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Forum

Registry of REACH- CLP- and PIC-obligations addressed in past inspection and enforcement campaigns of the ECHA Forum – an outline

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Introduction

The present document gives an overview of the legal provisions covered by the harmonised enforcement projects of the Forum. Its sole intention is to inform the interested parties on the various articles of REACH, CLP and PIC Regulations covered up to now by the harmonized enforcement campaigns undertaken by the Forum.

1. REACH

(ECHA consolidated version 1 MARCH 2018)

1.1 Registration obligations

Article 5
No data, no market
Subject to Articles 6, 7, 21 and 23, substances on their own, in mixtures or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.

Article 6
General obligation to register substances on their own or in mixtures
1. Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more mixture(s), in quantities of one ton or more per year shall submit a registration to the Agency.
2. For monomers that are used as on-site isolated intermediates or transported isolated intermediates, Articles 17 and 18 shall not apply.
3. Any manufacturer or importer of a polymer shall submit a registration to the Agency for the monomer substance(s) or any other substance(s), that have not already been registered by an actor up the supply chain, if both the following conditions are met:
(a) the polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);
(b) the total quantity of such monomer substance(s) or other substance(s) makes up one ton or more per year.
4. A submission for registration shall be accompanied by the fee required in accordance with Title IX.

Article 7
Registration and notification of substances in articles
1. Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:
(a) the substance is present in those articles in quantities totaling over one ton per producer or importer per year;
(b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.
A submission for registration shall be accompanied by the fee required in accordance with Title IX.
2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1), if both the following conditions are met:
(a) the substance is present in those articles in quantities totaling over one ton per producer or importer per year;
(b) the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w).

3. Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.
4. The information to be notified shall include the following:
(a) the identity and contact details of the producer or importer as specified in section 1 of Annex VI, with the exception of their own use sites;
(b) the registration number(s) referred to in Article 20(1), if available;
(c) the identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI;
(d) the classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI;
(e) a brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s);
(f) the tonnage range of the substance(s), such as 1 to 10 tons, 10 to 100 tons and so on.
5. The Agency may take decisions requiring producers or importers of articles to submit a registration, in accordance with this Title, for any substance in those articles, if all the following conditions are met:
(a) the substance is present in those articles in quantities totaling over one ton per producer or importer per year;
(b) the Agency has grounds for suspecting that:
(i) the substance is released from the articles, and
(ii) the release of the substance from the articles presents a risk to human health or the environment;
(c) the substance is not subject to paragraph 1.
A submission for registration shall be accompanied by the fee required in accordance with Title IX.
6. Paragraphs 1 to 5 shall not apply to substances that have already been registered for that use.
7. From 1 June 2011 paragraphs 2, 3 and 4 of this Article shall apply six months after a substance is identified in accordance with Article 59(1).
8. Any measures for the implementation of paragraphs 1 to 7 shall be adopted in accordance with the procedure referred to in Article 133(3).

Article 8

Only representative of a non-Community manufacturer
1. A natural or legal person established outside the Community who manufactures a substance on its own, in mixtures or in articles, formulates a mixture or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under this Title.
2. The representative shall also comply with all other obligations of importers under this Regulation. To this end, he shall have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 36, shall keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31.
3. If a representative is appointed in accordance with paragraphs 1 and 2, the non-Community manufacturer shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation.

Article 10

Information to be submitted for general registration purposes
A registration required by Article 6 or by Article 7(1) or (5) shall include all the following information:
(a) a technical dossier including:
(i) the identity of the manufacturer(s) or importer(s) as specified in section 1 of Annex VI;

(ii) the identity of the substance as specified in section 2 of Annex VI;
(iii) information on the manufacture and use(s) of the substance as specified in section 3 of Annex VI; this information shall represent all the registrant's identified use(s). This information may include, if the registrant deems appropriate, the relevant use and exposure categories;
(iv) the classification and labelling of the substance as specified in section 4 of Annex VI;
(v) guidance on safe use of the substance as specified in Section 5 of Annex VI;
(vi) study summaries of the information derived from the application of Annexes VII to XI;
(vii) robust study summaries of the information derived from the application of Annexes VII to XI, if required under Annex I;
(viii) an indication as to which of the information submitted under (iii), (iv), (vi), (vii) or subparagraph (b) has been reviewed by an assessor chosen by the manufacturer or importer and having appropriate experience;
(ix) proposals for testing where listed in Annexes IX and X;
(x) for substances in quantities of 1 to 10 tons, exposure information as specified in section 6 of Annex VI;
(xi) a request as to which of the information in Article 119(2) the manufacturer or importer considers should not be made available on the Internet in accordance with Article 77(2)(e), including a justification as to why publication could be harmful for his or any other concerned party's commercial interests.

Except in cases covered under Article 25(3), Article 27(6) or Article 30(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (vi) and (vii) for the purpose of registration;

(b) a chemical safety report when required under Article 14, in the format specified in Annex I. The relevant sections of this report may include, if the registrant considers appropriate, the relevant use and exposure categories.

Article 11

Joint submission of data by multiple registrants

1. When a substance is intended to be manufactured in the Community by one or more manufacturers and/or imported by one or more importers, and/or is subject to registration under Article 7, the following shall apply.

Subject to paragraph 3, the information specified in Article 10(a)(iv), (vi), (vii) and (ix), and any relevant indication under Article 10(a)(viii) shall first be submitted by the one registrant acting with the agreement of the other assenting registrant(s) (hereinafter referred to as the lead registrant).

Each registrant shall subsequently submit separately the information specified in Article 10(a)(i), (ii), (iii) and (x), and any relevant indication under Article 10(a)(viii).

The registrants may decide themselves whether to submit the information specified in Article 10(a)(v) and (b) and any relevant indication under Article 10(a)(viii) separately or whether one registrant is to submit this information on behalf of the others.

2. Each registrant need only comply with paragraph 1 for items of information specified in Article 10(a)(iv), (vi), (vii) and (ix) that are required for the purposes of registration within his tonnage band in accordance with Article 12.

3. A registrant may submit the information referred to in Article 10(a)(iv), (vi), (vii) or (ix) separately if:

(a) it would be disproportionately costly for him to submit this information jointly; or
(b) submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or
(c) he disagrees with the lead registrant on the selection of this information.

If points (a), (b) or (c) apply, the registrant shall submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment or the nature of the disagreement, as the case may be.

4. A submission for registration shall be accompanied by the fee required in accordance with Title IX.

Article 12

Information to be submitted depending on tonnage

1. The technical dossier referred to in Article 10(a) shall include under points (vi) and (vii) of that provision all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant and as a minimum the following:

(a) the information specified in Annex VII for non-phase-in substances, and for phase-in substances meeting one or both of the criteria specified in Annex III, manufactured or imported in quantities of one ton or more per year per manufacturer or importer;

(b) the information on physicochemical properties specified in Annex VII, section 7 for phase-in substances manufactured or imported in quantities of one ton or more per year per manufacturer or importer which do not meet either of the criteria specified in Annex III;

(c) the information specified in Annexes VII and VIII for substances manufactured or imported in quantities of 10 tons or more per year per manufacturer or importer;

(d) the information specified in Annexes VII and VIII and testing proposals for the provision of the information specified in Annex IX for substances manufactured or imported in quantities of 100 tons or more per year per manufacturer or importer;

(e) the information specified in Annexes VII and VIII and testing proposals for the provision of the information specified in Annexes IX and X for substances manufactured or imported in quantities of 1 000 tons or more per year per manufacturer or importer.

2. As soon as the quantity of a substance per manufacturer or importer that has already been registered reaches the next tonnage threshold, the manufacturer or importer shall inform the Agency immediately of the additional information he would require under paragraph 1. Article 26(3) and (4) shall apply adapted as necessary.

3. This Article shall apply to producers of articles adapted as necessary.

Article 14

Chemical safety report and duty to apply and recommend risk reduction measures

1. Without prejudice to Article 4 of Directive 98/24/EC, a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter in quantities of 10 tons or more per year per registrant.

The chemical safety report shall document the chemical safety assessment which shall be conducted in accordance with paragraphs 2 to 7 and with Annex I for either each substance on its own or in a mixture or in an article or a group of substances.

2. A chemical safety assessment in accordance with paragraph 1 need not be performed for a substance which is present in a mixture if the concentration of the substance in the mixture is less than:

(a) the cut-off value referred to in Article 11, paragraph 3 of Regulation (EC) No 1272/2008;

(b) 0,1 % weight by weight (w/w), if the substance meets the criteria in Annex XIII to this Regulation.

3. A chemical safety assessment of a substance shall include the following steps:

(a) human health hazard assessment;

(b) physicochemical hazard assessment;

(c) environmental hazard assessment;

(d) persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment.

4. If, as a result of carrying out steps (a) to (d) of paragraph 3, the registrant concludes that the substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

(a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

(b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on

development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
(c) hazard class 4.1;
(d) hazard class 5.1,
or is assessed to be a PBT or vPvB, the chemical safety assessment shall include the following additional steps:
(a) exposure assessment including the generation of exposure scenario(s) (or the identification of relevant use and exposure categories if appropriate) and exposure estimation;
(b) risk characterisation.
The exposure scenarios (where appropriate the use and exposure categories), exposure assessment and risk characterisation shall address all identified uses of the registrant.
5. The chemical safety report need not include consideration of the risks to human health from the following end uses:
(a) in food contact materials within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food;
(b) in cosmetic products within the scope of Directive 76/768/EEC.
6. Any registrant shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets which he supplies in accordance with Article 31.
7. Any registrant required to conduct a chemical safety assessment shall keep his chemical safety report available and up to date.

Article 17
Registration of on-site isolated intermediates
1. Any manufacturer of an on-site isolated intermediate in quantities of one tonne or more per year shall submit a registration to the Agency for the on-site isolated intermediate.
2. A registration for an on-site isolated intermediate shall include all the following information, to the extent that the manufacturer is able to submit it without any additional testing:
(a) the identity of the manufacturer as specified in Section 1 of Annex VI;
(b) the identity of the intermediate as specified in Sections 2.1 to 2.3.4 of Annex VI;
(c) the classification of the intermediate as specified in Section 4 of Annex VI;
(d) any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted;
(e) a brief general description of the use, as specified in Section 3.5 of Annex VI;
(f) details of the risk management measures applied.
Except in cases covered under Article 25(3), Article 27(6) or Article 30(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (d) for the purpose of registration.
The registration shall be accompanied by the fee required in accordance with Title IX.
3. Paragraph 2 shall apply only to on-site isolated intermediates if the manufacturer confirms that the substance is only manufactured and used under strictly controlled conditions in that it is rigorously contained by technical means during its whole lifecycle. Control and procedural technologies shall be used to minimise emission and any resulting exposure.
If these conditions are not fulfilled, the registration shall include the information specified in Article 10.

Article 18
Registration of transported isolated intermediates
1. Any manufacturer or importer of a transported isolated intermediate in quantities of one ton or more per year shall submit a registration to the Agency for the transported isolated intermediate.
2. A registration for a transported isolated intermediate shall include all the following information:
(a) the identity of the manufacturer or importer as specified in Section 1 of Annex VI;
(b) the identity of the intermediate as specified in Sections 2.1 to 2.3.4 of Annex VI;

(c) the classification of the intermediate as specified in Section 4 of Annex VI;
(d) any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted;
(e) a brief general description of the use, as specified in Section 3.5 of Annex VI;
(f) information on risk management measures applied and recommended to the user in accordance with paragraph 4.

Except in cases covered under Article 25(3), Article 27(6) or Article 30(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (d) for the purpose of registration.
The registration shall be accompanied by the fee required in accordance with Title IX.
3. A registration for a transported isolated intermediate in quantities of more than 1 000 tonnes per year per manufacturer or importer shall include the information specified in Annex VII in addition to the information required under paragraph 2.
For the generation of this information, Article 13 shall apply.
4. Paragraphs 2 and 3 shall apply only to transported isolated intermediates if the manufacturer or importer confirms himself or states that he has received confirmation from the user that the synthesis of (an)other substance(s) from that intermediate takes place on other sites under the following strictly controlled conditions:

(a) the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage;
(b) procedural and control technologies shall be used that minimise emission and any resulting exposure;
(c) only properly trained and authorised personnel handle the substance;
(d) in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;
(e) in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures;
(f) substance-handling procedures are well documented and strictly supervised by the site operator.

If the conditions listed in the first subparagraph are not fulfilled, the registration shall include the information specified in Article 10.

Article 19

Joint submission of data on isolated intermediates by multiple registrants
1. When an on-site isolated intermediate or transported isolated intermediate is intended to be manufactured in the Community by one or more manufacturers and/or imported by one or more importers, the following shall apply.
Subject to paragraph 2 of this Article, the information specified in Article 17(2)(c) and (d) and Article 18(2)(c) and (d) shall first be submitted by one manufacturer or importer acting with the agreement of the other assenting manufacturer(s) or importer(s) (hereinafter referred to as 'the lead registrant').
Each registrant shall subsequently submit separately the information specified in Article 17(2)(a), (b), (e) and (f) and Article 18(2)(a), (b), (e) and (f).
2. A manufacturer or importer may submit the information referred to in Article 17(2)(c) or (d) and Article 18(2)(c) or (d) separately if:

(a) it would be disproportionately costly for him to submit this jointly; or
(b) submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or
(c) he disagrees with the lead registrant on the selection of this information.

If points (a), (b) or (c) apply, the manufacturer or importer shall submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment, or the nature of the

disagreement, as the case may be.
3. A submission for registration shall be accompanied by the fee required in accordance with Title IX.

Article 22

Further duties of registrants
1. Following registration, a registrant shall be responsible on his own initiative for updating his registration without undue delay with relevant new information and submitting it to the Agency in the following cases:

(a) any change in his status, such as being a manufacturer, an importer or a producer of articles, or in his identity, such as his name or address;
(b) any change in the composition of the substance as given in Section 2 of Annex VI;
(c) changes in the annual or total quantities manufactured or imported by him or in the quantities of substances present in articles produced or imported by him if these result in a change of tonnage band, including cessation of manufacture or import;
(d) new identified uses and new uses advised against as in Section 3.7 of Annex VI for which the substance is manufactured or imported;
(e) new knowledge of the risks of the substance to human health and/or the environment of which he may reasonably be expected to have become aware which leads to changes in the safety data sheet or the chemical safety report;
(f) any change in the classification and labelling of the substance;
(g) any update or amendment of the chemical safety report or Section 5 of Annex VI;
(h) the registrant identifies the need to perform a test listed in Annex IX or Annex X, in which cases a testing proposal shall be developed;
(i) any change in the access granted to information in the registration.

The Agency shall communicate this information to the competent authority of the relevant Member State.
2. A registrant shall submit to the Agency an update of the registration containing the information required by the decision made in accordance with Articles 40, 41 or 46 or take into account a decision made in accordance with Articles 60 and 73, within the deadline specified in that decision. The Agency shall notify the competent authority of the relevant Member State that the information is available on its database.
3. The Agency shall undertake a completeness check according to Article 20(2) first and second subparagraphs of each updated registration. In cases where the update is in accordance with Article 12(2) and with paragraph 1(c) of this Article then the Agency shall check the completeness of the information supplied by the registrant and Article 20(2) shall apply adapted as necessary.
4. In cases covered by Articles 11 or 19, each registrant shall submit separately the information specified in paragraph 1(c) of this Article.
5. An update shall be accompanied by the relevant part of the fee required in accordance with Title IX.

Article 24

Notified substances
1. A notification in accordance with Directive 67/548/EEC shall be regarded as a registration for the purposes of this Title and the Agency shall assign a registration number by 1 December 2008.
2. If the quantity of a notified substance manufactured or imported per manufacturer or importer reaches the next tonnage threshold under Article 12, the additional required information corresponding to that tonnage threshold, as well as to all the lower tonnage thresholds, shall be submitted in accordance with Articles 10 and 12, unless it has already been submitted in accordance with those Articles.

Article 40

Examination of testing proposals.

1. The Agency shall examine any testing proposal set out in a registration or a downstream user report for provision of the information specified in Annexes IX and X for a substance. Priority shall be given to registrations of substances which have or may have PBT, vPvB, sensitising and/or carcinogenic, mutagenic or toxic for reproduction (CMR) properties, or substances above 100 tons per year with uses resulting in widespread and diffuse exposure, provided they fulfil the criteria for any of the following hazard classes or categories set out in Annex I of Regulation (EC) No 1272/2008:

(a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

(b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;

(c) hazard class 4.1;

(d) hazard class 5.1.

2. Information relating to testing proposals involving tests on vertebrate animals shall be published on the Agency website. The Agency shall publish on its website the name of the substance, the hazard end-point for which vertebrate testing is proposed, and the date by which any third party information is required. It shall invite third parties to submit, using the format provided by the Agency, scientifically valid information and studies that address the relevant substance and hazard end-point, addressed by the testing proposal, within 45 days of the date of publication. All such scientifically valid information and studies received shall be taken into account by the Agency in preparing its decision in accordance with paragraph 3.

3. On the basis of the examination under paragraph 1, the Agency shall draft one of the following decisions and that decision shall be taken in accordance with the procedure laid down in Articles 50 and 51:

(a) a decision requiring the registrant(s) or downstream user(s) concerned to carry out the proposed test and setting a deadline for submission of the study summary, or the robust study summary if required by Annex I;

(b) a decision in accordance with point (a), but modifying the conditions under which the test is to be carried out;

(c) a decision in accordance with points (a), (b) or (d) but requiring registrant(s) or downstream user(s) to carry out one or more additional tests in cases of non-compliance of the testing proposal with Annexes IX, X and XI;

(d) a decision rejecting the testing proposal;

(e) a decision in accordance with points (a), (b) or (c), if several registrants or downstream users of the same substance have submitted proposals for the same test, giving them the opportunity to reach an agreement on who will perform the test on behalf of all of them and to inform the Agency accordingly within 90 days. If the Agency is not informed of such agreement within such 90 days, it shall designate one of the registrants or downstream users, as appropriate, to perform the test on behalf of all of them.

4. The registrant or downstream user shall submit the information required to the Agency by the deadline set.

Article 41

Compliance check of registrations

1. The Agency may examine any registration in order to verify any of the following:

(a) that the information in the technical dossier(s) submitted pursuant to Article 10 complies with the requirements of Articles 10, 12 and 13 and with Annexes III and VI to X;

(b) that the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in Annexes VII to X and with the general rules set out in Annex XI;

(c) that any required chemical safety assessment and chemical safety report comply with the requirements of Annex I and that the proposed risk management measures are adequate;

(d) that any explanation(s) submitted in accordance with Article 11(3) or Article 19(2) have an objective basis.

2. The list of dossiers being checked for compliance by the Agency shall be made available to Member States competent authorities.

3. On the basis of an examination made pursuant to paragraph 1, the Agency may, within 12 months of the start of the compliance check, prepare a draft decision requiring the registrant(s) to submit any information needed to bring the registration(s) into compliance with the relevant information requirements and specifying adequate time limits for the submission of further information. Such a decision shall be taken in accordance with the procedure laid down in Articles 50 and 51.

4. The registrant shall submit the information required to the Agency by the deadline set.

5. To ensure that registration dossiers comply with this Regulation, the Agency shall select a percentage of those dossiers, no lower than 5 % of the total received by the Agency for each tonnage band, for compliance checking. The Agency shall give priority, but not exclusively, to dossiers meeting at least one of the following criteria:

(a) the dossier contains information in Article 10(a)(iv), (vi) and/or (vii) submitted separately as per Article 11(3); or

(b) the dossier is for a substance manufactured or imported in quantities of one tonne or more per year and does not meet the requirements of Annex VII applying under either Article 12(1)(a) or (b), as the case may be; or

(c) the dossier is for a substance listed in the Community rolling action plan referred to in Article 44(2).

6. Any third party may electronically submit information to the Agency relating to substances that appear on the list referred to in Article 28(4). The Agency shall consider this information together with the information submitted according to Article 124 when checking and selecting dossiers.

7. The Commission may, after consulting with the Agency, take a decision to vary the percentage of dossiers selected and amend or include further criteria in paragraph 5 in accordance with the procedure referred to in Article 133(4).

Article 46

Requests for further information and check of information submitted

1. If the competent authority considers that further information is required, including, if appropriate, information not required in Annexes VII to X, it shall prepare a draft decision, stating reasons, requiring the registrant(s) to submit the further information and setting a deadline for its submission. A draft decision shall be prepared within 12 months of the publication of the Community rolling action plan on the Agency's website for substances to be evaluated that year. The decision shall be taken in accordance with the procedure laid down in Articles 50 and 52.

2. The registrant shall submit the information required to the Agency by the deadline set.

3. The competent authority shall examine any information submitted, and shall draft any appropriate decisions in accordance with this Article, if necessary, within 12 months of the information being submitted.

4. The competent authority shall finish its evaluation activities within 12 months of the start of the evaluation of the substance or within 12 months of the information being submitted under paragraph 2, and notify the Agency accordingly. If this deadline is exceeded, the evaluation shall be deemed to be finished.

1.2 Supply chain related duties

Article 13

General requirements for generation of information on intrinsic properties of substances

1. Information on intrinsic properties of substances may be generated by means other than tests, provided that the conditions set out in Annex XI are met. In particular for human toxicity, information shall be generated whenever possible by means other than vertebrate

animal tests, through the use of alternative methods, for example, in vitro methods or qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across). Testing in accordance with Annex VIII, Sections 8.6 and 8.7, Annex IX and Annex X may be omitted where justified by information on exposure and implemented risk management measures as specified in Annex XI, section 3.
2. These methods shall be regularly reviewed and improved with a view to reducing testing on vertebrate animals and the number of animals involved. The Commission, following consultation with relevant stakeholders, shall, as soon as possible, make a proposal, if appropriate, to amend the Commission Regulation on test methods adopted in accordance with the procedure referred to in Article 133(4), and the Annexes of this Regulation, if relevant, so as to replace, reduce or refine animal testing. Amendments to that Commission Regulation shall be adopted in accordance with the procedure specified in paragraph 3 and amendments to the Annexes of this Regulation shall be adopted in accordance with the procedure referred to in Article 131.
3. Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate. The Commission shall adopt that Regulation, designed to amend the non-essential elements of this Regulation by supplementing it, in accordance with the procedure referred to in Article 133(4).
Information on intrinsic properties of substances may be generated in accordance with other test methods provided that the conditions set out in Annex XI are met.
4. Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable.
5. If a substance has already been registered, a new registrant shall be entitled to refer to the study summaries or robust study summaries, for the same substance submitted earlier, provided that he can show that the substance that he is now registering is the same as the one previously registered, including the degree of purity and the nature of impurities, and that the previous registrant(s) have given permission to refer to the full study reports for the purpose of registration.
A new registrant shall not refer to such studies in order to provide the information required in Section 2 of Annex VI.

Article 31

Requirements for safety data sheets
1. The supplier of a substance or a mixture shall provide the recipient of the substance or mixture with a safety data sheet compiled in accordance with Annex II:
(a) where a substance or mixture meets the criteria for classification as hazardous in accordance with Regulation (EC) No 1272/2008; or
(b) where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII; or
(c) where a substance is included in the list established in accordance with Article 59(1) for reasons other than those referred to in points (a) and (b).
2. Any actor in the supply chain who is required, under Articles 14 or 37, to carry out a chemical safety assessment for a substance shall ensure that the information in the safety data sheet is consistent with the information in this assessment. If the safety data sheet is developed for a mixture and the actor in the supply chain has prepared a chemical safety assessment for that mixture, it is sufficient if the information in the safety data sheet is consistent with the chemical safety report for the mixture instead of with the chemical safety report for each substance in the mixture.
3. The supplier shall provide the recipient at his request with a safety data sheet compiled in accordance with Annex II, where a mixture does not meet the criteria for classification as hazardous in accordance with Titles I and II of Regulation (EC) No 1272/2008, but contains:
(a) in an individual concentration of ≥ 1 % by weight for non-gaseous mixtures and ≥

0,2 % by volume for gaseous mixtures at least one substance posing human health or environmental hazards; or
(b) in an individual concentration of ≥ 0,1 % by weight for non-gaseous mixtures at least one substance that is carcinogenic category 2 or toxic to reproduction category 1A, 1B and 2, skin sensitiser category 1, respiratory sensitiser category 1, or has effects on or via lactation or is persistent, bioaccumulative and toxic (PBT) in accordance with the criteria set out in Annex XIII or very persistent and very bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII or has been included for reasons other than those referred to in point (a) in the list established in accordance with Article 59(1); or
(c) a substance for which there are Community workplace exposure limits.

4. The safety data sheet need not be supplied where hazardous substances or mixtures offered or sold to the general public are provided with sufficient information to enable users to take the necessary measures as regards the protection of human health, safety and the environment, unless requested by a downstream user or distributor.

5. The safety data sheet shall be supplied in an official language of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide otherwise.

6. The safety data sheet shall be dated and shall contain the following headings:

1. identification of the substance/mixture and of the company/undertaking;
2. hazards identification;
3. composition/information on ingredients;
4. first-aid measures;
5. fire-fighting measures;
6. accidental release measures;
7. handling and storage;
8. exposure controls/personal protection;
9. physical and chemical properties;
10. stability and reactivity;
11. toxicological information;
12. ecological information;
13. disposal considerations;
14. transport information;
15. regulatory information;
16. other information.

7. Any actor in the supply chain who is required to prepare a chemical safety report according to Articles 14 or 37 shall place the relevant exposure scenarios (including use and exposure categories where appropriate) in an annex to the safety data sheet covering identified uses and including specific conditions resulting from the application of Section 3 of Annex XI.
Any downstream user shall include relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for identified uses.
Any distributor shall pass on relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for uses for which he has passed on information according to Article 37(2).

8. A safety data sheet shall be provided free of charge on paper or electronically no later than the date on which the substance or mixture is first supplied.

9. Suppliers shall update the safety data sheet without delay on the following occasions:
(a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available;
(b) once an authorisation has been granted or refused;
(c) once a restriction has been imposed.

The new, dated version of the information, identified as 'Revision: (date)', shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or mixture within the preceding 12 months. Any updates following registration shall include the registration number.

10. Where substances are classified in accordance with Regulation (EC) No 1272/2008 during

the period from its entry into force until 1 December 2010, that classification may be added in the safety data sheet together with the classification in accordance with Directive 67/548/EEC. From 1 December 2010 until 1 June 2015, the safety data sheets for substances shall contain the classification according to both Directive 67/548/EEC and Regulation (EC) No 1272/2008. Where mixtures are classified in accordance with Regulation (EC) No 1272/2008 during the period from its entry into force until 1 June 2015, that classification may be added in the safety data sheet, together with the classification in accordance with Directive 1999/45/EC. However, until 1 June 2015, where substances or mixtures are both classified and labelled in accordance with Regulation (EC) No 1272/2008 that classification shall be provided in the safety data sheet, together with the classification in accordance with Directives 67/548/EEC and 1999/45/EC respectively, for the substance, the mixture and its constituents.

Article 32

Duty to communicate information down the supply chain for substances on their own or in mixtures for which a safety data sheet is not required

1. Any supplier of a substance on its own or in a mixture who does not have to supply a safety data sheet in accordance with Article 31 shall provide the recipient with the following information:
   (a) the registration number(s) referred to in Article 20(3), if available, for any substances for which information is communicated under points (b), (c) or (d) of this paragraph;
   (b) if the substance is subject to authorisation and details of any authorisation granted or denied under Title VII in this supply chain;
   (c) details of any restriction imposed under Title VIII;
   (d) any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied including specific conditions resulting from the application of Section 3 of Annex XI.
2. The information referred to in paragraph 1 shall be communicated free of charge on paper or electronically at the latest at the time of the first delivery of a substance on its own or in a mixture after 1 June 2007.
3. Suppliers shall update this information without delay on the following occasions:
   (a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available;
   (b) once an authorisation has been granted or refused;
   (c) once a restriction has been imposed.

In addition, the updated information shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or mixture within the preceding 12 months. Any updates following registration shall include the registration number.

Article 33

Duty to communicate information on substances in articles

1. Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.
2. On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

The relevant information shall be provided, free of charge, within 45 days of receipt of the request.

Article 34

Duty to communicate information on substances and mixtures up the supply chain

Any actor in the supply chain of a substance or a mixture shall communicate the following information to the next actor or distributor up the supply chain:

(a) new information on hazardous properties, regardless of the uses concerned;
(b) any other information that might call into question the appropriateness of the risk management measures identified in a safety data sheet supplied to him, which shall be communicated only for identified uses.

Distributors shall pass on that information to the next actor or distributor up the supply chain.

Article 35

Access to information for workers

Workers and their representatives shall be granted access by their employer to the information provided in accordance with Articles 31 and 32 in relation to substances or mixtures that they use or may be exposed to in the course of their work.

Article 36

Obligation to keep information

1. Each manufacturer, importer, downstream user and distributor shall assemble and keep available all the information he requires to carry out his duties under this Regulation for a period of at least 10 years after he last manufactured, imported, supplied or used the substance or mixture. That manufacturer, importer, downstream user or distributor shall submit this information or make it available without delay upon request to any competent authority of the Member State in which he is established or to the Agency, without prejudice to Titles II and VI.
2. In the event of a registrant, downstream user or distributor ceasing activity, or transferring part or all of his operations to a third party, the party responsible for liquidating the registrant, downstream user or distributor's undertaking or assuming responsibility for the placing on the market of the substance or mixture concerned shall be bound by the obligation in paragraph 1 in place of the registrant, downstream user or distributor.

Article 56

General provisions

1. A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV, unless:
(a) the use(s) of that substance on its own or in a mixture or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been authorised in accordance with Articles 60 to 64; or
(b) the use(s) of that substance on its own or in a mixture or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been exempted from the authorisation requirement in Annex XIV itself in accordance with Article 58(2); or
(c) the date referred to in Article 58(1)(c)(i) has not been reached; or
(d) the date referred to in Article 58(1)(c)(i) has been reached and he made an application 18 months before that date but a decision on the application for authorisation has not yet been taken; or
(e) in cases where the substance is placed on the market, authorisation for that use has been granted to his immediate downstream user.
2. A downstream user may use a substance meeting the criteria set out in paragraph 1 provided that the use is in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use.
3. Paragraphs 1 and 2 shall not apply to the use of substances in scientific research and development. Annex XIV shall specify if paragraphs 1 and 2 apply to product and process orientated research and development as well as the maximum quantity exempted.
4. Paragraphs 1 and 2 shall not apply to the following uses of substances:
(a) uses in plant protection products within the scope of Directive 91/414/EEC;
(b) uses in biocidal products within the scope of Directive 98/8/EC;
(c) use as motor fuels covered by Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels;
(d) uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems.

5. In the case of substances that are subject to authorisation only because they meet the criteria in Article 57(a), (b) or (c) or because they are identified in accordance with Article 57(f) only because of hazards to human health, paragraphs 1 and 2 of this Article shall not apply to the following uses:

(a) uses in cosmetic products within the scope of Directive 76/768/EEC;

(b) uses in food contact materials within the scope of Regulation (EC) No 1935/2004.

6. Paragraphs 1 and 2 shall not apply to the use of substances when they are present in mixtures:

(a) for substances referred to in Article 57(d), (e) and (f), below a concentration limit of 0,1 % weight by weight (w/w);

(b) for all other substances, below the values specified in Article 11(3) of Regulation (EC) No 1272/2008 which result in the classification of the mixture as hazardous.

Article 65

Obligation of holders of authorisations

Holders of an authorisation, as well as downstream users referred to in Article 56(2) including the substances in a mixture, shall include the authorisation number on the label before they place the substance or a mixture containing the substance on the market for an authorised use without prejudice to Directive 67/548/EEC and Regulation (EC) No 1272/2008.

This shall be done without delay once the authorisation number has been made publicly available in accordance with Article 64(9).

Article 67

General provisions

1. A substance on its own, in a mixture or in an article, for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. This shall not apply to the manufacture, placing on the market or use of a substance in scientific research and development. Annex XVII shall specify if the restriction shall not apply to product and process orientated research and development, as well as the maximum quantity exempted.

2. Paragraph 1 shall not apply to the use of substances in cosmetic products, as defined by Directive 76/768/EEC, with regard to restrictions addressing the risks to human health within the scope of that Directive.

3. Until 1 June 2013, a Member State may maintain any existing and more stringent restrictions in relation to Annex XVII on the manufacture, placing on the market or use of a substance, provided that those restrictions have been notified according to the Treaty. The Commission shall compile and publish an inventory of these restrictions by 1 June 2009.

1.3 Use related duties

Article 14

Chemical safety report and duty to apply and recommend risk reduction measures

1. Without prejudice to Article 4 of Directive 98/24/EC, a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter in quantities of 10 tonnes or more per year per registrant.

The chemical safety report shall document the chemical safety assessment which shall be conducted in accordance with paragraphs 2 to 7 and with Annex I for either each substance on its own or in a mixture or in an article or a group of substances.

2. A chemical safety assessment in accordance with paragraph 1 need not be performed for a substance which is present in a mixture if the concentration of the substance in the mixture is less than:

(a) the cut-off value referred to in Article 11, paragraph 3 of Regulation (EC) No 1272/2008;

(b) 0,1 % weight by weight (w/w), if the substance meets the criteria in Annex XIII to this Regulation.

3. A chemical safety assessment of a substance shall include the following steps:
(a) human health hazard assessment;
(b) physicochemical hazard assessment;
(c) environmental hazard assessment;
(d) persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment.
4. If, as a result of carrying out steps (a) to (d) of paragraph 3, the registrant concludes that the substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:
(a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
(b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
(c) hazard class 4.1;
(d) hazard class 5.1,
or is assessed to be a PBT or vPvB, the chemical safety assessment shall include the following additional steps:
(a) exposure assessment including the generation of exposure scenario(s) (or the identification of relevant use and exposure categories if appropriate) and exposure estimation;
(b) risk characterisation.
The exposure scenarios (where appropriate the use and exposure categories), exposure assessment and risk characterisation shall address all identified uses of the registrant.
5. The chemical safety report need not include consideration of the risks to human health from the following end uses:
(a) in food contact materials within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food;
(b) in cosmetic products within the scope of Directive 76/768/EEC.
6. Any registrant shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets which he supplies in accordance with Article 31.
7. Any registrant required to conduct a chemical safety assessment shall keep his chemical safety report available and up to date.

Article 37

Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures
1. A downstream user or distributor may provide information to assist in the preparation of a registration.
2. Any downstream user shall have the right to make a use, as a minimum the brief general description of use, known in writing (on paper or electronically) to the manufacturer, importer, downstream user or distributor who supplies him with a substance on its own or in a mixture with the aim of making this an identified use. In making a use known, he shall provide sufficient information to allow the manufacturer, importer or downstream user who has supplied the substance, to prepare an exposure scenario, or if appropriate a use and exposure category, for his use in the manufacturer, importer or downstream user's chemical safety assessment.
Distributors shall pass on such information to the next actor or distributor up the supply chain. Downstream users in receipt of such information may prepare an exposure scenario for the identified use(s), or pass the information to the next actor up the supply chain.
3. For registered substances, the manufacturer, importer or downstream user shall comply with the obligations laid down in Article 14 either before he next supplies the substance on its own or in a mixture to the downstream user making the request referred to in paragraph 2 of this Article, provided that the request was made at least one month before the supply, or within one month after the request, whichever is the later.
For phase-in substances, the manufacturer, importer or downstream user shall comply with

this request and with the obligations laid down in Article 14 before the relevant deadline in Article 23 has expired, provided that the downstream user makes his request at least 12 months before the deadline in question.
Where the manufacturer, importer or downstream user, having assessed the use in accordance with Article 14, is unable to include it as an identified use for reasons of protection of human health or the environment, he shall provide the Agency and the downstream user with the reason(s) for that decision in writing without delay and shall not supply downstream user(s) with the substance without including these reason(s) in the information referred to under Articles 31 or 32. The manufacturer or importer shall include this use in Section 3.7 of Annex VI in his update of the registration in accordance with Article 22(1)(d).
4. A downstream user of a substance on its own or in a mixture shall prepare a chemical safety report in accordance with Annex XII for any use outside the conditions described in an exposure scenario or if appropriate a use and exposure category communicated to him in a safety data sheet or for any use his supplier advises against.
A downstream user need not prepare such a chemical safety report in any of the following cases:

(a) a safety data sheet is not required to be communicated with the substance ormixture in accordance with Article 31;
(b) a chemical safety report is not required to be completed by his supplier in accordance with Article 14;
(c) the downstream user uses the substance or mixture in a total quantity of less than one tonne per year;
(d) the downstream user implements or recommends an exposure scenario which includes as a minimum the conditions described in the exposure scenario communicated to him in the safety data sheet;
(e) the substance is present in a mixture in a concentration lower than any of the concentrations set out in Article 14(2);
(f) the downstream user is using the substance for the purposes of product and process oriented research and development, provided that the risks to human health and the environment are adequately controlled in accordance with the requirements of legislation for the protection of workers and the environment.

5. Any downstream user shall identify, apply and where suitable, recommend, appropriate measures to adequately control risks identified in any of the following:

(a) the safety data sheet(s) supplied to him;
(b) his own chemical safety assessment;
(c) any information on risk management measures supplied to him in accordance with Article 32.

6. Where a downstream user does not prepare a chemical safety report in accordance with paragraph 4(c), he shall consider the use(s) of the substance and identify and apply any appropriate risk management measures needed to ensure that the risks to human health and the environment are adequately controlled. Where necessary, this information shall be included in any safety data sheet prepared by him.
7. Downstream users shall keep their chemical safety report up to date and available.
8. A chemical safety report prepared in accordance with paragraph 4 of this Article need not include consideration of the risks to human health from the end uses set out in Article 14(5).

Article 38

Obligation for downstream users to report information
1. Before commencing or continuing with a particular use of a substance that has been registered by an actor up the supply chain in accordance with Articles 6 or 18, the downstream user shall report to the Agency the information specified in paragraph 2 of this Article, in the following cases:

(a) the downstream user has to prepare a chemical safety report in accordance with Article 37(4); or
(b) the downstream user is relying on the exemptions in Article 37(4)(c) or (f).

2. The information reported by the downstream user shall include the following:

(a) his identity and contact details as specified in Section 1.1 of Annex VI;

(b) the registration number(s) referred to in Article 20(3), if available;
(c) the identity of the substance(s) as specified in Section 2.1 to 2.3.4 of Annex VI;
(d) the identity of the manufacturer(s) or the importer(s) or other supplier as specified in Section 1.1 of Annex VI;
(e) a brief general description of the use(s), as specified in Section 3.5 of Annex VI, and of the conditions of use(s);
(f) except where the downstream user is relying on the exemption in Article 37(4)(c), a proposal for additional testing on vertebrate animals, where this is considered necessary by the downstream user to complete his chemical safety assessment.

3. The downstream user shall update this information without delay in the event of a change in the information reported in accordance with paragraph 1.
4. A downstream user shall report to the Agency if his classification of a substance is different to that of his supplier.
5. Except where a downstream user is relying on the exemption in Article 37(4)(c), reporting in accordance with paragraphs 1 to 4 of this Article shall not be required in respect of a substance, on its own or in a mixture, used by the downstream user in quantities of less than one tonne per year for that particular use.

Article 39

Application of downstream user obligations

1. Downstream users shall be required to comply with the requirements of Article 37 at the latest 12 months after receiving a registration number communicated to them by their suppliers in a safety data sheet.
2. Downstream users shall be required to comply with the requirements of Article 38 at the latest six months after receiving a registration number communicated to them by their suppliers in a safety data sheet.

Article 55

Aim of authorisation and considerations for substitution

The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.

Article 56

General provisions

1. A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV, unless:
(a) the use(s) of that substance on its own or in a mixture or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been authorised in accordance with Articles 60 to 64; or
(b) the use(s) of that substance on its own or in a mixture or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been exempted from the authorisation requirement in Annex XIV itself in accordance with Article 58(2); or
(c) the date referred to in Article 58(1)(c)(i) has not been reached; or
(d) the date referred to in Article 58(1)(c)(i) has been reached and he made an application 18 months before that date but a decision on the application for authorisation has not yet been taken; or
(e) in cases where the substance is placed on the market, authorisation for that use has been granted to his immediate downstream user.

2. A downstream user may use a substance meeting the criteria set out in paragraph 1 provided that the use is in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use.
3. Paragraphs 1 and 2 shall not apply to the use of substances in scientific research and

development. Annex XIV shall specify if paragraphs 1 and 2 apply to product and process orientated research and development as well as the maximum quantity exempted.
4. Paragraphs 1 and 2 shall not apply to the following uses of substances:
(a) uses in plant protection products within the scope of Directive 91/414/EEC;
(b) uses in biocidal products within the scope of Directive 98/8/EC;
(c) use as motor fuels covered by Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels;
(d) uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems.
5. In the case of substances that are subject to authorisation only because they meet the criteria in Article 57(a), (b) or (c) or because they are identified in accordance with Article 57(f) only because of hazards to human health, paragraphs 1 and 2 of this Article shall not apply to the following uses:
(a) uses in cosmetic products within the scope of Directive 76/768/EEC;
(b) uses in food contact materials within the scope of Regulation (EC) No 1935/2004.
6. Paragraphs 1 and 2 shall not apply to the use of substances when they are present in mixtures:
(a) for substances referred to in Article 57(d), (e) and (f), below a concentration limit of 0,1 % weight by weight (w/w);
(b) for all other substances, below the values specified in Article 11(3) of Regulation (EC) No 1272/2008 which result in the classification of the mixture as hazardous.

Article 60

Granting of authorisations
1. The Commission shall be responsible for taking decisions on applications for authorisations in accordance with this Title.
2. Without prejudice to paragraph 3, an authorisation shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled in accordance with Section 6.4 of Annex I and as documented in the applicant's chemical safety report, taking into account the opinion of the Committee for Risk Assessment referred to in Article 64(4)(a). When granting the authorisation, and in any conditions imposed therein, the Commission shall take into account all discharges, emissions and losses, including risks arising from diffuse or dispersive uses, known at the time of the decision.
The Commission shall not consider the risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices or Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
3. Paragraph 2 shall not apply to:
(a) substances meeting the criteria in Article 57(a), (b), (c) or (f) for which it is not possible to determine a threshold in accordance with Section 6.4 of Annex I;
(b) substances meeting the criteria in Article 57(d) or (e);
(c) substances identified under Article 57(f) having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties.
4. If an authorisation cannot be granted under paragraph 2 or for substances listed in paragraph 3, an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. This decision shall be taken after consideration of all of the following elements and taking into account the opinions of the Committee for Risk Assessment and the Committee for Socio- economic Analysis referred to in Article 64(4)(a) and (b):
(a) the risk posed by the uses of the substance, including the appropriateness and effectiveness of the risk management measures proposed;
(b) the socio-economic benefits arising from its use and the socio- economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties;

(c) the analysis of the alternatives submitted by the applicant under Article 62(4)(e) or any substitution plan submitted by the applicant under Article 62(4)(f), and any third party contributions submitted under Article 64(2);
(d) available information on the risks to human health or the environment of any alternative substances or technologies.

5. When assessing whether suitable alternative substances or technologies are available, all relevant aspects shall be taken into account by the Commission, including:
(a) whether the transfer to alternatives would result in reduced overall risks to human health and the environment, taking into account the appropriateness and effectiveness of risk management measures;
(b) the technical and economic feasibility of alternatives for the applicant.

6. A use shall not be authorised if this would constitute a relaxation of a restriction set out in Annex XVII.

7. An authorisation shall be granted only if the application is made in conformity with the requirements of Article 62.

8. Authorisations shall be subject to a time-limited review without prejudice to any decision on a future review period and shall normally be subject to conditions, including monitoring. The duration of the time- limited review for any authorisation shall be determined on a case-by-case basis taking into account all relevant information including the elements listed in paragraph 4(a) to (d), as appropriate.

9. The authorisation shall specify:
(a) the person(s) to whom the authorisation is granted;
(b) the identity of the substance(s);
(c) the use(s) for which the authorisation is granted;
(d) any conditions under which the authorisation is granted;
(e) the time-limited review period;
(f) any monitoring arrangement.

10. Notwithstanding any conditions of an authorisation, the holder shall ensure that the exposure is reduced to as low a level as is technically and practically possible.

Article 65

Obligation of holders of authorisations

Holders of an authorisation, as well as downstream users referred to in Article 56(2) including the substances in a mixture, shall include the authorisation number on the label before they place the substance or a mixture containing the substance on the market for an authorised use without prejudice to Directive 67/548/EEC and Regulation (EC) No 1272/2008.
This shall be done without delay once the authorisation number has been made publicly available in accordance with Article 64(9).

Article 66

Downstream users

1. Downstream users using a substance in accordance with Article 56(2) shall notify the Agency within three months of the first supply of the substance.

2. The Agency shall establish and keep up to date a register of downstream users who have made a notification in accordance with paragraph 1. The Agency shall grant access to this register to the competent authorities of the Member States.

Article 67

General provisions

1. A substance on its own, in a mixture or in an article, for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. This shall not apply to the manufacture, placing on the market or use of a substance in scientific research and development. Annex XVII shall specify if the restriction shall not apply to product and process orientated research and development, as well as the maximum quantity exempted.

2. Paragraph 1 shall not apply to the use of substances in cosmetic products, as defined by

Directive 76/768/EEC, with regard to restrictions addressing the risks to human health within the scope of that Directive.
3. Until 1 June 2013, a Member State may maintain any existing and more stringent restrictions in relation to Annex XVII on the manufacture, placing on the market or use of a substance, provided that those restrictions have been notified according to the Treaty. The Commission shall compile and publish an inventory of these restrictions by 1 June 2009.

2. CLP

(ECHA consolidated version 1 MARCH 2018)

Article 4

General obligations to classify, label and package

1. Manufacturers, importers and downstream users shall classify substances or mixtures in accordance with Title II before placing them on the market.
2. Without prejudice to the requirements of paragraph 1, manufacturers, producers of articles and importers shall classify those substances not placed on the market in accordance with Title II where:
   (a) Articles 6, 7(1) or (5), 17 or 18 of Regulation (EC) No 1907/2006 provide for registration of a substance;
   (b) Articles 7(2) or 9 of Regulation (EC) No 1907/2006 provide for notification.
3. If a substance is subject to harmonised classification and labelling in accordance with Title V through an entry in Part 3 of Annex VI, that substance shall be classified in accordance with that entry, and a classification of that substance in accordance with Title II shall not be performed for the hazard classes or differentiations covered by that entry.
However, where the substance also falls within one or more hazard classes or differentiations not covered by an entry in Part 3 of Annex VI, classification under Title II shall be carried out for those hazard classes or differentiations.
4. Where a substance or mixture is classified as hazardous, suppliers shall ensure that the substance or mixture is labelled and packaged in accordance with Titles III and IV, before placing it on the market.
5. In fulfilling their responsibilities under paragraph 4, distributors may use the classification for a substance or mixture derived in accordance with Title II by an actor in the supply chain.
6. In fulfilling their responsibilities under paragraphs 1 and 4, downstream users may use the classification of a substance or mixture derived in accordance with Title II by an actor in the supply chain, provided that they do not change the composition of the substance or mixture.
7. A mixture referred to in Part 2 of Annex II that contains any substance classified as hazardous shall not be placed on the market, unless it is labelled in accordance with Title III.
8. For the purposes of this Regulation, the articles referred to in section 2.1 of Annex I shall be classified, labelled and packaged in accordance with the rules for substances and mixtures before being placed on the market.
9. Suppliers in a supply chain shall cooperate to meet the requirements for classification, labelling and packaging in this Regulation.
10. Substances and mixtures shall not be placed on the market unless they comply with this Regulation.

Article 6

Identification and examination of available information on mixtures

1. Manufacturers, importers and downstream users of a mixture shall identify the relevant available information on the mixture itself or the substances contained in it for the purposes of determining whether the mixture entails a physical, health or environmental hazard as set out in Annex I, and, in particular, the following:
   (a) data generated in accordance with any of the methods referred to in Article 8(3) on the mixture itself or the substances contained in it;
   (b) epidemiological data and experience on the effects on humans for the mixture itself or the substances contained in it, such as occupational data or data from accident databases;
   (c) any other information generated in accordance with section 1 of Annex XI to Regulation (EC) No 1907/2006 for the mixture itself or the substances contained in it;
   (d) any other information generated under internationally recognised chemical programmes for the mixture itself or the substances contained in it.

The information shall relate to the forms or physical states in which the mixture is placed on the market and, when relevant, in which it can reasonably be expected to be used.

2. Subject to paragraphs 3 and 4, where the information referred to in paragraph 1 is available for the mixture itself, and the manufacturer, importer or downstream user has ascertained that information to be adequate and reliable and where applicable, scientifically valid, that manufacturer, importer or downstream user shall use that information for the purposes of the evaluation pursuant to Chapter 2 of this Title.
3. For the evaluation of mixtures pursuant to Chapter 2 of this Title in relation to the 'germ cell mutagenicity', 'carcinogenicity' and 'reproductive toxicity' hazard classes referred to in sections 3.5.3.1, 3.6.3.1 and 3.7.3.1 of Annex I, the manufacturer, importer or downstream user shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture.
Further, in cases where the available test data on the mixture itself demonstrate germ cell mutagenic, carcinogenic or toxic to reproduction effects which have not been identified from the information on the individual substances, those data shall also be taken into account.
4. For the evaluation of mixtures pursuant to Chapter 2 of this Title in relation to the 'biodegradation and bioaccumulation' properties within the 'hazardous to the aquatic environment' hazard class referred to in sections 4.1.2.8 and 4.1.2.9 of Annex I, the manufacturer, importer or downstream user shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture.
5. Where no or inadequate test data on the mixture itself of the kind referred to in paragraph 1 are available, the manufacturer, importer or downstream user shall use other available information on individual substances and similar tested mixtures which may also be considered relevant for the purposes of determining whether the mixture is hazardous, provided that that manufacturer, importer or downstream user has ascertained that information to be adequate and reliable for the purpose of the evaluation pursuant to Article 9(4).

Article 9

Evaluation of hazard information for substances and mixtures
1. Manufacturers, importers and downstream users of a substance or a mixture shall evaluate the information identified in accordance with Chapter 1 of this Title by applying to it the criteria for classification for each hazard class or differentiation in Parts 2 to 5 of Annex I, so as to ascertain the hazards associated with the substance or mixture.
2. In evaluating available test data for a substance or a mixture which have been obtained from test methods other than those referred to in Article 8(3), manufacturers, importers and downstream users shall compare the test methods employed with those indicated in that Article in order to determine whether the use of those test methods affects the evaluation referred to in paragraph 1 of this Article.
3. Where the criteria cannot be applied directly to available identified information, manufacturers, importers and downstream users shall carry out an evaluation by applying a weight of evidence determination using expert judgement in accordance with section 1.1.1 of Annex I to this Regulation, weighing all available information having a bearing on the determination of the hazards of the substance or the mixture, and in accordance with section 1.2 of Annex XI to Regulation (EC) No 1907/2006.
4. Where only the information referred to in Article 6(5) is available, manufacturers, importers and downstream users shall apply the bridging principles referred to in section 1.1.3 and in each section of Parts 3 and 4 of Annex I for the purposes of the evaluation.
However, where that information permits the application neither of the bridging principles nor the principles for using expert judgement and weight of evidence determination as described in Part 1 of Annex I, manufacturers, importers and downstream users shall evaluate the information by applying the other method or methods described in each section of Parts 3 and 4 of Annex I.
5. When evaluating the available information for the purposes of classification, the manufacturers, importers and downstream users shall consider the forms or physical states in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used.

Article 10
Concentration limits and M-factors for classification of substances and mixtures
1. Specific concentration limits and generic concentration limits are limits assigned to a substance indicating a threshold at or above which the presence of that substance in another substance or in a mixture as an identified impurity, additive or individual constituent leads to the classification of the substance or mixture as hazardous.
Specific concentration limits shall be set by the manufacturer, importer or downstream user where adequate and reliable scientific information shows that the hazard of a substance is evident when the substance is present at a level below the concentrations set for any hazard class in Part 2 of Annex I or below the generic concentration limits set for any hazard class in Parts 3, 4 and 5 of Annex I.
In exceptional circumstances specific concentration limits may be set by the manufacturer, importer or downstream user where he has adequate, reliable and conclusive scientific information that a hazard of a substance classified as hazardous is not evident at a level above the concentrations set for the relevant hazard class in Part 2 of Annex I or above the generic concentration limits set for the relevant hazard class in Parts 3, 4 and 5 of that Annex.
2. M-factors for substances classified as hazardous to the aquatic environment, acute category 1 or chronic category 1, shall be established by manufacturers, importers and downstream users.
3. Notwithstanding paragraph 1, specific concentration limits shall not be set for harmonised hazard classes or differentiations for substances included in Part 3 of Annex VI.
4. Notwithstanding paragraph 2, M-factors shall not be set for harmonised hazard classes or differentiations for substances included in Part 3 of Annex VI for which an M-factor is given in that Part.
However, where an M-factor is not given in Part 3 of Annex VI for substances classified as hazardous to the aquatic environment, acute category 1 or chronic category 1, an M-factor based on available data for the substance shall be set by the manufacturer, importer or downstream user. When a mixture including the substance is classified by the manufacturer, importer or downstream user using the summation method, this M-factor shall be used.
5. In setting the specific concentration limit or M-factor manufacturers, importers and downstream users shall take into account any specific concentration limits or M-factors for that substance which have been included in the classification and labelling inventory.
6. Specific concentration limits set in accordance with paragraph 1 shall take precedence over the concentrations in the relevant sections of Part 2 of Annex I or the generic concentration limits for classification in the relevant sections of Parts 3, 4 and 5 of Annex I.
7. The Agency shall provide further guidance for the application of paragraphs 1 and 2.

Article 11
Cut-off values
1. Where a substance contains another substance, itself classified as hazardous, whether in the form of an identified impurity, additive or individual constituent, this shall be taken into account for the purposes of classification, if the concentration of the identified impurity, additive or individual constituent is equal to, or greater than, the applicable cut- off value in accordance with paragraph 3.
2. Where a mixture contains a substance classified as hazardous, whether as a component or in the form of an identified impurity or additive, this information shall be taken into account for the purposes of classification, if the concentration of that substance is equal to or greater than its cut-off value in accordance with paragraph 3.
3. The cut-off value referred to in paragraphs 1 and 2 shall be determined as set out in section 1.1.2.2 of Annex I.

Article 13
Decision to classify substances and mixtures
If the evaluation undertaken pursuant to Article 9 and Article 12 shows that the hazards associated with the substance or mixture meet the criteria for classification in one or more hazard classes or differentiations in Parts 2 to 5 of Annex I, manufacturers, importers and

downstream users shall classify the substance or mixture in relation to the relevant hazard class or classes or differentiations by assigning the following:

(a) one or more hazard categories for each relevant hazard class or differentiation;

(b) subject to Article 21, one or more hazard statements corresponding to each hazard category assigned in accordance with (a).

Article 14

Specific rules for the classification of mixtures

1. The classification of a mixture shall not be affected where the evaluation of the information indicates any of the following:

(a) that the substances in the mixture react slowly with atmospheric gases, in particular oxygen, carbon dioxide, water vapour, to form different substances at low concentration;

(b) that the substances in the mixture react very slowly with other substances in the mixture to form different substances at low concentration;

(c) that the substances in the mixture may self-polymerise to form oligomers or polymers, at low concentration.

2. A mixture need not be classified for explosive, oxidising, or flammable properties as referred to in Part 2 of Annex I provided that any of the following requirements are met:

(a) none of the substances in the mixture possesses any of those properties and, on the basis of the information available to the supplier, the mixture is unlikely to present hazards of this kind;

(b) in the event of a change in the composition of a mixture, scientific evidence indicates that an evaluation of the information on the mixture will not lead to a change in classification.

Article 15

Review of classification for substances and mixtures

1. Manufacturers, importers and downstream users shall take all reasonable steps available to them to make themselves aware of new scientific or technical information that may affect the classification of the substances or mixtures they place on the market. When a manufacturer, importer or downstream user becomes aware of such information which he considers to be adequate and reliable, that manufacturer, importer or downstream user shall without undue delay carry out a new evaluation in accordance with this Chapter.

2. Where the manufacturer, importer or downstream user introduces a change to a mixture that has been classified as hazardous, that manufacturer, importer or downstream user shall carry out a new evaluation in accordance with this Chapter where the change is either of the following:

(a) a change in the composition of the initial concentration of one or more of the hazardous constituents in concentrations at or above the limits in Table 1.2 of Part 1 of Annex I;

(b) a change in the composition involving the substitution or addition of one or more constituents in concentrations at or above the cut-off value referred to in Article 11(3).

3. A new evaluation in accordance with paragraphs 1 and 2 shall not be required if there is valid scientific justification that this will not result in a change of classification.

4. Manufacturers, importers and downstream users shall adapt the classification of the substance or the mixture in accordance with the results of the new evaluation except where there are harmonised hazard classes or differentiations for substances included in Part 3 of Annex VI.

5. For paragraphs 1 to 4 of this Article, when the substance or mixture concerned is within the scope of Directive 91/414/EEC or Directive 98/8/EC, the requirements of those Directives shall also apply.

Article 16

Classification of substances included in the classification and labelling inventory

1. Manufacturers and importers may classify a substance differently from the classification already included in the classification and labelling inventory, provided they submit the reasons for the classification to the Agency together with the notification in accordance with Article 40.

2. Paragraph 1 shall not apply if the classification included in the classification and labelling inventory is a harmonised classification included in Part 3 of Annex VI.

Article 17

General rules

1. A substance or mixture classified as hazardous and contained in packaging shall bear a label including the following elements:

(a) the name, address and telephone number of the supplier(s);

(b) the nominal quantity of the substance or mixture in the package made available to the general public, unless this quantity is specified elsewhere on the package;

(c) product identifiers as specified in Article 18;

(d) where applicable, hazard pictograms in accordance with Article 19;

(e) where applicable, signal words in accordance with Article 20;

(f) where applicable, hazard statements in accordance with Article 21;

(g) where applicable, the appropriate precautionary statements in accordance with Article 22;

(h) where applicable, a section for supplemental information in accordance with Article 25.

2. The label shall be written in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Suppliers may use more languages on their labels than those required by the Member States, provided that the same details appear in all languages used.

Article 18

Product identifiers

1. The label shall include details permitting the identification of the substance or mixture (hereinafter referred to as 'product identifiers').

The term used for identification of the substance or mixture shall be the same as that used in the safety data sheet drawn up in accordance with Article 31 of Regulation (EC) No 1907/2006 (hereinafter referred to as 'safety data sheet'), without prejudice to Article 17(2) of this Regulation.

2. The product identifier for a substance shall consist of at least the following:

(a) if the substance is included in Part 3 of Annex VI, a name and an identification number as given therein;

(b) if the substance is not included in Part 3 of Annex VI, but appears in the classification and labelling inventory, a name and an identification number as given therein;

(c) if the substance is not included in Part 3 of Annex VI nor in the classification and labelling inventory, the number provided by the CAS (hereinafter referred to as 'the CAS number'), together with the name set out in the nomenclature provided by the IUPAC (hereinafter referred to as 'the IUPAC Nomenclature'), or the CAS number together with another international chemical name(s); or

(d) if the CAS number is not available, the name set out in the IUPAC Nomenclature or another international chemical name(s).

Where the name in the IUPAC nomenclature exceeds 100 characters, one of the other names (usual name, trade name, abbreviation) referred to in section 2.1.2 of Annex VI to Regulation (EC) No 1907/2006 may be used provided that the notification in accordance with Article 40 includes both the name set out in the IUPAC Nomenclature and the other name used.

3. The product identifier for a mixture shall consist of both of the following:

(a) the trade name or the designation of the mixture;

(b) the identity of all substances in the mixture that contribute to the classification of the mixture as regards acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, specific target organ toxicity (STOT) or aspiration hazard.

Where, in the case referred to in (b), that requirement leads to the provision of multiple chemical names, a maximum of four chemical names shall suffice, unless more than four names are needed to reflect the nature and the severity of the hazards.

The chemical names selected shall identify the substances primarily responsible for the major health hazards which have given rise to the classification and the choice of the corresponding hazard statements.

Article 19
Hazard pictograms
1. The label shall include the relevant hazard pictogram(s), intended to convey specific information on the hazard concerned.
2. Subject to Article 33, hazard pictograms shall fulfil the requirements laid down in section 1.2.1 of Annex I and in Annex V.
3. The hazard pictogram relevant for each specific classification is set out in the tables indicating the label elements required for each hazard class in Annex I.

Article 20
Signal words
1. The label shall include the relevant signal word in accordance with the classification of the hazardous substance or mixture.
2. The signal word relevant for each specific classification is set out in the tables indicating the label elements required for each hazard class in Parts 2 to 5 of Annex I.
3. Where the signal word 'Danger' is used on the label, the signal word 'Warning' shall not appear on the label.

Article 21
Hazard statements
1. The label shall include the relevant hazard statements in accordance with the classification of the hazardous substance or mixture.
2. The hazard statements relevant for each classification are set out in the tables indicating the label elements required for each hazard class in Parts 2 to 5 of Annex I.
3. Where a substance is included in Part 3 of Annex VI, the hazard statement relevant for each specific classification covered by the entry in that Part shall be used on the label, together with the hazard statements referred to in paragraph 2 for any other classification not covered by that entry.
4. The hazard statements shall be worded in accordance with Annex III.

Article 22
Precautionary statements
1. The label shall include the relevant precautionary statements.
2. The precautionary statements shall be selected from those set out in the tables in Parts 2 to 5 of Annex I indicating the label elements for each hazard class.
3. The precautionary statements shall be selected in accordance with the criteria laid down in Part 1 of Annex IV taking into account the hazard statements and the intended or identified use or uses of the substance or the mixture.
4. The precautionary statements shall be worded in accordance with Part 2 of Annex IV.

Article 23
Derogations from labelling requirements for special cases
The specific provisions on labelling laid down in section 1.3 of Annex I shall apply in respect of the following:

(a) transportable gas cylinders;
(b) gas containers intended for propane, butane or liquefied petroleum gas;
(c) aerosols and containers fitted with a sealed spray attachment and containing substances or mixtures classified as presenting an aspiration hazard;
(d) metals in massive form, alloys, mixtures containing polymers, mixtures containing elastomers;
(e) explosives, as referred to in section 2.1 of Annex I, placed on the market with a view to obtaining an explosive or pyrotechnic effect;

(f) substances or mixtures classified as corrosive to metals but not classified as skin corrosion or as serious eye damage (Category 1).

Article 25

Supplemental information on the label

1. Statements shall be included in the section for supplemental information on the label where a substance or mixture classified as hazardous has the physical properties or health properties referred to in sections 1.1 and 1.2 of Annex II.

The statements shall be worded in accordance with sections 1.1 and 1.2 of Annex II and Part 2 of Annex III.

Where a substance is included in Part 3 of Annex VI, any supplemental hazard statements given therein for the substance shall be included in the supplemental information on the label.

2. A statement shall be included in the section for supplemental information on the label where a substance or mixture classified as hazardous falls within the scope of Directive 91/414/EEC.

The statement shall be worded in accordance with Part 4 of Annex II and Part 3 of Annex III to this Regulation.

3. The supplier may include supplemental information in the section for supplemental information on the label other than that referred to in paragraphs 1 and 2, provided that that information does not make it more difficult to identify the label elements referred to in Article 17(1) (a) to (g) and that it provides further details and does not contradict or cast doubt on the validity of the information specified by those elements.

4. Statements such as 'non-toxic', 'non-harmful', 'non-polluting', 'ecological' or any other statements indicating that the substance or mixture is not hazardous or any other statements that are inconsistent with the classification of that substance or mixture shall not appear on the label or packaging of any substance or mixture.

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6. Where a mixture contains any substance classified as hazardous, it shall be labelled in accordance with Part 2 of Annex II.

The statements shall be worded in accordance with Part 3 of Annex III and shall be placed in the supplemental information section of the label.

The label shall also include the product identifier referred to in Article 18 and the name, address and telephone number of the supplier of the mixture.

Article 26

Principles of precedence for hazard pictograms

1. Where the classification of a substance or mixture would result in more than one hazard pictogram on the label, the following rules of precedence shall apply to reduce the number of hazard pictograms required:

(a) if the hazard pictogram 'GHS01' applies, the use of the hazard pictograms 'GHS02' and 'GHS03' shall be optional, except in cases where more than one of these hazard pictograms are compulsory;

(b) if the hazard pictogram 'GHS06' applies, the hazard pictogram 'GHS07' shall not appear;

(c) if the hazard pictogram 'GHS05' applies, the hazard pictogram 'GHS07' shall not appear for skin or eye irritation;

(d) if the hazard pictogram 'GHS08' applies for respiratory sensitisation, the hazard pictogram 'GHS07' shall not appear for skin sensitisation or for skin and eye irritation;

(e) if the hazard pictogram 'GHS02' or 'GHS06' applies, the use of the hazard pictogram 'GHS04' shall be optional.

2. Where the classification of a substance or mixture would result in more than one hazard pictogram for the same hazard class the label shall include the hazard pictogram corresponding to the most severe hazard category for each hazard class concerned.

For substances that are included in Part 3 of Annex VI and also subject to classification pursuant to Title II, the label shall include the hazard pictogram corresponding to the most severe hazard category for each relevant hazard class.

Article 27
Principles of precedence for hazard statements
If a substance or mixture is classified within several hazard classes or differentiations of a hazard class, all hazard statements resulting from the classification shall appear on the label, unless there is evident duplication or redundancy.

Article 28
Principles of precedence for precautionary statements
1. Where the selection of the precautionary statements results in certain precautionary statements being clearly redundant or unnecessary given the specific substance, mixture or packaging, such statements shall be omitted from the label.
2. Where the substance or mixture is supplied to the general public, one precautionary statement addressing the disposal of that substance or mixture as well as the disposal of packaging shall appear on the label, unless not required under Article 22.
In all other cases, a precautionary statement addressing disposal shall not be required, where it is clear that the disposal of the substance or mixture or the packaging does not present a hazard to human health or the environment.
3. Not more than six precautionary statements shall appear on the label, unless necessary to reflect the nature and the severity of the hazards.

Article 29
Exemptions from labelling and packaging requirements
1. Where the packaging of a substance or a mixture is either in such a shape or form or is so small that it is impossible to meet the requirements of Article 31 for a label in the languages of the Member State in which the substance or mixture is placed on the market, the label elements in accordance with the first subparagraph of Article 17(2) shall be provided in accordance with section 1.5.1 of Annex I.
2. If the full label information cannot be provided in the way specified in paragraph 1 the label information may be reduced in accordance with section 1.5.2 of Annex I.
3. When a hazardous substance or mixture referred to in Part 5 of Annex II is supplied to the general public without packaging it shall be accompanied by a copy of the label elements in accordance with Article 17.
4. For certain mixtures classified as hazardous to the environment, exemptions to certain provisions on environmental labelling or specific provisions in relation to environmental labelling may be determined in accordance with the procedure referred to in Article 53, where it can be demonstrated that there would be a reduction in the environmental impact. Such exemptions or specific provisions are defined in Part 2 of Annex II.
5. The Commission may request the Agency to prepare and submit to it further draft exemptions from labelling and packaging requirements.

Article 31
General rules for the application of labels
1. Labels shall be firmly affixed to one or more surfaces of the packaging immediately containing the substance or mixture and shall be readable horizontally when the package is set down normally.
2. The colour and presentation of any label shall be such that the hazard pictogram stands out clearly.
3. The label elements referred to in Article 17(1) shall be clearly and indelibly marked. They shall stand out clearly from the background and be of such size and spacing as to be easily read.
4. The shape, colour and the size of a hazard pictogram as well as the dimensions of the label shall be as set out in section 1.2.1 of Annex I.
5. A label shall not be required when the label elements referred to in Article 17(1) are shown clearly on the packaging itself. In such cases, the requirements of this Chapter applicable to a label shall be applied to the information shown on the packaging.

Article 35

Packaging

1. Packaging containing hazardous substances or mixtures shall satisfy the following requirements:

(a) the packaging shall be designed and constructed so that its contents cannot escape, except in cases where other more specific safety devices are prescribed;

(b) the materials constituting the packaging and fastenings shall not be susceptible to damage by the contents, or liable to form hazardous compounds with the contents;

(c) the packaging and fastenings shall be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling;

(d) packaging fitted with replaceable fastening devices shall be designed so that it can be refastened repeatedly without the contents escaping.

2. Packaging containing a hazardous substance or a mixture supplied to the general public shall not have either a shape or design likely to attract or arouse the active curiosity of children or to mislead consumers, or have a similar presentation or a design used for foodstuff or animal feeding stuff or medicinal or cosmetic products, which would mislead consumers.

Where the packaging contains a substance or mixture which meets the requirements in section 3.1.1 of Annex II it shall have a child-resistant fastening in accordance with sections 3.1.2, 3.1.3 and 3.1.4.2 of Annex II.

Where the packaging contains a substance or mixture which meets the requirements in section 3.2.1 of Annex II it shall bear a tactile warning of danger in accordance with section 3.2.2 of Annex II.

Where a liquid consumer laundry detergent, as defined in Article 2(1a) of Regulation (EC) No 648/2004 of the European Parliament and of the Council, is contained in a soluble packaging for single use, the additional requirements of section 3.3 of Annex II shall apply. ▼B

3. The packaging of substances and mixtures shall be deemed to satisfy the requirements of paragraph 1(a), (b) and (c) if it complies with the requirements of the rules on the transport of dangerous goods by air, sea, road, rail or inland waterways.

Article 40

Obligation to notify the Agency

1. Any manufacturer or importer, or group of manufacturers or importers (hereinafter referred to as 'the notifier(s)'), who places on the market a substance referred to in Article 39, shall notify to the Agency the following information in order for it to be included in the inventory referred to in Article 42:

(a) the identity of the notifier(s) responsible for placing the substance or substances on the market as specified in section 1 of Annex VI to Regulation (EC) No 1907/2006;

(b) the identity of the substance or substances as specified in section 2.1 to 2.3.4 to Annex VI to Regulation (EC) No 1907/2006;

(c) the classification of the substance or substances in accordance with Article 13;

(d) where a substance has been classified in some but not all hazard classes or differentiations, an indication of whether this is due to lack of data, inconclusive data, or data which are conclusive although insufficient for classification;

(e) specific concentration limits or M-factors, where applicable, in accordance with Article 10 of this Regulation together with a justification using the relevant Parts of sections 1, 2 and 3 of Annex I to Regulation (EC) No 1907/2006;

(f) the label elements specified in points (d), (e) and (f) of Article 17(1) for the substance or substances together with any supplemental hazard statements for the substance, determined in accordance with Article 25(1).

The information referred to in (a) to (f) shall not be notified, if it has been submitted to the Agency as part of a registration pursuant to Regulation (EC) No 1907/2006, or if it has already been notified by that notifier.

The notifier shall submit this information in the format specified pursuant to Article 111 of Regulation (EC) No 1907/2006.

2. The information listed in paragraph 1 shall be updated and notified to the Agency by the notifier(s) concerned when, pursuant to the review in Article 15(1), a decision to change the classification and labelling of the substance has been taken.

3. Substances placed on the market on or after 1 December 2010 shall be notified in accordance with paragraph 1 within one month after their placing on the market. However, substances placed on the market before 1 December 2010 may be notified in accordance with paragraph 1 before that date.

Article 48

Advertisement

1. Any advertisement for a substance classified as hazardous shall mention the hazard classes or hazard categories concerned.
2. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) which allows a member of the general public to conclude a contract for purchase without first having sight of the label shall mention the type or types of hazard indicated on the label.

The first subparagraph shall be without prejudice to Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts.

Article 49

Obligation to maintain information and requests for information

1. The supplier shall assemble and keep available all the information used by that supplier for the purposes of classification and labelling under this Regulation for a period of at least 10 years after the substance or the mixture was last supplied by that supplier.

The supplier shall keep this information together with the information required in Article 36 of Regulation (EC) No 1907/2006.

2. In the event of a supplier ceasing activity, or transferring part or all of his operations to a third party, the party responsible for liquidating the supplier's undertaking or assuming responsibility for the placing on the market of the substance or mixture concerned shall be bound by the obligation in paragraph 1 in place of the supplier.
3. The competent authority or the enforcement authorities of a Member State in which a supplier is established or the Agency may require the supplier to submit to it any information referred to in the first subparagraph of paragraph 1.

However, where that information is available to the Agency as part of a registration pursuant to Regulation (EC) No 1907/2006 or a notification pursuant to Article 40 of this Regulation, the Agency shall use that information and the authority shall address itself to the Agency.

3. PIC

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Article 8

Export notifications forwarded to Parties and other countries

1. In the case of substances listed in Part 1 of Annex I or mixtures containing such substances in a concentration that triggers labelling obligations under Regulation (EC) No 1272/2008 irrespective of the presence of any other substances, paragraphs 2 to 8 of this Article shall apply regardless of the intended use of the chemical in the importing Party or other country.

2. When an exporter is due to export a chemical referred to in paragraph 1 from the Union to a Party or other country for the first time on or after the date on which it becomes subject to this Regulation, the exporter shall notify the designated national authority of the Member State in which he is established (the 'exporter's Member State'), no later than 35 days before the expected date of export. Thereafter the exporter shall notify that designated national authority of the first export of the chemical each calendar year no later than 35 days before the export takes place. The notifications shall comply with the information requirements laid down in Annex II and shall be made available to the Commission and to the Member States by means of the Database.

The designated national authority of the exporter's Member State shall check compliance of the information with Annex II and if the notification is complete forward it to the Agency no later than 25 days before the expected date of export.

The Agency shall, on behalf of the Commission, transmit the notification to the designated national authority of the importing Party or the appropriate authority of the importing other country and take the measures necessary to ensure that they receive that notification no later than 15 days before the first intended export of the chemical and thereafter no later than 15 days before the first export in any subsequent calendar year.

The Agency shall register each export notification and assign it a reference identification number in the Database. The Agency shall also make available to the public and the designated national authorities of the Member States, as appropriate, an updated list of the chemicals concerned and the importing Parties and other countries for each calendar year by means of the Database.

3. If the Agency does not receive from the importing Party or other country an acknowledgement of receipt of the first export notification made after the chemical is included in Part 1 of Annex I within 30 days of the dispatch of such notification, it shall, on behalf of the Commission, submit a second notification. The Agency shall, on behalf of the Commission, make reasonable efforts to ensure that the designated national authority of the importing Party or the appropriate authority of the importing other country receives the second notification.

4. A new export notification shall be made in accordance with paragraph 2 for exports which take place subsequent to the entry into force of amendments to Union legislation concerning the marketing, use or labelling of the substances in question or whenever the composition of the mixture in question changes so that the labelling of such mixture is altered. The new notification shall comply with the information requirements laid down in Annex II and shall indicate that it is a revision of a previous notification.

5. Where the export of a chemical relates to an emergency situation in which any delay may endanger public health or the environment in the importing Party or other country, an exemption from the obligations set out in paragraphs 2, 3 and 4 in whole or in part may be granted at the reasoned request of the exporter or the importing Party or other country and at the discretion of the designated national authority of the exporter's Member State, in consultation with the Commission assisted by the Agency. A decision on the request shall be considered to have been made in consultation with the Commission if there is no dissenting response from the Commission within 10 days of the designated national authority of the Member State sending it details of the request.

6. Without prejudice to the obligations set out in Article 19(2), the obligations set out in paragraphs 2, 3 and 4 of this Article shall cease when all of the following conditions are fulfilled:

(a) the chemical has become a chemical subject to the PIC procedure;
(b) the importing country is a Party to the Convention and has provided the Secretariat with a response in accordance with Article 10(2) of the Convention indicating whether or not it consents to import of the chemical; and
(c) the Commission has been informed of that response by the Secretariat and has forwarded that information to the Member States and the Agency.

Notwithstanding the first subparagraph of this paragraph, the obligations set out in paragraphs 2, 3 and 4 of this Article shall not cease where an importing country is a Party to the Convention and explicitly requires continued export notification by exporting Parties, for example through its import decision or otherwise.

Without prejudice to the obligations set out in Article 19(2), the obligations set out in paragraphs 2, 3 and 4 of this Article shall also cease when both of the following conditions are fulfilled:

(a) the designated national authority of the importing Party or the appropriate authority of the importing other country has waived the requirement to be notified before the export of the chemical; and
(b) the Commission has received the information from the Secretariat or from the designated national authority of the importing Party or the appropriate authority of the importing other country and has forwarded it to the Member States and the Agency, which has made it available by means of the Database.

7. The Commission, the relevant designated national authorities of the Member States, the Agency and the exporters shall, on request, provide importing Parties and other countries with available additional information concerning the exported chemicals.

8. Member States may establish, in a transparent manner, systems obliging exporters to pay an administrative fee for each export notification made and for each request for explicit consent made, corresponding to the costs they incur in carrying out the procedures set out in paragraphs 2 and 4 of this Article and in Article 14(6) and (7).

Article 14

Obligations in relation to export of chemicals other than export notification

1. The Commission shall immediately forward to the Member States, the Agency and European industry associations the information which it receives, whether in the form of circulars or otherwise, from the Secretariat regarding chemicals subject to the PIC procedure and the decisions of importing Parties regarding import conditions applicable to those chemicals. It shall also immediately forward to the Member States and the Agency information concerning any cases of failure to transmit a response in accordance with Article 10(2) of the Convention. The Agency shall assign each import decision a reference identification number and keep all information regarding such decisions publicly available by means of the Database, and provide anyone with that information upon request.

2. The Commission shall assign each chemical listed in Annex I a classification in the European Union's Combined Nomenclature. Those classifications shall be revised as necessary in the light of any changes made in the World Customs Organisation's Harmonised System Nomenclature or in the European Union's Combined Nomenclature for the chemicals concerned.

3. Each Member State shall communicate the information and decisions forwarded by the Commission under paragraph 1 to those concerned within its jurisdiction.

4. Exporters shall comply with decisions in each import response no later than six months after the Secretariat first informs the Commission of such decisions under paragraph 1.

5. The Commission, assisted by the Agency, and the Member States shall advise and assist importing Parties, upon request and as appropriate, in obtaining further information needed to prepare a response to the Secretariat concerning the import of a given chemical.

6. Substances listed in Part 2 or 3 of Annex I or mixtures containing such substances in a concentration that triggers labelling obligations under Regulation (EC) No 1272/2008 irrespective of the presence of any other substances shall, regardless of their intended use in the importing Party or other country, not be exported unless either of the following conditions is fulfilled:

(a) explicit consent to import has been sought and received by the exporter through the designated national authority of the exporter's Member State in consultation with the

Commission, assisted by the Agency, and the designated national authority of the importing Party or an appropriate authority in an importing other country;
(b) in the case of chemicals listed in Part 3 of Annex I, the latest circular issued by the Secretariat pursuant to paragraph 1 indicates that the importing Party has given consent to import.

In the case of chemicals listed in Part 2 of Annex I that are to be exported to OECD countries, the designated national authority of the exporter's Member State may, at the request of the exporter, in consultation with the Commission and on a case-by-case basis, decide that no explicit consent is required if the chemical, at the time of importation into the OECD country concerned, is licensed, registered or authorised in that OECD country.
Where explicit consent has been sought pursuant to point (a) of the first subparagraph, if the Agency has not received a response to the request within 30 days, the Agency shall, on behalf of the Commission, send a reminder unless the Commission or the designated national authority of the exporter's Member State received a response and forwarded it to the Agency. Where appropriate, if there is still no response within a further 30 days, the Agency may send further reminders as necessary.
7. In the case of chemicals listed in Part 2 or 3 of Annex I, the designated national authority of the exporter's Member State may, in consultation with the Commission assisted by the Agency, on a case-by- case basis and subject to the second subparagraph, decide that the export may proceed, if no evidence from official sources of final regulatory action to ban or severely restrict the use of the chemical taken by the importing Party or other country exists and if, after all reasonable efforts, no response to a request for explicit consent pursuant to point (a) of paragraph 6 has been received within 60 days and where one of the following conditions is met:

(a) there is evidence from official sources in the importing Party or other country that the chemical is licensed, registered or authorised; or
(b) the intended use declared in the export notification and confirmed in writing by the natural or legal person importing the chemical into a Party or other country, is not in a category for which the chemical is listed in Part 2 or 3 of Annex I, and there is evidence from official sources that the chemical has in the last five years been used in or imported into the importing Party or other country concerned.

In the case of chemicals listed in Part 3 of Annex I, an export based on the fulfilment of the condition under point (b) may not proceed if the chemical has been classified in accordance with Regulation (EC) No 1272/2008 as carcinogenic category 1A or 1B, or mutagenic category 1A or 1B, or toxic for reproduction category 1A or 1B or the chemical fulfils the criteria of Annex XIII to Regulation (EC) No 1907/2006 for being persistent, bioaccumulative and toxic or very persistent and very bioaccumulative.
When deciding on the export of chemicals listed in Part 3 of Annex I, the designated national authority of the exporter's Member State shall, in consultation with the Commission assisted by the Agency, consider the possible impact on human health or the environment of the use of the chemical in the importing Party or other country, and submit relevant documentation to the Agency, to be made available by means of the Database.
8. The validity of each explicit consent obtained pursuant to point (a) of paragraph 6 or decision to proceed with export in the absence of explicit consent pursuant to paragraph 7 shall be subject to periodic review by the Commission in consultation with the Member States concerned as follows:

(a) for each explicit consent obtained pursuant to point (a) of paragraph 6 a new explicit consent shall be required by the end of the third calendar year after the consent was given, unless the terms of that consent require otherwise;
(b) unless a response to a request has been received in the meantime, each decision to proceed without explicit consent pursuant to paragraph 7 shall be valid for a maximum period of 12 months, upon expiry of which explicit consent shall be required.

In the cases referred to in point (a) of the first subparagraph, exports may, however, continue after the end of the relevant period, pending a response to a new request for explicit consent, for an additional period of 12 months.
9. The Agency shall register all requests for explicit consent, responses obtained and decisions to proceed without explicit consent, including the documentation referred to in the third

subparagraph of paragraph 7, in the Database. Each explicit consent obtained or decision to proceed without explicit consent shall be assigned a reference identification number and shall be listed with all relevant information concerning any conditions attached, such as validity dates. The non-confidential information shall be made publicly available by means of the Database.
10. No chemical shall be exported later than six months before its expiry date, where such a date exists or can be inferred from the production date, unless the intrinsic properties of the chemical render that impracticable. In particular, in the case of pesticides, exporters shall ensure that the size and packaging of containers is optimised so as to minimise the risk of creating obsolete stocks.
11. When exporting pesticides, exporters shall ensure that the label contains specific information about storage conditions and storage stability under the climatic conditions of the importing Party or other country. In addition, they shall ensure that the pesticides exported comply with the purity specification laid down in Union legislation.

Article 15
Export of certain chemicals and articles
1. Articles shall be subject to the export notification procedure laid down in Article 8 if they contain any of the following:
(a) substances listed in Part 2 or 3 of Annex I in unreacted form;
(b) mixtures containing such substances in a concentration that triggers labelling obligations under Regulation (EC) No 1272/2008 irrespective of the presence of any other substances.
2. Chemicals and articles the use of which is prohibited in the Union for the protection of human health or the environment, as listed in Annex V, shall not be exported.

Article 17
Information to accompany exported chemicals
1. Chemicals that are intended for export shall be subject to the provisions on packaging and labelling established in, or pursuant to, Regulation (EC) No 1107/2009, Directive 98/8/EC and Regulation (EC) No 1272/2008, or any other relevant Union legislation.
The first subparagraph shall apply unless those provisions would conflict with any specific requirements of the importing Parties or other countries.
2. Where appropriate, the expiry date and the production date of chemicals referred to in paragraph 1 or listed in Annex I shall be indicated on the label, and if necessary such expiry dates shall be given for different climate zones.
3. A safety data sheet in accordance with Regulation (EC) No 1907/2006 shall accompany chemicals referred to in paragraph 1 when exported. The exporter shall send such a safety data sheet to each natural or legal person importing the chemical into a Party or other country.
4. The information on the label and on the safety data sheet shall as far as practicable be given in the official languages, or in one or more of the principal languages, of the country of destination or of the area of intended use.

Annex 1. – Registry of legal duties enforced (Excel version 2018)

The Excel document is published separately in the ECHA website section of enforcement.

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