Annex

Annex 1

Not translated

Proposed amendments in EC legal acts regarding documentation requirements, new risk phrases and restrictions of CMR and PB substances

Contents

1 General

This Annex contains a model for how parts of the Committee's proposals having to do with knowledge requirements and phase-out of products containing certain dangerous substances could be implemented by amendments to existing Community legislation. A proposal for adoption of the precautionary principle in the restrictions directive is also presented. The memorandum should be regarded as a rough sketch for a technical solution and makes no claim on completeness.

2 Regulation (EEC) No 793/93

Via the proposal for amendments in Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances, deadlines are introduced for submitting fundamental data on existing substances. The data requirements are equivalent to those made on new substances today, with the addition of extended requirements on testing of persistence and liability to bioaccumulate. The current data requirements for new substances are found in Annexes VII and VIII to Directive 67/548/EEC. According to the proposal, manufacturers and importers shall in an initial stage notify the substances for which data will be submitted. Those substances that have not been notified will then be removed from EINECS. For the remaining substances, documentation shall be furnished by different deadlines, depending on how large a quantity has been placed on the market during certain specified years.

A prohibition is tied to the different deadlines whereby substances may not be placed on the market or used if they are not on EINECS and have not been notified as new substances in accordance with Directive 67/548/EEC (the dangerous substances directive). Furthermore, a manufacturer or importer who has furnished information that satisfies the data requirements for a given quantity of a substance may not place more of the substance on the market until the data requirements for the larger quantity have been met.

According to the proposal, manufacturers and importers are given broader responsibility in that they must also conduct an initial risk assessment and adopt the precautionary measures following from the new knowledge of the substances. Amendments below are underlined. Omitted text is indicated by ”(...)”.

Article 1

Aims and scope

1. This Regulation shall apply to

a) the collection, circulation and accessibility of information on existing substances,

b) the evaluation of the risks of existing substances to man, including workers and consumers, and to the environment, in order to ensure better management of those risks within the framework of Community provisions.

c) a prohibition on the placing on the market of existing substances for which fundamental information is lacking.

According to the proposal, the aims are broadened to include the prohibition proposed in Articles 12b and 12c.

Article 2

Definitions

For the purpose of this Regulation:

a) *substances* means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

b) *preparations* means mixtures or solutions composed of two or more substances;

c) *importing* means bringing into the customs territory of the Community;

d) *producing* means the production of substances which are isolated in a solid, liquid or gaseous form;

e) *existing substances* means substances listed in EINECS.

f) *placing on the market* means making available to third parties. Importation into the Community customs territory shall be deemed to be placing on the market for the purposes of this Regulation.

The proposed provisions regarding reporting of data and prohibition contain the phrase ”placing on the market”. Since the meaning of this phrase varies in different legal acts, a definition should be incorporated into the Regulation. The proposal coincides with the definition in the dangerous substances directive.

Article 4a

Without prejudice to Article 6 (1), any manufacturer or importer who intends to furnish information in accordance with Article 4b shall notify this to the Commission by not later than 31 December 2004.

Article 4b

Without prejudice to point 4 or Article 6 (1):

1. For a substance that has been notified in accordance with Article 4a, any manufacturer or importer who has placed at least 1,000 tonnes of the substance, as such or in a preparation, on the market during any of the three years preceding or the year following the entry into force of this provision, shall by not later than 31 December 2005 have submitted to the Commission information and testing results that satisfy the requirements in Directive 67/548/EEC and Annexes VII .A and VIII, Levels 1 and 2, to the Directive.

2. For a substance that has been notified in accordance with Article 4a, any manufacturer or importer who has placed at least 10 tonnes, but less than 1,000 tonnes, of the substance, as such or in a preparation, on the market during any of the three years preceding or the year following the entry into force of this provision, shall by not later than 31 December 2009 have submitted to the Commission the following information and testing results:

If the quantity of the substance during any of these years has been

– at least 100 tonnes but less than 1,000 tonnes: documentation meeting the requirements in Article 7 (1) in Directive 67/548/EEC and Annexes VII. A and VIII, Level 1, to the Directive,

– at least 10 tonnes but less than 1,00 tonnes: documentation meeting the requirements in Article 7 (1) in Directive 67/548/EEC and Annex VII. A to the Directive,

3. For a substance that has been notified in accordance with Article 4a, any manufacturer or importer who has placed less than 10 tonnes of the substance, as such or in a preparation, on the market during any of the three years preceding or the year following the entry into force of this

> provision, shall by not later than 31 December 2010 have submitted to the Commission the following information and testing results:
>
> If the quantity of the substance
>
> – during any of these years has been at least one tonne but less than 10 tonnes: documentation meeting the requirements in Article 7(1) in Directive 67/548/EEC and Annex VII. A to the Directive,
> – during each of these years has been less than one tonne: documentation meeting the requirements in Article 8 (1) in Directive 67/548/EEC and Annex VII. B to the Directive,
> – during each of these years has been less than 100 kg: documentation meeting the requirements in Article8 (2) in Directive 67/548/EEC and Annex VII. C to the Directive,
>
> 4. For polymers that have been notified in accordance with Article 4a, any manufacturer or importer who has placed the polymer on the market during any of the three years preceding or the year following the entry into force of this provision, shall by not later than 31 December 2010 have submitted to the Commission information that satisfies the requirements in Annex VII. D to Directive 67/548/EEC:

According to the proposal, notification of data for substances shall take place in stages. In the first stage, any manufacturers or importers who intend to furnish data on a substance shall make a notification to the Commission prior to the expiry of 2004. Data on the substances that have been notified shall first be reported for substances which a manufacturer or importer has placed on the market during any of certain specified years in a quantity of 1,000 tonnes or more (HPV substances). Subsequently, information shall be furnished on substances for which the quantity has in a similar manner amounted to at least 10 tonnes but less than 1,000 tonnes. In the final stage, substances placed on the market in smaller quantities and polymers shall be reported.

The data requirements for the different quantities are determined on the basis of equivalent requirements for new substances in accordance with the dangerous substances directive, although the quantity limits there pertain to both the total quantity placed on the market and how the quantity is distributed between the manufacturers per year. Since many of the existing substances are manufactured and imported by several companies, and it cannot be required that they procure knowledge of the total quantity of the substance that is placed on the market in the EU or how that quantity is distributed per manufacturer, the quantity limits shall, according to the proposal, apply to each individual company’s manufacture or imports during each of certain specified years.

Article 4c

> 1. Additional information on substances for which documentation has been submitted in accordance with Article 4b shall, on expiry of the deadlines stipulated there, be furnished by manufacturers and importers who intend to place the substance on the market in such a quantity that the documentation requirements for the substance as set forth in Article 4b are no longer satisfied. Information that satisfies the requirements laid down in Article 4b shall be furnished before the substance is placed on the market in the greater quantity.
>
> 2. If the Commission so requests, any manufacturer or importer who has placed at least 10 tonnes of an existing substance, as such or in a preparation, on the market during any of the three years preceding or the year following the entry into force of this provision, shall within one year of the request have submitted to the Commission documentation meeting some or all of the requirements in Annex VIII, Level 1, to Directive 67/548/EEC.

The proposed provisions in point 1 entail that when the deadlines set forth in Article 4b have been passed, further information shall be furnished by any manufacturer or importer who intends to place an already documented substance on the market in such a quantity that the documentation requirements are no longer satisfied. In such cases, the substance shall thus not be treated as a new substance; instead, supplementary information shall be furnished within the framework of this Regulation. The proposal further entails that the stricter documentation requirements must be satisfied before the substance is placed on the market in the larger quantity. The provisions apply to both manufacturers and importers who have previously furnished information on a substance, as well as new manufacturers and importers of the substance.

The proposal for paragraph 2 is equivalent to the provisions for new substances laid down in Article 7 (2) in the dangerous substances directive.

Article 5

Exemptions

1. The provisions of Articles 3, 4, 4a, 4b and 4c shall not be applied in the following cases:

– Substances listed in Annex II. However, information on the substances listed in Annex II may be requested by a procedure laid down in accordance with the procedure referred to in Article 15.

– Additives and substances used exclusively in animal feedingstuffs as covered by Directives 70/524/EEC and 82/471/EEC.

– Substances used exclusively in as additives foodstuffs as covered by Directive 89/107/EEC, and substances used exclusively as flavourings in foodstuffs and which are covered by Directive 88/388/EEC.

– Active ingredients used exclusively in medicinal products for human or veterinary use, as defined in Directive 65/65/EEC. This does not include chemical intermediates.

– Substances for exclusive use in other product sectors for which Community notification or approval procedures exist and for which the requirements for data submission are equivalent to those laid down in this Directive. The Commission shall, in accordance with the procedure laid down in Article 15, establish a list of such Community legislation. This list will be re-examined periodically and revised as necessary in accordance with the said procedure.

2. Manufacturers and importers who satisfy the following conditions do not have to furnish information on a substance:

– The manufacturer/importer places smaller quantities than 10 kg per year of the substance on the market and satisfies all the conditions imposed by the Member States where the substance is placed on the market. These conditions shall not exceed the information provided for in Annex VII. C to Directive 67/548/EEC, points 1 and 2.

– The substance is placed on the market in limited quantities, and in any case not exceeding 100 kg per manufacturer per year, and is intended solely for purposes of scientific research and development carried out under controlled conditions.

Any manufacturer or importer making use of this exemption must maintain written records containing the identify of the substance, labelling data, quantities and a list of customers. This information shall be made available on request to the competent authorities of each Member State where the manufacture, importation or scientific research and development takes place.

- The substance is sold to a limited number of registered customers for the purposes of process-orientated research and development in quantities that are limited to what is required for the process-orientated research and development. These substances shall qualify for an exemption for a period of one year, provided firstly that the manufacturer or importer communicates their identity, labelling data, quantity, the justification for the quantity and a list of customers and the research and development programme to the competent authorities of each Member State where the manufacture, importation or process-orientated research and development takes place; and secondly that he complies with any conditions imposed by these authorities or the Member States on such research and development. The conditions imposed by the Member States may include information not exceeding that provided for in Article 8 of Directive 67/548/EEC. After one year, these substances will normally be subject to notification. The manufacturer or importer shall also give an assurance that the substance or the preparation in which it is incorporated will be handled only by the customer's staff under controlled conditions and will not be made available to the general public at any time, on its own or in a preparation. If the competent authority considers that there may exist an unacceptable risk for man and the environment, it may extend the restriction referred to above to include any products containing the new substances which were produced during the process-orientated research and development.

The one-year exemption period referred to above may in exceptional circumstances be extended for a further year if the notifier can demonstrate, to the satisfaction of the competent authorities, that such an extension is justified.

3. The substances referred to in paragraph 2 must be packaged and provisionally labelled by the manufacturer or his representative in accordance with the rules laid down in Directive 67/548/EEC. Where a substance as referred to in paragraph 2, labelled in accordance with the principles set out in Article 23 of Directive 67/58/EEC, is very toxic, toxic, carcinogenic, toxic for reproduction or mutagenic, the manufacturer or importer must transmit to the competent authority any appropriate information as regards Annex VII. A, Sections 2.3, 2.4 and 2.5. Moreover, acute toxicity data shall be furnished where available.

4. Any manufacturer or importer who wishes to refer to any of the exemptions set forth in Article 7 (2), second indent, or Annex VII or VIII to Directive 67/548/EEC, shall submit an application for approval of the exemptions to the Commission. The Commission shall decide in accordance with the procedure laid down in Article 15.

According to the proposal for paragraph 1, firstthe same exemptions that applied at the time of the previous notification in accordance with this Regulation shall also apply at the time of the new notification. The other exemptions proposed in paragraph 1 and in paragraphs 2 and 3 are essentially equivalent to the exemptions that apply to new substances (cf. Articles 13 of the dangerous substances directive).

According to the proposal for paragraph 4, it shall be possible to request an exemption from the requirements to submit certain information on a substance to the same extent that this is possible for new substances in accordance with Article 7 (2) and Annexes VII and VIII to the dangerous substances directive. According to the proposal for Article 12a, only exemptions that have been approved, not applications for exemptions, shall be taken into consideration when revising EINECS. This provides an incentive for the companies to submit their applications in good time.

Article 6

Procedure for data reporting

1. In the case of a substance produced or imported by several manufacturers or importers, the information referred to in Articles 3, 4 (2), 4a, 4b and 4c may be submitted by one manufacturer or importer acting, with their agreement, on behalf of other manufacturers or importers concerned. The latter shall nevertheless submit to the Commission the information specified in points 1.1–1.19 of the data set laid down in Annex III and, in doing so, shall make reference to the data set submitted by the manufacturer or importer.

2. In submitting the information referred to in Articles 3, 4 (1), 4a, 4b and 4c, the manufacturers and importers shall use the special software package on diskette made available free of charge by the Commission or fill in the form that is available at the Internet address: [http://www.yyy.zzz].

3. Documentation in support of information furnished in accordance with Articles 4b and 4c shall be submitted to the Commission together with the information.

(….)

Modern technology makes it possible to submit information in such a manner that it is entered directly into the database. It also enables the Member States to obtain direct access to the database. This will render unnecessary the submission of data to the Member States that is provided for in the current provisions of Articles 6 (3) and 6 (4). It is, however, impossible to predict which technical solution will be employed.

It should also be possible for the general public to obtain access to information in the database, in so far as there is no need for secrecy. To enable above all the national regulatory authorities and the Commission to check the accuracy of the furnished information, the documentation on which the information is based shall also be accessible. It is easier to check the information if all the documentation on a substance is gathered in one place. In accordance with the proposal, all documentation in support of the information shall therefore be submitted to the Commission.

Article 7

Updating of the reported information and obligation to submit certain information spontaneously

1. Manufacturers and importers who have submitted information on a substance in accordance with Articles 4b and 4c shall update the information forwarded to the Commission.

In particular, they shall submit, where appropriate:

a) new uses of the substance which substantially change the type, form, magnitude or duration of exposure of man or the environment to the substance;

b) new data obtained on the physico-chemical properties, toxicological or ecotoxicological effects where this is likely to be relevant to the evaluation of the potential risk presented by the substances;

c) any change in the provisional classification under Directive 67/548/EEC.
(…)

2. Any manufacturer or importer of an existing substance who acquires knowledge which supports the conclusion that the substance in question may present a serious risk to man or the environment shall immediately report such information to the Commission and to the Member State in which he is located.
(…)

According to the proposal, the reporting manufacturers and importers are obliged to update the information submitted in accordance with Articles 4b and 4c. It is proposed that the obligation to update information submitted previously according to the previous reporting procedure should be abolished.

Article 7a

Initial risk assessment and own precautionary measures

1. On the basis of the information submitted in accordance with Articles 4b and 4c, manufacturers and importers shall, within one year of having submitted the information, have carried out an initial risk assessment in accordance with the guidelines that shall be adopted by not later than 31 December 2003 in accordance with the procedure laid down in Article 15. These guidelines shall be re-examined periodically and revised, if necessary, following the same procedure. The documentation with the risk assessment shall be kept available to the Member States and any others who may need to consult it.

2. On the basis of the risk assessment, manufacturers and importers shall adopt the precautionary measures that are necessary to prevent, impede and counteract harm to human health or the environment. The precautionary measures shall include informing distributors, retailers and users of the risks posed by the substance and necessary protective measures, beyond the risk phrases and safety phrases that shall be used in accordance with Directive 67/548/EEC. The information shall be furnished in safety data sheets and other suitable fashion.

The proposal entails broadened responsibility for manufacturers and importers, since they are obliged to carry out an initial risk assessment on the basis of the information that has been obtained on the substances. Guidelines should be established for such a risk assessment. No guidelines are proposed here, however.

According to the proposal, manufacturers and importers shall also adopt whatever precautionary measures are needed, including forwarding information on risks and necessary protective measures to actors further down in the distribution and user chain. The provisions pertaining to obligation to investigate and precautionary measures in the Environmental Code already impose similar requirements on manufacturers and importers in Sweden today. According to the proposal, the information shall be furnished in safety data sheets and other suitable fashion. This part of the proposal may necessitate amendments to the directive on safety data sheets (Directive 91/155/EEC), which is under revision.

The proposal does not entail that the companies’ own initial risk assessments and precautionary measures will take the place of risk assessments and risk limitation measures adopted at the Community level. It is, however, important that the data collected on the properties of substances be used to reduce the risks until such time as the Community has made a decision on the need for measures for a substance. The companies’ own measures will also supplement the more general measures taken at the Community level. An example of own precautionary measures is that a manufacturer refrains from selling a substance for a specific use that can entail unacceptable risks and provides information on the risks posed by such a use, even if there are no restrictions on this use in the legislation.

Article 8 (1)

Priority lists

1. On the basis of the information submitted by manufacturers and importers in accordance with Articles 3, 4, 4b and 4c, and on the basis of the national lists of priority substances, the Commission, in consultation with Member States, shall regularly draw up lists of priority substances or groups of substances (hereinafter referred to as priority lists) requiring immediate attention because of their potential effects on man or the environment. These lists shall be adopted in accordance with the procedure laid down in Article 15 and shall be published by the Commission for the first time in the course of the year following the entry into force of the Regulation.

Article 9 (1)

Data to be supplied for substances appearing on the priority lists

1. For the substances included in the priority lists referred to in Article 8 (1), manufacturers and importers who have submitted information on a substance in accordance with Articles 3, 4, 4b and 4c shall, within six months of publication of the submitted information on a substance, submit to the rapporteur designated in accordance with Article 10 (1) all relevant available information and corresponding study reports for risk assessment of the substance concerned, in addition to the information and the documentation that has previously been submitted to the Commission.

Article 9 (2)

> 2. In addition to the requirement specified in paragraph 1, and without prejudice to the testing which may be required under Article 10 (2), if any of the particulars listed in Annex VII. A to Directive 67/548/EEC are not available for a given priority substance, the manufacturers and importers who have submitted information on a substance in accordance with Articles 3, 4, 4b and 4c shall be obliged to carry out the testing necessary to obtain the missing data and to provide the test results and test reports to the rapporteur within 12 months.

Risk assessment of existing substances is done today on the basis of priority lists established in accordance with the committee procedure laid down in the Regulation. According to the proposal, Article 9 is also adjusted to cover manufacturers and importers who have submitted information in accordance with the new reporting procedure. If the particulars listed in VII. A to the dangerous substances directive are not available for a substance included in a priority list, then in accordance with the proposal the data submitters shall obtain the missing data. For the substances referred to in Articles 4b and 4c, this will eventually only be necessary for substances that have not been manufactured or imported by anyone in quantities of one tonne or more.

Article 10 (1)

> **Risk evaluation of the substances on the priority lists at the level of the Member State designated as rapporteur**
>
> 1. For each substance on the priority lists a Member State shall be given responsibility for its evaluation in accordance with the procedure laid down in Article 15, whilst ensuring fair burden sharing between Member States.
>
> The Member State shall designate a rapporteur for that substance from among the competent authorities referred to in Article 13.
>
> The rapporteur shall be responsible for evaluating the information submitted by the manufacturer(s) or importer(s) in conformity with the requirements of Articles 3, 4, 4b, 4c, 7 and 9 and any other available information, and for identifying, after consultation of the producers or importers concerned, whether, for the purpose of the risk evaluation, it is necessary to require the above manufacturers or importers of priority substances to submit further information and/or to carry out further testing.

Article 12

> **Obligations relating to the provision of further information and to further testing**
>
> 1. Any manufacturer or importer of a substance on the priority lists referred to in Article 8 (1) and who has submitted the information under Articles 3, 4, 4b and 4c must, within a given time limit, supply the rapporteur with the data and test results concerning that substance referred to in Article 9 (1) and (2) and those referred to in Article 10 (2).

The proposal entails that Articles 10 and 12 be adjusted to cover risk assessment of the substances for which data has been submitted in accordance with the new provisions.

Article 12a

> 1. After 31 December 2004, EINECS shall be revised by removal from the list of those substances that have not been notified in accordance with Article 4a. A decision on the revised EINECS list shall be made not later than 30 June 2005 in accordance with the procedure laid down in Article 15.
>
> 2. When a deadline as referred to in Article 4b has expired, EINECS shall be revised by specification for every substance of the quantity for which information as referred to in Article 4b has been submitted or may be submitted later within other deadlines as referred to in Article 4b. Exemptions approved by the Commission in accordance with Article 5 (4) shall thereby be taken into consideration. A decision on the revised EINECS list shall be made within 6 months of the expiry of a deadline as referred to in Article 4b.
>
> 3. After 31 December 2010, those substances for which no information has been notified in accordance with Article 4b shall be removed from EINECS. A decision on the revised EINECS list shall be made not later than 30 June 2010. Subsequently, EINECS shall be revised once a year with reference to information submitted in accordance with article 4c and decisions made in accordance with paragraph 4.
>
> 4. If closer examination of the information for a substance submitted in accordance with Articles 4b and 4c shows that the data requirements laid down in Article 4b are not satisfied for the quantity in question, the quantity specified in EINECS shall be reduced to the quantity for which the data requirements have been satisfied. If the examination shows that the information do not satisfy the requirements laid down in Article 4b for any quantity, the substance shall be removed from EINECS.

> 5. Decisions in accordance with this article shall be made in accordance with the procedure laid down in Article 15. Revised EINECS lists shall be published in the Official Journal of the European Communities.

As information is submitted in accordance with Articles 4a, 4b and 4c, EINECS should be revised. It will be time-consuming to verify that the submitted information satisfies the requirements in 4b in terms of quality. A decision to revise EINECS should therefore not be delayed pending closer examination of the information. If later examination shows that the established requirements are not satisfied, the data on the substance in EINECS should be changed at that time.

Article 12b

> 1. A manufacturer or importer may not place a substance which has been removed from EINECS on the market 12 months after the publication of a revised EINECS list unless the substances has been notified in accordance with Directive 67/548/EEC and the deadlines specified therein have been observed.
>
> 2. A retailer may not place a substance which has been removed from EINECS on the market 18 months after the publication of a revised EINECS list if the substance may not, in accordance with paragraph 1, be placed on the market by the manufacturer or importer.
>
> 3. Commercial use of a substance is not permitted 24 months after the publication of a revised EINECS list if the substance has been omitted from the revised EINECS list and may not be placed on the market in accordance with paragraph 1.

The proposal entails a prohibition against placing on the market and commercial use of a substance that has been removed from EINECS according to a revised list, unless the substances has been notified as a new substance. The prohibition will enter into force gradually some time after the publication of the new revised list.

Article 12c

> A manufacturer or importer may not place a substance on the market 12 months after the publication of a revised EINECS list in a larger quantity than that specified in the revised list unless additional information has been submitted in accordance with Article 4c.

The proposal entails a prohibition for manufacturers and importers to exceed the quantity limits specified in a revised EINECS list.

Article 16.1

Confidentiality of data

1. If he considers that there is a confidentiality problem, the manufacturer or importer may indicate the information provided for in Articles 3, 4, 4b, 4c, 7 and 12, which he considers to be commercially sensitive and disclosure of which might harm him industrially or commercially, and which he therefore wishes to be kept secret from all persons other than Member States and the Commission. Full justification must be given in such cases.

Industrial and commercial secrecy shall not apply to:

– the name of the substance, as given in EINECS,

– the name of the manufacturer or importer,

– data on physico-chemical properties of the substance and pathways and environmental fate,

– the summary results of the toxicological and ecotoxicological tests, in particular data on carcinogenicity, mutagenicity and/or the substance's toxicity for reproduction,

– any information relating to the methods and precautions relating to the substance and the emergency measures,

– any information which, if withheld, might lead to animal experiments being carried out or repeated needlessly,

– analytical methods that make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans to the substance.

If the manufacturer or importer should himself later disclose previously confidential information, he shall inform the competent authority accordingly.

The main rule in accordance with Article 16 is that the information is public unless the authority receiving the information finds, at the request of the manufacturer or importer, that there is reason for secrecy (Article 16 (2)). Certain specified information does not qualify for secrecy. The proposal entails that the same rules for confidentiality shall also apply to information submitted in compliance with Articles 4b and 4c. There may be reason for additional amendments for the purpose of increasing transparency, but no such proposals are submitted here.

Article x

> Not later than one year after the adoption of this Regulation, the Member States shall establish appropriate legal or administrative measures in order to deal with non-compliance with the provisions of this Regulation.

The proposal concerns the time for implementation of supplementary national provisions on sanctions for infractions.

3 Directive 67/548/EEC – the dangerous substances directive

3.1 Prior notification

The proposal for amendment of the articles in the dangerous substances directive is intended to adjust the rules for prior notification of new substances in such a way that they can also be applied in connection with prior notification of substances that have been removed from EINECS.

Article 2 (1)

> **Definitions**
>
> 1. For the purposes of this Directive:
>
> a) ”substances” means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
>
> b) ”preparations” means mixtures or solutions composed of two or more substances;
>
> c) ”polymer” means a substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. In the context of this definition a ”monomer unit” means the reacted form of a monomer in a polymer;

d) ”notification” means the documents, with the requisite information, presented to the competent authority of a Member State:

– for new substances manufactured within the Community, by the manufacturer who places a substance, either on its own or in a preparation, on the market,

– for new substances manufactured outside the Community, by any person established in the Community who is responsible for placing the substance, either on its own or in a preparation, on the Community market, or alternatively by the person established within the Community who is, for the purposes of submitting a notification for a given substance placed on the Community market, either on its own or in a preparation, designated by the manufacture as his sole representative.

– for substances that have previously been listed in EINECS, by the manufacturers or importers who place a substance, either on its own or in a preparation, on the market, or by a manufacturer or importer who represents the other manufacturers and importers with their consent.

The person submitting the notification, as described above, shall be referred to as ”the notifier”;

e) ”placing on the market” means the making available to third parties. Importation into the Community customs territory shall be deemed to be placing on the market for the purposes of this Directive;

f) ”scientific research and development” means scientific experimentation, analysis or chemical research carried out under controlled conditions; it includes the determination of intrinsic properties, performance and efficacy as well as scientific investigation related to product development;

g) ”process-orientated research and development” means the further development of a substance in the course of which pilot plant or production trials are used to test the fields of application of the substance;

h) ”EINECS” means the European Inventory of Existing Commercial Substances. This inventory contains the definitive list of all substances deemed to be on the Community market on 18 September 1981.

i) ”new substances” means substances that are not, and have not been, listed in EINECS.

The term ”new substances” should be introduced since different rules are needed in some cases for substances that have previously been listed in EINECS and ones that have never been listed there. There is, for example, reason to – as is proposed in d) – differentiate in the two cases between who can make notification.

Article 8a

> Notifiers of new substances that have been notified not later than 31 December 2004 shall not later than 31 December 2005 submit the information on persistence and liability to bioaccumulate that is referred to in Annex VII. The information does not, however, need to be furnished for substances that are polymers.

Additional data requirements are proposed with regard to persistence and liability to bioaccumulate in Annexes VII and VIII. These new requirements should – with the exception of polymers – also apply to new substances that have already been notified when the new data requirements enter into force for existing substances.

Article 11

> **Substances notified by several notifiers**
>
> Where, for new substances manufactured outside the Community, more than one notification exists for a substance manufactured by the same manufacturer or a substance which has previously been listed in EINECS, the cumulative yearly tonnages placed on the Community market shall be determined by the Commission and the national authorities on the basis of the information submitted under Articles 7 (1), 8 (1) and 14. The obligation to carry out supplementary testing in accordance with Articles 7 (2) and 8a will fall collectively on all notifiers.

The wording of this article needs to be changed slightly so that it will also include notifiers of substances which have previously been listed in EINECS.

Article 13 (3)

> 3. The substances referred to in paragraph 2 and not listed in Annex I must, in so far as the manufacturer may reasonably be expected to be aware of their dangerous properties, be packaged and provisionally labelled by the manufacturer or his representative in accordance with the rules laid down in Articles 22 to 25 and with the criteria imposed in Annex VI.
>
> If it is not possible to label the substances completely, and in accordance with the principles set out in Article 23, because the results of tests provided for in Annex VII. A are not available, the label should bear, in

> addition to the label deriving from tests already carried out, the warning ”Caution – substance not yet fully tested”.

According to Article 13 (2), substances shall be considered to have been notified with the meaning of the dangerous substances directive if certain conditions are fulfilled. This is the case, for example, for substances placed on the market in quantities of less than 10 kg per year per manufacturer, under certain conditions. Article 13 (3) contains provisions concerning e.g. provisional labelling for such substances. The situation could arise for an existing substance which is classified and listed in Annex I if it is notified as a new substance, even if it is unlikely that this would occur other than very rarely. According to the proposal, such cases are exempted from the obligations laid down in Article 13 (3), since there are already applicable provisions regarding classification and labelling of the substance. However, this does not mean that substances in Annex I are exempted from the special provisions in section 4 of Annex VI concerning provisional labelling and reporting obligation for substances suspected of being carcinogenic, mutagenic or toxic for reproduction.

Article 14 (2)

> 2. Any importer of a new substance produced by a manufacturer established outside the Community who imports the substance within the framework of a notification previously submitted by a sole representative in accordance with Article 2 (1) (d) shall be required to ensure that the sole representative is provided with up-to-date information concerning the quantities of the substance introduced by him on the Community market. As regards substances previously listed in EINECS, manufacturers and importers shall submit the same information to their representative in accordance with Article 2 (1) (d).

Article 16 (4)

> 4. For substances referred to in Article 11 for which more than one notification has been submitted (...) the competent authorities, together with the Commission, shall be responsible for calculating the annual and cumulative tonnages placed upon the Community market. If the tonnage thresholds detailed in Article 7 (2) are attained, the competent authority responsible for receiving the notification(s) shall contact each notifier informing them of the identity of the other notifiers and drawing their attention to their collective responsibility as outlined in Article 11.

The proposal for a new wording entails that the provisions in question are extended to include substances previously listed in EINECS as well.

Article 19

> **Confidentiality of data**
>
> 1. If he considers that there is a confidentiality problem, the notifier may indicate the information provided for in Articles 7, 8 and 14 which he considers to be commercially sensitive and disclosure of which might harm him industrially or commercially, and which he therefore wishes to be kept secret from all persons other than the competent authorities and the Commission. Full justification must be given in such cases. With respect to the notifications and information submitted in conformity with Articles 7 (1) and (2), 8 (1), (2) and (3), industrial and commercial secrecy shall not apply to:
>
> a) the trade name of the substance;
>
> b) the name of the manufacturer and the notifier;
>
> c) physico-chemical data concerning the substance in connection with section 3 of Annexes VII. A, VII. B and VII. C;
>
> d) the possible ways of rendering the substance harmless;
>
> e) the summary results of the toxicological and ecotoxicological tests;
>
> f) if essential to classification and labelling for the purpose of introducing the substance into Annex I, the degree of purity of the substance and the identify of impurities and/or additives which are known to be dangerous within the meaning of Article 2 (2);
>
> g) the recommended methods and precautions referred to in Annex VII, section 2.3, and the emergency measures referred to in Annex VII, sections 2.4 and 2.5;
>
> h) the information contained in the safety data sheet,
>
> i) in the case of substances in Annex I, analytical methods that make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans;
>
> j) any information which, if withheld, might lead to animal experiments being carried out or repeated needlessly.
>
> If the notifier, manufacturer or importer should himself later disclose previously confidential information, he shall inform the competent authority accordingly.

The intention of the addition in point j) is to prevent secrecy from contributing to more animal experiments. A similar provision is found in

Article 16 of Regulation 793/93. There may be reason for amending the secrecy provisions for new substances as well for the purpose of increasing transparency, but no such proposals are submitted here.

3.2 New testing requirements regarding persistence and liability to bioaccumulate

In order to permit a phase-out of persistent and bioaccumulative substances, knowledge is needed concerning which substances possess such properties. The new requirements should apply to both new and existing substances and are introduced according to the proposal in Annexes VII and VIII to the dangerous substances directive.

Annex VII. A

5.2 Degradation

- biotic
- abiotic

If the substance is not readily biodegradable then a simulation test or the equivalent shall be carried out to determine half-life.

5.3 Absorption/desorption screening test

5.4 Liability to bioaccumulate

If log Pow > 3.0 then BCF shall be calculated [(Q)SAR] or determined experimentally.

Annex VII. B

5.2 Degradation

- biotic
- abiotic

If the substance is not readily degradable then a simulation test or the equivalent shall be carried out to determine half-life.

5.4 Liability to bioaccumulate

If log Pow > 3.0 then BCF shall be calculated [(Q)SAR] or determined experimentally.

Annex VII. C

3.8 n-octanol/water partition coefficient

5.2 Degradation

- biotic
- abiotic

If the substance is not readily degradable then a simulation test or the equivalent shall be carried out to determine half-life.

5.4 Liability to bioaccumulate

If log Pow > 3.0 then BCF shall be calculated [(Q)SAR] or determined experimentally.

Annex VIII, Level 1

Ecotoxicological studies

- Prolonged toxicity study with Daphnia magna (21 days)
- Test on higher plants
- Test on earthworms
- Further toxicity studies with fish
- Tests for species accumulation; one species, preferably fish, unless BCF is experimentally determined

(...)

- Further studies on absorption/desorption dependent upon the results of the investigations laid down in Annex VII.

Annex VIII, Level 2

Ecotoxicological studies

- Additional studies for accumulation, degradation, mobility and absorption/desorption
- Further toxicity studies with fish
- Toxicity studies with birds
- Additional toxicity studies with other organisms

According to the current provisions in Annexes VII and VIII, there are certain requirements on testing of degradability and bioaccumulation for new substances. According to the proposal, the requirements are broadened so that there will be sufficient data on a substance, regardless of what quantity of it has been placed on the market, to make it possible to classify a substance in accordance with the new criteria regarding persistence and bioaccumulation that are proposed below.

3.3 New classification and labelling rules

According to the proposal, new criteria should be introduced in Annex VI to the dangerous substances directive for classification of persistent and bioaccumulative substances. Two new risk phrases are proposed for substances that meet the criteria. Such substances shall also be labelled with the symbol for danger for the environment. The substances will further be subject to limitations in accordance with new provisions that are proposed in the restrictions directive (see below).

5. CLASSIFICATION ON THE BASIS OF ENVIRONMENTAL EFFECTS

5.2 Criteria for classification, danger indication, choice of risk phrases

5.2.1 Aquatic environment

5.2.1.1 Substances shall be classified as dangerous for the environment and assigned the symbol ”N” and the appropriate indication of danger, and assigned risk phrases in accordance with the following criteria:

a) R51: Toxic to aquatic organisms
and
RX: Great risk for long-term adverse effects in the aquatic environment
Acute toxicity: 96 hr LC50 (for fish) 1 mg/l < LC50 ≤ 10 mg/l
or 48 hr EC50 (for Daphnia) 1 mg/l <EC50 ≤ 10 mg/l
or 72 hr IC50 (for algae) 1 mg/l < IC50 ≤ 10 mg/l

and the half-life in water or sediment > 8 weeks in a simulation test at 20°C and calculated or experimentally determined BCF > 2,000
or the results of other reliable scientific studies or internationally accepted calculation methods are judged to be equivalent to these criteria.

b) RX: Great risk for long-term adverse effects in the aquatic environment

The half-life in water or sediment > 8 weeks in a simulation test at 20°C
and
calculated or experimentally determined BCF > 2,000
or
the results of other reliable scientific studies or internationally accepted calculation methods are judged to be equivalent to these criteria.

Experimental data shall always take precedence.

c) R 50: Very toxic to aquatic organisms
and
R 53: May cause long-term adverse effects in the aquatic environment

Acute toxicity: 96 hr LC50 (for fish) ≤ 1 mg/l
or 48 hr EC50 (for Daphnia) ≤ 1 mg/l
or 72 hr IC50 (for algae) ≤ 1 mg/l

and the substance is not readily degradable

or the substance's log Pow (low octanol/water partition coefficient) ≤ 3.0 (unless the experimentally determined BCF ≤ 100).

d) R 50 Very toxic to aquatic organisms

Acute toxicity: 96 hr LC50 (for fish) ≤ 1 mg/l
or 48 hr EC50 (for Daphnia) ≤ 1 mg/l
or 72 hr IC50 (for algae) ≤ 1 mg/l.

e) R 51 Toxic to aquatic organisms
and
R 53 May cause long-term adverse effects in the aquatic environment

Acute toxicity: 96 hr LC50 (for fish) 1 mg/l < LC50 ≤ 10 mg/l
or 48 hr EC50 (for Daphnia) 1 mg/l < EC50 ≤ 10 mg/l
or 72 hr IC50 (for algae) 1 mg/l < IC50 ≤ 10 mg/l

and the substance is not readily degradable

or the substance's log Pow ≤ 3.0 (unless the experimentally determined BCF ≤ 100).

Applies only to substances that do not fall under the criteria laid down in a).

5.2.2 Non-aquatic environment

5.2.2.1 Substances shall be classified as dangerous for the environment and assigned the symbol ”N” and the appropriate indication of danger, and assigned risk phrases in accordance with the following criteria:

RY: Great risk for long-term adverse effects in the environment
The half-life in soil > 8 weeks in a simulation test at 20°C
and
calculated or experimentally determined BCF > 2,000
or
the results of other reliable scientific studies or internationally accepted calculation methods are judged to be equivalent to these criteria.

(5.2.2.2 and 5.2.2.3 are renumbered)

Previous 5.2.2.1:
5.2.2.2 Substances shall be classified as dangerous for the environment and assigned the symbol ”N” and the appropriate indication of danger, and assigned risk phrases in accordance with the following criteria:

R 54 Toxic to flora
R 55 Toxic to fauna
R 56 Toxic to soil organisms
R 57 Toxic to bees
R 58 May cause long-term adverse effects in the environment

Substances which on the basis of available evidence concerning their properties, persistence, potential to accumulate and their predicted or observed environmental fate and behaviour may present a danger, immediate or long-term and/or delayed, to the structure and/or functioning of natural ecosystems other than those covered under 5.2.1 above. The risk phrase ”May cause long-term adverse effects in the environment” shall only be applied to substances that do not fall under the criteria laid down in 5.2.2.1. Detailed criteria will be elaborated later.

3.4 Time for implementation

Article y

Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive by not later than 30 June 2004. They shall forthwish inform te Commission

> thereof. They shall apply these provisions as from 1 January 2005. When these measures are adopted by Member States, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

The date for application of the new provisions in the dangerous substances directive should coincide with the expiry of the time for notification of substances laid down in Article 4a in Regulation 793/93.

4 Directive 1999/45/EG – the dangerous preparations directive

The proposal establishes a concentration limit that determines how high the concentration of a substance that is classified as persistent and bioaccumulative in accordance with the new criteria shall be in a preparation in order for the preparation to be classified in the same way.

Annex III, PART B

> **Concentration limits to be used for the evaluation of environmental hazards**
>
> I. *For the aquatic environment*
>
> The concentration limits fixed in the following tables, expressed as a weight/weight percentage, determine the classification of the preparation in relation to the individual concentration of the substance(s) present whose classification is also shown.

Table 1

Acute aquatic toxicity and long-term adverse effects

Classification of the substance	Classification of the preparation			
	N, R51-X	N, R50-53	N, R51-53	R52-53
N, R51-X	Cn ≥ 0.25%			
N, R50-53		Cn ≥ 25%	2.5% ≤ Cn < 25%	0.25% ≤ Cn < 2,5 %
N, R51-53			Cn ≥ 25%	2.5% ≤ Cn < 25%
R52-53				Cn ≥ 25%

Table 4

Long-term adverse effects

Classification of the substance	Classification of the preparation	
	RX	R53
N, RX	Cn ≥ 0.25%	
N, R51-X	Cn ≥ 0.25%	
N, R53		Cn ≥ 25%
N, R50-53		Cn ≥ 25%
N, R51-53		Cn ≥ 25%
R52-53		Cn ≥ 25%

II. For the non-aquatic environment

Table 6

Dangerous in terrestrial environment

Classification of the substance	Classification of the preparation
	N, RY
N, RY	Cn ≥ 0.25%

5 Directive 76/769/EEC – the restrictions directive

The proposed changes have to do with introducing the precautionary principle into the restrictions directive and introducing additional restrictions for CMR substances and new restrictions for PB substances.

5.1 The precautionary principle

Article 1

> Without prejudice to the application of other relevant Community provisions aimed at the protection of human health and the environment, this Directive is concerned with restricting the marketing and use in the Member States of the Community, of the dangerous substances and preparations listed in the Annex as well as of finished products containing such substance and preparations.
>
> The rules shall aim at an approximation of the of the laws, regulations and administrative provisions of the Member States to protect human health and the environment from being harmed by the use of dangerous substances and preparations and finished products containing dangerous substances or preparations. Provisions on restrictions in accordance with this Directive shall be adopted as soon as there is reason to assume that such use could lead to harm, even if the risk of harm is not fully scientifically established.

The proposal for a new wording of Article 1 is aimed at introducing the precautionary principle into the restrictions directive. In addition, the proposal is aimed at clarifying what the Directive intends to protect and its relationship to other Community provisions. By the term ”finished products”, which is already used in the restrictions directive, is meant products other than chemical products (substances and preparations).

5.2 CMR and PB substances

According to the present wording of points 29–31 in the restrictions directive, carcinogenic, mutagenic and reproduction-toxic substances, categories 1 and 2 (CMR substances), may not be used in substances and preparations placed on the market for sale to the general public. However, the provisions do not apply to certain specified products, e.g. motor fuels.

With these provisions as a model, the proposal calls for a gradual introduction of restrictions on substances classified in accordance with the new criteria for persistent and bioaccumulative substances (PB substances) and extended restrictions for CMR substances, as well as for preparations and finished products that contain PB or CMR substances.

The provisions are tied to the EU’s classification of a substance. This means that the provisions do not become applicable to an individual substance until the substance has been classified as a CMR or PB substance.

The currently applicable exemptions from the provisions concerning CMR substances for e.g. medicinal, veterinary and cosmetic products are also proposed to apply under the new provisions. According to Article 2 of the Directive, marketing or use for research and development or analysis purposes is generally exempted from the restrictions laid down in the Directive. Additional exemptions for certain use of a substance or preparation or for marketing of a given type of substance, preparation or finished product may be allowed after notification in accordance with the proposal for Articles 2b–2d (see below).

As from 1 January 2005:

Point 31a in Annex I

31a. New substances which, according to Directive 67/548/EEC

– have been notified after 31 December 2004,

– are listed in Annex I to the Directive,

– are classified as dangerous for the environment and, on their own or in combination with each other or with other risk phrases, are labelled with risk phrase RX ”Great risk for long-term adverse effects in the aquatic environment” or RY ”Great risk for long-term adverse effects in the environment”.

Without prejudice to provisions with stricter restrictions in other points in Annex I to Directive 76/769/EEC:

1. May not be used in substances and preparations placed on the market in individual concentration equal to or greater than

– either the concentration specified in Annex I to Directive 67/548/EEC,[1] or

– the concentration specified for preparations in Annex III to Directive 1999/45/EC[2].

2. Substances and preparations containing any of these substances in the concentration specified in paragraph 1 may not be placed on the market.

3. Substances and preparations referred to in paragraph 2 may not be intentionally added during the manufacture of finished products to be placed on the market.

4. New finished products containing substances or preparations referred to in paragraph 2 may not be placed on the market if the substances or preparations have been intentionally added.

By ”intentionally added” is meant in paragraphs 3–4 that the substance or preparation has been added to be a constituent in the finished product.

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[1] OJ No 196, 16.8.1967, p. 1/67.

[2] OJ No L 200, 30.7.1999, p. 1.

By way of derogation, the provisions in paragraphs 1–4 do not apply to

a) medicinal or veterinary products as defined by Directive 65/65/EEC[3],

b) cosmetic products as defined by Directive 76/768/EEC[4],

c) – motor fuels which are covered by Directive 85/210/EEC[5],

– mineral oil products intended for use as fuel in mobile or fixed combustion plants,

– fuels sold in closed systems (e.g. liquid gas bottles),

c) artists' paints covered by Directive 88/379/EEC[6].

d) substances and preparations which are placed on the market to be used in industrial installations, provided that the packaging, in addition to complying with other regulations, is legibly and indelibly labelled with the text: "For industrial use only. Release of the substance or preparation is prohibited." As regards use, the exemption applies only in industrial installations and provided that the user adopts measures to ensure that the substance or preparation is not released to the environment at any point in the process.

In an initial stage, it is proposed that a new point 31a be incorporated in the restrictions directive restricting the use of persistent and bioaccumulative substances that are classified as dangerous for the

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[3] OJ No L22, 9.2.1965, p. 369/65.
[4] OJ No L 262, 27.9.1976, p. 169.
[5] OJ No L 69, 3.4.1985, p. 25
[6] OJ No L 187, 16.7.1988, p. 14.

environment and are labelled with the new proposed risk phrases ”RX” or ”RY”, as well as finished products containing such substances.

As far as preparations are concerned, reference is made to the concentration limits that apply in order for a preparation in accordance with the provisions of the dangerous substances directive and the dangerous preparations directive to be classified in the same way as the pure substance. For substances with the two new risk phrases, it is proposed above that such a concentration limit (Cn 0.25%) be introduced in Annex III of the dangerous preparations directive.

As from 1 January 2007:

Points 29-31 in Annex I

29. Substances which appear in Annex I to Directive 67/548/EEC classified as carcinogen category 1 or carcinogen category 2 and labelled at least as ”Toxic (T)” with risk phrase R45: ”May cause cancer” or risk phrase R49: ”May cause cancer by inhalation” (…).

30. Substances which appear in Annex I to Directive 67/548/EEC classified as mutagen category 1 or mutagen category 2 and labelled with risk phrase R46: ”May cause heritable genetic damage” (…).

31. Substances which appear in Annex I to Directive 67/548/EEC classified as toxic for reproductive purposes category 1 or toxic for reproductive purposes category 2 and labelled with risk phrase R60: ”May impair fertility” and/or R61: May cause harm to the unborn child” (…).

Without prejudice to provisions with stricter restrictions in other points in Annex I to Directive 76/769/EEC:

1. May not be used in substances and preparations placed on the market for sale to the general public in individual concentration equal to or greater than

– either the concentration specified in Annex I to Directive 67/548/EEC[7], or

– the concentration specified for preparations in Table VI in Annex II to Directive 1999/45/EG[8].

2. Substances and preparations containing any of these substances in the concentration specified in paragraph 1 may not be placed on the market for sale to the general public.

3. Substances and preparations referred to in paragraph 2 may not be intentionally added during the manufacture of finished products

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[7] OJ No 196, 16.8.1967, p. 1/67.

[8] OJ No L 200, 30.7.1999, p. 1.

to be placed on the market for sale to the general public.

4. New finished products containing substances or preparations referred to in paragraph 2 may not be placed on the market for sale to the general public if the substances or preparations have been intentionally added.

By ”intentionally added” is meant in paragraphs 3–4 that the substance or preparation has been added to be a constituent in the finished product.

Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of dangerous substances and preparations, the packaging of such substances, preparations and finished products must be marked legibly and indelibly as follows: Restricted to professional users”. Finished products that lack packaging at the time of sale shall be marked on the product.

By way of derogation, the provisions in paragraphs 1–4 do not apply to

a) medicinal or veterinary products as defined by Directive 65/65/EEC[9],

b) cosmetic products as defined by Directive 76/768/EEC[10],

c) motor fuels which are covered by Directive 85/210/EEC[11],

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[9] OJ No L 22, 9.2.1965, p. 369/65

[10] OJ No L 262, 27.9.1976, p. 169.

[11] OJ No L 96, 3.4.1985, p. 25.

[12] OJ No L 187, 16.7.1988, p. 14.

	– mineral oil products intended for use as fuel in mobile or fixed combustion plants, – fuels sold in closed systems (e.g. liquid gas bottles), d) artists' paints covered by Directive 88/379/EEC[12].

In a second stage it is proposed that points 29–31 be extended to include use of CMR substances in consumer products and placing on the market of such finished products. The changes also entail that chemical products containing CMR substances may not be placed on the market for sale to the general public. The restrictions will thereby cover chemical products imported from a third country. The present-day regulation only covers the use of CMR substances in chemical products. Another change that is proposed is that the restrictions shall follow directly from the classification. According to the present-day provisions, a substance must also be listed in an appendix to the restrictions directive's annex to be covered by the restrictions.

As from 1 January 2010:

Point 31a–31b in Annex I

31a. New substances which, according to Directive 67/548/EEC – have been notified after 31 December 2004, – are listed in Annex I to the Directive, – are classified as dangerous for the environment and, on their own or in combination with each other or with other risk phrases, are	Without prejudice to provisions with stricter restrictions in other points in Annex I to Directive 76/769/EEC: 1. May not be used in substances and preparations placed on the market in individual concentration equal to or greater than – either the concentration specified in Annex I to Directive

labelled with risk phrase RX ”Great risk for long-term adverse effects in the aquatic environment” or RY ”Great risk for long-term adverse effects in the environment”.

31b. Substances which

– are listed in EINECS* or are new substances which have been notified before 1st January 2005 ,

– are listed in Annex I to Directive 67/548/EEC,

– are classified as dangerous for the environment and, on their own or in combination with each other or with other risk phrases, are labelled with risk phrase RX ”Great risk for long-term adverse effects in the aquatic environment” or RY ”Great risk for long-term adverse effects in the environment”,

– have a half-life > 6 months and whose calculated or experimentally determined bioconcentration factor (BCF) > 5,000,

– are listed in the addendum.

67/548/EEC[13], or

– the concentration specified for preparations in Annex III to Directive 1999/45/EC[14].

2. Substances and preparations containing any of these substances in the concentration specified in paragraph 1 may not be placed on the market.

3. Substances and preparations referred to in paragraph 2 may not be intentionally added during the manufacture of finished products to be placed on the market.

4. New finished products containing substances or preparations referred to in paragraph 2 may not be placed on the market if the substances or preparations have been intentionally added.

By ”intentionally added” is meant in paragraphs 3–4 that the substance or preparation has been added to be a constituent in the finished product.

By way of derogation, the provisions in paragraphs 1–4 do not apply to

a) medicinal or veterinary products as defined by Directive 65/65/EEC[15],

b) cosmetic products as defined by

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*EINECS (The European Inventory of Existing Commercial Chemical Substances): European list of substances considered to be on the market between 1 January 1971 and 18 September 1981.

[13] OJ No 196, 16.8.1967, p. 1/67.

[14] OJ No L 2000, 30.7.1999, p. 1.

[15] OJ No L22, 9.2.1967, p. 369/65.

[16] OJ No L 262, 27.9.1976, p. 169.

[17] OJ No L 96, 3.4.1985, p. 25.

[18] OJ No L 187, 16.7.1988, p. 14.

Directive 76/768/EEC[16],

c) motor fuels which are covered by Directive 85/210/EEC[17],

– mineral oil products intended for use as fuel in mobile or fixed combustion plants,

– fuels sold in closed systems (e.g. liquid gas bottles),

d) artists’ paints covered by Directive 88/379/EEC[18],

e) substances and preparations which are placed on the market to be used in industrial installations, provided that the packaging, in addition to complying with other regulations, is legibly and indelibly labelled with the text: ”For industrial use only. Release of the substance or preparation is prohibited.” As regards use, the exemption applies only in industrial installations and provided that the user adopts measures to ensure that the substance or preparation is not released to the environment at any point in the process.

The third stage entails that existing substance and new substances which have been notified before 2005 that are particularly persistent and liable to bioaccumulate are also subject to the restrictions. Since different assessments can be made of whether a substance meets the criteria or not, for the sake of clarity the substances that are covered should be listed in an addendum. Thus, the restrictions do not follow directly from the classification in this case.

As from 1 January 2015:

Point 31a in Annex I

31a. Substances which appear in Annex I to Directive 67/548/EEC classified as dangerous for the environment and, on their own or in combination with each other or with other risk phrases, are labelled with risk phrase RX ”Great risk for long-term adverse effects in the aquatic environment” or RY ”Great risk for long-term adverse effects in the environment”	Without prejudice to provisions with stricter restrictions in other points in Annex I to Directive 76/769/EEC: 1. May not be used in substances and preparations placed on the market in individual concentration equal to or greater than – either the concentration specified in Annex I to Directive 67/548/EEC[19], or – the concentration specified for preparations in Annex III to Directive 1999/45/EC[20]. 2. Substances and preparations containing any of these substances in the concentration specified in paragraph 1 may not be placed on the market. 3. Substances and preparations referred to in paragraph 2 may not be intentionally added during the manufacture of finished products to be placed on the market. 4. New finished products containing substances or preparations referred to in point 2 may not be placed on the market if the substances or preparations have been intentionally added. By ”intentionally added” is meant in paragraphs 3–4 that the substance or preparation has been added to be a constituent in the finished product.

[19] OJ No 196, 16.8.1967, p. 1/67.
[20] OJ No L 200, 30.7.1999, p. 1.

By way of derogation, the provisions in paragraphs 1–4 do not apply to

a) medicinal or veterinary products as defined by Directive 65/65/EEC[21],

b) cosmetic products as defined by Directive 85/210/EEC[22],

c) motor fuels which are covered by Directive 76/768/EEC[23],

– mineral oil products intended for use as fuel in mobile or fixed combustion plants,

– fuels sold in closed systems (e.g. liquid gas bottles),

d) artists' paints covered by Directive 88/379/EEC[24],

e) substances and preparations which are placed on the market to be used in industrial installations, provided that the packaging, in addition to complying with other regulations, is legibly and indelibly labelled with the text: ”For industrial use only. Release of the substance or preparation is prohibited.” As regards use, the exemption applies only in industrial installations and provided that the user adopts measures to ensure that the substance or preparation is not released to the environment at any point in the process.

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[21] OJ No L 22, 9.2.1965, p. 369/65.

[22] OJ No L 262, 27.9.1976, p. 169.

[23] OJ No L 96, 3.4.1985, p. 25.

[24] OJ No L 187, 16.7.1988, p. 14.

As from 2015, it is proposed that the restrictions shall apply to all substances that are classified as environmentally hazardous (dangerous for the environment) and shall be labelled with the new risk phrases.

In the long term:

Points 29–31 in Annex I

29. Substances which appear in Annex I to Directive 67/548/EEC classified as carcinogen category 1 or carcinogen category 2 and labelled at least as ”Toxic (T)” with risk phrase R45: ”May cause cancer” or risk phrase R49: ”May cause cancer by inhalation”.

30. Substances which appear in Annex I to Directive 67/548/EEC classified as mutagen category 1 or mutagen category 2 and labelled with risk phrase R46: ”May cause heritable genetic damage”.

31. Substances which appear in Annex I to Directive 67/548/EEC classified as toxic for reproductive purposes category 1 or toxic for reproductive purposes category 2 and labelled with risk phrase R60: ”May impair fertility” and/or R61: May cause harm to the unborn child”.

Without prejudice to provisions with stricter restrictions in other points in Annex I to Directive 76/769/EEC:

1. May not be used in substances and preparations placed on the market in individual concentration equal to or greater than

– either the concentration specified in Annex I to Directive 67/548/EEC[25], or

– the concentration specified for preparations in Table VI in Annex II to Directive 1999/45/EG[26].

2. Substances and preparations containing any of these substances in the concentration specified in paragraph 1 may not be placed on the market **(...)**.

3. Substances and preparations referred to in paragraph 2 may not be intentionally added during the manufacture of finished products to be placed on the market **(...)**.

4. New finished products containing substances or preparations referred to in paragraph 2 may not be placed on the market if the substances or preparations have been intentionally added **(...)**.

By ”intentionally added” is meant

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[25] OJ No 196, 16.8.1967, p. 1/67.

[26] OJ No L 200, 30.7.1999, p. 1.

in paragraphs 3–4 that the substance or preparation has been added to be a constituent in the finished product.

(...)

By way of derogation, the provisions in points 1–4 do not apply to

a) medicinal or veterinary products as defined by Directive 65/65/EEC[27],

b) cosmetic products as defined by Directive 76/768/EEC[28],

c) motor fuels which are covered by Directive 85/210/EEC[29],

– mineral oil products intended for use as fuel in mobile or fixed combustion plants,

– fuels sold in closed systems (e.g. liquid gas bottles),

d) artists’ paints covered by Directive 88/379/EEC[30],

e) substances and preparations which are placed on the market to be used in industrial installations, provided that the packaging, in addition to complying with other regulations, is legibly and indelibly labelled with the text: ”For industrial use only. Release of the substance or preparation is prohibited.” As regards use, the exemption applies only in industrial installations and provided that the user adopts measures to ensure that the substance or preparation is not

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[27] OJ No L 22, 9.2.1965, p. 369/65.

[28] OJ No L 262, 27.9.1967, p. 169.

[29] OJ No L 96, 3.4.1985, p. 25.

[30] OJ No L 187, 16.7.1988, p. 14.

released to the environment at any point in the process.

The last step entails that points 29–31 are changed to also include, with certain exemptions, professional use of CMR substances and finished products containing such substances.

Exemptions for which approval is required

Article 2b

Member States shall appoint the competent authority or authorities to participate in the work referred to in Articles 2c–2d.

Article 2c

1. Anyone who considers that a given use subject to the provisions in 29–31a (*at first only 31a in the following, during a certain period points 31a and 31b)*) in Annex I is necessary shall notify this to the competent authority in a Member State where such use is being considered. The same applies to anyone who considers it necessary to place a substance, a preparation or a finished product subject to the provisions in 29–31a in Annex I on the market. Notification shall in such cases take place to the competent authority in a Member State where the product is intended to be placed on the market.

2. The notification shall contain information on the substance, preparation or finished product being notified. Regarding finished products, the content of the product as regards substances and preparations subject to the provisions in points 29–31a in Annex I shall in particular be specified. Further, detailed information shall be furnished in the notification regarding the intended use, or the quantity in which the product is intended to be placed on the market, whichever is applicable. In addition, the notification shall contain the reasons on which it is based and the information needed by the competent authority to make its decision in accordance with what is laid down in paragraphs 3 and 4.

3. Within 90 days of receiving a notification, the competent authority shall either

a) turn over the documents to the Commission with a ruling in which the notification is approved, or
b) inform the notifier that the notification is not approved.

4. In its decision as set forth in point 3, the competent authority shall take into consideration

> a) the social benefits of the use, or of the substance, the preparation or the finished product to be placed on the market, whichever is applicable
> b) whether there are acceptable alternatives to the use, or to the substance, the preparation or the finished product to be placed on the market, whichever is applicable
> c) whether work is under way to develop alternatives,
> d) whether the notifier has shown that precautionary measures that are to be taken will result in limited risks to health and the environment in both the short and long term.
>
> 5. In the cases referred to in paragraph 3(a), the ruling shall contain the conditions considered necessary by the competent authority.
>
> 6. The calculation of the 90-day period mentioned in paragraph 3 shall not include time during which the competent authority has waited for supplementary information from the notifier.

The proposal for Article 2b–2c entails a possibility to grant time-limited exemptions for certain use of substances and preparations that are subject to the proposed restrictions in points 29–31a (in stage one only point 31a, during a certain period points 31a and 31b) in Annex I concerning CMR and PB substances. It shall also be possible to grant exemptions to permit a certain kind of substance, preparation or finished product subject to the restrictions to be placed on the market.

According to the proposal, notification shall be made to the competent authority in a Member State where use is being considered, or where the product is intended to be placed on the market, whichever is applicable. If several Member States are involved, it is thus possible to choose the state for notification. The competent authority shall either turn over the documents to the Commission with a ruling that approves the notification or inform the notifier that the notification is not approved. The Member State shall take certain circumstances set forth in 2c(4) into consideration in its decision.

Article 2d

> 1. When the Commission has received the documents referred to in Article 2c.(3), it shall immediately distribute them to the competent authorities in all Member States. The Commission shall inform the authority that has turned over the documents of the date of the distribution.
>
> 2. If no Member State has registered any objections within 60 days of the distribution of the documents, the competent authority shall give its written consent to the notification, which shall contain the conditions

> issued by the authority. The consent shall be valid for a period not exceeding five years. The competent authority shall inform the other Member States and the Commission of the consent.
>
> 3. If a competent authority in any other Member State has an objection, and it is not possible for the concerned competent authorities to come to an agreement within the time period stipulated in paragraph 2, a decision shall be made in accordance with the procedure laid down in Article 2a.
>
> 4. If the decision is positive, the competent authority that received the original notification shall give its written consent containing the issued conditions. The consent shall be valid for a period not exceeding five years. The competent authority shall inform the other Member States and the Commission.
>
> 5. Consent as described in paragraph 2 or 4 may not be given to use of substances mentioned in points 29–31 in Annex I in substances and preparations intended to be placed on the market for sale to the general public.
>
> 6. When a written consent has been given for a given use or for the placing of a substance preparation or finished product on the market, use or placing on the market, whichever is applicable, may take place within the entire Community without further notifications, provided that the conditions for the consent are complied with. The consents with conditions shall be listed by the Commission in Annex x.
>
> 7. The Member States shall adopt the necessary measures to ensure that the conditions laid down in the written consent are complied with.

The proposal for Article 2d entails that the competent authorities in other Member States are given an opportunity to register objections to a notification. In the event no objections have been registered within the specified period of time, the competent authority shall give its written consent, which shall contain the conditions issued by the authority. If any competent authority has an objection and it is not possible for the authorities to come to an agreement, a decision shall be made by the European Commission in accordance with the same committee procedure used to decide on adaptations of the Directive to technical progress. According to the proposal, however, consent may not be given to use of CMR substances in substances and preparations intended for sale to the general public. Such use is prohibited under current rules, without the possibility of exemption.

Persistent and bioaccumulative organic substances

Contents

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

A persistent organic substance is defined here as one which is stable in the environment, i.e. the substance resists the physical, chemical and biological processes in the environment that lead to degradation of other, less resistant substances.

Degradation is defined here as complete decomposition to harmless end products,[1] which in most cases involves mineralization.[2] This is known as ultimate degradation. Sometimes a substance is regarded as degraded if it has disappeared, without knowing whether the degradation is complete. This is called primary degradation. Knowing that a substance has undergone primary degradation does not necessarily mean it can be known whether the degradation is complete or not, i.e. whether ultimate degradation has been achieved.

One should also be aware of the fact that even a substance that undergoes rapid and ultimate degradation to harmless end products may have intermediates[3] that are highly reactive and toxic. These intermediates may cause long-lasting damage in the environment, i.e. have a persistent effect. Such substances cannot, however, be subject to the Chemicals Committee’s criteria for persistence, but must be assessed on the basis of the effects of their reactive intermediates.

[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.

[2] Decomposition to carbon dioxide, water, mineral salts and other simple, inorganic compounds of whatever other elements, besides carbon and hydrogen, comprised the parent molecule (for example oxygen, which furthermore often plays an active role in the mineralization process).

[3] Products that arise as an intermediate step in the degradation process, in cases where this process consists of several steps.

1.1 What determines whether a substance is persistent?

Summary

A substance is to be regarded as persistent if it:

- possesses high resistance to degradation processes, or
- gives rise to persistent degradation products as a result of incomplete degradation.

One practical way to ascertain the persistence of a substance is to determine the rate at which the substance is broken down in the environment.

Microorganisms are the principal agents of the degradation process, but abiotic processes may also be of great importance.

Persistence can have several causes. A substance can resist degradation because it is more or less inert, in which case it has a molecular structure that hinders it from reacting with other substances to a high degree. This means that the substance is only affected to a very limited extent by the biotic (biological) and abiotic (chemical and photochemical) degradation processes that occur in the environment. When it comes to an inert substance, persistence can be said to be an inherent property of the substance. Well-known examples of bioaccumulative substances that are highly inert are many organohalogens, such as most congeners[4] of polychlorinated biphenyls (PCBs), and organometallic compounds such as tetramethyl lead. Such substances can be regarded as persistent in the deepest sense of the word.

However, even a more or less readily degradable substance can behave as persistent in the environment. One reason may be that the conditions for degradation are unfavourable. This is dealt with at greater length in section 1.4.

A readily degradable substance can also be falsely perceived as persistent if it is released to the environment at the same rate as, or at a faster rate than, it degrades. If it ceases to be released, however, the concentrations in the environment decline relatively rapidly.

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[4] PCBs are blends of polychlorinated biphenyls with different degrees of chlorination and different location of the chlorine atoms, with 209 possible variants. These variants are called congeners.

1.1.1 Substances with persistent degradation products should also be regarded as persistent substances

When a substance is investigated with regard to degradability, it is important to keep track of the substance’s degradation products, i.e. what other substances arise as a result of the degradation process. If a persistent substance arises as a result of the degradation of a relatively short-lived ”parent molecule”, the original substance (parent molecule) should, in the opinion of the Committee, be judged according to the properties of its long-lived (persistent) degradation products. A well-known example of a bioaccumulative substance that is relatively degradable, but which gives rise to a very persistent product, is DDT, which is relatively rapidly transformed into the highly stable metabolite DDE.

It is therefore of great importance that degradation studies not be limited to investigating whether the studied substance disappears, i.e. primary degradation, but also extend to identification of the degradation products.

1.1.2 The degradation rate in the environment determines how persistent a substance is

A practical way to obtain knowledge on the persistence of a substance is to determine the rate at which the substance is broken down in the environment. Persistent substances are poorly degradable and are broken down very slowly or not at all. Short-lived substances are readily degradable and are broken down rapidly. One of the Committee’s tasks is to draw the line between, on the one hand, bioaccumulative organic substances that are so persistent, i.e. so poorly degradable, that the possibility cannot be ruled out on good grounds that they may give rise to future problems for man and the environment if they are incorporated in new products and in industrial processes, and on the other hand the bioaccumulative organic substances that are so degradable that their use cannot be expected to give rise to future problems that can be related to their persistence.

The biodegradation of organic substances in the environment is normally driven by microorganisms that have the capability to use the substances as a substrate for their growth. A prerequisite for microbial degradation is that the substance is available for microbial activity, i.e. can be taken up by microorganisms or can be reached by the degrading enzymes secreted by the microorganisms. Secreted enzymes can in some cases also degrade substances which the microorganisms are incapable of utilizing as a source of nutrition and energy in so-called co-metabolic processes. Degradation products resulting from such processes may, however, be utilized by other types of microorganisms, which complete the degradation process.

Higher organisms can also be capable of degrading man-made organic substances. A prerequisite for this is that the substances are bio-available, i.e. can be taken up by the organism and interact with its metabolic processes. Substances that are taken up in higher organisms can also be secreted intact or be stored in the organism, depending on the properties of the substance (see further section 2, on bioaccumulation).

The degradation processes can also have non-biological (abiotic) components, which can act separately or interact with the biological (biotic) processes. Hydrolysis is an important abiotic degradation process in the aquatic environment, and photochemical degradation is an important abiotic degradation process in air as well as on surfaces such as land, water and vegetation.

As the ecological system has evolved, however, microorganisms are the ”cleaners” of the natural world. They have evolved to fill the role of degradation specialists, where they decompose and mineralize dead organic material of both animal and vegetable origin, and thereby return the chemical building blocks of life to the natural cycle. In the end it is always the ability of microorganisms to degrade a substance that is most decisive, regardless of whether it can also be degraded by higher organisms or not. Substances that are secreted by or stored up in higher organisms always face microbial degradation processes in the end. Tests of degradability are therefore normally carried out under conditions where microbial activity constitutes a dominant element in the degradation process. Microorganisms thus play the leading roles in the natural degradation processes, although abiotic processes can also be of great importance.

1.1.3 The half-life is a measure of the degradation rate

Often the degradation rate of a substance is approximated by the time it takes for half of a certain quantity of the substance to be broken down to harmless products. This time is called the half-life of the substance. Determining the half-life of a substance in the natural environment is difficult, however. Substances can partition themselves among several different environmental media – such as soil, water and air – where their degradation rates are different. Furthermore, degradation seldom follows a simple course and is moreover influenced strongly by environmental factors (see section 1.4). The degradation of a substance is therefore investigated primarily in tests conducted under controlled conditions in the laboratory.[5]

The degree of comparability between such investigations, conducted at different times and at different laboratories, increases if the investigations are carried out in a standardized, internationally recognized manner, i.e. the same stipulated conditions are observed on every occasion the investigation is performed. Both simple standardized tests that only measure whether a substance is readily or poorly degradable, and more sophisticated tests where a measure of the substances' half-times can be obtained, have been developed for this purpose. It should be emphasized that the greater the simplification entailed by a test, the greater the risk that it will not reflect what happens to a substance in the natural environment. The result of a simple test cannot be directly extrapolated to another environment.

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[5] This means that all conditions that influence the investigation are known and documented, so that the investigation will exhibit a high degree of reproducibility (produce the same results) if it is repeated under the same conditions.

1.2 Biodegradability tests

Summary

There are standardized, internationally recognized testing methods which can determine in a relatively simple manner whether a substance is readily or poorly biodegradable, whereas half-lives are more difficult to determine.

The simpler the test is, however, the more uncertain it is to extrapolate the results to apply to the natural environment.

Tests of Ready Biodegradability primarily provide information on which substances are readily biodegradable. Substances that are not degraded in such tests are not necessarily persistent, but substances that are degraded by less than 20 percent in these tests can be suspected on good grounds of being so.

Tests of structurally determined biodegradability (Inherent Biodegradability) only provide information on which substances are poorly biodegradable. Substances that are degraded in such tests are not necessarily readily biodegradable.

Simulation tests measure half-lives and provide a better measure of the degradability of organic substances than simpler tests do.

In field studies it may be difficult to distinguish degradation from adsorption, emission and other forms of transport.

In certain tests of microbial degradation, oxygen consumption and carbon dioxide evolution can provide information on whether the degradation is complete or not.

Testing methods for abiotic hydrolysis and photochemical degradation are not designed to show whether a substance is degraded to harmless products or not.

International organizations such as ISO (see section 8.6.1 in Chapter 8) and the OECD (see section 8.3 in Chapter 8), and national authorities such as the US EPA (see section 4.5), have developed standardized testing methods for determining the degradability of organic substances. Many of these testing methods are internationally recognized, which is a prerequisite if the test results are to be considered acceptable in international contexts.

In order to determine whether a substance is readily or poorly biodegradable, guidelines for standardized testing methods have been developed within the framework of the OECD’s work. These tests are relatively simple to perform at laboratories. Biodegradability is examined by subjecting the test substance to microbial activity in e.g. water, sediment or soil. The most widely used tests to date are of two kinds: those that measure Ready Biodegradability and those that measure Inherent (structurally determined, or potential) Biodegradability. There are also tests that are designed in such a way that they provide a measure of the substances' half-lives. These simulation tests can be expected to acquire increasing importance in future studies of the degradability of various substances.

There are also standardized testing methods for certain types of abiotic degradation.

1.2.1 Readily biodegradable substances are broken down rapidly by unprepared microorganisms (test of Ready Biodegradability)

Ready Biodegradability is defined in the OECD's test guidelines 301 A-F (OECD, 1992). The OECD's technical requirements that have to be met in order for substances to be regarded as readily biodegradable are that they be degraded by more than 70 percent in the tests that are based on measurement of the total quantity of dissolved organic carbon, and by more than 60 percent in the tests that measure oxygen consumption or carbon dioxide evolution, within a time frame of ten days counting from the time when 10 percent of the substance has been degraded, but within no more than 28 days of the start of the test.

All organic substances that are broken down to the same or greater extent than that required in order for a standard test for ready degradability to have an approved result can be regarded as readily biodegradable – and even as rapidly biodegradable. The OECD's guidelines for these kinds of biodegradability tests stipulate that the microorganisms used in the test shall not previously have had an opportunity to adapt to the substance whose ready biodegradability is to be tested. The microbial degraders must thus be unprepared for the substance to which they will be exposed. In most tests, complete (ultimate) degradation to harmless products can be indicated, since the biodegradability of a substance is studied by measuring the consumption of oxygen or evolution of carbon dioxide. This is done by estimating how much oxygen must be consumed and how much carbon dioxide must be evolved during the complete degradation of a substance and then comparing these figures with the test results.

A substance which is judged to be readily biodegradable in a test of this kind can usually be regarded as persistent, and as relatively readily biodegradable in the environment. However, a substance that is not degraded in a ready degradability test is not necessarily sufficiently poorly biodegradable to warrant its being considered persistent without further investigation. In some ready biodegradability tests, for example, relatively high concentrations of the test substance are used, and there may be reason to consider the possibility that the substance has a toxic effect on the microorganisms in the test. However, there may be good grounds for suspecting that substances which are degraded by less than 20 percent in a ready biodegradability test are persistent.

In the OECD's guidelines 301 A–F, substances are tested in a freshwater environment, but there is also an equivalent test for seawater, OECD 306. Substances that meet the biodegradation criteria in the latter test are also considered readily biodegradable, since organic substances are normally broken down more slowly in a marine environment than in fresh water.

1.2.2 Poorly biodegradable substances are not broken down rapidly even by prepared microorganisms (test of Inherent Biodegradability)

Tests that measure structurally determined biodegradability (Inherent Biodegradability) are defined in the OECD's guidelines for testing 302 A–C (OECD, 1992). Like the ready biodegradability tests 301 A–F, these tests are carried out in an aquatic (freshwater) environment, but differ in that the conditions for the microbial degradation processes have been optimized. For one thing, the microorganisms may have been given an opportunity to adapt to the substance to be tested for several generations, allowing those microorganisms that are able to break down the test substance most rapidly to be selected. Furthermore, only primary biodegradation is determined in many Inherent Biodegradability tests (Pedersen et al., 1999).

Structurally determined biodegradability shows that there is nothing in the molecular structure of the substance that prevents or appreciably impairs biodegradability. Substances that are broken down by more than 70 percent in 28 days in this test are to be regarded as structurally biodegradable. This does not necessarily mean that they are readily biodegradable in a Ready Biodegradability test, or in nature. Substances that are not degraded by more than 70 percent in an Inherent Biodegradability test can, on the other hand, be regarded as poorly biodegradable and thereby potentially persistent in the environment. Substances that are degraded by less than 20 percent in these tests can on good grounds be presumed to have high persistence.

OECD 304 A, which tests the biodegradation of a substance in soil, is also an Inherent Biodegradability test. However, it differs from other such tests in that ”unprepared” microflora are used from natural soil samples.

1.2.3 The simpler tests provide limited information that may need to be followed up

Thus, Ready Biodegradability tests are intended to distinguish readily biodegradable substances, which there is then no reason to regard as persistent. The original idea was that organic substances that had not been approved in a Ready Biodegradability test should be further tested with respect to structurally determined biodegradability (Inherent Biodegradability). This would determine which substances were persistent and which were not. Due to the nature of the tests intended to determine Inherent Biodegradability, however, many substances that are degraded in such tests are in practice poorly biodegradable, i.e. persistent in the environment. Inherent Biodegradability tests are therefore considered unsuitable today for deciding whether a substance is persistent or not.

Thus, there is a grey zone in the OECD’s guidelines for Ready Biodegradability and Inherent Biodegradability where it is difficult to determine with simple tests to what extent the substances are readily biodegradable or persistent.

Today it is considered preferable to follow up the substances that are not found to be readily degradable in Ready Biodegradability tests with a simulation test (section 1.2.4), where the purpose is to obtain a measure of the half-life of the substance.

Can simple tests give more than a yes or no answer?

Ready Biodegradability tests are designed to provide only a simple yes or no answer. However, in several of the tests it is possible to some extent to determine more exactly the degree to which a substance has been broken down after a given time. But this is not considered relevant for e.g. classification purposes in EU and OECD contexts. Nevertheless, it may be acceptable to use such figures in setting up priority lists of organic substances.

The same applies to a great extent to estimates of half-lives based on tests of Ready Biodegradability and Inherent Biodegradability. Such estimates are presented in e.g. the EU’s TGD (1996).[6] Readily biodegradable substances are estimated to have a half-life of not more than 15 days in surface water. For ”structurally biodegradable” substances, the equivalent half-life is estimated at not more than 150 days. In soil, readily biodegradable substances with low adsorption are estimated to have a half-life of not more than 30 days. The estimated half-life in soil then rises with the adsorption capacity of the substances.

1.2.4 Half-lives of substances can be determined in simulation tests

The substances that are not broken down in Ready Biodegradability tests should be further investigated in simulation tests, where a measure of the half-life of the substances can be obtained. A simulation test lies closer to the actual degradation situation in the environment than the simpler tests, and is also more complicated to perform. A simulation test should be able to provide information at least on the degradation rate, both for primary and ultimate degradation, and enable any metabolites[7] formed during degradation to be determined. Several simulation tests have been implemented within the framework of the ISO system. For example, ISO 11734 pertains to biodegradability under anaerobic conditions, while ISO 14592 pertains to biodegradability in surface water. Additional simulation tests, e.g. for biodegradation in sediment, are under development.

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[6] The assessment is based on an estimate of the constant for the degradation rate in degradation according to first-order kinetics.

[7] Transformation products as a result of the organism’s metabolism

The OECD’s guidelines for testing include a simulation test today, 303 A. However, this test simulates biodegradation under the conditions prevailing in waste sludge, and the results of this test cannot be extrapolated to apply to natural waters (Pedersen et al., 1999). Nor is it considered possible to use the results of this test as a basis for classification of organic substances. Efforts are currently under way within the OECD to incorporate additional simulation tests in the organization’s guidelines for testing.

1.2.5 What do field studies and other scientific studies say?

Studies of the degradation of organic substances in the field may naturally seem to have a great potential for answering questions on the degradability of the substances. However, one big problem with field studies is that it is difficult to demonstrate ultimate degradation to harmless products. The reason a substance ”disappears” in soil, for example, is not necessarily that it has been degraded; it may instead have been adsorbed so tightly that it can no longer be extracted from the soil samples that are taken (Bergström & Stenström, 1998). The degradation of an organic substance in the field can also vary widely between different environments (see further section 1.4 and, for example, Torstensson & Stenström, 2000). A substance can also disappear from soil due to evaporation, and because it is more mobile and has been transported to deeper-lying soil strata during the course of the study. Where suitable, such disappearances that are not due to degradation can be compensated for to some extent in degradation studies by making use of a radioactively marked test substance. With such methods, it is possible in some cases to determine the fraction of a substance that is so tightly bound it cannot be extracted.

Field studies and other scientific studies of the degradability of substances often make greater allowance for the partitioning of the substances between different environmental media than standardized testing methods do. There may therefore be good reasons for taking these kinds of studies into account as well when determining the degradability of a substance in the environment.

1.2.6 Abiotic hydrolysis does not necessarily entail ultimate degradation

Hydrolysis entails that water reacts with an organic substance and breaks up certain chemical bonds. A standardized testing method for hydrolysis is described in OECD guideline 111.

Hydrolysis is often the first step in the degradation that is measured in e.g. ready biodegradability tests. Hydrolysis alone does not necessarily entail degradation to harmless end products. In other words, knowing that a substance is hydrolyzed does not mean that the creation of persistent hydrolysis products can be ruled out.

1.2.7 Photochemical degradation is not necessarily ultimate either

Photochemical degradation entails that light, often in the ultraviolet part of the spectrum, renders a substance so unstable that chemical bonds are broken and the substance falls apart. There is today no standardized OECD testing method for photochemical degradation in the aquatic environment, although the EPA’s guidelines OPPTS 835.2210 and OPPTS 835.5270 test photolysis experimentally under different conditions. There is, however, a draft in the OECD for a guideline for ”direct photolysis in water” (GD(97)21).

Nor is there any standardized, experimental method for the determination of photochemical degradation in air; instead, a calculation model is recommended by the OECD (Sijm et al., 1999; see also section 1.3.2).

Photochemical degradation does not necessarily entail degradation to harmless end products. In other words, knowing that a substance is degraded photochemically does not mean that the creation of persistent degradation products can be ruled out.

1.3 Can degradability be estimated?

Summary

Estimated biodegradability can provide predictions with an accuracy of up to 90 percent, but it is recommended that biodegradation results from calculation models be interpreted conservatively.

There are no standardized calculation models for estimating half-lives for biodegradation.

There are calculation models for estimating abiotic hydrolysis and photochemical degradation in air, but these are uncertain because they have not been validated.

One way to obtain data on the degradability of organic substances when reliable experimental data are not available is to estimate degradability theoretically based on the molecular structure of the substances. Different computer programs are available for estimating degradability by calculation of ”Quantitative Structure-Activity Relationships”, QSARs (see also section 2).

1.3.1 Is 90 percent sufficient for estimated ready biodegradability to be accepted?

Within the framework of the Dutch environment ministry’s ”General Assistance for the National Policy towards Substances”, a report has recently been produced for the EU’s Directorate of Chemicals, External Safety and Radiation Protection, for the purpose of inventorying ”simple” methods to assess the persistence, bioaccumulation potential and toxicity of substances in cases where experimental data are lacking or unreliable (Sijm et al., 1999). Two different programs (”the ECB model” and ”the Syracuse program BIODEG”) are held up in the report as being best at predicting ready biodegradability. Validation of the performance of the programs in this respect showed that ready biodegradability was correctly predicted for approximately 80 percent and 90 percent, respectively, of the readily biodegradable substances included in the validation. Non-ready biodegradability was correctly predicted for about 85 percent with the ECB model, while BIODEG incorrectly identified 56 percent of the non-readily biodegradable substances included in the validation as being readily biodegradable.

An improved calculation model was recently presented by Loonen et al. (1999). This model makes only around 10 percent incorrect predictions. The authors contend that the model is useful for determining whether an organic substance is readily biodegradable or not, in particular considering the fact that experimental studies often give answers with margins of error in the same order of magnitude.

It is possible that calculation models for ready degradability will eventually be developed to the point that they can gain international acceptance as substitutes for experimental studies. In the EU (TDG, 1996), however, it is recommended today that the results of these models only be taken into account if they are interpreted conservatively, i.e. that the substances indicated by the model as being poorly biodegradable can be regarded as such, while substances indicated as being readily biodegradable should not be regarded as such. Models of this kind can thereby already be used today to reduce the need for experimental testing for the substances indicated as being non-readily biodegradable.

There are no standardized calculation models today for estimating half-lives as a result of biodegradation, and estimates of half-lives based on results from simple biodegradability tests are not accepted today as a ground for classification. The EPA recommends, however, that half-life in the aquatic environment be calculated using ”the Ultimate Survey Model” in the EIP BIOWIN program (Boethling et al., 1994; EPA, 1999).

1.3.2 Hydrolysis and photochemical degradation can also be estimated

There are programs for estimating hydrolytic and photochemical degradation processes as well (Sijm et al., 1999). But there is no information on validation of the calculation program for hydrolysis described by Sijm et al. (1999).

For photochemical degradation in air, the OECD (1992) recommends a calculation program in lieu of a standardized experimental test for this process. However, according to Sijm et al. (1999), who discuss the program recommended by the OECD as well as one other one, these programs have not yet been validated externally, i.e. against other organic substances than those included in devising the relevant algorithm. Furthermore, the programs produce highly varying results, which makes it difficult to judge their value.

1.4 The biodegradability of organic substances in the environment varies widely

Summary

The biodegradability of organic substances in the environment is dependent on:

- whether biodegrading organisms are present,
- whether the substances occur in concentrations sufficient to sustain microbial activity,
- whether the environmental conditions permit microbial activity.

Conditions in the environment differ greatly from the conditions in standardized testing systems, both in character and with regard to temporal variations. It is therefore difficult to say anything about the fate of a substance in the environment based on its test results.

1.4.1 Biodegrading organisms are not always present

Microbial activity varies widely between different environments, in part depending on whether biodegrading microorganisms are present or not. This activity may be high in forest soil, is often lower in arable soil, and is virtually zero on e.g. gravel surfaces. Microbial activity is higher in topsoil than in deeper soil layers. It is normally high in surface waters and sediments, but low in groundwater.

1.4.2 Biodegradation is dependent on the concentrations of the substances

The microbial degradation capacity is also dependent on such factors as in what concentration a substance occurs in the environment. If the concentration is too low, the degradation processes may not start. If, on the other hand, the concentration is too high, even a source of nutrients and energy that is attractive to many microorganisms may have an inhibitory effect on the degradation process. An example of the latter is ordinary sugar, which has a preservative effect on foods in high concentrations.

The presence of other, competing substrates may also influence the biodegradation of a substance.

1.4.3 Biodegradation is dependent on where in the environment the substances occur

The partitioning of substances between different environmental media or compartments – such as soil, water and air – is a factor that has a large influence on the biodegradation of a substance (Beyer, et al., 2000; Gouin et al., 2000). In order to obtain a detailed determination of the biodegradation of a substance in the environment, it is therefore necessary to know the proportions in which a substance is partitioned among different environmental media, and how it is biodegraded in the different environmental compartments.

The degradation of a substance is further influenced by many environmental factors. In cold climates, temperature is normally the most important limiting factor. Other factors of great importance can be e.g. moisture content, oxygen supply, acidity and nutrient supply.

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

Summary

A bioaccumulative substance is available for uptake by organisms.

A bioaccumulative substance is metabolized or secreted at a low rate and is persistent.

Bioaccumulation potential is usually indicated as a bioconcentration factor, experimentally determined for fish, or estimated based on the fat solubility of a substance.

The bioconcentration factor may underestimate the bioaccumulation potential of substances in cases where this property is dependent to some extent on other factors than fat solubility.

Highly bioaccumulative substances can be biomagnifying. This means that their concentration rises at higher trophic levels in a food chain.

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 bioaccumulation factor (BAF), which is obtained by dividing the equilibrium concentration in the organism by the concentration in the surrounding environment and in food. In practice, the BAF is often replaced by the bioconcentration factor (BCF), which is easier to determine experimentally. There are standardized, internationally recognized testing methods for determining the BCF in an aquatic environment. An example of such a testing method is OECD guideline 305. The BCF is, like the BAF, a measure of the partitioning of a substance between an organism and the surrounding medium at equilibrium, but in contrast to the BAF the BCF is based solely on uptake directly from the surrounding medium via skin and mucous membranes. The BCF for fish thus reflects above all uptake and equilibration over the gill membrane. A detailed description of how bioconcentration is defined and can be determined is found in Commission Directive 98/73/EC on the adaptation to technical progress of Council Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances.

For highly fat-soluble, bioavailable organic substances, the BCF can be assumed to comprise a fairly good estimate of the BAF. Substances with very low water solubility may, however, obtain a low BCF value in experimental determination of the BCF, even though they are potentially bioaccumulative. The BCF can also be expected to constitute an underestimate of the BAF for substances whose bioaccumulative potential is wholly or partially dependent on factors other than fat solubility, for example that the substance are bound to macromolecules such as proteins. Despite these limitations, the BCF is a relatively useful parameter for describing the uptake of neutral organic substances in organisms in an aquatic environment. However, there is as yet no equivalent standardized test by means of which it is possible to estimate bioaccumulation in a terrestrial environment (van Leeuwen & Hermens, 1995).

The BCF for a fat-soluble substance is closely related to the substance's degree of fat solubility. This can be determined as the partitioning of the substance at equilibrium between the organic solvent n-octanol and water. The partition coefficient, K_{ow}, indicates the degree of fat solubility and is often expressed logarithmically, as log K_{ow}. When the BCF is unknown, it can be estimated for fat-soluble substances with the aid of calculation models (QSAR, see also section 1.3) based on K_{ow}. For bioavailable, fat-soluble, neutral organic substances, the agreement between measured and estimated values is considered to be good in the log K_{ow} range 1 to 7 (Sijm et al., 1999; see also van Leeuwen & Hermens, 1995).

A bioaccumulative substance can often be passed on in the food chain. Very highly bioaccumulative substances that are transferred via food can be biomagnifying (see Figure 5.3 in Chapter 5). The contribution made by the food to enrichment in food chains is expressed by a biomagnification factor (BMF). This means that the concentration of a substance, normalized to the fat content of the organisms, rises with rising trophic level in a food chain. This can lead to such high concentrations of a substance at high trophic levels in the food chain that the predators at these high levels are exposed to harmful effects, called secondary poisoning, by a substance that is not capable of causing these effects at a lower trophic level (e.g. in prey animals) in the food chain. Environmental contamination with well-known, persistent and bioaccumulative toxic pollutants, such as the insecticide DDT and the seed disinfectant methyl mercury, led to the discovery of this kind of effect.

Biomagnifying substances may also be discovered in screening studies and environmental monitoring. An example is brominated flame retardants, many of which are currently increasing both in the environment and in e.g. breast milk (de Wit, 1999; see also Figure 2.2 in Chapter 2).

3 Why is the use of persistent and bioaccumulative organic substances a problem?

Summary

Man-made substances that are persistent and liable to bioaccumulate may sooner or later pose a risk to man and the environment.

It is not possible to completely absolve a substance of possible toxic effects. There is always a residual risk of, for example:

- overlooked and unforeseeable effects
- effects in a more sensitive system than that studied
- additive effects
- synergistic effects
- chronic low-dose effects.

Persistent and bioaccumulative substances that get out into the environment are difficult to remedy. The ”braking distance” is long.

The dispersion of substances with finished products is an increasingly important transport pathway.

Supplementary measures are needed against substances with other, e.g. toxic, properties. (Some of these are dealt with by the Committee in Chapter 5, sections 5.2 and 5.3.)

3.1 Persistence and liability to bioaccumulate increase the risk of exposure

Neither persistence nor liability to bioaccumulate are properties which in themselves necessarily lead to undesirable effects for organisms. But these two properties in substances increase the risk that exposure and uptake will eventually occur, in particular if the substances are very persistent and bioaccumulative. Then unexpected adverse effects may manifest themselves, even of substances which have not been found to be toxic in different tests.

The strategy of proposing measures against substances that are persistent and bioaccumulative is thus based on the judgement that many of these substances will eventually pose a risk to man and the environment, particularly if other unfavourable factors are added, such as toxicity and large production volumes. There are no methods today for screening out substances that will pose a long-term risk, so we regard the entire group as if it can give rise to future risks of which we are not aware today.

There are numerous examples of exposure situations that could not have been predicted. Today’s increase in the concentrations of brominated flame retardants in human beings and other organisms is a topical example (de Wit, 1999). These substances can be detected in human blood plasma from today at the same low levels as PCBs can be detected in plasma from the 1940s. The concentration of PCBs in blood plasma from today, however, is ten times higher than in plasma from the 1940s (Hardell, 2000).

Experience from the use of persistent and bioaccumulative substances (PB substances) such as DDT and PCB should be taken to heart. This experience shows that it can take many decades from when a substance begins to be used until it has been identified as a problem. In the meantime the substance may have been transported long distances and to environments where it was not at all intended to be. While risk reduction measures, such as phasing out the substances from use, lead to reduced emissions, it may take a very long time, perhaps several generations, for contaminated environments to recover and for the risk of further damage to be eliminated.

Many PB substances have serious effects on living organisms, including human beings (see e.g. the Swedish EPA, 1998). It is fully justified to assume that other PB substances also have as yet unknown harmful effects. Tyle and Nimelä (1998) proposed that persistent organic pollutants (POPs) should be screened out solely on the basis of estimated persistence, volatility and bioaccumulation potential, while data on toxicity should not be needed since substances with high fat solubility would be screened out as toxic in calculation models anyway. The precautionary principle also dictates that measures should be taken against PB substances, even in cases where toxicity has not been demonstrated conclusively or is not known.

3.2 It is difficult to fully elucidate toxicity

Knowledge is normally required concerning the toxicity of a substance in order to assess the risk of harmful effects. But obtaining such knowledge poses a problem, due to limitations in the existing testing systems, plus the fact that toxicity data are lacking for a very large number of substances. Moreover, it is not possible to completely absolve a substance from possible toxic effects. There is always a residual risk of e.g.:

- overlooked and unforeseeable effects
- effects in a more sensitive system than that studied
- additive effects
- synergistic effects
- chronic low-dose effects

Thus, the accumulation in the environment of countless persistent and bioaccumulative substances could conceivably give rise to an abundance of undesirable effects of an unpredictable nature. Man and the environment would be affected in a ”diffuse” manner, where the mechanisms behind the effects would presumably be too complex for one or two substances to be singled out as the only or even the principal causes.

3.3 What do we protect and what do we fail to protect by measures against PB substances in products and production processes?

The increasingly borderless trade in goods constitutes today an increasingly dominant transport pathway for substances contained in products. These substances may be released in conjunction with the production of a given product, or they may be emitted from the product during its storage, distribution and use, and when the product enters the waste stream. A central question in this context is what protection is provided and what is missed when measures are taken against substances in production processes and in finished products solely on the basis of their persistence and liability to bioaccumulate.

The important, positive effect is that the risk of unpleasant future surprises due to the release of persistent and bioaccumulative substances from products and production processes is eliminated. Moreover, it is not necessary to await the results of the exhaustive, costly and time-consuming risk assessment processes that are required today before regulatory authorities can even propose restrictions on existing substances.

The environmental objective of a non-toxic environment is, however, not achieved merely by phasing out man-made organic substances whose persistence and liability to bioaccumulate exceed a given level. Many substances with lower persistence and liability to bioaccumulate may also pose a problem. Other man-made substances that do not fall under the persistence and bioaccumulation criteria may also give rise to undesirable effects and may therefore need to be regulated for other reasons. An example is substances that are carcinogenic, mutagenic, toxic for reproduction and endocrine-disruptive. These substances are dealt with by the Committee in section 5.2 and in Chapter 5. Man-made substances can also give rise to other toxic effects (see section 2.2.3 in Chapter 2).

4 Provisions and work with criteria for persistent and bioaccumulative substances in other fora

This section briefly describes some of the positions taken by some international organizations, as well as some national authorities inside and outside Sweden, with regard to criteria for persistent and bioaccumulative substances. Both general chemicals and pesticides are touched upon. The scope of the account is limited to the EU, the UN, the OECD and the USA and Japan. The criteria used by the Swedish National Chemicals Inspectorate for persistent and bioaccumulative substances in the Observation List and in pesticide assessment are also dealt with.

4.1 The European Union (EU)

4.1.1 EU rules for classification and labelling of environmentally hazardous substances

Summary

In the EU's provisions for classification and labelling, substances are classified as dangerous for the environment if they:

- are not readily degradable, and
- have a log $K_{ow} \geq 3.0$ (unless it can be shown that $BCF \leq 100$), and
- have a water solubility lower than 1 mg/l.

The EU's provisions for classification and labelling (in the EC's dangerous substances directive, 67/548/EEC, see section 6.3 in Chapter 6) allow for the labelling of substances as dangerous for the environment solely on the grounds of their being persistent and bioaccumulative. The provisions are implemented by the National Chemicals Inspectorate in its Regulations on the Classification and Labelling of Chemical Products (KIFS 1994:12). Toxic substances that are not readily degradable shall be classified as dangerous for the environment.[8] Substances of unknown toxicity, or for which toxicity has not been able to be demonstrated, can be classified as dangerous for the environment if they are not readily degradable and have a log $K_{ow} \geq 3.0$ (unless it can be shown that $BCF \leq 100$) and furthermore have a water solubility lower than 1 mg/l.[9]

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[8] The risk phrases R 52 ”Harmful to aquatic organisms” and R 53 ”May cause long-term adverse effects in the aquatic environment”

[9] The risk phrase R 53 ”May cause long-term adverse effects in the aquatic environment”

4.1.2 EU rules for examination of pesticides

In the EU, pesticides are subdivided into plant protection products and biocidal products (see Chapter 6).

Summary

The EC’s directive on plant protection products gives as undesirable properties:

- that the active substance or residues thereof, during tests in the field, persist in soil for more than one year, or, during laboratory tests, form non-extractable residues in amounts exceeding 70% of the initial dose after 100 days with a mineralization rate of less than 5% in 100 days,
- that, where there is a possibility of birds and other non-target terrestrial vertebrates being exposed, the bioconcentration factor (BCF, related to fat tissue) for the active substance is greater than 1,
- that, where there is a possibility of aquatic organisms being exposed, the maximum BCF for the active substance exceeds

⇒ 1 000 for plant protection products containing active substances which are readily biodegradable, or

⇒ 100 for those which are not readily biodegradable.

The EC’s directive on biocidal products gives as undesirable properties of an active substance or substance of concern that it:

- during tests in the field, persists in soil for more than one year, or during laboratory tests, forms non-extractable residues in amounts exceeding 70% of the initial dose after 100 days with a mineralization rate of less than 5% in 100 days,
- has a bioconcentration factor (BCF) related to fat tissues in non-target vertebrates that is above 1,
- has a bioconcentration factor (BCF) which is greater than

⇒ 1 000 for substances which are readily biodegradable, or

⇒ 100 for those which are not readily biodegradable.

4.1.2.1 Plant Protection Products Directive

Plant protection products are dealt with in Directive 91/414/EEC[10] (see also section 6.7 in Chapter 6). The directive is currently being reviewed. For plant protection products previously registered in the EU, a complete data set and dossier is required prior to the end of 2003 for continued use to be allowed. This requirements will presumably not be met for more than 200 substances, which means that the rest will be banned after that time (Törnqvist, 1999). However, the Member States will probably be given an opportunity to phase out these substances over a longer period, after 2003.

Council Directive 97/57/EC establishing Annex VI to Directive 91/414/EEC contains principles for assessing dossiers on plant protection products. When it comes to effects on the environment and on non-target organisms, the directive prescribes that no authorization shall be granted for a plant protection product:

> ”if the active substance and, where they are of significance from the toxicological, ecotoxicological or environmental point of view, metabolites and breakdown or reaction products, after use of the plant protection product under the proposed conditions of use:
>
> – during tests in the field, persist in soil for more than one year (i.e. DT90 > 1 year and DT50 > 3 months), or
>
> – during laboratory tests, form non-extractable residues in amounts exceeding 70% of the initial dose after 100 days with a mineralization rate of less than 5% in 100 days, unless it is scientifically demonstrated that under field conditions there is no accumulation in soil at such levels that unacceptable residues in succeeding crops occur ...”
>
> ”where there is a possibility of birds and other non-target terrestrial vertebrates being exposed ... if the bioconcentration factor (BCF, related to fat tissue) is greater than 1, unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable effects occur – directly or indirectly – after use of the plant protection product according to the proposed conditions of use.”
>
> ”where there is a possibility of aquatic organisms being exposed ... if the maximum bioconcentration factor (BCF) is greater than 1 000 for plant protection products containing active substances which are readily biodegradable or greater than 100 for those which are not readily biodegradable, unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact on the viability of exposed species (predators) occurs – directly or indirectly – after use of the plant protection product according to the proposed conditions of use.”

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[10] also called the ”Plant Protection Products Directive”, PPP.

4.1.2.2 Biocidal Products Directive

Biocidal products are dealt with in the Biocidal Products Directive, 98/8/EC[11] (see also section 6.7 in Chapter 6). This directive is also under review, which should be finished in May 2000. After that, concerned companies have 1.5 years to notify support for products and submit dossiers (Persson, 1999).

The implementation of the Biocidal Products Directive in May 2000 will lead to a harmonized legislation concerning the placing of biocidal products on the market in the Member States of the EU. The directive presumes the mutual approval of biocidal products, i.e. if a biocidal product is approved in one Member State, it shall also be approved in the other Member States. The authorities responsible for the approval of biocidal products in the Nordic countries have suspected that degradation, mobility, uptake and effects of biocidal products are worse under Nordic conditions than in southern and central Europe. The Nordic Council of Ministers has funded an investigation on the fate and effects of chemicals in the Nordic environment (Braunschweiler & Koivisto, 2000).

The Technical Guidance Document for risk assessment (TGD, 1996) is planned to be used for the EU’s risk assessment of biocidal products. This TGD is currently being used as a basis for risk assessment of new and existing substances, as well as by EUSES’s exposure calculation model. The Nordic countries do not represent a climatically or geographically uniform region. But what they do have in common is a low mean temperature compared with the temperature assumed in EUSES, and the Nordic countries represent a worst case situation for the occurrence and dispersion of chemicals, mainly due to slow degradation and impaired adsorption, compared with the conditions assumed in the EUSES model. Braunschweiler & Koivisto (2000) conclude, however, that Nordic environmental conditions do not have a clear-cut effect on the uptake and toxicity of chemicals.

Annex VI to the directive contains common principles for the evaluation of dossiers for biocidal products. As regards effects on the environment and on non-target organisms, the directive prescribes that a biocidal product shall not be authorized:

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[11] Biocidal Products Directive, BPD.

> *”where unacceptable contamination of soil is likely to occur ... [due to the fact that] the active substance or substance of concern contained in it, after use of the biocidal product:*
>
> *- during tests in the field, persists in soil for more than one year, or,*
> *- during laboratory tests, forms non-extractable residues in amounts exceeding 70% of the initial dose after 100 days with a mineralization rate of less than 5% in 100 days,*

or for an active substance or substance of concern:

> *”if the bioconcentration factor (BCF) related to fat tissues in non-target vertebrates is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable effects occur, either directly or indirectly, after use of the product according to the proposed conditions of use.”*
>
> *”if the bioconcentration factor (BCF) is greater than 1 000 for substances which are readily biodegradable or greater than 100 for those which are not readily biodegradable unless it is clearly established in the risk assessment that under field conditions no unacceptable impact occurs ... after use of the biocidal product according to the proposed conditions of use.”*

4.2 United Nations (UN)

4.2.1 The UN’s work on a POPs convention

Summary

The UN’s work on a convention on persistent organic pollutants (POPs) stipulates as undesirable properties of a substance with respect to persistence and bioaccumulation in order for it to be nominated as such within the framework of the convention:

- that its half-life exceeds
  - ⇒ [2][6] months in water, or
  - ⇒ 6 months in soil or in sediment, or
  - ⇒ 2 days in air for air-transported substances, and
- that its bioaccumulation or bioconcentration factor exceeds
  - ⇒ 5 000, or, in the absence of these data, that its octanol-water partition coefficient (log Kow) exceeds [4][5].

A working group within the United Nations Environment Programme (UNEP)[12] is currently developing criteria for the nomination of additional persistent organic pollutants for consideration for future, international restrictions, in addition to the substances already being

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[12] United National Environment Programme (http://www.chem.unep.ch/pops/)

discussed today (see section 8.2.2 in Chapter 8). The criteria are currently under discussion and values for persistence and bioaccumulation have been agreed upon, with the exception of a persistence criterion for water where two limits for half-life are still under discussion, and a criterion for bioaccumulation where two limits for the octanol-water partition coefficient (log K_{ow}) are still under discussion (the alternatives are given in square brackets below, as well as in the box; UNEP 2000). In order for the substances to be regarded as possible POPs, these criteria shall be fulfilled together with additional criteria for e.g. the substances' long-range transport potential and undesirable effects in the environment.

The criteria with respect to persistence that have been proposed entail that the half-life of the substances in water shall exceed [2][6] months, and that their half-lives in soil and sediments shall exceed six months. The criteria with respect to bioaccumulation that have been proposed entail that the bioconcentration or bioaccumulation factor shall exceed 5 000, or that log K_{ow} shall be greater than [4][5].

4.2.2 UN Economic Commission for Europe's Convention on Long-Range Transboundary Air Pollution (CLRTAP) – protocol on persistent organic pollutants

Summary

The UN/ECE Convention on Long-Range Transboundary Air Pollution stipulates as undesirable properties of a substance with regard to persistence and bioaccumulation in order for it to be nominated within the framework of the convention:

- that its half-life exceeds
  - ⇒ 2 days in air, and
  - ⇒ 2 months in water, or
  - ⇒ 6 months in soil or in sediment, and
- that its bioaccumulation or bioconcentration factor exceeds
  - ⇒ 5 000, or
  - ⇒ log K_{ow} exceeds 5.

The UN Economic Commission for Europe's Convention on Long-Range Transboundary Air Pollution (CLTRAP) (see section 8.2.3 in Chapter 8) has stipulated in its Protocol on Persistent Organic Pollutants[13] that in order for substances beyond those covered by the convention today to be brought up for discussion within the framework of the convention, they shall have a vapour pressure of less than 1 000 Pa and a half-life in the atmosphere exceeding 48 hours, or data shall be available showing that the substances are found in remote regions, far from industrial activities. Furthermore, the substances shall be toxic and therefore harmful for health and the environment, persistent in water (t½ > 2 months) or in the soil or in sediments (t½ > 6 months), and bioaccumulative (BCF > 5 000, or log K_{ow} > 6). Substances can be deemed to be of interest for the convention even if not all of these criteria are satisfied.

4.3 OECD

Summary

In the OECD's proposal for harmonized provisions for classification and labelling, substances are proposed to be classified as environmentally hazardous if they:

- are not rapidly degradable, and
- have a log $K_{ow} \geq 4.0$ (unless it can be shown that $BCF \leq 500$), and
- have a water solubility lower than 1 mg/l.

The OECD[14] (see further section 8.3 in Chapter 8) has proposed a harmonized classification and labelling system for health and environmental hazards of chemical substances (OECD, 1998). According to the proposed system, substances can be classified as hazardous for the aquatic environment solely on the basis of their being persistent and bioaccumulative, if they are also poorly soluble (water solubility < 1 mg/ml). The proposed classification limits encompass substances that do not degrade rapidly, as shown by the results of ready biodegradation tests or other equivalent studies, and which have a bioconcentration factor (BCF) greater than 500, or have a log K_{ow} value greater than 4 (in cases where a BCF value is lacking).

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[13] POPs Protocol, http://www.unece.org/leginstr/cvenvi.htm

[14] Organisation for Economic Co-operation and Development; http://www.oecd.org/

4.4 Oslo and Paris Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR)

Summary

In OSPAR-DYNAMEC's work to develop selection criteria for hazardous substances, five different combinations of persistence, liability to bioaccumulate and toxicity are discussed, with different weightings.

The criteria which select substances with the highest persistence and liability to bioaccumulate include substances which:

- are not inherently biodegradable
- have a bioconcentration factor greater than 5 000

The criteria that select substances with the lowest persistence and liability to bioaccumulate include substances which:

- are not readily biodegradable
- have a bioconcentration factor greater than 500.

Within the framework of the Oslo and Paris Convention (OSPAR; see section 8.4.3 in Chapter 8), a working group (DYNAMEC)[15] has been developing criteria for selecting and identifying the substances to be prioritized in OSPAR's work. DYNAMEC's selection criteria include persistence (P), liability to bioaccumulate (B) and toxicity (T). However, even substances that do not satisfy all the criteria defined for these three properties may be selected, to the extent it is nevertheless deemed urgent to take measures against the substances (OSPAR, 2000). The criteria currently being discussed consist of five different combinations of P, B and T, weighted in different ways.

As far as the persistence criteria are concerned, the possibility of using the half-times of the substances as a point of departure has been discussed thoroughly. Since half-times for one and the same substance can vary widely with environmental conditions, such as temperature, the selection will however probably ultimately be made on the basis of data from the Ready Biodegradability test and Inherent Biodegradability test, or the equivalent (OSPAR, 2000; see also section 1.2.3). Another

[15] OSPAR Ad Hoc Working Group on the Development of a Dynamic Selection and Prioritisation Mechanism for Hazardous Substances (DYNAMEC); http://www.ospar.org/

argument for this is that most data on biodegradability available today are based on this kind of test.

The criteria for liability to bioaccumulate are based on bioconcentration factors (BCFs) for aquatic organisms. In cases where no data are available on the BCFs of substances, log K_{ow} values or calculated (QSAR) BCFs can be used. Measured BCFs always take precedence, however.

The five combinations of criteria now being discussed by OSPAR-DYNAMEC, which select a small number of substances with high persistence and liability to bioaccumulate, define these substances as non-inherently biodegradable, and entail that their BCF exceeds 5 000. The criteria combination which selects a larger number of substances, with lower persistence and liability to bioaccumulate, define these substances as non-readily biodegradable, and entail that their BCF exceeds 500. The latter criterion agrees with the one proposed for environmental hazard classification (on the basis of P and B) within the framework of the harmonization proposed by the OECD.

A decision is expected to be made on which substances are to be prioritized in OSPAR's work at the OSPAR commission's meeting in June 2000.

4.5 The US EPA's policy for persistent and bioaccumulative substances

Summary

The US EPA proposes emission limits for substances which have

- a half-life in the aquatic environment greater than 2 months, and
- BCF ≥ 1 000,

and believes that new substances should not have

- a half-life in the aquatic environment greater than 6 months
- BCF ≥ 5 000.

The US EPA[16] is defining criteria for persistent and bioaccumulative substances in its work to improve the regulatory situation in conjunction

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[16] United States Environmental Protection Agency; http://www.epa.gov/

with e.g. notification of new substances (EPA, 1999). In the proposed system, the criteria for substances to be subject to emission controls are that their calculated half-life in the aquatic environment (Boethling et al., 1994) exceeds 2 months and that their bioaccumulation, for example measured as BCF for fish, is greater than 1 000. The intention is to prevent substances from being released on the market at all if their half-life in the aquatic environment exceeds 6 months and their bioaccumulation is greater than 5 000. Data on toxicity shall be ascertained as needed.

4.6 Japan

The Japanese classification system for chemical substances entails that substances with low biodegradability, high bioaccumulation and considerable toxicity may not be produced, imported or used. Today nine such substances are identified, and they are identical to the substances covered by the UN's POPs convention (see section 8.2.2 in Chapter 8), with the exception of mirex and toxaphene, which have never been used in Japan, and dioxins and furans, which are always inadvertently formed and therefore not covered by requirements on classification.

Substances with limited biodegradability and considerable toxicity but with low bioaccumulation require notification of planned and previous use as well as labelling.

There are no defined classification criteria, but substances are judged by experience to be bioaccumulative if they have a BCF > 1 000. Readily biodegradable substances are considered safe and do not need to be further tested. Further studies are required for non-readily biodegradable substances. Most substances that are banned from use have BCF > 10 000 and log $K_{ow} > 5$.

4.7 Sweden

4.7.1 National Chemicals Inspectorate's Observation List

Summary

On the National Chemicals Inspectorate's Observation List, substances are listed as dangerous for the environment if:

- they are not readily degradable
- their BCF > 1 000, or, in lieu of a BCF, log $K_{ow} > 4$.

The National Chemicals Inspectorate's Observation List (National Chemicals Inspectorate, 2000) is a list of examples of classified substances requiring particular attention (see Annex 9). The substances are chosen on the basis of certain selection criteria for ”danger to human health” and ”danger for the environment”. Those substances that satisfy any of the criteria shall be risk-assessed by the prospective user in order to limit the risks of use, for example by handling precautions, or by abandoning the use of the substance in favour of another, less dangerous substance that has an equivalent function.

Substances that satisfy at least two of the criteria for danger for the environment regarding persistence, bioaccumulation and toxicity are regarded as being dangerous for the environment. The criterion given for persistence is low degradability in biodegradation tests, for example the OECD's guidelines for testing of Ready Degradability. The criterion given for bioaccumulation (high potential for bioaccumulation) is BCF > 1 000 or, where an experimental BCF value is lacking, log $K_{ow} > 4$.

4.7.2 The National Chemicals Inspectorate's preliminary assessment of pesticides

Summary

The National Chemicals Inspectorate's guidelines for preliminary assessment of pesticides state the active substances and their degradation products are undesirable if they, in addition to satisfying criteria for exposure and mobility in soil:

- have a half-life longer than

⇒ 7 weeks at 25° C,
⇒ 10 weeks 20 °C,
⇒ 14 weeks at 15 °C, or
⇒ 20 weeks at 10 °C, and

- have a BCF > 500,

and as unacceptable if they, besides satisfying criteria for mobility in soil:

- have a half-life longer than

⇒ 18 weeks at 25 °C,
⇒ 26 weeks at 20 °C,
⇒ 37 weeks at 15 °C, or
⇒ 52 weeks at 10 °C, and

- have a BCF > 2 000.

In the National Chemicals Inspectorate's guidelines for preliminary assessment of pesticides (Andersson, et al., 1992), the potential danger to the environment of pesticides is assessed on the basis of their persistence and bioaccumulation, as well as mobility in soil. The assessment includes both the parent substance and any toxic degradation products.

Persistence is assessed from the standpoint of both abiotic degradation (photolysis and hydrolysis) and biodegradability in plants, water and soil. Temperature is also taken into account, and the criteria are given as half-lives at different temperatures.

Potential to bioaccumulate is determined on the basis of BCFs from standardized tests in an aquatic environment, usually with fish. An experimentally determined BCF is not required for substances with log $K_{ow} < 3$.

The guidelines also designate pesticides as undesirable if they have half-lives in excess of 7 weeks at 25ºC, 10 weeks at 20ºC, 14 weeks at 15ºC, or 20 weeks at 10ºC, and BCF > 500. An assessment of potential exposure is required for such pesticides, and their mobility in soil must be taken into account in deciding whether they are to be allowed or not.

The guidelines designate pesticides as unacceptable if they have half-lives in excess of 18 weeks at 25ºC, 26 weeks at 20ºC, 37 weeks at 15ºC, or 52 weeks at 10ºC, and BCF > 2 000. No expert assessment is required for such pesticides, but their mobility in soil is taken into account. Pesticides that satisfy these criteria are not normally allowed, but there is some possibility that exceptions can be made if deemed justified.

Bibliography

Andersson, L., Gabring, S., Hammar, J. & Melsäter, B. (1992) Principles for identifying unacceptable pesticides. KEMI Report No 4/92.

Bergström, L. & Stenström, J. (1998) Environmental fate of chemicals in soil. Ambio, 27:16-23

Beyer, A., Mackay, M., Matties, M., Wania, F. & Webster, E. (2000) Assessing long-range transport potential of persistent organic pollutants. Environmental Science & Technology, 34:699-703

Boethling, R.S., Howard, P.H., Meylan, W., Stiteler, W., Beauman, J., Tirado, N. (1994). Group contribution method for predicting probability and rate of aerobic biodegradation. Environmental Science & Technology 28: 459-465.

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.

de Wit, C.A. (1999) Brominated flame retardants in the environment – an overview. Organohalogen Compounds, 40:329-332.

EPA (1999) Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. Federal Register: November 4, 1999 (Volume 64, Number 213). http://www.epa.gov/oppt/newchems/pbtpolcy.htm

Gouin, T., Mackay, D. Webster, E. & Wania, F. (2000) Screening chemicals for persistence. Environmental Science & Technology, 34:881-884

Hardell, L. (2000) Vilka är hälsoriskerna med svårnedbrytbara organiska ämnen? Lecture at the Swedish Society for Nature

Conservation’s Environmental Objectives seminar No 5: Kemikalier i samhället och naturen. Stockholm, 13 January.

Ikeda, M. (1999) Japanese experiences on POPs under the Law of chemicals safety evaluation and control in relation to biodegradation and biocontrol issues. Summary report from round-table discussion on criteria for phasing out persistent and bioaccumulating organic chemicals, Steningevik, Sweden, 10-11 December 1999, verbal communication. (See Annex 7).

National Chemicals Inspectorate’s (2000) Observation List. Examples of substances requiring particular attention, 2nd revised edition. http://www.kemi.se

Loonen, H., Lindgren, F., Hansen, B., Karcher, W., Niemelä, J., Hiromatsu, K., Takatsuki, M., Peijnenburg, W., Rorije, E. & Struijs, J. (1999) Prediction of biodegradability from chemical structure: Modelling of ready biodagradation test data. *Environmental Toxicology and Chemistry* 18:1763-1768.

Swedish Environmental Protection Agency (1998) Persistent Organic Pollutants. A Swedish View of an International Problem, Monitor 16. Swedish EPA.

OECD (1992) Guidelines for the testing of chemicals, OECD, Paris. (Se även http://www.oecd.org/ehs/test/degrad.htm)

OECD (1998) Harmonized integrated hazard classification system for human health and environmental effects of chemical substances. As endorsed by the 28th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals in November 1998. http://www.oecd.org//ehs/Class/hclfinaw.doc

OSPAR (2000) Briefing document on the work of DYNAMEC and the DYNAMEC mechanism for the selection and prioritisation of hazardous substances. OSPAR CC 00/2/1, 15 May 2000.

Pedersen, F., Helweg, C., Madsen, T., Clausen, H. & Tyle, H. (1999) OECD harmonisation of classification criteria, 3rd draft.

Persson, M. (1999) Pesticides – biocidal products. Verbal communication at the National Chemical Inspectorate’s reference group meeting for EU questions. Solna, 25 November.

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.

Torstensson, L. & Stenström, J. (2000) Influence of soil and climatic factors on the kinetics of transformations of herbicides in soil. I: M. Munawar and M. Luotola (red.): The Contaminants in the Nordic Ecosystem: Dynamics, Processes & Fate. Ecovision World Monograph Series. pp. 151-162.

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.

Tyle, H. och Niemelä, J. (1998) Use of QSARs for selection of POPs. Danish EPA, draft of November 1998.

Törnqvist, L. (1999) Pesticides – plant protection products. Verbal communication at the National Chemical Inspectorate’s reference group meeting for EU questions. Solna, 25 November.

UNEP (2000) Report of the intergovernmental negotiating committee for an internationally legally binding instrument for implementing international action on certain persistent organic pollutants on the work of its fourth session. Bonn, 20-25 March 2000, UNEP/POPS/INC.4/5.

van Leeuwen, C.J. & Hermens, J.L.M. (1995) Risk assessment of chemicals: an introduction. Kluwer Academic Publishers, Dordrecht, Nederländerna.

Present-day use of carcinogenic, mutagenic and reproduction-toxic substances in Sweden

The occurrence of substances that are carcinogenic, mutagenic or reproduction-toxic (CMR substances) in chemical products manufactured in or imported to Sweden today is described in this annex.

The total manufacture and import of CMR substances (classified in categories 1 and 2) in chemical products was approximately 27 000 000 tonnes, according to the National Chemicals Inspectorate’s products register. This is equivalent to around 35 percent of the total manufacture and import of chemical products in Sweden today. To this must be added the volumes that enter Sweden via imports in other types of finished products. These volumes are not reported in the products register.

Substances classified as carcinogens dominate the CMR group. It should be mentioned in this context that tests and assessments of carcinogenicity have been performed for a longer time than assessments of mutagenicity or reproduction toxicity. Sometimes carcinogenic substances are also classified as mutagenic, and occasionally also as toxic for reproduction. The group of substances that is classified as toxic for reproduction but not carcinogenic accounts for more than 800,000 tonnes, where carbon monoxide, which is contained in manufactured and imported fuels (e.g. town gas), is completely dominant. If all carbon monoxide is disregarded, the manufactured and imported quantity in this group is 772 tonnes.

Of the total quantity of CMR-classified substances, 69 percent consists of petroleum (crude oil), which is the raw material for fuels (petrol, diesel fuel, heating oils, etc.) and, to a lesser extent, asphalt and lubricants. An addition 26 percent consists of extracts and distillates of petroleum. If we consider the group of substances that is not petroleum or extracts and distillates etc. of petroleum, it constitutes only 5 percent of the total volume (see Table 1).

With regard to the function of the CMR substances, synthesis intermediates dominate, owing to the large quantity of petroleum (Table 2). Other synthesis intermediates, e.g. plastic raw materials and feedstocks in the basic chemicals industry, account for just under 2 percent of the total volume. Other fuels and fuel oils comprise 29 percent, and other types of CMR substances 5 percent. Substances that are not direct refinery products of petroleum and that are used in other functions than as synthesis intermediates and fuels amount to 10 000 tonnes, or 0.037 percent of the total quantity of CMR substances in the products register. This may not sound like much, but compared with other substances in similar functions, 10 000 tonnes is a considerable quantity. Examples of areas of application for this group are binders, electrolytes, pigments and wood preservatives. Depending on area of application, the substances can be assumed to be present to a varying degree in products that reach private consumers.

Table 1. Manufacture and import of CMR substances in Sweden in 1998, broken down by type of substances according to the National Chemicals Inspectorate’s products register.

Type of substance	Quantity (tonnes)	Percentage of total quantity
Petroleum	18 900 000	69
Extracts, distillates etc. of petroleum	7 110 000	26
Other substances	1 450 000	5

Table 2. Manufacture and import of CMR substances in Sweden in 1998, broken down by functions according to the National Chemicals Inspectorate’s products register.

Function	Quantity (tonnes)	Percentage of total quantity
Synthesis intermediates (petroleum)	17 500 000	64
Synthesis intermediates (others)	474 000	2
Fuels, fuel oils	8 010 000	29
Other substances (asphalt, lubricants, paints etc.)	1 410 000	5

A very large percentage of the carcinogenic products are thus petroleum and petroleum products. Petroleum consists of a blend of different substances, which can vary depending on where the oil was extracted. Carcinogenicity is largely associated with the content of aromatic hydrocarbons. The rules for labelling of chemical products allow for exemptions if it can be shown that the concentrations of certain components, e.g. benzene, benz(a)pyrene or aromatic substances, are low.

Endocrine-disruptive substances

Contents

1 What are endocrine-disruptive effects?

Chemical substances that damage or disrupt the function of the body’s endocrine (hormone-producing and -secreting) 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 e.g. cancer, reproduction toxicity (reproductive impairment or birth defects), and adverse effects on the immune system and the nervous system, the latter of which can lead to behavioural disturbances.

Thus, ”endocrine effects” and ”endocrine-disruptive” or ”hormone-disruptive” impacts are to be regarded more as mechanisms or modes of action for substances that can cause damage to organisms, populations or ecosystems than as health and environmental effects in themselves.

The organs that produce hormones in mammals include the endocrine glands, which in turn include the gonads (ovaries and testicles), the adrenal glands, the thyroid, the pancreas and neuroendocrine centres in the central nervous system (the hypophysis or pituitary gland and the hypothalamus). A list of examples of hormone-dependent and hormone-controlled controlled organs, cell types and functions in the body could be made very long. Hormonal regulation is one of the organism’s most important means of maintaining physiological equilibrium. Furthermore, reproduction physiology, including foetal development, is largely hormone-controlled.

Well-functioning endocrine systems are thus a prerequisite for maintaining many physiological functions of mammals, other vertebrates and even lower animals. Reproduction, sexual differentiation (e.g. development of internal and external genitalia), foetal development, growth, basal metabolism, immune defences, behaviour etc. can be adversely affected by disturbances in the endocrine systems. Furthermore, many forms of cancer are associated with endocrine imbalances.

An important group of hormones is the steroid hormones, which include the primary sex hormones oestrogen and testosterone. Peptide hormones are another group of active substances in the endocrine system that regulate production of sex hormones. Control of the organism’s levels of steroid hormones is a complex process that includes a finely-tuned interplay between neuroendocrine centres in the central nervous system (the hypothalamus and the pituitary), the gonads (testicles and ovaries) and the organs that are responsible for synthesis of steroids and steroid precursors as well as degradation of steroids. Steroid formation in mammals mainly takes place in the adrenal cortex, the gonads and the placenta.

Oestrogen and anti-oestrogen effects are two of the many types of endocrine-disruptive impacts that can be caused by chemicals. Other sex hormone effects are androgenic and anti-androgenic impact.

The oestrogenic effect of a chemical can be caused by the fact that the substance exhibits ”oestrogen activity” by binding to and activating the receptors that are normally supposed to be regulated by endogenous oestrogen. The body can thereby be subjected to abnormally high oestrogen stimulation. The same effect can be achieved if a chemical increases the availability of endogenous oestrogen by e.g. liberating the hormone from depots in the blood. The metabolism of oestrogen can also be altered by e.g. increased formation of hormonally more potent oestrogen metabolites or reduced transformation of oestrogen to inactive metabolites.

Anti-oestrogen and anti-androgen effects can e.g. be caused by a chemical’s blocking the oestrogen or androgen (e.g. testosterone) from binding to its natural receptor by reducing the number of receptors or by hastening/altering the degradation of the hormone.

Besides substances that can have effects that act on the steroid hormones, there are also substances that affect hormones such as thyroxins and retinoids. In many cases it is the same groups of chemicals that act on all of these hormone systems. Thyroxins are of importance for growth, differentiation and metabolism.

Retinoids, or vitamin A, play a central role in the life processes, from the very earliest cell divisions through the organism’s entire life. In contrast to classical hormones, which are synthesized and released in a regular manner by specific organs or glands in the organism, vitamin A is a substance which is not converted to a hormone until it enters the body. A functioning retinoid system is needed to maintain growth, general health, vision, reproduction and development of tissues and cell types, particularly during the foetal period. The retinoid system interacts with several other hormone systems. Disturbances in the retinoid system can give rise to a multitude of direct or indirect effects.

The fact that chemicals can affect the endocrine systems and cause adverse effects on reproductive organs and other hormone-producing or hormone-dependent organ systems has been known for several decades (e.g. that DDT and PCBs cause reproductive disruptions in birds, seals and other top consumers). In recent years, it has also been discovered that many ordinary chemicals are endocrinologically active. Furthermore, the intensive growth of knowledge within fields such as physiology, endocrinology and, above all, molecular and cellular biology have contributed to a greater understanding of the importance of the endocrine systems.

However, there are large knowledge gaps with regard to which substances have endocrine action, their relative endocrinal potency and the aggregate effect of the total exposure to substances with endocrine action.

It is important to note the difference between individuals as regards sensitivity and possible effects of exposure to endocrinologically active substances during the period as an embryo, foetus and child compared with exposure during adult life. In early developmental stages, even a brief exposure to endocrine-disruptive chemicals at sensitive junctures can give rise to permanent changes. This can become manifest later in life in the form of reproduction problems, deformation, behavioural disturbances or cancer. The background to this sensitivity during foetal development is that the hormonal signal systems during this period have an organizing and differentiating function. This means they have a potential to cause lasting 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 action, which primarily results in transient changes that are reversed when the exposure ceases. More long-lasting and high-level exposure of adults is probably required to cause irreversible damage, such as cancer.

2 Criteria for endocrine-disruptive substances

There are as yet no generally accepted criteria for endocrine-disruptive substances. International organizations such as the IPCS (International Program on Chemical Safety) and the OECD have used the following definitions of the terms ”endocrine disruptors” (in this report usually called ”endocrine-disruptive substances”) and ”potential endocrine disruptors”:

- An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations.
- A potential endocrine disruptor is an exogenous substance or mixture that possesses properties that might be expected to lead to endocrine disruption in an intact organism, or its progeny, or (sub)populations.

The first definition focuses on the need to demonstrate actual adverse effects in an organism, its progeny or the population level at which environmental effects occur. The second definition opens up possibilities to go even further, since it is sufficient to demonstrate properties that might be expected to lead to hormonal disturbance. Both definitions place a great emphasis on studies of effects in living, intact organisms, which means that e.g. effects that have only been found in artificial test systems (cell tests, receptor binding studies and the like) will be accorded little importance.

In order to be able to apply these definitions and eventually develop operational assessment grounds and even formal classification criteria, however, extensive development of old and new testing methods is needed.

In this context, a comparison with the criteria in the dangerous substances directive (67/548/EEC) for carcinogenic, mutagenic and reproduction-toxic properties may serve to illustrate how data on action mechanisms have been used in criteria. Mutations and genetic damage can lead to increased risk of heritable genetic diseases due to damage to the sex cells. The purpose of the criteria for mutagenic properties is to provide guidance in the assessment of a substance’s capacity to cause such heritable defects. If this type of genetic damage occurs in body cells, there is reason to suspect that the substance has carcinogenic properties. The criteria for carcinogenic properties thus provide some possibility for tightening of the cancer classification for so-called genotoxic substances and vice versa, i.e. some possibility for lower classification of substances that lack this property.

The criteria for carcinogenic properties further contain a passage that provides some possibility for a lower classification for substances where a secondary action mechanism exists. Hormonal effects on target organs or physiological regulatory processes are hereby given as a relevant example.

The criteria for reproduction-toxic properties also mention the action mechanism disturbed hormone balance. Here it can contribute to both stricter and more lenient classification with respect to fertility effects, depending on the relevance of the mechanism to man in the individual case.

3 Ongoing work with development of testing methods and programmes for testing

As we have seen, there are as yet no standardized, internationally recognized testing methods for endocrine-disruptive effects. The OECD has had a special project area for endocrine disruptors since 1996. The project includes both coordination of activities between the Member States 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. The chemical industry in Europe, the USA and Japan are working via their organizations on the development of testing methods for fish, birds and reptiles. Sweden is leading a joint Nordic project with funding from the Nordic Council of Ministers where tests of endocrine-disruptive effects on fish are also being developed. The methods being developed by different countries and organizations will serve as a basis for development of testing methods in the OECD.

The methods for testing endocrine-disruptive effects can be divided into different levels. The first level is simple and quick tests of e.g. binding to different receptors. At the next level, it is tested whether the substances can function as hormones in living organisms. Finally, there are tests that extend over more than one generation, where effects on progeny can be studied. A compilation of the testing methods currently being used by the OECD in human toxicology can be found in Appendix 1 to this

Annex, while Appendix 2 contains an equivalent compilation for ecotoxicology.

An Endocrine Disruptor Screening Program was set up by the US EPA in which a large number of substances were to undergo simple tests. However, the receptor binding tests that were to be used turned out to be insufficiently developed to provide the intended information, so the program has been postponed.

4 Lists of substances with suspected endocrine effects

Even though there are no standardized testing methods, and thereby no criteria based on such methods, concern for hormonal effects has led to the publication of lists of substances suspected of being endocrine disruptors by many public agencies and environmental organizations.

The National Chemicals Inspectorate published a report on hormonal effects in 1997, and the Swedish EPA made a knowledge compilation in the field in 1998 (National Chemicals Inspectorate, 1997; and Olsson et al., 1998). Both reports contain surveys of substances discussed in conjunction with hormonal effects. The substances of interest in this context include some pesticides, many of which are banned (e.g. DDT and lindane), as well as substances that arise unintentionally, such as polychlorinated dibenzodioxins and dibenzofurans, and industrial chemicals, some of which are banned (e.g. PCBs). Most of the substances that are still in use in Sweden have long been subject to risk reduction efforts due to their health or environmental hazards. A review of these groups of substances is found in Appendix 3.

The Committee has performed a cursory examination of lists of endocrine-disruptive substances prepared by a number of EU states, Japan, the USA, OSPAR, the WWF and Greenpeace. If these lists are compared with use statistics for the substances from the Swedish products register, the same picture emerges as before, namely that the substances that are listed and simultaneously occur in chemical products in Sweden are for the most part substances that are already subject to restrictions. Some additional substances can enter the country in other types of products than chemical products, but we cannot quantify this flow at present.

5 The European Commission's strategy for endocrine disruptors

The European Parliament has urged the Commission to take action concerning endocrine-disruptive substances. The Commission was further urged at the Environment Council meeting in June 1999 to prepare a policy document as soon as possible 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-term (1–2 years), medium-term (2–4 years) and long-term (more than 4 years) actions.

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 reproductive 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.

Bibliography

Government Bills

En god livsmiljö. Gov. Bill 1990/91:90. (Summary in English: A living environment.)

Svenska miljömål. Gov. Bill 1997/98:145. (Summary in English: Swedish Environmental Quality Objectives.)

Reports of the Government Commissions

PVC – en plan för att undvika miljöpåverkan. The Ecocycle Commission's account of a Government commission on PVC. SOU 1994:104 (in Swedish only)

Other sources

National Chemicals Inspectorate, 1995. Tillsatser i plast. KemI Report 15/95.

National Chemicals Inspectorate, 1996. Additives in PVC. KemI Report 9/96.

National Chemicals Inspectorate, 1997. Hormonella effekter av kemikalier – en sammanfattning av kunskapsläget. KemI Report 1/97.

KOM(1999)706 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.

Olsson, P-E., Borg, B., Brunström, B., Håkansson, H. and Klasson-Wehler, E., 1998. Endocrine disrupting substances – Impairment of reproduction and development. Swedish EPA Report 4859.

Appendix 1

Description of the status of the OECD’s work with old and new testing methods for endocrine-disruptive chemicals in the field of human toxicology.

Introduction

The OECD’s test guidelines programme includes a number of testing methods that are already being used today to obtain information on the reproduction toxicity and endocrine-disruptive properties of chemicals. Development of both old and new testing methods is also under way. This Appendix contains a compilation of human toxicology testing methods that can potentially provide information on the effects of endocrine-disruptive chemicals (with the exception of cancer tests and tests of chronic toxicity).

Existing testing methods

Existing testing methods are constantly being revised within the OECD. In this work, the two-generation reproduction test has just been updated, which has resulted in the introduction of some parameters that will make it easier to identify endocrine-disruptive chemicals. This guideline for testing methods will further be revised once again immediately with a focus on effects specific to endocrine-disruptive chemicals.

Teratogenicity studies may also be of interest for identification of endocrine disruptors. However, the dosing period is relatively short and the assessment of the foetuses is so simple that the test can in reality only provide information on certain deformities.

The compilation also contains some comments on the OECD’s ”Reproduction toxicity screening tests”, which are short, less sensitive screening studies that have not been used particularly often so far, but which are expected to be used more in the future.

Development of new testing methods

The development of new testing methods for endocrine-disrupting chemicals is being conducted within the OECD in a working group called EDTA (Endocrine Disrupters Testing and Assessment). International validation of two new short-term *in vivo* testing methods has been initiated there. In one method, the uterus of young exposed females is weighed, which can identify (anti-)oestrogens. In the other, prostates of exposed castrated males are weighed, which can identify (anti-)androgens. Furthermore, an enhanced 28-day study already in use is being prevalidated, under the auspices of industry.

A new testing method for developmental neurotoxicity is in preparation and will probably be adopted within a year or two. It has not been developed with a view towards endocrine-disruptive chemicals, but will probably enhance the possibilities of finding ”subtle” effects of endocrine disruptors on development and behaviour.

Following is a very brief description of the aforementioned tests. The tests are intended to be performed on rats (414 also on rabbits and 407 also on mice).

Two-generation test

OECD Test Guideline 416 – Two-Generation Reproduction Toxicity Study

The purpose of this study is to provide information on the harmful effects of chemicals on fertility, reproduction, parturition, lactation, growth, development and sexual maturity of offspring. The test was revised in 1999 and now includes:

- Analysis of number, morphology and motility of sperm in 20 animals per group
- Evaluation of the oestrous cycle
- Enhanced histopathological examination of gonads in several generations
- The uterus shall be examined with regard to implantations
- Macroscopic examination of one pup per sex per litter from all litters
- Weight of gonads, adrenal glands, pituitary, thyroid, thymus, spleen, liver, kidney and brain
- Determination of timing of sexual maturation and sex ratio, and possibly anogenital distance
- Functional examinations of the offspring are recommended (sensory

function, reflex ontogeny and motor activity).

- A new revision has been commenced. Potential additions that have been mentioned are:
  - Hormone analyses
  - Studies of immunological functions
  - Studies of functions in the central nervous system

Test of foetal damage and simple reproduction test

OECD Test Guideline 414 – Prenatal Developmental Toxicity Study (previously called Teratogenicity Study)

This test was recently revised and renamed. It is a teratogenicity study. No functional studies of offspring can be carried out. Dosing (of at least 20 females per dose group) is started not later than day 5 post-mating, and is concluded the day prior to the expected day of delivery, when the mothers are killed. The uterus is dissected, weighed and examined in detail macroscopically. The foetuses are removed by caesarean section, weighed, sexed, and examined macroscopically for variations and malformations. The gonads shall be examined extra carefully.

OECD Test Guideline 421–422 – Reproduction/Developmental Toxicity Screening Test and Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test:

The biggest differences between these two testing methods and TG 416 is that the number of animals is halved and the dosing period is greatly limited (offspring and mothers are killed on day 4 post-partum) compared with the two-generation study. Since a negative result cannot absolve a chemical, and a positive result is not certain enough as a basis for e.g. a risk assessment, industry itself has chosen not to use these studies. A possible development, however, is that the American initiative to test several thousand high-production-volume chemicals by not later than 2004 will lead to the use of this test.

The US EPA has even proposed that new (notified) chemicals that satisfy certain criteria for persistence and bioaccumulation potential must be tested with one of these tests.

The same dosing schedule is used for both tests (TG 421 and 422). The males are dosed for four weeks, with mating after two weeks of dosing. Fertility is therefore not a good indicator of testicular toxicity, and a detailed histopathological examination of the testicle is therefore required. Exposure of females starts two weeks prior to mating, and continues until they are killed 4 days post-partum. The gonads of the adult animals are weighed and examined macroscopically and histopathologically. Offspring are counted, sexed, weighed and examined macroscopically for malformations.

TG 422 also includes the examinations that are normally done in TG 407 – Repeated Dose 28-Day Oral Toxicity Study. These examinations include haematology, clinical biochemistry, weighing of 7 organs and histopathological analysis of around 20 organs.

Due to the low number of animals, a statistical analysis of all parameters is not necessary.

Test of developmental neurotoxicity

OECD Test Guideline 426 (Developmental Neurotoxicity Study)

This test is being developed from an existing US guideline for testing methods. The purpose of the test is to produce data on the potential functional and morphological changes that can occur in the nervous system of offspring after exposure via their mothers (exposure *in utero* and through lactation). The study can either be used as a separate, independent study or as a follow-up to e.g. a two-generation study.

At least 20 pregnant females are exposed from gestation day 6 to postnatal day 20. The mothers are observed very carefully at least once a week with regard to e.g. appearance, secretions, respiration, movements, posture, tremors, bizarre behaviour and aggression. The offspring shall be observed at least twice daily for signs of toxicity and mortality, and at least once a week they shall be observed as carefully as the mothers. At least 10, but preferably 20, pups of each sex (representing different litters) are used for the various tests.

Short-term tests

Uterotrophic assay

This is a method that has been used for a long time with good results, and which should therefore be able to be validated and accepted relatively rapidly. It is based on the principle that oestrogens increase the uterine weight of females. To prevent endogenous oestrogen from interfering, prepubertal or ovariectomized animals who have been exposed to the test substance for three days are used. Then the uterus is weighed. A weight increase indicates an oestrogenic effect of the chemical.

To find potential anti-oestrogens, test substance and oestrogen are given to one group, while the controls only receive oestrogen. In this case a weight decrease (actually a reduced weight increase) indicates that the test substance has blocked the effect of the oestrogen, and that it is accordingly an anti-oestrogen (oestrogen antagonist).

Even though it is mainly chemicals that bind to the oestrogen receptor that are detected, chemicals with certain other action mechanisms can also be detected.

Herschberger assay

Experience of this method is limited. It is based on the principle that the weight of the prostate gland is dependent on testosterone. In the absence of testosterone, the prostate atrophies. In principle, anti-androgens can therefore be detected in normal male animals. Castrated young males are, however, needed to identify androgenically active chemicals (the atrophied prostate will gain weight in response to androgens). In the method being validated, castrated males are therefore used in both cases for identification of anti-androgens, but in combination with testosterone. Daily dosage of test substance and possibly testosterone is begun one to two weeks after castration. After seven days the animals are killed and the organs of reproduction are removed and weighed carefully.

As in the uterotrophic assay, substances with certain other action mechanisms than via direct receptor binding can be identified with this method.

OECD Test Guideline 407 (Repeated Dose 28-Day Oral Toxicity Study)

Industry has expressed an interest in investigating whether TG 407 can be enhanced so that endocrine-disruptive chemicals can be identified in this basic test, which is very early in the testing process. Warning has been given, however, that this test with these changes and enhancements will be very expensive to perform.

The preliminary changes and enhancements that have been discussed and are to be investigated are as follows:

- The dose levels that are normally used are too high to be relevant in studies of endocrine effects, and more lower dose levels must therefore be included.
- The oestrous cycle (2 cycles) will be investigated.
- All endocrine glands (including the gonads) will be subjected to detailed histopathological examination.
- Since stress affects the endocrine systems, the concentration of corticosterone in the blood will be investigated as a marker of stress. The quantity of blood is, however, not enough for other hormone analyses (the biochemical investigations are prioritized).
- The animals will be examined ”functionally” (sensory reactivity to stimuli of different types, assessment of grip strength and motor activity).
- Sperm analyses will be done.

Simple screening tests

Within the American EDSTAC (Endocrine Disruptor Screening and Testing Advisory Committee) programme, three *in vitro* methods have been discussed: binding of chemicals to the oestrogen or androgen receptor, and studies of the effects of chemicals on the activity of steroidogenic enzymes in testicle homogenate. These methods have, however, not been discussed by the OECD yet. The US EPA has commenced receptor binding studies, but so far the results have not been particularly promising.

Test of effects on the thyroidal hormone system

EDSTAC has also discussed FETAX (Frog Embryo Teratogenesis Assay-Xenopus) as a potential *in vivo* method for detection of the effects of chemicals on the thyroidal hormone system. The OECD has not included FETAX in its programme, but is following developments in the area.

Appendix 2

Situation description of the OECD’s test guidelines programme concerning effects of endocrine disruptors in the ecotoxicology field

Existing testing methods

None of the OECD’s existing testing methods are designed to detect effects of endocrine-disruptive chemicals. Most tests are limited to determining the acute to subacute effects of chemicals on biota. Typical effects that are studied are mortality (expressed as LD_{50} or LC_{50}) and a rough examination of external changes and behaviour. With the exception of previously described mammal studies, there are only two guidelines for testing methods in the ecotoxicology field that are intended for studying reproduction, and which can therefore potentially be used to detect hormonal effects on reproduction. Of these, only OECD TG 206, Avian Reproduction Test, includes sexual reproduction, since OECD TG 211, Daphnia Reproduction Test, concerns reproduction in Daphnia (water flea). Following is a brief description of these testing methods.

OECD Test Guideline 206 (Avian Reproduction Test)

Birds (mallard duck, bobwhite quail and Japanese quail) are fed with a diet containing the test substance in different concentrations for at lest 20 weeks. Artificial light is used to induce the birds to lay eggs. These eggs are collected, incubated and hatched during a period of ten weeks. Hatchlings are fed for two weeks. Mortality in the control group may not exceed 10 percent at the end of the test. At least 14 young in the mallard control group or 12 in the bobwhite quail or Japanese quail control group shall have survived at the end of the test.

Mortality of adult birds and signs of toxicity shall be reported daily. Body weights of adult birds shall be reported at the start of the test, prior to the onset of egg laying, and at the end of the test. Body weights of young shall be reported at the age of 14 days. Food consumption of adult birds shall be checked at two- to three-week intervals throughout the study. Food consumption of young shall be studied during the first and second week after hatching.

Moreover, egg production, cracks or other damage to egg shells, eggshell thickness, viability, hatchability and effects on young between control and test concentrations shall be compared.

OECD Test Guidelines 211 (Daphnia sp. Reproduction Test)

This test covers the effects of chemicals on asexual reproduction (parthenogenesis) in Daphnia. The relevance of asexual reproduction in this context can be discussed. The test has the potential ability to detect hormonal (and of course purely toxic) effects on parthenogensis, but no mechanistic information is obtained. It is furthermore not likely that this test can generally detect hormonal effects on invertebrates, in view of the differences in endocrine systems and reproductive strategies that exist in this diverse group of organisms. There is a great need for research in this field, and the development of new guidelines for testing methods would appear to be limited by this fact in the immediate future.

Other testing methods

Aside from the tests described above, OECD TG 210 – Fish, Early-Life Stage Toxicity Test – appears to be the testing method that can most easily be modified to detect endocrine-disruptive effects in early developmental stages in fish. This is above true of vitellogenin induction in male fish, but differences in sex ratio, for example, can also be determined if the exposure period is adapted to this.

Development of new testing methods

Among the member countries of the OECD, there is generally considered to exist a need to develop new guidelines for testing methods that focus on reproduction-related hormonal effects in aquatic and terrestrial organisms. A development project has been initiated within the OECD’s Working Group on Endocrine Disrupters Testing and Assessment (EDTA) to develop new testing methods for endocrine-disruptive chemicals. In the field of ecotoxicology, development of fish tests is the primary concern. An expert meeting initiated by the OECD for the purpose of identifying the need for new fish tests recommended the development of a full life cycle test on fish (from fertilized eggs (F0) to sac-fry (F1)). As a contribution to this work, Sweden is involved in a Nordic project aimed at developing a multi-generation test on zebrafish.

Besides development of a new life cycle test on fish, it is also possible to develop existing fish tests to detect relevant effects. For example, analysis of vitellogenin concentration in blood from male fish can be mentioned as a quantitative measure of oestrogen stimulation, gonad morphology, secondary sex characteristics and sex ratio.

At the present time it has not been considered possible to recommend *in vitro* tests (with the possible exception of the trout liver culture system) with regard to vitellogenin induction, due to limitations in these tests. The problems are above all the dependence on metabolic systems, the specificity and sensitivity of the tests, and the coupling to intact organisms. Developments in this area should be monitored, however.

Appendix 3

Examples of use of some substances suspected of having hormonal effects and Previous risk reduction of these substances. The figures on manufactured/imported volumes pertain to 1998, unless otherwise specified.

Phthalates

The phthalates that are discussed in conjunction with endocrine-disruptive effects are mainly butyl benzyl phthalate (BBP) and dibutyl phthalate (DBP), which are manufactured in or imported to Sweden in quantities of 1 000 and 375 tonnes, respectively. Sometimes diethyl hexyl phthalate (DEHP) is also mentioned in this connection, with a manufactured/imported quantity of just over 60 000 tonnes. Phthalates are mainly used as plasticizers in PVC plastics. Short-chain phthalates, such as DBP, can occur in caulking compounds, adhesives, etc.

Previous risk reduction

The Government Bill *En god livsmiljö* (Gov. Bill 1990/91:90, bet. 1990/91:JoU30, rskr. 1990/91:338, English summary available entitled ”A living environment”) says that use shall be restricted. The goal is a rapid phase-out of the most harmful substances in the group. The use and effects of phthalates have been investigated in several contexts, for example:

- PVC – en plan för att undvika miljöpåverkan. The Ecocycle Commission’s account of a Government commission on PVC (SOU 1994:104, in Swedish only)
- Tillsatser i plast (KemI Report 15/95)
- Additives in PVC (KemI Report 4/97).

The Government Bill *Svenska miljömål* (Gov. Bill 1997/93:145, bet. 1998/99:MJU6, rskr. 1998/99:87, English summary available entitled ”Swedish Environmental Quality Objectives”) contains phase-out targets for the majority of the uses of DEHP with deadlines of 2001 and 2005. The Government’s appraisal is that use in toys for children up to the age of three should be banned. Sweden now has such a ban in place.

Several phthalates are currently undergoing risk assessment in the EU’s programme for existing substances.

Since the objective of limiting the use of phthalates came, certain risk reduction measures have been adopted, such as switching from smaller to larger phthalate molecules in order to reduce the leaching of phthalates from finished products. Despite certain risk reduction measures, however, very large quantities of phthalates are still being handled in society. The results of the new objectives in *Svenska miljömål* cannot yet be seen in the statistics.

Chloroparaffins

Within the group chloroparaffins, there are substances with varying carbon chain lengths and degrees of chlorination. The short-chain chloroparaffins have mainly been used in cutting fluids for machining. Other chloroparaffins have chiefly been used as plasticizers and flame retardants in plastics and rubber. Imports of chloroparaffins to Sweden in 1995 amounted to just over 1 100 tonnes.

Previous risk reduction

The Government Bill *En god livsmiljö* says that use shall be reduced. The goal is a rapid phase-out of the most harmful substances in the group. A decision on phase-out of short-chain highly chlorinated paraffins was taken by OSPAR in 1995. The Government Bill *Svenska miljömål* says that the remaining use of short-chain highly chlorinated paraffins should be phased out by 2000, along with all use of chloroparaffins in PVC products. Chloroparaffins with short and medium-long carbon chains are being risk-assessed within the EU’s programme for existing substances.

Various risk reduction measures reduced the use of chloroparaffins by 70 percent during the period 1990–1995. The reduction during the same period for short-chain chloroparaffins used as cutting fluids in machining was 90 percent.

Alkylphenols

The alkylphenol group is dominated by nonyl- and octylphenols. They are used as antioxidants in plastics, but above all they are used for the production of nonyl- and octylphenol ethoxylates (NPEs and OPEs). These are surface-active and have been used in a variety of products, such as detergents, paints, adhesives, cold degreasers, pesticides and refrigerants. The alkylphenol ethoxylates (APEs) are transformed back into the original alkylphenols in the environment.

Previous risk reduction

The Government Bill *En god livsmiljö* lays down the objective that at least 90 percent of the use of NPEs in Sweden should have ceased by 2000. Targets for restrictions have been set within OSPAR.

The Government Bill *Svenska miljömål* states that the remaining use of NPEs, which leads to direct emissions, should be phased out by 2000.

Nonylphenol is being risk-assessed within the EU’s programme for existing substances.

The use of nonylphenol ethoxylates decreased by 70–80 percent during the period 1990–1995. Consumption in cleaning agents, where there is a great potential for release to the environment, has declined very sharply.

PBBs and PBDEs

Polybrominated biphenyls (PBBs) and polybrominated diphenyl ethers (PBDEs) are used as flame retardants. All PBBs and most PBDEs that come to Sweden are present in finished products. The quantity of PBDEs imported in chemical products in 1997 was about 120 tonnes.

Previous risk reduction

The Government Bill *En god livsmiljö* lays down the objective that the use of brominated flame retardants shall be restricted. The goal is a rapid phase-out of the most harmful substances in the group. Since then, risk reduction measures have been undertaken nationally and internationally. The National Chemicals Inspectorate has conducted a flame retardant project that has resulted in commitments by several sectors to restrict use. The phase-out has not proceeded fast enough, however, and in March 1999 the National Chemicals Inspectorate presented a proposal to the Government for a ban of PBBs and PBDEs.

PBDEs are being risk-assessed within the EU’s programme for existing substances.

Bisphenols

Bisphenol A is used as an intermediate in the synthesis of other substances, whereby its chemical identify is altered. There is also some use as an additive in plastics, which means the substance exists in its original form and can be leached out.

Previous risk reduction

There are no national restriction targets for bisphenol A. Bisphenol A is being risk-assessed within the EU’s programme for existing substances.

Pesticides

Several groups of pesticides figure in the discussion of substances with endocrine effects. The largest group in terms of quantity is dithiocarbamates, with substances such as mancozeb and maneb, which are intended for potato growing. The other pesticides entered on lists of endocrine-disruptive substances are used in very small quantities in Sweden, totalling a few tonnes.

Previous risk reduction

Mancozeb is still used in approved pesticides, but is subject to phase-out plans and the areas of application have been restricted. Maneb is no longer present in any approved pesticides. Mancozeb and maneb were sold in the early 1990s in quantities of several hundred tonnes per year. Use of agricultural preparations containing mancozeb today is less than 100 tonnes.

Tributyltin compounds

Tributyltin compounds are used in antifouling paints on boat hulls and in small quantities as preservatives in e.g. plastics.

Previous risk reduction

Use is regulated in such a way that the antifouling paints may only be used on ocean-going vessels longer than 25 metres. A project has been under way since 1998 within the IMO (International Maritime Organization) aimed at phasing out organotin compounds in marine antifouling paints.

Metals and metal compounds

Contents

The Government’s new guidelines on metals

The Committee’s commission regarding metals:

The Committee is supposed to submit proposals on how the Government’s new guidelines for metals are to be implemented. The goal is that they should be implemented within 10–15 years. The guidelines are as follows:

- New products introduced on the market are largely free from mercury, cadmium, lead and their compounds.
- 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.

The Government’s guidelines are one step along the road to achieving the national environmental quality objective of a non-toxic environment, which is supposed to have been achieved within a generation. The objective entails that concentrations of substances that occur naturally in the environment must be close to background levels.

1 Metals – general

1.1 Definitions

When the word ”metals” or the name of a given metal is used in this Annex, both the metal and its compounds are intended, unless otherwise evident from the context.

1.1.1 What characterizes metals?

A metal is an element which has a characteristic lustre and which is an efficient conductor of heat and electricity. The majority of the over one hundred elements known to man are considered metals. Only around 20 elements are considered non-metals (e.g. carbon, oxygen, nitrogen and the noble gases).

Blends of metals in their metallic form are called alloys. Metals can also be incorporated in various chemical compounds, which may possess properties that differ significantly from those possessed by the metal in its pure form.

1.1.2 Some frequently used terms in conjunction with metals

Semimetals

A few elements possess both properties that are typical for metals and properties that are typical for non-metals. These elements are usually termed semimetals. The semimetals coincide fairly well with the elements that meet the requirements to be regarded as semiconductors. According to Hägg (1966), the semimetals are germanium, tin, arsenic, antimony, tellurium and astatine. Sometimes silicon and selenium are also intended when the term ”semimetals” is used. When the term ”metals” is used in this Annex, it includes the substances defined by Hägg as semimetals.

Heavy metals

The term ”heavy metals” is often used to refer to toxic metals. By ”heavy metals” is meant metals with a density above a certain value. There is no clear-cut limit for the density a metal must have to be classified as a heavy metal, but values of around 5 g/cm^3 are usually given. There is, however, no strict link between the density of metals and their hazard. The hazard of metals must be evaluated individually. The term ”heavy metals” is therefore not used henceforth in this Annex.

Essential metals

By ”essential substances” is meant substances which humans, animals and/or plants must ingest in order to sustain vital processes. A number of metals are essential. Sodium, potassium, calcium and magnesium are the metals found in the highest concentrations in the human body. Other metals that have important functions are e.g. iron, copper, zinc, cobalt, manganese and molybdenum. Metals can occur in humans, animals and plants in enzymes, proteins, vitamins and many other substances that sustain or control the vital functions.

Organometallic compounds

As mentioned previously, metals can be incorporated in chemical compounds. A special case is organometallic compounds. By ”organometallic compounds” is meant compounds with at least one covalent bond between a carbon atom and a metal atom.

1.2 Why give metals special treatment?

In addition to the specific guidelines for metals given in the above box, there are new guidelines on chemicals policy under which new products shall within 10–15 years be free from carcinogenic, mutagenic, reproduction-toxic and endocrine-disruptive substances as well as organic substances that are persistent and bioaccumulative. The Chemicals Committee has been commissioned to develop general criteria for when substances are to be phased out based on these properties.

The Chemicals Committee’s interprets the guidelines to mean that those metals and metal compounds that can cause cancer or are mutagenic, toxic for reproduction or endocrine-disruptive are to be assessed according to these properties in the same way as organic substances.

Measures of persistence and bioaccumulation have primarily been developed with respect to organic substances. In the USA there is a testing strategy for new substances based on persistence, bioaccumulation and toxicity (PBT). The US EPA makes the appraisal that the criteria for persistence and bioaccumulation can be applied to metals – metals are persistent and bioaccumulation can be measured by tests of bioconcentration in fish. Others maintain that problems exist in applying criteria for these properties to metals, which are elaborated on below. Organometallic substances comprise a special case, which is also elaborated on below.

1.2.1 Degradability and bioavailability

Metals are elements and cannot as such either be formed or broken down. On the other hand, the availability of metals to living organisms can vary. In the bedrock and in sediments, metals are not available to living organisms other than in the very uppermost strata. But even in surface waters and soil, metals can in principle be unavailable to living organisms, e.g. by virtue of the fact that they are bound in such a chemical form that they cannot be taken up. Where metals are and what their chemical form of occurrence is thus determine their bioavailability.

Forms of occurrence can vary over time, depending on e.g. pH and oxygen supply.

1.2.2 Bioaccumulation

Metals can accumulate in living organisms, just like organic substances. Determining the degree of this bioaccumulation can be associated with certain problems, however. Many organisms have a capacity to take up certain metals actively and to maintain a constant concentration of them in the body regardless of the concentration in the surrounding media. Certain other metals can also be taken up actively due to the fact that they resemble essential metals. The organism’s endeavour to maintain a constant concentration in the body regardless of the concentration in the surrounding media means that bioaccumulation will be extra high at low concentrations in the environment. Thus, different values of bioaccumulation will be obtained depending on the environmental concentration at which the test has been conducted. Furthermore, uptake can be affected by other metals present in the environment and taken up via the same mechanism.

1.2.3 Organometallic compounds

Organometallic compounds can be assessed based both on their metal component and their organic component. All metals and compounds of metals are dealt with in this Annex. No distinction has been made between metal compounds and organometallic compounds. The organometallic compounds that are persistent and bioaccumulative should, however, be dealt with in the same way as other organic compounds with these properties. Organometallic compounds can thus be assessed in two ways. If this leads to a conflict regarding choice of measures, the measure leading to the highest level of protection shall be chosen.

1.2.4 Man redistributes metals in the environment in different ways

Metals have been of crucial importance for human development. Metal ploughshares permitted great advances in agriculture, and metals played a vital role in the industrial revolution. The mass production of all kinds of goods was made possible by machines and instruments of metal. Metals are also one of the cornerstones of our modern IT society.

Due to their desirable technical properties, man has extracted and processed metals for thousands of years. At first this took place on a relatively modest scale, but the extraction rate has increased by leaps and bounds, particularly in recent decades. Man’s exploitation of metals is leading to their redistribution from the bedrock to society, and via society they can enter the natural environment.

Animals and plants have evolved over millions of years and adapted to an environment where certain metals, such as iron and aluminium, have been present in high concentrations while other metals, such as mercury, silver, tellurium and platinum, have been present in very low concentrations. Due to man’s redistribution of metals, their concentrations in air, soil and water have increased. This in turn often leads to increased metal exposure, which, if it becomes excessive, cannot be handled by organisms but leads to adverse effects.

Metals may escape into the environment at different stages, for example during extraction of the ore or processing of the metal, or in conjunction with the manufacture of various products containing the metal. During the useful life of the metal product, metal loss may occur due to corrosion or abrasion. Finally, environmental contamination can take place when the metal has entered the waste stream.

Metal emissions to air and discharges to water from the mining and metal-processing industries previously took place on a large scale, and old mining waste heaps are still an important source of metal pollution. But industrial emissions have been sharply reduced in recent years, increasing the relative importance of metal emissions during the useful life of the metals and in the waste stage. The magnitude of emissions during use depends on the area of application of the metal. Examples of areas of application that give rise to metal emissions are pesticides, peeling paints, copper in brake linings and zinc in rubber tyres. Metals in engineering materials, which may have very long useful lives, may eventually corrode.

The flows of metals from society to the environment may go directly to the atmosphere or surface water. Another dispersion pathway is via wastewater to sewage treatment plants, where a large portion of the metals is separated with the sludge, while the remainder accompanies the discharged, treated water. The metals in the sludge end up where the sludge is deposited, e.g. on agricultural land or on landfills. Metals can also enter the soil directly, e.g. in the form of lead shot or pesticides. Most of the metal quantities that are used are not emitted during their useful life, but accompany the waste streams and, if they are not recovered and recycled, end up on landfills either directly or in slag and ashes from waste incineration. If the metal concentrations in the ashes are high, they must be disposed of in compliance with special requirements. Nevertheless, landfilling of metals generally poses a long-range threat of metal contamination of the surrounding environment.

Once out in the environment, metals may be more or less mobile. For example, mercury can be transported long distances in the atmosphere, owing to its relatively (for a metal) high volatility. Lead moves very slowly in the soil, while metals such as cadmium and zinc move more rapidly through the soil and out into surface water or groundwater, particularly if the soil is acidic. Acidification thereby affects the distribution of the metals among different environmental media as well as the availability of the metals to living organisms.

Metals can thus be dispersed in different ways in conjunction with their deliberate production and use. But there are also other reasons why metals can be redistributed from depots in the rock in such a manner that they become available to living organisms. Here are some examples:

- Different metals occur together in the bedrock. For example, zinc almost always occurs together with smaller quantities of cadmium and often together with lead. The deliberate extraction of one metal (e.g. zinc) thus leads to the inadvertent redistribution of other metals from the bedrock. Depending on what the other metals are, they may then comprise a by-product in the production of the principal metal, remain in the mining waste after concentration, or be included as an impurity in the produced metal.

- Certain metals occur in fossil fuels. Our use of fossil fuels leads to redistribution of metals together with the fuels from the bedrock and emission to the atmosphere in conjunction with combustion of the fuels.
- Phosphate is mined to manufacture commercial fertilizer. This phosphate may contain cadmium and other metals in various concentrations, which are thereby redistributed and may be spread together with the fertilizer.
- During drilling of wells, an increased oxygen supply may cause metals to be leached out from the bedrock. This is particularly the case for deep-drilled wells in areas with sulphide mineralizations. Such wells may yield water with very high concentrations of e.g. arsenic.

Metals can also be inadvertently concentrated from natural materials in other ways. For example, metals are taken up by plants and are therefore present in biofuels. The metal concentrations in the ashes resulting from combustion of the biofuel can be high.

As a consequence of man’s use of metals over the centuries, the concentrations of certain metals in the soil at certain places in the country has been elevated many times over above the natural background levels. Long-term use of metals has also led to the accumulation of large quantities of metals in society in the most diverse products such as cars, lampposts, computers, plastics, etc. Metals that have accumulated in society and will eventually escape into the environment can give rise to further increases in concentrations.

Man’s use of metals can also lead to alterations in the chemical form of occurrence of the metals due to the manufacture of various metal-containing compounds. These compounds may be more or less dangerous than the original form of occurrence. For example, organotin compounds are much more toxic than metallic tin, and metals that can be inhaled can be much more dangerous than metals in food and drink.

1.3 Different ways to calculate and evaluate emissions of metals

1.3.1 Input to society in relation to natural flows

Azar (1995) calculated the quantity of metal that is put into circulation by man via mining and extraction of fossil fuels and compared it with natural fluxes via weathering, volcanic eruptions, etc. The conclusion of this work is that man in some cases introduces metals to society at a rate that is much greater than the flux due to natural processes (Table 1).

Table 1 Relationship between anthropogenic input to society and natural flux for some metals.

The global ratio between anthropogenic input to society (mining and fossil fuels) and natural flux for some metals (from Azar, 1995).

Substance	Input/ Natural flux
Copper	24
Silver	22
Lead	12
Tin	11
Zinc	8
Antimony	6
Nickel	5
Chromium	5
Iron	1.4
Aluminium	0.048

Since the pattern of use for metals differs between countries, at the same time as the natural flows also vary, global data cannot be directly applied to Swedish conditions. A rough calculation has been made for substances of which Sweden is a major producer (Bergman et al., 1987). This calculation naturally indicates figures that are greater than the global ones.

1.3.2 Emissions related to natural flows

In the above case, the quantity of metal mined by man was related to the natural flux. A similar calculation, but based on emissions instead of total mined quantities, has been done by Nriagu (1990). The calculation includes fourteen metals and is done on a global scale. According to these calculations, anthropogenic emissions (i.e. emissions caused by man) to the atmosphere exceed natural emissions (e.g. from volcanic eruptions and forest fires) by a factor of between 3 and 28 for lead, cadmium, vanadium and zinc. Anthropogenic emissions of arsenic, copper, mercury, nickel and antimony lead to more than a doubling of the natural flows.

The calculations are based on data from the late 1980s. Diffuse emissions from finished products have not been included in the model, resulting in an underestimation of the values. On the other hand, emissions from point sources have decreased in many countries since the 1980s.

In the same way as in section 1.3.1, global data cannot be directly applied to Swedish conditions in this case either.

1.3.3 Calculations of consumptive emissions based on emission factors

Calculating the emissions of a metal over time is associated with certain difficulties. The emissions that take place from point sources can be measured and are relatively easy to calculate. The diffuse emissions that take place from products in use are much more difficult to estimate. In a calculation of emissions of certain metals in the USA during the past century, Ayres and Ayres (1993) propose emission factors for eight metals. The factors give the fraction of a used quantity of metal that can be released during a ten-year period. The emission factors vary depending on the metal in question and the area of application. Lower factors have, for example, been set for applications where the metal is enclosed than for applications where the metal is exposed to the elements.

1.3.4 Calculations of consumptive emissions based on corrosion

The Swedish EPA has conducted a long-term research project called *Metaller i stad och land* (”Metals in town and country”, Bergbäck and Johansson, 1994, in Swedish only). In this project, the emission of metals from various surfaces has been investigated. Such studies yield values for metal emission that are more exact than the emission factors described above. Experimentally investigating the emission of metals from various surfaces is time-consuming, however, since each metal and material must be investigated individually. Furthermore, environmental factors such as pH will also influence the outcome, which means the investigation may have to be performed in different environments. Factors based on actual corrosion will therefore have to be supplemented with rougher emission factors in the foreseeable future.

The corrosion factors that have been found in the research project *Metaller i stad och land* have been used in the same project to quantify emissions of metals from products in Stockholm. The fractions of the total accumulated quantity of a given metal that come into contact with soil, water or air have thereby been calculated and the factors have then been used to calculate the emissions of the metal in question.

1.4 Inherent dangerous properties of metals and their compounds

The toxicological and ecotoxicological properties of metals are different. Examples of the inherent properties of metals are given in this section.

The fact that a substance has hazardous inherent properties does not necessarily mean that the substance poses a risk. The risk is dependent on how great the exposure of man or the environment is. The effects that can be expected from today’s exposure to copper, zinc, chromium and nickel are discussed in section 3.3. Furthermore, detailed risk assessments of numerous metals are being performed within the EU’s programme for existing substances, see 1.5.2.

1.4.1 The chemical form matters

The properties of metals vary depending on how they occur. One and the same metal can be used in the form of both a solid metal and numerous different chemical compounds. Copper, for example, is used as a solid metal in roofing, as copper oxide in marine antifouling paints, and as cupric chloride hydroxide as a fungicide. The metal's hazard varies to a high degree between its different forms of occurrence. A metal can be toxic both in ionic form and in organic or inorganic complexes. Leaching of copper ions can take place both from copper roofs and from marine antifouling paints, but the leach rate is much higher from the latter.

The form in which the metal is used is of great importance in judging health risks as a result of direct contact with metals. The form of occurrence during use is not necessarily of such great importance in assessing risks to the environment. This is because the metal in the environment can change forms anyway according to conditions in the environment, such as pH and oxygen supply. Since metals are not broken down, they remain in the environment for a long time and can thereby be exposed to changed conditions. When assessing risks to the environment, it is thus of interest to consider the metal as such and not just what compound it occurs in.

1.4.2 Certain metals are needed in low concentrations – essential metals

Certain metals are essential to life for humans, animals and plants (see 1.1.2). Other metals have no known function in living organisms. The fact that a metal is essential does not mean that it is non-hazardous. There is an optimum concentration of each essential metal in the organism. The width of the interval between deficiency and toxic effect can be different for different metals. The optimal concentration can also vary between different organisms. Some metals are essential for certain groups of organisms but have no function in other organisms.

According to the Environmental Health Commission (SOU 1996:124), nutrient deficiency in human beings is very uncommon in Sweden today (with the exception of iron deficiency). On the other hand, certain metals may have to be added to e.g. farmland to counteract deficiency symptoms in the environment, since the crop continuously depletes the soil.

1.4.3 Environmental hazard

Metals can be toxic to organisms both in the soil and in the aquatic environment. In forest land, metals can, for example, inhibit micro-organisms in such a manner that degradation of dead organic matter, and thereby release of nutrients, is slowed down. A slower cycling of nutrients will in turn have consequences for the plants in the forest. In agricultural land as well, metals can disturb the soil-living organisms, or have a toxic effect on the plants. A big problem with metals in agricultural land is that they can be taken up to varying degrees by the crop and thereby give rise to exposure of man.

Many metals are dangerous for aquatic organisms. Of the most common metals, copper, zinc, chromium and nickel in ionic form are toxic or very toxic for aquatic organisms such as algae, zooplankton and fish. Many metals and metal compounds are classified as dangerous for the environment (see further 1.5.1).

1.4.4 Health hazard

The health hazard posed by metals varies from one compound to another. Many metals and metal compounds are classified as dangerous to health, and there are metals or metal compounds in all hazard classes. Appendix 1 to this Annex gives examples of the classification of some metal compounds in accordance with the EC's dangerous substances directive (Council Directive 67/548/EEC), which has been implemented by the National Chemical Inspectorate's regulations, KIFS 1994:12.

1.5 Ongoing work in the EU and internationally

1.5.1 The EU's system for classification and labelling of chemical substances

The EC's dangerous substances directive lays down rules for how chemical substances are to be classified and labelled. A long Annex to the directive contains a list of substances that have been assessed by the European Commission. The list shows how the substances are classified with regard to health and environmental hazard and how they are to be labelled. Originally, the list included only harmful, flammable and explosive substances. These substances have since been reviewed and assessed with regard to danger for the environment. This work is almost finished.

A relatively large number of metals and metal compounds are included in the list. The assessment of metals with regard to environmental hazard has, however, involved certain difficulties, some of which remain to be solved. The difficulties mainly concern how existing criteria for environmental hazard classification are to be applied to solid metals and poorly soluble metal compounds. One way to handle this has been to classify solid metals and particularly poorly soluble metal compounds for which readily soluble salts of the same metal have been assessed as dangerous for the environment with risk phrase R 53 (”May cause long-term adverse effects in the aquatic environment”). These classifications may later be changed based on an agreed-upon classification strategy when additional information on the conversion/solubility of these substances becomes available. Substances with risk phrase 53 do not have to be labelled with the symbol for dangerous for the environment.

In order to enter a new substance on the list due to environmental hazard, the substance must have been assessed with regard to all classification-relevant properties. It can therefore take a long time to add new environmentally hazardous substances, including metals, to the list, since their health hazard classification must be awaited.

1.5.2 The EU’s work with risk assessment and risk reduction

Risk assessment

Risk assessment of over 100 substances is being carried out within the EU’s programme for existing substances. The substances selected so far for assessment are placed on one of the three priority lists that have been published. The lists are included as annexes to Council Regulation No 739/93 on the evaluation and control of the risks of existing substances.

Table 2 Metals or metal compounds included on one of the three priority lists published to date.

Zn	Zinc plus the following compounds: zinc distearate, zinc oxide, zinc chloride, zinc sulphate, trizinc bis(orthophosphate)
Cd	Cadmium and cadmium oxide
Ni	Nickel and nickel sulphate
Cr	Chromium trioxide, sodium chromate, potassium chromate and ammonium dichromate

In addition to these, there are a number of sodium-containing compounds on the list. But the purpose is not to evaluate sodium in itself.

The risks assessment for the substances in Table 2 are not yet finished. The fourth priority list, which has not yet been approved, includes copper and copper compounds. It also includes antimony trioxide, which is mainly used as a flame retardant.

The risk assessments in the programme are based on a Technical Guidance Document (TGD, 1996). The guidance document was mainly developed for assessment of organic substances. Special adaptations may have to be made for assessment of metals. An example of a problem that arises in risk assessment of metals and other naturally occurring substances is that due to the safety margins used in the assessments, the concentration at which the metal is calculated to pose a risk may lie below the natural background level. Such problems are dealt with briefly in the TGD.

An updating of the TGD is now being commenced and can be expected to be finished within a couple of years. The EU has listed the areas that need to be revised, which include the need for more guidance in the assessment of metals.

Risk reduction

When the risk assessments in the existing substances programme are finished, risk management strategies will be devised for the substances found to constitute a risk. This work has not yet begun for any metals.

Rules on restrictions of individual metal compounds in different areas of application can be found in several places in the EU's *acquis* *communautaire*. The restrictions directive (76/79/EEC) contains rules on restrictions on the use of some metals, e.g. nickel in jewellery and arsenic compounds and organotin compounds in process water. There are also general rules on carcinogenic, mutagenic and reproduction-toxic substances which have some bearing on metal compounds, e.g. chromates.

Examples of other directives that may regulate the use of individual metals are the plant protection products directive (91/414/EEC), the biocidal products directive (98/8/EC), the water framework directive (currently in progress) and the directive on producer responsibility for different product groups. Producer responsibility normally regulates recycling of products, but a draft directive on producer responsibility for electrical and electronic equipment has gone one step further and listed some metals that may not be used in the products. The Commission has not yet submitted a formal proposal, however, which means that changes can still be made.

1.5.3 OSPAR

Work is currently under way in OSPAR to select the substances to be subject to the requirements of the Esbjerg Declaration, i.e. substances for which discharges to the North Sea shall have ceased within one generation. The work is largely focused on organic substances.

The Nordic countries and the Netherlands have worked on making an initial selection of substances. It includes some metal and organometallic compounds (e.g. organotin compounds). The members of OSPAR have agreed that the outcome of such a selection process – which is based on persistence, bioaccumulation and toxicity – should be open to the addition of other dangerous substances proposed by the Member States. Metals and metal compounds are particularly singled out as a group of substances for which this procedure is appropriate, since the criteria for persistence and bioaccumulation have been especially developed for organic substances.

1.5.4 The OECD’s work with classification and testing methods

The members of the OECD have agreed on harmonized criteria for classification of environmentally hazardous substances. These criteria largely agree with the EU’s rules for classification and labelling. The USA does not yet have any system for labelling of environmentally hazardous substances.

A guide to the interpretation of data and application of the harmonized criteria is in progress. Assessment of the environmental hazards of metals is planned to comprise a special chapter in the guidance document.

1.5.5 The United Nations

A Protocol on Heavy Metals was added to the UN Convention on Long-Range Transboundary Air Pollution (CLRTAP) in 1998. The risk reduction measures in the protocol mainly cover lead, cadmium and mercury.

The work of the IPCS (The International Program on Chemical Safety), which is a joint programme of three UN bodies (ILO, UNEP and WHO), includes assessment of the health and environmental risks of chemical substances. Appendix 2 to this Annex contains a list of the 17 metals so far assessed within the programme.

The JECFA (Joint FAO/WHO Expert Committee on Food Additives) has developed provisional values for acceptable intake of bio-accumulative metals in connection with the consumption of various foods.

1.6 How are the metals grouped in the following sections?

The metals could be roughly graded on the basis of hazard. Among the most dangerous metals are mercury, cadmium and lead. These three metals should in principle be phased out, which has been previously proposed in the Government Bills *En god livsmiljö* (Gov. Bill 1990/91:90, bet. 1990/91:JoU30, rskr. 1990/91:338, English summary available entitled ”A living environment”) and *Svenska miljömål* (Gov. Bill 1997/93:145, bet. 1998/99:MJU6, rskr. 1998/99:87, English summary available entitled ”Swedish Environmental Quality Objectives”). According to the Government’s new guidelines, new products shall be largely free from these metals within 10–15 years. Work on restricting the use of the metals has been under way for the past few decades.

At the other end of the scale are metals that are very common in the natural environment, such as iron, aluminium, calcium, magnesium, sodium and potassium, and probably titanium. These metals are not to be regarded as completely harmless, but are nevertheless not expected to give rise to problems in normal use.

Between these extremes are a large number of metals with varying degrees of hazard. Knowledge regarding these metals varies widely. Relatively good knowledge regarding health and environmental hazards and exposure situations exists for the most common metals, but knowledge is sometimes rather scarce for the less common ones. Uncertainty exists in certain areas even for the most widely used metals, however, for example exposure in different population groups, as well as the health and environmental impact to which the heavy accumulation of metals in society might give rise over the long term.

Appendix 3 to this Annex shows how the metals have been grouped as a basis for the subdivision in the continued treatment. Following sections deal with other metals, with the exception of those that occur naturally in large quantities – iron, aluminium, sodium, potassium, calcium, magnesium and titanium. All of these occur in soil in concentrations of around 1 mg/g or more (Appendices 4–6).

2 Lead, cadmium and mercury

2.1 Why should lead, mercury and cadmium be phased out?

The Swedish state has many reasons for phasing out the three metals lead, cadmium and mercury, which are described in conjunction with previous decisions and position statements, e.g. in the Government Bills *En god livsmiljö* (1990/91:90, English summary entitled ”A living environment”) and *Svenska miljömål* (1997/98:145, English summary entitled ”Swedish Environmental Quality Objectives”). Only a brief summary is therefore given here.

To protect the external environment, it is urgent to take measures against mercury, cadmium and lead. The concentrations of these three metals are greatly elevated in Swedish forest land. There is thereby a risk of large-scale effects on microorganisms and invertebrates in the soil layer, and every additional input worsens the situation. The metals also exhibit a greatly elevated concentration in lakes.

Use of lead, mercury and cadmium over many decades has led to accumulation of these metals in urban environments, and considerable diffuse leaching has occurred from these urban areas to surrounding waters. The concentrations of lead, mercury and cadmium in the sediments in the water areas around Stockholm are very high as a result of this diffuse outward transport.

From a health perspective, cadmium and mercury require the most urgent measures. Cadmium can cause kidney damage, and even at prevailing intakes of cadmium, sensitive individuals can be expected to suffer some impairment of kidney function (Järup et al., 1998). Some correlation has also been found in Sweden between cadmium exposure and osteoporosis.

The National Board of Agriculture judges that cadmium contamination is the greatest threat today to the long-range usefulness of arable soil for food production (National Board of Agriculture, 1999). Due to the composition of the bedrock, even the background levels of cadmium in arable soil are high at some places in Sweden, for example in some parts of Skåne (Scania, the southernmost part of Sweden). Atmospheric deposition and cadmium in commercial fertilizer have further loaded the arable soil over the years. The concentration of cadmium in wheat kernels probably doubled during the 20th century.

Mercury concentrations in fish lie at higher levels than is acceptable from a health point of view. It is estimated that half of the nation’s lakes (about 40 000) have pike with mercury concentrations above 0.5 mg/kg, which is the limit value recommended by Codex Alimentarius (the UN food agency). Mercury occurs in fish in the form of methylmercury. Mercury (especially in the form of methylmercury) can cause damage to the nervous system. Foetuses are particularly sensitive to mercury exposure. Exposure to mercury occurs not only via food, but also e.g. via dental amalgam.

When it comes to lead, exposure of the general population has fallen sharply as a result of the elimination of lead from petrol. This has greatly reduced the risk of health effects in the general population. Individuals can be subjected to high lead exposure directly from finished products in rare cases today (see 2.2.4). If an individual is exposed to lead, it can cause damage to the nervous system, and if pregnant women are exposed to lead there is a risk of damage to the foetus, which is extra sensitive.

2.2 Lead

2.2.1 Rules, conventions and previous policies

2.2.1.1 Rules and agreements in Sweden and the EU

The Government Bill *En god livsmiljö* (1990/91:90, English summary entitled ”A living environment”), presented in 1991, stated the objective that use of lead should be discontinued in the long term.

The Government Bill *Svenska miljömål* (1997/98:145, English summary entitled ”Swedish Environmental Quality Objectives”), presented in 1998, stated that the use of lead in PVC products should have ceased by not later than 2002, and that the Government makes the judgement that lead shot should be banned. In conjunction with its treatment of the Bill, the Riksdag (Swedish Parliament) made a proclamation to the Government that such a ban, pending the development of adequate alternatives, shall be combined with the possibility of granting certain exemptions.

The Government’s new guidelines entail that new products shall largely be free from lead within 10–15 years.

The use of lead in petrol (gasoline) has been restricted by the Motor Gasoline (Petrol) Ordinance (1985:838). The Ordinance was amended during the 20th century in such a manner that leaded petrol may not be used today except within certain exempted areas, e.g. for vehicles in the service of the National Defence and for piston engines in aircraft.

According to the Swedish EPA’s Ordinance with regulations concerning hunting (SNFS 1994:3, Swedish EPA, 58, in Swedish only), hunting with lead shot is not permitted within certain geographic areas, particularly wetlands. As from 1 July 1998, lead shot may not be used for hunting duck and geese either.

Beyond this there are certain other regulations that concern lead in chemical products and finished products. For example, lead carbonates and lead sulphates may not be used in paints, according to the EC's restrictions directive (76/769/EEC), implemented in Swedish legislation through the National Chemicals Inspectorate's regulations KIFS 1998:8. According to the same rules, substances with certain risk phrases for cancer, genetic damage and impaired fertility may not occur in chemical products sold to the general public. This pertains to lead compounds in general, since they are classified as toxic for reproduction. The Ordinance on Prohibition in Connection with Handling, Importation and Exportation of Chemical Products Etc. (Certain Cases) (1998:944, in Swedish only) regulates the occurrence of lead in packaging.

A directive is currently being framed in the EU regarding producer responsibility for electrical and electronic equipment. There is as yet no finished proposal from the Commission, but according to a draft proposal of the directive, lead is to be phased out of electrical and electronic equipment by 1 January 2004. Exemptions are proposed for lead in radiation shielding, lead in glass for incandescent light bulbs, fluorescent tubes and cathode ray tubes, lead in electronic ceramic parts and lead as an alloying element in steel (up to 0.3 percent), aluminium (up to 0.4 percent) and copper (up to 4 percent). It is proposed that the exemptions be subject to continuous review, which could result in the addition or deletion of areas of application from the list of exemptions.

The European Commission has presented a proposal for a directive on end-of-life vehicles. According to the proposal, the Member States shall ensure that lead, mercury and cadmium and hexavalent chromium contained in vehicles put on the market after 1 January 2003 is prevented from being shredded in vehicle shredders and from being disposed of as landfill or in any installation incinerating or co-incinerating waste, with or without energy recovery. It is proposed that lead used as solder in electronic circuit boards shall be exempted from this requirement.

2.2.1.2 OECD

During the 1990s, the OECD has pursued a risk reduction program for certain selected substances, including lead. The work was concluded when the environment ministers of the OECD member countries adopted a Declaration on Risk Reduction for Lead (C(96)42/Final). In the declaration, highest priority is given to actions which address the risk of exposure from food and beverages, water, air, occupational exposure and other potential pathways in accordance with an annex, where the following points are listed:

- progressively phase down use of lead in gasoline except where needed for essential or specialized uses for which there are not practical, viable alternatives;
- eliminate exposure of children to lead from toys;
- reduce exposure to lead from materials such as packaging, ceramic ware and crystal ware, via food and beverages;
- phase down the use of lead in paint and rust-proofing agents, except in cases of essential or specialized uses for which there are no practical alternatives;
- restrict the use of lead shot in wetlands and promote the use of alternatives to lead sinkers;
- establish strategies to abate significant exposures arising from the historic use of lead-containing materials in buildings.

The rest of the declaration deals with increasing recycling of lead, reducing occupational exposure and reducing emissions from point sources, as well as monitoring the levels in the environment.

2.2.1.3 UN Convention on Long-Range Transboundary Air Pollution (CLRTAP) – Protocol on Heavy Metals

Within the UN Convention on Long-Range Transboundary Air Pollution, CLRTAP, a Protocol on Heavy Metals was adopted in June 1998 at a meeting in Aarhus, Denmark. The Protocol had been signed by 35 individual countries (European countries, USA, Canada) and the EU. As of March 2000, the Protocol had only been ratified by three countries (Canada, Norway and Sweden).

The Protocol deals with the metals lead, cadmium and mercury. The parties undertake to reduce their emissions of the three metals compared with 1990 (or another year between 1985 and 1995). The purpose is to reduce emissions from industrial sources, combustion installations and waste incineration installations. According to the Protocol, the parties must phase out the use of leaded petrol. The Protocol contains no additional phase-out requirements for specific areas of application for lead.

2.2.1.4 Work in individual countries – Denmark

In December 1998, Denmark notified an ordinance on prohibition of lead to the European Commission. The prohibition is intended to cover importation, sale and production of lead and lead compounds, as well as products containing lead or lead compounds. The ordinance does not concern provisions on lead that are a consequence of previous legislation, e.g. in the areas of medical devices, packaging, motor petrol, batteries, ammunition, slag and fly ash as well as sludge. An annex to the ordinance gives the date from which use of lead is prohibited, broken down by product category. The date lies within the period November 1999 to November 2003. For certain products the exemptions are indefinite.

The Danish notification brought reactions from many Member States. The objections mainly pertained to the fact that the Danish ban leads to trade barriers, at the same time as a satisfactory assessment of the risks is lacking. An area that has been highlighted by several countries in this respect is crystal glass. Since the notification provoked detailed comments, the moratorium period during which the proposal may not be adopted was extended by three months until 1 July 1999. The lead industry has also reacted to the fact that the Danish ban violates free trade agreements, and that the risks have not been demonstrated to a sufficient degree, and that a review of the risks associated with the substitutes is lacking. Denmark is reconsidering the proposal. The intention is that the ordinance should enter into force in 2000.

2.2.2 Use of lead in Sweden today – how is the phase-out work going?

During the period from 1880 to today, more than 2 million tonnes of lead have been used in Sweden. It is estimated that approximately 400 000 tonnes of lead is in use in society today, while the rest exists in the form of waste (Bergbäck, 1998). In the middle of the 1990s, Sweden was a net exporter of lead, i.e. exports of lead in the form of refined lead and alloys amounted to about 50 000 tonnes and thereby exceeded imports, which were dominated by waste and scrap and amounted to about 30 000 tonnes. Both mining of lead and reprocessing of recovered lead take place in Sweden.

In the mid-1990s, the annual input of lead in products in Sweden was about 40 000 tonnes. The new input of lead to society was, however, lower than that, since around half of the use consisted of recycled lead. Table 3 shows how the quantity of lead used was broken down among different areas in different years. It is important to observe that the way in which the values have been calculated varies slightly, so that direct comparisons between the years can lead to misinterpretations. The Table nevertheless provides a good picture of the overall situation regarding uses of lead.

The biggest single area of application for lead is lead batteries and other accumulators. Accumulators are estimated to account for around three quarters of the total use. Other areas of application 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. 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.

Table 3 Lead use in Sweden.

Estimated use of lead in Sweden in manufacturing, broken down among different areas during the period 1989/90 to 1996 (National Chemicals Inspectorate, 1997).

Area of application	**1989/1990**	**1992**	**1996**
Accumulators/batteries	22 000	22 000	35 800[7]
Cable sheathing	3 000	< 3 000	1 225[4]
Plastics, stabilizers and pigments	2 000	2 000	< 900[3]
Glass	1 500	1 320[1]	< 900
Shot and bullets	800-900	1 200	< 1 000[6]
Petrol	600	340	< 9[2]
Paints and anti-corrosives	200	90[1]	70[5]
Lead-soldered tins	25	< 25	0
Rubber	10	no data	no data
Explosives	10	no data	no data
Ceramics	10	no data	no data
Other use of metallic lead	> 200	150	no data
Fishing	no data	600	132[7]
Construction, chimney flashing	no data	500	no data
Weights	no data	1 000	2 000[7]
Metal alloys	no data	900	no data
Electronics, visual display units, light bulbs and soldering	no data	1 300	about 1 300
Total	**about 30 355**	**about 34 400**	[8]

[1] Data pertain to 1991.
[2] Data pertain to 1991 and 1996, see further the National Chemicals Inspectorate's report.
[3] Data pertain to 1994, see further the National Chemicals Inspectorate's report.
[4] The quantity of lead to Sweden is estimated at < 10 tonnes.
[5] Datum pertains to 1995.
[6] Sold quantities assuming that the quantity of lead in bullets has not changed.
[7] Use in manufacture has been reported for 1996. Exports and imports not taken into account. The actual use of lead in fishing sinkers in Sweden can be estimated at 600 tonnes.
[8] Adding up the quantities is not meaningful, since the uncertainties in the estimates are great in many cases and imports and exports have not been taken into account.

Following is a review of the biggest remaining areas of application for lead.

2.2.2.1 Batteries

Very large quantities of lead are used in batteries. Lead use is split between starter batteries (about 60 percent) and stationary and traction batteries (about 40 percent). Stationary batteries are used for standby power for industrial installations, hospitals etc., while traction batteries are used for operation of e.g. warehouse trucks. The production of lead batteries is increasing globally. The increase for starter batteries is 2 percent per annum, and for other batteries 5 percent per annum.

Product development

Two types of batteries are used in vehicles – starter batteries and traction batteries. Starter batteries are present in all vehicles, and all starter batteries are manufactured from lead today. Traction batteries are needed in new types of vehicles, such as electric and hybrid vehicles. Development of traction batteries is mainly concentrated on other battery systems than lead batteries.

Lithium batteries and nickel-metal-hydride batteries have quickly replaced e.g. nickel-cadmium batteries in many products. Scientists say that the development of lithium batteries and even nickel-metal-hydride batteries has come sufficiently far for these to be used as starter batteries (Thomas, 1999). However, the battery manufacturers and the auto industry say that it takes around ten years to retool production, and there is no real incentive for such a retooling today (Aronsson, 1999 and Johansson, 1999).

A 3-year research project concerning lithium batteries is being conducted in the EU. Lithium batteries contain, in addition to lithium, aluminium and copper as carriers, metal oxide and some polymer. The metal oxide may be an oxide of iron, manganese, vanadium, cobalt or nickel. An endeavour is being made to use iron and to replace copper with aluminium. The metal part of nickel-metal-hydride batteries consists of e.g. lanthanum.

Lead batteries are also undergoing development aimed at making them smaller and increasing their useful life. It is possible that the quantity of lead per battery can be reduced within a ten-year period from today’s 60 percent to 50 percent, and that their useful life can be increased from 5 to 6–7 years.

Development of bipolar batteries is also in the research stage. If they can be made to work satisfactorily, the quantity of lead per battery can be reduced to 30 percent. The uncertainties surrounding the future of bipolar batteries are, however, as great as for lithium and nickel-metal-hydride batteries (Aronsson, 1999).

A switch to alternative batteries is probably even farther in the future for stationary and traction batteries than for starter batteries.

Recovery and recycling

A system for take-back of starter batteries weighing over 3 kg has been in place in Sweden for about 10 years. This system was expanded in 1998 to include all lead batteries. Take-back of batteries is regulated in the Battery Ordinance (1997:645, in Swedish only). Anyone placing a battery on the market pays a fee that goes to a battery fund administered by the Swedish EPA. The scrap trade, which then receives the spent batteries, delivers them to Boliden Bergsöe AB. Boliden Bergsöe AB reports to a special company, Returbatt AB, how many tonnes of lead batteries have been turned in from each scrap supplier. Returbatt AB submits these figures to the Swedish EPA, which pays out money from the battery fund. There is about SEK 150 million in the battery fund today. The collection rate is high. Statistics concerning starter batteries from the years 1989 to 1997 show that the collection rate was just over 100 percent of the market influx for these years (Blomgren, 2000). The reason the collection rate exceeded 100 percent is that when the system was introduced in 1989 there were large quantities of batteries stored in various places. Statistics on the collection of stationary and traction batteries are also available from 1998, but statistics on market influx are incomplete, which means it is not possible to calculate the collection rate.

Boliden Bergsöe AB receives collected lead from the entire Nordic region. Most is lead from batteries. All lead from batteries does not go back into the production of new batteries, however. There are two reasons for this: one is that it can be more profitable to sell the lead to other areas of application; and the other is that the recovered lead is contaminated with other metals so that it is not suitable for certain functions in a new battery. An example of an area of application for recovered battery lead, other than new batteries, is lead roofing. The impurities that limit the usefulness of the recovered lead are mainly silver and bismuth.

At a production volume of 35 000 tonnes of batteries per year, approximately 21 000 tonnes of recovered lead and 14 000 tonnes of newly mined lead is used in the manufacture of new batteries. In order to be able to use more recovered lead, Boliden Bergsöe AB must purify the lead better and/or the battery manufacturers must develop their batteries to make them less sensitive to impurities. Boliden Bergsöe AB and Tudor AB both believe that it would be possible within 10 years to achieve one hundred percent recycling of battery lead to new batteries.

2.2.2.2 Ammunition and fishing sinkers

Ammunition and fishing sinkers differ from other remaining areas of application for lead in that their use in most cases leads to a direct dispersion of metallic lead to the environment.

The use of lead in ammunition can be divided into bullets, shot for sport shooting and shot for hunting. The use of lead in shot has been monitored by the National Chemicals Inspectorate. During the period 1992 to 1996, the use of shot for sport shooting declined by nearly 40 percent. This was partially a result of a reduction in the amount of shot per cartridge. During the same time, there was a slight increase in the use of lead shot for hunting. The total use of lead in shot amounted to about 700 tonnes in 1996. Equivalent figures are lacking for bullets, but at the beginning of 1990 annual use was 300 tonnes. Sales of alternative shot amounted to only a few tonnes in 1996 (National Chemicals Inspectorate, 1997).

The use of lead in fishing is divided between professional fishing and sport fishing. The use of lead in fishing was about 600 tonnes per year in the mid-1990s, of which 400 tonnes went to professional and household fishing, mainly in the form of lead-lines for nets. In sport fishing, casting of sinkers from recovered lead in the home is common practice. This involves special exposure risks.

In order to achieve voluntary restriction of lead emissions in the form of fishing sinkers, the National Chemicals Inspectorate carried out an information campaign in the spring and summer of 1999 in cooperation with national organizations of sport fishermen and water owners. It is still too early to gauge the results of the campaign.

2.2.2.3 Weights

The two chief areas of application for lead weights are yacht keels and wheel balancing weights. Switching to new wheels with better rims, e.g. aluminium rims, reduces the need for balancing weights. Progress towards reducing the need for lead in balancing weights is relatively slow, however. Lead weights are also found in other areas, e.g. in lifts, industrial robots, toys, curtain fabrics, cars and furniture. Weights can also be made of iron, but lead has a higher density and the lead weights can therefore be made smaller than iron weights of equivalent weight. Recycling of lead weights is probably high, but statistics are lacking.

2.2.2.4 Electronics, visual display units and soldering

Lead is used, sometimes alloyed with tin, for soldering of printed circuit boards and assembly boards, in visual display units (VDUs) and in light bulbs. Previously, electronic products were sometimes surface-treated with lead. It is uncertain whether this occurs in Sweden today.

In the phase-out project (National Chemicals Inspectorate, 1997), the appraisal was made that use of lead in incandescent light bulbs and fluorescent tubes was to be phased out by 1999. This has not happened (Ålåker, 1999).

Glass for VDUs contains lead oxide to improve its formability during production. The pace of the phase-out here is determined by the pace of the introduction of flat VDUs in television sets and computers. This is a technology that exists today but is still very expensive.

2.2.2.5 Crystal glass

The use of lead in what has been called semi-crystal glass has ceased. Use in full crystal has also declined. The lead imparts special working properties to the glass and it is only in products that require such working that lead is still used. The manual glass industry is working in collaboration with the Swedish Glass Research Institute to replace lead entirely. The use of lead in raw material for the Swedish manual glass industry and the Swedish studio glassworks was 560 tonnes (Wergemann, 2000).

2.2.3 Estimation of emissions to the Swedish environment

Emissions of lead to the atmosphere declined from 950 tonnes to 37 tonnes between 1985 and 1995. The biggest contribution to this reduction came from road traffic. Industrial emissions also decreased markedly during this period. If we consider the total deposition of lead from the atmosphere in southern Sweden, approximately 80 percent derives from foreign sources today (Johansson et al., 2000).

Lead discharges to water have also been sharply reduced, from 200–250 tonnes per annum during the 1970s to 13 tonnes in 1995. The greatest reduction is accounted for by non-ferrous metal works and iron/steel works.

Emissions from lead-containing products during their useful life have been estimated by Bergbäck (1998). Use of lead ammunition leads to a direct release of metallic lead to the environment on the order of 1000 tonnes per year. Fishing sinkers also release metallic lead directly to the environment, which, if it were as great as the annual consumption of lead in sinkers, would be around 600 tonnes. For all other areas of application, a rough calculation arrives at 500 tonnes per annum as the future leach rate from consumption during the period 1986–1995. Dominant sources would be accumulators, glass/ceramic ware, paints, cable sheathing, weights and additives in plastics. This figure is uncertain, however.

Lead emissions from products in Stockholm were calculated in the project *Metaller i stad och land* (see 1.3.4). Another method was used for this, starting from exposed metal surfaces and corrosion rates. According to these calculations, lead emissions are dominated by ammunition and fishing sinkers. Other sources of importance are vehicles and surfaces painted with Falu red ochre paint (Bergbäck et al., 2000). Falu red ochre paint contains lead naturally, unlike other paints to which lead is added actively, as pigment or desiccant. Dissipative losses of lead and other metals from brake linings are dealt with at greater length in section 3.2.1.

Lead is also used in fireworks. The report of the Pyrotechnical Commission states that annual emissions of lead from fireworks amount to about 3 tonnes (SOU 1999:128).

In comparisons of emissions, the fact that the forms of occurrence of lead vary must be taken into account. The lead that is released via vehicle exhaust emissions was much more bioavailable than the lead that was, and still is, released via ammunition.

2.2.4 Estimation of the exposure of the Swedish population to lead

Important sources of lead exposure of the population have been exhaust gases from motor vehicles that use leaded petrol, lead-soldered tins, lead paints and industrial emissions. Since the use of leaded petrol ceased in 1994, the concentrations of lead in the blood of both children and adults have fallen drastically (Vahter, 1998).

Today lead exposure takes place chiefly via diet. Previously, lead-soldered tins and wine bottles sealed with lead were important sources of exposure that way. Today the sources are more hard to identify.

There are isolated cases where individuals are subjected to high lead exposure directly from products today. An example of such a product that was on the Swedish market in 1999 was gel candles with a lead-cored wick, which produced lead fumes as the wick burned. Another example from the USA is that children have become contaminated with high blood lead levels after sucking on necklaces imported from China which were found to contain lead. Exposure to lead can also be a side-effect of casting of lead-containing objects in the home, such as fishing sinkers and tin soldiers.

2.3 Cadmium

2.3.1 Rules, conventions and previous policies

2.3.1.1 Rules and agreements in Sweden and the EU

In the Government Bill *En god livsmiljö* (1990/91:90, English summary available entitled ”A living environment”), presented in 1991, the Swedish Government took the position that use of cadmium must be sharply reduced.

The Government’s new guidelines entail that new products shall be largely free from cadmium within 10–15 years.

Batteries containing more than 0.025 percent cadmium by weight are defined as dangerous for the environment. The Battery Ordinance (1997:645) contains rules for how such batteries may be sold, as such or in products, and how they are to be managed as waste in order to permit recycling. Fees to be charged when batteries are placed on the market for the purpose of covering the costs of recycling are also regulated.

Cadmium for surface treatment and in stabilizers and pigments in plastics was banned in the 1980s. The rules can be found in the Ordinance on Prohibition in Connection with Handling, Importation and Exportation of Chemical Products Etc. (Certain Cases) (1998:944). A number of exemptions from the rules are given in the National Chemicals Inspectorate's regulations KIFS 1998:8. Most of the exemptions apply indefinitely. The Ordinance 1998:944 also contains rules on maximum permissible concentration of cadmium in packaging materials, as well as on the concentration of cadmium in sewage sludge for agricultural purposes.

On joining the EU in 1995, Sweden was granted a four-year exemption allowing the Swedish rules for cadmium, which are more far-reaching than the EU rules, to continue to apply. The exemption was supposed to have expired in 1999, but after negotiations Sweden was allowed to keep its rules for surface treatment, stabilizers and pigments until the end of 2002. Before then, the European Commission will review the common rules in the restrictions directive. Now the results of a risk assessment of cadmium being conducted within the programme for existing substances are being awaited. This assessment may be of great importance for changes in the regulation of cadmium at Community level.

Cadmium can occur in commercial fertilizer as an impurity. The rules in Ordinance 1998:944 state that commercial fertilizer may contain no more than 100 g Cd/t of phosphorus. According to the Act (1984:409) on Tax on Fertilizers (in Swedish only), a tax shall be paid for fertilizers that contain between 5 and 100 g of Cd/t of phosphorus.

Sweden has had an exemption from the EU rules for commercial fertilizer as well. This exemption has now been extended until the end of 2001. A review of the EC's fertilizer directive is currently being carried out by a working group to the Commission.

A directive on producer responsibility for electrical and electronic equipment is currently being framed within the EU. According to the draft of the proposed directive, cadmium shall be phased out of these products by 1 January 2004. Exemptions are made for cadmium on the surface of selenium photocells, as an anti-corrosive agent and in cathode ray tubes for atomic absorption spectroscopy and other instruments for measuring heavy metals. The proposal for a directive on end-of-life vehicles issued by the European Commission also concerns cadmium (see section 2.2.1).

According to the EC's restrictions directive (76/769/EC), implemented in Swedish legislation through KIFS 1998:8, substances with certain risk phrases for cancer, genetic damage and impaired fertility may not occur in chemical products sold to the general public. This pertains to cadmium compounds, since they are classified as carcinogenic and in some cases also toxic for reproduction.

2.3.1.2 UN Convention on Long-Range Transboundary Air Pollution (CLRTAP) – Protocol on Heavy Metals

Within the UN Convention on Long-Range Transboundary Air Pollution, CLRTAP, a Protocol on Heavy Metals was adopted in June 1998 (see section 2.2.1.3). The Protocol covers cadmium, but contains no requirements on phase-out within any specific areas of application.

2.3.2 Use of cadmium in Sweden today – how is the phase-out work going?

2.3.2.1 Batteries

The biggest area of application for cadmium is batteries. Use of cadmium in batteries increased continuously from the 1950s up to the first half of the 1990s. Since then, this use has begun to decline. The Swedish EPA estimates that the quantity of cadmium in sold, closed nickel-cadmium batteries in 1997 was about 60 tonnes, while it was about 35 tonnes in 1998 (Olsson, 2000). The batteries are imported into Sweden, often installed in different products. New batteries, e.g. nickel-metal-hydride and lithium batteries, have replaced or begun to replace nickel-cadmium batteries in most types of consumer products, such as telephones, computers and electric shavers, and now also in electric hand tools. It has been a problem to find alternatives in emergency lighting, since other batteries cannot withstand the high temperatures reached under the casings; but by changing the armatures, the alternatives can be used there as well.

Cadmium batteries are also used in the form of large open batteries for standby power at industrial installations, hospitals etc. The annual consumption of cadmium for such batteries is about 20 tonnes. The recycling rate is high. There are no alternatives at the present time, aside from the option of switching to lead batteries.

2.3.2.2 Surface treatment, stabilizers and pigments

Surface treatment, and stabilizers and pigments in plastics, were previously major uses of cadmium. These uses were banned in the 1980s. There are numerous exemptions, however, and most exemptions apply indefinitely. Use of cadmium within the exempted areas is little. According to the National Chemicals Inspectorate's products register, approximately 500 kg of cadmium was used in chemical products in 1998. The areas of application were metal surface treatment, glazes and enamels, paints and lubricants. Despite the small volumes, artists' paints probably constitute a significant source of cadmium in sewage sludge (Bergbäck et al., 2000).

2.3.2.3 Commercial fertilizer

Cadmium can occur as an impurity in commercial fertilizer. The cadmium concentration varies depending on where in the world the phosphorus in the fertilizer has been mined. We have commercial fertilizer on the Swedish market today that contains around 5 g Cd/t of phosphorus. The relatively low cadmium content is a result of the fact that phosphates with a low cadmium content have been chosen in the production of the fertilizer.

Phosphates with a low cadmium content are a limited raw material, however. During the past few decades, research and development has been pursued for the purpose of developing methods to remove cadmium from phosphates. There are a number of possible methods, and phosphorus purification is also done at several operational plants, but none of these plants purify phosphates intended to be used in commercial fertilizer. Building a plant of this kind requires large production volumes and thereby large markets, which means that more countries must back phosphate purification.

2.3.2.4 Other areas of application

Cadmium can also occur in other products not covered by regulations. For example, the National Chemicals Inspectorate reports the presence of cadmium in automotive brake linings and in photographic paper (Gustafsson, 1996). Cadmium emissions were estimated at several kg per year from each application.

In 1997, the National Chemicals Inspectorate brought attention to the presence of cadmium and lead in the so-called lens blocking compound used in eyeglass manufacture, and in this connection urged Sweden’s eyeglass manufacturers to switch material in the blocking compounds.

A case of use of cadmium-containing alloy in submarine cable was recently debated.

2.3.3 Estimation of emissions to the Swedish environment

As for most other metals, emissions of cadmium from point sources have decreased considerably in the past few decades. Emissions to the atmosphere in 1995 were 0.8 tonne, compared with 12 tonnes in 1977. Equivalent figures for discharges to water were 1.8 tonnes in 1995, compared with 4 tonnes in 1977.

Due to the reduced domestic load, foreign sources currently account for about 80 percent of the airborne deposition of cadmium in southern Sweden. On agricultural land, deposition deriving from foreign and domestic sources together accounts for 2/3 of the annual cadmium input (National Board of Agriculture, 1999).

Commercial fertilizer has previously been a very important source of cadmium input directly to arable soil. In the early 1970s, 3 g Cd/ha and year was added to soil with fertilizer. Today, this input is about 0.11 g Cd/ha.

The spreading of sewage sludge on arable land can give rise to a large input of cadmium locally. The limit value for cadmium in sludge for spreading on arable land was reduced in 1998 to 2 mg/kg dry solids. In Sweden as a whole, nearly 90 percent of the total sludge volume in 1995 complied with this limit value. Since sludge only contains about 3 percent phosphorus, the cadmium content of sludge that lies around the limit value is high compared with the fertilizer that is sold today. The cadmium concentration in sludge that lies around the limit value is 66 mg/kg of phosphorus, compared with 5 mg/kg of phosphorus for commercial fertilizer. A sludge dose of 45 mg Cd/kg of phosphorus, which is the mean value in the sludge currently spread, corresponds to 10–25 years' fertilizing with commercial fertilizer (NPK) from the biggest supplier in Sweden.

The cadmium that is present in sludge comes from products in use, among other sources. Cadmium emissions from products in Stockholm were calculated in the research project *Metaller i stad och land*. The dominant source was motor vehicles, which gave rise to emissions primarily via car washes. These emissions were followed by emissions from artists' paints, street lighting and gardening fertilizer (Bergbäck et al., 2000). It is estimated that around three quarters of the cadmium emissions in Stockholm end up in sewage sludge.

2.3.4 Estimation of the exposure of the Swedish population to cadmium

An important source of cadmium exposure is cigarette smoke. Smokers are therefore a particularly high-risk group, since cadmium in cigarette smoke can be absorbed via the lungs.

For non-smokers, diet is the most important source of cadmium exposure. The average daily intake is around 15 µg, but there are large individual variations depending on total energy intake and dietary habits. For example, a high intake of fibre-rich food or shellfish results in a larger cadmium exposure than a more varied diet. Persons with iron deficiency, who have elevated uptake in the intestines, and persons who regularly eat foods with a high cadmium content are particularly at risk. The concentration of cadmium in wheat kernels probably doubled during the 20th century. The concentration of cadmium in the liver in the Swedish population has increased several times over in the past century. There is nothing to suggest that the exposure of the general population to cadmium will decrease anytime soon (Järup et al., 1998).

2.4 Mercury

2.4.1 Rules, conventions and previous policies

3.4.1.1 Rules and agreements in Sweden and the EU

The Government Bill *En god livsmiljö* (1990/91:90, English summary entitled ”A living environment”), presented in 1991, stated the objective that use of mercury should be discontinued in the long term.

The Government Bill *Bättre kontroll över miljöfarligt avfall* (Gov. Bill 1998/94:163, bet. 1993/94 JoU23, rskr. 1998/94:273) stated the objective that use of dental amalgam should be phased out by 1997. The same Bill also contains an objective regarding collection of end-of-life products containing mercury and final disposal of these products.

The Government Bill *Svenska miljömål* (1997/98:145, English summary entitled ”Swedish Environmental Quality Objectives”) stated as the Government’s appraisal that the use of mercury in the chloralkali industry must cease by 2010. Other use of mercury should be phased out by 2000, with certain exemptions for analytical chemicals and light sources.

The Government’s new guidelines entail that new products shall largely be free from mercury within 10–15 years.

According to the Ordinance on Prohibition in Connection with Handling, Importation and Exportation of Chemical Products Etc. (Certain Cases) (1998:944), mercury is banned in thermometers, measuring instruments etc.

Use of mercury in batteries is regulated by the EC’s battery directive (91/157/EEC), implemented through the Battery Ordinance (1997:645).

A directive is currently being formulated in the EU regarding producer responsibility for electrical and electronic equipment. According to the draft proposal of the directive, mercury shall be phased out of these products by 1 January 2004. Exemptions are made for mercury in fluorescent tubes, lamps and laboratory equipment.

2.4.1.2 UN Convention on Long-Range Transboundary Air Pollution (CLRTAP) – Protocol on Heavy Metals

Within the UN Convention on Long-Range Transboundary Air Pollution, CLRTAP, a Protocol on Heavy Metals was adopted in June 1998 (see section 2.2.1.3). The Protocol covers mercury and contains measures to reduce mercury exposure from products such as batteries. Furthermore, measures are proposed for other mercury-containing products, such as electrical components, measuring devices, fluorescent tubes, dental amalgam, pesticides and paints.

2.4.1.3 OSPAR

There is a decision within OSPAR that chloralkali manufacture according to the amalgam method shall be phased out by 2010 at the latest. Furthermore, there is a decision that mercury thermometers shall be phased out.

2.4.1.4 Individual countries

Denmark has had a general prohibition on sales and exports of mercury and mercury-containing products since 1998. There are a number of general exemptions from the prohibition, some of which are time-limited and others indefinite.

2.4.2 Use of mercury in Sweden today – how is the phase-out work going?

The biggest area of application for mercury is in the chloralkali industry. This is followed by use of mercury in dental amalgam and mercury in batteries and lamps. The input of mercury to society in 1997 is shown in Table 4.

Table 4 Input of mercury to Swedish society in 1997.

Input of mercury to Swedish society in 1997 (National Chemicals Inspectorate, 1998a). Since then, use has declined in several of the areas.

Input to society in 1997 (kg)	
Chloralkali industry	9 000
Dental amalgam	980
Batteries	800
Lamps	152
Regulated products	40–50

2.4.2.1 The chloralkali industry

The chloralkali industry accounts for the biggest input of mercury to Swedish society. Two plants in Sweden still use the amalgam method for manufacturing chlorine and alkali. This method uses mercury. Sweden has acceded to OSPAR's decision that chloralkali manufacture in accordance with the amalgam method shall be phased out by not later than 2010. One of the two Swedish plants that still use mercury has announced that they intend to switch to a mercury-free method prior to 2010.

2.4.2.2 Dental amalgam

The use of amalgam in dental care decreased in the early 1990s and then levelled off. The objective set up by the Government in the Bill *Bättre kontroll över miljöfarligt avfall* (1993/94:163) that the use of amalgam in dental care should cease by 1997 has not been attained. Dental care compensation ceased to be paid for amalgam fillings in 1999, which has made it more expensive to use amalgam. The changed price picture should lead to reduced use of amalgam. But it is still slightly cheaper for the patient in many county council districts to use amalgam than alternative materials.

2.4.2.3 Batteries

Use of mercury in batteries has decreased sharply and was in 1997 almost down to only one-tenth of the amount in 1985. The EC's battery directive was amended in 1998. The amendment entails that batteries with a mercury content in excess of 0.0005 percent by weight are defined as dangerous for the environment. They may not be marketed, as such or incorporated into appliances. Button cells with a mercury content of no more than 2% by weight are exempted from this prohibition.

The new rules mean that mercury oxide batteries may no longer be sold. Mercury oxide batteries accounted for 700 kg of approximately 800 kg of mercury in batteries in 1997. The new rules have therefore led to a very sharp reduction in sold quantities of mercury in batteries. The amount of mercury in sold batteries for 1999 is estimated to be around 100 kg (Olsson, 2000). The collection rate for button cell batteries lies around 50 percent.

2.4.2.4 Light sources

Mercury is used in various kinds of discharge lamps, such as fluorescent tubes and low-energy lamps. The total quantity of mercury in light sources has declined slightly in the past few years. The total quantity of mercury in light sources sold in Sweden in 1995 was 150 kg, and declined to 117 kg in 1999 (Frantzell, 2000).

Product development is being pursued for the purpose of finding mercury-free solutions. Today there are high-pressure sodium lamps and other lamps for outdoor use that are mercury-free. Mercury-free flat fluorescent tubes that can be used in e.g. computers have also been developed. Adequate technical alternatives to mercury in ordinary fluorescent tubes and low-energy lamps are still lacking, however. The concentrations of mercury in fluorescent tubes has been reduced in recent years, but an equivalent development has not occurred for low-energy lamps. At the same time, there is an interest in increasing the use of this type of light source, since they are energy-saving in relation to ordinary incandescent light bulbs. New areas of application are also being added. Recently, certain car manufacturers have begun using headlamps containing mercury.

2.4.2.5 Certain other products

The use of certain mercury-containing products was regulated in 1991. These rules are now incorporated in the Ordinance on Prohibition in Connection with Handling, Importation and Exportation of Chemical Products Etc. (Certain Cases) (1998:944). According to the Ordinance, commercial manufacture, sales and use of e.g. thermometers, level switches, pressure switches, thermostats, relays and electric circuit breakers containing mercury is prohibited. The National Chemicals Inspectorate has estimated that new use in regulated products was 40–50 kg in 1997 (National Chemicals Inspectorate, 1998a), which is a sharp reduction compared with before the regulation.

2.4.3 Estimation of emissions to the Swedish environment

Emissions of mercury from point sources have declined considerably in recent decades. Emissions to the atmosphere were estimated to be 7 tonnes in 1977, compared with 0.9 tonne in 1995. An equivalent comparison cannot be made for discharges to water, since the statistics for different years are gathered in different ways.

The dominant source of emissions and discharges is dental amalgam. Of the 900 kg of mercury that was emitted to the air in 1995, nearly 300 kg came from crematoria, where the mercury derives from dental amalgam. Mercury also gets into wastewater as a result of wear of fillings in teeth. This total flow has been estimated at about 45–150 kg/year. Amalgam is the predominant source of mercury in sewage sludge (Bergbäck et al., 2000).

Other atmospheric emissions come mainly from the chloralkali industry, combustion of fossil fuels and biofuels, iron and steel works, and waste incineration. Discharges to water are dominated by municipal sewage treatment plants, from which total discharges in 1995 lay in the range 100–500 kg, amalgam included.

As a result of the reduction in domestic emissions of mercury, 80% of the atmospheric deposition of mercury over southern Sweden now derives from airborne transport from other countries. The total deposition of mercury over Sweden, from domestic and foreign sources together, is around 4 tonnes per annum, about one-tenth of which is estimated to come from finished products.

2.4.4 Estimation of the exposure of the Swedish population to mercury

Dental amalgam comprises the largest source of exposure of the general population to mercury. Consumption of fish from certain areas can lead to considerable exposure to methylmercury. It is estimated that half of the nation's lakes (about 40 000) have pike with mercury concentrations above 0.5 mg/kg, which is the limit value recommended by Codex Alimentarius (the UN food agency). Both mercury vapour and methylmercury are readily transferred between mother and foetus, which is serious since foetuses are extra sensitive to mercury. The National Food Administration has issued dietary recommendations saying that girls and women of childbearing age should limit their consumption of lake fish.

3 Some metals with high use (copper, zinc, chromium and nickel)

A general review of areas of application and emissions of the four metals in Sweden is done in section 3.1. A more detailed review of the areas of application of the greatest importance for the diffuse emissions of the metals follows in section 3.2. These areas of application have mainly been selected with the aid of the calculations done in the project *Metaller i stad och land* (Bergbäck and Johansson, 1994). Emissions from certain areas were, however, not quantified in the project, so there may be other important sources than those reported here. Finally, the effects of the metals are dealt with in section 3.3.

3.1 Use and emissions

3.1.1 Copper

Use

The total accumulated quantities of copper in Swedish society – in use and as waste – have been calculated to be about 2.2 million tonnes. Consumption of copper in Sweden has increased sharply. According to official statistics, which only provide an approximate measure since they include exported quantities, consumption increased from about 75,000 tonnes/year at the beginning of the 1950s to about 160,000 tonnes in 1995.

The total recycling rate can be calculated in different ways. If it is related to total consumption 40–45 years ago, when many of the copper products which are entering the waste stream today were produced, it is 60–70 percent (Landner and Lindeström, 1999).

Mining of copper gives rise to large quantities of mining wastes. The quantity depends on how high-grade the mined ore is. For each tonne of copper produced in Sweden, 600 tonnes of mining wastes are produced (Swedish EPA, 1998). The World Resource Institute has calculated the average waste quantity to be 250–300 tonnes per tonne of useful copper (Adriaanse et al., 1997). Copper is used in Sweden mainly in the electrical and electronics industry, for manufacture of cable, wire, transformers and motors. The construction industry is a large copper consumer, for products such as roofing, pipe and cable.

The fraction of copper that ends up in consumer products is about 13 percent. Approximately 1 percent goes to production of chemical compounds. Among the chemical products that contain copper compounds are wood preservatives and certain other pesticides, pigments, metal coating compounds and fertilizers (Landner and Lindeström, 1999).

Emissions

Point emissions of copper to air were calculated to be 10 tonnes, and discharges to water 50 tonnes, in 1995. Emissions to air were dominated by non-ferrous metal works and incineration. Discharges to water were dominated by mining wastes, followed by municipal sewage treatment plants and the pulp and paper industry (Statistics Sweden, 1999).

Road traffic accounts for the greatest diffuse emissions of copper, from wear of tyres and asphalt surfaces, but above all from abrasion of brake linings. The total release of copper from road traffic can be estimated at about 90 tonnes per annum, of which brake linings account for about 75 tonnes per annum (Landner and Lindeström, 1999).

The use of copper in pesticides gives rise to a release to the environment which may be more or less drawn-out over time. Use as a plant protection product leads to a direct release to the environment at the time of use, use in marine antifouling paints leads to a release spread out over several years, while use for wood preservation leads to a release that is spread out over several decades. The total consumption of copper in pesticides is about 290 tonnes per year.

Copper is also released via corrosion from roofing, cladding and water supply systems. The rate of release is dependent on such factors as the presence of contaminants in rainwater and the chemical composition of the drinking water. The total influx of copper from these sources to surface water has been estimated by Landner and Lindeström (1999) to be around 7 tonnes per year. In addition, these sources contribute to the copper concentrations in sludge from the sewage treatment plants. In the City of Stockholm alone, it is estimated that approximately 4 tonnes of copper reaches sewage sludge from the tap water system every year (Bergbäck et al., 2000).

Emissions and discharges of copper from products in the City of Stockholm have been calculated in *Metaller i stad och land*. The relationship between different sources is slightly different in a city than when counted for the entire nation. In Stockholm, tap water pipes were calculated to be the largest source, followed by emissions from brake linings and then by aerial power lines and roofing and cladding (Bergbäck et al., 2000).

3.1.2 Zinc

Use

The total accumulated quantities of zinc in Swedish society have been calculated by Landner and Lindeström (1998) to be 630 000 tonnes, and the quantity of zinc that has entered the waste stream to date has been calculated to be around 1 400 000 tonnes. The Swedish EPA (1996) calculates the accumulated quantity of zinc in Swedish society to be 2 500 000 tonnes. Swedish consumption of zinc in 1994 was 36 000 tonnes, which was slightly lower than at the end of the 1980s. In 1996, the quantity of recycled zinc amounted to 36 percent of new production. If the recycled amount is related to production 31 years ago (which is the mean service life of zinc in products), 70 percent was estimated to be recovered (Eriksson, 2000).

The predominant area of application for zinc is galvanization of steel and other corrosion protection. This is followed by brass products (brass is an alloy based on zinc and copper), die-cast products, paints, activators for vulcanization of rubber tyres, other chemicals, dry cell batteries, sacrificial anodes and feedingstuff additives.

Emissions

Point emissions of zinc to air in 1995 amounted to 140 tonnes, while point discharges to water amounted to 580 tonnes. The largest sources of emissions to air were the engineering industry, followed by combustion (industrial and in housing) and iron and steel works. By far the dominant source of discharges to water was mining wastes. Other sources were the pulp and paper industry, municipal sewage treatment plants and the rayon industry (Statistics Sweden, 1999).

Diffuse emissions of zinc can be estimated at around 1 000 tonnes per year. The predominant source of diffuse emissions is corrosion and runoff from products of galvanized steel. Other important sources are abrasion of automotive tyres, brake linings and asphalt, and household waste (Landner and Lindeström, 1998).

Emissions and discharges of zinc from products in the City of Stockholm have been calculated in *Metaller i stad och land*. The greatest emissions come from tyres, followed by galvanized surfaces on products in the infrastructure, e.g. posts and rails, and galvanized sheet used for roofing and cladding. Other sources are sacrificial anodes on boats, tap water systems and brake linings (Bergbäck et al., 2000).

3.1.3 Chromium

Use

The principal use for chromium is in stainless steel. Annual consumption of stainless steel in Sweden more than quintupled from the end of the 1950s to the mid-1990s.

Total net imports of chromium to Sweden during the period 1900–1992 have been calculated by Palm et al. (1995), based on official statistics, to be about 2 000 000 tonnes, which is completely dominated by chromium in steel. An unknown percentage of this influx has entered the waste stream. The Swedish Ironmasters’ Association and Avesta

Sheffield (in Walterson, 1999) estimate, from their own statistics, the accumulated quantity of stainless steel in Sweden to be about 800 000 – 1 000 000 tonnes. The chromium quantities in the steel can vary, but a common alloying rate is 18 percent. If the content of chromium in the accumulated quantity of steel is assumed to be 18 percent, then the estimated quantity of chromium in stainless steel in society, based on industry statistics, is 144 000 – 180 000 tonnes.

During 1996, 50 percent of the chromium need for steelmaking in Swedish steel works was met by recycled material.

Chromium is also contained in wood preservatives. Consumption of chromium in wood preservatives was 258 tonnes in 1996. According to Statistics Sweden, consumption of chromium-containing chemicals has decreased substantially during the 1990s. Examples of areas of application for chromium-containing chemicals are tanning of leather, chromium-plating, metal surface treatment, synthesis intermediates and paints. A reason for the reduced use of chromium in the tanning industry is that the number of Swedish plants that tan leather has declined. Tanned leather products are instead imported, and chromium thus enters the country in the products rather than as a chemical.

Emissions

Point emissions of chromium to air in 1995 amounted to 14 tonnes, while point discharges to water totalled 11 tonnes. Emissions to air were dominated by ferroalloying works, iron and steel works, combustion and the engineering industry. Predominant sources for discharges to water were mining wastes, the pulp and paper industry, municipal sewage treatment plants and iron and steel works (Statistics Sweden, 1999).

Walterson (1999) estimates diffuse chromium emissions and discharges from Swedish society to air and water to be about 60 tonnes, of which 35 tonnes come from wear of asphalt surfacing on roads. The next most important source is wood preservatives. Considering the use profile for stainless steel, the industry estimates that dissipative release of chromium is about 3 tonnes per annum.

Emissions of chromium from products in the City of Stockholm have been calculated in *Metaller i stad och land*. The greatest emissions come from tyres and road surfacing. Emissions from preservative-treated wood, cement, paints, etc. have not been estimated (Bergbäck et al., 2000)

3.1.4 Nickel

Use

Nickel, like chromium, is primarily used in the production of stainless steel. Net imports of nickel during the period 1960–1992 have been estimated by Palm et al. (1995) from official statistics to be just under 400 000 tonnes, and are dominated completely by stainless steel.

If a similar calculation is done as for chromium, based on industry statistics for quantities of stainless steel in use and a normal nickel alloying rate of 8 percent, the accumulated quantity of nickel in Swedish society is 64 000 – 80 000 tonnes.

Areas of application of nickel, aside from stainless steel, are e.g. other alloys, castings, nickel-plating, batteries (nickel-cadmium, nickel-iron and nickel-metal-hydride) and catalysts.

Emissions

Emissions to air of nickel from point sources in 1995 amounted to 32 tonnes, while point discharges to water totalled 15 tonnes. Emissions to air were dominated by combustion, followed by iron and steel works. Discharges to water were dominated by municipal sewage treatment plants, the pulp and paper industry and iron and steel works (Statistics Sweden, 1999).

Walterson (1999) estimates diffuse nickel emissions and discharges from society to air and water to be about 40 tonnes per annum. Road traffic accounts for 21 tonnes and is dominated by wear of asphalt surfacing. This is followed by leaching from agricultural land (9 tonnes per annum) and from municipal landfills (4 tonnes per annum). Leaching from stainless steel is estimated at 2 tonnes per annum.

Emissions and discharges of nickel from products in the City of Stockholm have been calculated in *Metaller i stad och land*. Just as for chromium, the greatest emissions come from road surfacing and tyres (Bergbäck et al., 2000).

3.2 Areas of application of great importance for diffuse emissions

3.2.1 Brake linings

The composition of brake linings varies between different manufacturers. In an assignment for the Environmental Administration in Stockholm, SBL-analys (Stockholms buller och luftanalys = Stockholm Noise and Air Analysis) has investigated the metal content of brake linings from a large number of motor vehicle models (SBL-analys, 1998). As a rule, the linings contain high concentrations of copper (around 10 percent of the total weight), lead and zinc. There are, however, certain brake linings that contain very low concentrations of copper and lead. The zinc concentrations are also lower in some of these. Brake linings with low concentrations of copper, lead and zinc are available for cars, trucks and buses.

In May 1999, the Swedish EPA requested a report from the Association of Swedish Automobile Manufacturers and Wholesalers on the possibilities of phasing out copper in brake linings. The Association replied that the changeover time for brake linings is long and that Sweden has few means to influence the situation, with reference to the EC directive on type-approval of motor vehicles. The Association has initiated a project at IVL (the Swedish Environmental Research Institute) concerning metal emissions from road traffic. The Association believes that this can give Sweden additional evidence if they wish to bring up the issue in the EU[1].

3.2.2 Tyres

Zinc is used together with fatty acids as an activator in the vulcanization of the rubber used in tyres. Emissions of zinc oxide from tyres in Sweden amount to around 150 tonnes per annum (Duus and Ahlbom, 1994). There are no obvious alternatives to zinc as an activator, nor is any active research and development being pursued in the area.

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[1] Correspondence between the Swedish EPA and the Association of Swedish Automobile Manufacturers and Wholesalers, Swedish EPA’s record number 558-2982-99Hk

Use of zinc has nevertheless been reduced. Before it was common to add an excess of zinc oxide in the process, but over the past ten years most manufacturers have optimized the use of zinc oxide, so that zinc oxide is now added in just the right quantity.

The European tyre industry organization, BLIC (Council of Liaisons of the Rubber Industry of the EU), has brought up the issue of zinc. BLIC is planning, in cooperation with the zinc industry, to conduct a study of the short- and long-term effects of zinc emissions from tyres.

Tyres are also a source of emissions of other metals – mainly chromium, copper, lead and nickel. Annual emissions of these metals via abrasion of tyres are, however, in the order of a hundredth of the emissions of zinc. No metals other than zinc are added actively to tyres. The presence of other metals stems from the fact that they occur as impurities in other components in tyres, e.g. in the petroleum-based oils (HA oils) which certain manufacturers still use as plasticizers in the rubber. Metal compounds may also be present in various process chemicals used in rubber manufacture.

3.2.3 Building materials

Building materials are an important source of copper and zinc emissions. The largest emissions of copper from building materials come from water pipes, while zinc emissions are dominated by losses from zinc-coated surfaces in the infrastructure.

Water pipes

The greatest leaching of copper from building materials comes from tap water pipes. Tap water pipes are a major source of copper in sewage sludge, and copper also affects the drinking water, although it is uncertain whether or not this has given rise to any adverse health effects (Environmental Health Commission, SOU 1996:124).

Efforts are under way in the City of Stockholm, as well as in some other major Swedish cities, to find alternatives to copper in water pipes. Stainless steel is one alternative. It is used today in sewage treatment plants and to some extent in industry and district heating systems. Stainless steel contains nickel and chromium and can thereby give rise to some leaching of these metals. Another alternative is various plastic materials, mainly polyethylene or polypropylene. An important prerequisite for such alternatives is that dangerous additives do not leach from them. There are no deadlines for when use of copper pipe must cease.

Zinc also leaches from tap water pipes. The source is iron pipes coated on the inside with zinc. Iron pipes were more often used during the first half of the 20th century than later.

Zinc as an anti-corrosive agent

Zinc is used as a rust inhibitor on many surfaces of iron and steel. The steel can be coated with zinc in production by electrolytic precipitation (galvanization). Another method is hot-dip galvanizing, whereby the item to be galvanized is immersed in molten zinc. New and existing structures can be painted with zinc-containing anti-corrosive paint. Examples of structures whose surfaces may be treated with zinc are roofing and cladding, power line poles, lampposts, contact line poles along railways, guard rails and bridges.

The durability of surfaces coated with zinc as new is generally long. The National Road Administration estimates that a bridge painted with zinc-containing paint when new does not need to be repainted for 50–60 years (Thorén, 1999). Coating new steel with zinc is by far the leading method of preventing corrosion. Alternatives to zinc galvanizing exist in the research stage. Organically based alternatives are, for example, being developed in the USA.

When zinc paints are to be used for touch-up, a clean substrate is essential for good results. Existing anti-corrosive paint is then blasted off, resulting in a waste consisting of blasting sand and old anti-corrosive product. So-called red lead was previously used for touch-up on existing structures. Zinc-containing anti-corrosive agents have taken the place of red lead for environmental reasons. There are also other anti-corrosives that contain neither lead nor zinc. Examples are oils that create an impervious layer on the metal surface, such as linseed oil and fish oil. The National Road Administration has tested a system based on linseed oil, but arrived at the conclusion that repainting is necessary after only 10 years. Within the National Rail Administration, painting with linseed-oil-based systems comprises one percent or so of the total use of anti-corrosive agents. The systems are inexpensive and can be used on objects that will soon be replaced or in environments where corrosion is naturally very slow, such as in Norrland (Kristensson, 1999).

3.2.4 Pesticides

Marine antifouling paints

Copper is an active ingredient in many marine antifouling paints and other paints for preventing marine growth. The National Chemicals Inspectorate has decided not to grant approval for products for use on pleasure craft and other vessels mainly operated on the east coast of Sweden starting in 1999. Products with limited copper leaching will be approved for use on the west coast through 2001. Certain exemptions have been granted for the east coast that permit sale during 1999 and 2000. Special rules apply to vessels over 12 metres in length.

Wood preservatives

There are different types of wood preservatives. Many of them contain copper, arsenic and/or chromium. Some are even zinc-based.

Certain wood preservatives are intended for industrial pressure treatment and may not be used by private consumers. The pressure-treated wood is divided into different classes for use in different environments. The National Chemicals Inspectorate’s Chemical Products and Biotechnical Organisms Regulations (1998:8) contains rules on how preservative-treated wood is to be handled. Wood treated with compounds of chromium or arsenic may, for example, only be used when long-term protection is required. There are no such general rules regarding copper.

The wood preservatives which private consumers are allowed to buy to treat wood themselves may contain zinc naphthenate, zinc decanoate or copper naphthenate.

The use of chromium, arsenic and copper in wood preservatives has been relatively constant during the 1990s. Development in the field has been limited by the lack of alternatives.

Wood preservatives are biocidal products and will therefore be subject to the examination of such substances that will take place within the framework of the EC’s biocidal products directive (98/8/EC). All biocidal products will be assessed during a ten-year period, and those substances that can be used in the EU will be entered in Annex 1 to the Directive. It is probable that wood preservatives will be one of the first substances to be assessed, which means that EU-wide assessments of these substances should be available around 2003. There is some possibility for refusing authorization to preparations containing substances in Annex 1 in the national examination of biocides, e.g. with reference to climatic factors, but that possibility is relatively limited.

3.2.5 Miscellaneous

It was concluded in *Metaller i stad och land* that wear of asphalt is a large source of dissipative release of many metals. Asphalt represents a large portion of the total diffuse emissions of chromium and nickel. The metals occur naturally in the fractions contained in asphalt, i.e. gravel particles and bitumen.

Zinc is released from sacrificial anodes, which can be used in various applications to protect objects from corrosion. Sacrificial anodes are, for example, used on boats to protect hulls and propellers. The zinc that is emitted ends up directly in the marine environment.

3.3 Can copper, zinc, chromium and nickel be expected to have adverse effects on health and the environment?

Copper, chromium and zinc are essential metals, which means that they are needed by living organisms in small quantities. The same applies to nickel – at least for certain organisms. At the same time, all four metals have toxic and ecotoxic effects that are well-documented from laboratory studies. The four metals and their compounds are all included on the so-called ”Sunset List” prepared by the National Chemicals Inspectorate of substances that are dangerous to both health and the environment (National Chemicals Inspectorate, 1994a).

A cursory review of the problems which can be caused by use of the four metals is presented in this section. An actual risk assessment, where all exposure situations are weighed against the effects of the metals, is not performed. Such an assessment is a very extensive undertaking, and risk assessments are currently being conducted within the EU programme for existing substances (see section 1.5.2).

The problem picture in brief

The problem picture regarding copper, zinc, chromium and nickel has undergone a shift in recent decades. Emissions from point sources have decreased as a result of the measures taken, while emissions from products in use have not been targeted to the same extent.

Metals are released today for the most part from areas where metals are in use, for example in cities and along highways. In these environments, metal concentrations in soil are increasing, and there are indications that the copper concentrations outside Stockholm are already so high that they may have effects. In the sea, copper is released from antifouling paints, and the copper concentrations in marinas are so elevated that effects on bladder wrack can be feared. The concentrations of copper in sludge are above the limit values in approximately 10 percent of the produced quantity of sludge, and then prevent the sludge from being used on agricultural land. The situation regarding zinc, chromium and nickel is similar.

Aside from in the densely populated areas, local problems exist near mining and metalworking facilities. Old mine dumps are still important sources of metal contamination. Currently active waste landfills comprise a smaller problem, but will eventually require action by future generations so that the metals used by us and generations before us will not contaminate the environment.

In areas that are unaffected by local sources, copper, zinc, chromium and nickel have not given rise to any known problems in forest soil or lakes, i.e. the problem of long-distance transport is not as great for these metals as for lead, cadmium and mercury.

Allergies caused by nickel in particular, but also by chromates, are a large-scale health problem in the general population. Otherwise there is no research showing that current use of the four metals leads to such exposure that it entails a health problem for the general population. Based on previous experience, however, care should be taken in using metals in such a way as, e.g. in the case of brake linings, that they give rise to a fine metal-containing dust that is disseminated in traffic environments where many people are present.

Occurrence and effects in the environment

When metal concentrations in the environment are studied, it can be concluded that a clear shift has taken place in the problem picture in recent decades. Sharp reductions of point-source emissions have been achieved. This has increased the relative importance of leaching of metals from products. Table 5 shows releases of copper, zinc, chromium and nickel in Stockholm from products and from industry.

Table 5 Emissions of metals in Stockholm in 1995.

Emissions of metals from products and industry in Stockholm in 1995, tonnes per year. Question marks indicate that further sources may exist that have not been quantified (Bergbäck et al., 2000).

	Products	Industry
Copper	12+?	0.2
Zinc	24+?	0.05
Chromium	0.8+?	0.05
Nickel	0.6+?	0.05

The concentrations in the aquatic environment in Stockholm are clearly elevated compared with the areas around the city. The copper and zinc concentrations in sediments in Lake Mälaren and the Baltic Sea near Stockholm are lower today than in the 1970s, but are still 3–4 times higher than in the surrounding area (Östlund et al., 1998). If the concentrations are compared with the Swedish EPA’s quality criteria for lakes and watercourses, the copper concentrations are to be regarded as high and the zinc concentrations as moderately high.

The concentrations in the groundwater are also elevated in Stockholm compared with normal levels in forested areas. The elevation is 10 times for copper and 3–4 times for chromium and nickel (Bergbäck et al., 2000).

The metal concentrations in soil around Stockholm are increasing. When the concentrations increase, the risks of harmful effects also increase. Investigations indicate that the copper concentrations in soil ten or so kilometres from Stockholm, which has been affected by traffic, are already elevated in such a manner that soil respiration has been impacted (Bringmark and Bringmark, 2000).

Soil respiration reflects the biological activity in the soil – when soil respiration decreases, the rate of release of nutrients in the soil decreases, which in turn affects the vegetation. Metals added to the soil remain there for a very long time. This means that the ”braking distance” for effects in soil is long, i.e. it takes a long time for the levels to fall, even if sharp reductions occur in emissions.

In the aquatic environment, copper can cause effects even at low concentrations. Studies have shown that a temporary increase in the copper concentrations to 2.5 µg/l is sufficient to seriously affect the reproduction of bladder wrack, which is a very essential species for the whole coastal ecosystem. The copper concentrations in the water have been measured in marinas on both the east and west coasts and were found to be 2–3 µg/l at the time of the measurements (National Chemicals Inspectorate, 1998b), i.e. the levels are so high that effects can be anticipated. Antifouling paints on boats are an important source of copper in these environments. The concentrations in Norrström (in downtown Stockholm) are also so high that effects can be feared [2].

It is primarily the free copper ion that causes effects in the aquatic environment. Studies have shown that the concentration of free copper ions can increase dramatically when the substances which copper binds to are saturated. These substances are normally present in concentrations only slightly higher than the total concentration of copper, as a result of which small increases in the total concentration can give drastic changes in the concentrations of bioavailable copper (Sternbeck, 2000).

It is also probable that copper can under certain conditions form organic complexes (e.g. with amino acids) with low polarity and high bioavailability (Campbell, 1995). Uptake of metals (e.g. copper) via food in aquatic animals can exceed uptake from the water and be solely responsible for poisoning of fish and other animals (Woodward et al., 1994; Schleket and Luoma, 2000).

Considering Sweden as a whole, deposition of airborne metals, from domestic and foreign sources, declined continuously from the mid-1970s until today. Deposition has been monitored by analyzing the metal content of moss every fifth year since 1975.

Johansson et al. published a study in 1995 of the metal concentrations in

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[2] Data on concentration from SLU (Swedish University of Agricultural Sciences), http://info1.ma.slu.se/ma/www_ma.acgi$Station?ID=Intro&S=137

Swedish forest soil. The concentrations of lead, cadmium and mercury were several times higher than the natural background levels. The concentrations of copper and zinc, on the other hand, were at the most twice as high as the background levels, with the exception of areas with mining or metalworking plants, where the increase was greater. Tyler (1992) has stated that effects on the microorganisms in the soil can occur at a concentration increase for copper and zinc of 3–5 times the background values. In view of present-day knowledge, it can thus be feared that copper and zinc may have caused effects on the ecosystem in Swedish forest soil far from sources.

A national inventory of Sweden's lakes was conducted in 1995, including metal analyses of water from 1 165 lakes. The Swedish EPA has published quality criteria that indicate at what metal concentrations effects can occur in lakes and watercourses. As a rule, the concentrations of copper, zinc, chromium and nickel lie below the levels that cause effects. There are, however, certain exceptions when it comes to copper and zinc. The highest zinc concentrations are found in acidified areas and can be explained by the fact that zinc becomes extra mobile under acidic conditions and leaches out of the soil. The highest copper concentrations in the study were measured in lakes without any direct source of pollution. The explanation for the high concentrations may be natural variation.

In addition, studies have been made in lakes that are locally impacted by copper and zinc from e.g. mining tailings. Effects have been found in these lakes on e.g. plankton communities and benthic fauna (Swedish EPA, 1998).

Metals as obstacles in nutrient cycles

Phosphorus is a non-renewable resource. In the Government Bill *Svenska miljömål* (1997/98:145, English summary entitled ”Swedish Environmental Quality Objectives”), the Government makes the appraisal that future sustainable water supply and sewage systems should be designed so that closed-loop cycles are created between society and agriculture for nutrients and humic substances, above all phosphorus. The objective is simultaneously that sludge use shall not lead to negative health or environmental effects, either in the short or long term. Sludge from sewage treatment plants contains metals in varying concentrations. The sludge's metal content can thus put limitations on spreading of the sludge on agricultural land to close the loop for phosphorus. The Ordinance on Prohibition in Connection with Handling, Importation and Exportation of Chemical Products Etc. (Certain Cases) (1998:944) specifies which concentrations of the four metals may not be exceeded in sludge to be spread on arable land. According to information from the Swedish EPA, approximately 10 percent of the total quantity of sludge in 1995 had copper concentrations in excess of current limit values. The equivalent percentages for zinc, chromium and nickel were about the same.

Metals on dumps and landfills

Judging from metal use today, it can be assumed that most of the used quantities will, when they finally leave the ecocycle, end up on dumps and landfills. The metals can then be leached by water from the dumps/landfills at a rate determined by how old the dump/landfill is, i.e. what evolutionary stage it is in, how it is constructed and what other materials it consists of. The greatest risk of leaching is associated with mine dumps, and older mine dumps are important sources of metal contamination. But metals are also leached from landfills for household waste.

To limit the spread of dangerous substances, leachate from many newer landfills is collected and treated. Leaching of metals from active landfills is so low today that it only has a very marginal effect on metal pollution. However, leaching can be expected to continue for several thousand years, which means that the need of landfill maintenance to ensure that metals will not escape into the environment is very long-term.

Health effects

Certain metals can cause allergies. Nickel is the most common cause of contact allergy in the industrialized world. More than 10 percent of women and 2–5 percent of men are allergic to nickel. We know that nickel allergy is increasing, particularly among young women. It is well-known that nickel allergy symptoms can be provoked by jewellery and watches, for example. Nickel can also cause hand eczema. In a study of hand tools carried out in 1995, it was found that 27 percent of the hand-held tools that have metal parts that come into contact with the skin emitted nickel to such an extent that normal handling entails a risk of contact allergy (Lidén and Röndell, 1997).

Unlike nickel, chromium in metallic form does not cause allergies. Chromates, however, are allergenic. Previously, contact allergy caused by chromates was mainly an occupational health problem that afflicted construction workers who handled chromium-containing cement. Better occupational hygiene, in combination with regulation of the chromium content of cement, has reduced the incidence of allergy cases. But chromium allergy is still a problem. A Danish study showed that approximately a half a percent of the population were allergic to chromates (Nielsen and Menné, 1992). Today, many women are also affected. This suggests other causes of the allergy. Chromium-tanned leather might be one cause.

Several studies have been done regarding health effects of copper in drinking water. They have mainly been focused on infant diarrhoeas. In a study recently performed in Uppsala and Malmö, the relationship between infant diarrhoeas and the copper content of the water was examined. But no relationship could be found between the incidence of infant diarrhoeas and the copper content of the water (Pettersson and Rasmussen, 1997 and 1999).

Like other substances, metals can cause direct poisonings, both in the home and in the working environment. The Swedish Poisons Information Centre has studied poisoning cases in the home from 1996 (National Institute of Public Health, 1998). Poisonings with moderate symptoms led as a rule to medical care, and in one-fourth of the cases to hospitalization for a few days. Some ten or so such poisonings were caused by metals or metal compounds, usually ”metal fume fever” in conjunction with welding. There were no serious or life-threatening poisonings and no deaths occurred.

Otherwise there are many knowledge gaps with regard to actual health effects of metals. It is unclear whether present-day use entails a health problem for the general population. Knowledge is lacking regarding the degree to which humans are exposed, from what sources the exposure takes place, and whether it is a health risk in view of the intrinsic toxic properties and form of occurrence of the metals.

4 Other metals including the so-called ”new metals”

This chapter provides a description of the occurrence of other metals, with an emphasis on the so-called ”new metals”. The term ”new metals” has come to be used for those metals that have been used to a small extent in the past, but which, due to new technology (e.g. electronic products), have acquired increasing use. The concept is not strictly defined, but may also include other metals whose health and environmental risks have previously received little attention. Both of these groups will be dealt with in this section.

The efforts that have so far been made to trace the flows in society and the health and environmental effects of metals have only focused to a limited extent on these metals. The lack of knowledge regarding their occurrence and effects is therefore still great.

A knowledge compilation regarding health and environmental effects, use, waste management and emissions of 18 ”new metals” has been performed by Sternbeck and Östlund (1999). Based on the data that have been gathered on the different metals, Sternbeck and Östlund point out groups of metals for which it is particularly urgent to increase the recycling rate and knowledge of flows and effects. This group comprises silver, bismuth, indium, palladium, platinum, antimony, selenium and tellurium. Appendix 7 gives examples of how these metals are used.

Influx to society

In a 10–20-year perspective, global production, and probably also Swedish consumption, of silver, indium, palladium, platinum, antimony, selenium, tellurium, and vanadium have increased markedly. This probably also applies to germanium, gallium and thallium. Production of bismuth, barium and titanium has been stable, while the trend for arsenic has been clearly downward during the same period (Sternbeck and Östlund, 1999).

Metals are also present in fossil fuels, which when burned give rise to direct emissions of the metals to the environment in varying degrees. If the metal influx to society via consumption of products is compared with the input via coal and oil, the latter source dominates for thallium and gallium. For barium, beryllium, lithium, selenium and vanadium it is unclear which source is of the greatest importance (Sternbeck and Östlund, 1999).

The relationship between consumption and natural weathering can, even if both measures are not completely comparable, provide a rough picture of the importance of the anthropogenic quantities. Consumption of silver, bismuth, palladium, platinum, antimony and tellurium exceeds the rate of natural weathering by at least as much as it does for cadmium or copper (Sternbeck and Östlund).

Occurrence in sludge

Emissions of metals can take place when they are being used as chemical products or in finished products. One sign of this is that the concentrations of silver, bismuth, palladium, antimony, selenium, tellurium, and in some cases indium, are markedly elevated in sediments and sewage sludge. The platinum concentrations in sludge from road surface water reservoirs are also greatly elevated (Sternbeck and Östlund, 1999). There are no rules today restricting the presence of these metals in sewage sludge spread on arable land.

Analyses of a large number of metals in moss, mor[3] and digested sludge have also been carried out at the Institute for Applied Environmental Research (ITM). The results of these analyses are presented in a preliminary report (Lithner and Holm, 2000). The study showed particularly elevated levels of silver, gold, antimony, bismuth and tungsten in digested sludge.

On the basis of ITM’s analyses, Wallgren (2000) has roughly calculated how long it would take to double the concentrations of different metals in arable soil if 1 tonne of sludge per hectare is spread annually and there is no removal. For silver this would take less than 10 years. For tungsten and gold it would take 10–100 years. Among the metals for which doubling would take 100–1000 years are bismuth, molybdenum, selenium, tin, thallium, uranium, rhodium, platinum, antimony and tellurium.

[3] In a podzol (ordinary coniferous forest soil), the uppermost layers consist primarily of organic matter. The uppermost layer is called litter (organic debris) and consists of plant remains that have begun to decompose. Below this comes the *mor*, which consists of older plant remains in which decomposition has progressed further.

Waste and recovery

For most of the metals, the potential for environmental contamination is probably greatest when they become waste. If the metals are present in products that go to incineration, it is theoretically possible that they can be emitted with the flue gases. Data on this are lacking, however.

The potential for recovery of these metals is often limited by the fact that they comprise a very small fraction of the products in which they are incorporated. Dismantling and reprocessing are therefore necessary to recover the less common metals, and the procedure can be expensive. The recovery potential of the more precious metals is greatest, since there are clear economic incentives for their recovery.

Long-range transport

ITM’s study of moss and mor (Lithner and Holm, 2000) reflects the deposition of various metals. The study showed a long-range transport of arsenic, selenium, molybdenum, antimony, thallium, bismuth, germanium, indium, silver, tungsten and tin.

Local concentrations and local sources

A soil geochemical and biogeochemical mapping of the country has been under way at the Geological Survey of Sweden (SGU) since the 1980s (Andersson et al., 1997, and Holmberg et al., 1999). The study shows with high resolution the occurrence of various elements in soil and the metal concentration in aquatic plants (mosses, plant roots, etc.). Local differences can usually be explained by natural variations in bedrock composition, but in cases where high metal concentrations in biological material cannot be explained by the composition of the bedrock or the soil layers, it can be assumed on good grounds that they have anthropogenic causes.

The Committee does not analyze local differences in metal concentrations, but concludes that SGU’s mapping provides data for identifying local sources of metal contamination.

Health effects

Several of the metals in the group can cause allergies. Around 1 percent of the Swedish population are allergic to cobalt, which means that cobalt allergy is more common than allergy to chromates. The reasons for cobalt allergy are poorly understood, however. Examples of other metals that can cause allergies when they occur in ionic form are palladium, platinum and rhodium (Lidén et al., 1995).

Otherwise, very little is known about the exposure of the general population to these metals. We do not know today whether the increasing use of certain metals is leading to effects on human beings or risks leading to such effects in the long term.

5 Potential for recovery and recycling of metals

5.1 Recovery and recycling of metals today

The statistics that are available regarding recovery and recycling of metals vary greatly between different metals and between different areas of application. Metal recycling can also be calculated in different ways. One way is to calculate the quantity of recovered metal that is used in production of new products today. Another way is to relate the quantities recovered today to the production volumes of the principal product types when they were produced. If, for example, a product has a mean useful life of 50 years, the recovered quantities today are related to the production volumes 50 years ago. This provides a picture of the theoretically possible recovery rate.

In some applications, e.g. batteries, there are rules mandating special collection systems. These rules also require statistics to be kept of the quantities that are placed on the market and the quantities that are collected. The statistics are therefore relatively comprehensive. Rough estimates can be made for other areas. For yet other metals and areas of application, no estimates can be made at all, due to the fact that no one knows what quantities enter and leave the Swedish market in products every year, nor how much is present in particulate matter etc. that is taken out of the country for reclamation.

In order for recovery to be practical, the metals must be separated from the waste. In some cases this is achieved by source separation, so that the metals are never mixed with other waste. This is true for e.g. batteries, aluminium cans, large fractions of scrap metal from end-of-life products and waste that arises directly in production processes. Many other metals, however, are present in complex products and are mixed up with other material even more in the waste stream. A certain amount of metal, for example, accompanies household waste to incineration or landfill and is never subjected to recovery and recycling.

Metals can be separated from scrap at several points along the chain – first by the scrap dealer who sorts the metals manually, then metals remaining in the scrap can be separated in a shredder, and metals in complex mixtures that remain after that can finally be separated from each other in smelters. There are five shredders in Sweden, and a number of smelters that receive recovered metals. Two specialize in aluminium scrap (mainly from aluminium cans), one in lead batteries and other waste containing lead and tin, and a dozen or so in steel. The Rönnskär Works has a licence to produce nine different metals from newly mined or recovered raw materials. These metals are copper, nickel, gold, silver, tellurium, platinum, selenium, zinc and lead. In some cases, compounds of one of these metals are produced and not the metal in pure form. When mixed products from recovery of e.g. electronics scrap are delivered to the Rönnskär Works, an analysis is made of which metals it contains.

The residual products that arise in various steps in the handling of scrap metal, or in conjunction with reprocessing at smelters, may contain many metals besides those recovered in processes in Sweden. Such materials are exported to e.g. the UK and Germany for further processing.

5.1.1 Importance of the application for potential to limit exposure by recovery and recycling

Applications that lead to small losses of the metal during its period of use, and where the metal exists in a sufficiently pure chemical form and high concentration, are well suited to recycling. Examples of such use may be enclosed sheaths for large undersea cables, large accumulators for commercial use and major metal fractions in white goods.

Often, recovery is profitable and therefore does not require any extra incentives from the national authorities, but when the world market price of the metal is low, the incentive for recycling may be less and the need for economic or other policy instruments may thereby be greater.

Examples of applications that present themselves immediately are ones where most of the metal remains in a form suitable for recycling, but where small losses take place continuously. Examples of such applications are roofing, water pipe and railway rails. Sometimes the use is so great that even small losses lead to substantial emissions of the metal. The corrosion rate is sometimes dependent on the amount of air pollutants, which means that measures to reduce air pollution have a positive influence on the potential to reduce releases of the metal.

It is more difficult to recover metals that are present in a chemical form suitable for recycling, but in small and dispersed quantities. Examples of such an area of application is electronics waste. Systems are required to identify and separate the metals. Knowledge of where the metals are and how end-of-life products should be handled is required at several points along the chain. As less precious metals are used in electronic products, the profitability of recycling dwindles.

Another situation is metals that exist in metallic form during the period of use, but where the application leads to heavy abrasion and/or dispersion, for example brake linings and ammunition. In the case of brake linings, some metal remains after the period of use, and this metal can be recovered. Ammunition can be collected to some extent. But it is hardly possible to achieve such a high recovery rate that it has an appreciable effect on the dispersion of the metal.

Another area is metal compounds which are additives in other materials with little wear during their period of use, e.g. certain plastic and rubber items. It is difficult to recover the metal as such in this group. Chemical recovery is theoretically possible, but seldom occurs in practice. The metal can be recovered together with the other material. Depending on the function of the metal compound, more of it may have to be added when e.g. the plastic is recycled. In this case, recovery of the material leads to a delay in the flow of the metal into the waste stream, but the influx of new metal is not reduced. Ultimately, the material ends up on a landfill or in an incinerator, or remains in the environment.

In the case of metal compounds that are additives or impurities in other materials that are abraded during their period of use, e.g. rubber tyres and pressure-treated wood, the potential for recovery is more limited. The abraded fraction can seldom be collected and recycled, which means that recovery is meaningless. The same applies to metal compounds that are incorporated in other materials that are not abraded, but where the metal compounds as such are leached out (may apply to dyes in textiles, for example).

Certain metal compounds that are used as e.g. process chemicals can be kept in closed-loop cycles. Metal compounds can also be used in such a way that direct release can occur or is inevitable in the long run, i.e. they are impossible to keep in closed-loop cycles. Examples of such areas of application are pesticides, anti-corrosive agents and paints.

Aside from the ways described above that metals can be present in end products, metal-containing waste can also arise industrially in the form of large scrap fractions or as metal shavings. Even if the large fractions are sorted out for recovery, the small fractions may accompany other waste to the landfill. Here as well there is a potential for increasing recovery.

The Committee’s appraisals of the potential for recovery of metals are summarized in Table 6.

Table 6 Potential for recovery of metals.

	Metals in pure form or alloys	Metal compounds as such	Metal compounds in other material
No wear	Very good	Good	Small for the metal
Moderate wear/leaching	Good but incomplete	Good but incomplete	Small and incomplete
Dissipative loss deliberate or unavoidable	Very small	Very small	Very small

Bibliography

Government Bills

En god livsmiljö. Prop. 1990/91:90. (Summary in English: A living environment.)

Bättre kontroll över miljöfarligt avfall. Gov. Bill 1993/94:163

Svenska miljömål. Prop. 1997/98:145. (Summary in English: Swedish Environmental Quality Objectives.)

Reports of the Government Commissions

Miljö för en hållbar hälsoutveckling. Report of the Environmental Health Commission. SOU 1996:124.

Ja till fyrverkerier – men med färre skador. Report of the Pyrotechnical Commission. SOU 1999:128.

Other sources

Adriaanse, A., Bringezu, S., Hammond, A., Moriguchi, Y., Roenburg, E., Rogich, D. och Schütz, H. (1997) Resource flows: The material basis of industrial economies. World Resource Institute, Washington D.C.

Andersson, M., Johansson, P. and Lax, K. (1997) Markgeokemiska kartan i södra Norrbottens inland, västa Småland och södra Halland. Geological Survey of Sweden, Reports and bulletins No 94.

Aronsson, R. (1999) Robert Aronsson, Tudor AB. Personal communication.

Ayres, R. and Ayres, L. (1993) Consumptive uses and losses of toxic heavy metals in the United States: 1880–1980. Industrial Metabolism. Ayres and Simones (Eds.) UN University Press.

Azar, C. (1995) Long-term environmental problems Economic measures and physical indicators. Thesis, Institute of Physical Resource Theory, Chalmers University of Technology, Göteborg University, Göteborg.

Bergbäck, B. (1998) Bly – förekomst och flöden i Sveriges teknosfär samt belastning på miljön. Del 1 av Bly i samhället och miljön. KemI-PM 8/98.

Bergbäck, B., Johansson, K. and Mohlander, U. (2000) Urban Metal Flows – Review and Conclusions. A case study of Stockholm. Manuscript.

Bergbäck, B. and Johansson, K. (1994) Metaller i stad och land – kretslopp och kritisk belastning. Research programme for the period 1994-1999. Swedish EPA Report 4382.

Bergman, C., Boge, R., Johansson, G., Bengtsson, G., Lindell, B. och Snihs, J.O. (1987) Acceptance criteria for disposal of high level radioactive waste. In: The geological disposal of high level radioactive wastes. Editor: Douglas Brookins. Theophrastus Publications, S.A., Aten.

Blomgren, B. (2000) Communication from Björn Blomgren, Returbatt AB, to the Committee on New Guidelines on Chemicals Policy, dnr 2000:66.

Bowen, H. J. M. (1979) Environmental chemistry of the elements. Academic Press,1979.

Bringmark, L. and Bringmark, E. (2000) Soil respiration in relation to small-scale patterns of lead and mercury in mor layers of South Swedish forest sites. Water, Air and Soil Pollution, in publication.

Campbell, P. G. C. (1995) Interactions between trace metals and aquaticorganisms: a critique of the free-ion activity model. In: Metal speciation and bioavailability in aquatic systems. Eds: A. Tessier & D.R. Turner. John Wiley & Sons Ltd.

Duus, U. and Ahlbom, J. (1994) Nya hjulspår. KemI Report 6/94.

Eriksson, H. (2000) Zink Info Norden AB. Personal communciation.

National Institute of Public Health (1998) Akuta förgiftningsfall och förgiftningstillbud vid hobbyverksamhet och hemsysslor. National Institute of Public Health 1998:12.

Frantzell, M. (2000) Magnus Frantzell, Swedish Lamp Manufacturers' Association. Personal communication.

Gustafsson, B. (1996) Tillsynsprojekt kadmium i varor. KemI-PM 3/96, National Chemicals Inspectorate.

Holmberg, J., Ohlsson, S-Å., and Ressar, H. (1999) Geokemiska kartan, Biogeokemi, Tungmetaller i bäckvattenväxter. Geological Survey of Sweden.

Hägg, G. (1966) Allmän och oorganisk kemi. Almqvist & Wiksell. Uppsala.

Johansson, K., Bergbäck, B. och Tyler, G. (2000) Impact of atmospheric long range transport of lead, mercury and cadmium on the Swedish forest environment- Review and conclusions. Manuscript.

Johansson, G. (1999) Göran Johansson, Volvo Cars. Personal communication.

Johansson, K., Andersson, A. och Andersson, T. (1995) Regional accumulation pattern of heavy metals in lake sediments and forest soils in Sweden. The Science of the Total Environment, 160/161 (1995) 373–380.

National Board of Agriculture (1999) Ett rikt odlingslandskap. Miljökvalitetsmål 9. National Board of Agriculture Report 18-1999.

Järup, L., Berglund, M., Elinder, C-G., Nordberg G. och Vather, M., (1998) Health effects of cadmium exposure. A review of the litterature and risk estimate. Scand. Work. Environ. Health, 24, Suppl. 1, 52p.

National Chemicals Inspectorate (1994a) Selecting multiproblem chemicals for risk reduction. KemI Report 13/94.

National Chemicals Inspectorate (1994b) Plastadditivprojektet – Metaller i plast. KemI PM No 11/94.

National Chemicals Inspectorate (1997) Avvecklingsprojektet. Rapport från ett regeringsuppdrag. KemI Report 6/97.

National Chemicals Inspectorate (1998a) Kvicksilveravvecklingen i Sverige – redovisning av ett regeringsuppdrag. KemI Report 5/98.

National Chemicals Inspectorate (1998b) Antifoulingprodukter – fritidsbåtar. PM decision 1998-02-24 rev. 1998-12-18.

Kristensson, B. (1999) Björn Kristensson, National Rail Administration. Personal communication.

Landner, L. and Lindeström, L. (1998) Zink in society and in the environment. Swedish Environmental Research Group, Stockholm.

Landner, L. och Lindeström, L. (1999) Copper in society and in the environment: An account of the facts on fluxes, amounts and effects of copper in Sweden. 2nd Revised Edition. Swedish Environmental Research Group, Stockholm.

Lidén, C., Maibach, H. and Wahlberg, J. (1995) Skin. In: Metal Toxicology. Academic Press.

Lidén C. and Röndell, E. (1997) Nickel i handverktyg. KemI-rapport 7/97. National Chemicals Inspectorate.

Lithner, G. and Holm, K. (2000) Förekomst och gradering av 55 olika grundelement i den svenska miljön. Institute for Applied Environmental Research. Manuscript.

Swedish EPA (1996) Metaller – Materialflöden i samhället. Report 4506.

Swedish EPA (1998) Gruvavfall – Miljöeffekter och behov av åtgärder. Report 4948.

Nielsen, N. H. and Menné, T. (1992) Allergic Contact Sensitization in an Unselected Danish Population. Acta Derm Venereol (Stockh) 1992; 72:456-460.

Nriagu, J. (1990) Global metal pollution. Environment. Vol. 32, No 7.

Olsson, S. (2000) Sigrid Olsson, Swedish EPA. Personal communication.

Palm, V., Bergbäck, B. and Östlund, P. (1995) Chromium and nickel in Sweden. KemI Report 14/95. National Chemicals Inspectorate.

Pettersson, R. and Rasmussen, F. (1997) Småbarns exponering för koppar via dricksvatten och risken för diarréer. In: Swedish EPA’s Report 4734.

Pettersson R. and Rasmussen, F. (1999) Daily intake of copper from drinking water among young children in Sweden. Environ Health Perspectives 107, 441-446.

SBL-analys (1998) Metallemissioner från trafiken i Stockholm – Slitage av bromsbelägg. Reports from SBL-analys No 2:98.

Statistics Sweden (1999) MiljöSverige – Metallutsläpp till vatten och luft från olika källor. Website www.scb.se.

Schleket, C. E. och Luoma, S. N. (2000) You are what you eat: incorporating dietary metals uptake into environmental quality guidelines for aquatic ecosystems. Learned discourses in SETAC GLOBE, 1:2, 38-39.

Sternbeck, J. (2000) Uppträdande och effekter av koppar i vatten och mark. IVL Report B1349.

Sternbeck, J. and Östlund, P. (1999) Nya metaller och metalloider i samhället. IVL Report B 1332.

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.

Thomas, J. (1999) Josh Thomas, Ångströmlaboratoriet, Uppsala University. Personal communication.

Thorén, Y. (1999) Yngve Thorén, Vägverket. Personal communication.

Tyler, G. (1992) Critical concentrations of heavy metals in the mor horizon of Swedish forests. Swedish EPA Report 4078.

Vahter, M. (1998) Health Effects of Metals in the General Population. In: The Impact of Metals on the Environment. Proceedings from an IVA Symposium, March 12-13,1998.

Wallgren, B. (2000) ”Ovanliga” metaller i slam. Swedish EPA, internal PM 2000-03-27.

Walterson, E. (1999) Krom, nickel och molybden i samhälle och miljö. Swedish Environmental Research Group.

Wergeman, G. (2000) Georg Wergeman, Swedish Glass Manufacturers' Association. Personal communication.

Woodward, D. F., Brumbaugh, W. G., DeLonay, A. J., Little, E. E. and C. E.Smith. (1994) Effects on rainbow trout fry of metals-contaminated diet of benthic invertebrates from the Clark Fork River, Montana. Trans. Am.Fish. Soc. 123, 51-62.

Ålåker, L. (1999) Lars Ålåker, Philips AB. Personal communication.

Östlund, P., Sternbeck, J. and Brorström-Lundén, E. (1998) Metaller, PAH, PCB och totalkolväten i sediment runt Stockholm – flöden och halter. IVL Report B1297.

Appendices

Appendix 1

Examples of the classification of metals and metal compounds with regard to health hazard. The list is by no means complete. For complete information on the classification of metals and metal compounds, we refer to the National Chemicals Inspectorate's regulations on the classification and labelling of chemical products.

Danger class	**Metal or metal compound**
Very toxic	aluminium phosphide arsenic hydride and arsenic trioxide beryllium and beryllium compounds except beryllium aluminium silicates several chromates several mercury compounds several organotin compounds osmium tetraoxide thallium and thallium compounds trizinc diphosphide uranium and uranium compounds
Toxic	antimony trifluoride arsenic and several arsenic compounds beryllium and beryllium compounds except beryllium aluminium silicates hexa- and tetrachloroplatinates several chromates several mercury compounds several organotin compounds trisodium hexafluoroaluminate vanadium pentoxide
Carcinogenic	antimony trioxide several arsenic compounds beryllium and beryllium compounds except beryllium aluminium silicates cobalt chloride and cobalt sulphate chromates nickel and nickel compounds
Mutagenic	several chromates vanadium pentoxide zinc bis(N,N-dimethyl dithiocarbamate)
Toxic for reproduction	lead compounds vanadium pentoxide

Danger class	**Metal or metal compound**
Corrosive	aluminium chloride antimony trichloride and antimony pentachloride arsenic trioxide several phenylmercuric compounds hexachloroplatinic acid potassium lithium and several lithium compounds sodium osmium tetraoxide silver nitrate tin tetrachloride and tin methane sulphonate zinc chloride
Irritant	barium polysulphides beryllium and beryllium compounds except beryllium aluminium silicates dithallium sulphate hexa- and tetrachloroplatinates several copper compounds several chromates molybdenum trioxide several organotin compounds several titanium compounds vanadium pentoxide several zinc compounds
Harmful	several antimony compounds several barium compounds several cobalt compounds several copper compounds several chromates several manganese compounds molybdenum trioxide vanadium pentoxide several zinc compounds

Appendix 2

Metals that have been assessed by the IPCS. The assessments are published in EHC (Environmental Health Criteria) reports. The number and publishing year of the EHC report is given for each metal.

Aluminium, No 194, 1997
Arsenic, No 18, 1981
Barium, No 107, 1990
Beryllium, No 106, 1990
Cadmium, No 134, 1992
Cadmium, environmental aspects, No 135, 1992
Chromium, No 61, 1988
Copper, No 200, 1998
Lead, No 3, 1977
Lead, inorganic, No 165, 1995
Lead, environmental aspects, No 85, 1989
Manganese, No 17, 1981
Mercury, No 1, 1976
Mercury, environmental aspects, No 86, 1989
Mercury, inorganic, No 118, 1991
Methylmercury, No 101, 1990
Nickel, No 108, 1991
Platinum, No 125, 1991
Selenium, No 58, 1986
Thallium, No 182, 1996
Tin and organotin compounds, No 15, 1980
Titanium, No 24, 1982
Vanadium, No 81, 1988

Appendix 3

Grouping of metals

The purpose of Appendix 6 is to describe the knowledge situation and the need for measures for metals and their compounds. For this purpose the metals have been grouped as follows:

- Metals that are very common in the bioavailable part of the soil and, with the exception of aluminium and titanium, that occur in relatively large quantities in the human body (compared with other metals): *aluminium, iron, sodium, potassium, magnesium, calcium, titanium*
- Metals that are to be phased out according to the guidelines: *lead, cadmium, mercury*
- Other metals:
  - with wide use over a long period of time: *copper, zinc, chromium, nickel*
  - all others (arranged according to atomic weight, lanthanides and actinides at the end): *lithium, beryllium, scandium, vanadium, manganese, cobalt, gallium, germanium, arsenic, rubidium, strontium, yttrium, zirconium, niobium, molybdenum, technetium, ruthenium, rhodium, palladium, silver, indium, tin, antimony, tellurium, cesium, barium, lutetium, halfnium, tantalum, tungsten, rhenium, osmium, iridium, platinum, gold, thallium, bismuth, polonium, francium, radium, lawrencium,* lanthanides: *lanthanum, cerium, praseodymium, neodymium, promethium, samarium, europium, gadolinium, terbium, dysprosium, holmium, erbium, thulium, ytterbium, lutetium,* actinides: *actinium, thorium, protactinium, uranium, neptunium, plutonium, americium, curium, berkelium, californium, einsteinium, fermium, mendelevium, nobelium.*

Appendix 4

Concentrations of metals.

Arranged according to falling concentrations in mor (with 34% minerogenic material) from northern Sweden. The data on concentrations in mor were determined at the Institute for Applied Environmental Research (Lithner and Holm, 2000). Concentrations in global bedrock are taken from Bowen (1979). DS = dry solids.

	Total concentration in mor, northern Sweden (µg/g DS)	**Global bedrock (µg/g DS)**
Al	17 900	82 000
Fe	5 400	41 000
Mn	450	950
Ba	227	500
Gf	66	
Zr	65	190
Zn	56	75
Sr	54	370
Rb	36	90
Pb	32	14
V	16.9	160
Ce	15.6	68
Cr	14.4	100
La	8.2	32
Nd	7.0	38
Cu	6.4	50
Ga	5.6	18
Ni	5.5	80
Li	3.22	20
As	2.1	1.5
Pr	1.90	9.5
Hf	1.76	5.3
Th	1.70	12
Sn	1.7	2.2
Ti	1.41	5.6
Sm	1.28	7.9
Gd	1.28	7.7
Cs	1.28	3
Ag	1.02	0.07
Dy	0.88	6

	Total concentration in mor, northern Sweden (µg/g DS)	**Global bedrock (µg/g DS)**
Ge	0.88	1.8
Mo	0.76	1.5
Se	0.7	0.05
U	0.67	0.48
Sb	0.61	0.2
Er	0.56	3.8
Yb	0.54	3.3
W	0.44	1
Tl	0.35	0.6
Cd	0.34	0.11
Ta	0.325	2
Bi	0.24	0.048
Ho	0.18	1.4
Hg	0.159	0.05
Lu	0.082	0.5
Tm	0.08	0.48
Te	0.04	0.005
In	0.019	0.049
Y	no data	30
Co	no data	20
Nb	no data	20
Sc	no data	16
Eu	no data	2.1
Tb	no data	1.1
Au	no data	0.0011
Ru	no data	0.001
Pt	no data	0.001
Pd	no data	0.0006
Re	no data	0.0004
Rh	no data	0.0002
Os	no data	0.0001
Pm	no data	no data
Ir	no data	no data
Po	no data	no data

Appendix 5

Concentrations of elements in soil in mg/kg, by percentiles (non-metals in italics). The figures come from SGU’s soil geochemical mapping programme and pertains to those parts of the country that have been mapped up to and including 1994 (Andersson et al., 1997).

Element, species	**10th percentile**	**50th percentile**	**maximum**
Al_2O_3	11 900	13 800	31 900
TiO_2	5 500	7 400	2 600
SiO2[1]	6 000	6 800	7 900
Fe_2O_3	2 400	3 600	15 400
K_2O	2 400	3 000	6 000
Na_2O	1 900	2 600	4 700
CaO	1 300	2 100	55 000
MgO	700	1 300	7 900
Zr	330	466	2 231
P_2O_5	160	240	1 970
Sr	110	171	664
S	102	161	29 494
BaO	44	58	216
V	38	56	467
MnO	39	55	1124
Zn	29	50	2 165
Cr	24	48	389
Pb	18	23	543
Co	13	19	93
Ni	8	16	204
Cu	6	14	400
Li	4	11	98
As	<5	8	175
Be	0.2	0.4	3.9
Au	<0.001	<0.001	0.485

[1] Does not pertain to the nation, but an area in the interior of Norrland.

Appendix 6

Concentration of certain metals in dried soil.

Metal	**Calculated conc. in soil, range, (µg/g)**	**Calculated conc. in soil, mean, (µg/g)**
Aluminium[2]	10 000 – 300 000	71 000
Iron[2]	7 000 – 550 000	38 000
Potassium[1]	14 000 – 28 200	23 200
Sodium[1]	7 000 – 21 000	15 000
Calcium[1]	5 800 – 17 400	10 000
Magnesium[1]	1 600 – 12 400	5 900
Titanium[2]	1 000 – 10 000	5 000
Manganese[2]	100 – 4 000	850
Barium[2]	100 – 3 000	500
Strontium[2]	50 – 1 000	300
Chromium[2]	5 – 3 000	100
Zinc[2]	10 – 300	50
Nickel[2]	10 – 1 000	40
Copper[2]	2 – 100	20
Tin[2]	2 – 200	10
Lead[2]	2 – 200	10
Cobalt[2]	1 – 40	8
Molybdenum[2]	0,2 – 5	2
Antimony[2]	no data	1
Cadmium[2]	0.01 – 0.7	0.06

[1] The figures are based on Swedish mineral soils.

[2] The figures are based on international literature and are to be regarded as theoretical mean values for the whole planet. (National Chemicals Inspectorate, 1994b)

Appendix 7

Examples of international areas of application for some ”new metals” (based mainly on information from Sternbeck and Östlund, 1999).

Silver: Industrial catalysts, batteries (e.g. watches and cameras), surface-treated steel, electronics (contacts, conductors, fuses, switches, etc.), bactericide in water purification, heat-reflecting layers on windscreens, and jewellery.

Bismuth: Medicine, cosmetics, areas within the petroleum and metallurgical industries. Bismuth has sometimes been held forth as a possible alternative to lead in e.g. ammunition and glazes. Bismuth production is based largely on the bismuth obtained as a by-product in the mining of lead.

Indium: Thin surface layers in LCDs and VDUs and on windscreens. Alloys and solders with low melting point, e.g. in the electronics industry. Solar cells. Corrosion protection in cars and for marine use. Alloy in dental gold.

Palladium: Catalytic converters for automobile exhaust gases, electronics, dental gold, medicine and the chemical industry.

Platinum: Catalytic converters for automobile exhaust gases, catalysts in the chemical and petroleum industries, coating on hard discs and in the glass on VDUs, degreasing agents, jewellery. Fuel cells for electric cars may be a future area of application.

Antimony: Flame retardant in e.g. plastics, textiles and electronics, lead alloys for e.g. batteries, bearings and cable sheathing, VDU glass, catalysts in the chemical industry.

Selenium: Glass, copying machines, electronics e.g. laser printers, IR detectors, solar cells, X-ray equipment, in combination with cadmium as a pigment, alloying element for steel and copper, dietary supplement. Selenium is produced as a by-product of copper.

Tellurium: Steel and copper alloys for improving machinability, accelerator in rubber manufacture, pigment in glass and ceramics, electronics e.g. thermoelectronics, copying machines, detectors for gamma rays and X-rays, and solar cells.

Summary Report from Round-Table Discussion on Criteria for Phasing Out Persistent and Bioaccumulating Organic Chemicals

Steningevik, Sweden, 10–11 December 1999

Contents

1 Summary Conclusion

- in order to phase out a chemical which is highly persistent and bioaccumulative it would not be necessary to consider toxicity information, nor to perform risk assessment.
- criteria to select persistent and bioaccumulative chemicals should be held as simple as possible.
- new and existing chemicals should eventually be subject to the same regulation, but more stringent criteria could be applied to new chemicals at an earlier point in time.
- the lack of information about the properties of many anthropogenic chemicals is a major obstacle, impeding hazard assessment.

2 Background

2.1 The Task of the Committee

The Swedish Government has proposed fifteen overarching environmental quality targets for the future environmental management (Ministry of the Environment, 1998). One of the targets concerns the achievement of an environment free from toxic chemicals. To realise this, the Government has decided on New Guidelines on Chemicals Policy, and our Committee has been assigned the task of concretising the Government's New Policy Guidelines on Chemicals (Ministry of the Environment, 1999). The Government intends to work to ensure the implementation of its guidelines within 10-15 years.

A general approach, focusing on chemical substances with documented health-endangering properties, and on organic, man-made substances which are bioaccumulative and persistent, should be adopted, to supplement present-day risk assessment methods. Among the tasks of the Committee is to propose more exact definitions of when an anthropogenic substance is so persistent and bioaccumulative as to be affected by the phase-out requirements of the guidelines.

The proposal of the Committee should be scientifically based on internationally accepted definitions, if such exist.

2.2 The Conditions of the Discussion

The purpose of the discussion was to obtain scientific views on a draft proposal on general definitions, and on a criteria model for selecting which persistent and bioaccumulative substances are not to be used in future, manufactured products and goods, nor in production processes unless the producer can show that the use is of no risk to human health or the environment.

The form of the meeting is given by the program (Annex 1), which includes a list of participants. The summary below adheres to the program, as far as applicable, and covers solely the discussion sessions. For clarity, some definitions have been added from the draft proposal (as *the Committee's starting point*), opening sections 3.1 and 3.2.

3 Summary of the Discussions

3.1 Persistence

In conclusion,

- persistence carries more weight than bioaccumulation, because persistent substances give rise to a risk of prolonged exposure and exposure far from the source.
- degradation half-life is an adequate expression of persistence.
- simple, general criteria of persistence, with the starting point in results from standardised tests, are preferrable, although any additional, relevant information should also be considered.

The Committee´s starting point

Persistence implies that a substance will be stable in the environment resisting chemical, physical and biological transformation reactions leading to degradation. Inert, or 'truly persistent', compounds have a chemical structure impeding the chemical reactions necessary for degradation. Degradation processes may be biotic, such as microbial degradation in water and sediments, and abiotic, such as photolysis in air and hydrolysis in water. The degradation of a substance should not be considered as complete until 'ultimate degradation' to harmless products is proven to be the case.

Persistence is a key property

The view held by the Committee, that persistence can be regarded as a key criterion, carrying more weight than bioaccumulation potential, received substantial support by the group of participants. The reason for this view is that persistence implies an extended risk of exposure, over a long period of time, which may cause undesirable, adverse effects already at a moderate degree of bioaccumulation potential, if the substance is capable of producing such effects. Persistence also implies that a substance may be transported long distances, causing exposure far from the source.

It was concluded, however, that persistence, defined as resistance to degradation, is not merely an intrinsic property of a chemical, but may to a large extent depend on environmental conditions, and also on which degradation mechanisms are in progress. Furthermore, degradation kinetics may vary, and degradation may take place in several consecutive time-phases.

Half-lives should be determined in standardised tests

Degradation half-lives were agreed to be an adequate expression of persistence. Half-lives should reflect the persistence in the relevant environmental compartment, and take into account mobility between compartments. However, experimentally determined half-lives can be expected to vary considerably depending on under which conditions they are determined. To try to account for many possible conditions of degradation would add back a substantial complexity to the model, the aim of which is to provide simple, general criteria. Therefore, preferably, data from standardised laboratory determinations should be used, honoring adequate safety margins, to keep criteria as simple (non-complex) as possible.

In e.g. OECD’s Ready Biodegradability tests it is possible to distinguish between easily degradable and potentially persistent compounds. But chemicals with degradation characteristics ‘in between’ are problematic to distinguish. It was asked what is the best acceptable evidence for degradability, and there was agreement that data from ready biodegradability tests could be used. However, available methods to determine half-lives, using today’s simulation tests, should be considered in addition.

It was emphasised that if favouring a simple model for the determination of persistence it is still necessary to be aware of which aspects are lacking. Not only half-lives (DT50) may be of interest, but also DT90 (the time after which 90 % of a compound has been degraded), in particular for very bioaccumulating compounds. Also, it was pointed out, besides results from tests employed to provide information to match certain criteria, all other information available on the degradability of a chemical under relevant environmental conditions should be considered.

Half-lives in water and air

It was generally agreed that it is justified to apply demands of shorter half-lives to the aquatic environment than to the terrestrial (soil) environment, with regard to persistent compounds distributing to these compartments.

Regarding persistence in air, the view was expressed that a limitation set at a half-life longer than two days is only applicable to semi-volatile compounds that are prone to redistribute to the terrestrial and aquatic environment. Highly volatile compounds, which are not likely to be deposited after volatilisation, could be considered to be of concern if their atmospheric half-lives exceed two weeks.

It was also pointed out that it is possible today to calculate overall half-lives for chemicals by multi-media models, taking into account compartment specific degradability and distribution coefficients.

3.2 Bioaccumulation

In conclusion,

- BCF values measured according to the OECD methodology are a good indicator of the potential for a substance to bioaccumulate, but for non-ionic molecules, logKow may be a surrogate up to values of about 6-7.
- bioaccumulation caused by other intrinsic properties than lipid solubility, e.g. protein-binding, should also be considered.
- the presence of significant amounts of a substance in biota can in certain cases be used as an indicator of bioaccumulation.

The Committee´s starting point

Bioaccumulation potential is understood as the tendency for a substance to be enriched in organisms by uptake from the surrounding medium and from the food. Commonly, bioaccumulation is approximated using bioconcentration, which in a fish reflects primarily the uptake from water via the gills. Bioconcentration applies mainly to fat-soluble, neutral substances of relatively low molecular weight (LMW). The bioconcentration factor (BCF) is determined as the ratio between the concentrations of a substance in the organism and in the surrounding medium at equilibrium. In order for a substance to bioaccumulate or bioconcentrate it must be bioavailable, that is available for passive or active uptake by organisms.

The bioaccumulation potential of most LMW organic compounds is closely linked to their lipid solubility, and for such compounds the BCF is often related to the partitioning of the substance between octanol and water, expressed as the K_{ow}.

Bioaccumulating substances may be biomagnifying, that is, the concentration increases from one trophic level to the next, moving up in the food web.

Bioaccumulation is not fully covered by BCF values

It was regarded as being of importance to consider not only bioconcentration by uptake from surrounding water, sediment and soil, but also bioaccumulation via uptake from food, and in the atmospheric compartment, bioconcentration in vegetation by air exposure.

Bioconcentration factors (BCF), measured in standardised tests using fish, it was further pointed out, may ‘miss’ compounds that accumulate by binding for example to plasma proteins, that is compounds such as pentachlorophenol. Unlike partitioning phenomena modelled by K_{ow}, protein binding is quite organism-specific, and can not easily be determined except by experiment on different species.

Are BCF values more relevant than logK_{ow}?

It was stressed that biomagnification is a problem also in the terrestrial environment, while standardised BCF tests using fish will only approximate the bioaccumulation in an aquatic model system. Bioavailability can be very different in terrestrial and aquatic environments. For example, compounds with very high logK_{ow}, bound mainly to particulate matter, may be quite unavailable in an aquatic system, but highly available if deposited on vegetation and consumed by herbivores.

The use of different fish in the aquatic OECD standard test will introduce some variation in the BCF values. Variation, however, may result also from e.g. experimental artefacts. Still, many participants argued that ‘aquatic’ BCF is a better measure of bioaccumulation potential than is logK_{ow}, one reason being that an experimental BCF value reflects the uptake by a living organism upon exposure. Another opinion, however, was that logK_{ow} gives a measure which is independent of variations between species. A problem, it was observed, is that BCF determinations sometimes have been performed using the compound of interest at a ‘concentration above its solubility’. The issue of which of BCF and logK_{ow} values is more appropriate to use could not be settled to full satisfaction by the participants, although the general trend of the discussion was in favour of using BCF rather than logK_{ow}.

It was further pointed out that certain compounds are bioaccumulating despite the fact that, nominally, their molecular size is too large. And it was noted that elimination by excretion of a persistent compound by one organism can lead to bioaccumulation in another organism, having less capacity for excretion of the compound. The answer is in the environment, one participant stated. What chemicals are present in organisms at high trophic levels? Monitoring data was agreed to be a good source of information, but the possibility of presence of anthropogenic substances in biota because of continuous exposure also has to be taken into account. And it is important to keep in mind that only relatively few substances are being monitored.

At what limit is BCF of concern?

In a discussion of which BCF limits would be scientifically justified to consider to be of concern, the following, different opinions were expressed:

> ”A limit of BCF > 10,000 is enough for easily degradable compounds.”
>
> ”A lower limit than BCF > 5,000 cannot be scientifically justified, even if the toxicity is unknown.”
>
> ”A lower limit than BCF > 5,000 is justified for compounds that do not distribute globally by transport with air, unlike in the criteria under discussion by, for example, UNEP, where globally distributing compounds are considered.”
>
> ”A limit of BCF > 3,000 is justified considering the risk of biomagnification at higher trophic levels.”
>
> ”A limit of BCF > 1,000 is reasonable for the aquatic environment.”
>
> ”A limit of BCF > 100 is justified for truly persistent compounds.”

3.3 Persistence and Bioaccumulation

In conclusion,

- P and B criteria are necessary, but not sufficient to address all substances of potential concern.
- the industry should be responsible for providing the needed data.
- the same policy should be applied to both new and existing chemicals. The ultimate goal is the same (no accumulation in the environment) but the timing for implementation of the criteria could be different.

As a general conclusion, it was –after some discussion – agreed upon that it can be scientifically justified to take regulatory action against the most persistent and bioaccumulating chemicals, without considering toxicity information. Future, possible problems of persistent, bioaccumulating substances cannot be known. It was pointed out that it can be justified by the Precautionary Principle to use criteria only regarding persistence and bioaccumulation, provided that it is still understood that toxicity properties are important. Furthermore, it was stressed that criteria with regard to persistence and bioaccumulation potential do not provide a complete solution to all problems with man-made chemicals.

Tiered system favoured

The tiered approach suggested by the Committee received substantial support. This approach implies that immediate action can be taken based on relatively simple criteria, such as the lack of data, in which case the worst case would be presumed. With regard to persistence this approach would furter imply that not ready biodegradable compounds could be subject to regulation, when no other data on degradability is at hand, while ultimate criteria allowing for longer half-lives than those estimated to correspond to not ready degradability would demand information from simulation tests. This approach also would involve the possibility for re-evaluation when data of higher quality become available, which was favoured by most participants. So was also the basic idea that it is the responsibility of the ‘provider’ to produce the necessary information.

It was suggested that monitoring data could be used to check whether the criteria adress the relevant compounds. But, it was objected, only a few classes of compounds are regularly monitored. With this reservation in mind, however, monitoring data could be a valuable complement. And to find xenobiotics in biota is reason enough for action, several participants pointed out.

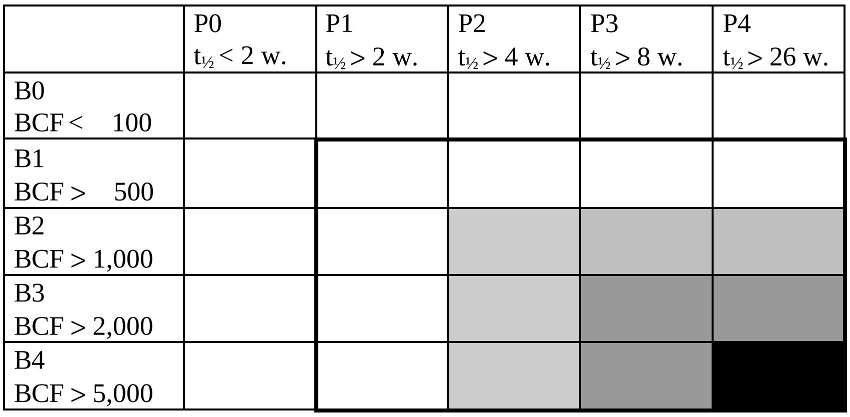
The ‘P/B matrix’ suggested by the Committee (Figure 1) was generally accepted as a tool, in particular for initial screening, although some participants regarded it to be too simplistic. The model was suggested to be a good starting point for identifying chemicals of concern within EU, and to bring to the attention of the industry which properties in chemicals are not wanted. It was put forward that screening criteria possibly could be set at the EU classification limits.

Limits of concern

It was generally agreed that immediate action could be taken to initiate the phase out of existing ‘P4/B4 chemicals’ (Figure 1), while less stringent measures (applying lower P and B values) could be considered against new compounds. It is easier to avoid the use of new compounds of persistent and bioaccumulating nature, than to cease using the existing ones. But, it was observed, among existing chemicals, a considerable portion are not in practical use, or marketed today. For new chemicals, a number of participants remarked, restrictions could possibly extend outside P4/B4, e.g. to P3/B3 or even to P2/B2.

Figure 1 The ‘P/B-matrix’

The ‘P/B-matrix’ suggested as a possible, conceptual tool by the Committee. The values of persistence (P), expressed as half-lives ($t_{½}$) and bioaccumulation (B), expressed as bioconcentration factors (BCF) refer to determination in the aquatic environment. The EU classification limits for compounds potentially hazardous to the environment is given by the open, bold-lined square. The black field represents persistence and bioaccumulation properties that could be considered for priority regulatory action, and the shadowed field properties that could possibly be considered for future regulatory action, even in the absence of toxicity information. (*Note that the class borders and ‘fields’ examplified are not necessarily those that will be finally proposed by the Committee*).



	P0 $t_{½} < 2$ w.	P1 $t_{½} > 2$ w.	P2 $t_{½} > 4$ w.	P3 $t_{½} > 8$ w.	P4 $t_{½} > 26$ w.
B0 BCF < 100					
B1 BCF > 500					
B2 BCF > 1,000			░	░	░
B3 BCF > 2,000			░	▓	▓
B4 BCF > 5,000			░	▓	█

The action to initiate phase-out, some participants argued, would need to include considerations of exposure potential by the chemical throughout its life cycle and an analysis of the problems arising from alternative solutions which would be considered in the final decision to phase out the chemical.

It was stressed, however, by several participants, that it is important to start now, and act on data at hand. Still after 50 years of environmental chemistry only a few POPs are considered for action, one participant emphasized, and expressed hope that the further forwarding and promotion of the approach under discussion would be without too much of ‘paving the road with delays’ in the form of requests for more data, call for further research, urge for definitive evidence, etc. as conditional in processes of direct phasing-out. But, it was remarked by a number of participants, it is important to make clear how the process should be.

3.4 Other Comments

In conclusion,

- risk assessment does not have to be performed before regulatory action is taken against the most persistent and bioaccumulating anthropogenic chemicals.
- for less persistent and bioaccumulating anthropogenic chemicals additional information is needed.
- phasing out the most persistent and bioaccumulating anthropogenic chemicals will provide increased (but not full) protection to organisms primarily at higher trophic levels. To protect biodiversity, additional properties in chemicals need to be considered.
- the lack of information about the properties of many anthropogenic chemicals is yet a major obstacle, impeding hazard assessment.
- it is desirable that the future process, with the aim to introduce regulatory restrictions against persistent and bioaccumulating anthropogenic chemicals, is transparent, and open for input by other authorities, NGOs, and industry.

3.4.1 Toxicity and other factors

To some extent, in particular in the beginning of the discussions, the view was expressed that information on toxicity has to be collected, and risk assessment has to be performed, before action can be taken. Finally, however, the participants came to the conclusion that risk assessment does not have to be performed before action can be taken against ”P4/B4” chemicals. None of the participants could come up with an example of a compound fitting the P4/B4 criterion that also was not toxic.

Toxicity **or** *persistence and bioaccumulation potential*

It was clarified by the chairman that toxicity, in the form of carcinogenicity, mutagenicity, reproductive disturbance, and endocrine disruption, is covered elsewhere in the directive of the Committee. However, it was still questioned by several participants why, in particular, ecotoxicity and neurotoxicity were not considered.

One suggestion was made to use the P/B-matrix (Figure 1) as the starting point of a tiered procedure, where increasing demands on other information than persistence and bioaccumulation data are taken into account as the focus is shifted off the ”P4/B4” area. Such an approach could be particularly suitable to apply to existing chemicals. It was again pointed out that it is important to specify what actions are to be taken against toxic compounds with persistence and bioaccumulation properties *not* falling for the future criteria.

The possibility to merge the perspective of the Committee with the approaches of other, current programs, aimed to minimise risks of dangerous chemicals, was seen as highly desirable. A holistic approach to the future chemicals policy on the international level should be adopted.

Exposure

Several participants missed considerations regarding exposure in the document under discussion. It was emphasised by the Chairman, however, that it is understood that high persistence and bioaccumulation potential will eventually result in exposure, at least in the long-term perspective. It was, furthermore, remarked, that chemicals are found today in biota that were earlier not expected to give rise to exposure.

Mobility

Another factor, that was pointed out by several participants as being of importance, is mobility. The opinion was expressed, that high mobility in combination with persistence could be reason enough to restrict the use of an organic, anthropogenic chemical.

Protection goal

There was also some discussion on whether in the draft document, distributed by the Committee, the protection goal is defined or not. Among the protection goals in a long-term perspective, it was made clear, however, is that the environment must be free from man-made substances that represent a threat to human health or biological diversity. And the risk of exposure and future harm is higher for more persistent and bioaccumulating substances. In the discussions, the protection goal was further defined to include animals at the higher trophic levels. It was concluded, however, that it is not possible to provide the same protection to organisms at lower trophic levels by applying restrictions to chemicals only with regard to persistence and bioaccumulation potential. Furthermore, such restrictions will not give full protection to organisms at higher trophic levels. Thus, to protect biological diversity, criteria with regard to other properties, such as ecotoxicity, have to be added.

3.4.2 Data availability

The overwhelming lack of data with regard to persistence and bioaccumulation properties was generally acknowledged. To an extent, it was concluded, data problems can be met by estimating properties, calculated as '(quantitative) structure-activity relationships', (Q)SARs. In addition, attention was drawn to a recent report demonstrating that more data on High Production Volume Chemicals is publicly available than previous studies have shown (Allanou *et al*., 1999). Still, however, the information is insufficient for hazard assessment for most of the substances.

3.4.3 On the future process

It was pointed out by the chairman that the proposals of the Committee are not only intended to be the starting point for a national scheme, but to be an input to the discussion of a new chemicals policy also on the EU level.

It was generally agreed that a transparent process is advantageous in the further development of the persistence and bioaccumulation criteria by the Committee, and that it would be desirable to provide additional opportunities for the exchange of ideas with representatives of other authorities, NGOs and the industry.

References

Allanou, R., Hansen, B.G. & van der Bilt, Y. (1999) Public availability of data on EU high production volume chemicals. EUR 18996 EN, European Commission Joint Research Centre, Institute of Health Consumer Protection, Chemical Bureau, I-21020 Ispra, Italy.

Ministry of the Environment (1998) Swedish Environmental Quality Objectives – a summary of the Swedish Government's Bill 1997/98:145. Information Office, SE-103 33 Stockholm, Sweden, June 1998.

Ministry of the Environment (1999) Committee on New Guidelines on Chemicals Policy, Sweden. Fact Sheet, June 1999.

Appendix

Round-Table Discussion on Criteria for Phasing Out Persistent and Bioaccumulating Organic Chemicals,

Steningevik, Sweden, 10-11 December 1999

Program

991210	**Introduction**
10.00-10.10	Welcome adress Arne Kardell, Chairman of the Swedish Committee on New Guidelines on Chemicals Policy
10.10-10.30	The Chemicals Policy in Sweden *Kjell Larsson, Minister for the Environment*
10.30-10.40	Procedural matters for the meeting *Cynthia de Wit, Director and Associate Professor, Institute of Applied Environmental Research, Stockholm University; Chairman of the meeting and of the Committee's National Scientific Reference Group*
10.40-10.50	Short presentation of participants
	Overview
10.50-11.05	POP criteria from the UNEP perspective *Bo Wahlström, Senior Scientific Advisor Chemicals, UNEP*
10.05-11.20	OSPAR criteria for dangerous substances *Håkan Björndal, Associate Professor, Swedish EPA*
11.20-11.35	Japanese experiences on POPs under the Law of Chemicals Safety Evaluation and Control in relation to biodegradation and biocontrol issues *Masayuki Ikeda, Professor, Kyoto Industrial Health Organisation*
	The Draft Proposal of the Committee
11.35-12.05	The draft model and proposed phase-out criteria *Peter Sundin, Secretary to the Swedish Committee on New Guidelines on Chemicals Policy*

Round-Table Discussion I: Persistence

13.30-13.40 Introduction to the discussion of the interpretation by the Committe of ”persistence” as a component in the phase-out criteria
Anders Södergren, Professor, Department of Ecology, Lund University; Member of the Committee’s National Scientific Reference Group

13.40-14.40 Open discussion

Round-Table Discussion II: Bioaccumulation

15.00-15.10 Introduction to the discussion of the interpretation by the Committe of ”bioaccumulation” as a component in the phase-out criteria
Dag Broman, Professor, Institute of Applied Environmental Research, Stockhom University; Member of the Committee’s National Scientific Reference Group

15.10-16.10 Open discussion

Round-Table Discussion III: The Criteria Model and Criteria proposed by the Committee

16.20-16.30 Introduction to the discussion of the proposal by the committe with respect to persistence and bioaccumulation phase-out criteria
Peter Sundin

16.30-17.30 Open discussion

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09.00-10.30 Summary and continued discussion

10.45-12.00 Concluding discussion

12.00-12.10 Chairman’s conclusions
Cynthia de Wit

12.10-12.20 Closure of the meeting
Arne Kardell

List of Participants

Scientific Experts

Reiner Arndt	Institute of Occupational Safety and Health (Germany)
Åke Bergman	Department of Environmental Chemistry, Stockholm University (Sweden)
Linda Birnbaum	National Health and Environmental Effects Laboratory (USA)
Ingvar Brandt	Department of Environmental Toxicology, Uppsala University (Sweden)
Dag Broman	Institute of Applied Environmental Research, Stockholm University (Sweden)
Finn Bro-Rasmussen	Technical University of Denmark (Denmark)
Davide Calamari	University of Insubria (Italy)
Erik Dybring	National Institute of Public Health (Norway)
Björn Hansen	European Commission Joint Research Center/ECB/ (Italy)
Paul Hayes	European Commission DG Environment (Belgium)
Helén Håkansson	Institute of Environmental Medicine, Karolinska Institutet (Sweden)
Masayuki Ikeda	Kyoto Industrial Health Association (Japan)
Bo Jansson	Institute of Applied Environmental Research, Stockholm University (Sweden)
Paul Johnston	Greenpeace (UK)
Henrik Kylin	University of Agricultural Sciences (Sweden)
André Lecloux	Euro Chlor (Belgium)
Bert-Ove Lund	National Chemicals Inspectorate (Sweden)
Alf Lundgren	National Chemicals Inspectorate (Sweden)
Gwynne Lyons	World Wildlife Fund (UK)
Esa Nikunen	Finnish Environment Institute (Finland)
Ross Norstrom	Environment Canada (Canada)
Dick Sijm	National Institute of Health and the Environment (The Netherlands)
Klaus Steinhäuser	Umweltbundesamt/UBA (Germany)
Anders Södergren	Department of Ecology, Lund University (Sweden)
Jose V Tarazona	Department of Natural Resources Conservation CIT-INIA (Spain)
Bo Wahlström	United Nations Environment Programme (Switzerland)

Participants from the Swedish Committee on New Guidelines on Chemicals Policy

Arne Kardell	Chairman of the Committee
Ingela Andersson	Secretary to the Committee
Gunnar Bengtsson	Director General, Swedish National Chemicals Inspectorate
Håkan Björndahl	Swedish Environmental Protection Agency
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Anita Ringström	Executive Vice President, Association of Swedish Chemical Industries
Eva Sandberg	Deputy Director, Ministry of the Environment
Maria Sandqvist	Desk Officer, Ministry of Industry, Employment and Communication
Peter Sundin	Secretary to the Committee

Others

Susanne Hagenfors	Project Coordinator, Swedish Society for the Conservation of Nature (Sweden)
Per Sandin	Postgraduate student, the Royal Institute of Technology at Stockholm (Sweden)

Annex 8

Not translated

Annex 9

Not translated