[X1 ANNEX I

GENERAL PROVISIONS FOR ASSESSING SUBSTANCES AND PREPARING CHEMICAL SAFETY REPORTS

Editorial Information

X1 Substituted by Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Official Journal of the European Union L 396 of 30 December 2006).

0. INTRODUCTION

0.1. The purpose of this Annex is to set out how manufacturers and importers are to assess and document that the risks arising from the substance they manufacture or import are adequately controlled during manufacture and their own use(s) and that others further down the supply chain can adequately control the risks. This Annex shall also apply adapted as necessary to producers and importers of articles required to make a chemical safety assessment as part of a registration.

0.2. The chemical safety assessment shall be prepared by one or more competent person(s) who have appropriate experience and received appropriate training, including refresher training.

0.3. The chemical safety assessment of a manufacturer shall address the manufacture of a substance and all the identified uses. The chemical safety assessment of an importer shall address all identified uses. The chemical safety assessment shall consider the use of the substance on its own (including any major impurities and additives), in a **[**[F1]mixture**]** and in an article, as defined by the identified uses. The assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses. The chemical safety assessment shall be based on a comparison of the potential adverse effects of a substance with the known or reasonably foreseeable exposure of man and/or the environment to that substance taking into account implemented and recommended risk management measures and operational conditions.

Textual Amendments

F1 Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).

0.4. Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or ‘category’ of substances. If the manufacturer or importer considers that the chemical safety assessment carried out for one substance is sufficient to assess and document that the risks arising from another substance or from a group or ‘category’ of substances are adequately controlled then he can use that chemical

safety assessment for the other substance or group or 'category' of substances. The manufacturer or importer shall provide a justification for this.

0.5. The chemical safety assessment shall be based on the information on the substance contained in the technical dossier and on other available and relevant information. Manufacturers or importers submitting a proposal for testing in accordance with Annexes IX and X shall record this under the relevant heading of the chemical safety report. Available information from assessments carried out under other international and national programmes shall be included. Where available and appropriate, an assessment carried out under Community legislation (e.g. risk assessments completed under Regulation (EEC) No 793/93) shall be taken into account in the development of, and reflected in, the chemical safety report. Deviations from such assessments shall be justified.

Thus the information to be considered includes information related to the hazards of the substance, the exposure arising from the manufacture or import, the identified uses of the substance, operational conditions and risk management measures applied or recommended to downstream users to be taken into account.

In accordance with section 3 of Annex XI in some cases, it may not be necessary to generate missing information, because risk management measures and operational conditions which are necessary to control a well-characterised risk may also be sufficient to control other potential risks, which will not therefore need to be characterised precisely.

If the manufacturer or importer considers that further information is necessary for producing his chemical safety report and that this information can only be obtained by performing tests in accordance with Annex IX or X, he shall submit a proposal for a testing strategy, explaining why he considers that additional information is necessary and record this in the chemical safety report under the appropriate heading. While waiting for results of further testing, he shall record in his chemical safety report, and include in the exposure scenario developed, the interim risk management measures that he has put in place and those he recommends to downstream users intended to manage the risks being explored.

0.6. A chemical safety assessment performed by a manufacturer or an importer for a substance shall include the following steps in accordance with the respective sections of this Annex:

1. Human health hazard assessment.

2. Human health hazard assessment of physicochemical properties.

3. Environmental hazard assessment.

4. PBT and vPvB assessment.

If as a result of steps 1 to 4 the manufacturer or importer concludes that the substance or the **[**[F1]mixture**]** meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB, the chemical safety assessment shall also consider the following steps:

5. Exposure assessment

5.1. The generation of exposure scenario(s) or the generation of relevant use and exposure categories if appropriate.

5.2. Exposure estimation.

6. Risk characterisation

A summary of all the relevant information used in addressing the points above, shall be presented under the relevant heading of the Chemical Safety Report (Section 7).

0.7. The main element of the exposure part of the chemical safety report is the description of the exposure scenario(s) implemented for the manufacturer's production, the manufacturer or importer's own use, and those recommended by the manufacturer or importer to be implemented for the identified use(s).

An exposure scenario is the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These sets of conditions contain a description of both the risk management measures and operational conditions which the manufacturer or importer has implemented or recommends to be implemented by downstream users.

If the substance is placed on the market, the relevant exposure scenario(s), including the risk management measures and operational conditions shall be included in an annex to the safety data sheet in accordance with Annex II.

0.8. The level of detail required in describing an exposure scenario will vary substantially from case to case, depending on the use of a substance, its hazardous properties and the amount of information available to the manufacturer or importer. Exposure scenarios may describe the appropriate risk management measures for several individual processes or uses of a substance. An exposure scenario may thereby cover a large range of processes or uses. Exposure scenarios covering a wide range of processes or uses may be referred to as Exposure Categories. Further mention of Exposure Scenario in this Annex and Annex II includes Exposure Categories if they are developed.

0.9. Where information is not necessary in accordance with Annex XI, this fact shall be stated under the appropriate heading of the chemical safety report and a reference shall be made to the justification in the technical dossier. The fact that no information is required shall also be stated in the safety data sheet.

0.10. In relation to particular effects, such as ozone depletion, photochemical ozone creation potential, strong odour and tainting, for which the procedures set out in Sections 1 to 6 are impracticable, the risks associated with such effects shall be assessed on a case-by-case basis and the manufacturer or importer shall include a full description and justification of such assessments in the chemical safety report and summarised in the safety data sheet.

0.11. When assessing the risk of the use of one or more substances incorporated into a special **[**[F1]mixture**]** (for instance alloys), the way the constituent substances are bonded in the chemical matrix shall be taken into account.

0.12. Where the methodology described in this Annex is not appropriate, details of alternative methodology used shall be explained and justified in the chemical safety report.

0.13. Part A of the chemical safety report shall include a declaration that the risk management measures outlined in the relevant exposure scenarios for the manufacturer's or importer's own use(s) are implemented by the manufacturer or importer and that those exposure scenarios for the identified uses are communicated to distributors and downstream users in the safety data sheet(s).

1. HUMAN HEALTH HAZARD ASSESSMENT

1.0. Introduction

1.0.1. The objective of the human health hazard assessment shall be:

— to determine the classification and labelling of a substance in accordance with Directive 67/548/EEC, and

— to derive levels of exposure to the substance above which humans should not be exposed. This level of exposure is known as the Derived No-Effect Level (DNEL).

1.0.2. The human health hazard assessment shall consider the toxicokinetic profile (i.e. absorption, metabolism, distribution and elimination) of the substance and the following groups of effects, (1) acute effects (acute toxicity, irritation and corrosivity), (2) sensitisation, (3) repeated dose toxicity and (4) CMR effects (carcinogenity, mutagenicity and toxicity for reproduction). Based on all the available information, other effects shall be considered when necessary.

1.0.3. The hazard assessment shall comprise the following four steps:

Step 1 : Evaluation of non-human information.
Step 2 : Evaluation of human information.
Step 3 : Classification and Labelling.
Step 4 : Derivation of DNELs.

1.0.4. The first three steps shall be undertaken for every effect for which information is available and shall be recorded under the relevant section of the Chemical Safety Report and where required and in accordance with Article 31, summarised in the Safety Data Sheet under headings 2 and 11.

1.0.5. For any effect for which no relevant information is available, the relevant section shall contain the sentence: ‘This information is not available’. The justification, including reference to any literature search carried out, shall be included in the technical dossier.

1.0.6. Step 4 of the human health hazard assessment shall be undertaken by integrating the results from the first three steps and shall be included under the relevant heading of the Chemical Safety Report and summarised in the Safety Data Sheet under heading 8.1.

1.1. Step 1: Evaluation of non-human information

1.1.1. The evaluation of non-human information shall comprise:

— the hazard identification for the effect based on all available non-human information,

— the establishment of the quantitative dose (concentration)-response (effect) relationship.

1.1.2. When it is not possible to establish the quantitative dose (concentration)-response (effect) relationship, then this should be justified and a semi-quantitative or qualitative analysis shall be included. For instance, for acute effects it is usually not possible to establish the quantitative dose (concentration)-response (effect) relationship on the basis of the results of a test conducted in accordance with test methods laid down in a Commission Regulation as specified in Article 13(3). In such cases it suffices to determine whether and to which degree the substance has an inherent capacity to cause the effect.

1.1.3. All non-human information used to assess a particular effect on humans and to establish the dose (concentration)-response (effect) relationship, shall be briefly presented, if possible in the form of a table or tables, distinguishing between *in*

vitro, *in vivo* and other information. The relevant test results (e.g. LD50, NO(A)EL or LO(A)EL) and test conditions (e.g. test duration, route of administration) and other relevant information shall be presented, in internationally recognised units of measurement for that effect.

1.1.4. If one study is available then a robust study summary should be prepared for that study. If there are several studies addressing the same effect, then, having taken into account possible variables (e.g. conduct, adequacy, relevance of test species, quality of results, etc.), normally the study or studies giving rise to the highest concern shall be used to establish the DNELs and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier. Robust summaries will be required of all key data used in the hazard assessment. If the study or studies giving rise to the highest concern are not used, then this shall be fully justified and included as part of the technical dossier, not only for the study being used but also for all studies demonstrating a higher concern than the study being used. It is important irrespective of whether hazards have been identified or not that the validity of the study be considered.

1.2. Step 2: Evaluation of human information

If no human information is available, this part shall contain the statement: 'No human information is available'. However, if human information is available, it shall be presented, if possible in the form of a table.

1.3. Step 3: Classification and Labelling

1.3.1. The appropriate classification and labelling developed in accordance with the criteria in Directive 67/548/EEC shall be presented and justified. Where applicable Specific Concentration limits, resulting from the application of Article 4(4) of Directive 67/548/EEC and Articles 4 to 7 of Directive 1999/45/EC, shall be presented and, if they are not included in Annex I to Directive 67/548/EEC, justified. The assessment should always include a statement as to whether the substance fulfils or does not fulfil the criteria given in Directive 67/548/EEC for CMR, categories 1 and 2.

1.3.2. If the information is inadequate to decide whether a substance should be classified for a particular end-point, the registrant shall indicate and justify the action or decision he has taken as a result.

1.4. Step 4: Identification of DNEL(s)

1.4.1. Based on the outcomes of steps 1 and 2, (a) DNEL(s) shall be established for the substance, reflecting the likely route(s), duration and frequency of exposure. For some endpoints, especially mutagenicity and carcinogenicity, the available information may not enable a threshold, and therefore a DNEL, to be established. If justified by the exposure scenario(s), a single DNEL may be sufficient. However, taking into account the available information and the exposure scenario(s) in Section 9 of the Chemical Safety Report it may be necessary to identify different DNELs for each relevant human population (e.g. workers, consumers and humans liable to exposure indirectly via the environment) and possibly for certain vulnerable sub-populations (e.g. children, pregnant women) and for different routes of exposure. A full justification shall be given specifying, *inter alia*, the choice of the information used, the route of exposure (oral, dermal, inhalation) and the duration and frequency of exposure to the substance for which the DNEL is valid. If more than one route of exposure is likely to occur, then a DNEL shall be established for each route of exposure and for the exposure from

all routes combined. When establishing the DNEL, the following factors shall, *inter alia*, be taken into account:

(a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;

(b) the nature and severity of the effect;

(c) the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies.

1.4.2. If it is not possible to identify a DNEL, then this shall be clearly stated and fully justified.

2. PHYSICOCHEMICAL HAZARD ASSESSMENT

2.1. The objective of the hazard assessment for physicochemical properties shall be to determine the classification and labelling of a substance in accordance with Directive 67/548/EEC.

2.2. As a minimum, the potential effects to human health shall be assessed for the following physicochemical properties:

— explosivity,
— flammability,
— oxidising potential.

If the information are inadequate to decide whether a substance should be classified for a particular end-point, the registrant shall indicate and justify the action or decision he has taken as a result.

2.3. The assessment of each effect shall be presented under the relevant heading of the Chemical Safety Report (Section 7) and where required and in accordance with Article 31, summarised in the Safety Data Sheet under headings 2 and 9.

2.4. For every physicochemical property, the assessment shall entail an evaluation of the inherent capacity of the substance to cause the effect resulting from the manufacture and identified uses.

2.5. The appropriate classification and labelling developed in accordance with the criteria in Directive 67/548/EEC shall be presented and justified.

3. ENVIRONMENTAL HAZARD ASSESSMENT

3.0. Introduction

3.0.1. The objective of the environmental hazard assessment shall be to determine the classification and labelling of a substance in accordance with Directive 67/548/EEC and to identify the concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur. This concentration is known as the Predicted No-Effect Concentration (PNEC).

3.0.2. The environmental hazard assessment shall consider the potential effects on the environment, comprising the (1) aquatic (including sediment), (2) terrestrial and (3) atmospheric compartments, including the potential effects that may occur (4) via food-chain accumulation. In addition, the potential effects on the (5) microbiological activity of sewage treatment systems shall be considered. The assessment of the effects on each of these five environmental spheres shall be presented under the

relevant heading of the Chemical Safety Report (Section 7) and where required and in accordance with Article 31, summarised in the Safety Data Sheet under headings 2 and 12.

3.0.3. For any environmental sphere, for which no effect information is available, the relevant section of the chemical safety report shall contain the sentence: 'This information is not available'. The justification, including reference to any literature research carried out, shall be included in the technical dossier. For any environmental sphere for which information is available, but the manufacturer or importer believes that it is not necessary to conduct the hazard assessment, the manufacturer or importer shall present a justification, with reference to pertinent information, under the relevant heading of the Chemical Safety Report (Section 7) and where required and in accordance with Article 31, summarised in the Safety Data Sheet under heading 12.

3.0.4. The hazard assessment shall comprise the following three steps, which shall be clearly identified as such in the Chemical Safety Report:

Step 1 : Evaluation of information.
Step 2 : Classification and Labelling.
Step 3 : Derivation of the PNEC.

3.1. Step 1: Evaluation of information

3.1.1. The evaluation of all available information shall comprise:

— the hazard identification based on all available information,

— the establishment of the quantitative dose (concentration)-response (effect) relationship.

3.1.2. When it is not possible to establish the quantitative dose (concentration)-response (effect) relationship, then this should be justified and a semi-quantitative or qualitative analysis shall be included.

3.1.3. All information used to assess the effects on a specific environmental sphere shall be briefly presented, if possible in the form of a table or tables. The relevant test results (e.g. LC50 or NOEC) and test conditions (e.g. test duration, route of administration) and other relevant information shall be presented, in internationally recognised units of measurement for that effect.

3.1.4. All information used to assess the environmental fate of the substance shall be briefly presented, if possible in the form of a table or tables. The relevant test results and test conditions and other relevant information shall be presented, in internationally recognised units of measurement for that effect.

3.1.5. If one study is available then a robust study summary should be prepared for that study. Where there is more than one study addressing the same effect, then the study or studies giving rise to the highest concern shall be used to draw a conclusion and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier. Robust summaries will be required of all key data used in the hazard assessment. If the study or studies giving rise to the highest concern are not used, then this shall be fully justified and included as part of the technical dossier, not only for the study being used but also for all studies reaching a higher concern than the study being used. For substances where all available studies indicate no hazards an overall assessment of the validity of all studies should be performed.

3.2. Step 2: Classification and Labelling

3.2.1. The appropriate classification and labelling developed in accordance with the criteria in Directive 67/548/EEC shall be presented and justified. Where applicable Specific Concentration limits, resulting from the application of Article 4(4) of Directive 67/548/EEC and Articles 4 to 7 of Directive 1999/45/EC, shall be presented and, if they are not included in Annex I to Directive 67/548/EEC, justified.

3.2.2. If the information are inadequate to decide whether a substance should be classified for a particular end-point, the registrant shall indicate and justify the action or decision he has taken as a result.

3.3. Step 3: Identification of the PNEC

3.3.1. Based on the available information, the PNEC for each environmental sphere shall be established. The PNEC may be calculated by applying an appropriate assessment factor to the effect values (e.g. LC50 or NOEC). An assessment factor expresses the difference between effects values derived for a limited number of species from laboratory tests and the PNEC for the environmental sphere[(1)].

3.3.2. If it is not possible to derive the PNEC, then this shall be clearly stated and fully justified.

4. PBT AND VPVB ASSESSMENT

4.0. Introduction

4.0.1. The objective of the PBT and vPvB assessment shall be to determine if the substance fulfils the criteria given in Annex XIII and if so, to characterise the potential emissions of the substance. A hazard assessment in accordance with Sections 1 and 3 of this Annex addressing all the long-term effects and the estimation of the long-term exposure of humans and the environment as carried out in accordance with Section 5 (Exposure Assessment), step 2 (Exposure Estimation), cannot be carried out with sufficient reliability for substances satisfying the PBT and vPvB criteria in Annex XIII. Therefore, a separate PBT and vPvB assessment is required.

4.0.2. The PBT and vPvB assessment shall comprise the following two steps, which shall be clearly identified as such in Part B, Section 8 of the Chemical Safety Report:

Step 1 : Comparison with the Criteria.
Step 2 : Emission Characterisation.

The assessment shall also be summarised in the Safety Data Sheet under heading 12.

4.1. Step 1: Comparison with the Criteria

This part of the PBT and vPvB assessment shall entail the comparison of the available information, which is submitted as part of the technical dossier, with the criteria given in Annex XIII and a statement of whether the substance fulfils or does not fulfil the criteria.

If the available information is not sufficient to decide whether the substance fulfils the criteria in Annex XIII, then other evidence like monitoring data available for the registrant and giving rise to an equivalent level of concern shall be considered on a case-by-case basis.

If the technical dossier contains for one or more endpoints only information as required in Annexes VII and VIII, the registrant shall consider information relevant for screening for P, B and T properties to decide whether further information needs to be generated to fulfil the objective of the PBT and vPvB assessment. In case the generation of further information is necessary and would require testing on vertebrate animals, the registrant shall submit a testing

proposal. However, such further information does not need to be generated if the registrant implements or recommends sufficient risk management measures and operational conditions that enable derogation according to Section 3 of Annex XI from testing relevant for PBT and vPvB assessment.

4.2. Step 2: Emission Characterisation

If the substance fulfils the criteria an emission characterisation shall be conducted comprising the relevant parts of the exposure assessment as described in Section 5. In particular it shall contain an estimation of the amounts of the substance released to the different environmental compartments during all activities carried out by the manufacturer or importer and all identified uses, and an identification of the likely routes by which humans and the environment are exposed to the substance.

5. EXPOSURE ASSESSMENT

5.0. Introduction

The objective of the exposure assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of the substance to which humans and the environment are or may be exposed. The assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the hazards identified in Sections 1 to 4. The exposure assessment shall entail the following two steps, which shall be clearly identified as such in the Chemical Safety Report:

Step 1	:	Generation of exposure scenario(s) or the generation of relevant use and exposure categories.
Step 2	:	Exposure Estimation.

Where required and in accordance with Article 31, the exposure scenario shall also be included in an annex to the Safety Data Sheet.

5.1. Step 1: Development of exposure scenarios

5.1.1. Exposure scenarios as described in Sections 0.7 and 0.8 shall be generated. Exposure scenarios are the core of the process to carry out a chemical safety assessment. The chemical safety assessment process may be iterative. The first assessment will be based on the required minimum and all available hazard information and on the exposure estimation that corresponds to the initial assumptions about the operating conditions and risk management measures (an initial exposure scenario). If the initial assumptions lead to a risk characterisation indicating that risks to human health and the environment are not adequately controlled, then it is necessary to carry out an iterative process with amendment of one or a number of factors in hazard or exposure assessment with the aim to demonstrate adequate control. The refinement of hazard assessment may require generation of additional hazard information. The refinement of exposure assessment may involve appropriate alteration of the operational conditions or risk management measures in the exposure scenario or more precise exposure estimation. The exposure scenario, resulting from the final iteration (a final exposure scenario), shall be included in the chemical safety report and attached to the safety data sheet in accordance with Article 31.

The final exposure scenario shall be presented under the relevant heading of the chemical safety report, and included in an annex to the safety data sheet, using an appropriate short title giving a brief general description of the use, consistent with those given in Section 3.5 of Annex VI. Exposure scenarios shall cover any manufacture in the Community and all identified uses.

In particular, an exposure scenario includes, where relevant, a description of:

Operational conditions

— the processes involved, including the physical form in which the substance is manufactured, processed and/or used,

— the activities of workers related to the processes and the duration and frequency of their exposure to the substance,

— the activities of consumers and the duration and frequency of their exposure to the substance,

— the duration and frequency of emissions of the substance to the different environmental compartments and sewage treatment systems and the dilution in the receiving environmental compartment.

Risk management measures

— the risk management measures to reduce or avoid direct and indirect exposure of humans (including workers and consumers) and the different environmental compartments to the substance,

— the waste management measures to reduce or avoid exposure of humans and the environment to the substance during waste disposal and/or recycling.

5.1.2. Where a manufacturer, importer or downstream user applies for an application for an authorisation for a specific use, exposure scenarios need only be developed for that use and the subsequent life-cycle steps.

5.2. Step 2: Exposure Estimation

5.2.1. The exposure shall be estimated for each exposure scenario developed and shall be presented under the relevant heading of the Chemical Safety Report and where required and in accordance with Article 31, summarised in an annex to the safety data sheet. The exposure estimation entails three elements: (1) emission estimation; (2) assessment of chemical fate and pathways; and (3) estimation of exposure levels.

5.2.2. The emission estimation shall consider the emissions during all relevant parts of the life-cycle of the substance resulting from the manufacture and each of the identified uses. The life-cycle stages resulting from the manufacture of the substance cover, where relevant, the waste stage. The life-cycle stages resulting from identified uses cover, where relevant, the service-life of articles and the waste stage. The emission estimation shall be performed under the assumption that the risk management measures and operational conditions described in the exposure scenario have been implemented.

5.2.3. A characterisation of possible degradation, transformation, or reaction processes and an estimation of environmental distribution and fate shall be performed.

5.2.4. An estimation of the exposure levels shall be performed for all human populations (workers, consumers and humans liable to exposure indirectly via the environment) and environmental spheres for which exposure to the substance is known or reasonably foreseeable. Each relevant route of human exposure (inhalation, oral, dermal and combined through all relevant routes and sources of exposure) shall be addressed. Such estimations shall take account of spatial and temporal variations in the exposure pattern. In particular, the exposure estimation shall take account of:

— adequately measured, representative exposure data,

— any major impurities and additives in the substance,

— the quantity in which the substance is produced and/or imported,

— the quantity for each identified use,

— implemented or recommended risk management, including the degree of containment,

— duration and frequency of exposure according to the operational conditions,
— the activities of workers related to the processes and the duration and frequency of their exposure to the substance,
— the activities of consumers and the duration and frequency of their exposure to the substance,
— the duration and frequency of emissions of the substance to the different environmental compartments and the dilution in the receiving environmental compartment,
— the physicochemical properties of the substance,
— transformation and/or degradation products,
— the likely routes of exposure of and potential for absorption in humans,
— the likely pathways to the environment and environmental distribution and degradation and/or transformation (see also Section 3 Step 1),
— scale (geographical) of exposure,
— matrix dependent release/migration of the substance.

5.2.5. Where adequately measured representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Appropriate models can be used for the estimation of exposure levels. Relevant monitoring data from substances with analogous use and exposure patterns or analogous properties can also be considered.

6. RISK CHARACTERISATION

6.1. The risk characterisation shall be carried out for each exposure scenario and shall be presented under the relevant heading of the Chemical Safety Report.

6.2. The risk characterisation shall consider the human populations (exposed as workers, consumers or indirectly via the environment and if relevant a combination thereof) and the environmental spheres for which exposure to the substance is known or reasonably foreseeable, under the assumption that the risk management measures described in the exposure scenarios in the Section 5 have been implemented. In addition, the overall environmental risk caused by the substance shall be reviewed by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

6.3. The risk characterisation consists of:
— a comparison of the exposure of each human population known to be or likely to be exposed with the appropriate DNEL,
— a comparison of the predicted environmental concentrations in each environmental sphere with the PNECs, and
— an assessment of the likelihood and severity of an event occurring due to the physicochemical properties of the substance.

6.4. For any exposure scenario, the risk to humans and the environment can be considered to be adequately controlled, throughout the lifecycle of the substance that results from manufacture or identified uses, if:
— the exposure levels estimated in Section 6.2 do not exceed the appropriate DNEL or the PNEC, as determined in Sections 1 and 3, respectively, and,
— the likelihood and severity of an event occurring due to the physicochemical properties of the substance as determined in Section 2 is negligible.

6.5. For those human effects and those environmental spheres for which it was not possible to determine a DNEL or a PNEC, a qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenario shall be carried out.

For substances satisfying the PBT and vPvB criteria, the manufacturer or importer shall use the information as obtained in Section 5, Step 2 when implementing on its site, and recommending for downstream users, risk management measures which minimise exposures and emissions to humans and the environment, throughout the lifecycle of the substance that results from manufacture or identified uses.

7. CHEMICAL SAFETY REPORT FORMAT

The Chemical Safety Report shall include the following headings:
CHEMICAL SAFETY REPORT FORMAT

PART A 1.SUMMARY OF RISK MANAGEMENT MEASURES

2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED

3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

PART B 1.IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

2. MANUFACTURE AND USES

2.1. Manufacture

2.2. Identified uses

2.3. Uses advised against

3. CLASSIFICATION AND LABELLING

4. ENVIRONMENTAL FATE PROPERTIES

4.1. Degradation

4.2. Environmental distribution

4.3. Bioaccumulation

4.4. Secondary poisoning

5. HUMAN HEALTH HAZARD ASSESSMENT

5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

5.2. Acute toxicity

5.3. Irritation

5.3.1. Skin

5.3.2. Eye

5.3.3. Respiratory tract

5.4. Corrosivity

5.5. Sensitisation

5.5.1. Skin

5.5.2. Respiratory system

5.6. Repeated dose toxicity

5.7. Mutagenicity

5.8. Carcinogenicity

5.9. Toxicity for reproduction

5.9.1. Effects on fertility

5.9.2. Developmental toxicity

5.10. Other effects

5.11. Derivation of DNEL(s)

6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

6.1. Explosivity

6.2. Flammability

6.3. Oxidising potential

7. ENVIRONMENTAL HAZARD ASSESSMENT

7.1. Aquatic compartment (including sediment)

7.2. Terrestrial compartment

7.3. Atmospheric compartment

7.4. Microbiological activity in sewage treatment systems

8. PBT AND VPVB ASSESSMENT

9. EXPOSURE ASSESSMENT

9.1. (Title of exposure scenario 1)

9.1.1. Exposure scenario

9.1.2. Exposure estimation

9.2. (Title of exposure scenario 2)

9.2.1. Exposure scenario

9.2.2. Exposure estimation

(etc.)

10. RISK CHARACTERISATION

10.1. (Title of exposure scenario 1)

10.1.1. Human health

10.1.1.1. Workers

10.1.1.2. Consumers

10.1.1.3. Indirect exposure to humans via the environment

10.1.2. Environment

10.1.2.1. Aquatic compartment (including sediment)

10.1.2.2. Terrestrial compartment

10.1.2.3. Atmospheric compartment

10.1.2.4. Microbiological activity in sewage treatment systems

10.2. (Title of exposure scenario 2)

10.2.1. Human health

10.2.1.1. Workers

10.2.1.2. Consumers

10.2.1.3. Indirect exposure to humans via the environment

10.2.2. Environment

10.2.2.1. Aquatic compartment (including sediment)

10.2.2.2. Terrestrial compartment

10.2.2.3. Atmospheric compartment

10.2.2.4. Microbiological activity in sewage treatment systems

(etc.)

10.x. Overall exposure (combined for all relevant emission/release sources)

10.x.1. Human health (combined for all exposure routes)

10.x.1.1.

10.x.2. Environment (combined for all emission sources)

10.x.2.1.**]**

(1) **[**[X1]In general, the more extensive the data and the longer the duration of the tests, the smaller is the degree of uncertainty and the size of the assessment factor. An assessment factor of 1 000 is typically applied to the lowest of three short term L(E)C50 values derived from species representing different trophic levels and a factor of 10 to the lowest of three long-term NOEC values derived from species representing different trophic levels.**]**

Editorial Information

X1 Substituted by Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Official Journal of the European Union L 396 of 30 December 2006).

Status:
Point in time view as at 27/06/2009.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council, ANNEX I.