proposes, with reference to the precautionary principle, that *a bioconcentration factor in excess of 2,000 shall comprise the phase-out criterion for bioaccumulation of persistent substances.*

5.1.6 The Committee's criteria in relation to criteria proposed by other agencies and organizations

Phase-out of substances solely on the basis of the properties persistence and bioaccumulation, as proposed in the Gov. Bill "Swedish Environmental Quality Objectives" (1997/98:145) is a previously untried method for risk management. Knowledge of the bioaccumulation (B) and persistence (P) of substances has, however, been proposed previously or used as a tool in a number of other contexts, though usually together with criteria for e.g. toxicity (T). The purpose has usually been to select and prioritize substances for various purposes such as risk assessment, or for classification (Figure 5.4).

On the National Chemicals Inspectorate's Observation List, however, one of the three independent criteria for environmental hazard (danger for the environment) is based solely on P and B (see Annex 3). Substances that are not readily degradable as defined by the OECD's ready degradability test, roughly equivalent to a half-life of over 2 weeks (see section 1.2.3 in Annex 3), and whose bioconcentration factor is greater than 1,000, meet the list's criteria for danger for the environment. The same criteria for danger for the environment are found, for example, on the Norwegian Observation List (SFT, 2000).

Figure 5.4 Criteria for persistence and bioaccumulation

The Committee's proposed phase-out criteria, plus criteria for unacceptable persistence (P) and bioaccumulation potential (B) that are applied or proposed by other fora. Observe that certain of the "PB criteria" apply independently, while others are linked to criteria for other properties such as toxicity and mobility. Based on the location of the letter, the criteria extend downward and to the right in the matrix below. The persistence criterion "not readily biodegradable" is considered to be equivalent to $t_{½}$ > 2 weeks. BCF = bioconcentration factor.

a) EC's directives on plant protection products and biocidal products (vertebrates; see section 4.1.2 in Annex 3.
b) EC's directives on plant protection products and biocidal products (readily biodegradable substances).
c) EC's directives on plant protection products and biocidal products (not readily biodegradable substances); EC's dangerous substances directive (environmental hazard classification; see section 4.1.1 in Annex 3).
d) OECD's proposal for harmonization (environmental hazard classification; see section 4.3 in Annex 3); OSPAR-DYNAMEC's selection criterion

under discussion, aimed at selection of substances with lower persistence and bioaccumulation potential than other limits being discussed (see section 4.4 in Annex 3).

e) environmental hazard criterion in the National Chemicals Inspectorate's Observation List (see section 4.7.1 in Annex 3).

f) **Committee's proposal for final phase-out criterion.** (Also marked with a light grey field).

g) UNEP's POPs convention, criterion under discussion, with lower limit for persistence (see section 4.2.1 in Annex 3).

h) UNEP's POPs convention, criterion under discussion with higher limit for persistence. **Committee's proposed criterion for first phase-out stage for existing substances.** (Also marked with a dark grey field).

	P1 $t_{½} < 2v$	P2 $2v \leq t_{½} < 8v$	P3 $8v \leq t_{½} < 26v$	P4 $t_{½} \geq 26v$
B0 BCF < 1				
B1 1≤ BCF < 100	**a**			
B2 100 ≤ BCF < 500		**c**		
B3 500 ≤ BCF < 1,000		**d**		
B4 1 000 ≤ BCF < 2,000	**b**	**e**		
B5 2 000 ≤ BCF < 5,000			**f**	
B6 BCF ≥ 5,000			**g**	**h**

Similarly, one of the classification criteria for environmental hazard in the EC's dangerous substances directive (67/548/EEC) is based solely on the properties of persistence and bioaccumulation without toxicity data being required for classification as dangerous for the environment (though there is an additional requirement on low water solubility, see Annex 3). The same applies to the harmonized classification criteria proposed by the OECD (see Annex 3).

Both within the EU's existing and the OECD's proposed systems, bio-accumulative substances are classified as dangerous for the environment if they meet the same persistence criterion as that given in the Observation List. In the EU's classification, however, readily bio-degradable substances with BCF > 100 are not regarded as being sufficiently bioaccumulative to be classified, while substances with BCF > 500 are regarded as being bioaccumulative in the harmonized classification proposed by the OECD.

The UNEP's and OSPAR's proposals for PB criteria (see Annex 3), which are still under discussion, apply together with at least criteria on T, and in some cases also together with additional criteria on other properties such as mobility. OSPAR's criteria for persistence are based on the OECD's guidelines for testing of Ready and Inherent Biodegradability. OSPAR's proposed criterion, which sets the highest limits for persistence and bioaccumulation potential, thereby exempting the greatest number of substances from being selected in relation to the other criteria being discussed, includes substances whose BCF > 5,000 and which are not biodegradable in the inherent biodegradability test. Non-biodegradable substances are identified in TGD (1996) as "eternally" persistent ("half-life ∞"). Within the UNEP, the circumstances under which the stated half-lives are to be determined are not specified, for example whether they are valid for laboratory tests or out in the field.

In the EC's directives on plant protection products and biocidal products, the point of departure as regards toxicity is given, i.e. that the substances of interest are toxic for the "target organism". The criteria given for the substances' highest acceptable persistence and bioaccumulation are set very low and apply provided that exposure is probable for "non target organisms" as well (see Annex 3).

The Committee's international scientific roundtable discussion

On 10–11 December 1999, we held a roundtable discussion to obtain the views of the international scientific community on our work with criteria for phase-out of substances solely on the basis of their persistence and bioaccumulation (see Annex 7).

The participants in the meeting were internationally recognized scientific experts in the field, representing national and international agencies and organizations, universities and the chemical industry, as well as several of the Committee's experts and specialists and representatives of the Committee's scientific reference group.

Among the most interesting conclusions of this discussion were the following:

- The participants were in full sympathy with the principle that criteria of the kind discussed should be kept as simple as possible.
- After thorough discussion, the participants unanimously supported the principle of phasing out substances solely on the basis of

persistence and bioaccumulation when these properties are so serious that they would correspond to the square B6/P4 in Figure 5.4, and were generally of the opinion that this can be regarded as scientifically justified.

- The participants unanimously supported the idea that this PB criterion should immediately be applied to new substances, without any additional requirements on toxicity data.
- Several of the participants supported the idea of phasing out substances on PB criteria entailing that substances with lower persistence and bioaccumulation are included, such as corresponding to the field B5B6/P3P4 in Figure 5.4.

Against the background of the discussions at the roundtable meeting in Steningevik, and ongoing international work regarding selection and prioritization of undesirable substances, as well as the work initiated within the EU aimed at proposing simplifications of the current risk assessment process in the existing substances programme, the Committee concludes that an approach based on phase-out of persistent substances with high bioaccumulation potential, and solely on these properties, has a good chance of being received with positive interest on the international plane today.

5.2 Phase-out criteria for carcinogenic, mutagenic, reproduction-toxic and endocrine-disruptive substances

According to the Swedish Government's guidelines, new products shall, within 10–15 years, be free from man-made substances that are carcinogenic, mutagenic and endocrine-disruptive – including those which have adverse effects on the reproductive system. Our Committee has been commissioned to clarify how the guidelines for these properties can be related to existing classification systems. In this section we examine the existing classification system for carcinogenic, mutagenic and reproduction-toxic substances (CMR substances). We also submit proposals on how the Government's guidelines can be tied in with the system. In the case of endocrine-disruptive substances, no criteria exist today for classification. We therefore deal with endocrine-disruptive substances separately in section 5.2.2. Annex 4 contains a description of how CMR substances are used in Sweden today. Annex 5 contains a more exhaustive treatment of endocrine-disruptive substances.

5.2.1 Carcinogenic, mutagenic and reproduction-toxic substances

The Committee's proposals

- The substances that are to be covered by the guidelines are the substances that are classified as carcinogenic, mutagenic or reproduction-toxic within category 1 or 2 according to the EC's dangerous substances directive (67/548/EEC).

5.2.1.1 What criteria exist today?

EU rules for classification and labelling of CMR substances

The EC's dangerous substances directive (67/548/EEC) contains definitions of what is meant by carcinogenic, mutagenic and toxic for reproduction. These definitions have also been incorporated in the National Chemicals Inspectorate's regulations (KIFS 1994:12) and entail the following:

- Substances and preparations shall be classified in the hazard class carcinogenic if – when inhaled or ingested or if they penetrate the skin – they may induce cancer or increase its incidence.
- Substances and preparations shall be classified in the hazard class mutagenic if – when inhaled or ingested or if they penetrate the skin – they may induce heritable genetic defects or increase their incidence.
- Substances and preparations shall be classified in the hazard class toxic for reproduction if – when inhaled or ingested or if they penetrate the skin – they may produce, or increase the incidence of, non-heritable adverse effects in the progeny and/or an impairment of male or female fertility.

The dangerous substances directive, as well as the Swedish rules, contain special criteria for classification of chemical substances with regard to their properties. Depending on how strong the scientific evidence is, the substances are placed in one of three categories. The following categories apply for carcinogenic substances:

- *Category 1* entails that there is clear evidence that the substance *is* carcinogenic to man.

- *Category 2* entails that the substance should *be regarded as* carcinogenic to man. Placement of substances in category 2 is generally based on results of long-term animal studies.
- *Category 3* entails that the substances *could possibly be* carcinogenic to man. Placement of substances in this category is based on the fact that there is some evidence from appropriate animal studies, but that this is insufficient to place the substance in category 2.

There is an equivalent division into categories for mutagenic and reproduction-toxic substances.

It is an important principle that no distinction is made between substances in category 1 and category 2, either with respect to labelling or in other provisions which refer back to the classification provisions. This means that clear evidence from animal studies weighs just as heavily from a rule viewpoint as if it were clearly proven that adverse effects occur in man.

The classification of a chemical product, i.e. placement in hazard class and assignment of risk phrases, determines how the product will be labelled. The classification determines which danger symbols (e.g. ”skull and crossbones”), which hazard indication (e.g. ”toxic”) or which risk phrases (e.g. ”May cause cancer”) and safety phrases (e.g. ”Avoid exposure – obtain special instructions before use”) shall be used in the labelling. In contrast to products with category 1 and 2 substances, products with category 3 substances are labelled not as toxic but as harmful.

Potency gradation

The classification of carcinogenic chemical substances is thus based on the degree of evidence indicating that the substances induce cancer. However, the division into the three categories does not take into account the degree of carcinogenicity (potency), i.e. how high a dose is required for a given percentage of a group of laboratory animals to get cancer. There is, however, a way to take the potency of substances into account by indicating special concentration limits for labelling of a chemical product that contains carcinogenic substances. The general rule is that a chemical product shall be labelled if it contains a substance classified as carcinogenic (category 1 or 2) in concentrations over 0.1 percent. The concentration limit can be lowered to 0.01 percent or even lower for

high-potency carcinogenic substances, and it can be raised for low-potency substances.

The Commission Working Group on the Classification and Labelling of Dangerous Substances (1999) has prepared a guidance document describing how concentration limits can be set in the labelling of chemical products. Concentrations lower than 0.1 percent are given for seven substances in the dangerous substances directive. Different concentration limits have long been used in Norway depending on the potency of the substances.

The purpose of potency gradation has thus so far been to provide guidance for the labelling of chemical products. Viewed from the perspective of the guidelines, which are aimed at a phase-out of carcinogenic substances, the judgement which serves as a basis for the choice of concentration limits can be useful for differentiating measures within the group of carcinogenic substances depending on the potency of the substances.

No gradation of potency is done today for reproduction-toxic and mutagenic substances. Discussions are, however, being held in the EU on this, and Germany has been commissioned to explore the possibilities of setting different concentration limits in the labelling of reproduction-toxic products.

5.2.1.2 Proposed phase-out criteria

The Committee's proposals are based, in keeping with its terms of reference, on the classification and labelling of chemical products in accordance with the dangerous substances directive (67/548/EEC), which has been implemented in Swedish legislation via the National Chemicals Inspectorate's regulations KIFS 1994:12. The Committee is of the opinion that it is a great advantage to start with an assessment of the substances that is internationally accepted when determining what is to be covered by the guideline.

In the EU's *acquis* there are already many restrictions regarding the use and handling of CMR substances in categories 1 and 2. So far a total of 832 substances have been classified as carcinogenic, mutagenic or toxic for reproduction (many of which are not individual substances but complex carbon- and petroleum-based "substances", see section 4.5). Of these, 801 are listed in an addendum to the dangerous substances

directive (76/769/EEC). The substances in the addendum may not occur in consumer-available chemical products in quantities exceeding the limit where the product must be provided with labelling regarding these properties. The substances that are not listed in the addendum are usually regulated in some other way. This means that nearly all CMR substances in categories 1 and 2 are covered by the rules. There are no such general restrictions for substances in category 3.

As previously noted, today's classification system is based on the degree of evidence and not on the potency of the substances. However, the Committee believes that potency should be given greater weight in classification contexts. Sweden has pursued this line in the EU, and the Committee believes that the aim should be that the potency of substances should be accorded greater importance, even though Sweden has so far had difficulty in getting support for this viewpoint.

The Committee has considered a couple of alternative proposals, subsequently abandoned. They are based on assessing the potency of the substances in relation to their concentration in a product or the total quantity of the substances on the Swedish market. The intention in these proposals was to include all substances in categories 1, 2 and 3.

The first alternative entails that the substances' ability to induce effect (potency) should be weighed together with the constituent concentration of the substances in a product in such a manner that higher concentrations of low-potency substances could be permitted and vice versa. This would be a step towards a system where a limit is set for the capacity to induce CMR effects for the products rather than the substances, which can be considered more relevant for the individual consumer.

The second alternative entails weighing together the potency of the substances with the total quantity occurring in the country. This may be relevant for substances which are persistent and to which people are thereby exposed via the external environment.

The reason the Committee has not opted for one of the alternatives described above is that they lie further from the existing *acquis* than the proposal put forth by the Committee and that they are more complicated, entailing disadvantages for both the companies and the supervisory authorities.
Furthermore, the alternatives are based on a system developed in the EU for how specific concentration limits for carcinogenic substances could

be set depending on the potency of the substances. At present, such assessments have only been made for a small number of substances, and the system is not designed in such a way that assessments are made automatically. For mutagenicity and reproduction toxicity, guidance is as yet lacking for how specific concentration limits can be set according to potency.

The Committee regards it as desirable in the long run to attach greater importance to the potency of substances in the interpretation of the guidelines, and we see it as possible to then be able to include high-potency substances in category 3.

5.2.2 Endocrine-disruptive substances

The Committee's proposals

- The testing methods in the field of reproduction toxicity should be made more thorough, and chemical substances should be tested using these methods. Above all, the methods should be strengthened with respect to developmental toxicology. This should enable the majority of the endocrine-disruptive substances to be covered.
- As far as endocrine-disruptive substances are concerned, Sweden should pursue its own activities and at the same time work internationally within the following areas:

1. Further research on hormonal effects
2. Development of testing methods
3. Requirements on testing of chemical substances
4. Greater emphasis on hormonal effects in risk assessments
5. Risk reduction measures

5.2.2.1 What are endocrine-disruptive effects?

Chemical substances that damage or disrupt the function of the body's or organisms' endocrine glands, affect the metabolism of hormones or disrupt the impact of the hormones on the target organs can give rise to so-called endocrine-disruptive effects. Such an impact on the body's endocrine system can in turn give rise to a number of pathological conditions: reproductive impairments, birth defects, cancer, diabetes,

effects on the immune system, cardiovascular disease, osteoporosis and effects on the nervous system, which can lead to behavioural disturbances.

It is important to note the difference with respect to sensitivity and possible effects on exposure to hormonally active substances during an individual's early developmental stages compared with exposure during adulthood. During early developmental stages, even a brief exposure to endocrine-disruptive chemical substances at sensitive junctures can give rise to lasting changes. This can manifest itself later in life in the form of reproductive problems, deformation, behavioural disturbances or cancer. Exposure during the foetal period is particularly sensitive. The hormonal signal systems have organizing and differentiating functions during this period, and thereby a potential to cause permanent harmful effects on the development of e.g. the genitals, the brain, the thyroid gland, the immune system and the liver.

In the adult individual, hormones generally have an activating effect, which primarily results in transient changes that are restored when the exposure ceases. More prolonged and intensive exposure is probably required in adults to cause irreversible damage such as cancer.

Reproduction toxicity includes both effects on reproductive capacity and effects on progeny development. Since early developmental stages are most sensitive to the influence of hormonally active substances, a large portion of the effects caused by endocrine disruptors can be attributed to the effect area of reproduction toxicity.

Endocrine effects and endocrine- or hormone-disruptive actions can thus give rise to a number of effects and are thus to be regarded more as mechanisms and modes of action for substances that can cause damage to organisms, populations or ecosystems rather than as health and environmental effects in themselves.

5.2.2.2 Ongoing work with regard to endocrine-disruptive substances

There are as yet no generally accepted criteria for endocrine-disruptive substances, nor any standardized, internationally recognized testing methods. Since 1996 the OECD has had a special project for substances with hormonal effects. The project includes both coordination of

activities between member countries and development of testing methods.

The OECD's work to develop standardized testing methods for endocrine-disruptive effects includes further development of other already standardized tests, e.g. reproduction toxicity tests, for the purpose of detecting effects caused by hormonal action. The work also includes evaluating existing non-standardized tests for such effects for the purpose of standardizing those that are of sufficiently high quality. It also includes developing new tests. Many countries and organizations are involved in the development of new testing methods. Annex 5 contains a progress report on the development of testing methods in the area.

Despite the fact that there are no standardized testing methods, and thereby no criteria based on such methods, concern about hormonal effects has led many government agencies and environmental organizations to publish lists of substances suspected of being endocrine disruptors. The Committee has conducted a cursory examination of a number of such lists, and if the substances on the lists are compared with data on chemicals use from the Swedish products register, it is found that the substances that are listed and also occur in chemical products in Sweden are for the most part substances that have already drawn attention due to their effects (both those due to their hormonal action and other effects), and many are subject to restrictions.

The European Parliament has urged the Commission to act on endocrine-disruptive substances. The Commission was further urged at the Environment Council meeting in June 1999 to prepare a policy document on how to identify and evaluate substances that affect the endocrine systems based on present-day methods.

In December 1999 the European Commission presented a strategy for endocrine disruptors (COM, 1999a). The strategy is divided into short, medium and long-term action.

In the short term (1–2 years), a priority list of suspected endocrine-disruptive substances will be drawn up. The substances on the list will undergo further evaluation with regard to their role in endocrine disruption. Then the Commission can urge the member states to expedite ongoing risk assessment or consider classification of the substances within the effect areas reproduction toxicity, carcinogenicity or danger for the environment. The list will be used to identify substances that are

prioritized for further testing and substances that can be subject to regulation, to identify particularly sensitive population groups that may be exposed to the substances, and to identify knowledge gaps regarding dose-response, exposure, etc.

In the medium term (2–4 years), further research will be conducted in the field and suitable testing methods will be developed, the latter in cooperation with the OECD. The Commission considers the need to develop testing methods to be particularly great in the ecotoxicity field. In the medium term, the goal is also to find suitable substitutes by means of voluntary initiatives by industry.

The plan in the long term (more than 4 years) is to make amendments to existing rules in the chemicals field in order to ensure that man and the environment will not be harmed by endocrine disruptors. Amendments may, for example, need to be made in the dangerous substances directive (67/584/EEC), the restrictions directive (76/769/EEC), the plant protection products directive (91/414/EEC) and the coming water framework directive.

The strategy was discussed at the Council's meeting in Brussels on 30 March 2000. The Council welcomed the strategy and asserted that the strategy must be coordinated with the Community's general strategy for chemical substances, which the Commission will propose. The Council stressed that the precautionary principle must be applied to respond to the problem quickly and effectively.

5.2.2.3 Proposed action plan for endocrine-disruptive substances

Since there are as yet no internationally accepted testing methods and criteria for endocrine-disruptive substances, we have not considered it possible to propose limits for when a substance is to be regarded as so endocrine-disruptive that it should not be allowed in products. On the other hand, it should be possible to act for individual substances on the basis of scientific studies. The Committee believes that an action plan describing research needs, development of testing methods, testing, risk assessment and risk management for endocrine-disruptive substances is needed to drive the work forward. The Committee makes the appraisal that an important feature of such a plan is to extend the testing methods within the effect area of reproduction toxicity. By extending these methods, it should be possible to cover most of the endocrine-disruptive substances (see further under point 2 below).

Our proposed action plan is aimed at describing within what areas Sweden should act and be a driving force in the EU and international organizations so that the guidelines can be achieved. The proposals have in several respects the same thrust as the Commission's recently presented EU strategy in the area and can be viewed as a contribution to continued efforts within the framework of the strategy. The action plan includes the following steps:

1. Further research on hormonal effects

Hormonal effects is not a homogeneous area. Hormones are active within many functions in the body throughout a person's lifetime, and disruptions in the endocrine systems can thereby manifest themselves in many different ways. Similarly, many types of disruptions give rise to similar or identical effects. The endocrine disruptions that have so far been studied the most are those associated with the sex hormones, while disruptions of other regulatory signal systems have been studied relatively little.

It is important to have broad and basic research within the entire field in order to clarify the relationships between exposure to chemical substances and the effects they can cause via endocrine disruptions. The research results comprise the knowledge base for the choice of areas where testing methods need to be developed. The effects which we know can be caused by endocrine-disruptive substances largely fall within the effect area of reproduction toxicity (which includes developmental toxicity), but further research may lead to the need to develop testing methods within other effect areas in order to detect the various effects of endocrine-disruptive substances.

Research may also lead to the development of simpler testing methods that are more exact. Research on critical effects and the mechanisms behind them may, for example, lead to the discovery of biomarkers that can be used in testing methods.

2. Development of testing methods

Today there are no standardized testing methods for hormonal effects. There are, on the other hand, standardized methods for a number of effects that can be caused by disruptions of the endocrine systems. The

development of testing methods can from this perspective be divided into two principal branches:

a) *Further development of existing tests, mainly within reproduction toxicity*. Endocrine disruptions are more to be regarded as action mechanisms than as effects in themselves. Most effects caused by disruptions of the endocrine systems should be able to be detected by reproduction toxicity tests spanning several generations, since the substances either disrupt the reproduction process directly or cause disruptions in the development of the embryo or foetus that can result in permanent damage or increased susceptibility to disease. The most extensive reproduction toxicity study is the one spanning two generations included in the OECD's test guideline 416 (see Annex 5). It is not, however, adequate for detecting all the effects that may result from an endocrine disruption. The test should therefore be extended so that progeny are tested for more possible effects. The testing method can also be used in combination with other OECD testing methods, for example the one now being developed on neurotoxicity during development.

   It is further very urgent that tests be developed within the ecotoxicity field, e.g. multi-generation studies of fish, and that they be developed into standards within the OECD.

b) *Development of screening tests.* The tests described under a) are costly and time-consuming. As a complement, simpler tests may be needed to screen out potentially endocrine-disruptive substances from those that are not. However, the weakness of the simple tests is that they do not show conclusively that a substance is endocrine-disruptive – only that it *could* be. It is therefore necessary to proceed to more advanced tests. Short-term tests (uterotophic and Hersberger assay, see Annex 5) can be used to screen pure estrogenic and androgen effects, but do not cover other hormonal mechanisms. Pure receptor binding studies give even less certain results at the present time, including both false-negative and false-positive results. It is desirable that the simple tests be refined to permit testing of many more chemical substances that is the case with the tests described under a).

3. Testing of chemical substances

When standardized testing methods have been developed, there must be requirements that substances be tested according to these methods. To

the extent that hormonal effects can be detected by refinement of existing tests within other effect areas, they will also automatically be included in the testing requirements for new and existing substances. However, requirements on testing of reproduction toxicity only exist for substances that are sold in very large quantities, and the tests in question are fairly simple.

The Committee believes that the best test for this purpose is that described in the OECD's Test Guideline 416. Other simplified tests – such as existing ones or those being developed under the OECD's test guidelines 421, 422 and 407 – risk giving a result that is not comprehensive enough to comprise a good basis for risk assessment.

Current ecotoxicity testing requirements do not include reproductive disruptions in relevant organisms, such as fish. The ecotoxicity testing requirements should therefore be extended. At the same time, simpler tests of the potential of substances to cause hormonal effects, e.g. receptor binding studies, should be adopted for substances sold in small quantities.

Sweden should advocate amendments of the EU directives and regulations containing requirements on testing, e.g. the dangerous substances directive (see Chapter 4).

In addition to amendments in directives, it may be necessary to influence the practice that is applied in assessing whether the test results submitted by industry are adequate or not.

Under today's rules, the amendments described above will only apply to substances introduced on the market from now on, plus substances that become subject to risk assessment in the programme for existing substances from now on. The proposals we make in Chapter 4 concerning testing requirements on all substances will therefore be of great importance in obtaining a broad testing of substances.

4. Greater emphasis on hormonal effects in risk assessments

Even though the principal purpose of our Committee is to devise *general* criteria for phasing out substances, existing models for risk assessment of individual substances may need to be reviewed. There is in the EU programme for existing substances a guidance document for how risk assessments should be performed (TDG, 1996). This guidance document should more clearly take into account effects resulting from hormonal action mechanisms. For example, in cases where the mechanism is known it should be possible to take into account the combined risk posed by substances which act in the same way, in view of the fact that it can be assumed on good grounds that substances with the same action mechanism have an additive effect.

5. Risk reduction

Classification and labelling of chemical products plays a central role in risk management. Labelling conveys information needed for an active product choice. In addition, there are several directives that regulate use and handling of chemical products of a given classification. Today, hormonal effects in themselves are not a basis for classification and labelling of chemical products. Hormonal disruptions are, on the other hand, action mechanisms that can lead to other effects that are in turn covered by the classification system.

If endocrine-disruptive effects are for the most part detected by the extension of existing testing systems in above all reproduction toxicity as described in point 2 above, this will provide a broader basis for classification of substances as reproduction-toxic. For such substances, the directives restricting use and handling that refer to this classification will be applicable immediately.

Sweden should promote the updating of the EU's priority list of suspected endocrine disruptors as new data become available. As additional test results become available, preparedness must exist to take action against substances that are found to cause endocrine disruptions. The greatest weight in this context is naturally carried by the results of standardized tests, but results from non-standardized tests and other scientific studies must also be monitored.

The Committee considers that it should primarily be the function of the National Chemicals Inspectorate to keep track of new data on the

endocrine-disruptive properties of substances and determine the need for taking action against them.

5.3 Metals and metal compounds

The Committee's appraisal and proposals

- New products shall, in accordance with the guidelines, be free from mercury, cadmium, lead and their compounds within 10–15 years.
- Metals shall otherwise, in accordance with the guidelines, be used in such a way than harm is not caused to man and the environment. In this context it is particularly important that measures be aimed at the uses that lead to a wide dispersal of metals.
- Guidelines on carcinogenic, mutagenic and reproduction-toxic properties should also be applied to metals and their compounds, and the guideline on persistent and bioaccumulative substances should be applied to organometallic substances.

There are two guidelines that have to do with metals. The one says that new products shall, in 10–15 years, for the most part be free from lead, cadmium and mercury. The other says that other metals shall be used in such applications that they are not released into the environment to a degree that causes harm to the environment or human health.

The guideline on mercury, cadmium and lead exhibits great similarities to the guidelines on persistent and bioaccumulative substances, as well as those on carcinogenic, mutagenic, reproduction-toxic and endocrine-disruptive substances. It entails a general approach that focuses on the presence of the substances in products. The difference is that the substances in this case have already been identified in the guidelines, which means that it has not been necessary for the Committee to develop any criteria. Nevertheless, we make the appraisal that mercury and cadmium should be given top priority within the group, in view of ongoing exposure and associated health effects (see Annex 6).

The guideline having to do with other metals differs from the other guidelines in that it does not mean that products have to be free from the substances, but rather that the metals should not be used in such a way that they pose any risks. The risk that a metal or metal compound will

cause adverse effects is dependent on its inherent properties (health and environmental hazard) and the exposure to which man and the environment is subjected. To meet the guideline, it is therefore important to avoid metals that pose a high danger to health and the environment, and to use the metals in such a way that they do not leak out from the products in which they occur. A large portion of the metal use in society today leads to very little release of metals to the environment, while certain uses (e.g. brake linings and pesticides) give rise to large releases. It is important to identify and focus measures on the latter types of uses.

The question of release to the environment must also be viewed in a long-term perspective. The large quantities of metals that are accumulating in society may, even if they do not constitute a problem today, eventually leak out to the environment if they are not controlled by closed-loop recycling with very small losses.

The guidelines overlap in some areas, for example as regards carcinogenic metal compounds. The Committee's appraisal is that the general criteria for carcinogenic, mutagenic and reproduction-toxic substances that have been presented in section 5.2. should be applied to metals and their compounds as well. Organometallic substances should also be covered by the general guidelines for persistent and bio-accumulative substances presented in section 5.1. Otherwise, metals and their compounds are dealt with individually.

5.3.1 General grounds for prioritization

The Committee's appraisal and proposals

Mercury, cadmium and lead shall be phased out in accordance with the Government's guidelines. Pending more complete knowledge, the following factors may provide guidance in setting priorities in the work with other metals:

- metals with high toxicity
- metals for which the concentrations in man or the environment are already elevated
- metals whose natural concentrations in the environment are low.

Knowledge regarding the properties of the metals should be available by 2010, and systems that provide information on the occurrence of the

metals in products on the market should be created (see further Chapters 4 and 7). Pending more complete knowledge, the above grounds for prioritization can provide some guidance. The prioritization grounds are intended to be used in various contexts. Companies which, in their product development, are faced with the choice of using a metal that meets any of the criteria should be extra careful to investigate whether the same function can be obtained in some other way. If not, the company should seek further knowledge on the metal and place particular importance on designing their product so that it does not lead to adverse effects during its life cycle.

The prioritization grounds can also be used by government agencies and researchers. In the case of metals whose concentration in the environment is increasing, it is extra important to obtain knowledge on any effects, and conversely it is extra important to follow the occurrence in man and the environment of metals with high toxicity. An additional prioritization ground that can be used by researchers and government agencies is the total use of a metal. Priority is naturally placed on keeping track of metals with high use, particularly if the metal has high toxicity or occurs naturally in very low concentrations. However, the fact that a metal is used by many other companies does not in itself constitute a ground for the companies to choose another metal. The criterion of high use can, on the other hand, in combination with the other criteria, provide guidance in prioritizing recycling efforts.

5.3.1.1 Metals with high toxicity

The Committee is of the opinion that knowledge concerning the toxicity of metals comprises a ground for prioritization of metals. Assessments of the toxic and ecotoxic inherent properties of substances are made in conjunction with the classification of chemical substances, in accordance with the EC's dangerous substances directive (67/548/EEC). The fact that a metal or metal compound is listed in the annex to the directive thereby provides information on the fact that the metal can in some respect have harmful effects. The list cannot, however, be interpreted as meaning that metals that are not listed are harmless – there is a great lack of data, and a complete review of all metals has not been performed. Pending more knowledge, a supplementary approach may be that presented below, under 5.3.1.3.

5.3.1.2 Results of measurements in the environment showing elevated concentrations

If measurements in the natural environment or man show that the concentrations are elevated above the natural background levels, this should be an important ground for investigating the effects of a metal if this has not already been done. Some recently performed investigations on ”new” metals are reported in Annex 6. Preliminary results from the Institute for Applied Environmental Research at Stockholm University indicate that arsenic, selenium, molybdenum, antimony, thallium, bismuth, germanium, indium, tin, and possibly silver and uranium are dispersed far from their sources (Lithner & Holm, 2000). The concentrations of several of these metals (silver, bismuth, antimony, selenium and indium) are also elevated in sediments and sewage sludge, according to analyses performed at the Swedish Environmental Research Institute, IVL (Sternbeck & Östlund, 1999). Furthermore, the concentrations of palladium, platinum and tellurium are elevated in sediments and sewage sludge, according to IVL’s research.

5.3.1.3 Metals that occur naturally at very low concentrations

Researchers have explored relationships between background concentrations and concentrations at which adverse environmental effects occur for a number of metals. Tyler (1992) has shown for five metals that a concentration increase by 3–5 times leads to adverse effects in forest soil, while Lithner (1989) has shown for nine metals that adverse effects can arise in nutrient-poor fresh waters at an elevation of 2–5 times the background levels.

It is not possible to draw the conclusion that these relationships can be generalized to all metals. On the contrary, there are indications for some metals that a concentration elevation of several times does not have any effects. The Committee nevertheless considers that assumptions concerning relationships between natural background concentration and concentrations at which adverse effects occur can serve as a preliminary basis for identifying metals of which we should be extra observant.

Annex 6 contains lists of the occurrence of a large number of metals in bedrock and soil. The values show present-day concentrations in soil and are not to be regarded as background levels. The data on the occurrence of the metals in bedrock and soil can nevertheless provide a rough picture of how common the metals are in the natural environment.

A general implication of the environmental quality objective of a non-toxic environment is that the concentrations of natural substances should be close to the background levels. In the case of the unusual metals, increased use can very quickly lead to a manifold increase in the environmental concentrations compared with the natural background concentration.

5.4 Views of the Association of Swedish Chemical Industries regarding phase-out of substances with particularly dangerous properties

The Association of Swedish Chemical Industries (2000b) believes that a general approach should be applied to the persistent and bio-accumulative substances that meet criteria established internationally or in the EU, in accordance with the Committee's proposal. But the Association feels that the group of carcinogenic, mutagenic and reproduction-toxic (including endocrine-disruptive) substances, in accordance with the proposed criteria, is far too large and heterogeneous to apply a general approach to. This group contains substances with low-potency, high-potency, more or less proven effects based on old, unproven test results as well as new, validated findings.

As far as phasing out the use of lead is concerned, the Association does not believe it is realistic to expect it to have completely ceased in the foreseeable future. But according to the Association, the risky use of lead has already ceased in Sweden, thanks to a functioning recycling system for batteries.

6 Proposed tightening-up of EU rules regarding restrictions of chemical substances

6.1 Introduction

The European Commission intends to submit a proposal for a new chemicals strategy in the EU during 2000. Work is also being pursued within the Commission on an integrated product policy. It is our hope that the proposals presented will be vigorous and far-reaching, and that the proposals we present can serve as a valuable platform for Swedish contributions to the further development of these proposals.

This chapter begins with a description of the legislation and legal grounds underlying the EU's chemical rules. This is followed by proposals of which issues Sweden should pursue within the framework of our membership in the EU. In *Annex 2* we present a sketch with proposals for statutory amendments that show how the Committee's standpoints can be implemented in the EU's *acquis communautaire*. The Annex can serve as a reference document for the Swedish Government in continued discussions of the development of the EU's chemicals control.

This chapter contains proposals that concern all the new guidelines on Swedish chemicals policy. The issue of better documentation of the properties of chemical substances, which is an important basis for being able to identify the substances that should be covered by phase-out requirements, must also be pursued in the EU. We have chosen to treat this issue separately in Chapter 4, and a prerequisite for identifying the substances covered by phase-out requirements is that the proposals in Chapter 4 are implemented.

In order to implement the guidelines calling for a phase-out based on general criteria, the Committee proposes a system that includes amendments to the dangerous substances and preparations directives, as well as the restrictions directive and the pesticides directives. Risk

assessment will still be needed for substances not subject to general phase-out. According to the guidelines, this applies to e.g. metals except lead, cadmium and mercury. With regard to these latter metals, several directives that regulate their use today should be tightened up. In addition, Chapter 7 contains proposals for Swedish rule changes that are supposed to be notified within the EU and can thereby help expedite work with these metals in the EU.

In addition, this chapter deals with implementation and enforcement questions within the EU, product directives and product standards, as well as the environmental management system, EMAS.

6.2 EU rules in the chemicals field

6.2.1 Legal basis for EU's chemical rules

The EC treaties are called the EC's primary law, while the more implementing legislation consisting of regulations, directives, decisions, recommendations and opinions is called the EC's secondary law. The EC's regulations apply directly as law within all member states, while the directives outline the results to be achieved by national legislation. The concrete form taken by such national legislation is left to the member states. Directives are the legal form that is most often used in the chemicals field, but there are also regulations.

An assessment of the importance of EC law in the chemicals field cannot be limited to an analysis of the legal acts alone. The provisions of the EC Treaty itself on the common and internal market are of great importance, and the practice established by the EC Court of Justice in the application of the treaty and the legal acts must also be taken into account.

The EC's legal acts in the chemicals field can be divided into harmonized rules and minimum rules. The fact that rules are harmonized means that the member states may not deviate from them and adopt stricter requirements for e.g. environmental reasons. Rules that have been adopted to realize the internal market are based on Article 95 (formerly 100a) in the treaty. They contain harmonized requirements. However, Articles 95.4 (formerly 100a 4) and 5, the so-called environmental guarantee, allow the member states some leeway in applying stricter requirements even in the harmonized area. Most legal acts in the chemicals field are based on Article 95, i.e. they are harmonized directives.

Some legal acts in the chemicals field are based on Article 175 (formerly 130s) in the EC Treaty. These legal acts are designed as minimum rules (e.g. a minimum level of protection) which are to apply in all member states. This means that the individual member states may apply stricter environmental requirements than those prescribed in the legal acts, within the frames of the treaty. Most directives regarding emission restrictions are designed as minimum directives.

6.2.2 Legal acts in the chemicals field

The chemicals field is one of the oldest areas covered by Community legislation (see section 3.2). To get an overview of what is regulated, the rules in the chemicals field can be subdivided in different ways. One way is the following grouping:

- *Rules governing knowledge about and assessment of new and existing substances.* For existing substances there is a system for devising risk management strategies, based on an assessment of the risks posed by the substances (Regulation (EEC) No 793/93). For new substances there are requirements on reporting test results, effects, evaluation etc. of the substances before they may be placed on the market (sequel directive to 67/548/EEC, see below).
- *Rules governing classification and labelling*. The classification systems make a distinction between substances, which are regulated in the dangerous substances directive (67/548/EEC), and preparations, which are regulated in the dangerous preparations directive (directive 1999/45/EC, formerly 88/379/EEC). The rules are based on the inherent properties of the chemical. The classification rules are accompanied by special requirements on labelling, packaging etc. The directives are linked to each other and are continuously amended. The dangerous substances directive is updated regularly, usually via so-called technical progress adaptations. The dangerous preparations directive is updated by technical progress adaptations resulting from amendments to the dangerous substances directive.
- *Rules governing restriction of use and placing on the market of dangerous chemical substances and preparations*. The rules may include prohibition or restriction of the use or placing on the market of dangerous chemicals in accordance with the restrictions directive (76/769/EEC) or take the form of a system for common approval procedures for certain categories of chemicals, for example plant

protection products (directive 91/414/EEC) or biocidal products (directive 98/8/EC).

In addition, there are a large number of other legal acts pertaining to the chemicals field, e.g. a number of different emission regulations, rules on worker protection, rules on major chemical accidents (the ”Seveso” directive), rules on pharmaceuticals and rules on food additives.

In the following table is a list of what our Committee considers to be the most important legal acts in the chemicals field. The table shows the legal basis of the acts in the EC Treaty, and which directorate-general in the Commission is responsible for the directive. Each of the directives is described and dealt with later in section 6.3.

Table 6.1 The most important legal acts in the chemicals field

Legal act	Original basis in treaties[1]	Directorate Responsible directorate-general		
		Enterprise policy	Consumer protection	Environ-ment
Classification and labelling – dangerous substances directive (67/548/EEC)	94			●
Testing of new chemicals (79/831/EC, replaced by 92/32/EEC – amendments of directive 67/548/EEC)	94/95			●
Classification and labelling – dangerous prep. dir. (88/379/EEC, new 1999/45/EC)	95	●		
Restrictions directive (76/769/EEC)	94	●		
Plant protection products dir. (91/414/EEG)	37		●	
Directive prohibiting certain pesticide substances (79/117/EEC)	94		●	
Biocidal products directive (98/8/EC)	175			●
Council Regulation (EEC) No 2455/92 concerning the export and import of certain dangerous chemicals	95			●
Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances	95			●
Directive on pollution caused by dangerous substances in water (76/464/EEC)	94 and 308			●
Integrated pollution prevention and control – IPPC directive 96/61/EC	175			●

[1] The legal basis given depends e.g. on whether the legal act originated before 1987, when the Single European Act entered into force, or later. For example, Article 100a (present Article 95) was not in the EC Treaty until 1987. Legal acts that originated before 1987 therefore have Article 100 (present Article 94) as their original basis in the treaty. These acts have basically the same implications, i.e. they contain harmonized rules. The new article numbers are given in the table. Legal acts which are based on Article 130s (current Article 175) contain minimum rules.

6.3 Classification and labelling of chemical substances (67/548/ECC)

The Committee's appraisal and proposals

Sweden should advocate the following amendments to the dangerous substances directive (67/548/EEC):

- New classification criteria and labelling provisions shall be introduced for substances that fulfil the Committee's proposal for persistent and bioaccumulative substances (see Chapter 5). The risk phrases are proposed to have the following wording: "High risk for long-term adverse effects in the aquatic environment" and "High risk for long-term adverse effects in the environment". The substances shall be labelled with the symbol for dangerous for the environment.
- The new classification criteria and labelling provisions should be applied from 2005.
- The data requirements made in the dangerous substances directive (currently pertain to notification of new substances) must be extended with regard to the persistent and bioaccumulative properties of substances and, as soon as testing methods are available, with regard to endocrine-disruptive properties as well. The testing requirements should also be reviewed regularly for the purpose of reducing the number of animal tests (see Chapter 4).

Provisions on classification, labelling and packaging of chemical substances are provided in Council Directive 67/548/EEC, known as the dangerous substances directive, which was adopted in 1967. The purpose was to prevent trade barriers due to differences in national provisions.

The directive is updated continuously. Responsibility for the technical work, which also includes classification and labelling, rests with the European Chemicals Bureau, ECB, but the member states participate via e.g. Competent Authority Meetings. Annex I to the directive (67/548/EEC) contains a list of the classification and labelling of chemical substances. The annex is continuously updated by the experts jointly. Assessments are made in different expert groups and decisions are then taken in an executive committee. The formal decision to adopt a directive on the new substances to be included is made by the Commission.

Assessment of the possible dangers to health and the environment posed by a substance are made on the basis of existing data. In the case of substances for which data are lacking, it is at present not possible to make precise requirements on further testing.

More or less the same substances that were originally only classified as dangerous to health and/or dangerous due to physical-chemical properties have been examined for an assessment of whether they also have environmentally hazardous properties. Several of the substances have now also been classified as dangerous for the environment, but for a large portion of the examined substances, data from the manufacturers permitting an assessment of environmental hazard are lacking.

New substances not previously classified are assessed on the basis of both health hazard and environmental hazard for the purpose of classification.

The classification determines how a substance or preparation will be labelled. The labelling consists of one or more danger symbols, risk phrases and safety phrases. The danger symbol for dangerous for the environment shows a dead tree and a dead fish. There are several danger symbols for different health hazards. Carcinogenic, mutagenic and reproduction-toxic substances in categories 1 and 2 (see section 5.2) shall be labelled with a symbol showing a skull and crossbones. The safety phrases tell how to protect oneself and the environment, e.g. ”Keep out of reach of children” or ”Do not empty into drain”.

The dangerous substances directive contains a number of risk phrases for substances dangerous to health and the environment. The risk phrases clarify in what way the substance is dangerous. The risk phrase is thereby an important part of the information conveyed by the labelling.

Of particular importance for persistent and bioaccumulative substances is risk phrase R53: ”May cause long-term adverse effects in the aquatic environment.” If data on the ecotoxicity of the substances are lacking, or if the ecotoxicity is so low that labelling is not required, the risk phrase R53 shall be used if the substances have low water solubility and are not readily biodegradable, and also have some bioaccumulation potential. R53 can also be used in combination with other risk phrases. Substances that only have the risk phrase R53 do not need to be labelled with the symbol for dangerous for the environment.

For substances that can entail immediate, long-term or delayed dangers for the structure or function of other natural ecosystems than the aquatic environment, the risk phrase R58 is used: ”May cause long-term adverse effects in the environment.” The assessment shall be based on data on the substances’ properties, persistence and bioaccumulation potential, as well as their expected or observed behaviour and fate in the environment.

The dangerous substances directive also contains provisions on criteria and methods for testing of the dangerous properties of new chemical substances (see Chapter 4).

Classification used as a basis for certain restrictions

In a number of contexts, the opinion has been expressed that the approach used for risk assessment and risk management should be changed from treating each substance separately to a more general approach, where groups of substances are dealt with in a uniform manner. This approach is already applied today in risk management in the EU, in that many other provisions refer to the classification provisions in the dangerous substances and preparations directives.

The classification of a chemical substance usually entails not just a change in labelling, but also requirements on e.g. safety data sheets, prohibitions on certain uses, handling prohibitions for certain risk groups, a register of exposed persons, and strict storage rules. The majority of substances that are restricted today are so as a consequence of their classification (e.g. CMR-classified substances). Only for a few of the substances whose occurrence is restricted is the decision based on risk assessment and consequence analyses of individual substances.

Particularly for substances classified as carcinogenic, mutagenic or toxic for reproduction (categories 1 and 2), the consequences in other directives are great. However, under current provisions, the classification never entails a prohibition on all use of a substance. Such prohibitions currently require risk assessments and consequence analyses of the individual substance.

The influence of the classification on other directives is called ”downstream consequences” in the EU, and in a review from May 1999 the Commission singles out 30 directives which in different ways refer to the dangerous substances directive. Among these directives are both ones

that entail occurrence restrictions etc. and ones that lead to other types of exposure restrictions. Some examples are:

- Prohibitions on the occurrence of the majority of substances classified as carcinogenic, mutagenic and toxic for reproduction (categories 1 and 2) in substances and preparations intended for consumer use (Council Directive 76/769/EC). There is, however, an exemption for e.g. petrol.
- Strong restrictions (shall be replaced wherever possible as soon as possible) on organic solvents classified as carcinogenic, mutagenic or toxic for reproduction (categories 1 and 2) within a number of application areas (Council Directive 99/13/EC).
- Requirements on what information is to be furnished in material safety data sheets for substances and preparations classified as dangerous to health (Commission Directive 91/155/EC).
- Restrictions on how workers who are pregnant, have recently given birth or are breastfeeding are allowed to carry out work duties in which they may be exposed to substances classified as carcinogenic, mutagenic or toxic for reproduction (Council Directive 92/85/EC).
- Special rules on the protection of workers from the risks related to exposure to substances classified as carcinogenic or mutagenic (Council Directive 90/394/EC).

The Committee's appraisal and proposals

Our Committee believes that new classification criteria should be introduced for substances that meet the following criteria with respect to persistence and bioaccumulation:

- Half-life in water or sediment > 8 weeks (in simulation test at 20ºC) and
- a bioconcentration factor higher than 2000.

The classification criteria should also be applied to substances which are judged to meet these criteria on the basis of other reliable scientific studies or internationally accepted calculation methods (see section 5.1). The environmentally hazardous substances covered by the new classification criteria are proposed to be labelled with the danger symbol for dangerous for the environment plus one of the risk phrases:

- "Great risk for long-term adverse effects in the aquatic environment."

- ”Great risk for long-term adverse effects in the environment.”

The dangerous substances directive also contains rules regarding prior notification of new substances. The rules specify which data must be gathered on a substance, starting with volume. The Committee is of the opinion that the same requirements that are made on new substances today should also apply to existing substances (see Chapter 4).

The data requirements stipulated in the dangerous substances directive will then apply to all substances. However, these data requirements need to be augmented in some respects to make it possible to identify substances covered by the guidelines. For example, extended requirements are needed regarding the persistent and bioaccumulative properties of substances, as well as their endocrine-disruptive properties. The testing requirements should also be reviewed regularly for the purpose of reducing the number of animal tests (see Chapter 4).

6.4 Classification and labelling of chemical preparations (Directive 1999/45/EC)

The Committee’s appraisal and proposals

Sweden should advocate the following amendments to the dangerous preparations directive (directive 1999/45/EC):

- Amendments are needed to determine the concentration at which a preparation containing persistent and bioaccumulative substances should be classified in the same way as the substance and labelled with the symbol for danger for the environment and the new risk phrases. The concentration limit is proposed to be 0.25 percent.
- A rule should be adopted that manufactures shall date their material safety data sheets and review them at least every third year, or as soon as new knowledge becomes available.

Council Directive 88/379/EEC, the dangerous preparations directive, contains provisions on classification, labelling and packaging of chemical preparations, i.e. mixtures of two or more substances. This directive is linked to the dangerous substances directive (67/548/EEC). The provisions are updated regularly as a result of amendments to the dangerous substances directive.

A new dangerous preparations directive (1999/45/EC) was adopted in 1999, entailing several large and important changes. Previously, environmental hazard criteria have only existed for pure substances, but with the new directive they are also adopted for chemical preparations.

The Committee's appraisal and proposals

The dangerous preparations directive stipulates what concentrations of constituent dangerous substances must be found in the composite chemical preparation for it to be classified as dangerous and be subject to the requirement on labelling with danger symbols and risk phrases. Since we propose that two new risk phrases be incorporated in the dangerous substances directive for the substances that meet our proposed criteria for persistence and bioaccumulation, amendments are also needed in the dangerous preparations directive to regulate how chemical products containing such substances are to be classified and labelled.

The Committee proposes that chemical preparations containing more than 0.25 percent of a substance that meets the criteria shall be classified in the same way as the substance and labelled with the danger symbol for dangerous for the environment (dead tree and dead fish) and with the new risk phrases. (See Annex 2 with legislation proposals.)

More detailed provisions on material safety data sheets are found in Commission Directive 91/155/EEC. The directive shall be amended to adapt it to the new dangerous preparations directive (cf. Article 14 (2.3) in directive 1999/45/EC). Article 1 (2) in directive 91/155/EEC states that the companies shall revise their material safety data sheets when significant new information regarding safety or protection of health and the environment becomes available. We consider that there is reason to require companies to update and review their material safety data sheets after a given period of time, even if new information has not become available. An appropriate such period would be three years.

6.5 Restrictions of dangerous substances and preparations (Directive 76/769/EEC)

The Committee's appraisal and proposals
Sweden should advocate the following amendments to the restrictions directive (76/769/EEC):

- The precautionary principle shall be incorporated in the restrictions directive.
- New substances that have been notified in accordance with the dangerous substances directive after 2004 and that fulfil the new classification criteria with respect to persistence and bio-accumulation shall not be allowed to be used in chemical products (substances and preparations) placed on the market from 2005.
- Chemical products as per above shall not be allowed to be placed on the market either. The prohibition should also extend to finished products containing such substances or preparations.
- Existing substances and new substances notified before 2005 shall from 2010 be subject to the above new restrictions if they:
  – are labelled with the new risk phrases and
  – have a half-life > 6 months and a bioconcentration factor > 5,000, and
  – are included in a special list.
- From 2015, the restrictions shall also apply to all substances labelled with the new risk phrases.
- Today's restrictions for carcinogenic, mutagenic and reproduction-toxic substances and preparations should be extended by not later than 2007 to include other consumer-available products as well. Professional use of chemical products and other products should also be included in a later stage.
- Certain general exemptions are needed from the prohibitions, e.g. for use in industrial plants provided that the enterprises adopt measures to prevent release to the environment, research purposes, etc.
- It should also be possible to grant time-limited exemptions for a given use or type of product. An exemption should apply generally within the entire Community.
- Sweden should advocate the declaration of a total ban on the use of cadmium in the EU.

Council Directive 76/769/EC contains provisions regarding the use and placing on the market of certain dangerous substances and preparations. The marketing and use of certain consumer-available products containing such substances or proparations are also regulated in the directive. The thrust of the directive is to establish harmonized provisions in order to eliminate barriers to the free movement of goods that can arise as a consequence of restrictions in the member states regarding chemical products and finished products containing dangerous substances. Through the directive, harmonized provisions are introduced in those areas where it is agreed they are needed to protect health and the environment.

The directive also identifies which substances or preparations are to be restricted.

The Committee's appraisal and proposals

Below we submit proposals for augmentations of existing rules. Existing, stricter rules should, in the opinion of the Committee, not be changed due to our proposals.

The precautionary principle should be introduced into the restrictions directive

According to Article 174.2 of the EC Treaty, Community policy on the environment shall be based on the precautionary principle. According to Article 6, environmental protection requirements must be integrated into the definition and implementation of Community policies. We believe it is important that such an integration be effected by introduction of the precautionary principle into the EC legal acts in the chemicals field. There is a particularly great need that the principle find expression in the restrictions directive.

It should be stated in the restrictions directive that the rules are intended to protect human health and the environment from harm caused by use of dangerous substances and preparations and finished products containing dangerous substances or preparations. Measures in accordance with the restrictions directive should be able to be adopted as soon as there is reason to assume that this use could lead to harm, even if the risk of harm is not fully scientifically substantiated.

Restrictions for persistent and bioaccumulative substances

Our Committee proposes that a generally acting rule that refers to the substances classified in accordance with the new criteria we propose be incorporated in the restrictions directive. We recommend that the new rule should entail that the substances that fulfil the criteria and are to be labelled with the new risk phrases may not be used in chemical products if they are present in such concentration that the product also fulfils the criteria (see 6.4).

Since the new guidelines on chemicals policy entail that bioaccumulative and persistent organic substances should not occur in finished products, we believe that the proposed amendment to the directive should also extend to such products.

The restrictions should be introduced in stages. In an initial stage, in 2005, they should apply to new substances that have not yet been placed on the market when the prohibition enters into force. In a second state, in 2010, the prohibition should apply to certain additional substances that are particularly persistent and bioaccumulative. From 2015, the prohibition should apply to all substances that fulfil the new criteria. The proposal is summarized in Figure 6.1 below.

Figure 6.1 The Committee's proposed phase-out criteria with respect to persistent and bioaccumulative substances.

The Committee's proposed phase-out criteria with respect to persistent (P, given as half-life, t½) and bioaccumulative (B, given as bioconcentration factor, BCF) substances. The field marked with light grey corresponds to the values of these properties that are to serve as a basis for phase-out of new substances which have been notified after 2005 from 2005 and existing substances from 2015, while the field marked with dark grey corresponds to existing substances and new substances which have been notified before 2005 from 2010. The area framed with a bold, solid line corresponds to the criteria with respect to these properties that exist today in the EU's provisions on classification and labelling of chemical products, while the area framed with a dashed line corresponds to the criteria in the National Chemicals Inspectorate's Observation List.

	P1 $t_{½} < 2v$	P2 $2v \leq t_{½} < 8v$	P3 $8v \leq t_{½} < 26v$	P4 $t_{½} \geq 26v$
B0 BCF < 1				
B1 1≤ BCF < 100				
B2 100 ≤ BCF < 500				
B3 500 ≤ BCF < 1 000				
B4 1 000 ≤ BCF < 2 000				
B5 2 000 ≤ BCF < 5 000				
B6 BCF ≥ 5 000				

Restrictions for carcinogenic, mutagenic and reprotoxic substances

The directive today contains rules stating that carcinogenic, mutagenic and reproduction-toxic substances (categories 1 and 2) may not occur in consumer-available chemical products (substances and preparations). The directive should, when it comes to these substances, be extended to include other products than chemical products as well, in accordance with the Government's guidelines.

Accordingly, the restrictions should, in an initial stage, be extended to include consumer-available products. In the next stage, professional use of both chemical products and other products containing these substances should also be restricted. The primary purpose of restricting professional use as well is to protect e.g. residents from substances used by professionals in residences. The reason for this is that substances that are used e.g. in materials in a building can leak out over a long period,

and give rise to exposure of the residents. Restrictions on professional use should therefore mainly apply to chemical products and finished products that are used on temporary worksites, i.e. for work that is temporarily carried out on a given site, e.g. a building site, or in repairs in existing buildings.

Restrictions on the professional use of carcinogenic, mutagenic and reproduction-toxic substances can be achieved in several ways. One is to make use of the restrictions directive. Carcinogenic and mutagenic substances are regulated in Council Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work. According to the directive, substances which are mutagenic or can cause cancer (categories 1 and 2) should be replaced if possible, or if this is not possible used in a closed system, or if this is not possible handled so that exposure is as low as possible. The directive contains EU-wide limit values.

Another directive in the area is Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work. This directive contains provisions prohibiting the production, manufacture and use at work of four carcinogenic substances. This directive in particular could be used to ban the professional use of carcinogenic, mutagenic and reproduction-toxic substances.

The proposals submitted by the Committee regarding carcinogenic, mutagenic and reproduction-toxic substances will be of importance for complying with the guideline on lead, since lead compounds are classified as toxic for reproduction. The same applies to cadmium, since certain cadmium compounds are classified as carcinogenic and sometimes also as toxic for reproduction. If the prohibition on carcinogenic and reproduction-toxic substances is extended to embrace all products, not just chemical products as today, this will mean that lead compounds and more cadmium compounds will not be allowed in new products after 2007.

Concentration limits in products

The concentration limits that are set for classification in accordance with the new criteria for persistent and bioaccumulative substances and preparations should, as mentioned above, apply as limits for prohibitions with regard to chemical products. However, when it comes to both

persistent and bioaccumulative substances, and carcinogenic, mutagenic and reproduction-toxic substances, the Committee considers that it would be too complicated to set concentration limits for products. While we believe that it would be reasonable to use the same concentration limits for finished products as for chemical products, we also see the practical difficulties involved in ensuring compliance with these limits.

A concentration limit would be difficult to apply for the manufacturers and importers as well. In the case of finished products, the restrictions should therefore entail that no deliberate addition of the substance may take place. By ”deliberate addition” we mean that the substance has been used to be a constituent in the final product. This means that, for example, a substance included in the manufacture of a plastic for the purpose of being polymerized and thereby losing its chemical identity is not to be regarded as a deliberately added substance.

Exemption for motor fuels

The restrictions directive’s existing rules for carcinogenic, mutagenic and reproduction-toxic substances in consumer-available chemical products make an exemption for motor fuels. In terms of quantity, motor fuels comprise a dominant portion of cancer-classified substances (see Annex 4a).

The issue of carcinogenic substances in motor fuels is of great importance, but we judge this question to be far too complex to be solved by changing existing exemptions in the restrictions directive. The way to address this problem is to alter the composition of these fuels or switch to other fuels. The issue is of great concern to the energy and transport field, and we therefore propose that it be investigated separately (see further Chapter 7).

Other exemptions

In the same way as is already done today in existing rules for carcinogenic, mutagenic and reproduction-toxic substances, exemptions should be made until further notice for pharmaceuticals, cosmetics and artists’ paints, in addition to motor fuels. With the exception of artists’ paints, these areas of use are regulated in other directives. However, we believe that several of these exemptions, e.g. cosmetics and artists’ paints, should be reconsidered. A general exemption is made in Article 2

of the directive for marketing and use for research and development or analysis purposes. This exemption should also be made with regard to our proposed restrictions.

If persistent and bioaccumulative substances are only used in industrial plants, and the user ensures that the substances do not risk getting out into the environment via releases or products, exemptions may also be made from the prohibition. For us in industrial plants, a general exemption should therefore be made from the prohibition providing the packaging is provided with a label clearly stating that it is only intended for industrial use. Similar exemptions are made today for several other substances already regulated via the directive.

Time-limited exemptions should be able to be granted for persistent and bioaccumulative substances after consideration for a specific use or placing on the market of a specific type of chemical product or manufactured product. The same applies for carcinogenic, mutagenic and reproduction-toxic substances with regard to finished products, but not chemical products. An application for exemption should be able to be made to the competent authority in one of the member states where the chemical product or manufactured product is intended to be used or placed on the market. Other member states and the Commission should be given an opportunity to proffer objections, which should lead to a decision being taken at the Community level. A granted exemption should apply generally within the Community and thus be able to be utilized by others besides the applicant.

Special considerations regarding cadmium

The restrictions directive contains special rules on cadmium. Here, however, Sweden has more far-reaching rules, and Sweden has an exemption that expires at the end of 2002. The Commission will review present-day provisions on cadmium in the restrictions directive before the Swedish exemption expires. An important point of departure in the review will be the risk assessment on cadmium that is currently under way within the existing substances programme (see section 6.6). Before the risk assessment is finished, it is difficult to judge how great changes in existing rules Sweden will be able to gain a hearing for. Sweden should, of course, continue to advocate retention of the current Swedish level of protection.

We also recommend that Sweden work within the EU to bring about the adoption of a total ban on products containing cadmium. Certain exemptions may have to be made from such a ban, however. In the opinion of the Committee, the cadmium content may also continue to be regulated separately in the battery directive and the fertilizer directive (see section 6.9). Similarly, the occurrence of cadmium in sludge and fossil fuels should be regulated separately.

6.6 Risk assessment of existing substances – existing substances regulation (793/93/EEC)

The Committee's appraisal and proposals

- For substances that do not fulfil the general phase-out criteria proposed by the Committee, risk assessments will be the basis of restrictions in the future as well. Simplifications in the requirements and in the risk assessment work are needed, however. Work in this direction is being pursued both in Sweden and in the EU.
- In the work of achieving compliance with the Government's guidelines, risk assessments are of special importance for metals.

Sweden should advocate the following amendments to the Regulation (EEC) No 793/93 on existing substances:

- The precautionary principle should be incorporated in the regulation.
- Methods for risk assessment (called risk evaluation in the regulation) should be changed in order to speed up the assessments and better take account of important factors such as:
  – contribution of products to emissions of a substance
  – persistent and bioaccumulative properties of substances
  – interaction between different substances.
- Sweden should contribute to the risk assessments and the development of strategies for risk management for metals in the EU. It is particularly important that the data on emissions from different product groups obtained in current research be utilized in the EU work.

Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 contain provisions on the assessment (evaluation) and control of the risks of existing substances.

The main principle of the regulation is that control of dangerous chemicals should be based on an assessment of the real risk to man and the environment instead of solely on the inherent dangerous properties of the substance.

Manufacturers and importers shall compile existing information on production, use, toxicity, ecotoxicity, etc. for substances produced or imported in quantities exceeding 1,000 tonnes per year on the EU market during certain specified years (1991–1994). The information is collected in the EU database IUCLID.

Which substances are to be prioritized for evaluation within the existing substances programme is determined by the Commission in consultation with the member states. The substances are placed on priority lists. There is a detailed Technical Guidance Document (TGD, 1999) describing how the risk assessments should be done. In the risk assessment, exposure of man and the environment is weighed together with data on the inherent properties of the substances. Various factors can be used in the assessment to handle uncertainties. For example, in the assessment of risks to the environment, larger factors (i.e. larger safety margins) are used if data on the toxicity of the substance is only available for a single species than for several species at different trophic levels in the food chain. If the assessment shows that risks exist, a strategy shall be developed for how to manage the risks. There are instructions for this as well.

In October 1999, preliminary risk assessments existed from the rapporteur country for 77 of the 110 substances that had then been prioritized in the programme. Final publication of the assessments had taken place for 4 of these 32 substances in the Official Journal of the European Communities. Proposals for risk management existed for a few additional substances.

Criticism has been levelled from various sources in recent years at the EU's programme for existing substances. Many feel that the work is proceeding far too slowly. The complete risk assessments that are supposed to be done are very resource- and time-consuming. The Commission has undertaken to review the programme for existing substances, and according to what the Committee has learned, the

Commission will submit a document on this in the summer of 2000. The work of streamlining the risk assessment work within the framework of the programme has also been commenced.

The Committee shares the opinion that the programme is too time-consuming and should be revised for the purpose of speeding up the process, and that there are several ways to accomplish this. We believe that the companies should be given greater responsibility for making preliminary risk assessments (see proposal in Chapter 4). It should be possible to save time if the authorities can base their risk assessment work on preliminary assessments from industry. We also believe that it should be possible to focus the risk assessments on certain effect areas which, based on preliminary assessments or other knowledge, can be assumed to be particularly relevant for a certain substance.

It would appear important that risk assessments, where appropriate, also take advantage of the opportunities for other simplifications and general assessments. For example, assessments based on chemical structure (QSAR; see Annex 3) may be sufficient for strict measures in a shorter time perspective. If a more complete risk assessment subsequently reveals that a relaxation of the restrictions is warranted, this should be possible.

We are also of the opinion that the precautionary principle should be introduced into the existing substances regulation. As mentioned previously, Community policy on the environment is supposed to be based on the precautionary principle, according to Article 174.2 of the EC Treaty. According to Article 6, environmental protection requirements must be integrated into the definition and implementation of Community policies. We believe it is important that such an integration take place by the introduction of the precautionary principle into the EC legal acts in the chemicals field. In the existing substances regulation, measures should be proposed as soon as there is reason to assume that the use can entail harm, even if the risk of harm is not completely scientifically established.

Need for method development

Certain weak points exist today in the methods for risk assessment. The methods therefore need to be developed in certain areas so that more factors can be taken into account, when relevant. For example, the methods need to be developed when it comes to estimating and weighing

in emissions of substances from products. In this context the chemicals suppliers should bear principal responsibility, as they do today; but the manufacturers of products also need to be given a clearer responsibility for procuring data. Another area is synergistic effects between substances. In those cases where substances are very closely related, or the mechanisms behind an effect are known and are the same for several substances, it should be possible to assess the risks stemming from the combined exposure. This may, for instance, be relevant for endocrine-disruptive substances (see section 5.2.2). Furthermore, it should be possible to attach greater weight to long-term effects, whereby persistence is of great importance.

We do not believe that a refinement of the methods for risk assessment need conflict with the overall objective of speeding up the assessments. The assessments should be more focused, and refinement of methods does not mean that additional parameters have to be weighed into the assessments of all substances, but rather that it is possible to take these factors into consideration in cases where they are of great importance.

Risk assessment of metals

The Committee is of the opinion that substances that fulfil the general criteria which we presented in Chapter 5 as well as the metals lead, cadmium and mercury should be able to be phased out without prior risk assessment. However, some of these substances (cadmium, for instance) are already subject to ongoing assessment. It is important that Sweden actively follow and contribute to this risk assessment, since it will comprise an important basis for the review of the rules concerning cadmium in the restrictions directive planned by the Commission. The work is of great importance if Sweden is to be able to preserve the current protection level and take action against the remaining use of cadmium.

According to the Government's guidelines on other metals, they shall be used in such a way that they do not leak out into the environment to a degree that causes harm to the environment or human health. This means that the determination of what is to be regarded as acceptable use and acceptable leakage shall rest on a risk assessment. The risk assessments of metals that are under way in the EU will therefore be of particular importance for the application of this guideline.

Within the EU's programme for existing substances, risk assessments are under way of zinc and certain zinc compounds, certain chromates, and nickel and nickel sulphate. Moreover, risk assessment is planned of additional nickel compounds as well as copper and copper compounds. The results provided by the risk assessments will serve as a basis for the necessary risk reduction measures. The EU's guidance document on risk assessment contains several methodological weaknesses, however, not least when it comes to the contribution made by emissions from products to the total exposure.

The sources of emissions of copper, zinc, chromium and nickel have been traced in the Swedish EPA's research programme *Metaller i stad och land* ("Metals in town and country"). The study contains a large database regarding emissions from products (Bergbäck et al., 2000). It is very important that Sweden contribute this knowledge to the risk assessments of the metals. If emissions from products are not taken into account, the calculated exposure of man and the environment that is obtained as a step in the risk assessment may be underestimated. This in turn may lead to an underestimate of the risks.

When the risk assessments are finished, the next stage in the existing substances programme begins, involving development of strategies for risk management. Here as well it is important that Sweden act to find an effective solution to the risks found in the risk assessments, e.g. by amendments to the restrictions directive. In this phase as well, it is important that diffuse emissions from products be taken into account.

The Committee thus concludes that one way to get a good assessment of the risks associated with the four metals zinc, chromium, nickel and copper, and to bring about action against any risks at the EU level, is for Sweden to contribute actively to ongoing and planned efforts within the existing substances programme.

6.7 The pesticide directives (plant protection products and biocidal products)

The Committee's appraisal and proposals

Sweden should advocate the following amendments to the pesticides directives:

- The substitution principle and the precautionary principle should be introduced into directive 91/414/EEC on plant protection products.
- According to directive 98/8/EC on biocidal products, the substitution principle shall be applied in decisions on active substances in biocidal products. The directive should be amended so that the principle is applied in authorization of the products as well.

In the EU, pesticides are subdivided into plant protection products and biocidal products. Plant protection products are dealt with in directive 91/414/EEC concerning the placing of plant protection products on the market, and biocidal products are dealt with in directive 98/8/EC concerning the placing of biocidal products on the market. Directive 98/8/EC regulates other pesticides than plant protection products – for instance, slimicides, rodenticides, disinfectants, wood preservatives and anti-fouling products.

The plant protection products directive is designed so that the member states shall approve products complying with the directive's requirement rules, provided that the product's active substance is included in Annex I, the so-called positive list. This determination is made in accordance with the rules in Article 5 of the directive. The regulation regarding approval of the actual product/pesticide is in Article 4 and is further defined in Annex VI to the directive on uniform principles for authorization. The biocidal products directive is similarly constructed.

The Committee's appraisal and proposals regarding the substitution principle

According to the Environmental Code, anyone conducting an operation or taking measures must avoid using or selling chemical products that

might entail risks to human health or the environment if they can be replaced with such chemical products as may be assumed to be less hazardous. This is what we usually call the substitution principle, or the product choice principle. The biocidal products directive (98/8/EC) contains such a substitution principle (Article 10 (5)), but the principle is lacking in the plant protection products directive (91/414/EEC).

In order to obtain a better tool for eliminating the most harmful plant protection products, the substitution principle should also be incorporated in the plant protection products directive.
In the biocidal products directive, the substitution principle finds expression in the rules regarding which substances are to be included on the positive list (Article 10 (5)). Beyond this, the substitution principle also needs to find expression in Article 5 on conditions for authorization of the biocide.

Such an amendment would entail that not only the Standing Committee on Plant Health would apply the principle, but also that the member states would apply the principle in connection with authorization of the plant protection product.

In order for the principle to influence the authorization of the plant protection product, it must find expression in Article 4 of the plant protection products directive. Furthermore, it should be included – in line with the biocidal products directive – in the regulation in Article 5 concerning which active substances are to be included in the directive's positive list, i.e. Annex I to the directive. The National Chemicals Inspectorate has had a consultant prepare a proposal (Ardesjö, 1997) on how the substitution principle could be incorporated in directive 91/414/EEC.

The Committee's appraisal and proposals regarding substances subject to the Government's new guidelines

The Committee's overall appraisal when it comes to pesticides is that the same principles proposed by the Committee for general chemicals must also apply to pesticides.

The work in the EU on examining active substances in plant protection products is in an important buildup phase where important policy decisions are being made, for example regarding Annex I (the positive

list), which is creating the consensus needed for the future examination work.
There are no specific criteria today for listing of active substances in the annexes. Instead, reference is made to general criteria (Article 5 in 91/414/EEC).

The EU work on the further design and application of the biocidal products directive is also in an intensive phase. According to the proposed timetable for the review programme, the first phase (data collection) is now in progress, January 2000 – June 2001.

Sweden has wide experience when it comes to mitigating the risks of pesticides. In Sweden, for example, the volumes of pesticides have decreased sharply over the past ten years, and many of the most harmful pesticides have been prohibited. It is urgent that the Swedish experience be brought to bear within the EU. Sweden has a unique head start in the work of risk mitigation and examination of pesticides.

In order to achieve compliance with the guideline on metals, it is important that Sweden contribute to the assessment of biocidal products and plant protection products within the EU.

Wood preservatives and anti-fouling compounds are biocidal products and will be included in the examination that will take place of such substances within the framework of the EC's biocidal products directive (98/8/EC). All biocides will be assessed during a ten-year period, and the substances that are authorized for use in the EU will be entered on a list annexed to the directive (Annex I). It is probable that wood preservatives will be among the first substances to be assessed, which means that EU-wide assessments of them should be available in around 2003.

It is possible to deny authorization to preparations that contain substances on the list in Annex I in conjunction with the national examination of biocidal products, for example with reference to climate factors, but this possibility is relatively limited. In view of the fact that the possibility is so limited, it is important that Sweden take an active role in the assessment of substances when they are examined in the EU.

6.8 Product directives and harmonized product standards

The Committee's appraisal and proposals

- The relationship between rules concerning restrictions of products containing dangerous chemicals and EC directives that regulate products should be investigated to ascertain any rule conflicts and the need for any amendments to EC legislation to facilitate the enforcement and implementation of provisions on restrictions.
- The consequences of Mutual Recognition Agreements (MRAs) for the enforcement and implementation of restrictions should also be investigated.
- Environmental and health aspects must be taken into account in designing new harmonized product standards and integrated into existing standards. Each new product standard should undergo an environmental assessment.
- The sectoral authorities that participate in the standardization work should take greater responsibility for environmental and health aspects in designing new harmonized product standards.

The traditional approach for restricting dangerous chemicals has been to regulate their use in processes and to stipulate requirements on releases. To the extent the restrictions have concerned trade in products it has primarily involved restrictions on substances and preparations (chemical products), such as requirements on classification and labelling or restrictions regarding the use and placing on the market of the chemical products by themselves or in certain finished products.

There are some examples in the EU of restrictions applying to the use and placing on the market of finished products containing certain chemical products, e.g. finished products containing asbestos or cadmium (points 6 and 24 in Annex I to the restrictions directive). There are also cases where such restrictions have been adopted nationally, e.g. the Swedish regulations of certain products containing mercury.

Adopting restrictions – at the national and Community level – on products containing dangerous substances brings up a number of legal questions. In particular, questions arise regarding the scope of a number of EC directives whose purpose is to eliminate barriers to the free movement of goods. This group includes the new approach directives and other directives that lay down requirements on CE marking or type-

approval of products. There are also points of overlap with directives that stipulate quality requirements for a given type of product. In some contexts, the term ”product directives” is used as a collective term for these groups of directives.

If rules concerning restrictions on products are adopted at the Community level, for example in the restrictions directive, and this has the result that a product will be covered both by the restriction rules and the provisions of one or more product directives, questions arise regarding the interrelationships of the legal acts and which provisions should take precedence.

Regulations in the new approach directives

The Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards has led to a great change in the work of removing technical trade barriers and ensuring the free movement of goods within the Community. The directives that apply the new approach only define the general essential requirements with which products must comply, instead of prescribing detailed rules on design, packaging and testing methods, etc. The requirements concern safety and health, and in some cases also certain environmental aspects, e.g. noise from machines. There are more than twenty new approach directives regulating e.g. machines, building products, medical devices and toys.

Technical specifications for products that conform to the essential requirements are found in harmonized standards. Standards are developed by the European standardization bodies (CEN, CENELEC and ETSI) in response to a mandate from the Commission according to the procedure laid down in directive 98/34/EC. Applying a harmonized standard is voluntary. Manufacturers can choose to comply with the essential requirements in the directives in another manner. A product that conforms to a harmonized standard is presumed to fulfil the essential requirements. This presumption enters into force when the Commission has published a reference to the standard in the Official Journal (OJ) of the European Communities and when the standard has been adopted at the national level.

To certify that a product meets the requirements, an EC declaration of conformity is issued. Further, the products must in most cases be marked with the CE mark. The directives also contain different procedures for certification of conformity. In many cases an assessment by an approved certification body is required.

The member states must presume that products bearing the CE marking comply with the provisions of the directives. They may not prohibit, restrict or impede CE-marked products from being placed on the market, unless the provisions have been incorrectly applied. The directives also contain an obligation for the member states to take action against CE-marked products which, when used in the intended fashion, might compromise human health or other public interests covered by the directive.

A product can be subject to several new approach directives and must then comply with all requirements for CE marking according to the directives. The legal foundation for the new approach directives is current Article 95 of the EC Treaty.

The question of the scope of the new approach directives is of great interest in an assessment of the impact of future restrictions of products containing dangerous substances. The Commission has issued a ”Guide to the implementation of Directives Based on the New Approach and Global Approach” in which the question is touched upon. According to the Commission, such directives are generally designed to cover all hazards related to the general interest that the directive intends to protect. It is often necessary to apply several new approach directives and other Community legislation simultaneously.

Some elements have been left outside of the scope of applicable EC legislation. In the view of the Commission, the member states may then enact national legislation in accordance with Articles 28 and 30 of the EC Treaty. Further, the Commission considers that member states may prohibit, restrict or impede the free movement of products bearing CE marking if this is warranted by a hazard that is not covered by the applicable directives, also taking into account Articles 28 and 30 of the EC Treaty. However, the Commission provides no further guidance on how to judge what is meant by ”a hazard”. A question that can be asked is whether the hazards that are intended to be counteracted by the Committee’s proposals concerning persistent and bioaccumulative substances (danger for the environment) and carcinogenic, mutagenic or reproduction-toxic substances (long-term harmful health effects) would

be considered to be covered by the new approach directives, which stipulate essential requirements with regard to safety and health, but not to the environment. There is reason to assert that the provisions concerning persistant and bioaccumulative substances do not pertain to hazards covered by the directives, since the latter do not include environmental requirements. It can further be discussed whether the health requirements in the new approach directives do not pertain solely to acute health hazards and thus do not cover the danger for long-term harmful health effects caused by carcinogenic, mutagenic or reproduction-toxic substances.

In the new approach directives, the general provisions on essential requirements according to the directive do usually not contain provisions on chemicals. An exemption is directive 88/378/EEC concerning the safety of toys (the toy directive), whose Annex II, which lays down essential safety requirements for toys, contains a section on chemical properties (part 2, section 3). Point 3.1 states that toys must in all cases comply with the relevant Community legislation relating to certain categories of products or to the prohibition, restriction of use or labelling of certain dangerous substances and preparations. Thus, in contrast to other new approach directives, the CE marking of toys would thus seem to cover safety and health risks relating to chemical products. Despite the fact that environmental safety is not included in the purposes of the toy directive, such aspects will be considered indirectly in that other Community provisions on e.g. restrictions of dangerous substances and preparations must be observed.

Harmonized standards usually lay down functional requirements without prescribing which material or substance is to be used. There are, however, standards which stipulate requirements on a certain substance, an example being harmonized standards that prescribe mercury in thermometers according to Council Directive 93/42/EEC concerning medical devices. Sweden has rules today prohibiting mercury thermometers. There are several exemptions from the prohibition, though not for thermometers according to directive 93/42/EEC. If Sweden intends to extend its mercury ban, the question of the relationship between the national rules and the new approach directives will probably come up.

There are also examples of standards which do not in themselves entail requirements on the use of substances, but whose functional requirements entail that a given substance must be used. The Committee finds

some lack of clarity regarding the significance of different types of standards for the scope of a new approach directive.

Other product directives

The new approach has not been applied in sectors that were regulated prior to 1985, or where provisions for finished products and hazards related to such products cannot be laid down. Examples of EC legislation that does not apply the new approach are the directives on foodstuffs, chemical products, pharmaceutical products, cosmetic products, motor vehicles and tractors.

These directives regulate in greater detail the requirements that are to be made on a product and often contain an examination procedure. The legal foundation for the directives is usually current Article 94 or 95 of the EC Treaty.

In a preliminary ruling (case C-329/95)[1], the European Court of Justice has ruled on national legislation requiring a national certificate showing that the vehicle complied with national requirements on exhaust emissions. Such a certificate was even required for vehicles which have a valid Community certificate of compliance with directive 70/156/EEC relating to the type-approval of motor vehicles (the motor vehicles directive). The European Court of Justice found that the motor vehicles directive precludes such national legislation with reference to Articles 7 (1) and 7 (3) of the directive. These provisions state that a member state may not refuse to register a vehicle with a valid Community type-approval certificate unless it finds that the vehicle is a serious risk to road safety. The European Court of Justice found that legislation under which registration can be refused for environmental protection considerations does not satisfy the prescribed conditions governing derogation.

Conflicts between the motor vehicles directive and national rules could, for example, arise in the event of an extension of the Swedish mercury ban to include light sources when these rules are to be applied to type-approved cars with the new type of headlight containing mercury. The aforementioned ruling could be interpreted as implying that there is not allowance whatsoever for applying environmental rules to a type-

[1] VAG Sverige AB [1997] ECR I-2675.

approved vehicle, which would mean that the Swedish rules could not be applied.

There are also directives whose principal purpose is to lay down quality requirements instead of safety requirements. An example of such a directive is directive 69/493/EEC on crystal glass, which prescribes minimum limits for lead for different descriptions of categories of crystal glass. The question of the scope of the directive could thus be of interest if restrictions are introduced for lead that encompass crystal glass.

Another example is the Swedish rules setting a limit value for cadmium in commercial fertilizer in relation to directive 76/116/EEC on fertilizers. Sweden, Finland and Austria were granted a time-limited derogation from the directive in the treaty of accession. The derogation has since been extended to apply until 31 December 2001 (directive 98/97/EC). Since a derogation was considered necessary, this should mean that in the judgement then made by the Commission and the member states, directive 76/116/EEC covers the area for the national restrictions.

Restrictions of dangerous substances in products in the restrictions directive

The restrictions directive (76/769/EEC) identifies the substances and preparations that are restricted and stipulates in what respects the restrictions apply. For the most part, the use and placing on the market of substances and preparations, by themselves or in stipulated products, is regulated. In some cases, as mentioned above, products containing the substances in question are also regulated.

The restrictions directive differs from other directives whose purpose is to remove barriers to the internal market in that it contains neither a safety clause nor any clause on free movement of goods that meet the requirements of the directive. According to Article 1, the provisions of the directive shall apply without prejudice to the application of other relevant Community provisions. European Court of Justice case C-232/97 dealt with the possibility for a member state to adopt more stringent measures than those provided for in the restrictions directive. The Court found that this was permitted, with reference to Article 1 of the directive.

Mutual Recognition Agreements (MRAs)

Mutual Recognition Agreements (MRAs) between the EC and non-EU countries are one of several methods for removing barriers to trade and facilitating access to the market. It may, for example, be a question of agreements on procedures for assessing conformity (testing and certification etc.) or of equivalent technical regulations and standards. The goal of MRAs is that a product should be able to be accepted globally if it is based on a product specification and a procedure that judges whether the product conforms to the product specification.

Need for investigation

The questions dealt with above will have great importance in connection with an assessment of the scope and consequences of the Committee's proposal for a prohibition in the restrictions directive against products containing persistent and bioaccumulative substances or carcinogenic, mutagenic or reproduction-toxic substances, particularly in view of the fact that the number of products covered by the product directives is constantly growing.

These questions will also arise if Sweden enacts new national restrictions on mercury, cadmium and lead. A final answer to the questions can, of course, only be provided if they are ruled on by the European Court of Justice. However, the Committee believes that it would be valuable if the rule conflicts could be further clarified and any need for amendments to the product directives and other EC legislation be identified. The consequences of the Mutual Recognition Agreements (MRAs) for the possibility of enforcing and implementing restrictions also need to be investigated.

The results of such an investigation would be of use as a basis for determining if and how Sweden should act to bring about changes in the EC legislation and in the MRAs for the purpose of improving the efficacy of restrictions of products containing dangerous chemicals. We therefore believe that the Government should have these matters investigated.

6.9 Proposed amendments to certain individual product directives

6.9.1 The crystal glass directive

The Committee's appraisal and proposals

- Sweden should advocate amendment of the EC's crystal glass directive (69/493/EEC) so that use of lead is not required.

As has been mentioned in section 6.8, the primary purpose of the crystal glass directive is to lay down quality requirements, not safety requirements. The directive prescribes how much lead the glass has to contain to be marketed under certain category descriptions. The directive is outdated insofar as the quality requirements focus on the content of a given substance instead of on the physical properties of the glass, e.g. its refractive index. In this way the directive preserves the status quo, since anyone who wants to use the directive's category descriptions in their marketing must use lead, even if they could manufacture glass of the same quality without lead.

Sweden should therefore continue to press its demands for amendment of the directive. Crystal glass should be defined on the basis of functional requirements, such as refractive index, and not its content of specific substances. The Swedish glass industry has been working for several years through its cooperative bodies in the EU to gain acceptance for such a view.

6.9.2 The battery directive

The Committee's appraisal and proposals

- Sweden should advocate prompt adaptation of the EC's battery directive (91/157/EEC) to the technical progress that has been made with regard to cadmium batteries.
- Sweden should advocate tightening-up of the EC's battery directive so that all remaining use of mercury ceases by 2003.

Cadmium

The largest area of application for cadmium in Sweden is batteries. The use of nickel-cadmium batteries in Sweden is currently declining rapidly from year to year, and today there are alternatives to cadmium batteries in most consumer products.

Today, the EC's battery directive contains no rules prohibiting the marketing of cadmium-containing batteries, which is the case for mercury batteries. Sweden should advocate the introduction of rules banning sales of cadmium batteries into the battery directive. The amendments should be made as alternatives become available on the market in order to eliminate all remaining sales of batteries where alternatives are available and to bar the possibility of returning to cadmium batteries later on. This is in accordance with the intentions of the directive, where it says that the Commission shall adapt the directive to technical progress. A review of the directive has been initiated. Since alternatives to cadmium batteries already exist for most consumer products today, it should be possible to tighten up the directive considerably. Sweden should act to bring about the completion of the initiated review of the directive within the near future.

Mercury

The EC's battery directive was amended in 1998 so that batteries with a mercury content of more than 0.0005 % by weight were defined as dangerous for the environment. They may not be marketed as such or incorporated into appliances. However, button cell batteries with a mercury content of no more than 2 % by weight have been exempted from this prohibition. There are battery cell batteries on the market today that contain only a few tenths of a percent of mercury.

The new rules have led to a sharp reduction in the quantities of mercury sold in batteries in Sweden. However, the remaining use of mercury in button cell batteries makes it impossible to fully comply with the guideline on mercury, since it is possible today to have up to 2 % mercury by weight in them. There is therefore reason for Sweden to urge a new review of the battery directive for the purpose of prohibiting the remaining use of mercury by not later than 2003.

6.9.3 The fertilizer directive

The Committee's appraisal and proposals

- Sweden should continue to advocate a tightening-up of the EC's fertilizer directive (76/116/EEC) with respect to the fertilizer's content of cadmium.

Commercial fertilizer is an important source of the cadmium contamination of agricultural soil, which is of great importance for the occurrence of cadmium in foodstuffs and thereby exposure of man.

Sweden should urge a tightening-up of the EU's rules regarding fertilizers. We in Sweden already have low concentrations of cadmium in fertilizers today, thanks to factors such as demand from the using sector and a tax on fertilizers. But if further reduction of the concentrations is to be possible, and if more countries are to gain access to fertilizers with a low cadmium content, then purification of phosphate will be necessary. This requires collaboration between countries, which is one reason for Sweden to push for requirements on fertilizers in the EU.

6.9.4 Directive on type-approval of motor vehicles

The Committee's appraisal and proposals

- Sweden should advocate the introduction of restrictions regarding the chemical content of vehicles in the directive on type-approval of motor vehicles (70/156/EEC). For example, it should be possible to stipulate requirements there regarding the composition of brake linings.

Court practice with regard to the directive relating to the type-approval of motor vehicles can be interpreted as implying that the free movement of a type-approved vehicle may only be hindered if there is a serious risk to road safety. This means that a member state may not prevent sales of cars of a given approved model due to its content of a certain chemical. Such requirements must be made in the directive. The directive relating to the type-approval of motor vehicles is special in this respect; in new product directives it is normal that the free movement of goods can be hindered by other rules that lie outside the jurisdiction of the directive.

The Committee's appraisal and proposals

Brake linings contain, among other things, lead, copper and zinc. Emissions of these metals from brake linings to the environment are very great. Several measures are needed in order to bring about substitution with better materials in terms of environment and health. Firstly, the companies should act voluntarily (see 7.4.2), but since a large portion of the vehicles are imported, Sweden should also advocate the introduction of rules at the EU level. A suitable way to proceed in this context may be to advocate an amendment to the directive relating to the type-approval of motor vehicles. All three metals should be included in these efforts, but lead and copper should be given top priority.

6.10 EMAS

The Committee's appraisal and proposals

Sweden should advocate the following amendments to the EMAS regulation:

- The chemical aspects should be clarified in the regulation. This can be done by adding use of chemicals to the examples of what can be included in the environmental statement's summary of data concerning the organization's environmental work (point 3.2 (e) in Annex III).
- Use of chemicals should be included in the enumeration of the direct environmental aspects that can have a significant environmental impact (point 6.2 in Annex VI) and in the points that can be considered in establishing criteria for assessing which environmental aspects have a significant environmental impact (point 6.4 (b) in Annex VI).

EMAS is regulated in an EC regulation from 1993 on a voluntary eco-management and audit scheme. The purpose of the system is to improve and evaluate industry's environmental work and furnish public information on this work. The regulation presumes that each member state makes it possible for companies to participate voluntarily in EMAS. The EMAS work started in Sweden in 1995.

The purpose of EMAS is to stimulate companies to further develop their environmental work in a systematic and uniform way beyond the requirements made by the legislation. This is done by means of a detailed

programme with clearly defined goals, action programmes and evaluation of all essential environmental conditions affected by the activities.

Today more than 1,200 European companies have been registered in EMAS. In Sweden, 90 companies are registered. All EMAS-registered companies are allowed to make use of an official EMAS symbol.

In Sweden, AB Miljöstyrningsrådet has been commissioned by the Government to furnish information on EMAS and register companies who meet the requirements. In order for a company to be registered, it must have adopted an environmental policy, conducted a thorough environmental review, introduced an environmental programme and introduced an environmental management system with organizational structure, division of responsibilities and documentation and work methods.

EMAS is based on three premises: openness, credibility and business opportunities. Transparency and the requirement that the companies shall annually publish audited and approved environmental statements are important. The environmental statement shall describe the objective of the environmental work as well as how the work is conducted and its results.

The Committee's appraisal and proposals

Particularly dangerous substances (including those subject to the new guidelines) should, according to the Committee, be prohibited or restricted by 2010 in the EU. The work of achieving the overall objective of a non-toxic environment is complex and must moreover principally take place among those who conduct the activities where the chemicals are used. The knowledge possessed by those conducting the activities and market forces should be utilized. This will improve the chances of achieving the objective in a cost-effective manner. Legislation is primarily needed as a means for establishing a minimum level for protection of human health and the environment. Numerous measures are required beyond this. We therefore believe that various market-driven or softer instruments – including environmental management systems – should be utilized immediately for the purpose of increasing awareness of the chemicals issues. However, many of the market-driven instruments need to be expanded, augmented or clarified in terms of the chemicals issues. Environmental management systems integrate

environmental concerns into the company's activities and better enable the companies to shoulder their responsibility for contributing towards achievement of the environmental objectives.

On 28 February 2000, the Council adopted a common position in the question of a new regulation on the Community's eco-management and audit scheme (EMAS). Among other things, the new regulation entails that there is room to adapt EMAS to encompass ISO 14001 and that EMAS can be applied within all sectors by organizations that impact the environment. EMAS places special significance on legal compliance (cf. point 15 of the preamble and Article 2a). This should also apply to the chemicals legislation, including in cases where such Community legislation aims at the free movement of goods. The use of chemicals is, however, not expressly mentioned at any place in the regulation's provisions.

The Committee considers that Sweden should advocate clarification of the chemical questions in the regulation. This can be done, for example, by adding use of chemicals to the examples of what can be included in the environmental statement's summary of data on the organization's environmental work (point 3.2 (e) in Annex III of the regulation). Further, use of chemicals should be included in the enumeration of the direct environmental aspects that can have a significant environmental impact (point 6.2 in Annex VI) and in the points that can be considered in establishing criteria for assessing which environmental aspects have a significant environmental impact (point 6.4 (b) in Annex VI).

6.11 Directives on producer responsibility

The Committee's appraisal and proposals

- Producer responsibility can be an important instrument in phasing out dangerous substances in products.
- The importance of producer responsibility in phasing out dangerous substances in products should be elucidated, e.g. by the Government's special investigator, who recently began his work.

Sweden should advocate the following in the EU:

- New directives on producer responsibility should be formulated so that it is clearly evident that producers are responsible for designing their products in such a way that they can be recycled, which may entail that the content of dangerous substances should be restricted.
- Sweden should advocate the introduction of producer responsibility for electrical and electronic products. Such rules may have great importance for e.g. restricting the use of lead and, to some extent, cadmium and mercury.

Producer responsibility is an important and fundamental principle. Only when producers are forced to take care of their products as waste will they also take responsibility for the materials used and thereby also the chemical substances contained in the product and in the materials. Thus, the purpose of producer responsibility for end-of-life products is to encourage more environmentally sound product development by giving producers responsibility for the products they place on the market.

In Sweden, the Government recently decided (6 April 2000, dir. 2000:28) to appoint a special investigator to conduct a broad survey of producer responsibility and investigate how guarantees could be designed for the fulfilment and function of producer responsibility. Any proposals must take into account the EC's *acquis communautaire* and its development. The investigator shall submit a report on the commission to the Government by not later than 31 July 2001. We believe that this investigation is urgent and that the question of dangerous substances in products covered by producer responsibility should also be examined by the investigator.

In general, it is our experience that a statutory producer responsibility for end-of-life products can be an important instrument for phasing out

dangerous substances in products. We therefore believe that the possibility of whether producer responsibility can be extended to embrace more product groups should be considered. Firstly, requirements can be laid down in the rules governing producer responsibility that the products may not contain certain dangerous substances; secondly, the producers are given a general and strong incentive to remove dangerous substances from their products, since they are made responsible for recycling/reuse. We also contend that producer responsibility should cover the entire life cycle of the product.

In the proposals for producer responsibility for end-of-life vehicles and electrical and electronic products which the European Commission is currently working on, there are examples of how the use of individual substances can be restricted by means of rules on producer responsibility.

Electrical and electronic products contain, for example, a relatively large residual use of lead and certain other substances. If the EU adopts a directive on producer responsibility for these products in accordance with the existing draft of the proposed directive, this would mean that lead, cadmium, mercury, hexavalent chromium and certain brominated flame retardants would be banned in electrical and electronic equipment. However, the proposal contains several exemptions from the ban. If the proposal is adopted, Sweden should advocate periodic review of the exemptions or that an expiration date be set for the exemptions.

6.12 Export and import of certain dangerous chemicals

The Committee's appraisal and proposals

- If changes in the form of restrictions are made in the manufacture, sale and use of substances, this should lead to changes in the rules on export and import as well.
- The obligations to classify and label chemicals intended for export should be extended to include requirements to furnish safety data sheets as well. This is particularly significant in the case of exports to developing countries.

Council Regulation (EEC) No 2455/92 contains provisions concerning the export and import of certain dangerous chemicals. The regulation,

which is directly binding upon the member states, deals with the same dangerous substances as directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances. It also includes a number of additional substances. The purpose of the regulation is to establish a common system of notification and information for imports from and exports to third countries of certain chemicals which are banned or severely restricted. Another purpose of the regulation is to ensure that the provisions of the directive on the classification and labelling of substances (67/548/EEC) are also applied to exports.

If changes in the form of restrictions are made in the manufacture, sale and use of substances in the EU, this should lead to changes in the EU's rules on export and import as well. One reason for this is that responsibility should be taken for developing countries. According to EC regulation 2455/92, industry is obligated to classify and label chemicals when they are exported as well. These obligations should be extended to include requirements to furnish safety data sheets for exported chemicals as well.

6.13 Emission regulations

The Committee's proposals:

- Sweden should advocate inclusion of the substances subject to phase-out requirements according to the Committee's proposals (see Chapter 5) among those covered by the coming Water Framework Directive until prohibitions enter into force (see section 6.5).

Rules governing water pollution

Several EU directives deal with pollution caused by emission of certain dangerous substances to air or water. The Committee is of the opinion that the coming Water Framework Directive may be particularly important for the implementation of the new guidelines on chemicals policy.

There are some fifteen or so directives in the EU that deal with pollution etc. of water, for example rules governing discharges of certain dangerous substances in water, rules for drinking water quality, bathing

water quality, groundwater, water favourable to shellfish growth and fresh water.

An effort is currently under way within the EU to rewrite the legislation on water quality and gather it under a Water Framework Directive. The proposed directive is currently subject to a reconciliation process between the Parliament and the Commission.

Within the framework of the directive, water quality standards and emission limits will be established. First some 30 substances will be selected for which water quality standards and emission limits will be established. The substances will be selected with the aid of a calculation model that weighs together persistence, bioaccumulation and toxicity with data on measured values in the environment. When water quality standards and emission limits have been established, risk mitigation measures may be called for. From various international lists of priority substances, some 500 substances have been selected in an initial stage. The number will be further reduced based on data in IUCLID with the aid of EURAM (a calculation program in which persistence and bioaccumulation are included as selection criteria). Monitoring data (involving some 90-odd substances) will be used in a second stage, along with toxicity data.

Rules on measures to prevent and restrict pollution

The directive concerning integrated pollution prevention and control (IPPC directive, 96/61/EC) concerns point emissions from large industrial plants. The directive prescribes certain principles on best available techniques, precaution and substitution. The directive states in the definitions in Article II that special consideration should be given to the items listed in Annex VI in determining the best available techniques. The most important items as far as we are concerned are:

- the use of less hazardous substances
- the use of low-waste technology
- the furthering of recovery and recycling of substances generated and used in the process
- the consumption of raw materials used in the process and energy efficiency
- technological advances and changes in scientific knowledge and understanding.

The Committee's appraisal and proposals

The Committee makes the appraisal that one way to pave the way for taking action in the EU against persistent and bioaccumulative substances, solely on the basis of their inherent properties, can be to give greater weight to these properties in the Water Framework Directive. This can be done by means of changes in the calculation model used to prioritize substances that should be covered by the directive.

The Committee's proposals in previous chapters entail that the substances that fulfil the criteria which we propose in Chapter 5 shall be prohibited in products. Nor shall these substances be allowed to occur in production processes if they risk escaping into the environment or accompanying the products. The Committee therefore considers that rules governing emission restrictions in the Water Framework Directive can serve as a first step on the road towards a phase-out of these substances. As prohibitions for substances enter into force, however, the need for special emission regulations will diminish.

6.14 Enforcement and inspection activities in the EU

The Committee's appraisal and proposals

- Enforcement by the member states is an important part of the risk limitation work and a prerequisite for the credibility of the EU's *acquis communautaire*. Questions regarding enforcement and compliance must therefore be given greater attention and emphasis in the political discussion of a new chemicals strategy. The ongoing work in the EU is therefore positive.
- Guidance documents, for example in the form of a recommendation from the Council, with minimum requirements on enforcement and compliance with the chemicals rules, should be produced.
- The work being pursued within the framework of IMPEL and CLEEN is important and should be promoted and supported by the Commission.

Description of IMPEL and CLEEN

The IMPEL Network (European Union Network for the Implementation and Enforcement of Environmental Law) is a network with participants from all EU member states. IMPEL has been instructed by the European Commission to come up with proposals for recommendations for minimum criteria for enforcement of environmental law. This proposal is currently being considered by the Council. The purpose is to create common principles for inspection of industrial plants in particular.

IMPEL's work has so far mainly been concerned with permits and emissions, and IMPEL is therefore of subordinate importance when it comes to oversight of chemical products and other products. For regulatory authorities in charge of the chemical rules, another formal network has existed for over a year now called CLEEN (Chemical Legislation European Enforcement Network).

Like IMPEL, the purpose of CLEEN is to develop and coordinate inspection methods and exchange experience and information. An important premise that distinguishes the two enforcement networks is that IMPEL works with enforcement of rules concerning the external environment which are normally minimum rules (individual member states can impose stricter requirements than those prescribed in the directive), while CLEEN works with oversight over chemical products and other products that have free movement in the EU, where e.g. restrictions are introduced via harmonized directives which the countries have to enact (little possibility for individual countries to have deviant rules). This distinction means that the work conducted within IMPEL and CLEEN is different in nature and thrust.

With the support of CLEEN, the member states' regulatory authorities also coordinate enforcement of the chemical rules in the EU, which doesn't take place within IMPEL. The CLEEN projects are effective due to joint priorities and joint enforcement activities, so that the focus of the project (e.g. a rule or a product group) gets attention in all EU countries at the same time.

Coordinated enforcement of the chemical rules in the EU started in 1995 at the initiative of the Netherlands. Altogether, four enforcement projects have been carried out or commenced:

- The NONS project was conducted between 1995 and 1996 and was focused on enforcement of the rules concerning prior notification of

new substances and the rules concerning material safety data sheets (directives 92/32/EEC and 67/548/EEC).

- The SENSE project was conducted between 1996 and 1997 and was focused on enforcement of the same directives as above.
- The EUREX project was conducted between 1998 and 1999 and was focused on enforcement of regulation (EEC) No 793/93 on existing substances.
- The EUROCAD project was started in 1999 and is focused on the rules concerning restriction of cadmium (directives 76/769/EEC and 91/338/EEC).

As an example of results of the inspection within the framework of the SENSE project, where 1,905 substances were checked at 100 companies, 100 (5 percent) of the substances could not be identified (Ministry of Housing, Spatial Planning and Environment, 1998). It was found that 1,572 substances (83 percent) were existing substances and 233 (12 percent) were new and should thereby be subject to the requirements on prior notification of new substances. Of these 233 substances, 11 had not been notified.

Within the framework of the same project, compliance with the rules on health and environmental hazard classification was also checked for the substances in question. Of those that should have been classified according to Annex I of the directive on classification and labelling, 75 percent were correctly classified and 58 percent were correctly labelled. Material safety data sheets existed for 66 percent of the substances that were checked, of which 80 percent were correct.

In summary, the project showed that 32 of the 100 companies that were inspected had not complied with the rules in the dangerous substances directive (no or incorrect notification, incorrect classification, incorrect labelling or incorrect material safety data sheets, etc.). More than 600 inquiries for supplementary information and 200 warnings were sent to the inspected companies as a result of the project. Most of the inspected companies showed a great willingness to cooperate, and as a result of the joint project it was also concluded that the inspectors had informed and learned from each other so that knowledge of the rules on prior notification of new substances was disseminated and reinforced.

The Netherlands and Greece have jointly taken on the work of the CLEEN secretariat. Today there is no financial support from the

Commission for this work; only support for holding of the conferences has been granted.

Minimum criteria for environmental inspections in the member states for activities requiring permits

The European Commission has presented a proposal for recommendations for minimum criteria for environmental inspections.[2] The EU's environment ministers have also discussed a common position on a recommendation for minimum criteria for environmental inspections. The European Parliament has offered viewpoints on the Commission's proposal. The Parliament expressed a wish for a directive with minimum criteria instead of a recommendation. The Parliament also wishes to strengthen the role of IMPEL. A partially amended Commission proposal is expected to be considered by the Council in the near future.

The purpose of the recommendation is to establish guidelines for how environmental inspections are to be carried out in the member states by establishing minimum criteria for how the inspections should be organized, carried out and followed up. The goal is to achieve greater harmonization with Community environmental legislation by a more consistent implementation and a more consistent verification of compliance with the same in the member states.

The recommendation applies to environmental inspections of industrial installations, enterprises or facilities whose emissions and/or discharges to the environment, waste management or recycling activities are regulated by the issuing of permits or licences or by Community legislation ("Controlled Installations").

The recommendation is particularly aimed at two types of environmental inspections: routine inspection visits that are performed as part of a planned inspections programme, and non-routine inspection visits that are carried out in response to serious complaints concerning the environment, in the investigation of accidents, incidents and occurrences of non-compliance, or as part of the process leading up to the issuance of a permit or licence for a Controlled Installation.

[2] COM(98) 772 final COD980358, amended proposal COM(1999)652 final.

The recommendation calls upon the member states to draw up nation-wide plans on how environmental inspections are to be carried out in each member state. These plans shall be made available to the public.

The Committee's appraisal and proposals

A large portion of the chemical products and other products on the Swedish market are made in countries outside Sweden, and a large portion outside the EU. In view of the fact that they often enter Sweden via other EU countries, it is becoming increasingly urgent for Sweden that chemical oversight and rule enforcement be effective throughout the entire EU. It is, for example, important for all EU states to have satisfactory control of imported products, since the products will then flow freely on the EU market. In this context it can also be noted that it is difficult to enforce special national rules for products, underlining the importance of working for common legislation that guarantees a high level of protection within the EU.

Implementation and enforcement of the EU's common environmental legislation needs to be given much greater attention. In decisions concerning the future EU chemicals and product policy, attention must be given to the fact that real improvements in health and the environment are predicated on a practical implementation and enforcement of the legislation that will be enacted. This is particularly important in view of the fact that the implementation of the *acquis communautaire* will require even greater efforts in those countries that are now candidates for EU membership. Putting adopted measures into practice must therefore be an important priority in a new chemicals and product policy within the EU. This will require continued commitment and perseverance on the part of all member states. It can be assumed that many of the new candidates for EU membership will, within a few years, have the practical means to comply with the chemical rules that exist in the EU.

The National Chemicals Inspectorate, in an analysis leading up to the in-depth probe of the agency (National Chemicals Inspectorate, 2000), found that there is a risk of a considerable circulation in the EU of chemical products and finished products that do not comply with the EU's rules if free movement of goods from the new members states is applied before chemicals control in these countries works. The Inspectorate concluded that attempts to impede the circulation of such chemicals and products would require great efforts in the other member states in the form of oversight of the flows of chemicals and products.

In a communication on the state of implementation published by the Commission in 1996, it was noted that the Community's environmental legislation is often implemented in an unsatisfactory fashion on the national plane.

In 1998, the Commission registered some 600 suspected breaches of EC environmental law based on complaints from the public, parliamentary questions and petitions, and cases detected by the Commission. Of the 123 cases for which an application was lodged with the Court in 1998, 49 concerned the environment (COM, 1999b).

The main reasons for this currently unsatisfactory situation are to be found in the legal and technical complexity of the legislation and in the difficulty in balancing the interests of the stakeholders concerned. In some cases, environmental legislation relates to general interests in which there is not always a proprietary interest. There is also a shortage of qualified staff and resources for the complex function of inspection and enforcement at national and local levels.

Furthermore, there is a lack of dissuasive, effective and proportionate sanctions in member states when measures are not properly implemented.

Efforts have been made to ensure that all relevant actors and sectors are involved in the legislative process, including the IMPEL network of environmental law inspectors. The Commission has proposed the development of Community-wide minimum criteria for the carrying out of environmental inspection tasks by member state authorities.

It is thus important to strengthen the verification of compliance with rules in the EU, and the Committee believes that the member states themselves should be responsible for enforcement and verification of compliance.

A basis for uniform enforcement of the chemical rules is found in the common rules, but a strengthening of the actual enforcement of the chemical rules is needed. This can be accomplished by, for instance, allocating resources for common inspection activities (e.g. within CLEEN) and by making coordinated prioritizations of product groups, special rules etc. Within the CLEEN project, a coordination of the inspection methods is also taking place, which is good when different

regulatory authorities exercise oversight over the same rule system. It is important that the EU support EU-coordinated enforcement.

Better supervision of enforcement is needed to ensure that the legislation is being implemented correctly. The Commission should work to improve information to e.g. the public on the results of enforcement and compliance.

The EU already ensures that its directives have been implemented in the legislation of all its member states. But the EU should also ensure that the rules are complied with. A summarizing accounting of compliance and the prerequisites for compliance is important not just for the credibility of the system, but also for feedback from enforcement to those who design the actual *acquis*.

7 Proposed measures in Sweden

In this chapter we present proposals for measures that are needed in Sweden to implement the new guidelines on chemicals policy. We start by going through the Environmental Code and its body of rules from a chemical and product perspective in section 7.1. Our proposals for measures that should be taken pursuant to the Environmental Code are presented in section 7.2. In section 7.3 we go through the informational and market-driven instruments on a national level and offer proposals for changes in these instruments. In section 7.4 we have gathered our proposals for continued national efforts in government agencies and the business community as regards their contributions towards implementation of the new guidelines on chemicals policy.

7.1 Description of the Environmental Code from a chemicals and products perspective

The Environmental Code (SFS 1998:808) entered into force on 1 January 1999. The rules laid down in 15 Swedish acts of law have been brought together in this Code, for example the Chemical Products Act, the Environment Protection Act and the Public Health Act. The Environmental Code is a comprehensive body of law with 33 chapters and nearly 500 sections. In addition, more detailed provisions are found in numerous ordinances.

The purpose of assembling a body of legislation in the Environmental Code is to make the legislation more comprehensible, to strengthen the rules in areas where regulation is inadequate, and to regulate all activities that can contribute to a bad environment. With the amalgamation of the 15 previous acts, numerous redundant rules have been replaced with common rules.

Below is a general review of the provisions of the Environmental Code and those of its ordinances that have to do with the work of our Committee.

7.1.1 Background, objectives and scope

According to Chapter 1, Section 1 of the Environmental Code, the provisions of the Code are aimed at promoting sustainable development to ensure a healthy and good environment for present and future generations. Sustainable development shall be based on the realization that nature is worthy of protection and that man's right to alter and utilize nature is linked to a responsibility to manage nature well. How the Code should be applied so that its objectives are achieved is also described, for example it is stated that the Environmental Code shall be applied so that:

- human health and the environment are protected against harm and nuisance, regardless of whether they are caused by pollution or other impact,
- valuable natural and cultural environments are protected and conserved,
- biological diversity is preserved,
- land, water and the rest of the physical environment are used so that good long-term management of resources is assured from an ecological, social, cultural and socio-economic viewpoint, and
- reuse and recycling, along with other forms of conservation of materials, raw materials and energy, are promoted so that a closed-loop management of resources is achieved (called ”ecocycle” in Swedish).

Thus, the Environmental Code has a very wide scope. The rules can be applied to all activities and all measures that affect the environment – from large industrial projects to the small individual actions of private persons.

7.1.2 The ”general rules of consideration”

Chapter 2 of the Environmental Code contains ”general rules of consideration” that apply to all measures that are not of negligible significance in the individual case. This is an important change compared with previous legislation, although the previous legislation

also contained general rules of consideration where chemicals are concerned.

Reversed burden of proof (Chapter 2 Section 1)

According to the Environmental Code, the operator of an activity is obligated, in connection with permit application review and regulatory inspection, to show that the Code's general rules of consideration are being observed. In other words, the burden of proof is reversed. It is incumbent upon the party applying for a permit under the Environmental Code to show via investigations and by other means that the activity can be conducted in an acceptable fashion in relation to the rules of consideration. It is also incumbent upon the operator of an activity to show to the supervisory authority that the activity being conducted or the measure being taken does not lead to effects or otherwise counteract the objectives of the Environmental Code in a way that could not be limited, or lead to nuisances to human health or the environment to such a degree that it cannot be accepted.

Knowledge (Chapter 2 Section 2)

A fundamental prerequisite for all public health and environmental protection work is knowledge of what problems exist and, wherever possible, how they can be solved. It is, for example, reasonable that a party intending to commence an activity should first acquire the knowledge required to determine the environmental effects that may arise.

In the application of the Code, it is the possible effect of a measure that shall determine what knowledge is needed. According to the Government (Gov. Bill 1997/98:45, Environmental Code, Part 2, p. 14):

> *".....the requirements in daily life are limited to the being able to obtain information provided by labels of contents etc. on product packages and otherwise readily available information from e.g. the municipality or government authorities. It can, however, be required of those who conduct industrial activities that they obtain whatever relevant knowledge exists inside and outside the country and, in lieu of previous experience, carry out their own studies and investigations whenever there is reason to assume that the activity has some bearing on health and environment. In the exercise of authority where the Code is to be applied, very extensive requirements on knowledge regarding the health and environmental consequences of the decision may be imposed."*

The Chemical Products Act also made it incumbent upon anyone manufacturing or importing chemical products to obtain, by his own research or other means, relevant knowledge to determine what health or environmental detriment the products may cause. Access to chemical and toxicological knowledge was also required.

The more concrete requirements on knowledge are also found in the Code's chapter on supervision (Chapter 26 Section 19).

According to the Code, the knowledge requirement is also applicable to products that contain or have been treated with a chemical product. This is new in relation to previous legislation.

Precautionary measures (Chapter 2 Section 3)

The fundamental rule of consideration in the Environmental Code entails that anyone planning to take a measure must carry out whatever protective measures, observe whatever restrictions and adopt whatever other precautionary measures are needed so that the measure will not cause harm to health or the environment.

According to the rule on precautionary measures, harm or nuisance to health or the environment shall be prevented, impeded or counteracted.

Both physical and mental harm to human health are included. The expression "nuisance to human health" is defined in Chapter 9 Section 3 as a disturbance which, according to medical or hygienic evaluation, may have a detrimental effect on health and is not trivial or purely temporary. According to the Government (Gov. Bill 1997/98:45, p. 15), consideration shall also be given to persons who are slightly more sensitive than normal, for example allergy sufferers.

In commercial operations, the best possible technology shall be used to avoid harmful effects. The technology must be industrially feasible, from a technical and economic viewpoint, to use in the sector in question. This means that it must be available and not only exist in the experimental stage. The technology does not have to exist in Sweden, however.

In judging what precautionary measures are to be taken, cost and benefit must be weighed against each other in accordance with the reasonableness rule described in Chapter 7 Section 7 (see below).

The precautionary measure rule can be said to be a natural consequence of the principle worked out in the OECD in the early 1970s – the polluter pays principle, which also finds expression in the obligation to remedy damage described in Chapter 2 Section 8 of the Environmental Code.

The obligation to take precautionary measures is also closely associated with the internationally accepted precautionary principle. The precautionary principle is expressed in Chapter 2 Section 3: precautionary measures shall be taken as soon as there is reason to assume that a measure may harm human health or the environment. The operator of the activity cannot excuse himself by claiming that absolute scientific evidence of harm is lacking.

The product choice principle (Chapter 2 Section 6)

Anyone who conducts or intends to conduct an activity or take a measure shall avoid using or selling chemical products that can harm human health or the environment if they can be replaced with products that can be presumed to be less hazardous. Similar requirements also apply to finished products that contain or have been treated with a chemical product. In previous legislation, the product choice principle was called the substitution principle.

According to the Government (Gov. Bill 1997/98:45, Part 2, pp. 21–24), an assessment must be made in each individual case. General prohibitions on use or sale can never be imposed for a chemical product or manufactured product based solely on the product choice principle in Chapter 2 of the Environmental Code. General prohibitions may, on the other hand, be decreed under the provisions of Chapter 14 Sections 24 and 25 of the Environmental Code.

The product choice principle further entails that harmful substances and preparations which are in themselves permissible shall be avoided or, if the user nevertheless achieves the purpose of the use, be replaced with ones that are less risky or completely safe. Anyone using a chemical product shall judge whether they can achieve the same results with another chemical product that is less dangerous or completely safe.

It is often much easier for the party selling such a product than for the buyer to determine whether there are less dangerous alternatives for a particular use. The prerequisite is then that the seller knows or can

predict how the buyer intends to use the product. By giving the customers information on the importance of observing the product choice principle, combined with information on the health and environmental properties of different chemical products and finished products, the seller can actively influence the product choice to the benefit of health and the environment.

According to the precautionary measure principle, it is also desirable to replace the use of a chemical product with another method that precludes the need for the use of any chemical products at all.

For an environmentally good product choice to be possible, the products must be labelled in such a way that the user obtains accurate information on the environmental properties of the product. This is regulated in Chapter 14 of the Environmental Code.

It also states in the Government Bill on the Environmental Code (Gov. Bill 1997/98:45) that the reasonableness rule in Chapter 2 Section 7 shall be applied in the application of the product choice principle, as well as in the application of other rules of consideration. A balance must thereby be struck in deciding what can be considered to be reasonable with regard to normally acceptable behaviour and interests other than environmental interests. Examples given are personal integrity and freedom of choice.

Furthermore, in the case of commercial activities, the product choice principle can serve as a basis for permit conditions for the activity and in this manner be defined more precisely in the individual case. An important standpoint which the Government (Gov. bill 1997/98:45) put forth was that it is often not sufficient for a single operator to make a reasonableness assessment solely with reference to the fact that the effects of his own limited use are small in relation to the costs for him to find a substitute for a chemical product or manufactured product. This is the case e.g. with the use of chemical products or finished products if the adverse effects are the sum of the use in a very large number of activities. This is in fact a very common situation, not least in the chemicals and products area.

The product choice principle is beginning to gain some support in Community law. An example is the IPPC (Integrated Pollution Prevention and Control) directive (96/61/EC), where it is stated that in determining best available techniques, special consideration shall be given to e.g. the use of less hazardous substances.

Resource management principle and ecocycle principle (Chapter 2 Section 5)

Anyone who conducts an activity or takes a measure shall conserve raw materials and energy and make use of the opportunities for reuse and recycling. Renewable energy sources shall be used where possible. This provision gives expression to the resource management and ecocycle principles.

As regards both of these principles, the best effects are achieved in conjunction with design and manufacture. The provision shall be applied e.g. in connection with review of applications for permits for environmentally hazardous activities. This extends the scope of permit review compared with former legislation.

Reasonableness rule (Chapter 2 Section 7)

According to Chapter 2 Section 7, the requirements on consideration set forth in Sections 2–6 shall apply to the extent it cannot be considered unreasonable to satisfy them. In making this assessment, special account shall be taken of the benefit of protective measures compared with the costs of such measures. This judgement may not entail disregard of any environmental quality standard.

Additional general rules of consideration etc.

Besides the aforementioned principles and rules, additional general rules are set forth in Chapter 2 of the Environmental Code. They are the siting principle (Section 4), liability to remedy damage (which, like the rules on precautionary measures, is an expression of the polluter pays principle) (Section 8), and the stop rule (Section 9).

7.1.3 Environmental quality standards

Chapter 5 of the Environmental Code contains provisions on environmental quality standards. The option of imposing environmental quality standards is an important new feature of the legislation and entails that the Government may issue regulations for certain geographical areas or for the whole country regarding the quality of land, water, air or the rest of the environment if this is needed for the long-term protection of

human health or the environment or to remedy damage. These environmental quality standards are a new tool in Swedish legislation.

Environmental quality standards are supposed to specify the highest pollution levels or disturbance levels to which humans or the environment can be exposed without risk of significant nuisance. The levels specified by the environmental quality standards must be complied with after a certain stated date, and they may, for example, stipulate the maximum concentrations of chemicals in soil, water or air.

In contrast to limit values and target values, environmental quality standards should only focus on what man and the environment can bear – without consideration of economic or technical factors.

If an environmental quality standard has been issued, national and local authorities must ensure that the standard is complied with when they make plans, review permit applications, grant approvals and exemptions, consider notification matters, exercise supervision and issue regulations. Permits shall not be issued for activities that contribute towards contravention of an environmental quality standard. Permits and conditions have to be reconsidered if an activity of any importance contributes towards contravention of an environmental quality standard.

Furthermore, action plans shall be prepared by the Government or other authorities if this is necessary for an environmental quality standard to be met.

Today environmental quality standards have been approved for nitrogen dioxide, sulphur dioxide and atmospheric lead. There are also a number of EC directives that contain limit values for environmental quality.

7.1.4 Special provisions concerning environmentally hazardous activities and public health

Chapter 9 of the Environmental Code contains special provisions concerning environmentally hazardous activities and public health. The Environmental Code's common rules, such as the common rules of consideration in Chapter 2, also apply to environmentally hazardous activities and other measures that can affect public health.

By "environmentally hazardous activities" is meant all use of land, buildings or fixed installations that entails emissions to soil, air or water. To be considered an environmentally hazardous activity, the activity does not have to be environmentally hazardous in the individual case. Nor should too much be read into the word "activity". The term "use" is to be regarded in a long-term perspective, which means for example that a rubbish dump that no longer receives waste is an environmentally hazardous activity as long as it can result in pollution. It is the effect of the activity and not its actual operation that is crucial.

With the support of the Environmental Code, The Government lays down requirements on permits or notification for environmentally hazardous activities in the Ordinance (1998:899) on environmentally hazardous activities and public health. In an annex to the ordinance there is a list of environmentally hazardous activities that require permits from the Environmental Court, whose permit applications must be reviewed by the county administrative boards, and environmentally hazardous activities that have to be notified to the county administrative board or the municipality.

Changes in ongoing activities may also require permits. In such cases, an integrated review must be conducted of the entire activity.

Previously, permit review of an environmentally hazardous activity only included emissions from the activity. A broader review will be made under the Environmental Code. Such aspects as resource management and chemicals use will also be considered from the perspective of the Code's rules of consideration and be subject to conditions. This means that attention must be given to both the precautionary principle and the product choice principle in conjunction with the review.

According to the Government (Gov. Bill 1997/98:45, Part 1, p. 347), it has previously been a shortcoming that the supervisory authority, in reviewing permit applications under the Environment Protection Act, has not been able to review the chemicals use in environmentally hazardous activities in a more independent fashion. Only to the extent that the chemicals have been of importance for emissions has chemicals use been reviewed, and the emission quantities have therefore been crucial in this review. Such a point of view is, according to the Government, far too static and is based on an antiquated view of what a permit review should entail. It is therefore, according to the Government, incumbent upon the permit authority to consider, in reviewing an environmentally hazardous activity under the Environmental Code, the use of chemicals and establish rules for chemicals handling by means of conditions. The chemicals handling in question here is that which can lead to adverse effects on conditions in the external environment, e.g. via the products' environmental impact.

According to the Government, it should therefore be emphasized that it is a question of a review according to the product choice principle and not to determine whether the manufactured product may be marketed or not. The special regulations concerning chemical products in Chapter 14 of the Environmental Code shall be applied for such determinations. The conditions should therefore be formulated so that they do not make it impossible for the operator to apply the product choice principle himself in conducting his activity. It can be added that the product choice principle shall be applied by all operators, regardless of whether they have permits or not and regardless of whether the chemical aspects have been reviewed.

Additional rules of consideration that are to be applied in reviewing environmentally hazardous activities are the ecocycle principle (reuse, recycling and recovery) and the principle of conservation of raw materials and energy. The possibilities of recycling and reusing materials and waste management aspects should be given special attention, according to the Government. Whether or not the manufactured product should be allowed to be placed on the market should not be judged here either.

The application of the rules of consideration described above is also supported by Community law. Council Directive 96/61/EC concerning integrated pollution prevention and control (the IPPC directive) states in the definitions in Article 2 that special consideration should be given to the items listed in Annex 4 in determining the best available techniques.

The most important items for our Committee are the use of low-waste technology, the use of less hazardous substances, the furthering of recovery and recycling of substances generated and used in the process, the consumption of raw materials used in the process and their energy efficiency, and technological advances and changes in scientific knowledge and understanding.

7.1.5 Special provisions on chemical products

The Environmental Code's rules on chemical products do not entail any significant changes in relation to the former Chemical Products Act.

The general rules of consideration in Chapter 2 of the Environmental Code apply to handling and other measures with chemical products. Of particular importance are, as mentioned previously, the requirements on knowledge, precautionary measures and product choice. In addition, Chapter 14 of the Code contains special provisions on chemical products. These rules can be extended to cover finished products as well (see below).

Ordinances issued concerning chemical products and finished products include:

- The PCB Ordinance (1985:837)
- The Chemical Products and Biotechnical Organisms Ordinance (1998:941)
- The Pesticides Ordinance (1998:947)
- The Ordinance on Prohibition in Connection with Handling, Importation and Exportation of Chemical Products Etc. (Certain Cases) (1998:944)

Finished products can also be covered

By "chemical products" according to the Environmental Code is meant chemical substances and preparations of chemical substances. The Government may also prescribe that the provisions on chemical products are to be applied to finished products that contain or have been treated with a chemical product. Examples of such products that have already been regulated are preserved wood, products containing asbestos and products containing mercury.

Requirements on environmental and health investigation

Anyone who manufactures or imports a chemical product shall ensure that a satisfactory environmental and health investigation is conducted. This obligation applies regardless of whether any concrete suspicions exist and applies continually, not ceasing when the product is placed on the market.

Requirements on product information

Anyone who commercially manufactures, imports or transfers a chemical product shall furnish, by labelling or other means, the information needed to protect human health or the environment. The Government has prescribed that this requirement also applies to finished products that contain or have been treated with a chemical product and can, due to their properties, be feared to cause harm to man or the environment. According to the National Chemicals Inspectorate's regulations, hazardous chemical products shall be labelled. When they are transferred to professional users, material safety data sheets shall also be furnished. When requirements on labelling do not exist, product information can be furnished in another manner, e.g. by enclosing an information sheet with the chemical product.

Products register

Chemical products that are commercially manufactured in or imported to Sweden shall be registered in a products register to the extent prescribed by the Government and the National Chemicals Inspectorate.

Rules on prior notification, permits and approval

Prior notification may be required for the manufacture and import of chemical products that have not previously been used in Sweden. Furthermore, a permit may be required for the import of particularly dangerous chemical products from countries that are not members of the EU and in connection with the commercial transfer and other handling of particularly dangerous products.

Special requirements apply to chemical pesticides, which may not be imported from countries outside the EU, placed on the market or used without being approved. Chemical products that have not been

approved, or are exempted from the requirement on approval, may be used as pesticides only if it is obvious that their use does not involve risks to human health or the environment.

Obligation to advise of harmful effects

Anyone who manufactures or places a chemical product on the market shall immediately advise the competent authority if new information comes to light that the product may be harmful.

Prohibitions

If it is of particular importance from the viewpoint of public health or environmental protection, chemical products may be prohibited generally. This may also be appropriate for products whose suspected harmful effects may not necessarily be serious in the individual case, but whose widespread use may lead to harmful effects.

The Ordinance on Prohibition in Connection with Handling, Importation and Exportation of Chemical Products Etc. (Certain Cases) (1998:944) contains prohibitions concerning e.g.:

- cadmium (surface treatment, stabilizers or as a colouring agent)
- certain chlorinated solvents
- mercury in certain finished products (thermometers, some equipment, measuring instruments, etc.)
- metals (mercury, lead, cadmium, hexavalent chromium) above certain concentrations in packaging materials

There are also prohibitions that apply to certain other hazardous chemical and finished products.

7.2 Proposed measures pursuant to the Environmental Code

In this section we present proposals for measures that should be adopted on the basis of the Environmental Code.

7.2.1 Proposed national ban on chemical products and finished products

The Committee's appraisal and proposals

Mercury, cadmium and lead should be phased out within the entire EU. For mercury and lead, notification of national bans within the EU could be an appropriate way to raise the issue in the Union. For proposals regarding cadmium, see Chapter 6.

Mercury

- The Swedish ban on the use of mercury must be made comprehensive by not later than 2003.

Lead

- Lead ammunition and lead fishing sinkers should be banned by national measures by not later than 2008.

Ongoing phase-out of mercury and lead

Despite the fact that the work to restrict the occurrence of mercury, cadmium and lead has been going on for many years, a number of areas of application remain. Following is a brief description of the situation regarding the phase-out of mercury and lead. A more detailed report on how far the phase-out work has come and what areas of application remain is given in Annex 6.

The current Swedish legislation on mercury is worded so that specific manufactured goods are identified in which mercury is not allowed. For example, it covers thermometers and measuring instruments. Mercury use in these areas has declined sharply since the rules were enacted in the early 1990s. However, certain important areas of application are not covered by the rules.

The chloralkali industry is responsible for the biggest annual input of mercury to society in Sweden. In the Government Bill ”Swedish Environmental Quality Objectives” (Gov. Bill 1997/98:145), the Government takes the position that use of mercury in the chloralkali industry may continue no longer than until 2010.

The predominant source in terms of emissions is amalgam. Around one-third of atmospheric mercury emissions in 1995 originated from crematoria, where the mercury came from amalgam fillings in teeth. The mercury also gets out into the wastewater as amalgam is worn off from the fillings. Amalgam is also the predominant source of mercury in sludge. The use of amalgam declined in the early 1990s, but subsequently levelled off.

Mercury is also used in batteries (see section 6.9) and as an analysis and reagent chemical at laboratories.

Mercury is also present in light sources, such as fluorescent tubes and low-energy light bulbs. Some decline in use has occurred in the past few years, however.

Mercury is an unusually volatile metal. As a result of the decline in domestic emissions of mercury, about 80 percent of the atmospheric deposition of mercury over southern Sweden derives from other countries. The total deposition of mercury over Sweden, from both domestic and foreign sources, is around 4 tonnes per annum, of which about one-tenth comes from finished products. International action is therefore necessary (see Chapter 8).

In the case of lead, the largest single use is car batteries and other accumulators. Accumulators are estimated to account for around three quarters of the total use (see further section 7.4.2). Other uses are ammunition, fishing sinkers, electronics, weights (e.g. yacht keels and balancing weights for wheels), cable sheathing, metal alloys, additives in plastics, building materials, glass, paints and anti-corrosive compounds.

The phase-out of lead has been successful in some areas. Use of lead in petrol has declined drastically as a result of changes in the Motor Gasoline (Petrol) Ordinance (see Figure 10.1). This has in turn led to greatly reduced emissions to air. In areas such as paints and anti-corrosive compounds, glass, cable sheathing and additives in PVC, voluntary measures from industry have led to a decline in use.

Progress has been slow in other areas. The influx of lead to society via accumulators is still very great. Consumption of lead for ammunition has declined somewhat during the 1990s, due to the fact that the quantity of lead per shot has declined. There has not, however, been any appreciable changeover to alternative materials. Nor has there been any significant changeover to alternative sinker materials in the fishing sector. Both ammunition and sinkers are areas of use that lead to direct release of metallic lead to the environment.

The Committee's appraisal and proposals

The Committee believes that the remaining use of mercury, cadmium and lead should be phased out. In view of the trade with products that contain these substances, and the dispersal of the metals via air, this should be done throughout the EU and eventually globally as well. There are already EU-wide rules in several areas that concern the three metals, for example in the battery directive, and new rules that may have a bearing on the metals are in the works, for example in the form of directives concerning end-of-life vehicles and producer responsibility for electrical and electronic products. Individual countries within the Union have imposed bans on one or more uses of these metals. Denmark, for example, has a ban on mercury (with a number of general exemptions, some of which are time-limited). Several countries within the Union (Denmark, the Netherlands, Finland) also have bans on lead shot, complete or partial.

There are several ways to bring up an item on the agenda in the EU. As far as general measures for persistent and bioaccumulative substances are concerned, which includes numerous substances and involves a new strategic approach, we have not judged notification of national proposals to be a feasible way. On the other hand, we believe it is possible to influence the EU by notification of national prohibitions when it comes to individual particularly dangerous substances such as mercury and lead.

The Committee has considered different alternatives as regards the scope of the bans for the two metals. Sweden has rules governing mercury today. According to the Ordinance on Prohibition in Connection with Handling, Importation and Exportation of Chemical Products Etc. (Certain Cases) (1998:944), mercury is prohibited in thermometers, measuring instruments, etc. It is the Committee's understanding that Sweden will notify an extension of the ordinance to several additional

areas of application during 2000. But in our judgement there is a manifest need for a general ban on mercury for the purpose of reducing the load on man and the environment and to prevent new uses of mercury from being introduced. The latter is urgent in view of the fact that mercury has begun to be used in new areas in recent years, such as in headlights for cars.

We have found that some uncertainties exist regarding whether substances contained in products can be prohibited if product directives exist within the areas of application where the substances occur (see section 6.8). Mercury is used today in several areas covered by product directives. However, we believe Sweden should try notifying a general ban on mercury. It should not be assumed in advance that the product directives preclude such a prohibition.

To the extent a prohibition is considered to conflict with EU-wide rules, Sweden should invoke the environmental guarantee. It is important that Sweden contribute to bringing further clarity into how much leeway is allowed by the environmental guarantee. Sweden should not refrain from notifying a total ban on mercury merely because this might lead to the matter being taken up in the EC Court of Justice. It is only via a ruling in the Court of Justice that it will become clear how much leeway is allowed by the environmental guarantee. Since mercury is one of the substances whose harmful effects are best documented, it is particularly suitable to obtain a ruling for mercury.

A general ban on mercury should allow the possibility of general time-limited exemptions. Such exemptions may be appropriate for e.g. light sources, until fluorescent tubes and low-energy lamps can be produced without mercury, and for the chloralkali industry up to 2010.

The Committee has considered the possibility of imposing a general ban on lead as well. However, in view of the fact that lead has a different pattern of use than mercury and that the risks of lead are not fully as salient as those of mercury, we have chosen not to propose any general ban on lead, but instead to focus the bans on two areas of application of great importance for direct release of the metal to the environment. This is complemented with other instruments for other areas of application (see further in section 7.4.2).

Direct emissions of lead in metallic form take place via ammunition and fishing sinkers. In the Government Bill ”Swedish Environmental Quality Objectives”, the Government makes the judgement that lead shot should

be banned. In its treatment of the Bill, the Riksdag made a declaration to the Government saying that the ban shall be combined with the option of exemptions in certain cases, pending the availability of satisfactory alternatives. It is the Committee's understanding that work is currently under way in the Government Offices on an ordinance prohibiting lead ammunition, where the need for exemptions or later effective dates for different areas is being considered. The Committee therefore offers no proposals for legislation.

In order to reduce emissions of lead in the form of fishing sinkers by voluntary means, the National Chemicals Inspectorate, in cooperation with the sport anglers' and water-owners' organizations, sponsored an information campaign in the spring and summer of 1999. It is still too early to judge the results of the campaign, but it should be followed up as soon as possible. At the same time, a final deadline for discontinuing the use of lead sinkers should be set, and we believe that the use of fishing sinkers containing lead should not be allowed after 2008.

7.2.2 Proposed environmental quality standards

The Committee's appraisal and proposals

- Environmental quality standards should comprise a policy instrument mainly for those substances that are not subject to a general phase-out.
- Environmental quality standards should be able to comprise an important policy instrument for limiting exposure to certain metals (other than mercury, cadmium and lead).
- The standards should be regarded as a complement to other policy instruments.

The Committee's appraisal and proposals

Our Committee is of the opinion that environmental quality standards should comprise a policy instrument mainly for those substances that are not subject to a general phase-out. Environmental quality standards could be used for the substances that are subject to the guidelines, but we doubt whether it is meaningful to have a standard for concentrations of a given substance, since the goal is that these particular substances shall be eliminated within one generation. The work regarding the

substances subject to the new guidelines in chemicals policy is thus primarily focused on a general reduction of the load – regardless of concentrations.

According to the Government's guidelines, metals may be used in the future if this use does not lead to harm to man and the environment. Environmental quality standards – which stipulate a concentration in the environment that is not to be exceeded since adverse effects can then occur – serve as a policy instrument for metals. A strength of environmental quality standards is that they are very close to the intentions of the guidelines. If the concentrations in the environment exceed the standard, this is a sign that the metal in question is being used in such a way that it is escaping on a scale that could cause harm to man and the environment. An action programme shall then be set up to reduce the releases.

Environmental quality standards should, however, not be the only policy instrument for metals, but a complement to instruments of a more preventive nature, since the "braking distance" from when a standard is exceeded until the problem is remedied can be very long. Moreover, adequate data for determining environmental quality standards are lacking for many metals.

At present there are only environmental quality standards for a few substances, one of which is atmospheric lead. That standard is primarily intended to protect human health. In the autumn of 1999, the Swedish EPA began a project to develop environmental quality standards for metals in lakes and watercourses. But it will take a few years before such environmental quality standards are available. It will take even longer for soil. Moreover, standards will only exist for a limited number of metals to start with.

One important, as yet unsolved problem when it comes to environmental quality standards for metals is whether they should be based on total concentrations or on the quantity of bioavailable metal. The latter is preferable, but is technically more complicated. Another question is whether the standards should be locally adapted, since the background concentrations vary. This also leads to a more complicated system than if the standards are set nationally with the possibility of special solutions in areas with naturally high background levels.

7.2.3 Proposals regarding environmentally hazardous activities

The Committee's appraisal and proposals

- In conjunction with review of a permit application for an environmentally hazardous activity, data shall be available on emissions and use of chemical substances that should be phased out according to the Committee's proposed phase-out criteria. The question of which rule changes this may require should be explored by the recently appointed Environmental Code Follow-Up Committee (M1999:03).
- The substances that are subject to the new guidelines on chemicals policy should be taken into consideration when general regulations (as per Chapter 9 Section 5 of the Environmental Code) are issued with regard to both emissions and use in chemicals and other products. The Environmental Code Follow-Up Committee should be commissioned to investigate the question of how general regulations can best be utilized as an instrument for phasing out such substances.
- The Government should commission the Swedish EPA to conduct sector-by-sector inventories to find out which sectors use substances subject to the Committee's phase-out criteria today, and which ones may be appropriate to regulate by general regulations. Ways to obtain voluntary commitments to phase out the substances in question should also be explored in this work.

he Government's new guidelines on chemicals policy are not only aimed at ensuring that products introduced on the market are free from certain substances. Two guidelines also have to do with production processes and emissions. They are formulated like this:

> *"Man-made organic substances that are persistent and bioaccumulative occur in **production processes** only if the producer can show that health and the environment will not be harmed. Permits and conditions under the Environmental Code are devised in such a way as to guarantee this guideline."*
>
> ***"**Metals are used in such a way that they are not released into the environment to a degree that causes harm to the environment or human health."*

Better information and knowledge needed

A valuable source of information for a decision on the use of chemicals in industry is the Swedish EPA's three-year project on chemicals use in industry. The purpose of the project has been to examine the risks to the environment and prioritize different possible measures. This has been done in cooperation with 14 different sectors. Different risk limitation measures have been discussed for 20–30 chemical substances in these sectors.

Besides interesting sector analyses and proposals, the Swedish EPA also draws some general conclusions, for example that a great difficulty in the work has been to obtain sufficient information to conduct a hazard analysis and a subsequent risk analysis. Companies, particularly small and medium-sized ones, are also poorly qualified to evaluate the information. This in turn influences their ability to make a good product choice.

A positive conclusion presented in the Swedish EPA's final report (Swedish EPA, 1999b) is that significant changes have occurred during the 1990s in e.g. the textile industry, the paint industry and the graphic arts industry. New technology has sometimes reduced the need for chemicals, and dangerous substances have in many cases been replaced with less dangerous ones. In many cases the customers have put pressure on the companies, influencing the positive trend.

The Swedish EPA finds that the engineering industry is more difficult to assess as regards the use of chemical substances. There are nearly 20,000 engineering companies in Sweden, most of which are small. A computer run showed that at least 2,000 chemical substances are used in the engineering industry, of which about 200 are dangerous in some way.

As far as the pulp and paper industry is concerned, the Swedish EPA's work showed that approximately 800 substances are used. In an earlier study from 1992, the Swedish EPA had listed some 20 substances that the industry should be particularly concerned about and preferably find substitutes for. In a follow-up in 1996, it was found that the use of only a few substances had declined, primarily chlorine for bleaching, while the use of other substances had increased or remained unchanged.

Permit review of environmentally hazardous activities

When an environmental court or county administrative board reviews an application for a permit for an environmentally hazardous activity, this shall be done in accordance with Chapter 1 Section 1 of the Environmental Code. The examining authority shall also apply the general rules of consideration in Chapter 2 of the Code, as well as the precautionary principle and the product choice principle (substitution principle). Passages in the Environmental Code Bill (Gov. Bill 1997/98:45, Part 1, pp. 162 ff. and Part 2, p. 8) make clear that the Environmental Code is an instrument for achieving environmental objectives set by the Riksdag and that the environmental objectives provide guidance regarding what requirements should be made on the operator of an activity. Emissions and use of substances that are to be phased out in accordance with the Government's guidelines, which have been adopted by the Riksdag, should thus be taken into account in the review of applications for permits for environmentally hazardous activities.

It is, however, not realistic to believe that this will happen if applicants are not required to furnish data on emissions and use of such substances in the activity. It could therefore be required that the data must be included in the application or in the environmental impact statement. The question of what rule changes are needed to introduce such requirements needs to be further explored, however. We propose that the question be investigated by the committee that has been commissioned to evaluate the implementation of the Environmental Code, i.e. the Environmental Code Follow-Up Committee (M1999:03, dir. 1999:109). This committee is supposed to devote special interest to the application of the Environmental Code's rules of consideration by courts and government agencies, and we therefore find that it should be particularly well-suited for this question.

General regulations

The Environmental Code allows general regulations to be issued for environmentally hazardous activities to a much greater extent than previous legislation. The Government may issue regulations or prohibitions on discharges of wastewater and solid substances and on gaseous emissions, or on the stockpiling of solid substances, in instances where the activity could give rise to pollution or other adverse effects in water areas, land or groundwater.

The idea behind providing for the possibility of issuing general regulations for environmentally hazardous activities is to replace permit issuance in individual cases.

In our opinion, the Environmental Code generally provides effective means for implementing the new guidelines on chemicals policy as far as production processes are concerned. Since present-day permit reviews of environmentally hazardous activities are supposed to take the precautionary principle and the product choice principle into consideration, the statutory framework already exists for dealing with the substances that are covered by the Government's new guidelines and defined in our proposals. But in order to more clearly define which substances are particularly urgent for environmentally hazardous activities, general regulations should also be able to include minimum requirements on emissions and handling of the substances defined in our proposals.

The Environmental Code is based on the principle that the Code's rules shall to a great extent be supplemented with regulations from the Government and regulatory authorities. Some of the laws that were brought together in the Environmental Code were framework laws, i.e. the law provided wide possibilities for regulating issues in ordinances and other regulations. This legislative technique was consistently implemented in the Chemical Products Act. On the other hand, the Environment Protection Act provided poorer possibilities in this respect due to the rules on individual review of environmentally hazardous activities. Nor did the Environment Protection Act provide sufficient possibilities for addressing problems caused by so-called diffuse (nonpoint) sources, or for achieving coordinated environmental solutions.

The Environmental Code is a framework law, which means that the Riksdag can draw up overall guidelines, leaving the details to the Government and regulatory authorities under the powers granted in the Code.

General regulations as an alternative and/or complement to individual review of environmentally hazardous activities for e.g. a given sector or type of facility should therefore serve as a good tool for the implementation of the Government's new guidelines on chemicals policy. The Environmental Code Follow-Up Committee (M 1999:03, dir. 1999:109) should be best suited to analyze the question of how general regulations can best be utilized as such a tool.

We believe that it should be possible to work with both general regulations and individual review. Both general regulations and individual review should focus on the essential basic requirements, which in our view should include the substances that should be subject to phase-out in accordance with the new guidelines on chemicals policy.

The Swedish EPA should draw on its experience and conduct sector-wise surveys to see which sectors currently use the substances that fall under the Committee's phase-out criteria and are suitable for the issuance of general regulations. In conjunction with this work, voluntary commitments from sectors to phase out the substances in question should also be considered.

7.3 Informational and market-driven instruments

This section deals with the softer instruments and tools which the Committee deems important; we call them informational and market-driven instruments.

7.3.1 National Chemicals Inspectorate's Observation List

The Committee's appraisal and proposals

- The National Chemicals Inspectorate should revise its Observation List – its introduction, language, explanatory texts, grouping of the substances (sequence) etc. – in the light of the viewpoints that have emerged in our evaluation. The purpose should be to make the list more user-friendly. Changes should be made in consultation with the different user groups and in consideration of the intended recipients' need for, and ability to comprehend, information on hazardous chemicals.
- Activity-specific information on hazardous chemicals should be furnished to a greater extent than today. The Government should consider commissioning the Swedish EPA and the National Chemicals Inspectorate to conduct a dialogue with a number of prioritized chemicals-using sectors on how activity-specific information on hazardous chemicals can be compiled and disseminated.

- The Inspectorate should revise its Internet-based information on hazardous chemicals, in the light of viewpoints that have emerged in our evaluation. Among other things, ways should be sought to develop present-day databases and search methods. The goal should be to create as complete and useful an information source as possible. The work should take into consideration the intended user groups' need for, and ability to comprehend, information on hazardous chemicals.
- The Government-appointed Committee for Ecologically Sustainable Procurement (EKU Committee), or the body charged with the task of administering the EKU Committee's tool for stipulating requirements in public procurement, shall furnish clear information, based on available knowledge and relevant rules, regarding what requirements can and should be stipulated when it comes to the use of chemicals in products and production processes.

Our Committee has evaluated the National Chemicals Inspectorate's Observation List. Our complete evaluation can be found in Annex 9; a summary of the evaluation is presented in this section, along with the Committee's appraisal and proposals.

The Observation List as an instrument

The studies that have been conducted in the course of our evaluation show that the Observation List has played a central role in the work of limiting the risks associated with chemicals use. The list is widespread and used both by companies and by the authorities in their chemicals oversight, in public procurement and in various projects and surveys at the local, regional and national level.

Many users regard it as a good aid in their chemicals work. It has, together with other measures, set in motion a process towards increased control and probably also decreased use of dangerous chemicals.

In the evaluation, however, problems have also been encountered in conjunction with the use of the Observation List, and it is, for pragmatic reasons, on these problems that we shall primarily focus in this section, not on the positive effects of the instrument.
The problems have largely arisen as a consequence of the fact that the Observation List is often used solely as a ”straight list”, i.e. the

occurrence of the substances that are on the list is checked, while substances that are not included as examples on the list but fulfil the list's criteria are seldom given the same attention. Moreover, the various actors seldom make risk assessments in conjunction with their use of the list.

The blame often lies with an inadequate knowledge of hazardous chemicals, caused by an insufficient allocation of resources for chemicals control and sometimes insufficient information.

The problems that have been identified should be viewed against the background of the very wide use of the Observation List. The recipient group is very large and heterogeneous, consisting of everything from environmental inspectors with a chemistry education to small companies that manufacture or import composite products. The broad range of use of the list, along with the large recipient group, probably lends it greater impact and effect, but also increases the risk of undesirable side-effects. It is of the utmost importance that information of the kind conveyed by the Observation List be adapted to its intended use and the intended group of recipients, and this is the purpose of the Committee's proposals.

The Observation List is well-established and many users regard it as a great aid in their chemicals work. It is therefore our firm opinion that the Observation List should continue to exist, albeit with some changes as well as additional information on hazardous chemicals.

Our general conclusion is that the information which the Observation List intends to convey must be made more user-friendly. The Observation List has had numerous positive effects, but certain changes and additions should enable the information to be disseminated and used to an even greater extent than today. To achieve this, the National Chemicals Inspectorate should revise the list in accordance with the first proposal in the above box. The information should further be broken down by sector so that it is better tailored to the different activities. The Inspectorate should also revise its Internet-based information.

National Chemicals Inspectorate should revise the design of the Observation List

The National Chemicals Inspectorate should revise the design of the Observation List – above all its introduction, language, explanatory texts, grouping of the substances (sequence) etc. – in the light of the viewpoints that have emerged in this evaluation. The purpose should be to make the list more user-friendly, and the changes should be made in consultation with the various user groups (companies etc.) and in consideration of the intended user groups' need for, and ability to comprehend, information on hazardous chemicals.

Many users have in the evaluation asserted that the Observation List as it is designed today is very functional and easy to use. Others, however, have offered the opinion that use of the list could be facilitated by certain changes.

Another viewpoint that has been offered is that extensive knowledge of chemistry is needed to use the list properly. Many companies and agencies therefore think the list should be made simpler so that it can be used in the proper manner to a greater extent than today.

One thing that many people have suggested is that it should be explained more clearly *why* a substance is dangerous and therefore included on the list. The Committee presumes that this viewpoint stems from the fact that many users find it difficult to interpret the criteria for danger to health and the environment that are described in the introduction and then referred to by different letters. One improvement would be to complement the criteria with explanations of terms such as ”bioaccumulation”, ”low degradability”, etc. Perhaps the hazard or danger could also be expressed in simpler language without compromising the scientific precision in the actual criteria.

Otherwise it is not so easy to see how the list could be made ”less chemical”, as some users have wished. This problem should therefore be examined in consultation with different user groups. The same applies to the language, which according to certain interview subjects should be simplified.

The fact that the Observation List is a selection of examples – far from complete – and that all substances are not subject to restrictions should be explained as clearly as possible. Apparently this information has not

reached all recipients, despite the fact that it is pointed out in the introduction. Many users probably do not read the introduction.

Many users feel that it should be stated more clearly in what contexts the substances can occur – which sectors, which product types, etc. The Committee finds that these wishes can also be met by means of more activity-specific information.

Another viewpoint that has been offered is that the Observation List should be made more complete, i.e. include more substances, which would reduce the risk of replacing one substance with another that is equally or more dangerous, but is not included on the list. At the same time, the viewpoint has been expressed that it becomes more complicated for the users, particularly small enterprises, the more substances are listed.

The Committee's recommendation in this question is to await the development of a more general system with activity-specific information to see what the future role of the Observation List should be. Perhaps it could then become a more general and comprehensive list from which more specific lists could be derived.

Another viewpoint is that the substances on the list should be grouped in a more functional manner. One suggestion that has been offered is that the list should follow the classifications of substances used on the material safety data sheets.

A suggestion which we have considered is that the legal text concerning the product choice principle should be included in the introduction to the Observation list. But our conclusion is that this is not appropriate, since the list would then be too closely linked with the product choice principle. This could lead to further misunderstandings of the nature that whatever is on the list should be avoided in all circumstances, while substances not included are suitable substitutes. It is in part for the purpose of avoiding such misunderstandings that the list does not have the status of a "general recommendation" from the National Chemicals Inspectorate. According to the contacts we have had with the Inspectorate, they concur in our judgement.

An addition that should be considered in the introduction to the Observation List is a "step-by-step instruction" on how companies should go about using the list. Such an instruction should describe the steps that should be taken by a company in using the Observation List in

its internal chemicals control, plus the questions of importance which the company should find answers to:

- Is the substance on the Observation List?
- Does the substance fulfil the list's criteria?
- Where can data on the substances be found?
- How is the substance used?
- How can the substance be tested if data are not available?
- How is a risk assessment performed?
- Where can further help and information be obtained – databases, public agencies, trade organization, consultant, etc.?

Activity-specific information is needed

The need for activity-specific information on dangerous chemicals has been confirmed from many sources. Breaking down the information provided by the Observation List by sector or field of activity could be a solution to many of the problems that have emerged in the evaluation. Activity-specific lists and information already exist today, compiled by certain trade organizations and individual companies.

Some of the problems that have existed in connection with the Observation List stem from the fact that use of the list is relatively seldom based on risk assessments, and that the list's criteria are relatively seldom used to identify dangerous substances that are not on the list.

Due to the fact that use of the list is not based on risk assessments – which means that it does not take into account how the substance is used, in what quantities, degree of exposure etc. – the list has in some cases been used as a prohibition list. The substances are banned, regardless of area of application etc. This can in some cases lead to undesirable effects.

Quite a few people have pointed out that if the list's criteria are not used, there is a risk that "wrong" substitutions will be made, i.e. that a substance from the list will be replaced with an equally dangerous, or even more dangerous, substance that is not on the list. Another negative effect to which the relatively sporadic application of the criteria gives rise is that fewer dangerous substances are singled out and targeted for substitution and other risk mitigation measures, since the Observation

list is only a list of examples. If the users are content to look only for the substances included on the list and do not use the criteria, they may miss other dangerous substances used in production.

Information that is tailored according to, for instance, what substances are used in a given activity and how they are used can contribute to avoidance of the problems described. More substances can be singled out. It should be considered whether the limit of one tonne – the quantity that must be exceeded for a substance to be included on the Observation List – could be abolished. This cut-off was used so that the Observation List would not be too long, but the problem is not as acute if the list is broken down into several lists.

The list should also provide information on certain additional substances identified with the aid of the criteria. In this way the risk of ”wrong” substitutions as described above can be limited.

The activity-specific information could also be elaborated. It could tell where in production and in what types of products various dangerous products can occur, and in which use the risks posed by the different substances are great or small. Based on existing knowledge, the list could also provide information on various measures to limit the risks of the substance – depending on in what context the substance is used. This information can probably only be made effective if it is tailored to the activity in question. Risk limitation measures could include using other technologies where the substance is not needed to the same extent or is not needed at all, changes in product development, etc. Information of this kind could lend the ”nuance” to the information on the hazards of different chemicals which many users feel is lacking today. In other words, it can lead away from the problem that all dangerous substances are banned, regardless of risk.

The Swedish EPA’s surveys of chemicals use in certain sectors (Swedish EPA, 1999b) should be able to serve as a basis for the formulation of activity-specific information.

Division of responsibility between government and industry

Activity-specific information on hazardous chemicals should be furnished to a greater extent than today. In the opinion of the Committee, responsibility for collecting, updating and maintaining activity-specific information of the kind described should rest with the sector in question,

in keeping with the obligation of the party conducting an activity to acquire the knowledge that is needed, in view of the nature and scope of the activity, to protect human health and the environment (Chapter 2 Section 2 of the Environmental Code).

In its report ”Market-driven chemicals work” (in Swedish only), the National Chemicals Inspectorate recommends that the sectors and trade organizations should offer recommendations and guidance on how the chemical issues should be tackled in different activities. The Committee concurs with this and with the Swedish EPA’s conclusion in its final report on the work with a chemical plan: that the trade organizations have a vital role to play by facilitating the transfer of information to above all small- and medium-sized enterprises (Swedish EPA, 1999b).

A particular sector is in a much better position to keep track of the development of products and technologies than, for example, a government agency. It is of the utmost importance that the information be kept up-to-date – for example regarding the use of new substances in production, or new-found knowledge on alternative or environmentally preferable substances and technologies.

A sector-oriented dialogue between government and industry is needed

The Government should consider commissioning the Swedish EPA and the National Chemicals Inspectorate to conduct a dialogue with a number of prioritized chemical-using sectors on how activity-specific information on hazardous chemicals can be compiled and disseminated. The importance of a dialogue is also emphasized in the Inspectorate’s report ”Non-toxic environment” (National Chemicals Inspectorate, 1999, in Swedish only).

In order to get this compilation of activity-specific information on hazardous substances going, it is desirable that the national authorities conduct a dialogue with a number of prioritized sectors on how activity-specific information should be gathered. An important start to such a dialogue is the Swedish EPA’s work with chemical plans within different branches of industry. An important function for such a dialogue is to disseminate knowledge from the authorities out to the sector, but also between the different sectors.

The project should initially be conducted for at least a couple of years. Depending on the outcome, the possibility of increasing the number of

sectors included in the dialogue can then be considered, along with whether the project can be supplemented or replaced with other work forms. The goal should be to get an ongoing effort going in as many sectors as possible to compile activity-specific information of the kind described in our evaluation of the Observation List (Annex 9).

Internet-based information should be developed

Our Committee proposes that the National Chemicals Inspectorate revise its Internet-based information on hazardous chemicals. Among other things, ways should be sought to develop present-day databases and search methods. The goal should be to create as complete and useful an information source as possible. The work should take into consideration the intended user groups' need for, and ability to comprehend, information on hazardous chemicals.

In our evaluation of the Observation List (Annex 9), it has emerged that the Inspectorate's website is a well-used information source regarding chemicals. Both companies and government agencies use it, for example to consult the Observation List. However, voices have been raised that this Net-based information could be made even better.

One wish that has been expressed is that it should be made easier to search on individual substances to obtain more complete information. The Inspectorate should explore whether it is possible to develop a broader search base, where data on the known health and environmental hazards of individual substances can be found, along with whether the substance is on the Observation List, subject to restrictions, meets other criteria for persistence, bioaccumulation or toxicity, etc. Where possible, it should also be explained, in as pedagogical and clear a manner as possible, why the substance is hazardous to human health or the environment. Furthermore, there should be links to activity-specific lists and other useful sources of information.

The Inspectorate's database could be of a general character, on the basis of which more activity-specific information can subsequently be obtained.

As use of the Internet spreads, it is becoming possible to reach more and more recipients this way. Even small enterprises can obtain access to comprehensive and useful information in a resource-efficient manner.

The Inspectorate should take immediate action to see whether minor changes to its website (http://www.kemi.se) can be made to make it even easier to quickly find the Observation List, since complaints have been made that this is not so easy.

7.3.2 Public procurement

The Committee's appraisal and proposals

- Public procurement could be an important driving force for phasing out the hazardous substances that are subject to the new guidelines on chemicals policy.
- In public procurement, it should be possible to require that the chemical products or finished products that are being procured not contain substances subject to the Committee's proposed criteria for phase-out.
- Use of the National Chemicals Inspectorate's Observation List in public procurement should be clarified.

Our Committee finds that public procurement could be an important driving force for phasing out the hazardous substances that are subject to the new guidelines on chemicals policy. In our evaluation, however, purchasing officers and others have reported that it can be difficult to determine how much importance should be accorded in procurement to environmental requirements, for example when it comes to chemicals. It has, for example, emerged that requirements are made according to the Observation List, but that when the time comes to choose a supplier, it is not clear how much consideration should be given to whether the requirements are met or not. As a result of difficulties of this kind, purchasing officers and others have called for clearer central guidelines regarding environmental requirements in procurement.

The Committee for Ecologically Sustainable Procurement (M1999:01, known as the EKU Committee) is charged with the task of actively promoting the integration of environmental considerations in public procurement. The new common tool/manual for ecologically sustainable procurement by state agencies, municipalities and county councils which the EKU Committee is in the process of producing also deals with requirements on chemical substances.

Our Committee believes that it should be possible in a procurement to require that the substances subject to the Committee's proposed criteria for phase-out not be contained in the chemical products or finished products that are being procured. A purchasing officer should also follow up such a requirement, so that, for instance, the substances to be phased out are not replaced with substances that still have unknown properties.

In other words, public and private purchasing officers should be able to require that the products being procured (e.g. computers, chemicals and building materials) do not contain persistent, bioaccumulative, carcinogenic, mutagenic and reproduction-toxic substances that fall under our phase-out criteria. The same requirements should be able to be made on mercury, cadmium and lead, which are also mentioned specifically by the Government in the new guidelines. We also wish to point out that EU rules exist in this area and should be followed.

When it comes to the use of the National Chemicals Inspectorate's Observation List as a tool in public procurement, we find that it should be clarified how the Observation List can and should be used in procurement.

7.3.3 Positive ecolabelling

The Committee's appraisal and proposals

- Positive ecolabelling is of great importance for getting out information on green products to consumers and small enterprises.
- In order for positive ecolabelling to fulfil its function, it needs to be extended to more product groups. As long as it is in an expansion phase, the need for some state aid may have to be considered – both in the form of financial funding and assistance by experts from the government agencies in the formulation of new criteria.
- Products containing substances subject to the new guidelines (according to the criteria proposed by the Committee in Chapter 5) should of course not be able to obtain a positive ecolabel.

Description of the systems

Voluntary positive ecolabelling is an important means for conveying information to the consumers on the environmental properties of different products for the purpose of effecting environmental improvements. The purpose of such labelling is that it should guide the consumers to choose the least environmentally harmful products and stimulate the producers to develop products that are less environmentally harmful than other comparable products.

There is often a strong societal interest in ecolabelling, evidenced by the fact that the state has in many cases played an active role together with other stakeholders. The ecolabelling systems are also characterized by broad participation of the actors on the market.

Voluntary ecolabelling can be divided into three types or categories:

- *Type I is ecolabelling with symbols, which is certified by a third party*. This third party ensures that the criteria for the ecolabel are satisfied. The symbol guarantees the product's good environmental characteristics and is affixed to, or close to, the product or the packaging. The most common ecolabels of this type are the Nordic Swan, the EU flower and the Good Environmental Choice Falcon. For food products there is the KRAV (organically grown) label, and for forest products there is the FCS (Forest Stewardship Council) label.

  The Swan is the official Nordic ecolabel for products that satisfy criteria set up by SIS Miljömärkning (SIS Ecolabelling). The EU flower is the EU's equivalent of the Nordic Swan. The Good Environmental Choice Falcon is the Swedish Society for Nature Conservation's symbol for the products that satisfy the Society's criteria.
- *Type II are the companies' self-declarations*. These are claims made by the companies and marketers concerning the environmental characteristics of the product, and they can be expressed in words or symbols. The statements are not checked or verified by any independent party.
- *Type III are environmental product declarations for goods and services.* The product's environment-impacting properties from a life cycle perspective are fully accounted for. The background is that companies are increasingly imposing environmental requirements on each other, which requires knowledge concerning the products' environmental impact. The information is verified by a third party.

The main target group is professional purchasers, and the idea is that the purchaser should compare the environmental aspects of different products and determine if the product is acceptable from an environmental viewpoint. The environmental product declarations make exacting demands on the consumers in terms of knowledge level and time to evaluate the information.

Below is a brief summary of some of the most common ecolabelling systems.

The Nordic ecolabel – the Swan

The ministers responsible for consumer affairs in the Nordic Council of Ministers decided in 1989 on guidelines for a harmonized, voluntary and positive ecolabelling of products. The symbol of the Nordic system is a stylized swan with the word ecolabelled.

The Swan has had good impact. Today there are criteria for 46 product groups, and there are more than 1,500 Swan-labelled products on the Swedish market, including toilet paper and paper towels, all-purpose cleaning agents, dishwashing liquids, sanitary cleaning agents, shampoos and soaps.

In a framework agreement, the countries agree to approve of each others' administration of the ecolabelling, each others' choice of testing institutes and each others' control and issuance of licenses on the basis of common criteria documents. The framework agreement is associated with a set of rules and procedures for determination of ecolabelling criteria and ecolabelling of products. The organizations' competence, registration of ecolabelled products etc. are also regulated.

A Nordic coordination body (NSO) exists as a common forum within the secretariat of the Council of Ministers.

In Sweden, the ecolabelling work is governed by an agreement between the state and the Swedish Institute for Standards (SIS). Starting in 1998, it is administered by SIS Miljömärkning AB (SIS Ecolabelling Co). This company is owned jointly by the state and SIS, and may not operate for profit.

The work of ecolabelling entails criteria development, information and marketing, licensing and market oversight. Criteria development, market

oversight and licensing of products take place on a national level. The Nordic countries have divided responsibility for ecolabelling among themselves. Sweden, for example, is responsible for white goods.

The country that proposes ecolabelling of a product group is also responsible for criteria development. To facilitate the final adoption of the criteria, the expert groups are as a rule composed of representatives of all the participating Nordic countries.

A company that wishes to label its product with the Swan applies to the ecolabelling body in the country that has developed the criteria for the product. The national ecolabelling organization conducts an investigation of the product and notifies the other Nordic countries of issued licences.

The criteria document stipulates what tests, analyses and examinations have to be carried out to verify that stipulated requirements are satisfied. The applicant is in principle free to choose any testing institute, laboratory etc. that is impartial and competent to carry out the testing in question. To the extent there are accredited laboratories for the analyses in question, they shall be utilized. Tests conducted in the manufacturer's own laboratory can in some cases be approved, the same being true of scientific reports after examination and evaluation.

In the work of developing criteria, the impact of the product is assessed during its entire life cycle. The criteria shall include both environmental requirements and requirements on function and quality. The period of validity of the criteria is generally three years.

The ecolabelling organization itself can also carry out inspection of production plants etc.

The licensee and the ecolabelling body shall carry out follow-up to make sure that a licensed product complies with stipulated requirements. If the licensee abuses a licence, it may be revoked.

The state contributed financially to building up the Nordic system. However, the long-term objective is that ecolabelling should be self-financing via remunerations and fees paid by the companies whose products are ecolabelled. The aid that has been paid to ecolabelling in recent years has been justified by the fact that the Nordic ecolabelling system required extensive Nordic cooperation. The aid has been intended

as a subsidy to cover the costs of criteria development and revision of already adopted criteria.

The Consumer Policy Committee 2000 proposes in its report on Nordic ecolabelling (SOU 1999:145) that the state aid be gradually reduced and, as of the end of 2001, be limited to aid for such development work as is not immediately economically profitable.

The Nordic Council of Ministers has commissioned an evaluation of the environmental effects of Swan labelling and what the consumers know about the labelling. The evaluation will also study how the labelling has worked as a tool of environmental and consumer policy. The results will be presented to the Council of Ministers at the end of 2000.

Swedish Society for Nature Conservation's Good Environmental Choice Falcon

The Swedish Society for Nature Conservation launched its own ecolabelling system in 1992 in close cooperation with the distribution chains ICA, KF and Dagab. Some cooperation also exists with the KRAV label, which covers organic farm produce.

Criteria development for the Good Environmental Choice Falcon has so far been concentrated on convenience goods. The criteria apply solely to the products' environmental characteristics; no functional requirements are stipulated. A special board consisting of an equal number of representatives from the Swedish Society for Nature Conservation and the retail trade is in charge of the programme. It is the board that decides what criteria are to be developed. The aim is to assess the product's environmental impact during its entire life cycle. A proposal is first circulated to concerned parties for comment, after which the criteria are adopted by the secretary-general of the Society.

Today, environmental criteria have been adopted for 13 different categories of products and services, such as detergents, cleaning agents and shampoos. Once the criteria have been adopted, interest companies can apply for permission to use the ecolabel. The applicant must submit precise and verified particulars on the product. If the product is approved, the company has to pay a licence fee for the right to use the ecolabel. The Society then has the right to perform recurrent inspections at the licensee's premises. If the product no longer satisfies the terms of the licence, the licence may be revoked.

The EU flower

The European Community decided to introduce an ecolabelling system in 1992. The rules have been approximated in Swedish legislation via the Act (1994:609) on a European Ecolabelling System. The system is a voluntary, positive system whose goal and structure are similar to the Swan labelling system. The symbol is an ”E” in a stylized flower, and the label is normally called the EU flower. The purpose is to harmonize nationally based ecolabelling.

The Commission makes decisions on criteria after a vote by a regulatory committee consisting of representatives of the member states. Concerned interest groups are consulted before such a vote is taken. There is also a consultation forum in which representatives of European industry, commerce, consumer organizations and environmental organizations participate.

Each member state shall designate a competent body to administer the system nationally and participate in the establishment of new criteria. The member states shall ensure that the competent bodies are composed to guarantee their independence and neutrality.

In Sweden, SIS is the competent body according to the Ordinance (1994:1169) on European Ecolabelling. SIS Miljömärkning is in charge of the work, according to the Ordinance.

Criteria development within the EU is initiated by the Commission or a competent body after a proposal from e.g. industry. The Commission’s committee and consultation forum prioritize and distribute the criteria development work to the competent body or bodies who volunteer. Criteria development follows a special procedure that is divided into phases with intervening decisions by the Commission and consultations of both the consultation forum and other bodies. In the final phase, the responsible competent body presents the proposal to the Commission who, after preparation in the consultation forum and the committee, can adopt the proposal by qualified majority in the latter body. If a qualified majority is not obtained, the matter is turned over to the Council of the European Union. As in the Swan system, there is a built-in dynamic in that the period of validity of a licence is limited to about three years.

The EU flower, like the Nordic Swan, is financed by an application fee and an annual fee paid by the applicant. The member states set and collect the fees themselves.

The system has not yet become widely accepted on the European market. So far the Commission has only adopted criteria for 14 product groups, and on the European market only about 200 products are labelled with the EU flower today, mainly paints.

Green brands

During the 1990s, green brands were launched by most large companies in the convenience goods trade. Many of these products also carry one of the certified ecolabels.

Are the consumers aware of the ecolabels?

Consumer perception of labelling and other consumer information has been the subject of a number of different surveys in recent years. TEMO AB and Kooperativa Konsumentgillet conducted surveys on consumer perception of ecolabelling on behalf of the ”Committee concerning Consumer Information on Convenience Goods” (see SOU 1997:7).

Certain respondents were found to have inadequate knowledge of the certified ecolabelling. They had difficulty distinguishing the certified ecolabels from the green brands. The level of recognition regarding the Swan and the Good Environmental Choice Falcon is, by contrast, high. The majority of the respondents usually also read information provided on the products’ (household chemicals, food and sanitary products) packages.

When it comes to household chemicals and sanitary products, the majority of the respondents read text that has to do with the dosage of the product. Many of them also read instructions for use, warnings and allergy and environmental information.

To see how the results of the commissioned surveys compared with the results of similar consumer surveys, the ”Committee concerning Consumer Information on Convenience Goods” went through relevant surveys in the field. The Committee found that the Swedish Consumer Agency (KOV) conducted three surveys of the environmental awareness of Swedish consumers during the period 1993–1995. The surveys were each based on 1,000 interviews of persons aged 16–74 years. The results showed that the level of recognition is relatively high when it comes to

symbols and green brands, and that the respondents have a relatively good idea of what the brands stand for. The results also show that there are clear differences between men and women as regards recognition of these brands. Of the respondents, 36 percent regularly read the list of ingredients or looked for ecolabelled products, and 33 percent reported that they sometimes buy such products (KOV, 1995/96:13).

The Swedish Consumer Agency's report "Knowledge, attitudes and behaviour of the public in environmental questions" (KOV 1998:7, in Swedish only) found that more than 90 percent of the respondents buy ecolabelled products. These persons are also prepared to pay a higher price if they know the products are environmentally compatible.

The Committee's appraisal and proposals

In the view of the Committee, positive ecolabelling is one of the most important policy instruments for getting consumers and small enterprises to take responsibility for sustainable development. Labelling is an effective way to convey knowledge of the products' environmental impact, since it is available prior to purchase, is easy to understand, weighs together the various important characteristics of the products and is reliable.

It is an effective way to convey knowledge of the products' environmental impact in a comprehensible fashion and at the right time during the purchasing process. We therefore consider it to be very important that more product groups are included in positive ecolabelling in the future.

As long as ecolabelling is in an expansive phase, state aid may be important, possibly in the form of both financial funding and assistance by experts from the government agencies in the formulation of new criteria.
Regarding state financial aid to the Nordic ecolabelling body, we think there is reason to consider whether state aid to the Nordic Swan ecolabelling system should be continued. The goal should be that the activity is self-supporting. But there may be a need in an expansive phase to provide financial support for participation in development work (criteria for new product groups) that is important from an environmental point of view but not economically profitable in the short term. The justification for the aid that has been given to ecolabelling in recent years is that the system requires extensive Nordic cooperation.

The purpose of the aid has been to cover the costs of criteria development and revision.

In the light of the new guidelines on chemicals policy, we would particularly like to emphasize that products that contain substances subject to the new guidelines according to the criteria proposed by the Committee in Chapter 5 should naturally not be able to obtain a positive ecolabel from any ecolabelling organization.

7.3.4 Environmental product declarations

The Committee's appraisal and proposals

- Information on the product's content of chemical substances should always be included in an environmental product declaration. The life cycle assessment on which the declaration is based should be such that it fully covers the impact on health and the environment caused by chemicals.

AB Svenska Miljöstyrningsrådet (the Environmental Management Council) presides over a national system for certified environmental product declarations, EPDs. They have developed requirements for certified EPDs, based on ISO/TR 14025. The Environmental Management Council and SMS (Swedish Materials & Mechanics Standards), in collaboration with industry representatives, are preparing product-specific information for EPDs based on these requirements. Product-specific premises are being devised as guidance for the life cycle assessment (LCA) on which certified EPDs are based. At present, product-specific premises have been determined for some ten or so product groups. Certified EPDs are registered with the Environmental Management Council; so far, eight certified EPDs have been registered.

The system is self-financing via fees. The system shall be open and accessible to all the market's actors in the field.

The target group for EPDs is primarily manufacturers and professional purchasers in industry and public administration. EPDs may also reach individual consumers when they purchase capital goods, but the intention is not to replace or compete with ecolabelling of type I (e.g. the Swan or Good Environmental Choice).

The EPDs contain no evaluation of environmental impact and environmental soundness, but are based on a quantitative description of important environmental properties, which are to be examined and approved by an independent and competent third party.

The idea is that the purchaser should compare the environmental aspects of different products and decide if the product is environmentally acceptable. It makes exacting demands on the consumers in terms of both knowledge level and time to evaluate the information.

EPDs are based on life cycle assessments (LCAs), and there are several methods for making such assessments. The methods produce rather different results, depending on how boundaries are drawn etc. – certain methods place a great emphasis on material consumption, others on energy consumption, etc. Several methods have recently been updated, or will be updated within the near future. The new generation of LCAs make greater allowance than before for exposure conditions and actual effects.

The integration of chemical aspects in the assessments varies between the different methods. SETAC Europe is working on a model for environmental impact assessment which, on the chemicals side, is based largely on methodology from risk assessment of existing substances in the EU and thereby makes a relatively far-reaching analysis of the impact of chemicals.

The Committee's appraisal and proposals

We believe that requirements on information concerning the product's content of chemical substances should always be included when requirements on product-specific environmental information are developed as a point of departure for environmental product declarations in new product groups. It is most urgent that information be furnished on the content of substances that are classified as dangerous to health or the environment and on the product's main constituents.

The life cycle assessment on which the declaration is based should also include the impact on health and environment caused by chemicals.

7.3.5 Environmental management systems

The Committee's appraisal and proposals

- The use of environmental management systems should be promoted.
- Chemical aspects should be clarified in the environmental management systems that are used. Use of chemicals should be included in the environmental statement's summary of data concerning the organization's environmental work (see section 6.10).
- Incentives that can lead to increased use of environmental management systems should be analyzed. A particularly important question is how small and medium-sized enterprises can be stimulated to implement environmental management systems.
- The supervisory authorities' competence on environmental management systems should be raised.
- The certification bodies' competence on chemical aspects should be raised.

Environmental management systems (EMSs) are tools for systematizing the environmental work in the private as well as the public sector. EMSs stipulate clear guidelines and goals in central control documents, clear divisions of responsibility, follow-up procedures and reporting of the results of the environmental work. Another requirements is that the EMS shall lead to constant improvements.

All companies and other parties conducting activities have a statutory environmental responsibility, and their environmental efforts are largely based on their taking this responsibility seriously. The companies' own commitments and initiatives are important and drive progress in the protection of health and the environment. This assumption of responsibility should be encouraged.

Voluntary EMSs aim at providing private- and public-sector organizations with tools for conducting preventive and cost-effective environmental work. The idea is also that they should give the companies who implement the systems market and competitive advantages. The implementation of an EMS is completely voluntary on the part of the companies.

ISO 14001 and EMAS are the two best-known environmental management systems and are becoming increasingly widespread in the business sector. Both of the systems were developed during the 1990s.

ISO 14001 is an international standardization system that is mainly intended to serve as an internal management system for quality-assuring the company's own environmental work. ISO 14001 has an important international dimension. It is one of the few tools on the market used by companies all over the world in their environmental work. EMAS is the EU's environmental management system (dealt with in section 6.10).

Sweden is one of the countries in the world with the largest number of certified/registered companies, but EMSs have begun to acquire increasing importance in Japan, Germany, the UK and the USA as well.

The Committee's appraisal and proposals

In section 6.10 we discuss EMAS and offer our opinions and proposals on how EMAS can be developed to deal adequately with chemical aspects. In section 8.6 we discuss the question of how chemical aspects should be clarified in ISO 14001. In this section we discuss national measures.

We conclude that the advantages of EMSs is that they provide a means for streamlining the environmental work in companies and public agencies. Often, companies with EMSs have internal requirements that are tougher than the relevant statutory requirements. Furthermore, EMSs provide a means for continuous development of the environmental work. In our opinion, incentives that can promote EMSs should be more thoroughly examined. There are various kinds of incentives for EMSs in several countries in Europe, for example the Netherlands, Germany and Denmark.

Many small and medium-sized enterprises may also lack the financial or knowledge resources to implement an EMS. A special question that needs further analysis is how such companies can be stimulated to implement EMSs. The work of NUTEK (Swedish National Board for Industrial and Technical Development) is important in this context. Experience from most companies who have tried to develop an EMS is that the costs of developing the system are quickly offset by more efficient operations.

In section 6.10 we conclude that the importance of the chemical aspects in the EMAS needs to be strengthened, and in section 8.6 we deal with the same question for ISO 14001. Moreover, we feel that the importance of the chemical aspects in the practical application and verification of EMAS and ISO 14001 needs to be strengthened. As regards the chemical aspects, we have therefore seen a special need to raise the competence of the certification bodies in these matters. The dialogue between government agencies and certification bodies should also be intensified. The competence of the supervisory authorities concerning environmental management systems in general may also need to be raised in many cases. Oversight should be able to be changed for organizations with EMSs.

7.4 Proposed continued work

In this section we present proposals for continued work in Sweden. The proposals have to do with commissions to committees of inquiry and commissions to government agencies.

7.4.1 Proposed further inquiries

The Committee's appraisal and proposals

- In order for the Government's guidelines to be fully implemented, the use and/or composition of *petroleum-based fuels* needs to be changed. A committee of inquiry should be appointed for the purpose of investigating how to better promote the use of vehicles that produce considerably lower emissions of e.g. carcinogenic substances via the vehicle tax and other policy instruments. The committee should also examine ways to encourage the use of fuels with low or no content of carcinogenic substances in applications where some of the fuels can be expected to be emitted in uncombusted form (e.g. from older highway vehicles or non-road vehicles).
- A system for *health and environmental information on products*, which includes information on chemical content, is needed to make it possible to know in what products the substances subject to the guidelines occur. How such a system should be designed should be specially investigated.

- *Limit values for sludge* should exist by 2012 for all metals used in Sweden. The Swedish EPA should be commissioned to propose limit values for metals that are not listed today in the Ordinance on Prohibition in Connection with Handling, Importation and Exportation of Chemical Products Etc. (Certain Cases) (1998:944), and review existing limit values. The limit value for cadmium in sludge should in particular be reconsidered with the aim of lowering the value.

We also propose inquiries at other places in this report. They concern:

- Product directives and product standards (section 6.8),
- Sector-by-sector inventories (section 7.2),
- General regulations according to the Environmental Code (section 7.2),
- Activity-specific information on hazardous chemicals (section 7.3),
- Priority substances that should be subject to global restrictions (chapter 8).

7.4.1.1 Petroleum-based fuels

Existing rules and ongoing work

Petroleum and many products made from petroleum contain carcinogenic substances. It is also likely that many substances that fall under the criteria for bioaccumulation and persistence will be in this category. When organic substances in petroleum-based products undergo combustion, they are optimally converted to carbon dioxide and water and thereby do not constitute any local health problem. However, there are several areas of application where far from all the fuel undergoes combustion. Instead, some is emitted in uncombusted or only partially combusted form to the air. This can occur as a result of evaporation between occasions of use or incomplete combustion in the engine. There are two ways of solving the problems of dangerous substances in fuels. One is to optimize combustion and prevent uncombusted substances from being emitted by evaporation. The other is to alter the composition of the fuel as such and reduce its content of dangerous substances.

Quality requirements exist today for both diesel fuel and petrol in Directive 98/70/EC of the European Parliament and of the Council relating to the quality of petrol and diesel fuels. The requirements

concern e.g. the content of aromatic hydrocarbons. For petrol, the requirements limit the benzene content to no more than 1 percent by volume. As from 2005, the EC requirements on petrol and diesel fuel will be further tightened. These requirements have not been finalized today. A proposal from the Commission is expected during 2000. The stricter rules will be based on the Auto-oil work.

An environmental classification system has existed in Sweden since the early 1990s whereby the lowest tax rate is imposed on petrol or diesel fuel that meets the strictest requirements. This further stimulates improvements in fuel quality.

In addition to the quality requirements on the fuel, there are also exhaust emission requirements for motor vehicles which are being progressively tightened. The exhaust emission requirements are met by improvements of the engines and by emission control equipment. Since 1989, Sweden has had such tough exhaust emission requirements that catalytic converters have been required to meet them. Catalytic converters break down substances such as benzene, but today's converters must be hot to work properly. Cold starts are therefore a considerable source of emissions of benzene and other volatile organic substances in urban air. These emissions can be reduced by the use of engine block heaters or other heating systems in the vehicle. As from 2002, special exhaust emission requirements will be introduced in the EU for cold starts at low ambient temperature. These more far-reaching exhaust emission requirements for new petrol-fuelled cars are expected to cut auto emissions of e.g. benzene by half.

A remaining significant source of emissions is evaporation from carburettors and petrol tanks. These "fugitive" emissions are particularly great from older-model cars (before 1989) which are not equipped with carbon canisters. In these cases, a restriction of the quantity of carcinogenic substances in petrol is of great importance.

Another area where fuel quality makes a difference is for engines where exhaust emission requirements have not yet been introduced, e.g. lawn mowers and pleasure craft. In such applications, some of the fuel passes out without being combusted. For example, 20–30 percent of the fuel passes uncombusted through an outboard two-stroke boat engine (Ahlbom & Duus, 1999). An EU project is currently under way to develop exhaust emission requirements for engines where such requirements are lacking today. So-called alkylate petrol, which does not contain any aromatic hydrocarbons at all, was originally developed for

use as a fuel for chain saws, but can also be used for other motorized implements and in boat motors. Alkylate fuel is taxed as ordinary fuel of environmental class 1. Special tax subsidies for this type of fuel have previously been proposed by the Environmental Class Committee (SOU 1996:184).

In April 2000, the Emissions Research Committee proposed a ten-year programme for emissions research (SOU 2000:35). The programme will be a joint project between government and industry. The purpose is both to reduce emissions and give Swedish industry a lead in the development of vehicles and fuels.

The Committee on Environmental Objectives describes within the framework of the objective of clean air (see section 2.3.2) a number of measures of importance for reducing emissions of carcinogenic substances from fuels, the most important of which are presented below. (For a more detailed account of the proposals, we refer to the report of the Committee on Environmental Objectives, SOU 2000:52):

- Premature introduction of 2005/2006 exhaust emission requirements for light-duty vehicles, further reducing hydrocarbon emissions.
- Reduction of volatile organic compounds in industry, for example at oil depots and refineries, is implemented via the Environmental Code.
- New exhaust emission requirements for pleasure craft engines from 2003.
- New exhaust emission requirements for snowmobiles. The requirements are based on the Environmental Class Committee's (SOU 1996:184) proposals and are proposed to enter into force in 2003.
- Premature introduction of non-road vehicles with better emission control. This alternative entails the implementation of stage 3 of the exhaust emission requirements via economic instruments or the like from 2006.
- The National Road Administration should, in its sector role, inform the business community and households on how they can reduce both their environmental impact and their costs by various means. This involves educating and informing companies on how they can improve their transport efficiency by an increased load factor, cargo consolidation, a fuel-efficient driving style, choice of environmentally-friendly vehicles, etc. For households, it involves educating and informing them about the environmental benefits of lower speeds, a fuel-efficient driving style, car-pooling, bicycling etc.

The Committee's deliberations and proposals

Correcting the problems caused by the use of petroleum-based fuels requires instruments that go beyond those normally used in chemicals policy. The question has a great bearing on Swedish energy and transport policy. In view of this, our Committee has not considered it possible to include the petroleum-based fuels in its phase-out proposals.

On the other hand, the Committee considers the question to be of great importance for the feasibility of implementing the Government's guidelines and achieving the objective of a non-toxic environment. We therefore believe that the proposals presented by the Committee on Environmental Objectives within the framework of the objective of clean air will significantly reduce future exposure to petroleum-based fuels in uncombusted form, in part due to the fact that exhaust emission requirements are imposed in new areas. These proposals should be supplemented by a special inquiry charged with the task of exploring how to better promote the use of vehicles that produce considerably lower emissions of e.g. carcinogenic substances via the vehicle tax and other policy instruments. The committee should also examine ways to encourage the use of fuels with low or no content of carcinogenic substances in applications where some of the fuels can be expected to be emitted in uncombusted form (e.g. in older highway vehicles or non-road vehicles). The proposal for a special inquiry has been checked with the Committee on Environmental Objectives.

7.4.1.2 Information on the chemical content of products

Knowledge regarding the properties and use of individual substances in chemical products has increased in recent decades, even though there is still a great lack of knowledge. To remedy this lack of knowledge, we propose in Chapter 4 that all substances should have fundamental documentation on health and environmental effects etc. in order to be released on the market. We propose a common EU system for this purpose. Today there is also a great lack of knowledge concerning the occurrence of the substances in finished products that are not chemical products (i.e. chemical substances or preparations). Diffuse (nonpoint) emissions of chemical substances that can give rise to harmful exposure of man and the environment are deemed today to occur to a large extent via the flow of products in society. Exposure by emission of the substances from the product can occur in all steps from production to the waste stream. How an individual substance is emitted from the product flow is not often known, nor where in the product's life cycle it can give rise to exposure.

Complex product chains in which the product, or different parts of the product, come from different countries make it difficult to obtain knowledge concerning which substances the products contain. Because health and environmental information is lacking for the products, it is difficult for the end consumer to exert pressure and make a health and environmental judgement when purchasing a product.

In their report "Non-toxic environment" (National Chemicals Inspectorate, 1999 – in Swedish only), the National Chemicals Inspectorate proposed a subgoal to achieve the objective of a non-toxic environment stating that by 2010, finished products should carry health and environmental information, and that knowledge should exist regarding where substances with dangerous properties occur in products and how they flow out into the environment. We concur with the Inspectorate's judgement that such knowledge is needed. We also note that a statutory system for product information that includes product labelling and material safety data sheets already exists for chemical products. This system permits safe handling by users and enables them to choose the environmentally superior product. A similar system is lacking for finished products. The Environmental Code's requirement that all handling stages shall take responsibility for passing on the information regarding a product's health and environmental hazards has thus not been realized throughout the handling chain.

In our judgement, voluntary systems, such as positive ecolabelling and environmental product declarations, are important but not sufficient. We therefore believe that a special system is needed for contents declaration of products so that it is possible to know in what products the substances that are subject to the guidelines occur. In our judgement, it must be an EU-wide system, in view of the extensive international trade in finished products. The question of how a system should be designed in detail is large and complex. We therefore propose, like the Committee on Environmental Objectives, that the Government conduct a special inquiry in this matter.

7.4.1.3 Metal content of sewage sludge

In the EU today there are rules regarding the metal content of sewage sludge in Council Directive 86/278/EEC on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture. The directive is a so-called ”minimum directive”, which means that Sweden may enact tougher requirements than those laid down in the directive.

In Sweden there are rules governing the metal content of sludge to be spread on agricultural land, according to the Ordinance on Prohibition in Connection with Handling, Importation and Exportation of Chemical Products Etc. (Certain Cases) (1998:944). The rules only apply to lead, cadmium, mercury, chromium, nickel, copper and zinc. But many more metals are discharged with wastewater to sewage treatment plants today. These metals can end up in the sewage sludge or accompany the outgoing water. We do not know today whether these metals cause problems in arable soils or lakes.

As is evident from Annex 6, it can be calculated, based on preliminary measurements of metal concentrations in sludge, that the concentrations of certain metals in the soil can rapidly double if the maximum sludge dose is spread on a field. Even though these data are as yet preliminary and furthermore reflect a worst-case scenario, they should be taken seriously.

Since modern analysis technique (ICP-MS) makes it possible to analyze many more metals simultaneously than before, more metals should be included in tests of metal concentrations in sludge. An extended analysis of metals in sludge also provides valuable information on diffuse emissions of metals in general.

The Committee proposes that the Swedish EPA be commissioned to develop new limit values. Since many metals are involved, the commission may have to be spread out in time. Guiding factors for which metals should be prioritized may be data on how rapidly the metal concentrations in the soils can be expected to increase at a maximum sludge application rate, plus data on the toxicity of the metals – both data that are known today and data that will become known in the future as a result of the work described in Chapter 4. It is desirable that future limit values be expressed as metal concentration per unit of phosphorus, since the dry solids content, which is used today, does not say anything about the sludge's content of nutrients.

The commission should also include reappraising present-day limit values. In this context we would particularly like to highlight cadmium. The use of sludge on farmland leads to a disproportionately large input of cadmium compared with the use of commercial fertilizer (up to 66 mg/kg phosphorus, compared with 5 mg/kg phosphorus for fertilizer). There are rules governing how much sludge may be applied to soil with a view towards the resulting metal content. These rules are to be found in the Swedish EPA's Ordinance on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture (SNFS 1994:2, in Swedish only). We nevertheless do not think it is reasonable that so much more cadmium is obtained per kilo of phosphorus if sludge is used than if fertilizer is used. A single application of sludge containing 45 mg Cd/kg phosphorus, which is the mean value in the sludge currently being spread, is equivalent to 10–25 years' application of commercial fertilizer from the largest supplier in Sweden. It is therefore particularly urgent to reconsider the limit value for cadmium in sludge.

It must be possible to combine tougher requirements on sludge with a utilization of the phosphorus contained in the sludge. The primary way to reduce the metal concentration in sludge is to reduce the metal input to the sewage treatment plants by various means. The proposals the Committee presents in Chapters 6 and 7 should towards this goal. Phosphorus can also be extracted from sludge by different methods. There is no economically viable method in commercial use today, but several methods are under development. For further elucidation of this question, we refer to the Committee on Environmental Objectives (SOU 2000:52), which in the objective of a good urban environment has an interim target regarding utilization of phosphorus from e.g. sludge.

7.4.2 Measures to limit the occurrence of metals in certain applications

The Committee's appraisal and proposals

- Lead accumulators should eventually be phased out. Pending the development of alternatives that are better from a health and environmental viewpoint, lead batteries can be used in closed-loop ecocycles. To be able to close the loop, the industry must improve the quality of the recovered lead so that new batteries can be produced exclusively from recycled batteries.
- The areas of application for lead that are not covered by the proposals in sections 6.9 and 7.2.1 will continue to be phased out voluntarily. The National Chemicals Inspectorate and the Swedish EPA should follow the voluntary phase-out of lead and, where necessary, propose supplementary measures.
- Action within the EU is the primary strategy proposed for the metals copper, zinc, chromium and nickel (see section 6.6). In parallel with this, measures should taken to stimulate a switch to better alternatives in terms of health and environment in the areas of application that lead to large diffuse emissions of the metals. Important areas to work with in this context are:
  – copper, lead and zinc in brake linings,
  – copper in water pipes,
  – copper in marine anti-fouling paints,
  – chromium and arsenic in wood preservatives,
  – zinc as an activator in rubber tyres,
  – zinc in anti-corrosive agents, particularly in the traffic environment,
  – nickel, nickel compounds and chromates in products that come in contact with skin.
- New data on metal emissions and effects must be continuously monitored by the National Chemicals Inspectorate and the Swedish EPA so that measures can be taken to limit exposure or use if necessary.

7.4.2.1 Lead batteries

Batteries are by far the biggest area of application for lead. Lead accumulators should eventually be phased out. New battery systems are under development, but it is doubtful whether they can be put into

production on a sufficient scale to replace lead batteries within a ten-year period. All starter batteries for motor vehicles are produced outside Sweden today. New batteries must be based on metals with low hazard. New systems for recycling may need to be built up for these batteries. (For research and development, see Chapter 9 and Annex 6.)

Regarding lead batteries, there is nearly 100 percent take-back of spent batteries today. However, only 60 percent of the battery lead that is recovered is used in new batteries, while newly-mined lead comprises the remaining 40 percent. There is thus no closed-loop ”ecocycle” for lead batteries. One reason for this is that the recycled lead is contaminated with other metals in such a way that it is not suitable for certain functions in a new battery.

The Committee concludes that, pending the development of alternatives that are better from a health and environmental viewpoint, lead batteries may be used, provided closed-loop ecocycles are created for their recycling. To enable used, recovered lead to be fully utilized, the recycling industry must purify the lead better, which can be combined with efforts by the battery manufacturers to develop the batteries so they are less sensitive to contaminants.

As other lead use is phased out in Sweden, as well as in many other countries in the western world, the alternative markets for recycled lead are shrinking, and it is becoming increasingly important to remove any technical barriers to the production of new batteries from recycled lead.

The work of closing the ecocycle for lead batteries must be followed up by the Swedish EPA.

7.4.2.2 Lead in other uses

Among other areas of application for lead not included in our proposals for regulation in sections 6.9 and 7.2.1 are some where voluntary phase-out has come far and where there are good prospects of achieving compliance with the intentions of the guidelines. These areas include stabilizers and pigments in plastics, paints and anti-corrosive agents, plus cable sheathing. In addition to these applications, lead can be found in many other, smaller areas.

In the Committee's view, remaining use should be phased out voluntarily. A continued voluntary phase-out should, as today, be followed by the National Chemicals Inspectorate and the Swedish EPA.

Lead is sometimes used in such a way that it leads to great direct exposure of human beings. Examples are aromatic candles and necklaces (see Annex 6). This type of use is best rectified by urging the suppliers to take the products off the market. An additional option is intervention under Swedish product safety and chemicals legislation.

7.4.2.3 Measures to reduce emissions of copper, zinc, chromium, nickel and arsenic

Sweden should contribute actively to the risk assessment and risk management of copper, zinc, chromium and nickel within the EU's programme for existing substances (see section 6.6). The EU's risk assessments often take a very long time, however. As a complement to the main strategy of acting within the EU, Sweden should therefore work in parallel to reduce exposure from the areas of application that give rise to the greatest diffuse emissions of the four metals. This should be done for the purpose of prevention, despite the fact that complete risk assessments are not available.

Against this background we submit below supplementary proposals for a number of application areas. These proposals are focused on the largest sources of diffuse emissions. Emissions of metals to soil have been given particular attention, since most metals are bound very effectively in the top layer of the soil. A constant influx leads to an increase in concentrations in the top layer of the soil so that harmful levels can be reached. Indications of effects can already be seen. A more exhaustive description of use, emissions and effects is given in Annex 6.

Possible alternatives can already be seen today within certain areas of application. In other areas there are no alternatives today, but research and development may lead to new solutions becoming available within 10–15 years. Industry should work by means of voluntary measures to limit diffuse metal emissions from finished products. This can be augmented by the application of soft instruments such as positive ecolabelling. We also prescribe harder instruments in some cases.

The effects of the measures should be followed up by monitoring of exposure, in accordance with what is proposed in Chapter 9.

Brake linings

Brake linings are a major source of emissions of copper, lead and zinc. The knowledge we have today indicates that the copper concentrations in soil, at least near roads, can cause adverse effects. Zinc concentrations in soil around urban areas are increasing. We don't know what health effects are caused by emissions of metals from brake linings. What we do know is that brake linings give rise to a fine metal-bearing dust that contaminates the air along residential streets. Based on existing knowledge and the precautionary principle, there is reason to avoid metals such as lead and copper in this type of use.

Brake linings with very low concentrations of copper, lead and zinc are available on the market today. It should therefore be possible within a ten-year period to stop using brake linings with copper, lead and zinc and switch to alternative linings.

It can also be noted that alternative vehicles, such as electric and hybrid vehicles, exhibit much less brake lining wear than traditional vehicles, since braking effort can be achieved electrically by feedback to the battery.

Brake linings are sold with new cars and as spare parts, since the linings have to be replaced roughly every four years. Rules regarding brake linings already exist in the National Chemicals Inspectorate's regulations (KIFS 1998:8), which state that they may not contain asbestos.

A changeover to brake linings that do not contain copper, zinc and lead should preferably be accomplished voluntarily. However, while voluntary national measures are of importance for the replacement market, they have little effect on the brake linings in new cars. To influence the composition of these brake linings, action must be taken in the EU or internationally. One way to pursue the issue in the EU may be to advocate a change in the rules relating to type-approval of motor vehicles (see section 6.9).

Tap water pipes

Tap water pipes of copper are an important source of copper in sewage sludge. Pipes installed in homes have a long life, which means that the choice of material in construction of new housing is of importance for a long time. Both local authorities and building firms have drawn attention

to the problem, and attempts have begun to be made to use pipes of other materials. Such initiatives should be encouraged. The alternatives may need to be tested in terms of both functionality and environmental effects.

Marine anti-fouling paints

Anti-fouling paints are an important source of copper in marinas and shallow sea bays with a lot of pleasure boat traffic. The concentrations of copper in marinas on both the east and west coasts of Sweden are so high that effects can be feared on, for example, bladder wrack. The National Chemicals Inspectorate has decided that copper paints may not be used on the east coast. On the west coast, the paints are allowed until the end of 2001.

The reason the paints may still be used on the west coast is that the need is greater there, since fouling of boat hulls by marine organisms such as barnacles is greater in saltier water. There are several alternatives to the use of copper-containing anti-fouling paints – both other paints and mechanical cleaning methods. The Committee believes it is important that the alternatives be further developed and tested so that copper paints can be phased out on the west coast as well. The continued phase-out should be possible within the framework of the National Chemicals Inspectorate's reappraisal of its approvals of these agents.

Wood preservatives

Wood preservatives may contain chromium, copper and arsenic (CCA preservatives), copper alone or zinc alone. From an environmental viewpoint, it is most urgent to phase out the use of chromium and arsenic. Wood preservatives that contain copper alone can be a temporary alternative, but in the long term a changeover to organic wood preservatives, other than creosote, is desirable. Such preservatives are beginning to come out on the market, although they are slightly more expensive than the traditional ones at the moment.

The continued phase-out of chromium and arsenic, and eventually copper, should be possible within the framework of the National Chemicals Inspectorate's reappraisal of its approvals of these agents. To achieve the long-term goal of phasing out copper in wood preservatives, more resources need to be invested in development of alternatives.

Tyres and anti-corrosive agents

Concentrations of zinc in soil are increasing steadily. It is therefore urgent to reduce exposure in the soil environment. Two important sources of zinc contamination of the soil are abrasion of rubber particles from tyres and loss of zinc from corrosion-protected structures in society.

Loss of zinc from rubber tyres must be reduced. According to the tyre industry, there are no alternatives to zinc today. It is therefore important that research and development be initiated in the area. According to what the Committee has learned, the European tyre industry plans to conduct a survey of the effects of zinc loss from tyres. The tyre industry should initiate research and development to find alternatives to zinc.

Zinc is used as an anti-corrosive coating on many surfaces of iron and steel used in the traffic environment, e.g. lampposts and guard rails. The surfaces of new objects are often galvanized (coated with zinc) industrially, and there is no adequate substitute for galvanization today. Research is therefore required. Existing structures can be painted with zinc-containing anti-corrosive agents, but metal-free, oil-based anti-corrosive compounds are also available. The latter compounds are, however, less effective than the zinc agents, which means there is no fully adequate alternative to the zinc paints in all environments. Alternative anti-corrosive agents can, however, be used in environments where corrosion is normally low and on objects with short residual lifetimes.

Large users of corrosion-protected structures and anti-corrosive agents, such as the National Road Administration, should keep close track of the development of alternatives and test them as they become available.

Nickel, nickel compounds and chromates in contact with skin

More than 10 percent of the women and 2–5 percent of the men in Sweden are allergic to nickel. Allergies caused by chromates afflict just under one percent of the population. To reduce the prevalence of allergies, it is important that the rules relating to nickel in jewellery etc. laid down in the EU's restrictions directive (76/769/EEC), which entered into force on 1 January 2000, really be enforced.

Certain nickel-containing products that can cause allergies are not covered by the rules in the restrictions directive. These include hand tools, door handles and keys. It is important to reduce nickel exposure for these product groups. Certain voluntary commitments have been made by the tool industry to reduce nickel exposure.

The National Chemicals Inspectorate should work to bring about further voluntary commitments within the areas of application that lead to skin contact. As better knowledge concerning products' content of dangerous substances becomes available, it should be possible to more clearly identify the applications that lead to exposure to chromates and work in a similar manner with voluntary commitments to reduce exposure.

7.4.2.4 Restrictions on use and exposure to other metals

The Committee's proposals in Chapter 4 will lead to increased knowledge of the properties of substances. In the case of persistent and bioaccumulative substances, as well as carcinogenic, mutagenic and reproduction-toxic substances, the new data can be compared with the criteria we propose as a basis for determining whether the substances should be subject to measures or not.

The criteria for carcinogenic, mutagenic and reproduction-toxic substances can also be applied to metals, but otherwise the guidelines for metals say they that should not be used in such a way that they cause harm to the environment or human health. To judge this, the new knowledge that becomes available must continuously evaluated by the authorities so that measures can be taken to prevent metals from being released in such a way that this can cause adverse effects on man or the environment, in a short or long perspective. Which measures are appropriate must be judged in each individual case.

7.4.3 Recycling of metals

The Committee's appraisal and proposals

- In order to mitigate the environmental and health risks posed by metals use, a high recycling rate should be a goal for all metals (except those to be completely phased out of the ecocycle).
- Better statistics are needed to be able to keep track of the recycling of metals and set targets for individual metals.
- Producer responsibility could be an important policy instrument for promoting metal recycling.
- Methods for recycling high-volume metals need to be further improved and new systems should be created for recycling of other metals. The latter in particular should be done in international collaboration.

In the judgement of the Committee, certain metals have such properties that they should not even occur in a closed-loop cycle (ecocycle). This is true of mercury and cadmium, with the exception of recycling to the very limited areas of application where the metals are still allowed, e.g. mercury in light sources. Recycling of lead in e.g. batteries may occur as a transitional solution while alternatives are being developed (see section 7.4.2). As further knowledge is gained, it may be decided that more substances should be added to the group of substances that should not occur in an ecocycle.

The Committee believes that recycling of metals should be maintained at a high level for several reasons:

1. Recycling reduces the long-term potential for emission of metals to the environment

Mining activities redistribute many metals from the bedrock to society at a pace that far exceeds the natural turnover of metals in the environment (see Annex 6). The Chemicals Policy Committee (SOU 1997:84) formulated as a criterion for sustainable use of chemicals that society's abstraction and use of substances from the earth's crust shall not lead to concentrations in nature that are appreciably higher than the natural levels. This means that the sum of anthropogenic releases and natural weathering shall not be appreciably greater than the long-term geological turnover of the metal in question.

The accumulation of metals in society does not necessarily lead to exposure of man or the environment, but the greater the quantity of metal that is built up in society, and the greater the quantity that accompanies the waste streams, the more difficult it becomes to ensure that exposure will not occur, now or in the future.

Technically speaking, each quantity of metal that is mined has a potential to end up in the environment in such a way that human beings or other living organisms can be exposed to it. Recycling of metals can reduce the rate of accumulation of metals in society and on landfills. In this way, their potential for future release to the environment is also reduced.

2. Recycling of metals does not generate mining wastes

A metal often occurs together with other metals in the bedrock. When the metal is mined, side flows of other metals are also obtained, and depending on the circumstances these metals may end up in the mining waste. If the metals in question are toxic, this is an environmental problem. By recycling a metal it is possible to reduce the quantities of mining wastes, and thereby the quantities of toxic metals in these wastes. In this way, recycling of a metal can reduce the release of other metals to the environment – which is directly related to the Government's guideline. Aside from this there are other advantages to reducing the quantities of mining wastes, one being conservation of the landscape.

3. Recycling of metals leads to other positive environmental effects such as better resource management and reduced energy use

There are also other gains with metal recycling. In this context we would just like to mention a few factors without elaborating further on them, since they are not of primary importance for complying with the guidelines that lie within the our Committee's commission. One of these factors is resource management, which is currently being investigated in an inquiry by the Resource Efficiency Committee (Fi 1999:02) concerning the relationship between growth and environment and measures for a more efficient use of natural resources for the purpose of achieving sustainable development.

Recycling is moreover energy-conserving in relation to mining of new metals. For example, copper recycling consumes only about 10 percent

of the energy quantity that is consumed by original production (MITF, 1998).

Maintaining a high recycling rate is naturally particularly urgent for metals where the quantity mined by man is large in relation to the natural turnover (reason 1). This criterion does not have such great relevance for a metal such as iron, but recycling can nevertheless be desirable for reasons 2 and 3 above.

Annex 6 contains a description of metal recycling today plus a discussion of the prospects for recycling in relation to the application of the metals.

The Committee's appraisal and proposals

Several types of measures are needed to achieve a higher rate of recycling of metals.

Today there are no reliable statistics on metal recycling in the country, except for certain special metals and areas of application. Furthermore, metal recycling can be expressed in many different ways. For it to be possible to define the goal of a high recycling rate more precisely and quantify it for different metals, the current recycling rate must be better known, and for that better statistics are needed. Better statistics are also needed to follow metal recycling and see whether it is being maintained at a sufficiently high level. The statistics must be based on data on influxes of metals to the Swedish market and quantities recycled.

The National Chemicals Inspectorate intends, within the framework of its ongoing work, to submit proposals on changes in rules for notification to the Inspectorate's products register. As an example of a possible change, they mention that metals in pure form could be covered by the register (Swedish EPA & National Chemicals Inspectorate, 1999).

The National Chemicals Inspectorate supports the proposal that the products register should be broadened to include metals in pure form. To be able to quantify influxes of metals, particularly "new" metals, the metal content of imported products must also be known (see proposal for special inquiry in section 7.4.1).

Statistics on quantities of metals recycled in the country are largely to be found within industry. However, recycling sometimes includes materials from other markets than the Swedish, necessitating adjustment of the figures. The statistics must be collected to provide a whole picture. The method used to calculate recycling varies widely today. There is therefore a need for more uniform calculation grounds so that recycling data can be compared over time and between different metals.

Statistics Sweden (SCB) presented a proposal for future national statistics on material flows (Jonsson et al., 2000). SCB presents a proposal whereby substance flow analyses could be performed for some fifteen or so persistent substances, including several metals such as copper, zinc, chromium and nickel. The proposal for substance flow analyses entails describing the following factors:

- net influx to society
- recycling
- accumulation in society
- emissions from point sources
- diffuse emissions
- accumulation on landfills and in the environment.

Simplified flow analyses can be done for additional substances, e.g. a number of ”new” metals.

Our Committee believes that it is urgent that a project be started to perform substance flow analyses of the kind described by SCB. As they are described, the analyses correspond well to the need for statistics in this area. They should be able to provide a valuable platform for future efforts in both recycling and exposure limitation.

In order for the objective of a high recycling rate to be achieved, the idea of recycling must permeate the thinking of actors throughout the product’s lifetime, ”cradle to grave”. In the product development stage it is important that the products be designed so that constituent metals can easily be recovered. It is an advantage if the metals can be kept in as pure fractions as possible. It is also important from a working environment viewpoint that the products do not require complicated dismantling, which leads to unnecessary exposure of employees in recycling companies. Here large metal suppliers and trade organizations have an important role to play by furnishing information to metal-using

companies about how the metals should be used to facilitate recycling. Certain initiatives of this kind have already been taken.

Information to the consumers may also be needed to clarify where the metals are. Many municipalities have special collection systems for metals. But when the metals are contained in small components in products of another material it is much more difficult for the consumer to know how the product should be disposed of. In order to achieve adequate recycling, it is not enough that producers are responsible for taking back discarded products. The consumers must also have the knowledge and the incentive to turn in the products at the right place.

The Swedish EPA proposes that the present-day wording regarding producer responsibility in the Environmental Code, Chapter 15 Section 6, be changed so that it is made clear that the producer also has a responsibility for designing and marketing his products in such a way that they can be reused or recycled (Swedish EPA, 1999d). The Committee supports this proposal.

The Swedish EPA also proposes other ways to improve the recycling of products, among other things by gradually expanding producer responsibility to include more product groups and by participating in the development of an integrated product policy (IPP) within the EU (Swedish EPA, 1999d). The National Chemicals Inspectorate deems these factors to be of importance for achieving better recycling of metals.

There is a need to improve the methods for recycling the metal that is collected. An application for a research project entitled ”Sustainable Use of Metals” was submitted to MISTRA (the Foundation for Strategic Environmental Research). A sub-programme in the project is concerned with optimized metal recycling by means of improved methods for scrap sorting, metal refining, etc. The sub-programme is primarily focused on high-volume metals such as aluminium, copper and iron and its alloys.

For certain metals a large potential exists for increased recycling. The zinc recycling rate on a global basis is about 30 percent today. The zinc industry estimates that it will be possible to recycle around 80 percent of the zinc that is currently used in corrosion protection and alloys (MITF, 1998).

Among other, lower-volume metals, the recycling rate varies widely. In general it can be said that the more precious the metal, the greater the incentive for recycling. Swedish smelters produce several precious

metals from recycled raw material, which often comes from a much larger market than the Swedish. When it comes to low-volume, non-precious metals, there is virtually no recycling in Sweden, and it is uncertain how much is recycled abroad. It is much easier to obtain profitability in the recycling if you have a production of the metal from newly-mined raw material as a basis, and many virgin metals are not mined in Sweden.

International collaboration will probably be needed to bring about a recycling of these metals. Economic instruments may also be needed. The question of how to create systems for the recycling of virgin metals needs to be further studied and may be a suitable subject for interdisciplinary research.

Until the recycling problem is solved, the residues of unusual metals that are technically complex to recycle will require careful waste management. In a long-term perspective, no such residues should end up on landfills.

7.4.3.1 Viewpoints of the Swedish Mining Association

The Swedish Mining Association does not consider that a high rate of recycling of metals should be a primary goal in itself. An optimal recycling of metals is a natural consequence of prevailing economic realities and not least of the much lower energy inputs required in the secondary production of most metals, compared with primary production (Swedish Mining Association, 2000).

8 Proposals for other international work

8.1 Chemicals, finished products and international trade

8.1.1 Introduction

Our Committee has previously observed that Sweden cannot implement the new guidelines on chemicals policy solely on a national level. In keeping with the Committee's conclusions, the emphasis in our proposals is mainly on amendments to EU legislation. In the long term, however, the EU alone is not sufficient, since many chemicals and finished products are both traded and developed on a global level. We have discussed the EU's role in Chapters 3, 4 and 6. In this chapter we discuss other international work on a global and regional level that is of importance for the implementation of the new guidelines in the chemicals field.

As we have mentioned previously, the international work in the chemicals field is of great importance, since the problems caused by chemicals cannot be solved solely on the national level. The globalization of the trade in chemicals and finished products and a shift in the manufacture of chemicals from OECD countries to other countries can also be noted.

The chemicals and finished products that are sold in Sweden are often manufactured in other countries, often outside Europe. If harmful chemicals are manufactured in countries with inadequate chemicals control, they can subsequently be rapidly dispersed all over the world by the trade streams. Such a dispersal of e.g. a persistent and bio-accumulative substance can result in harmful effects whose consequences often do not become apparent until large quantities of the substances have been used and dispersed. Even if a total global ban is

then imposed, detrimental effects may persist in the environment for a long time.

Aside from trade as a transport route, long-range transport of certain poorly degradable substances also takes place via winds to e.g. colder climates, where degradation of the substances proceeds much more slowly, such as in Sweden.

Sweden's national chemicals policy must therefore be internationally oriented in order that our environmental objectives and the new guidelines on chemicals policy can be achieved. Chemicals control is well-developed in Sweden, but many other countries must also improve their chemicals policy and chemicals control if we in Sweden are to achieve our objectives. Many substances which we in Sweden have banned in our chemical products are still used today in many other countries. These substances may occur in various chemical products and in finished products that contain or have been treated with a chemical product. When these finished products are imported, there is a risk that the substances will nevertheless enter Sweden, even though they are prohibited here.

Global trade also makes it difficult to oversee chemicals use in the manufacture or products, since the products have often passed through several production steps in different countries before they come to Sweden. Furthermore, a system disclosing the chemical content of a product is lacking today.

As the international trade in chemicals and finished products increases, the international work of chemicals control is taking on increasing importance. International cooperation in different bodies, as well as global and regional agreements on chemicals, are extremely important to reduce the health and environmental risks of chemicals use. An important foundation for the global work in the chemicals field was laid at the UN Conference on Environment and Development in 1992, for example.

Sweden's growing cooperation with other European countries and Swedish membership in the World Trade Organization (WTO) entail curtailments of national self-determination and obligations to ensure that environmental measures that may affect international trade comply with certain principles. This is another reason why the international work is so important.

In the long term, an international harmonization of rules and regulations should also be striven for. National markets are often not sufficient for many industries.

The fundamental strategy for Sweden's international efforts in the chemicals field is and should be to promote the adoption of Sweden's fundamental principles and new guidelines on chemicals control both globally and in the EU.

8.1.2 Trade policy and environmental protection

The Committee's appraisal and proposals

- Trade and chemicals policies should support each other.
- It is of the utmost importance to conclude international agreements on environment and chemicals. Such agreements must naturally be allowed to include measures that restrict the trade in dangerous chemicals and finished products.

Global trade agreements and the World Trade Organization (WTO)

The General Agreement on Tariffs and Trade (GATT) originated in 1947. The purpose was to try to create a common framework for international trade, which, after the two world wars, was hampered by trade barriers erected during the war years for reasons of national protection and security.

The GATT's legislative framework consists of rules, special decisions and agreements that set up binding rules governing trade policy. One of the main rules is that a country should treat imports from all member nations as favourably as the most favoured nation. No nation may be discriminated against in relation to the others[1].

Furthermore, according to Article III (on National Treatment) of the GATT agreement, member nations shall in principle not impose trade rules that discriminate against foreign products in relation to domestic ones. Paragraph 2 of the article says that imported products shall not be subject, directly or indirectly, to internal taxes or other internal charges

[1] Article 1 in the GATT, which has to do with the Most-Favoured-Nation (MFN) principle.

of any kind in excess of those applied, directly or indirectly, to like domestic products. The purpose is to prevent such an economic burden from being used to discriminate against imported products or afford protection to domestic industry. The protection may not be indirect either, i.e. a charge may not be imposed on a certain type of product in a manner in accordance with the agreement, where the effect is an improper protection for competing domestic products.

The GATT's rules also contain exceptions. Article 20 contains a general exception rule that says that measures are permitted in some cases provided they do not constitute a means of arbitrary or unjustifiable discrimination between countries or a disguised restriction on international trade. Such measures are allowed if they are:

- necessary to protect, animal or plant life or health, or
- aimed at the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption.

It is worth noting that the GATT is not an independent organization, but merely an agreement between a number of member nations, including Sweden.

When the Uruguay Round (concerning more open world trade) was concluded in 1994, the contracting parties to the GATT decided to create an international trade organization named the WTO (World Trade Organization). The WTO administers not only the GATT but also several other trade agreements. There is also a Committee on Trade and Environment under the WTO, founded in 1994.

Sweden participates in the international discussions on trade and environment both through the EU and through the WTO. According to the Government Bill "Swedish Environmental Quality Objectives" (Gov. Bill 1997/98:145), Sweden strives to make trade and environmental policies mutually supportive for the purpose of achieving sustainable development. The Bill states that the objective of this work is that Sweden's progressive (by international standards) environmental policy shall be supported and spread internationally, at the same time as our trade relations shall remain intact or be improved.

Via the EU, Sweden is active in the WTO's Committee for Trade and Environment (CTE), whose mandate is to identify the relationship between trade and environmental measures. The CTE shall also make

recommendations if changes are needed in the multilateral trade arrangements. No proposals for such changes have been presented yet.

According to the Government Bill ”Swedish Environmental Quality Objectives”, a high-priority question for Sweden and the EU in the CTE is to work to make it possible to eliminate risks of conflicts between multilateral environmental conventions and the WTO’s body of rules. According to the Government, it should be made clear that trade measures adopted within the framework of such environmental conventions fall under the general exceptions article (Article 20) of the GATT agreement.

Each member country of the WTO/GATT is obligated to notify all measures that can affect international trade. The notification procedure makes it possible for all member countries to safeguard their rights under the WTO/GATT. If one country contends that another country’s measures conflict with the GATT, bilateral consultations shall first be initiated. If a solution cannot be found in such discussions, the complainant can request that the WTO appoint a panel to review the dispute.

The use of product-related economic instruments, such as the Swedish taxes on commercial fertilizer and pesticides, does not constitute a general problem under the GATT, since foreign and domestic producers are treated equally in these cases.

Precautionary principle

According to the precautionary principle, preventive measures shall be taken as soon as there is reason to presume that a given measure or activity might harm human health or the environment. The principle is embodied in many international treaties and agreements, such as:

- The UN’s Rio Declaration from 1992 (Principle 15),
- The EU’s Maastricht Treaty from 1992 (the EC Treaty’s Article 130r, now the Amsterdam Treaty’s Article 174),
- The Convention on the Protection of the Marine Environment of the Baltic Sea (HELCOM),
- The Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR),
- The recently concluded negotiations on a Biosafety Protocol.

There is, on the other hand, no expressed precautionary principle in the WTO's body of rules.

Since the precautionary principle has been a guiding principle for many international environmental conventions, as well as the EU and EC treaties and the Rio Declaration, application of the principle has also been discussed in the WTO.

Disputes between parties in the WTO may become more common in the future if, for example, the EU begins to invoke the precautionary principle as a reason for measures in more cases. This can lead to review of the cases in WTO panels.

The precautionary principle exists today in the EU's *acquis communautaire*, but is lacking in the WTO's body of rules. As the number of international environmental conventions and trade regulations increases, the risk of conflicts between the trade and environmental agreements will probably also increase.

When it comes to chemicals, the precautionary principle is embodied in many different decisions e.g. regarding HELCOM and OSPAR (see section 8.4). Furthermore, it is embodied in the Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market

The Committee's appraisal and proposals

Trade and environment have been important items on the trade policy agenda in Sweden for ten years now. This work is conducted in parallel in the WTO, the OECD, the UN Conference on Trade and Development (UNCTAD) and the UN Environmental Programme (UNEP). The purpose is to strive to make trade and environmental policies mutually supportive, i.e. that measures within one policy area should also support progress in the other area.

The Environmental Advisory Council's report "Trade and environment – towards a sustainable playing field" (SOU 1993:79, in Swedish only) deals with the rules and prerequisites for trade. The report concludes that neither free markets nor free trade exist in the true sense of the words. Markets always function within various institutional frameworks and rules, while a truly free market would not be subject to any taxes, laws or international agreements. If trade were completely free, it would also

be possible to trade in anything anyone was willing to buy or sell – including human beings, narcotics, atom bombs and hazardous waste. In this light it is obvious that free trade in the true sense of the word is not something to strive for, which is also borne out by the fact that countries the world over have chosen to restrict different types of trade, such as in the aforementioned areas.

According to the Environmental Advisory Council's report, what is normally meant by free trade is an increased liberalization of international trade and a removal of barriers to trade that impede a free flow of goods between countries, resulting in less efficient resource utilization and thereby harming the general welfare. But just as there is good reason to stimulate a freer flow of goods across borders in certain respects, there are just as obviously good reasons for restricting trade in goods in other cases to improve the general welfare. This is recognized in both the WTO rules and in the EU via the freedom allowed to countries to adopt rules for environmental protection that may entail a restriction of trade.

The increasing awareness of the environmental impact of products means that problems must be solved with a focus on the products. It may, for example, be a question of eliminating the products' content of dangerous chemicals or stimulating the development of material- and energy-efficient products. International action is needed to do something about the environmental impact of the products. As international trade in goods increases, countries are becoming increasingly dependent on production systems and consumption patterns in other countries. Trade is particularly important for small, open countries like Sweden. Sweden is dependent on imported products to maintain its present level of material prosperity. But the production of many imported products has an adverse effect on human health and the environment. Furthermore, health and environment risk being adversely affected when the product is used and becomes waste.

The trends in environmental and trade policy are such that measures in one of the policy areas often have effects in the other policy area. As the focus shifts towards the environmental problems caused by products, trade policy and environmental policy overlap each other to an increasing degree. As a result of this increasing mutual impact between trade and environmental policy, many international organizations are working to clarify the relationships between environment and trade, for example the WTO, the OECD and the EU. Discussions have particularly concerned the possibilities of giving priority to environmental protection

measures with an impact on trade over more general trade rules, and what happens in the event of conflicts.

A fundamental strategy for trade and chemicals policies should be that they should mutually support each other. An open, international economic system and economic growth must be devised in interaction and taking into account their fundamental resources, i.e. environment and people, in order to lead to sustainable development. The philosophy behind Swedish policy should be that we must be able to achieve our environmental objectives while safeguarding the platform for Swedish trade policy, namely the free movement of goods and services. This means that we must advocate joint international measures in the EU, as well as globally and in other international contexts.

The Environmental Advisory Council (SOU 1993:79) notes that many countries deliberately or inadvertently avoid adopting environmental measures. In doing so, they are giving indirect subsidies to hazardous chemicals. To counteract this, the basic principle should be that those who cause environmental damage should bear its costs.

Environmental damage affects more than just the exporting country. Via the products and emissions of persistent and bioaccumulative substances, the effects are spread to many countries, which therefore involuntarily help to subsidize the offending production. International cooperation therefore needs to be developed so that as many countries as possible are interested in participating, despite varying capabilities, means and interests. In many cases it will be necessary to give various forms of assistance to e.g. developing countries so that they can raise their environmental standards.

The rules governing global trade may need to be developed to allow for the measures that may be required to achieve the environmental objectives. The Environmental Advisory Council's report stresses that it is not possible to say whether trade generally favours or harms the environment, but it is concluded that trade reinforces the tendencies that exist. Whether the trend is towards better or worse products, environmentally speaking, this trend is reinforced by increased trade.

Against the above background, it is urgent that development of the rules governing international trade should proceed in parallel with the development of more environmentally acceptable products. Today there are no global requirements that products should meet any minimum level of environmental acceptability or that they should be free from certain

dangerous chemicals. One problem is resistance on the part of the developing countries, who see such rules as a threat to their own economic growth. Many poor countries feel that the industrialized countries are trying in this way to erect trade barriers against the developing countries by limiting access to their markets. Low living standards in combination with a lack of democracy, freedom of speech and freedom of the press are probably strong contributing causes to environmental problems in many countries.

In the Government Bill ”Swedish Environmental Quality Objectives” (Gov. Bill 1997/98:145), the Government says that the ongoing effort to integrate environmental aspects in all development work should be intensified and deepened. One of the priority areas mentioned is chemicals. We maintain that this is particularly important in view of the fact that a large portion of the use and production of dangerous chemicals, as well as finished products containing such chemicals, takes place in developing countries. SIDA should therefore draw attention to these questions in its development assistance work.

Global conventions with bans on hazardous chemicals naturally influence the trade in those particular chemicals. We maintain that such conventions are extremely important if Sweden is to achieve its environmental objectives and mitigate the health and environmental problems caused by chemicals. As mentioned previously, joint solutions and better chemicals control in other countries are needed to achieve the objective of a non-toxic environment.

A question that is being discussed in the WTO is whether global environmental agreements should take precedence over the trade rules, or whether the WTO rules should take precedence. The EU, supported by Sweden, has advocated amending the WTO’s body of rules (Article 20) to say that the trade rules shall not retroactively override environmental agreements that apply to a large portion of the world’s countries or trade. Otherwise there is a risk that every environmental agreement aimed at improving the environment will be nullified by complaints to the WTO’s dispute settlement procedure. The question has not been resolved yet.

We consider it to be of the utmost importance both that global agreements on environment and chemicals should be concluded and that such agreements must naturally be allowed to contain provisions that restrict trade. In this light it is hardly acceptable that environmental conventions could be regarded as subordinate to the WTO rules.

8.2 United Nations (UN)

Various UN bodies have been working with chemicals for many years. We have conducted a cursory review of the UN's programmes and bodies as well as conventions that have a special bearing on the implementation of the new guidelines on chemicals control. In this section we describe what we judge to be particularly important work for implementation of the new guidelines in the chemicals field.

Much of the work of the UN is of great importance to the chemical safety work. But as far as the implementation of the new guidelines are concerned, we would particularly like to highlight the following:

- the Intergovernmental Forum on Chemical Safety (IFCS),
- the coming convention on global restrictions of the most harmful substances (the POPs convention), and
- the Convention on Long-Range Transboundary Air Pollution (CLRTAP).

Table 8.1 lists the various programmes and bodies in the UN that have to do with chemical safety. The table also shows that there are special joint bodies in the chemicals field between certain UN bodies, such as the International Programme on Chemical Safety (IPCS), which is a joint programme of the ILO, WHO and UNEP. Another joint body in the food area is Codex Alimentarius (between the FAO and WHO).

After the UN Conference on Environment and Development (UNCED) in Rio de Janeiro in 1992, an Intergovernmental Forum on Chemical Safety (IFCS) and a Commission on Sustainable Development (CSD) were also formed.

Table 8.1 Various UN programmes and organizations dealing with chemicals.

UN body/programme	**Convention, activity or work dealing with chemicals**
UNEP [1]	POPs convention[11] and PIC[12]
ILO [2]	Labelling and safety data sheets
WHO [3]	Environment-related health questions
FAO [4]	Pesticides
UN/ECE [5]	CLRTAP[13]
IFCS [6]	Coordination, prioritization and division of labour
CSD [7]	Agenda 21
IMO [8]	Marine antifouling paints
ECOSOC [9]	Harmonization of classification and labelling
IPCS [10]	Joint programme on chemical safety of the UNEP, ILO and WHO
Codex Alimentarius	Food standards
IOMC[14]	Coordinates the work of the UNEP, ILO, FAO, WHO, UNIDO, UNITAR and OECD in the chemical safety field

[1] United Nations Environmental Programme.
[2] International Labour Organization.
[3] World Health Organisation.
[4] Food and Agricultural Organization.
[5] United Nations Economic Commission for Europe.
[6] Intergovernmental Forum on Chemical Safety, for coordination, division of labour and harmonization of international efforts in the chemicals field.
[7] Commission on Sustainable Development. UN commission, follows up the implementation of the Agenda 21 action programme from the UN Conference on Environment and Development in Rio de Janeiro in 1992.
[8] International Maritime Organisation.
[9] Economic and Social Council.
[10] International Programme on Chemical Safety, a joint programme of the ILO, WHO and UNEP.
[11] Work is under way on a convention with global restrictions for the most harmful persistent organic pollutants (POPs), called the POPs convention.
[12] Prior Informed Consent, convention requiring notification of exports and approval of imports.
[13] Convention on Long-Range Transboundary Air Pollution, Geneva convention.
[14] Inter-organization Programme for the Sound Management of Chemicals

8.2.1 Intergovernmental Forum on Chemical Safety (IFCS)

The Committee's appraisal and proposals:

- The most important body for global propagation of a coherent Swedish chemicals policy, including the new guidelines in chemicals control, is the Intergovernmental Forum on Chemical Safety (IFCS).
- Within the IFCS, Sweden should promote the global propagation and application of the fundamental principles (mainly the precautionary principle, the substitution principle and the principle of producer responsibility) and the holistic view that exists in Swedish chemicals control work, which includes both health and environmental aspects.
- High-priority issues for Swedish action should be:
  - global phase-out of substances subject to the new guidelines in Swedish chemicals control,
  - global harmonization of the rules on classification and labelling of chemicals.

Sweden was one of the most active countries in the chemicals field at the time of the UN Conference on Environment and Development (UNCED, known as the Earth Summit) in Rio de Janeiro in 1992. On Sweden's initiative, chemicals were also given a special chapter (Chapter 19) in the Earth Summit's final document, Agenda 21. This chapter contains the principles that have guided Swedish chemicals control, e.g. the precautionary and substitution principles. On the eve of the Earth Summit, a special meeting was held on chemicals in London where the question of a special global forum on chemical safety was raised. At the Earth Summit, Sweden sent out invitations to a special chemical safety conference in Stockholm in 1994, where the Intergovernmental Forum on Chemical Safety (IFCS) was formed and the first meeting was held.

The purpose of the Forum is to streamline, coordinate and develop international efforts to promote chemical safety so that Chapter 19 of Agenda 21 can be implemented. The Forum has a coordinating role and helps to ensure that work in the various UN bodies is conducted in such a way that duplication of efforts is avoided and priorities are optimized. The Forum has an important policymaking and prioritizing role in the international chemical safety work.

The formation of the forum also led to the formation in 1995 of the Inter-organization Programme for the Sound Management of Chemicals (IOMC), which is a joint body among the UNEP, ILO, FAO, WHO, UNIDO[2], UNITAR[3] and OECD.

Work in the IFCS is based on the direct active participation of the member countries rather than the work being done by an institution, organization or secretariat. It is thus a non-institutional body where representatives from a large number of governments meet together with different intergovernmental organizations (IGOs) and non-governmental organizations (NGOs) approximately every third year. An Intersessional Group (ISG) with representatives from 26 countries meets and conducts work between sessions of the Forum. The ISG also prepares recommendations to present to sessions of the Forum.

In addition there is a Forum Standing Committee (FSC), which prepares both meetings of the ISG and sessions of the Forum under the Forum's chairman. Work is also pursued in regional working groups (mainly Africa, Central & Eastern Europe, Latin America and Western Europe). The WHO has an administrative secretariat for the Forum. Every national government has a vote in the Forum. The organizations, on the other hand, have no vote.

The next session of the Forum (Forum III) will take place in Brazil in October 2000. It will be the third session since the Forum was formed in Stockholm in 1994.

The Committee's appraisal and proposals

Our Committee notes that Sweden has participated actively in the formation of the IFCS. Through the National Chemicals Inspectorate, Sweden has also participated actively in the work of the Forum since it was founded, above all in development of international cooperation regarding:

- division of labour between the industrial countries (e.g. when it comes to evaluations of chemicals),
- coordination of international activities in different international bodies, and

[2] United Nations Industrial Development Organization.
[3] United Nations Institute for Training and Research.

- harmonization of different parts of chemicals control (e.g. when it comes to classification and labelling of chemicals).

The Committee considers this work to be valuable and highly urgent. Swedish chemicals control is of a high international standard and has long had well-developed chemicals monitoring with comprehensive legislation in which both health and environmental aspects of both industrial and consumer chemicals and pesticides are integrated.

We also note that the Chemicals Policy Committee, in its report ”A sustainable chemicals policy” (SOU 1997:84), emphasized the importance of Sweden’s prioritizing the work in the IFCS and maintaining a leading position in it. Furthermore, the Committee’s report stressed the importance of Sweden’s supporting the development of coherent chemicals control according to the Swedish model in the IFCS.

According to the Chemicals Policy Committee, the work in the IFCS represents the most constructive contribution towards implementing Chapter 19 of Agenda 21.

Like the Chemicals Policy Committee, our Committee considers the IFCS to be one of the most important arenas for advancing the global chemical safety work. In its policymaking and prioritizing role, the IFCS can set the international agenda for the global chemicals work. The Forum has become an important meeting-place for the organizations that must undertake much of the practical work of complying with international agreements.

Different initiatives can be discussed and coordinated in the Forum. It is therefore our opinion that an active Swedish participation in the Forum can enable Sweden to influence the thrust of the work so that e.g. the premises for and implementation of the new guidelines on Swedish chemicals policy are propagated as widely as possible. Sweden should therefore continue to prioritize the work in the IFCS. An important direction in the future work should be – in addition to the work already in progress to propagate our coordinated view of chemicals control where our fundamental principles are prioritized – that the new guidelines on Swedish chemicals policy are also discussed on a global level for the purpose of achieving accord on the objective and to be able to address the problems globally.

The IFCS is a body that can achieve global acceptance for tightened chemicals control, and the Committee has found some additional con-

crete areas where the Forum should be able to take action in the near future:

- promote requirements on testing regarding the health and environmental effects of new and existing substances,
- propose that appropriate UN bodies be given responsibility and resources to take care of certain investigations of existing substances that have been done within the OECD so that the investigations will gain global acceptance,
- propose that the OECD be given the task of updating criteria for the global harmonized system for classification and labelling of chemical products.

It should also be possible to add extra weight to the questions that come up within the IFCS in the near future by confirming them at the UN Conference on Environment and Development in 2002 (the so-called ”Rio + 10 conference”).

8.2.2 Convention with global restrictions for the most harmful substances (POPs)

The Committee’s appraisal and proposals

- Sweden and the EU should advocate the eventual expansion of the convention on persistent organic pollutants (POPs) to include those persistent and bioaccumulative substances that are subject to the phase-out criteria which we propose for these substances (see Chapter 5).
- Sweden should nominate a number of priority substances that should be subject to global restrictions within the framework of the convention. The National Chemicals Inspectorate should therefore be commissioned to prepare a list of priority substances.

In 1995 the UN Environmental Programme (UNEP) made a decision to initiate an international process to achieve a global convention on persistent organic pollutants. The negotiations were opened in the spring of 1998 and are expected to be completed in the spring of 2001. The concluding diplomatic conference for signing of the convention is scheduled for the spring of 2001 in Stockholm, in which case it will be known as the Stockholm Convention.

Persistent Organic Pollutants (POPs) are a group of toxic organic substances characterized by their poor degradability in the environment. This enables them to be transported long distances, thousands of kilometres from where they were used. The initial use of POPs is therefore a global problem. Via the UN Environmental Programme, a decision has been made to develop a globally binding legal instrument for 12 POPs to begin with. The substances being discussed for prohibition, restriction and phase-out are the following substances and groups of substances: aldrin, dieldrin, endrin, chlordane, DDT, heptachlor, HCB (hexachlorobenzene), mirex, PCBs, toxaphene, PCDDs (dioxins) and PCDFs (furans). All of these are already prohibited or strictly regulated in Sweden.

The 12 substances discussed so far represent only a few of the hazardous persistent substances that may be candidates for global restrictions. At the first negotiation conference in Montreal in 1998, a special expert group was therefore created to prepare proposals for criteria and a procedure for identifying new substances for measures within the convention (Criteria Expert Group, CEG, for POPs). The CEG is currently developing internationally accepted criteria based on the properties of the substances in order to be able to identify further substances to be covered by the convention. The CEG's proposals have been discussed at several negotiating sessions. The last negotiating session – before the convention will hopefully be signed in Stockholm in the spring of 2001 – is scheduled for December 2000 in South Africa. It should also be mentioned that the Nordic Council of Ministers, via the Nordic Committee of Senior Officials for Environmental Affairs, is actively supporting the work of developing criteria for incorporating new substances into the convention by contributing to the funding of a position tied to the UNEP secretariat for three years. The position entails heading the work of the secretariat and is held by a Swedish representative of the National Chemicals Inspectorate.

A description of the criteria work in the Criteria Expert Group is provided in section 4.2.1 of Annex 3.

The Committee's appraisal and proposals

We would like to stress the importance of gradually broadening the convention to include more substances. We therefore believe that Sweden should nominate a number of priority substances that should be covered by the convention. The selection should be able to be made by the National Chemicals Inspectorate based on the criteria that will be laid down in the convention, as well as with the support of the criteria we propose for organic persistent and bioaccumulative substances in Chapter 5. We propose that this task be delegated to the National Chemicals Inspectorate.

We would also like to underscore the importance of the continued work within the framework of the convention to incorporate new substances. Even if the criteria and the procedure for adding new substances will hopefully be included in the text of the convention, many areas will probably remain to be defined that can be of great importance for the practical application of the convention and the incorporation of new substances into the convention. Such areas may, for example, be how candidate substances are to be proposed for inclusion in the convention, requirements on the documentation of substances, methods for hazard and risk assessment, the application of the precautionary principle in assessments of new substances that should be incorporated, etc.

8.2.3 UN/ECE's Convention on Long-Range Transboundary Air Pollution (CLRTAP)

The Committee's appraisal and proposals

Sweden and the EU should advocate that:

- the convention be supplemented with an overall objective that emissions – both point emissions and diffuse emissions from products – of dangerous substances should cease by 2020,
- more substances be made subject to restrictions within the framework of the convention. Among other things, the Protocol on Heavy Metals should be broadened as soon as possible to further reduce the long-range atmospheric transport of cadmium and mercury,
- a more general approach be adopted to incorporate substances that should be covered by the convention's restrictions. This should apply to e.g. application of general criteria for substances with particularly dangerous inherent properties, primarily persistent

and bioaccumulative properties as well as carcinogenic, mutagenic, reproduction-toxic and endocrine-disruptive properties.

In 1979, the UN Economic Commission for Europe (UN/ECE) completed a Convention on Long-Range Transboundary Air Pollution (CLRTAP), also called the Geneva convention. One of the purposes of the convention was to reduce acidification.

At present, 41 countries and the European Commission are parties to the convention: the European countries, the USA, Canada and the Russian Federation. By means of special protocols to the convention, the parties have agreed on more specific commitments within the areas covered by the convention. The different protocols deal with different areas, including abatement of emissions of:

- sulphur compounds,
- nitrogen oxides,
- volatile organic compounds (VOCs),
- heavy metals,
- persistent organic pollutants (POPs).

The protocols covering the last two areas were signed in 1998 for the purpose of abating atmospheric emissions of toxic heavy metals and persistent organic pollutants.

The Protocol on Heavy Metals calls for the reduction of emissions of mercury, cadmium and lead. For products there are binding annexes with certain obligations regarding lead in petrol and certain batteries. For mercury there is a non-binding annex with recommendations on replacing or limiting the use of mercury in products.

The Protocol on Persistent Organic Pollutants either bans outright or calls for later elimination or restrictions on use of 16 substances. The substances included are aldrin, endrin, dieldrin, chlordane, chlordecone, DDT, toxaphene, heptachlor, hexabromobiphenyl, mirex, PCBs, PAHs, dioxins/furans (PCDDs/PCDFs), HCB (hexachlorobenzene), HCH and benzo(a)pyrene.

The Committee's appraisal and proposals

The work within the UN/ECE, which serves as the secretariat for the Convention on Long-Range Transboundary Air Pollution (CLRTAP), has been the basis for the globally oriented work in the UN Environmental Programme for a convention on persistent organic pollutants. The work within the CLRTAP has from the start been focused on emissions, but the protocols from 1998 aim at restrictions on both emissions and occurrence.

The Committee would like to stress that the work with regional conventions aimed at abatement and phase-out programmes that contain measures against release and use of chemicals is particularly important. Sweden and the EU should therefore advocate inclusion in the CLRTAP of the overall objective that emissions of dangerous substances – both point emissions and diffuse emissions from products – should cease by 2020. The formulation of the objective should be able to take as its point of departure the Esbjerg Declaration's objective and the Swedish objective of a non-toxic environment, which would mean that a great many more substances may need to be covered by restrictions within the convention.

We would also like to stress that a more general approach should be applied here as well. General criteria should be developed for substances with particularly dangerous inherent properties, primarily persistent and bioaccumulative properties as well as carcinogenic, mutagenic, reproduction-toxic and endocrine-disruptive properties.

Our Committee is also of the opinion that, in addition to national and EU-wide measures, international measures are needed to reduce the load of mercury, cadmium and lead in Sweden.

According to the Protocol on Heavy Metals under the CLRTAP, the parties are obligated to phase out the use of leaded petrol. It is of great importance for the transmission of lead to Sweden that the parties ratify the protocol and put it into force. According to the Committee, forceful international abatement measures are also needed in order to achieve far-reaching reductions of the mercury and cadmium load in Sweden. Such work should be prioritized in the CLRTAP. As far as the Protocol on Heavy Metals is concerned, it should be broadened with regard to cadmium and mercury in particular to reduce the long-range transport of these heavy metals.

8.2.4 Other work in the UN

UNEP

Within the UNEP, work is being pursued to develop cleaner and safer production and consumption. The UNEP has the issue of a chemicals strategy on the agenda of its next Governing Council meeting in February 2001.

World Health Organization (WHO)

The World Health Organization's global programmes in environment and health are well-coordinated with the follow-up of Agenda 21. The work includes both the health objectives in Agenda 21 and questions relating to environmental medicine, chemical safety, health risks and safety in industry, water and sanitation.

Environment-related health issues is an important field within the World Health Organization's European region. At the conference of the environmental and health ministers in Helsinki in 1994, it was decided that the member states should develop national plans for environment and health issues and that a European Environment and Health Committee should be established.

International Programme on Chemical Safety (IPCS)

The International Programme on Chemical Safety (IPCS) was established in 1980 as a joint programme of the three UN bodies ILO, UNEP and WHO. The work within the IPCS is coordinated and administered within the WHO, and the IPCS aims at establishing a scientific basis for safe use of chemicals and at strengthening national capabilities and capacities for chemical safety.

IPCS areas of activity include evaluation of chemical risks to health and the environment, methodologies for evaluation of hazards and risks, and prevention and management of toxic exposures and chemical emergencies. The IPCS also has a coordination group for the work of harmonization of classification systems.

Evaluations that have been carried out within the OECD of particularly urgent existing substances from a risk point of view need to gain the

global support and acceptance of various organizations. The IPCS has an important role in this work.

International Maritime Organisation (IMO)

An urgent project has been under way in the IMO since 1998 regarding antifouling paints, aimed particularly at phasing out organotin compounds. At present the IMO is working on an international treaty to phase out tributyl tin in ship antifouling paints.

The National Maritime Administration is the agency that represents Sweden in the IMO work, assisted by the National Chemicals Inspectorate.

UN Commission on Sustainable Development (CSD)

Follow-up of the Rio Conference is one of the most important international processes for sustainable development. The UN Commission on Sustainable Development (CSD) meets annually to urge on and facilitate the implementation of the recommendations in the action programme Agenda 21. Up until 2002, when a new overall evaluation will be carried out for the period 1997–2002, priority will be given in the Commission's work to the sectors freshwater management, industry, oceans and seas, tourism, management of land resources, agriculture and forests, and energy and transport. General issues that will be dealt with every year are poverty, and sustainable consumption and production patterns. Swedish priorities have been chemical issues, and sustainable consumption and production patterns.

In a final document submitted at the 1997 session of the UN General Assembly, numerous recommendations were made for further measures, with a stress on further measures in the chemicals field.

Global Convention on Prior Informed Consent (PIC)

The Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade was signed in 1998. The convention replaces the previous non-binding system of export notification. The purpose of the convention is to introduce a common system for notification and information regarding imports and exports of certain chemicals which are prohibited or subject to severe

restrictions due to their danger to health and the environment. The system lays down requirements on notification and prior consent by a country after the information has been furnished. Work on the convention has been pursued within the framework of the UNEP and the FAO. The OECD has also participated.

The convention will be of importance in improving the exchange of information between developed countries and developing countries regarding dangerous chemicals, and in this way will also restrict the trade in dangerous chemicals and reduce the risks associated with chemicals use by developing countries. So far the convention includes 22 pesticides and 5 industrial chemicals.

In the EU, the convention is incorporated in the Council Regulation (EEC) No 2455/92 concerning the export and import of certain dangerous chemicals. Annex I to the council regulation contains a list with around 40 substances or groups of substances that are subject to bans or severe restrictions within the EU. Information required according to the convention include identification particulars for the substance or preparation to be exported, information on the actual export (country of destination, country of origin, date of export, quantity of chemical, intended use, etc.), designated national authorities, information on precautionary measures, classification and labelling, etc.

8.3 Organization for Economic Cooperation and Development (OECD)

The Committee's appraisal and proposals

Sweden and the EU should advocate that:

- testing methods for endocrine-disruptive properties be developed and new OECD guidelines be based on such developed testing methods (see Chapter 5),
- the existing testing methods for reproduction-disruptive effects be further developed so that they are more sensitive in detecting endocrine-disruptive effects (see Chapter 5),
- new testing methods be developed for half-lives in the terrestrial environment and for bioaccumulation in the terrestrial environment (see Chapter 9),
- additional harmonized criteria for classification and labelling be developed,

- priority be given to the work of finding new testing methods that do not require animal experiments,
- the OECD's evaluations of the particularly urgent existing substances from a risk point of view gain global support and acceptance.

The Organization for Economic Cooperation and Development (OECD) consists of the USA, Canada, Australia, Japan, New Zealand, the EU countries and others. Well-developed environmental cooperation has long been pursued within the OECD, coordinated by a special Environmental Policy Committee. The work in the OECD that relates to the work of the our Committee is above all the OECD's work with:

- a Test Guidelines Programme for testing of chemicals,
- principles for Good Laboratory Practice,
- Council Decision on Mutual Acceptance of Data,
- documentation requirements,
- harmonization of classification and labelling systems for chemicals.

During 1997, the OECD presented a proposal for extended cooperation in the environmental field. In brief, the proposal entails that environmental cooperation shall be broadened by developing the OECD into a leading organization in the field of sustainable development.

At the meeting of the Environmental Policy Committee in 2000, the OECD's activities in the chemicals control field were given top ranking among the 15 areas included in the OECD's environmental work. The programme is effective and gives the countries an opportunity to develop strategies and principles in a cost-effective manner, above all for risks related to chemicals and biotechnical products.

An important project has been under way for a long time within the OECD in the parts of chemicals control that concern hazard and risk assessment, i.e. more scientifically oriented activities. Agreements on e.g. testing methods, Good Laboratory Practice (GLP), mutual acceptance of data and documentation requirements for new substances are examples of this. These agreements have underlain both national and international rules and systems. The OECD's work and agreements have led to harmonization and more efficient resource utilization for individual governments and industry. In recent years, risk assessment of individual substances, criteria development and efforts in the pesticides field have been an important part of the OECD's contributions to the

international chemicals work. On the other hand, the OECD has so far been less successful as a cooperation forum for risk reduction measures, such as occurrence restrictions.

Within the OECD's Test Guidelines Programme, which publishes testing methods in the form of Guidelines for Testing of Chemicals, the member states must, provided the tests are carried out according to GLP, accept test results that are performed in accordance with the guidelines (Council Decision on Mutual Acceptance of Data). This comprises an important basis for worldwide chemicals control.

The testing methods determine the classification criteria and thereby which substances are judged to have hazardous properties. Standardized testing methods are therefore an important prerequisite for product information and other risk reduction.

An area that will probably be prioritized in the international work in the next few years is development of testing methods for hormonal effects. According to the our Committee, the development of testing methods for endocrine-disruptive properties should be prioritized. New guidelines should also be based on these methods.

The existing testing methods for reproduction-toxic effects should be further developed so that they are more sensitive in detecting endocrine-disruptive effects (see further Chapter 9 about research and Chapter 5).

Another area is development of testing methods for poorly biodegradable organic substances. To make it possible to efficiently identify persistent organic substances, the OECD's guidelines will probably have to be supplemented with further methods for testing biodegradability (see Chapters 4 and 5).

Harmonization of classification and labelling rules is one of six programme areas in Chapter 19 of Agenda 21. The expert work for developing a global harmonized hazard classification and labelling system is being carried out by the OECD. Based on the OECD's work, the ILO (International Labour Organization) deals with such matters as labelling and safety data sheets. The OECD's work to constantly update criteria for health and environmental hazards is urgent.

As regards prior notification of new chemical substances, there is no international body that is pursuing such work on an ongoing basis. However, existing prior notification systems are based more or less on

agreements within the OECD. Industry would like to bring about international cooperation, mainly to reduce the differences in requirements between the EU, the USA and Japan. There is cooperation within the OECD for exchange of information on the various prior notification systems.

The OECD is also working on harmonization of risk reduction measures, but the work has made little progress so far.

The OECD's existing chemicals programme ends up with a risk assessment of relevant chemicals. The EU's member states are contributing assessments of the substances dealt with in the EU programme.

The OECD is also working to develop methods to make better use of data from environmental monitoring in the exposure part of risk assessments. This method development may eventually facilitate the assessment of exposure from products.

In 1991, Sweden and the USA initiated cooperation on pesticides within the OECD Working Group on Pesticides. The work is aimed at harmonizing the basis for risk assessments and data requirements, as well as collecting and publishing information about risk reduction activities in different countries. The purpose is to reduce duplication of work by both national authorities and industry by means of harmonized guidelines for testing, labelling, data requirements and formats for risk assessments.

In recent years, the Working Group on Pesticides has developed a programme on biocides. The programme includes harmonization of data requirements, development of criteria for acceptable efficacy, development of test guidelines for health and environmental effects, guidance on exposure and risk assessment, and cooperation between member countries in biocide reviews. The programme entails large cost savings for the countries, in that duplication of work can be avoided.

8.4 Other environmental conventions/declarations

International environmental conventions, in other words legally binding international treaties in the environmental field, are in many cases effective means for improving the state of the environment both globally and regionally. A number of important environmental conventions have come into being in recent decades. Some of them have been described here within the framework of the UN (e.g. the CLRTAP). Several other global (Montreal Protocol) and regional (OSPAR, HELCOM) environmental conventions, as well as the North Sea Conferences, are presented in this section.

Table 8.2 provides an overview of the work within the North Sea Conferences, the OSPAR Convention and the Helsinki Commission.

Table 8.2 Some regional environmental conventions or declarations that have a bearing on chemicals phase-out

North Sea Conferences	• North Sea • North Sea Conference in Esbjerg 1995 (Esbjerg Declaration)
OSPAR[1]	• North Sea and North-East Atlantic • In 1998, objectives were adopted in line with the objectives of the Esbjerg Declaration • Dynamec ad hoc Working Group[3]
HELCOM[2]	• Baltic Sea • In 1996, objectives were adopted in line with the objectives of the Esbjerg Declaration

[1] Oslo and Paris Convention, Convention for the Protection of the Marine Environment of the North-East Atlantic. Regional convention in Europe. The OSPAR Commission administers the work under the convention. The objectives of the Esbjerg Declaration were adopted in 1998.
[2] Helsinki Commission.
[3] Working group within the framework of OSPAR whose purpose is to prepare a list of substances for priority action under the objectives of the Esbjerg Declaration.

8.4.1 Substances that deplete the ozone layer – the Montreal Protocol

The Vienna Convention for the protection of the ozone layer, the atmosphere and the climate came in 1985. Under a subsequent amendment in the form of the Montreal Protocol, the states undertook to reduce consumption and production of products containing substances that deplete the ozone layer by 50 percent. At a meeting in London in 1990, a further amendment was made to the effect that the use of CFCs, halons and carbon tetrachloride shall gradually decrease so that total phase-out is achieved in 2000. The protocol can thus be seen as an action programme for the phase-out of ozone-depleting substances.

Together with the member states, the EU has acceded to the Montreal Protocol, and the EU's obligations under the Protocol are fulfilled through Council Regulation (EC) No 3093/94 of 15 December 1994 on substances that deplete the ozone layer.

The substances covered by the Montreal Protocol are CFCs, carbon tetrachloride, halons, 1,1,1-trichloroethane, HBFCs and methyl bromide. Methyl bromide is subject to gradual phase-out by 2005.

8.4.2 North Sea Conferences – Esbjerg Declaration

The Committee's appraisal and proposals

- The chemical issues and the substances subject to the objectives of the Esbjerg Declaration should be further elaborated on at the next North Sea Conference in 2002.
- In Sweden's work of developing a Swedish strategy by 2002 with proposals regarding what issues a consensus should be reached on at this conference, the purpose should be to achieve binding decisions within e.g. OSPAR. The substances for which we propose restrictions, i.e. the substances subject to our general phase-out criteria for persistent, bioaccumulative, carcinogenic, mutagenic, reproduction-toxic and endocrine-disruptive properties, should be prioritized in the future work.

In Bremen in 1984, the countries around the North Sea and the North-East Atlantic established cooperation to improve the marine environment of the North Sea. The joint work was organized via special North Sea

Conferences where the countries undertake to work towards certain common objectives both nationally and internationally. Three more North Sea Conferences have been held since 1984: in London in 1987, in the Hague in 1990 and in Esbjerg in 1995.

At the fourth North Sea Conference in Esbjerg in 1995, the environment ministers and the member of the European Commission responsible for environmental protection signed the fourth North Sea Declaration, known as the Esbjerg Declaration. The declaration defines common objectives aimed at substantially improving the marine environment in the North Sea. The guiding principle for achieving this objective is the precautionary principle. The Esbjerg Declaration covers eight special areas, including protection against pollution by hazardous substances. According to the declaration, hazardous substances are defined as:

- toxic
- persistent
- liable to bioaccumulate

The term ”toxic” includes chronic effects such as carcinogenic, mutagenic, teratogenic and effects that are harmful for the endocrine system (hormone system).

The ultimate aim according to the Esbjerg Declaration is that the concentrations in the environment shall be near background values for naturally occurring substances and close to zero concentrations for man-made synthetic substances.

The Esbjerg Declaration’s objective for hazardous substances[4] is formulated as follows:

> *”The Ministers agree that the objective is to ensure a sustainable, sound and healthy North Sea ecosystem. The guiding principle for achieving this objective is the precautionary principle.*
>
> *This implies the prevention of the pollution of the North Sea by continuously reducing discharges, emissions and losses of hazardous substances thereby moving towards the target of their cessation within one generation (25 years) with the ultimate aim of concentrations in the environment near background values for naturally occurring substances and close to zero concentrations for man-made synthetic substances.”*

[4] Esbjerg Declaration, Chapter III, The Prevention of Pollution by Hazardous Substances.

The work of implementation and concretization of the Esbjerg Declaration takes place largely via other bodies, e.g. OSPAR. The concerned environment ministers in the EU have, within the framework of OSPAR[5], adopted objectives in line with the objectives of the Esbjerg Declaration. Objectives for the Baltic Sea which are in line with the Esbjerg Declaration's objectives have also been adopted by the environment ministers of the Baltic Sea states within the framework of the Helsinki Convention. The Esbjerg Declaration also states the following:

> *"Competent international bodies such as the European Commission, the OECD, OSPAR and the UN/ECE/LRTAP are invited to develop further tools for assessing environmental risks of emissions and effluents containing complex mixtures of substances (i.e. assessment of toxicity, biodegradability and liability to bioaccumulate), and to develop further and use tools for the evaluation of risks of hazardous substances in the environment in order to set priorities."*

The Committee's appraisal and proposals

In the Government Bill "Swedish Environmental Quality Objectives" (Gov. Bill 1997/98:145, MJU:1998/99:6, rskr 1998/99:87), the Government states that it intends to devise a Swedish strategy prior to the next North Sea Conference that contains proposals regarding what issues a consensus should be reached on at this conference, with the ultimate purpose of achieving binding decisions. We would like to stress that the chemical issues and the substances subject to the objectives of the Esbjerg Declaration should be further elaborated on at the next North Sea Conference in 2002. In the work of developing a Swedish strategy with proposals regarding what issues a consensus should be reached on at this conference, the purpose should be to achieve binding decisions within e.g. OSPAR.

It is the opinion of the Committee that the substances for which we propose restrictions, i.e. substances subject to our general phase-out criteria for persistent, bioaccumulative, carcinogenic, mutagenic, reproduction-toxic and endocrine-disruptive properties, should be prioritized in the future work.

[5] Oslo and Paris Convention (Convention for the Protection of the Marine Environment of the North-East Atlantic). Of the EU countries, Austria, Greece and Italy do not participate in OSPAR.

8.4.3 Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR)

The Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR Convention) is a regional convention in Europe aimed at restricting waste dumping at sea and pollution of the North-East Atlantic from land-based sources. The convention replaces the Oslo Convention (Prevention of Marine Pollution by Dumping from Ships and Aircraft) and the Paris Convention (Prevention of Marine Pollution from Land-based Sources).

The OSPAR Convention is a cooperative undertaking by Iceland, Norway, Finland, Sweden, Denmark, Germany, the Netherlands, the UK, Ireland, Belgium, Luxembourg, France, Spain, Portugal, Switzerland and the European Commission. The OSPAR Convention was adopted in 1992 and entered into force on 25 March 1998. According to the new OSPAR Convention, a recommendation is binding on the contracting parties that voted for it. If unanimity cannot be reached, a recommendation can nonetheless be adopted by a three-quarters majority, but then it is not binding.

The convention's executive body is the commission, which meets once a year. Two committees[6] are associated with the commission, to which a number of working groups and project groups are in turn tied.

The first ministerial meeting of the OSPAR commission after the entry into force of the convention was held in July 1998 in Sintra, Portugal. A ministerial declaration and four strategies were adopted at the meeting. The four strategies concern:

- eutrophication
- hazardous substances
- radioactive substances
- ecosystems and biodiversity

The meeting also adopted an annex on the protection and conservation of the ecosystems and biological diversity of the maritime area. It was decided at the meeting that the contracting parties shall adopt the necessary measures to protect and conserve the ecosystems and

[6] The Programmes and Measures Committee, PRAM, and the Environmental Assessment and Monitoring Committee, ASMO.

biological diversity in the maritime area, and to restore, when practicable, marine areas which have been adversely affected.

In the strategy for toxic and hazardous substances, a working group was formed, the Dynamec ad hoc Working Group (under Diffuse Sources, DIFF). The group was formed to prepare a list of substances subject to the objectives of the Esbjerg Declaration, and it has been instructed to develop criteria for selection of substances for restrictions. At the OSPAR commission's meeting in June 2000, a decision is expected to be taken on the criteria, i.e. which substances are to be prioritized in the implementation of the strategy with regard to hazardous substances.

The work is politically important. The European Parliament is, for example, pursuing the line that the OSPAR strategy with regard to hazardous substances shall be implemented in the coming Water Framework Directive.

So far the working group has formulated the following three steps for selection of problem substances:

- Start with inherent properties for a first selection of substances. Here a Nordic group is working together with the Netherlands. A Nordic Substance Database with experimental values has been used, along with a Danish and a Dutch database with calculated values for biodegradability, liability to accumulate and toxicity (see Chapter 2).
- Risk evaluation for marine environment. So that no substances will be missed, it will be possible to add substances from monitoring programmes and substances with suspected endocrine-disruptive properties in this step.
- Final selection of a number of substances based on consideration of the objective.

The OSPAR work on criteria for persistence, liability to accumulate and toxicity is dealt with in section 4.4 in Annex 3.

The Committee's appraisal and proposals

A discussion is currently being held in OSPAR on how the work on hazardous chemicals should proceed. The work in OSPAR's expert groups of selecting substances for priority action is naturally urgent and should be prioritized. A decision is expected to be taken at the OSPAR

commission meeting in June on how the continued work on a strategy for hazardous substances should be developed.

We are of the opinion that the work within the framework of OSPAR concerning the substances that will be subject to the objectives of the Esbjerg Declaration should be carried further and given high priority. The objective is that diffuse emissions from the use of particularly hazardous substances in products and direct point emissions of such substances should not occur at all. The substances should therefore not be allowed in chemical products (substances and preparations) or finished products. Since national measures are not sufficient to achieve these objectives, Sweden must urge the EU to adopt common measures that restrict the use of substances that will be subject to OSPAR.

We also note that the work with a ”sector-by-sector” strategy should be an important complement for identifying and achieving phase-out of the hazardous substances. Such a strategy entails that instead of only analyzing and proposing measures for one priority toxic substance at a time, substances are also analyzed and measures proposed on a sectoral basis for the sectors that give rise to emissions of priority toxic substances under OSPAR. The Swedish EPA is currently working to develop such a strategy with the aim that it should be discussed and considered at the OSPAR commission meeting in June.

In summary, we believe that the substances we propose should be restricted, i.e. substances subject to our phase-out criteria (see Chapter 5), should be prioritized in OSPAR’s continued work with risk management measures. Sweden should therefore work to highlight the chemical issues prior to OSPAR’s next ministerial meeting in 2003 in order to achieve agreement on the new approach in chemicals policy, which includes phasing out the substances subject to our phase-out criteria. Persistent and bioaccumulative substances should be prioritized in this work.

Together with Norway and the European Commission, Sweden has sent out invitations to a workshop to discuss how different policy instruments can be used more effectively to achieve the objectives of the Esbjerg Declaration. Sweden will host the workshop, which is planned to be held in Stockholm in September 2000. We believe that it can be an important opportunity to urge the implementation of the hazardous substances strategy and bring up issues relating to the chemicals work within the EU. It should be possible for member countries of the EU and OSPAR,

as well as environmental organizations and representatives of industry, to attend the meeting.

8.4.4 Convention on the Protection of the Marine Environment of the Baltic Sea (Helsinki Convention)

The Committee's appraisal and proposals

- Sweden should advocate that use (both in chemical products and finished products as well as emissions) of the substances that will be subject to OSPAR should also be subject to the Helsinki Convention.
- The substances subject to the Committee's criteria for phase-out should be prioritized in the continued work with risk management measures.

The Convention on the Protection of the Marine Environment of the Baltic Sea has been adopted to promote cooperation on the environment of the Baltic Sea. It is called the Helsinki Convention and came into being in 1974. The present contracting parties are Denmark, Estonia, Finland, Latvia, Lithuania, Poland, Russia, Sweden, Germany and the European Commission.

The convention's executive body is a commission (HELCOM), which meets once a year. The commission has four permanent committees: Environment Committee, Technological Committee, Maritime Committee and Combating Committee. Under these committees are a number of working groups. The commission's recommendations are adopted unanimously by the parties to the convention. They are not yet binding, but are nonetheless expected to be incorporated into the national legislation of the parties to the convention. The convention has been reworked, and the reworked convention from 1992, which all countries have signed but has not yet entered into force, contains provisions that certain fundamental principles shall be incorporated in national legislation and that minimum requirements may also be issued. In 1992, the commission also adopted an environmental action programme for the Baltic Sea. A number of measures are to be implemented during a 20-year period.

The Committee's appraisal and proposals

The goal of cooperation under the Helsinki Convention is to protect and preserve the ecological balance of the Baltic Sea. This means that all types of discharges and emissions must be sharply reduced so that the Baltic Sea's sensitive ecosystems can recover. In May 1996, the objectives of the Esbjerg Declaration were also adopted by a ministerial meeting of HELCOM, and in March 1998 an action programme was adopted. Sweden has accepted responsibility for the work in an implementation group. HELCOM follows the work in OSPAR, but with a focus on specific Baltic Sea issues. HELCOM has, for example, also adopted a strategy for hazardous substances which largely coincides with the strategy adopted by OSPAR. Certain differences may, however, arise due to the special needs of the Baltic Sea. A special project group has been appointed for the implementation of this work, and Sweden has assumed responsibility for leading this work.

We believe that Sweden should advocate that the use – both from point sources and from diffuse emissions from products – of the substances subject to the phase-out criteria proposed by the Committee (see Chapter 5) should be prioritized in HELCOM's continued work with risk management measures. The substances in question are primarily persistent and bioaccumulative as well as carcinogenic, mutagenic, reproduction-toxic and endocrine-disruptive.

8.5 Nordic Council of Ministers

Nordic cooperation in the chemicals field takes place in the Nordic Council of Ministers under the Nordic Committee of Senior Officials for Environmental Affairs and its Chemicals Group.

Table 8.3 provides an overview of the work within the framework of the Nordic Council of Ministers that has a bearing on our inquiry.

Table 8.3 Nordic Council of Minister's work pertaining to chemicals

Nordic Council of Ministers Nordic Committee of Senior Officials for Environmental Affairs	
Chemicals Group	• Cooperation on testing methods, hazard criteria, etc. • Cooperation with other OSPAR countries on criteria and selection of substances for achieving Esbjerg Declaration objectives
Clean Technology Group	• Working Group for Product-Oriented Environmental Strategy

The work within the framework of the Nordic Council of Ministers has largely concerned information exchange, development issues, division of labour and joint efforts to pursue important issues in international bodies such as the OECD, the North Sea Conferences, OSPAR and HELCOM. The work has not focused on harmonization of rules, but has contributed towards giving the rule systems a similar orientation. After the EEA agreement and EU membership for Sweden and Finland, Nordic cooperation has become more EU-oriented with the aim of influencing the EU in areas where values coincide.

The Nordic countries, above all the regulatory authorities for plant protection products and biocides, cooperate in the Chemicals Group to reduce duplication of work and to achieve a harmonized view of risk assessment. Evaluations/risk assessments for new and old plant protection products are being exchanged. After Sweden's and Finland's entry into the EU, the work has been broadened to include collection of material for the EU as regards persistence and exposure models that take into account Nordic conditions. In the biocides field, efforts are being made to create common work procedures for documentation requirements, approval criteria, evaluations of active substances and information exchange.

The Nordic countries have long been cooperating in the Chemicals Group for development of testing methods and for coordination of viewpoints for presentation at OECD meetings on testing methods. Nordic cooperation is important for influencing the OECD work, which in turn influences the EU's work. An important Nordic cooperation project is developing testing methodology for endocrine-disruptive

effects on reproduction. The main purpose of this project is to contribute to the OECD's work on guidelines in the area.

Via the Nordic Committee of Senior Officials for Environmental Affairs, the Nordic Council of Ministers has also supported the global work within the framework of the POPs convention by contributing to the funding of a position tied to the UNEP secretariat for three years to work with the development of criteria for incorporating new substances into the POPs convention. The position is held by a Swedish representative, and the work has in our opinion been very valuable for Nordic interests.

The Nordic work regarding hazard criteria has long been aimed at influencing the EU's criteria work. Due to the importance of the international conventions for the chemical safety work, the Nordic countries have entered into cooperation with other OSPAR countries on criteria and selection of substances for achieving the objectives of the Esbjerg Declaration. Among other things, the Nordic Council of Ministers has taken the initiative to a Nordic Substance Database, which has been compiled for the purpose of facilitating the work of OSPAR-DYNAMEC with selection and prioritization of hazardous substances (see section 2.2.2 and section 4.4 in Annex 3).

As far as finished products are concerned, a Working Group for Product-Oriented Environmental Strategy has been established under the Clean Technology Group in the Nordic Council of Ministers. The purpose is to promote the production and marketing of greener products. The group has worked with surveying Nordic activities and proposing joint Nordic projects in the green products field. Work is currently being pursued to achieve a Nordic consensus. A counterpart to this work in the EU is the work with an Integrated Product Policy (IPP).

The Nordic authorities in charge of the products registers are pursuing a joint project where procedures for collection of information and systems for registration and data management are being discussed for the purpose of assessing harmonization possibilities and common statistics management.

8.6 International cooperation in industry

8.6.1 International Organization for Standardization, ISO

The Committee's appraisal and proposals

Sweden should advocate via the standardization organizations that:

- environmental and health aspects always be taken into consideration in devising new standards and that each new standard undergo an environmental assessment,
- environmental and health aspects be integrated into existing standards,
- ISO 14025 be developed in such a manner that declarations of contents are made compulsory in certified environmental product declarations,
- chemical aspects are clarified in ISO 14001, Environmental Management Systems. Use of chemicals should constitute an important environmental aspect. Use of chemicals should therefore be added to the areas mentioned in Annex A to ISO 14001 (the guidance document).

How does the standardization work take place and which standards have a bearing on chemicals?

We discussed the EU's role in the work of standardization in Chapter 6. The role and work of the International Organization for Standardization are dealt with in this section.

ISO (International Organisation for Standardisation) is a worldwide federation of national standards bodies from some 110 countries, one from each country. Sweden is represented by SIS (the Swedish Institute for Standards).

The work of standardization takes place in Technical Committees (TCs), subcommittees (SCs) and working groups (WGs). ISO's Technical Committee 207 was formed in 1993; this is the committee that develops and updates standards in the ISO 14000 series. The environmental standards in the ISO 14000 series deal with the following areas:

- environmental management
- environmental auditing
- environmental performance evaluation
- life cycle assessment
- environmental labelling (ecolabelling)
- environmental terminology
- environmental aspects of product standards

There are eight standards bodies in Sweden, and SIS is the central body for Swedish standardization. SIS does not conduct any standardization work of its own; all the work of preparing standards is divided among the eight standards bodies. Two of the standards bodies, SMS (Swedish Materials and Mechanics Standards) and STG (Swedish General Standards Institute), participate on behalf of Sweden in the work with ISO 14000.

ISO's Technical Committee 207 is the committee that develops and updates standards in the ISO 14000 series. As of March 2000, the number of participating member countries on the committee is 58, in addition to which there are 15 observing member countries and 43 liaison organizations (including UNEP, OECD and EU). SMS is participating in the work focusing on environmental labelling and life cycle assessment. STG is participating in the work focusing on environmental management.

The Committee's appraisal and proposals regarding environmental product declarations and life cycle assessments

The purpose of environmental product declarations is to present a product's environmental profile. There is a technical report in ISO, ISO TR 14025, which describes a type III environmental product declaration, i.e. a declaration to be verified by a third party. The technical report is a kind of precursor to a finished standard.

Data from life cycle assessments, LCAs, comprise an important basis for certified environmental product declarations. There are several standards for LCAs in the ISO 14040 series. According to the standard, the assessment shall focus in a systematic and appropriate manner on the environmental aspects of the product system. There are no detailed instructions on how the assessment is to be performed, which means that

the standard leaves quite a bit of leeway for those applying the standard to choose a method for their LCA. Today there are many alternative methods available which give widely differing results and place more or less emphasis on chemical aspects.

In addition to data from life cycle assessments and certain other data, an environmental product declaration may also include a declaration of contents. This is not a requirement at present, however, and in cases where such information is not furnished the recipient of the declaration does not get any information on what the product contains. This is a problem in itself, which is aggravated if the LCA on which the information in the declaration is based has been carried out in such a manner that little consideration has been given to chemical aspects.

It is our opinion that chemical aspects should be included more clearly in the environmental product declarations. We therefore propose that Sweden should advocate, through the standardization organizations, that ISO 14025 be developed in such a manner that declarations of contents are made compulsory in certified environmental product declarations.

The Committee's appraisal and proposals concerning environmental management systems

The main purpose of the environmental management standard ISO 14001 is to ensure compliance with applicable legislation and continual improvement. In certain sectors in Sweden, large portions of the supplier and production chains have introduced environmental management systems and are certified in accordance with ISO 14001.

The environmental management standard contains a number of requirements, but these are of a relatively general nature for the environmental work and give little or no special consideration to any aspects of chemicals use.

Nor does the environmental management standard have any formal requirements with regard to chemicals. Which environmental issues are to be dealt with and their priority is determined by whether they are identified as significant environmental aspects, and by significant environmental aspects is meant parts of an organization's activities, products or services which may have a significant environmental impact. The fact that the environmental impact of the product is expressly mentioned entails in itself a holistic perspective which may embrace

chemicals-related aspects, but the standard does not go into any further detail on this.

The process for identifying significant environmental aspects includes an environmental review. According to the guidance document ISO 14001, Annex A, this review should consider:

- emissions to air
- releases to water
- waste management
- contamination of land
- use of raw materials and natural resources
- other local environmental issues.

Some of the items may bear some relation to chemical issues, although the focus is more on other environmental issues. Otherwise, there is no emphasis on chemical issues, but neither is there any obstacle to or restriction on dealing with such issues in the environmental review.

The National Chemicals Inspectorate's report "Market-driven chemicals work" (no 3/99, in Swedish only) examines the role of chemicals in environmental management systems. The report concludes that one important aspect is how much control, if any, the companies have over the environmental properties of their products. The very identification of environmental aspects should pertain to those that are of such a nature that the organization can be expected to have some control and influence over them. This is reflected in the guidance document (14001, Annex A), where it is pointed out that the organization responsible for product design can alter the aspects considerably by changing, for example, a single input material. No further explanation is given, but this can be considered to provide clear support for e.g. replacement of dangerous substances or other chemical aspects related to the product.

The standard requires that the organization shall establish procedures for preventing and managing accidents. To some extent this is a chemicals-related requirements, since accidents are often connected with chemicals handling.

ISO 14004 contains general guidelines for implementing and maintaining an environmental management system. The standard is not a specification standard, but is intended to be used as a support, a source of ideas and a more forward-oriented tool. The basic principle is the

same as in the specification standard ISO 14001, and no special treatment of chemical-related issues is specified. However, the standard contains an annex section that presents guiding principles for the environmental work, which can serve as a basis for an environmental policy and an environmental management system. The examples presented are the principles of the Rio Declaration, where the precautionary principle is highlighted.

We consider it important that the ISO 14000 series is general in terms of requirements, so that it can be used by different types of companies and organizations. However, we find that chemical issues and the chemical problems associated with products seem to have been overlooked in the environmental management system. The chemical issues need to be clarified to focus attention on the environmental problems associated with chemical products and other finished products. Use of chemicals is without doubt an important environmental aspect, and we therefore propose that Sweden, via the standardization organizations, should advocate adding an item to Annex A to ISO 14001 (the guidance document) regarding use of chemicals.

8.6.2 Chemical industry: Responsible Care

In 1985, Responsible Care was started in Canada by the Canadian Chemical Producers' Association as a voluntary initiative and undertaking on the part of the chemical industry to work for continuous improvements in safety, health and environmental performance. The initiative has since spread all over the world, and Responsible Care is now represented in around 40 countries. The companies that commit to Responsible Care undertake to strive for constant improvements in safety, health and environmental performance and to provide open information on their activities and any progress that is made.

Responsible Care was introduced in Sweden in 1991 under the name *Ansvar och Omsorg* (Responsibility and Care).

9 Proposed research, environmental monitoring and other follow-up

It is the opinion of the Committee that the manufacturing and importing companies should bear principal responsibility for procuring knowledge on the health and environmental properties of substances and their occurrence in products. In addition investments in research, environmental monitoring and other follow-up are of great importance. The Committee's thoughts and proposals in this area are presented in the following chapter. The Committee's views on the current need for research are clarified in section 9.1 and considered in relation to current Swedish environmental research in the chemicals field. The Committee's proposals for urgent research and method development are then presented. Environmental monitoring in Sweden today is discussed in section 9.2 in the light of the new chemicals policy, and the Committee's proposals for how chemicals monitoring needs to be strengthened in this perspective are presented. The final section (9.3) consists of a brief discussion and commentary of the subgoals in the report "Non-toxic environment", the interim targets in the work of the Environmental Objectives Committee that have the greatest bearing on our Committee's inquiry, and our Committee's thoughts and proposals concerning the follow-up of the implementation of the guidelines proposed by the National Chemicals Inspectorate and the Environmental Objectives Committee.

9.1 Need for research

The need for research in the environmental field is increasing as new chemicals are developed and used. The EU's dangerous substances directive (see section 4.2.2) stipulates fundamental requirements regarding properties and effects for new substances placed on the market. However, research is needed if new harmful effects to health and the environment are discovered or suspected, often as a result of an unforeseen exposure situation. However, the greatest research need is

probably regarding existing substances, since in most cases very little is known about their properties and effects and how they are transported in the environment. The work towards the environmental objective of a non-toxic environment and the implementation of new guidelines on chemicals policy require a broadening of environmental research.

The research needs that are related to the Committee's commission regarding persistent and bioaccumulative organic substances, as well as substances that are carcinogenic, mutagenic, reproduction-toxic or endocrine-disruptive, do not by definition cover toxicity of the character neuro- and immunotoxicity and ecotoxicity. The Committee's commission regarding metals does not have any such limitation, however; all types of toxicity of metals and metal compounds are included in the problem area encompassed by the commission. However, since there is a great lack of knowledge regarding the toxic effects of organic substances in general, and in particular regarding fundamental effects and action mechanisms, the Committee does not find it meaningful to discuss the research need solely from the perspective of metals. Instead, we consider it important to discuss the great need for environmental chemistry and toxicological research that has been revealed in our contacts with the Committee's scientific reference group. This research need is also important to consider, since it aims at generating knowledge of great importance for achieving the overall objective of a non-toxic environment.

There is a general need for greatly increased knowledge concerning potential and existing health and environmental effects of both the organic substances and the metals that are used in products and occur in production processes. There is a very great need for basic research, both in the field of environmental chemistry and in the field of toxicology and developmental biology. Great demands will be made on this research due to the need for method and technology development. In order to learn more about the inherent properties of chemical substances such as persistence and liability to bioaccumulate, as well as effect-related properties such as carcinogenic, mutagenic, reproduction-toxic and endocrine-disruptive capability, new methods and technologies must in many cases be developed and old ones refined. Furthermore, it is particularly important here to underscore the importance of working to devise testing methods that reduce the need for animal experiments. Moreover, routine analytical techniques must be developed to enable more substances to be studied with regard to their flows with products and occurrence in the environment than is possible today.

It will also be necessary to intensify the development work concerning substitution of those chemical substances that will be subject to phase-out requirements. An important research field will be development of less chemical-consuming technologies to permit substitution in applications where large quantities of chemicals are used today.

In order to make it possible to reduce society's dependence on dangerous chemicals, the Committee also views social science research as vital, for example regarding policy instruments and the importance of behavioural changes on the part of various actors.

9.1.1 Current Swedish environmental research

The Committee's appraisal

A vigorous national programme of basic research in environmental chemistry, ecotoxicology and toxicology is a prerequisite for Sweden's ability to pursue chemicals issues in international fora in a knowledgeable, well-founded and thereby convincing fashion.

Swedish research in environmental chemistry and ecotoxicology enjoys an excellent international reputation, and Swedish research has had a very great influence in the identification, description and solution of global ecotoxicological problems (Norstrom, 1998). A prominent example is the discovery in 1964 that the PCB group of industrial chemicals were toxic pollutants (Jensen, 1972). Sweden's leading position in the field of environmental research is probably an important contributing reason for Sweden's international position as a driving force in the field of environmental policy.

Many of today's major research programmes in the fields of environmental chemistry and ecotoxicology may generate further basic knowledge and insights of great importance for Sweden's continued policy decisions in the environmental field. Examples of such programmes are the Swedish EPA's recently concluded project "Metals in town and country" (Bergbäck and Johansson, 1994, in Swedish only), MISTRA's (the Foundation for Strategic Environmental Research) project "A new strategy for risk assessment and risk management of chemicals" (News, 1999, in Swedish only), and SLU's (the Swedish University of Agricultural Sciences) programme for studies of flows of materials and energy between urban and rural areas in conjunction with waste

management (SLU, 1999) and its continuation ”Organic Waste – Resource or Risk in Sustainable Agriculture” (in English).

There is, however, some cause for concern in the fact that current Swedish environmental research, like much of the environmental research being done internationally, is largely characterized by a focus on the most spectacular environmental problems. The reason for this lies in the priorities that are made within limited economic frames. As a result, many successful researchers must limit themselves to the fields that are in greatest demand and where the most ready funding is available in order to try to safeguard their future research. Often these projects attract funding away from basic research that could otherwise generate knowledge of vital importance for the future. The consequences of such a short-sighted focusing on mainstream environmental research in limited fields with high publicity value may, however, be a lack of continuity, loss of competence, basic knowledge gaps, and neglect of very important but less ”glamorous” fields of research. This could rapidly lead to an undermining of Sweden’s formerly very advanced position in international environmental research.

A necessary prerequisite for Sweden to be able to continue in the forefront of chemicals control is that we maintain our leading position in basic environmental chemical and toxicological research. Urgent method development projects of the kind mentioned in section 9.1.5 can be conducted with success only if they constitute a part of a programme of environmental chemical and toxicological front-line research which is essentially researcher-controlled.

In its analysis of the need for toxicological research in the environmental field (FRN, 1998), the Council for Planning and Coordination of Research (FRN) stated that several previous government inquiries had already pointed out the need for more knowledge and competence in environment-related toxicology, and that the foremost reason for this need is the increasingly complicated situation as regards exposure of man and the environment to various chemicals and toxic pollutants. Despite this, FRN noted, environment-related toxicological research has experienced a period of cutbacks, in terms of both total funding and number of projects, at the same time as the research that has been done has become increasingly measure-oriented and problem-solving in its character, at the expense of e.g. researcher-initiated, more basic studies. FRN recommended:

- a considerable increase in resources for research in environment-related toxicology and environmental medicine,
- new resources for problem-seeking and exploratory research,
- giving high priority to research-initiated and researcher-controlled environment-related research,
- coordination of research funding, and
- a commitment to competence development and postgraduate studies.

The management group for the Swedish EPA's former project area "Persistent Organic Pollutants" held a seminar in 1999 on the theme "Can the national and international environmental objectives for persistent organic pollutants be met with present-day competence and resources?" (Utne-Skaare, 1999). The conclusions from the meeting were that the group:

- *"fears that with the present-day trend in Swedish toxic pollutant research, it will be difficult to satisfy the needs of government agencies and other clients, and sees with alarm that this can particularly lead to:*
- *much poorer prospects of achieving the environmental quality objective of a "Non-toxic environment"*
- *difficulties in continuing to pursue chemicals issues internationally*
- *difficulties in obtaining data for risk assessments/risk evaluation of POPs in foodstuffs, etc.*
- *problems for government agencies in dealing with acute issues*
- *reduced capability to meet the needs of the public and private sectors."*

Our Committee subscribes to FRN's analysis of the need for research and shares the concern expressed by the management group for the Swedish EPA's former project area "Persistent Organic Pollutants", and in addition notes that as a consequence of their conclusions the Government has, as from 2000, allocated additional resources to environmental research in the form of a research grant to the Swedish EPA. The funds are primarily to be used for research in the fields of environmental effects, ecotoxicology and ecocycles (closed-loop resource management), as well as for the research conducted jointly by the state and industry at the Swedish Environmental Research Institute (IVL)[1].

The Government Bill "Research for the future – a new organization for research funding" (Gov. Bill 1999/2000:18, in Swedish only) once again creates a new platform for environmental research, however, and it is as yet unclear what this will entail for the future funding of research in environmental chemistry and toxicology.

[1] see the Swedish EPA's website at http://www.environ.se/

In this connection, the Committee would like to emphasize that a vigorous commitment to basic research in environmental chemistry, ecotoxicology and toxicology is a prerequisite for Sweden's ability to pursue chemicals issues in international fora in a knowledgeable, well-founded and thereby convincing fashion.

9.1.2 Proposals for research on the properties and effects of substances

The Committee's appraisal and proposals

There is a great need for:

- studies of persistence and bioaccumulation and the relationship of these properties to the other inherent properties of chemical substances for the purpose of creating general tools for classification of chemical substances,
- studies of the relationship between bioaccumulation and biomagnification, and the importance of fat solubility in relation to other uptake and immobilization mechanisms, in land-based food chains as well,
- basic research on endocrine-disrupting effects, as well as in the fields of reproduction and developmental toxicology,
- basic research on the metabolism of substances in various organisms and their health and environmental effects, including synergy effects and chronic low-dose effects, as well as ecotoxicological effects,
- environmental medicine studies with a special emphasis on allergies and variations in sensitivity among different individuals, as well as effects on development, learning capacity and mental capacity,
- identification and quantification of new, potential environmental problems, including studies and evaluation of the importance of emissions of substances from products, as well as exposure conditions,
- studies of metal speciation and bioavailability of various metal compounds,
- long-term follow-up of effects and concentrations in connection with ongoing environmental monitoring, as well as opportunities to

cross-check these data with health data registers as a basis for research,
- refinement of methods for risk assessment.

In view of today's increasingly complex exposure situation, there are good reasons to focus research efforts on increasingly subtle effects on man and the environment. The Chemicals Policy Committee's report "A sustainable chemicals policy" (SOU 1997:84) stated:

> *"...that we humans, like other organisms in the ecosystems, are exposed to a very large number of substances from countless sources – most at low concentrations. At the same time, we see dramatic biological effects in ourselves and our surroundings whose causes we do not understand, but which we suspect are chemical-related."*

A compilation of knowledge and evaluation of possible connections between chemicals exposure and known or suspected disruptions of reproduction and foetal development, with a special emphasis on disruptions in the endocrine systems, has been done at the initiative of the Swedish EPA (Olsson et al., 1998). The report also contains recommendations for future research.

The possibility can, for example, not be ruled out that diffuse exposure during the foetal period to low doses of a large number of man-made chemical substances can lead to an increased tendency to develop several of the major national diseases, and that exposure in the past may have contributed to the increases we see now. The exposure conditions are poorly known, especially as regards the distribution of exposure over time. When do chemicals accumulate in humans and other organisms? What food sources and what congeners/substances contribute most to the risk? What sources other than food are contributory?

Better knowledge is needed regarding the properties, forms of occurrence, transport, transformation, bioavailability, and toxic effects in the environment and on health of toxic substances, as well as their interaction with different substances and effects in different types of environments. This is a large field and is best explored in international collaboration, in which Sweden should participate actively. It is important that resources be allocated for this work in Sweden, not least to permit assessment of the appearance and toxicity of the substances in the Swedish environment, which differs in many ways from the environment in other parts of the world.

In order to gradually accumulate knowledge in these areas and pursue the work efficiently, both national and international collaboration is desirable among many competence centres with expertise in the different disciplines such as environmental chemistry, human toxicology and toxic effects in soil and water. Coordination of the work of health and ecotoxicological risk assessment is furthermore resource-efficient and would be of particularly great value for both method development work and toxicity tests in the laboratory and in the field.

9.1.2.1 Bioaccumulation and biodegradation, as well as bioavailability, exposure and ecotoxicological effects

An urgent field of research is studies of persistence and bioaccumulation and the relationship of these properties to the other inherent properties of chemical substances for the purpose of creating general tools for classification of chemical substances.

As far as bioaccumulation is concerned, it is further essential to find out more about the relationship between bioaccumulation and biomagnification, as well as the importance of fat solubility in relation to other uptake and immobilization mechanisms. There is also a great need for studies of bioaccumulation and biomagnification in land-based food chains; this is a prerequisite for the development of relevant testing methods in this area. There appear to be great knowledge gaps in this area, particularly as regards uptake of pollutants via crops.

Degradation of organic pollutants under different conditions is a research field of great interest for urgent method development in the area. It is also of great interest to find out more about variations in degradability and their causes.

An area that requires new research efforts is identification and quantification of new, potential environmental problems. Emissions of substances from products may be important examples of such problems, for example:

- emissions from various materials and differences in emissions depending on what type of material a substance is present in and what kind of environment (air, soil, water, landfill) the material is present in,
- influence on emissions of abrasion, corrosion and migration of substances in and from materials,

- transformation (of additives, among other things) in products, biodegradation of different materials in landfills and in nature,
- methodology for estimation of accumulation in society of persistent products containing chemical substances for estimation of ”lifetime” emissions from various types of products, and for estimation of total emissions of a substance from the products that have accumulated in society,
- emission factors for different types of substances, materials and environments, for use when measurement data are lacking.

An area of great interest is ecotoxicological effect research in systems comprising several steps in the food chain, as well as the link between ecotoxicological effects of hazardous substances and biological diversity. This area also includes the impact of e.g. ”new” metals as well as persistent and bioaccumulative substances on degradation processes in soil and water. It is also of interest to study the ecotoxicological effects of modern pesticides. Knowledge is needed concerning their effects in other environments than those for which they are intended, with a link to biological diversity here as well.

An urgent research area is the ecotoxicological importance of various endocrine-disruptive substances with effects on both lower and higher organisms. It can furthermore be of interest to study effects of chemical substances that can influence chemical communication between organisms of the same and different species.[2]

Additional research is required to clarify where metals occur in society, transport pathways, and what exposure of man and the environment the occurrence of metals gives rise to. To permit preventive action, systems must be created where the occurrence of the metals and their health and environmental properties are already known when the products in which they are contained come out on the market. However, research on flows and effects and continuous monitoring of metal concentrations in man and the environment are still needed.

The research done to date on the occurrence of metals and their flows from society to the environment has mainly been focused on metals with widespread use. With the aid of the methods that have been developed and the experience that has been gained, it should be possible to go further with more metals relatively quickly, which is necessary so as not

[2] such substances are called pheromones and kairomones, respectively.

to miss ”new” metals which might otherwise become future environmental problems.

At the same time, it must be possible to update the surveys of metal flows that have been done, since the patterns of use of the metals can change over time. Metal speciation and bioavailability of different metal compounds are other research areas of interest.

In connection with ongoing environmental monitoring of chemical substances, it is urgent to perform a long-term follow-up of effects and concentrations, as well as to cross-check these data with health data registers as a basis for research.

9.1.2.2 Toxicological research, health effects, risk assessment

There is a great need for basic, mechanistic and epidemiological research in the field of endocrine-disruptive effects, as well as in the fields of reproduction and developmental toxicology, with a link to disruptions in reproductive capacity, deformities in progeny, cancer, diabetes, effects on the immune system, osteoporosis, cardiovascular disease, and effects on the nervous system that can lead to behavioural effects. This need for basic research regarding health and environmental effects, as well as metabolism studies, applies to both known toxic pollutants and probably many of the other substances affected by the Government’s guidelines. New suspicions of effects are constantly being revealed, such as that certain PCB congeners can cause osteoporosis (Lind, 2000). Studies of synergy effects and chronic low-dose effects of man-made chemical substances in a complex exposure situation are also of great interest.

Environmental medicine studies are also needed of the possible influence of chemical substances on development of allergies and on development, learning capacity and mental capacity. It is also of great interest to investigate the possibility of making use of genetic engineering research to identify sensitive groups and organisms.

Only certain limited information is available on the health effects of metals. The lack of knowledge is particularly great with regard to non-carcinogenic effects and variations in sensitivity among people. At the same time, knowledge of exposure conditions in the population is very poor as far as most metals are concerned. It is therefore urgent that investigations of health effects be integrated in new research programmes on metals to a greater extent than has been done to date.

Refinement of methods for risk assessment is another important area where more research is required. This applies, for example, to the relationship between the exposure and bioavailability of substances on the one hand and their extractability and chemical analyzability on the other hand. It also applies to relationships between exposure and degradability, mobility and toxic effects.

Research on risk assessment should also be focused on possible effects of use of biotechnical and genetically modified organisms in e.g. plant disease control. The action mechanisms of these microorganisms may be production of highly toxic substances. The area is new and growing, and it is important at this stage to try to clarify the risks that new problem substances will be released when biological control methods are substituted for chemical control methods.

9.1.3 Proposals for social science research

The Committee's appraisal

There is a great need for:

- studies of behavioural and attitude changes in society due to increased knowledge of chemical substances and various kinds of policy instruments,
- research on the efficacy of various policy instruments,
- studies of how policy positions are arrived at,
- refinement of methods for taking into account effects of chemicals in life cycle assessments,
- environmental economics research.

People's attitudes can be influenced when the general level of knowledge increases regarding various man-made chemical substances and their effects, and regarding their occurrence in industrial processes, in infrastructural installations, in finished products, and as pollutants in the environment. This can lead to changes in human behaviour on different planes. People can, for example, change their buying habits or their choice of means of transport, which can have an influence on both the market and the political process.
An illustrative example of this is how public opinion regarding the adverse effects of paper production from pulp bleached with chlorine-

containing chemicals at a certain point in time at the end of the 1980s had an influence on the market. In a relatively short space of time, production at many pulp bleaching plants was converted to bleaching without the use of chlorine gas, and at some to bleaching without use of any chlorine-containing chemicals at all. This took place both due to the increased incentive for voluntary measures and due to regulatory measures on the part of the public authorities. Portions of the market demanded paper products bleached without the use of chlorine-containing chemicals. The changeover to bleaching without chlorine gas was very significant on large parts of the European market, and all pulp bleaching plants in Sweden ceased using chlorine gas in the early 1990s.[3]

It is of great socio-scientific interest to study more closely how these kinds of attitude and behavioural changes arise and manifest themselves, as well as what effects they can have. Such knowledge is of particularly great interest in, for example, the evaluation of the use of various kinds of soft policy instruments such as ecolabelling and information campaigns, as well as free opinion formation.

When it comes to refinement of testing methods and of criteria for undesirable properties of chemical substances, it is important to conduct research that sheds light on the processes leading up to policy positions, for example as regards acceptance of various testing methods and criteria systems. Of particular interest is the interaction between science and politics, including the importance of various actors' opinions, knowledge, motives and authority, and not least how fundamental factors such as the precautionary principle are concretely applied. Beyond this, an interesting area of study would be to ascertain how the international work can best be influenced to win acceptance for new ideas, for example the phase-out of substances solely because they are persistent and bioaccumulative.

The Committee further sees a great need to refine methods for weighing in effects of chemicals in life cycle assessments. The risks posed by the content of chemical substances in different products need to be give greater attention in life cycle assessments than is the case today, which requires further development of the methodology for life cycle assessments.

[3] Approximately 2/3 of the producers use chlorine dioxide as a bleaching agent today, while 1/3 of the production is completely chlorine-free (Erik Nyström, Swedish EPA, personal communication).

Another very pivotal area of research that can provide important information for adopting positions in chemicals policy is research in environmental economics. It is, for example, urgent to study the effects of applying the Committee's fundamental principles – the precautionary principle and the substitution principle (see section 2.3.1) – from the perspective of environmental economics. Companies must have greater access than they do today to material on which to base their environmental economics analyses in the development of new utility chemicals.

9.1.4 Need for technical research

The Committee's appraisal

There is a great need for:

- development of less dangerous chemicals,
- development of less chemical-consuming technologies to permit substitution in applications where dangerous chemicals are used today,
- development of alternatives to e.g. lead accumulators as starter batteries, and zinc in automotive tyres.

There is a greater need for technical research and product development than is described here. The Committee contents itself with pointing out some important (in our view) basic principles, plus a couple of problem areas where we see a need for research and development.

In order that future generations will have an opportunity to enjoy the positive sides of the use of chemicals in technology which society is largely dependent on today, it is the general view today – as is indeed evident in the Government's new guidelines on chemicals policy – that we should strive to minimize the possible negative effects of this chemicals use on human health and the environment. In the judgement of the Committee, important steps in this direction are to develop and use chemicals that pose less risk of undesirable effects than many of the chemicals used today (the substitution principle), and to develop technical solutions that entail less dependence on chemicals, or that completely eliminate dependence on chemical substances and can be substituted for technologies where dangerous chemicals are used today.

The Committee would once again like to point out here that it is very important that the use of chemical substances in products be regarded from a life cycle perspective.

In section 7.4.2 we discuss a number of areas where the use of certain metals should be reduced. In some cases, technical research and development is required to permit a changeover to less dangerous alternatives. Two examples of such areas are alternatives to lead accumulators, particularly in their use as starter batteries for vehicles (see section 7.4.2.1), and alternatives to zinc in automotive tyres and in galvanization coatings for the purpose of corrosion protection (see section 7.4.2.3).

9.1.5 Proposals for method development

The Committee's appraisal and proposals

The Committee sees the following needs for method development and would particularly like to stress accompanying needs for validation, standardization and implementation of methods:

1. Development of methods that reduce the need for animal tests to determine the properties and effects of substances by:
- better utilizing the experimental animals so that the number of animals needed is reduced, while at the same time improving the animals' conditions,
- developing more non-animal methods that can take the place of certain animal tests,
- exploring the possibilities of using DNA microarrays, and
- developing calculation and prediction models towards greater accuracy.

2. Development and refinement of testing methods for endocrine-disruptive effects in order to be able to:
- identify different endocrine-disruptive properties of substances, and
- detect endocrine-disruptive effects in both higher and lower animals.

3. Development of testing methods to be able to determine how persistent and bioaccumulative substances are, by:
- being able to determine half-lives for the biodegradation of organic substances in various environmental media,
- being able to estimate bioaccumulation and biomagnification in land-based food chains as well.

4. Development of chemical analysis methods for environmental samples in order to:
- routinely be able to determine the substances subject to the Committee's phase-out proposals,
- routinely be able to determine the approved pesticides that are in use but cannot be analyzed routinely today,
- routinely be able to determine metals, particularly in kinds of samples that are difficult to analyze today, and
- achieve, where possible, good and inexpensive routine analysis methods that are less dependent on high-tech instrumentation.

The Committee judges the need for method development to be great, along with the need to validate, standardize and implement methods. The need for method development primarily exists in two areas:

- development of testing methods for properties and effects of substances,
- development of routine analysis methods where they are lacking today.

As far as development of testing methods is concerned, it is particularly urgent to devote research to devising methods that can reduce or eliminate the need for animal testing without diminishing the certainty in the risk assessment. In addition, there is a great need for extensive development of methods that identify endocrine-disruptive properties of substances, as well as refinement of methods for determining how persistent and bioaccumulative substances are.

When it comes to development of routine analysis methods where they are lacking today, this is of particular interest for finding out to what extent the substances that are used today leak out into the environment. This is true of many modern pesticides, only a few of which can be determined routinely in environmental samples (see section 9.1.5.4).

International collaboration is essential in both of these areas in order to avoid duplication of work in development, validation and testing of methods.

9.1.5.1 Development of alternative methods as a substitute for animal testing

When it comes to development of testing methods for determining the properties of substances, the Committee considers it particularly urgent that research that can lead to a reduced need for animal testing be stimulated. The objective in today's development of these alternative testing methods is that they shall:

- improve the conditions of the experimental animals,
- reduce the number of animals required, or
- completely take the place of animal testing.

Alternative methods may thus lead to a reduction in the number of animals needed in relative terms in some areas, and complete or partial replacement of animal testing with non-animal methods in other areas. It is important that the testing be developed and optimized so that a maximum of information can be obtained with a minimum of testing. Calculation and prediction models should also be refined as alternatives to testing. Here, for example, quantitative structure-activity relationships (QSAR) can be used for predictions of toxicity based on the inherent properties of chemicals (see Annex 3). In a similar manner, various measures of persistence can also be calculated by means of quantitative structure-property relationships (QSPR).

Modern genetic engineering opens up new possibilities. The use of DNA microarrays makes it possible in a relatively simple analysis to simultaneously study how tens of thousands of genes from a cell are expressed. It is hoped that patterns will eventually be seen, e.g. depending on exposure to a group of chemicals, or differences in expression between animals and humans. Perhaps impact indicators can be found in this way, e.g. a protein that acts as a marker for liver damage in humans. It is also hoped that light can be shed on individual differences in sensitivity to chemicals and mechanisms for harmful effects. It is, however, expected to take many years before these kinds of methods will reduce the number of animal experiments. The National Institute of Environmental Health Sciences in the USA has been conducting a very large research programme in this area since 1999.[4]

Council Directive 86/609/EEC prescribes that the Commission and the member states shall encourage research into the development and

[4] http://www.niehs.nih.gov/envgenom/

validation of alternative techniques which could provide the same level of information as that obtained in experiments using animals, and that animal experiments shall not be used where scientifically satisfactory results can be obtained by other methods. The Council of Europe's Convention (ETS 123, 1986) for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes contains a similar article on research support (Article 6). Sweden has been bound by the convention for many years.

In 1991, in order to coordinate the validation of alternative testing methods, the Europe Commission, together with the member states, industry and animal rights organizations, formed the "European Centre for the Validation of Alternative Methods" (ECVAM). Sweden participates today in the work of the ECVAM. A number of alternative tests have been proposed, some of which are under validation.

In the USA, "The John Hopkins Center for Alternatives to Animal Testing" is coordinating a project ("TestSmart") to shed light on the alternatives that are available for obtaining SIDS (Screening Information Data Set) within the American programme for high-production-volume chemicals. It may be of interest for Sweden and the EU to keep informed of this work, not least with a view towards the work of developing guidelines for testing in the OECD.

The Committee considers it urgent that Sweden continue to stimulate high-quality research that can lead to a reduction in the need for animal testing. The Committee would furthermore like to accentuate the importance of allocating money not only to research, but also to the validation and standardization of promising methods for routine use. This is an area that is often neglected today.

Even though the objective should be to switch completely to alternative testing methods in the future, it may be appropriate to underscore the fact that non-animal models will not be able to provide the same information as most testing methods on whole animals, such as cancer studies and multigenerational studies, within the foreseeable future.

Non-animal models can, however, be of very great importance for early screening of new chemicals, so that substances that exhibit known and undesirable properties, such as genotoxicity, can be screened out and not have to be tested on animals. Still, studies of whole animals will probably always be necessary for the final risk assessment, if the safety level we have today is to be maintained or raised. This is not least true

for quantitative risk assessment, i.e. calculation of what exposure level is acceptable – an assessment that is impossible to make today based on cell data.

In order to continue to strive for the introduction of more alternative methods, it is crucial to support basic toxicological research.

9.1.5.2 Development of testing methods for endocrine-disruptive effects

The Committee cannot set up any criteria today for when substances are so endocrine-disruptive that they should be phased out, since there are still no reliable testing methods available. Consequently, we see a great need for development and validation of testing methods in this area. There should be testing methods for various endocrine-disruptive effects that can detect disruptive effects in both higher and lower animals. In order to be able to develop screening-type testing methods in this area in the future, it is crucial that broad basic research be conducted to identify important mechanisms for the actions of endocrine-disruptive chemicals. The Committee's proposals for method development as far as endocrine-disrupting effects are concerned are described in greater detail in section 5.2.2 as a part of the plan of action that is proposed for the area.

Work is currently being pursued in this area within the framework of the OECD. This work aims at furnishing information and coordinating activities in the area, developing and revising guidelines for testing so that endocrine-disruptive effects can be determined, and working for harmonized hazard and risk assessment of endocrine-disruptive substances. The OECD is currently conducting a study within the framework of the "Task Force on Endocrine Disrupters Testing and Assessment" for the purpose of selecting promising existing testing methods, optimizing and refining the methods, and conducting validation studies. It is desirable that Sweden, aside from pursuing its own work in the area, be a driving force in the OECD's activities pertaining to endocrine-disruptive substances.

9.1.5.3 Development of testing methods for determination of how persistent and bioaccumulative substances are

Today's testing methods for biodegradation give limited answers. It is essential that methods be developed for testing of biodegradation in different environmental media aimed at determination of half-lives. This can be done by further development of present-day simulation tests, as well as by development of new simulation tests, which the Committee considers desirable.

The bioaccumulation potentials of substances are at best given today as bioconcentration factors (BCFs) that pertain to the aquatic environment. It is highly desirable that methods be developed for measuring BCFs that can be used to estimate bioaccumulation and biomagnification in land-based (terrestrial) food chains as well, comprising uptake in animals via food (including plants) and uptake in plants from air.

As is the case for all testing methods in the chemicals field, it is important that the goal of the method development be to get the methods internationally accepted by, for example, being adopted in the OECD's testing methods programme.

9.1.5.4 Development of analysis methods

There is a great need for development of chemical determination methods that can be used in routine determination of substances which are not included in today's environmental monitoring, but which it would be desirable to be able to monitor. This is above all true of the substances subject to the Committee's phase-out proposals.

There is also a great need for development of chemical determination methods for the approved pesticides that are used today, but for which there exist no methods for routine determination in any, or in sufficiently low, concentrations in environmental samples. Of the 350 or so substances that are registered in Sweden, only a limited number can be determined by means of routine analysis methods (30–70 percent, depending on the kind of pesticide; Hessel et al., 1997). The equivalent figure for the 800 active substances registered in the EU is 30 percent (Carter, 1998).

Analysis methods may need to be refined for a number of metals, although today's most modern analytical techniques (ICP-MS) provide

good results for the majority. But some metals are still difficult to measure, and certain kinds of samples, such as special soils, make the determination of most metals much more difficult. Development is thus needed in this area.

A targeted effort would also be desirable to develop good and inexpensive analysis methods that are not dependent on costly high-tech instrumentation as a substitute for or complement to other methods. With such simpler analysis methods, a large number of samples can be screened at low cost, and the content of any positive samples can, if needed, then be validated by other methods that can provide greater certainty in the determination.

The Council for Planning and Coordination of Research (FRN, 1998) has previously accentuated the need for development of analysis methods.

9.2 Need for environmental monitoring

Environmental monitoring of chemical substances is one way to acquire knowledge about which substances might constitute environmental problems. By measuring their occurrence in the physical environment as well as in human beings and other organisms, it is possible to obtain a picture of their occurrence in the environment, their pattern of distribution, and whether the concentrations are increasing or decreasing with the passage of time. From the viewpoint of the Committee, environmental monitoring is an important part of the follow-up of the measures that can be expected to result from the proposals that are being presented for the purpose of clarifying the effects of the measures. Environmental monitoring is also a significant source of information which, e.g. within the framework of the environmental objective of a non-toxic environment, can guide decisions on supplementary measures, such as cleanup.

A distinction is often made between screening studies and ongoing environmental monitoring programmes. Screening studies are normally temporary initiatives where an attempt is made during a limited period to create a picture of the occurrence of a wide spectrum of substances in the environment. This can lead to the inclusion of additional substances in existing environmental monitoring programmes.
In ongoing environmental monitoring of chemical substances, the occurrence of a given number of substances in a selected number of

media/species is determined with a given frequency. The ongoing environmental monitoring of chemical substances is limited by the number of substances chosen for measurement, inasmuch as there is little opportunity to find anything else besides what has been targeted.

9.2.1 Swedish environmental monitoring today

The Committee's appraisal and proposals

Environmental monitoring is an important follow-up instrument, as well as an important source of information to guide decisions on supplementary measures. The Swedish EPA is the government agency in charge of environmental monitoring in Sweden and should be commissioned to:

- together with the National Chemicals Inspectorate and the National Board of Agriculture, come up with proposals for funding and devise a programme for monitoring of pesticide residues in agricultural areas,
- propose a programme for extended health-related environmental monitoring to measure human exposure,
- propose an extended programme for regular screening studies of toxic pollutants in the environment and in organisms,
- find a way to obtain a general overview of the combined results of regional and local environmental monitoring,
- coordinate regular testing comparisons regarding determination of the pollutants that are measured by environmental monitoring.

In Sweden, environmental monitoring is one of the duties of the Swedish EPA. The Swedish EPA is responsible for and coordinates Swedish environmental monitoring, whose purpose is to keep a running record of the state of the environment and changes in it. Well-known toxic pollutants such as DDT and its degradation products, as well as PCBs, have been subject to environmental monitoring since the early 1970s, while substances such as hexachlorobenzene (HCB) and hexachlorohexane[5] (HCH) were not incorporated in the national environmental monitoring programme until the late 1980s (Swedish EPA, 1998). Other persistent organic pollutants (POPs) that are measured today within the framework of national environmental

[5] the pesticide lindane with isomers.

monitoring are chlorinated dioxins and furans, as well as certain brominated flame retardants. The scope of chemicals monitoring is limited to a great extent by the high costs of many analyses.

A number of metals are analyzed annually in a number of types of samples. All of them are obtained in the same analysis. We know that many of these metals – such as cadmium, mercury and lead – are causing or have caused problems. There is a great amount of data on concentrations of these metals in certain areas, for example the marine environment, while there is much less data in other cases. This is also true of metals used in relatively new sectors, such as the electronics industry. Broadened metals monitoring has been conducted within the framework of screening studies, where a number of the metals whose use has increased have been studied. The results show that there may be reason to keep closer track of concentrations in the environment of several unusual metals (see section 5.3.1.2 and Chapter 4 in Annex 6). In the Committee's opinion, such monitoring should be focused on sewage sludge and arable soil (see 9.2.2.1).

9.2.1.1 National environmental monitoring

A proposal for a new national environmental monitoring programme was presented by the Swedish EPA in June 1999 (Swedish EPA, 1999c). This proposal asserts that there is a great need for increased chemicals monitoring, and a group of substances that is particularly singled out is pesticides. Pesticide residues are not included at all in today's national environmental monitoring, with the exception of old chlorine-containing pesticides such as DDT and lindane.

However, the Swedish EPA foresees financial obstacles to extending environmental monitoring to include e.g. residues of the pesticides that are being used today. These obstacles are of two kinds: firstly, the analysis costs are high for these substances, as for other POPs; secondly, there is a great need for costly method development (see section 9.1.5.4). An application of the polluter pays principle is held out as desirable, but difficult to realize. The Committee considers it urgent that the problem of monitoring of pesticide residues in agriculture-intensive areas be solved and would like to point out that the National Chemicals Inspectorate and the National Board of Agriculture also have a responsibility in this area. The Committee therefore proposes that the Swedish EPA be commissioned to, together with these two other authorities, come up with proposals for a solution to the funding

problem and devise a programme for monitoring of pesticide residues which is relevant to their use in agriculture, preferably utilizing existing study sites for agricultural land. The sums spent on monitoring of diffuse sources of pollution in agriculture are greater today in Norway, and much greater in Denmark, than in Sweden.

The Swedish EPA's proposal for a new national environmental monitoring programme also emphasizes the need for extended health-related environmental monitoring. So far only a few projects have concerned human exposure. Following this up requires analysis of different chemicals in suitable indicator media – for example, cadmium, lead, PCBs, dioxins and brominated flame retardants in blood, and mercury in hair (which indicates exposure to methyl mercury via fish).

We would like to underscore that regularly recurrent screening studies are also of interest with regard to human exposure. A compilation of results from over 100 scientific reports identifies some 350 different organic pollutants that have at some time been encountered in breast milk, including some 90-odd dioxins and dioxin-like substances, plus some 190 volatile substances (WWF, 1999). Breast milk is thereby another type of sample that is well-suited for studies of human exposure (see also Figure 2.2 in Chapter 2).

9.2.1.2 Regional and local environmental monitoring

Regional and local environmental monitoring have great shortcomings, and there are above all two disadvantages that the committee sees as particularly troublesome. In the first place, it is very difficult to obtain an overview of the combined results of regional and local environmental monitoring. There are no means for compiling the results of regional and local environmental monitoring, and compilation is further complicated by the fact that the results can be stored in different formats and on different media.

In the second place, comparability of the results of local and regional environmental monitoring is limited by the fact that e.g. measurement programmes for pesticide residues in water may cover different groups of substances, due to fact that the programmes are not standardized. Furthermore, discrepancies may arise due to differences in results from the different analysis laboratories engaged to do the work. The latter is a problem that requires regular testing comparisons to be able to rectify. Such comparisons normally come from the laboratory in the country that

functions as the national reference laboratory in the area in question. This function does not exist in Sweden today, however, which the Committee considers a shortcoming. Furthermore, testing comparisons are organized solely to a limited extent and on local initiatives.

In cases where local monitoring is performed, it usually entails:

- carrying out mandatory inspection programmes,
- measuring atmospheric pollutants in an urban environment, and
- measuring mercury and certain metals in fish in lakes in the municipality.

Regional environmental monitoring of chemicals is very limited, but there are a number of examples. Some counties have combined resources and measure PCBs, DDT, HCG, HCB in fish in e.g. Lakes Vänern and Vättern. In other cases certain atmospheric measurements are made. A large integrated project has been conducted for several years in the drainage basin of the Emån River. On the West Coast, measurements of certain metals have been made in humans. In Värmland County, measurements have been made in fish and human hair. A number of agricultural counties have conducted campaigns to measure certain pesticide residues. There is usually no coherent regional chemicals monitoring, nor is there any good way of obtaining a comprehensive picture of the monitoring that is done.

Starting in 2000, the national environmental monitoring programme will fund environmental monitoring at one station, Vemmenhög, a background station on the south coast of Skåne, where certain pesticide residues will be measured during certain parts of the year (Swedish EPA, 1999c). The Vemmenhög area is one of the study sites on agricultural land included in what was previously called Recipient Monitoring in Agriculture, and is now incorporated for the most part in regional environmental monitoring.

9.2.2 Proposals for strengthened environmental monitoring

The Committee's appraisal and proposals

Sweden's national environmental monitoring should be expanded for the purpose of keeping track of those improvements in the state of the environment that can be expected to occur as a result of the measures that need to be taken to achieve the environmental objective of a non-toxic environment:

- Chemicals monitoring should take place closer to the source than is the case today, and focus more on the "worst case".
- Many of the phase-out substances that have not previously been subject to environmental monitoring should be followed.
- Environmental monitoring of pesticides should be introduced and concentrated primarily on agricultural areas.
- Chemicals monitoring should cover those substances that are prioritized in the EU's coming water framework directive.
- In large monitoring programmes, more metals that can be analyzed with modern analytical techniques should be included than is the case today, and the form of occurrence of certain metals should also be determined.
- "Environmental monitoring of products" should be developed and carried out.
- Screening studies should be conducted at regular intervals as a basis for designing and optimizing a chemicals monitoring programme.
- Regional chemicals monitoring must be better coordinated and provide a better overall picture of the situation.
- "Sample banks" must exist to permit back-tracing of any new toxic pollutant problems discovered in the future.
- Chemicals monitoring should be augmented with models that predict the transport of substances in the environment and are refined and validated by comparison with measurement results.

The Committee sees a need for strengthened environment monitoring in a number of areas. The national environmental monitoring programme should be expanded for the purpose of keeping track of those improvements in the state of the environment that can be expected to occur as a result of the measures that need to be taken to achieve the

environmental objective of a non-toxic environment. Are those substances that fall under the Committee's phase-out criteria present in the environment, and if so where? Do they reach man? Some success in this area can be achieved by better coordination of regional and local chemicals monitoring, for the purpose of both achieving higher cost-effectiveness and providing a better overall picture of the situation.

9.2.2.1 Ongoing chemicals monitoring

Chemicals monitoring should take place closer to the source than is the case today, and focus more on the "worst case" for the purpose of detecting problem chemicals at as early a stage as possible. Data on background levels must, however, be available as reference values for these measurements.

In the Committee's opinion, there may be a need for ongoing monitoring of several of the phase-out substances that have not previously been monitored. A continuous evaluation is also needed of long-term trends in changes of the concentrations of substances in the environment and in organisms in relation to how their use is regulated in society – among other things in order to permit follow-up via the indicators that are proposed by the Swedish EPA and the Environmental Objectives Committee (see section 9.3). The Swedish EPA should be commissioned to come up with proposals for substances to be included in such a programme, preferably with reference to those prioritized by OSPAR-DYNAMEC, as well as the substances that should be subject to target values in accordance with the proposals of the Environmental Objective Committee (SOU 2000:52). In conjunction with this, a review of sampling strategies and methods would be desirable for the purpose of bringing about improvements.

There is at present no reason to reduce the monitoring of the toxic pollutants that are included in today's chemicals monitoring. Regardless of whether restrictions are introduced in Europe, many such substances will reach us via long-distance transport. However, it is important to make sure that monitoring of toxic pollutants also covers those substances that are prioritized in the EU's coming water framework directive, which is currently under discussion.

Pesticides are the only chemical substances that are intentionally spread for the purpose of causing toxic effects, and their handling is strictly regulated. Despite today's controls and restrictions, however, pesticide

residues can be found in all parts of the environment (Kreuger, 1999). But a complete picture of the situation cannot be obtained, because only a limited number of the substances used today can be determined by routine analysis methods (see section 9.1.5.4). The Committee sees a need for environmental monitoring of both the pesticides that are used today and previously used pesticides that are persistent and still present in the environment. This monitoring should be concentrated primarily on agricultural areas.

Modern analytical techniques permit analysis of many more metals at the same time than was previously possible. Future environmental monitoring in the metals area should therefore be expanded to include as many metals as possible. In large monitoring programmes, more metals should be included than is the case today. In metals monitoring, the Committee sees reasons to determine the metals' speciation in many cases, since both the bioavailability of the metals and their toxicity are dependent on their form of occurrence. There may, for example, be reason to investigate the occurrence of methyl mercury in people who belong to high-exposure or particularly sensitive groups. When it comes to metals, suitable sampling strategies can be aimed at sewage sludge and near-urban environments, since it is presumably easiest to identify diffuse emissions there. Other interesting sample types are arable soil and foods. For example, the occurrence of cadmium in root vegetables such as potatoes and carrots should be followed.

Besides traditional environmental monitoring, environmental monitoring of products should be developed and carried out (see also section 9.1.2.1).

It is important that environmental samples be collected in "sample banks" to permit back-tracing of any new toxic pollutant problems discovered in the future. A spectrum of environmental samples must be collected from a sampling grid over Sweden and stored in such a sample bank.

9.2.2.2 Screening studies

Ongoing environmental monitoring of chemical substances is of great importance for follow-up of restrictive measures, in particular against substances that are persistent and bioaccumulative. Environmental monitoring does not, however, normally contribute to the discovery of new potential toxic pollutants. In order to obtain a broader overview of

which chemical substances occur in the environment, beyond those incorporated in environmental monitoring programmes, periodic screening studies are also needed. These studies should have a broader scope to detect the presence of possible toxic pollutants in the environment. A greater emphasis on screening can provide a better platform for designing and optimizing chemicals monitoring.

9.2.2.3 Transport models

Nevertheless, it is not possible to constantly measure everything everywhere. Instead, the knowledge obtained from limited measurements must to some extent be extrapolated to other substances and situations. Future environmental monitoring of chemical substances therefore needs to be augmented to a greater extent than today with models that predict the possible transport of the substances in the environment. These predictions will provide indications as to when, where and how we should take measurements. At the same time, the measurement results from chemicals monitoring provide important guidance for refinement and validation of the models.

9.3 Follow-up with the aid of indicators

It is the opinion of the Committee that most of the follow-up that is needed to ensure compliance with the new guidelines on chemicals policy should be able to be done with the aid of the indicators proposed by the Swedish EPA (Swedish EPA, 1999e; see also National Chemicals Inspectorate, 1999) and further developed by the Environmental Objectives Committee (M 1998:07), see (SOU 2000:52). The Environmental Advisory Council has also proposed indicators in the form of ”green headline indicators”. One of the headline indicators is aimed at use of chemicals (SOU 1999:127). Within the framework of these measures, however, we would like to stress that we consider it especially important to focus on those substances that will be subject to the Committee’s proposed phase-out criteria as well as the proposals concerning metals (see Chapter 5).

We do not consider it our primary task to submit proposals in this area. However, we would like to stress the need for the various public authorities, in their continued work with the proposed indicators, to refine and define the indicators more precisely so they can be used to follow up compliance with the new guidelines. In this section we

highlight those indicators which in our opinion are of particular importance for the follow-up of our proposals.

The idea is that the indicators should be expressed in a single digit. The system of indicators for following up the environmental quality objectives is largely based on existing systems for follow-up and monitoring, such as databases and results from environmental monitoring. We conclude that the existing systems and the indicators need to be developed to meet the follow-up needs stemming from the objective of a non-toxic environment and the new guidelines. For one thing, today's systems do not permit follow-up of the occurrence of chemical substances in finished products.

Knowledge goal

One of the indicators proposed by the Swedish EPA for follow-up of the knowledge goal is: ”number of substances for which minimum data exist”. The Swedish EPA says that this indicator needs to be developed. The Environmental Objectives Committee defines the indicator more precisely as ”number of substances with minimum data on properties”, which the Committee backs. The minimum data requirement should be equivalent to the requirements made on new substances, depending on their production and import volumes (see Chapter 4).

The Swedish EPA also maintains that an indicator that needs to be developed for the knowledge goal must take into account ”Material flows and metal balances”. The Committee would like to underscore that it is important to be able to measure flows of e.g. metals in society (see section 7.4.3) and that this is a prerequisite for being able to follow up compliance with the new guidelines.

Information goal

It is the judgement of the Committee that a system for information on the chemical content of products is imperative, and that such a system needs to be specially investigated (see section 7.4.1). We believe that the question of follow-up of this subgoal should mainly be addressed on the basis of the proposed investigation. Certain indicators can, however, be set up on the basis of existing systems.

The Swedish EPA proposes as an indicator for follow-up of compliance with the information goal: ”number of annually registered environmental product declarations which include declaration of chemical content”, which the Committee supports (see section 7.3.4). However, in our opinion the measure should rather be based on the total number of environmental product declarations to date, so that it does not only reflect the variation in number from year to year. Further, in our view the phrase ”declaration of chemical content” should perhaps be replaced with ”information on chemical content”, since the design of the system should perhaps permit information to be furnished without a declaration of the complete chemical content.

The Environmental Objectives Committee proposes as an indicator for the information goal: ”value of consumption of ecolabelled goods and services in society”. It is, however, the opinion of the Committee that it should perhaps be related to e.g. the consumer price index, to eliminate the risk that the indicator will only reflect inflation.

Goal regarding particularly dangerous substances

The Swedish EPA proposed as an indicator for follow-up of compliance with the goal regarding particularly dangerous substances: ”net influx of chemicals, number and quantity, and total for substances with particularly dangerous properties, plus hazard index for all classified substances”. In the opinion of the Committee, in this measure the phrase ”particularly dangerous substances” should be equated with those substances subject to our proposals in Chapter 5. Since we propose that exemptions from the phase-out criteria could be granted for use in industrial plants, a supplement to the products register is needed.

The Environmental Objectives Committee proposes as an indicator for the goal regarding particularly dangerous substances: ”emissions trends for substances in the chemical emissions register”. The Committee backs this measure and understands it to be the chemicals emissions register proposed by the Swedish EPA (Swedish EPA, 1999a).

Monitoring the occurrence of substances in imported products is not possible today. This will be made easier if a system is introduced for information on the chemical content of products. But if we assume today’s systems, then measurements in sewage sludge can, for example, provide an indication of whether diffuse emissions are taking place of the substances to be monitored. The sources must then be traced so that it

can be determined from which products the emissions are coming and whether they are old products or newly produced ones. Both the Swedish EPA and the Environmental Objectives Committee propose as an indicator for the goal regarding particularly dangerous substances: ”concentrations of chemicals in sludge (from sewage treatment plants)”, which the Committee supports.

The Environmental Objectives Committee also proposes as an indicator for the goal regarding particularly dangerous substances: ”proportion and quantity of products with content of heavy metals that are collected”. The Committee finds that it would be desirable to broaden the measure to include to as great an extent as possible the total recycling of metals, not just the group that falls within the less well-defined category ”heavy metals”.

10 Consequences of the Committee´s proposals

10.1 Consequence analyses etc.

According to its terms of reference, our Committee shall analyze the consequences of its proposals and submit proposals for funding in those cases where the proposals lead to consequences for public finances. The Government's terms of references to all committees and special investigators also apply to our Committee, which means that the Committee shall submit cost-benefit analyses, consider public obligations, assess regional policy consequences and report consequences for criminality and crime prevention, municipal self-government, small enterprises, gender equality, racial integration and personal integrity.

We do not expect our proposals to lead to any effects with regard to criminality and crime prevention, municipal self-government, gender equality, racial integration or personal integrity, so these consequence areas will not be discussed further here. As far as criminality is concerned, however, obviously every new regulation provides another opportunity for infraction.

What remains is to submit cost-benefit analyses, consider public obligations, assess regional policy consequences and report consequences for small enterprises.

10.1.1 How can the consequences be assessed?

Following is a more detailed description of the requirements on consequence analyses made on the Committee. At the same time we describe the delimitations that have been made in the work and summarize our appraisals. The Committee's points of departure in the consequence analysis work are presented in section 10.2, and the

consequences structured according to the guidelines are presented in 10.3.

Consideration of public obligations

According to our Committee's terms of reference, every public obligation shall be carefully considered and justified. The point of departure is that public obligations are only justified when the private market cannot satisfy the needs in question.

The Committee has striven as far as possible to place the responsibility for manufactured and chemical products on manufacturers and importers, but some measure of regulation and enforcement is necessary in order to achieve compliance with the guidelines. In the first place, laws and rules must establish the minimum acceptable level of protection in society, and in the second place enforcement must ensure that all enterprises can compete on fair and equal terms. There is no further discussion of the consideration of public obligations here. Chapters 6 and 7, however, explain why certain proposals involve EU regulation while others entail Swedish rules.

Consequences for employment and public services in different parts of the country

The goal of Swedish regional policy is to create the conditions necessary for sustainable economic growth, justice and freedom of choice so that living conditions are equivalent for citizens in all parts of the country. A holistic view is required in order to achieve this goal. The Committee has therefore asked itself the question of whether our proposals can have regional policy consequences, and we have arrived at the conclusion that the Committee's proposals do not have any impact on public services in any part of the country. The Committee also concludes that the conditions for enterprise are not affected differently in different parts of the country.

We have not been able to judge whether any particular company that accounts for a large portion of the jobs in a specific locality will be greatly impacted by the Committee's proposals. It is not possible to judge which companies will be affected due to a lack of knowledge regarding e.g. what chemical substances are present in finished products

today. The regional consequences are not discussed any further in this chapter.

Consequences for small enterprises

If the Committee's proposals have consequences for working conditions, competitiveness or other basic operating conditions for small enterprises in relation to larger enterprises, these consequences shall be described in the report. The Committee makes the general appraisal that requirements and regulations that lead to consequences for enterprises often impose a burden that is harder to bear for small enterprises than for large ones. Proposals that necessitate extensive changes in production or force the companies to furnish information entail costs that are greater in relation to turnover for small enterprises. The Committee's proposals also generally require companies to increase their knowledge and competence regarding chemicals. This competence is probably more difficult to build up in small enterprises, for whom hiring personnel with the necessary qualifications in chemistry and environmental engineering entails a greater burden. This situation is aggravated by the fact that small enterprises are in many cases not members of the trade associations in which the large enterprises are organized.

The consequences for small enterprises are not dealt with further in this chapter.

Costs and benefit for society, national and local government, companies and other individuals

According to the Committee's terms of reference and Section 14 of the Committee Ordinance, the Committee shall calculate and report the economic consequences of its proposals. This applies not only to consequences for the state, but also everyone who might conceivably be affected by the proposals. Funding shall be proposed for those proposals that raise costs or reduce revenues for national and local government (state, municipalities or county councils). Effects both with and without market value shall be reported in the integrated socio-economic analysis.

The Committee's cost calculation capabilities have been sharply curtailed by the fact that so many factors are still unknown. Instead we have mainly been restricted to qualitative discussions of the conse-

quences, illustrated by calculation examples based on assumptions concerning a number of currently unknown facts.

The Committee has not attempted to put price tags on items that cannot naturally be evaluated in money terms. Different types of effects are reported as positive or negative, and not weighed against each other.

10.2 Points of departure in the consequence analyses

Health, environment and economics

Society's environmental impact is closely related to its economic activities. The environment is affected by extraction of natural resources as well as by residual products (waste) that are generated and transported via air, soil and water. Such waste products arise in production, during use and when a chemical product or manufactured product has reached the end of its useful life.

Environmental and health aspects are also closely related. It is more than just a question of a bad environment being harmful to human health. It is also a question of the fact that methods and solutions must often be devised jointly to improve both the environment and public health. Man has always been exposed to various environmental factors that have had a greater or lesser effect on his health. As a result of the population increase and the rapid pace of technological development, man has impacted the environment to an ever-increasing extent. This impact can also pose a threat to our health.

To rectify the health problems that stem from society's environmental impact, it is necessary to consider not only the purely "technical" solutions, but also the underlying political, economic, and social mechanisms. Costs that arise as a result of health effects include both direct costs stemming from hospital care and loss of income, and indirect costs stemming from loss of well-being, such as mental suffering.

Changes in water and air quality are examples of changes in the environment that can lead to health effects. Chemicals that contaminate the water can lead to cancer, allergies or other health effects. Changes in the environment also affect the economy both directly and indirectly via effects on health and employment. The economy in turn can cause effects on both health and environment. Economic changes, for example,

influence how much money can be spent on health care and a better environment.

Previously, nature was viewed as an infinite resource from which raw materials could be taken without consequences. Today the economic system is not viewed as being independent of the ecological system, but rather as part of it.

The economic system is an open system, which means that input in the form of material and energy must eventually be returned to the ecocycle. Much of the energy and material that passes through the economy is ultimately released to the environment without recycling. Sometimes this process has a negative impact on the environment. Metals and chemical substances that are manufactured eventually end up in soil, water and air. One reason for this is that environmental products and services often have no price, which means that the market price of the products of the economic system do not reflect pollution. This can lead to overexploitation.

Environmental measures yield results

In some cases it is difficult to gauge the exact effects of a measure, in particular if several measures have been adopted simultaneously. There are, however, examples that show very clearly that environmental measures yield results. One such example is the fact that the levels of lead in children's blood declined when lead in petrol was banned (see Figure 10.1).

Figure 10.1. Relationship between lead concentrations in blood and petrol

The upper graph shows the concentrations of lead in the blood of 2,771 children in Landskrona (where a lead smelter is located) and in Trelleborg. The lower graph shows the estimated amounts of lead in the petrol that was sold in Sweden during the same years. (Skerfving et al., 1999)

Lead in blood (µg/l)

Lead in petrol (tonnes)

10.2.1 The Committee's view of cost-effectiveness

The Committee has adopted the view of cost-effectiveness in environmental endeavours presented in the Environmental Advisory Council's report "The principles of environmental policy" (SOU 1994:133, in Swedish only).

> *"When one examines different environmental actors' references to cost-effectiveness, two views of what this means crystallize. The first interpretation is that measures are cost-effective when the cost of the damage that arises if the measure is not adopted is greater than the cost of the measure. The other interpretation is that a cost-effective measure is the least expensive way to achieve a predetermined environmental objective (e.g. an emissions limit), quite irrespective of whether it has been possible to calculate the economic scope of the damage, and if so what the calculation shows. In this second interpretation, the cost of a measure is compared with the costs of alternative measures.*
>
> *"The strictest and most limited interpretation is of course that both criteria must be satisfied for a measure to be regarded as cost-effective. The cost of the measure in question would be lower than both the cost of the damage in the absence of the measure and the costs of alternative measures. However, if we look at the contexts in which references are made to cost-effectiveness, for example Principle 15 of the Rio Declaration, this strictest interpretation does not appear to be the most reasonable. Principle 15 of the Rio Declaration (embodying the precautionary principle) says '...lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.' Scientific certainty in the form of quantified cause-effect relationships is in most cases a prerequisite for being able to calculate the marginal cost of the damage and compare this with the marginal cost of the measure.*
>
> *"Accordingly, if it were necessary for determining whether measures are cost-effective to have this scientific certainty, which the statement of the precautionary principle says should not be needed, then the lawyers and diplomats responsible for the Rio Declaration would have created a Catch 22. This cannot have been their intention, from which it follows that a measure is by definition cost-effective if it is the least expensive alternative."*

The Swedish EPA shares this appraisal, which they expressed in conjunction with their work with environmental objectives (Swedish EPA, 1999e). Based on this definition, the Committee's endeavour has been to find the most cost-effective ways to comply with the guidelines in the Committee's terms of reference.

The long-term costs of the ”environmental debt”

A well-executed consequence analysis contributes to a better and more complete decision-making basis. Aspects that must be taken into account include the fact that there may be measures that affect several objectives simultaneously.

In general, it can be said that a selection of measures can be executed in different ways. The extreme cases for environmental measures are either to implement as many and as far-reaching measures as quickly as possible to achieve the objectives as soon as possible, or wait as long as possible to implement measures and thereby achieve the objectives as late as possible.

The first alternative will cost more than the second alternative in the short term. The cost for companies and the rest of society will be high due to a forced restructuring. On the other hand, the accumulation of adverse environmental impact that occurs in the second alternative, with adverse consequences on health and the environment, is avoided in the first alternative.

The second alternative will probably lead to less negative economic effects in the short term, since the work towards the environmental quality objectives proceeds at a slower pace. Those who are obligated to reduce their environmental impact have more time to explore possible measures and implement them gradually. On the other hand, this alternative leads to greater environmental impact and a higher risk of irreversible environmental damage, which can result in higher costs in the long term (Swedish EPA, 1999e).

It is therefore important to have a well thought-out strategy for which measures are to be implemented and when. Both the long-term and the short-term perspective must be kept in mind in devising such a strategy. A balance must be struck between economic considerations and a reduced risk to health and the environment. Here are some examples of questions that must be asked when selecting a strategy for choosing environmental measures and deciding when they should be implemented:

- Are there any effects of the activity that are particularly severe or impossible to correct?
- Which measures become more expensive the longer we wait?
- Which measures become less burdensome for the economic system if they are implemented far in the future?

It is also important to bear in mind that even if the choice stands between implementing the changes today or putting them off until a later date, the cost of exploiting the environment must be paid sometime. It is merely a question of what path of action to take and the pace at which it is taken.

Examples of costs in quantitative terms

Tracing, collecting and destroying or otherwise disposing of dangerous substances that have been dispersed in society can be very costly. Here are some examples of what it can cost to remedy environmental problems after the fact:

- The building sector's ecocycle council has roughly estimated that it would take 2000 man-years to clean up the PCBs in caulking compounds. To this must be added the costs for destroying the collected material. PCBs are also found in other products, such as small capacitors for e.g. fluorescent light fixtures and certain types of vinyl flooring (National Chemicals Inspectorate, 1999).
- In 1993, the Swedish EPA estimated that there were approximately 100 tonnes of mercury in circulation in products in society. SEK 18 million has been allocated to several projects by the Swedish EPA's action programme (1994–1999) against mercury. The projects have led to the collection of 6–7 tonnes. In addition there are about 3.5–4 tonnes that have been labelled in products and are still being used in society. Final repositories of mercury were also investigated in the action programme. The Swedish EPA proposes that mercury waste be converted to a stable, insoluble form and placed in a deep rock repository at a depth of several hundred metres. The costs of depositing mercury in a deep rock repository would amount to a total of roughly SEK 260 ± 80 million, according to calculations by the Swedish EPA (Swedish EPA 1997 and 1999g).
- The Swedish EPA estimates that it will cost SEK 20 billion to remediate the 10,000 top-priority (from a risk point of view) contaminated sites. There are a total of 22,000 contaminated sites that need to be remediated (National Chemicals Inspectorate, 1999).

During the past decades, in response to various kinds of legislation, companies have modified their process technology or installed pollution control equipment for the purpose of limiting damage to the environment. By means of preventive measures, chemical substances can be kept from contaminating the environment. This is particularly important, since adequate knowledge of how dangerous substances are

and in what products they are present is lacking today. Once the knowledge exists, it can be much more costly to restore the environment than to avoid causing damage to the environment and human health in the first place.

10.2.2 The importance of environmental requirements for profitability and competitiveness in business

The traditional view is that tougher environmental requirements increase the costs for the companies that have to comply with them. This is true no matter what form the requirements take. This view has been questioned, however. The economist Mikael Porter for one has asserted that environmental requirements make companies more efficient, and therefore have a beneficial effect on profitability and competitiveness. Porter's hypotheses have been vigorously challenged by other economists, however.

Empirical studies do not provide evidence for or against Porter's arguments, nor is it possible to detect either positive or negative effects for the economy as a whole. There are examples of companies where tougher environmental requirements have improved profitability, but there are also examples of the opposite (National Board of Trade, 1998).

Improved environmental performance can lead to increased demand for goods, services and systems in an increasingly environmentally aware society. "Sustainable Sweden – a SUCCESS story" (SOU 1998:118) observes:

> "...many companies discovered long ago that concern for the environment constitutes a business opportunity. The concrete work of environmental improvement is often – though not always – synonymous with more efficient use of raw materials and energy. This means that resource consumption per unit produced decreases, which can in turn boost profitability. In this way, ecological restructuring can be the bearer of growth, employment and prosperity."

The environmental quality objective of a non-toxic environment is a great challenge for industry. If the objective is to be achieved, chemicals and products containing substances with hazardous properties must be replaced with less risky substances. To bring down polluting emissions, industry must continue to the work of creating closed-loop manufacturing processes wherever possible as well. The health and

environmental impact of the products must be considered during their entire life cycle, ”cradle-to-grave”.

An example where environmental measures within companies have yielded positive consequences for the company’s financial performance is Electrolux, which by being early to offer alternatives to CFCs in refrigerators won shares on the world market when an international ban came. Another example is AB Exaktafjädrar, which previously cleaned all its springs in trichloroethylene. By ceasing to clean most of the springs and switching the method used for those that were cleaned to ultrasonic cleaning with a biodegradable cleaning and degreasing agent labelled with ”Good Environmental Choice”, the company makes an annual saving of nearly SEK 61,000 on an investment of about SEK 1,000 – in addition to the environmental and industrial hygiene gains.

There are many other positive examples, but finding examples where environmental requirements have had negative consequences for companies is not as easy, possibly because such examples have not been regarded as interesting to document and publicize to the same extent.

Importance of the time aspect

Long-term stability and consistency are important for industry. Most mechanical equipment and product ranges undergo at least one replacement during a ten-year period. Proposals for tough regulations that will enter into force in 10 years therefore have much milder effects than proposals that will enter into force in 1–2 years. Planning well in advance with clear signals from the national authorities should lead to the limited consequences for industry.

10.3 Consequences of the Committee’s proposals

The Committee’s proposals will have consequences in several different sectors in society, of which the most important consequences are described below.
First the economic consequences for Sweden of pursuing issues in the EU are described. This analysis applies to many of the proposals. The subsequent consequence descriptions are divided into consequences of the Committee’s proposals regarding knowledge of the health and environmental properties of substances, consequences of the Com-

mittee's proposals to phase out the use of PB and CBR substances, and consequences of the Committee's proposals regarding metals.

10.3.1 Consequences of pursuing issues in the EU

Many of the Committee's proposals are proposals that Sweden should pursue issues (advocate changes) in the EU (see Chapters 4 and 6). Pursuing issues in the EU is associated with costs – effort and resources are required to enlist support for ideas. These costs will be distributed between the Government Offices and the agencies that work with the relevant issues. Exactly how the costs are distributed will depend on what work method the Government chooses. The agency most concerned with the work of pursuing the Committee's proposals is the National Chemicals Inspectorate.

According to a Government decision of 18 May, our Committee has been given the extra assignment of reviewing the future thrust, activities and resources of the National Chemicals Inspectorate, taking into consideration the rules of the Environmental Code, the environmental quality objective of a non-toxic environment, and the trend in the chemicals field in the EU and internationally. The future role of the companies – as well as that of central, regional and local supervisory authorities – shall also be examined.

Based on the conclusions of this review, the Committee shall also submit proposals for the future scope and thrust of the activities of the National Chemicals Inspectorate and submit proposals on how the activities of the National Chemicals Inspectorate should be funded. Consequently, no further analysis of these costs is made in this report.

10.3.2 Consequences of the Committee's proposals regarding knowledge of the health and environmental properties of substances

In Chapter 4 we propose that knowledge corresponding to the requirements made on new substances shall be gathered for all chemical substances used on the market.

Financial consequences for the chemical industry

The Committee's appraisal

- The consequences for Swedish industry are dependent on a large number of factors not known today. Above all, no one knows how many substances are used on the market today.
- It is not possible to predict how the costs will be distributed between different companies.

Calculating the costs of gathering data on all relevant substances is of course very difficult, since many factors are unknown, above all how many and which substances require new or supplementary data. After contacts with the Association of Swedish Chemical Industries, we can conclude that the costs will probably be distributed quite differently among different companies. There is no picture today on what substances data are available for, and how great the need for supplementary tests is.

In principle, every step that would have to be taken in a cost calculation is associated with very great uncertainty. Step one is to determine how many substances the calculation should apply to. No one knows how many substances are used on the market today. The EU's database for existing substances, EINECS, contains more than 100,000 substances. The problem with this figure is that the companies knew when the database was established that data requirements would be made on substances that were not included in EINECS but which companies would later want to manufacture or import. As a result, the companies notified "all" substances – regardless of whether they manufactured or imported them or not. That means that EINECS today contains many more substances than actually occur on the market. Common guesses are that approximately 20,000–30,000 substances are used on the market today, others are 40,000–60,000 substances. The Swedish products

register contains 11,000 substances that are used in products on the Swedish market.

Step two is to determine how much data have already been compiled for various substances. The Committee finds it probable that the companies that manufacture or import various substances have some kind of knowledge about these substances. However, this knowledge is not always public, and it is impossible to know how extensive it is. Nor can the Committee know with certainty how much it costs to compile all the data for a substance.

According to a study by the US EPA, it costs USD 205,000 (about SEK 1,800,000) to compile data for a substance for which there are no data at all to start with and for which a complete SIDS (Screening Information Data Set) must be compiled according to the OECD. The European Chemical Industry Council (CEFIC) has also made an estimate of the cost of collecting complete SIDS data for HPV (high-production-volume) substances (CEFIC, 1999). Their estimate is much more approximate, however, and they calculate that the cost for substances that completely lack data today will be EUR 200,000–400,000 (about SEK 1,700,000–3,400,000).

As has already been mentioned, distribution of the costs is another uncertainty factor. Which companies will have to bear which costs. Will the costs be distributed among the companies in proportion to their share of the industry's total turnover, or will each company have to take sole responsibility for every substance it produces?

The Committee has no opinion on how the industry and the companies will solve this. According to the Association of Swedish Chemical Industries, it is not likely that the companies are prepared to bear the costs of their competitors, even if their own costs are also distributed.

Despite all the aforementioned uncertainty factors, the Committee has carried out three calculation examples to try to provide some idea of the approximate magnitude of the costs. However, it merits repeating that the uncertainty surrounding virtually all the values used in the examples is great, which means that the results are also very uncertain.

We have made three alternative assumptions regarding how many substances are used on the market and will be candidates for testing. Example 1 entails a minimum assumption of 11,000 substances. Example 2, which is the one we deem to be most realistic, assumes

20,000 substances. Example 3 is a worst-case assumption of 40,000 substances. We further assume that some data have already been gathered for half of these substances, while the other half completely lack data.

We figure on the cost the US EPA has calculated for collecting SIDS for HPV chemicals, namely USD 205,000. This cost is lower than what the actual cost for HPV and MPV (medium-production-volume) substances will be according to our proposals, however, since our proposals call for more data. However, the SIDS requirements are slightly greater than the requirements we propose for LPV (low-production-volume) substances. For those substances that have some data, we assume that the cost is on average half of the cost for complete testing.

The total cost for testing is then as follows: Example 1 about USD 1,700 million[1]; Example 2 about USD 3,000 million[2]; Example 3 about USD 6,100 million.[3]

If the costs are distributed among the countries in proportion to each country's chemical industry's share of the total turnover for all the countries that adopt the Committee's proposals, and provided that the EU, the USA and Japan adopt our proposals, the Swedish chemical industry's share of the test costs would be 0.5 percent and the EU's share would be 42 percent. This means that the costs for Swedish industry in Example 1 would be SEK 73 million,[4] in Example 2 about SEK 130 million[5], and in Example 3 about SEK 270 million.[6] The costs for EU industry in Example 1 would be about SEK 6,200 million,[7], in

[1] 1,000 substances x 0.5 x USD 205,000/substance + 11,000 substances x 0.5 x USD 205,000/2/substance = USD 1,691,250,000
[2] 20,000 substances x 0.5 x USD 205,000/substance + 20,000 substances x 0.5 x USD 205,000/s/substance = USD 3,075,000,000
[3] 40,000 substances x 0.5 x USD 205,000/substance + 40,000 substances x 0.5 x USD 205,000/2/substance = USD 6,150,000,000
[4] USD 691,250,000 x 0.005 = USD 8,456,250; USD 8,456,250 x SEK 8.67/USD = SEK 73,315,687.50
[5] USD 3,075,000,000 x 0.005 = USD15,375,000; USD15,375,000 x SEK 8.67/USD = SEK 133,301,250
[6] USD 6,150,000 x 0.005 = USD 30,750,000; USD 30,750,000 x SEK 8.67/D = SEK 266,602,500
[7] USD 1,691,250,000 x 0.42 = USD 710,325,000; USD 710,325,000 x 8.67 = SEK 6,158,517,750

Example 2 about SEK 11,200 million[8], and in Example 3 about SEK 22,400 million.[9]

We have then spread the cost out over nine years, i.e. the number of years proposed by the Committee after which no substance may be used without known data. For Sweden, this comes out to about SEK 8 million per year in Example 1, SEK 15 million per year in Example 2 and SEK 30 million per year in Example 3. For the EU, the equivalent figures are about SEK 700 million per year in Example 1, about SEK 1,000 million per year in Example 2 and about SEK 2,500 million per year in Example 3.

This can be compared with the total turnover of the chemical industry in Sweden and the EU, respectively, which is SEK 71,000 million for Swedish industry (Association of Swedish Chemical Industries, 2000a) and SEK 3,240,700 million for industry in the EU (CEFIC, 1999).

In the unlikely event that the testing costs were distributed evenly in relation to turnover, they would thus amount to between 0.01 percent and 0.04 percent of the chemical industry's annual turnover in Sweden, and between 0.02 percent and 0.08 percent of the chemical industry's annual turnover in the EU.

Today a project is under way to collect data on HPV chemicals that is quite independent of the Committee's proposals. In the USA, the US EPA has initiated a programme which aims at collecting data equivalent to the OECD's SIDS for all of the nearly 3,000 HPV chemicals used in the USA. In parallel with this project, a project is being conducted at the initiative of the ICCA (International Council of Chemical Associations) in which 1,000 HPV chemicals are to be tested. These two initiatives cover the same substances to some extent. These projects thus entail that some data will be gathered voluntarily for a substantial number of the substances regarding which the toughest requirements are to be made according to the Committee. However, the Committee proposes more extensive data requirements than those aimed at by the voluntary initiatives. These initiatives have not been taken into account in the above calculation examples.

[8] USD 3,075,000,000 x 0.42 = USD 1,291,500,000; USD 1,291,500,000 x 8.67 = SEK 11,197,305,000

[9] USD 6,150,000,000 x 0.42 = USD 2,583,000,000; USD 2,583,000,000 x 8.67 = SEK 22,394,510,000

As regards costs for the companies of an initial risk assessment and necessary precautionary measures, the Committee has not done any cost calculations, since this is already required according to the Environmental Code.

Viewpoints of the Association of Swedish Chemical Industries

The Association agrees with the Committee's appraisal that the consequences for Swedish industry are dependent on a number of currently unknown factors, and that it is not possible to predict how the costs will be distributed between different companies (Association of Swedish Chemical Industries, 2000b).

However, the Association objects to the approach used in the above calculation examples for two reasons. Firstly, they believe that the testing costs, especially for HPV substances, are underestimated, since the US EPA's calculations do not include expensive cancer and reproduction tests on the same level and scope as the EU requirements which the Committee proposes. Secondly, the costs cannot be distributed evenly within the Swedish chemical industry. Only those companies subject to investigation requirements will have to bear the costs, since the Swedish chemical industry does not comprise a common payment collective. On the other hand, Swedish industry shares the costs of gathering certain data on HPV substances of common interest with European producers of the same substance.

Requirements on more data lead to a need for a greater number of experimental animals

The Committee's appraisal and proposals

- Requirements to gather more data lead to an increased need for experimental animals. Alternative methods must therefore be developed.

Many of the tests required to meet the data requirements proposed by the Committee require tests on animals today. This means that a larger number of experimental animals will be used if our proposals are implemented. This is naturally a consequence which the Committee would preferably like to avoid. The Committee therefore makes pro-

posals in Chapters 4 and 9 for intensified work on the development and validation of alternative methods.

One way to look at this problem is that it is not really the increased data requirements that lead to an increased use of experimental animals, but rather the need to use a large number of different chemicals. The most effective way to keep the number of animal tests down is therefore to minimize the number of chemicals used in products. This is at the same time a way to keep down the costs of acquiring new knowledge.

For the same reason given in the discussion of the companies' costs, it is impossible to estimate how great the increase in experimental animal use will be before we know how many substances need to be tested. The number of animal tests that need to be performed is also dependent on whether new testing methods requiring fewer or no animal tests are developed and accepted.

Something can nevertheless be said about the number of animals per substance. With the standardized methods that are used today, between 150 and 200 animals (rodents and fish) per substance would be required for all substances that are to be used in quantities of one tonne or more. The data requirements are greater for substances to be used in larger quantities, requiring more animals tests. For the substances that are used in the largest volumes, 1,000 tonnes or more, roughly 2,500 mammals (preferably rats and mice, but also other rodents, such as rabbits) and 150–200 fish and birds are used. Approximately 2,500 substances are used in such large quantities in the EU.

Based on the same assumptions concerning the total number of substances as in the above calculation example, this would mean an increase in experimental animal use of between 6 and 14 million animals during the period of data collection for existing substances. Distributed over 9 years, this means 0.7–1.5 million animals per year. Approximately 11 million animals are used every year in the EU today. This includes all activities where animal testing is carried out. However, we would like to point out that these data will be collected irrespective of our proposals. This is true for many HPV substances, where the chemical industry has a voluntary programme for data collection. This work is taking place within the framework of the ICCA's initiative.

The Committee's appraisal is that it is still possible to reduce the number of animal tests compared with today's level once the knowledge requirement has been implemented. The same applies to the general

approach. For example, those substances that fall under the PB criteria (see section 5.1) do not have to undergo further testing.

According to what has been said previously, knowledge regarding the health and environmental properties of chemical substances is an important prerequisite for being able to protect biological diversity. In this context, the Committee would like to note that tests of ecotoxicity are included among those tests that require animal experiments. Knowledge from such tests can save entire species in nature, since handling of the substances can be based on awareness of the damage they can cause.

10.3.3 Consequences of the Committee's proposals to phase out the use of PB and CMR substances

The Committee proposes that Sweden should advocate that substances with PB and CMR properties should not be permitted after certain dates (the proposals are presented in Chapter 6).

The phase-out of substances that are used has many different effects. There is a reason why they are used – they have positive properties in at least certain respects and fulfil certain functions that are in demand. These functions must be fulfilled in other ways after the phase-out, by the use of less dangerous substances or by the development chemical-free solutions. The exact nature of these functions and how they can be achieved with alternative methods varies from substance to substance and sector to sector. There are already alternative methods for certain functions, while research and development is needed in other cases.

Financial consequences for Swedish industry

The Committee's appraisal

- The consequences for industry are unpredictable as long as we do not know the properties of all substances that occur on the market and thereby which substances will be subject to the phase-out requirements.
- EU regulations have less effect on the competitiveness of Swedish industry than national regulations.

The phase-out of substances that are carcinogenic, mutagenic, reproduction-toxic, endocrine-disruptive or persistent and bioaccumulative will affect numerous companies within a large number of sectors. Before knowledge is available on all substances used on the market, it is naturally very difficult to say with any degree of completeness or certainty which sectors are involved and how individual companies will be affected.

What we can report today as far as the number of substances that will be affected by the phase-out criteria is concerned is only a rough estimate based on present-day knowledge. So far a total of 832 substances have been classified as carcinogenic, mutagenic or reproduction-toxic in categories 1 and 2 (see section 5.2.1.1). However, many of these are not individual substances, but complex carbon- and petroleum-based ”substances” which in turn consist of many different chemical compounds (see section 4.5). As far as persistence and liability to bioaccumulate are concerned, we only have data on these properties for about 2,000 substances (see section 2.2.2). Furthermore, the persistence data are restricted in most cases to results from Ready Biodegradability tests (see Annex 3). We thereby have no way for even this limited selection to determine which substances fulfil the persistence criterion of a half-life in excess of 8 weeks (see section 5.1.4). According to TGD (1996), however, this criterion can be considered to be roughly fulfilled by substances that are not readily biodegradable. With this point of departure, approximately 200 substances (of the roughly 2,000 for which we can determine this today) will be subject to the phase-out criterion with regard to persistence and liability to bioaccumulate which we propose should be effective as from 2010.

The consequences for companies depend on to what extent alternatives to the substances to be phased out are already available, and how long the time from decision to effective date is. It is of course not possible to know to what extent alternatives will exist to the substances that fall under the Committee’s proposals before we know what substances we are talking about. It is also important to look beyond whether alternatives are available today, since the situation in ten years may be quite different. The Committee proposes a relatively long time until all substances that fall under the criteria are to be phased out. It can also be argued that because the Committee’s proposals are EU-level regulations, the consequences for the competitiveness of Swedish industry will be less than in the case of national restrictions.

There are certain substances which we already know today have properties that fall under the Committee's phase-out criteria. Here as well, however, only some of the consequences can be assessed, since the occurrence of the substances in finished products is not known, but rather only their use in chemical products. The Committee has not had the resources to conduct a comprehensive analysis of the consequences for all the sectors that use these substances. However, based on the National Chemicals Inspectorate's products register, the Committee has attempted to estimate which sectors will be affected most by the phase-out of the substances about which knowledge is available today and which fall under the Committee's criteria.

The selection has been made purely quantitatively based on which sectors use the largest number of known phase-out substances today, which use the largest quantity of phase-out substances, and which use phase-out substances in the most chemical products. Based on this quantitative estimate, the Committee has, after discussions with representatives of the Swedish EPA, chosen to take a closer look at the following sectors:

- Construction industry
- Paint and varnish industry
- Base chemicals industry
- Rubber products and recapping industry
- Construction plastics, plastic packaging and plastic products industry

The Committee has had contacts with various sectoral representatives to ascertain their views on the consequences of the proposals. The opinions of the representatives of the different industries are reported below, subject to the reservation that the time available for the appraisals for all sectors has been very limited, and it is difficult to say anything certain because all the substances that will qualify for the criteria are not known.

Construction industry

The Committee has had contacts with the Swedish Construction Federation, the Swedish Construction Material Group, Skanska and NCC.

The construction industry has made good progress in its environmental work, and efforts with the same thrust as the Committee's proposals are already under way within the industry. The representatives of the construction industry with whom the Committee has spoken judge the consequences for the industry to be moderate, but since the sector is so large and complex, the consequences naturally vary between different segments. For example, the consequences for building contractors are less than for material producers.

A representative for one of the large construction companies states that it will naturally be possible to build the functions that will be needed in society in 10–15 years even without the substances that fall under the Committee's criteria. The material producers, on the other hand, maintain that if it is necessary to replace large production plants, 10 years is a short time for the companies to make the transition.

The construction companies also point out that the consequences of not being able to use the substances in future production, as is proposed by the Committee, are much less than what the consequences would be of having to remove these substances from existing buildings.

In order to be able to assess the chemical content of the products and make choices that promote products without dangerous chemicals, chemical competence must be raised on a broad front, say industry representatives. Today only a handful of companies outside the very largest ones have this competence. The industry emphasizes that both increased chemical competence within the using companies and improved information from suppliers are needed. One group that is particularly in need of greater competence in the chemicals field is the buyers. As long as they have enough competence to ask the right questions, they can demand answers from the suppliers today. A general approach makes it easier for those who are not chemists but still want to be able to avoid chemical products and finished products containing dangerous substances. More chemistry courses in construction-related educational programmes in both universities and secondary schools are also called for.

More and more companies in the construction business are adopting environmental policies. Today, every major construction materials company has one. Skanska and NCC judge that the Committee's proposals lie well in line with the companies' environmental policies.

Base chemicals industry, paint and varnish industry, and construction plastics, plastic packaging and plastic products industry

The Committee has had contact with the Association of Swedish Chemical Industries, the Swedish Paint, Lacquer and Varnish Manufacturers' Association, and the Swedish Plastics and Chemicals Federation.

Competence in chemical companies to assess the properties of substances and search for alternatives is possessed both by the manufacturers and by the major retailers. Importers, who are merely middlemen, often have a poorer knowledge of chemistry. It was noted that it can be just as important to pass on the knowledge possessed by the manufacturers to the users as to acquire new knowledge.

It is difficult to say whether it will be possible to come up with alternatives within 10–15 years. Clear signals in plenty of time regarding what must be done are vital. Continuous efforts are being made to develop new products, and searching for alternatives to the substances proposed for phase-out by the Committee is a part of normal product development. Persistent and bioaccumulative substances are avoided wherever possible in new chemical products, as difficult as that may sometimes be. Persistent substances may, for example, be desirable since the market wants products that last. One of the representatives said that a lead time of 10–15 years is "a suitable transition period that this sluggish old system can manage". It was, however, pointed out that 10–15 years is not a long time for an industry with large fixed capital assets.

The Committee's proposals are in line with the sectors' visions for their work, for example several of the basic ideas in the proposals coincide closely with the chemical industry's "Responsible Care" programme. One consequence of this is that companies that act early can win market share.

Rubber products and recapping industry

The Committee has had contact with Trelleborg AB.

The assessment is that the consequences for the rubber industry will not be too drastic. The competence of the companies to judge which substances fall under the criteria and to search for alternatives is fairly good.

Swedish companies could consider including ideas similar to those proposed by the Committee in their policy documents. But maturity in these matters varies between different countries.

Specific problematical substances

A few substances have been designated as problematical by several sectors if they are judged to fall under the phase-out criteria. Examples of these anticipated problems are bitumen, which binds the gravel in asphalt, and hydrazine, which is used today as an anti-corrosive agent in certain district heating systems. Hydrazine is added to the circulating water. The district heating systems where hydrazine is used are already built and are intended to be used for many years.

It is likely that there are also other substances that fall under the phase-out criteria and that have such functions in society that a transition period longer than 10–15 years is needed before they can be replaced. In this context there is reason to point out that the Committee also proposes certain possibilities for exemptions from the phase-out criteria.

Consequences for human health

By phasing out the use of substances that can give rise to cancer, mutations, reproduction impairments or other injuries to human beings, the prospects for good human health can be improved. Besides the direct positive value of improved quality of life for the people who, thanks to the measures, are spared disease, society also gains in the form of reduced medical care costs.

There are many difficulties in quantifying societal gains of this type. For one thing it is difficult to distinguish the harmful effects of a single substance from the effects of everything else to which an individual is exposed. Another difficulty is to evaluate an individual’s health in

financial terms. The report of the Environmental Health Commission (SOU 1996:124, in Swedish only) describes a number of different methods for putting price tags on human life, but given the lack of knowledge that exists today there is no way for the Committee to make an estimate of the health consequences of the proposals in financial terms.

10.3.4 Consequences of our proposals concerning metals

Increased recycling

Metal recycling conserves both material and energy in many cases. And it is often a profitable operation. The recycling rate for certain metals is, however, low or non-existent. Creating systems for recycling of these metals may be associated with some costs.

In our proposals in section 7.4.3, we point out that better statistics are needed before targets can be set for the recycling of individual metals. Research and development is also needed to build up efficient recycling systems – mainly for the so-called new metals. At present we cannot calculate the costs of increased recycling.

In a long-range perspective, if demand for metals is constant or declines and if many countries increase their recycling, increased recycling may lead to some reduction in mining. This will then have consequences for the mining industry.

New limit values for metals in sludge

New limit values in sludge could have consequences in many segments of society. Consequences in the form of increased costs for managing sludge with excessive metal concentrations, and possibly treating it to remove the metals, must be considered in relation to the economic and ecological consequences of spreading sludge with high metal concentrations on farmland, eventually contaminating the soil so that it cannot be used for farming. The Committee concludes that the consequences of adopting new limit values must be determined by the Swedish EPA as a part of the commission we propose in section 7.4.1.

Exposure-limiting measures for copper, zinc, chromium and nickel

The Committee believes that Sweden should, in parallel with the work in the EU, act to reduce human exposure from the areas of application for copper, zinc, chromium and nickel that lead to the greatest diffuse emissions (see section 7.4.2).

Industry is continuously pursuing development work to come up with new and better products. This work is an important part of the effort to limit pollution by the above metals. For certain of the areas where metals are used, research needs to be strengthened with additional resources.

Phase-out of mercury, cadmium and lead

When it comes to mercury, cadmium and lead, the decision to phase out was made some time ago. Consequences assessments of the phase-out have already been performed by government agencies and by the Government. We therefore refer to the Government Bills ”Swedish Environmental Quality Objectives” (1997/98:145) and ”A living environment” (Gov. Bill 1990/91:90), as well as the National Chemicals Inspectorate’s report ”The mercury phase-out in Sweden – report on a Government commission” (National Chemicals Inspectorate, 1998, in Swedish only).

10.4 Funding of the Committee’s proposals

In view of the Committee’s extra assignment (see section 10.3.1), the Committee has not conducted any further analysis of what public costs might arise as a consequence of the Committee’s proposals. The Committee can therefore not make any funding proposals, but will return to this in the report on the extra assignment.

According to a Government decision of 18 May, our Committee has been given the extra assignment of reviewing the future thrust, activities and resources of the National Chemicals Inspectorate, taking into consideration the rules of the Environmental Code, the environmental quality objective of a non-toxic environment, and the trend in the chemicals field in the EU and internationally. Based on the conclusions of this review, the Committee shall also submit proposals for the future scope and thrust of the activities of the National Chemicals Inspectorate and submit proposals on how the activities of the National Chemicals

Inspectorate should be funded. Consequently, no further analysis of these costs is made in this report.

Bibliography

(Many Swedish references are only available in Swedish, while some have an English summary)

Government Bills

En god livsmiljö. Government Bill 1990/91:90. (Summary in English: A living environment).

Forskning för framtiden – en ny organisation för forskningsfinansieringen. Government Bill 1999/2000:81.

Miljöbalk. Government Bill 1997/98:45. (Summary in English: The Environmental Code.)

Svenska miljömål – miljöpolitik för ett hållbart Sverige. Government Bill 1997/98:145. (Summary in English: Swedish Environmental Quality Objectives.)

Reports of the Government Commissions

Bättre klimat, miljö och hälsa med alternativa drivmedel. Report of Environmental Class Commission. SOU 1996:184.

En hållbar kemikaliepolitik. Report of Chemicals Policy Committee. SOU 1997:84.

Framtidens miljö – allas vårt ansvar. Report of Environmental Objectives Committee. SOU 2000:52.

Gröna nyckeltal – följ den ekologiska omställningen. Report of the Environmental Advisory Council. (Summary in English: Green Headline Indicators – Monitoring Progress towards Ecological Sustainability.) SOU 1999:127.

Handel och miljö – mot en hållbar spelplan. Report of the Environmental Advisory Council. SOU 1993:79.

Kemikaliekontroll. Report of the Chemicals Commission. SOU 1984:77.

Miljö för en hållbar hälsoutveckling. Förslag till nationellt handlingsprogram. Report of the Environmental Health Commission. SOU 1996:124.

Miljöpolitikens principer. Report of the Environmental Advisory Council. SOU 1994:133.

Märk väl! Report of commission on consumer information on convenience goods. SOU 1999:7.

Nordisk miljömärking. Report of Consumer Policy Committee 2000. SOU 1999:145.

Ren luft på väg. Report of the Emissions Research Commission. SOU 2000:35.

Sustainable Sweden – a success story. Report of Environmental Export Commission. SOU 1998:118.

Other sources

Association of Swedish Chemical Industries (2000a) Facts and figures on the Internet, (March 2000).

Association of Swedish Chemical Industries (2000b) Communication to Chemicals Committee, dnr 2000:64.

Ahlbom, J. & Duus, U. (1999) Mindre gift på drift. Report of the Chemicals Project within the framework of the archipelago commission. County Administrative Board Västra Götaland report No 1999:37. Göteborg Region Association of Local Authorities.

Allanou, R., Hansen, B.G. & van der Bilt, Y. (1999) Public availability of data on EU high production volume chemicals. European Commission Joint Research Centre, Institute for Health and Consumer Protection, Chemical Bureau, I-21020 Ispra (VA), Italy, EUR 18996 EN.

Ardesjö, A. (1997) Förslag till inarbetande av substitutionsprincipen i direktiv 91/414/EEG, National Chemicals Inspectorate dnr 240-64-97.

Bergbäck, B. & Johansson, K. (1994) Metaller i stad och land – kretslopp och kritisk belastning. Research programme for the period 1994-1999. Swedish EPA report 4382.

Bergbäck, B., Johansson, K. & Mohlander, U. (2000) Urban Metal Flows – Review and Conclusions. A case study of Stockholm. Manuscript.

Beyer, A., Mackay, D., Matthies, M., Wania, F. & Webster, E. (2000) Assessing long-range transport of persistent organic pollutants. Environmental Science and Technology, 34: 699-703.

Braunschweiler, H. & Koivisto, S. (2000) Fate and effects of chemicals in the Nordic environment related to the use of biocides. Final manuscript, version 2.0, 2 March 2000. Finnish Environment Institute, Chemicals Division.

Carter, A. (1998) Pesticides in water – regulation, science and perception. Föredrag vid 2nd International Conference on Pesticides and Their Impact on the Aquatic Environment, London, England, 17-18 March (IBC Global Conferences).

CEFIC (1999) Confidence in chemicals, issue 1.

CEFIC (1999) Facts and figures, Nov. 1999.

Chernyak, S.M, Rice, C.P. & McConnell, L.L. (1996) Evidence of currently used pesticides in air, ice, fog, seawater and surface microlayer in the Bering and Chukchi Seas. Marine Pollution Bulletin 32:410-419.

COM (1999a) Community Strategy for Endocrine Disrupters: a range of substances suspected of interfering with the hormone systems of humans and wildlife. Communication from the Commission to the Council and the European Parliament, COM(1999)706 final.

COM (1999b) Europe's Environment: What directions for the future? The Global Assessment of the European Community Programme of Policy and Action in relation to the environment and sustainable development, 'Towards Sustainability'. Communication from the Commission, COM(1999)543 final.

Commission Working Group on the Classification and Labelling of Dangerous Substances (1999) Setting specific concentration limits for carcinogens in annex I of directive 67/548/EEC. Inclusion of potency considerations.

Eklund, A. (1998) Vattentemperaturer i sjöar, sommar och vinter – resultat från SMHI:s mätningar. Hydrologi Nr 74, SMHI.

EPA (1998) Chemical hazard data availability study. What do we really know about the safety of high production volume chemicals?. prepared by EPA´s Office of Pollution Prevention and Toxics. April 1998.

EPA (1999a) Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. Federal Register November 4, 1999, Volume 64, Number 213.

EPA (1999b) Persistent Bioaccumulative Toxic (PBT) Chemicals; Proposed Rule. Federal Register January 5, 1999, Volume 64, Number 2.

FRN (Council for Planning and Coordination of Research) (1998) Toxikologisk miljöforskning. Behovsanalys för den nya kemikaliepolitiken. FRN Report 1998:23.

Hessel, K., Kreuger, J. & Uhlén, B. (1997) Kartläggning av bekämpningsmedelsrester i yt-, grund-, och regnvatten i Sverige 1985–1995. Resultat från monitoring och riktad provtagning. Ekohydrologi 42, SLU, Uppsala.

Jensen, S. (1972) The PCB story. Ambio, 1:123-131.

Jonsson, K., Linder, I., & Palm. V. (2000) En framtida nationell materialflödesstatistik – användning av naturresurser, substanser och kemikalier i produktion och konsumtion. Statistics Sweden.

Ecocycle Commission (1997) Producentansvar för varor. Förslag och idé. Report 1997:19.

Kreuger, J. (1999) Pesticides in the environment – atmospheric deposition and transport to surface waters. Doktorsavhandling, SLU, Acta Universitatis Agriculturae Sueciae, Agraria 162.

Lind, M. (2000) Organochlorines and bone. Doctoral thesis, Uppsala University.

Lithner, G. (1989) Some fundamental relationships between metal toxicity in freshwater, physico-chemical properties and background levels. The Science of the Total Environment, 87/88 (1989) 365-380.

Lithner, G. & Holm, K. (2000) Förekomst och gradering av 55 olika grundelement i den svenska miljön. Institute for Applied Environmental Research (in compilation).

Magnusson, M. (1997) Air and soil temperatures in Europe. By contract from National Chemicals Inspectorate, SMHI, Norrköping.

Ministry of Housing, Spatial Planning, and Environment (1998) European inspection project ”Solid Enforcement of Substances in Europe” (SENSE), Final report, The Netherlands, 1998.

Ministry of Housing, Spatial Planning and Environment (1999) A New Policy on Existing Substances. Plan of Action for the period September 1999 – December 2000. The Hague. August 1999.

MITF (1998) The mining and metals industry, background information. Metal Information Task Force, 12/1 1998.

Morén, A.-S. & Perttu, K. (1994) Regional temperature and radiation indices and their adjustment to horisontal and inclined forest land. Studia Forestalia Suecica, 194.

National Chemicals Inspectorate (1998) Kvicksilveravvecklingen i Sverige - redovisning av ett regeringsuppdrag. Report 5/98.

National Chemicals Inspectorate (1999) Miljökvalitetsmål 12, Giftfri miljö, Redovisning av ett regeringsuppdrag om miljömål, Order No. 360 673.

National Chemicals Inspectorate (2000) Underlag för fördjupad prövning. National Chemicals Inspectorate, January 2000.

National Board of Trade, Swedish Competition Authority and NUTEK (Swedish National Board for Industrial and Technical Development) (1998) The Environment, Trade and Competition – playing rules for efficient markets. National Board of Trade report 1998:2 / National Board of Trade report series 1998:1 / NUTEK, INFO. 025 – 1998, April 1998.

News (1999) En ny strategi för riskbedömning och riskhantering av kemikalier. A research programme funded by MISTRA, the Council for Work Life Research, the Swedish EPA and the National Chemicals Inspectorate. Annual Report 1999.

Norén, K. & Meironyté, D. (2000) Certain organochlorine and organobromine contaminants in Swedish human milk in perspective of past 20–30 years. Chemospere 40(2000) p.111–1123.

Norstrom, R.J. (1998) Analysis of Swedish environmental toxicological research. I: FRN (1998) Toxikologisk miljöforskning. Behovsanalys för den nya kemikaliepolitiken. FRN Report 1998:23.

Olsson, P.E., Borg, B., Brunström, B., Håkansson, H. & Klasson-Wehler, E. (1998) Endocrine disrupting substances. Impairment of reproduction and development. Swedishi EPA Report 4859.

Rodan, B.D., Pennington, D.W., Eckley, N. & Boetling, R.S. (1999) Screening for persistent organic pollutants: techniques to provide a scientific basis for POPs criteria in international negotiations. Environmental Science and Technology, 33:3482-3488.

Rudén, C & Hansson, S-O (2000). Improving Incentives for Toxicity Testing. Manuscript, Philosophy Group, Royal Institute of Technology.

Seppälä, T. (1999) Using effective temperature sums in risk assessment of pesticides. Abstract (timo.seppala@vyh.fi).

SFT (2000) Om Obs-listen. SFT-fakta, TA-nummer 1709/2000. Norwegian Pollution Control Authority.

Sijm, D., Hulzebos, E. & Peijnenburg, W. (1999) Estimating the PBT-profile. RIVM report 601503 016. RIVM, P.O.Box 1, NL-3720 NA Bilthoven, the Netherlands.

Skerfving, S., Bencko, V., Vahter, M., Schütz, A. & Gerhardsson, L. (1999). Environmental health in the Baltic region - toxic metals. Scand J Work Environ Health 1999;25 suppl 3;40-64.

SLU (1999) Report for the Faculty Theme: 'Biological waste in circulation between urban and rural areas. Biology and flow of energy and material', final report for 1994-1999. SLU, Dept. of Microbiology.

Sternbeck, J. & Östlund, P. (1999) Nya metaller och metalloider i samhället. IVL Report B 1332.

Swedish Mining Association, 2000. Communication to Chemicals Committee dnr 200:45.

Swedish Consumer Agency (1995/96) Konsumenten och miljön, report 1995/96:13.

Swedish EPA (1997) Slutförvar av kvicksilver. Report 4752.

Swedish EPA (1998) Organiska miljögifter. Ett svenskt perspektiv på ett internationellt problem. Monitor 16, Naturvårdsverkets förlag.

Swedish EPA (1999a) Information till allmänheten om användning och utsläpp av farliga kemikalier. Swedish EPA, Dnr 619-4256-98.

Swedish EPA (1999b) Kemikalieanvändning i förändring, Plan för kemikaliearbetet – Slutrapport, Report 4983.

Swedish EPA (1999c) Nytt program för miljöövervakning. Report 4980.

Swedish EPA (1999d) Producenters ansvar för varors miljöpåverkan – underlag till en miljöanpassad produktpolitik Report 5043.

Swedish EPA (1999e) System med indikatorer för uppföljning av miljökvalitetsmålen. Report 5006.

Swedish EPA (1999f) Val av åtgärder. Report 5005.

Swedish EPA (1999g) Åtgärdsprogram för insamling av kvicksilver.

Report 5030.

Swedish EPA and National Chemicals Inspectorate (1999) Att finna farliga flöden. Kemikalier i samhället. Swedish EPA report 5036.

TGD (1996) Technical Guidance Document in support of the Commission Directive 93/67/EEC on risk assessment for new substances and Commission Regulation (EC) No 1488/94 on risk assessment for existing substances. ECB, Ispra, Italy.

Tyler, G. (1992) Critical concentrations of heavy metals in the mor horizon of Swedish forests. Swedish EPA Report 4078.

Utne-Skaare, J. (1999) Kan de nationella och internationella miljömålen för organiska miljögifter uppfyllas med nuvarande kompetens och resurser? Report from Future Seminar on 10 February 1999, Management Group for the project area Persistent Organic Pollutants, POPs.

WWF (1999) Chemical trespass: a toxic legacy. A report from WWF-UK, July 1999.