

## ANNEX-1

### GENERAL PROVISIONS FOR ASSESSING SUBSTANCES AND PREPARING CHEMICAL SAFETY REPORTS

#### 0. INTRODUCTION

- 0.1. The purpose of this Annex is to set out how manufacturers and importers are to assess and document that the risks arising from the substance they manufacture or import are adequately controlled during manufacture and their own use(s) and that others further down the supply chain can adequately control the risks. This Annex shall also apply adapted as necessary to producers and importers of articles required to make a chemical safety assessment as part of a registration.
- 0.2. Chemical safety assessment shall be prepared by chemical safety assessment expert.
- 0.3. The chemical safety assessment of a manufacturer shall address the manufacture of a substance and all the identified uses. The chemical safety assessment of an importer shall address all identified uses. The chemical safety assessment shall consider the use of the substance on its own (including any major impurities and additives), in a mixture and in an article, as defined by the identified uses. The assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses. The chemical safety assessment shall be based on a comparison of the potential adverse effects of a substance with the known or reasonably foreseeable exposure of man and/or the environment to that substance taking into account implemented and recommended risk management measures and operational conditions.
- 0.4. Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or 'category' of substances. If the manufacturer or importer considers that the chemical safety assessment carried out for one substance is sufficient to assess and document that the risks arising from another substance or from a group or 'category' of substances are adequately controlled then he can use that chemical safety assessment for the other substance or group or 'category' of substances. The manufacturer or importer shall provide a justification for this.
- 0.5. The chemical safety assessment shall be based on the information on the substance contained in the technical dossier and on other available and relevant information. Manufacturers or importers submitting a proposal for testing in accordance with Annexes IX and X shall record this under the relevant heading of the chemical safety report. Available information from assessments carried out under other international and national programmes shall be included. Where available and appropriate, an assessment carried out under legislation shall be taken into account in the development of, and reflected in, the chemical safety report. Deviations from such assessments shall be justified.

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

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

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

## 0.6. Steps of a chemical safety assessment

0.6.1. A chemical safety assessment performed by a manufacturer or an importer for a substance shall include the following steps 1 to 4 in accordance with the respective sections of this Annex:

1. Human health hazard assessment.
2. Human health hazard assessment of physicochemical properties.
3. Environmental hazard assessment.
4. PBT and vPvB assessment.

0.6.2. In the cases referred to in point 0.6.3 the chemical safety assessment shall also include the following steps 5 and 6 in accordance with Sections 5 and 6 of this Annex:

5. Exposure assessment.
  - 5.1. The generation of exposure scenario(s) (or the identification of relevant use and exposure categories, if appropriate).
  - 5.2. Exposure estimation.
6. Risk characterisation.

0.6.3. Where as a result of steps 1 to 4 in section 0.6.1 the manufacturer or importer concludes that the substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I to By-law on Classification, Labelling and Packaging of Substances and Mixtures or is assessed to be a PBT or vPvB, the chemical safety assessment shall also include steps 5 and 6 in accordance with Sections 5 and 6 of this Annex:

- (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, and 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.

0.6.4. A summary of all the relevant information used in addressing the points above (from 0.6.1 to 0.6.3) shall be presented under the relevant heading of the Chemical Safety Report (Section 7).

0.7. The main element of the exposure part of the chemical safety report is the description of the exposure scenario(s) implemented for the manufacturer's production, the manufacturer

or importer's own use, and those recommended by the manufacturer or importer to be implemented for the identified use(s).

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

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

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

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

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

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

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

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

## **1. HUMAN HEALTH HAZARD ASSESSMENT**

### **1.0. Introduction**

1.0.1. İnsan sağlığı zararlılık değerlendirmesinin amacı; Maddelerin ve Karışımların Sınıflandırılması, Etiketlenmesi ve Ambalajlanması Hakkında Yönetmeliğe göre maddenin sınıflandırmasını ve insanların maruz kalabileceği kabul edilebilir en yüksek düzeyi belirlemektir. Bu maruz kalma seviyesi, Türetilmiş Etki Gözlemlenmeyen Seviye (DNEL) olarak bilinmektedir.

The objectives of the human health hazard assessment shall be to determine the classification of a substance in accordance with By-law on Classification, Labelling and Packaging of Substances and Mixtures; and to derive levels of exposure to the substance above which humans should not be exposed. This level of exposure is known as the Derived No-Effect Level (DNEL).

1.0.2. The human health hazard assessment shall consider the toxicokinetic profile (i.e. absorption, metabolism, distribution and elimination) of the substance and the following groups of effects:

- a) acute effects such as acute toxicity, irritation and corrosivity;
- b) sensitisation;
- c) repeated dose toxicity; and
- ç) CMR effects (carcinogenicity, germ cell mutagenicity and toxicity for reproduction).

Based on all the available information, other effects shall be considered when necessary.

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

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

1.0.4. The first three steps shall be undertaken for every effect for which information is available and shall be recorded under the relevant section of the Chemical Safety Report and where required and in accordance with Article 27, summarised in the Safety Data Sheet under headings 2 and 11.

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

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

### **1.1. Step 1: Evaluation of non-human information**

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

- the hazard identification for the effect based on all available non- human information,
- the establishment of the quantitative dose (concentration)-response (effect) relationship.

1.1.2. When it is not possible to establish the quantitative dose (concentration)- response (effect) relationship, then this should be justified and a semi- quantitative or qualitative analysis shall be included. For instance, for acute effects it is usually not possible to establish the quantitative dose (concentration)-response (effect) relationship on the basis of the results of a test conducted in accordance with test methods laid down in By-law on Test Methods to Determine Physico-chemical, toxicological and Ecotoxicological Properties of Substances and Mixtures as specified in Article 14(3). In such cases it suffices to determine whether and to which degree the substance has an inherent capacity to cause the effect.

1.1.3. All non-human information used to assess a particular effect on humans and to establish the dose (concentration) – response (effect) relationship, shall be briefly presented, if possible in the form of a table or tables, distinguishing between in vitro, in vivo and other information. The relevant test results (e.g. ATE, LD50, NO(A)EL or LO(A)EL) and test conditions (e.g. test duration, route of administration) and other relevant information shall be presented, in internationally recognised units of measurement for that effect.

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

## **1.2. Step 2: Evaluation of human information**

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

## **1.3. Step 3: Classification and Labelling**

1.3.1. The appropriate classification developed in accordance with the criteria in By-law on Classification, Labelling and Packaging of Substances and Mixtures shall be presented and justified. Where applicable, Specific Concentration limits resulting from the application of Article 12 of the same By-law. If they are not included in Part 3 of Annex VI to same By-law this will be justified.

The assessment should always include a statement as to whether the substance fulfils or does not fulfil the criteria given in By-law on Classification, Labelling and Packaging of Substances and Mixtures for classification in the hazard class carcinogenicity category 1A or 1B, in the hazard class germ cell mutagenicity category 1A or 1B or in the hazard class reproductive toxicity category 1A or 1B.

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

#### **1.4. Step 4: Identification of DNEL(s)**

1.4.1. Based on the outcomes of steps 1 and 2, (a) DNEL(s) shall be established for the substance, reflecting the likely route(s), duration and frequency of exposure. ►M10 For some hazard classes, especially germ cell mutagenicity and carcinogenicity, the available information may not enable a toxicological threshold, and therefore a DNEL, to be established. ◀ If justified by the exposure scenario(s), a single DNEL may be sufficient. However, taking into account the available information and the exposure scenario(s) in Section 9 of the Chemical Safety Report it may be necessary to identify different DNELs for each relevant human population (e.g. workers, consumers and humans liable to exposure indirectly via the environment) and possibly for certain vulnerable sub-populations (e.g. children, pregnant women) and for different routes of exposure. A full justification shall be given specifying, inter alia, the choice of the information used, the route of exposure (oral, dermal, inhalation) and the duration and frequency of exposure to the substance for which the DNEL is valid. If more than one route of exposure is likely to occur, then a DNEL shall be established for each route of exposure and for the exposure from all routes combined. When establishing the DNEL, the following factors shall, inter alia, be taken into account:

- (a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
- (b) the nature and severity of the effect;
- (c) the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies.

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

## **2. FİZİKOKİMYASAL ZARARLILIK DEĞERLENDİRMESİ**

2.1. The objective of the hazard assessment for physicochemical properties shall be to determine the classification of a substance in accordance with By-law on Classification, Labelling and Packaging of Substances and Mixtures.

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

- explosivity,
- flammability,
- oxidising potential.

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

2.3. The assessment of each effect shall be presented under the relevant heading of the Chemical Safety Report (Section 7) and where required and in accordance with Article 27, summarised in the Safety Data Sheet under headings 2 and 9.

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

2.5. The appropriate classification developed in accordance with the criteria in By-law on Classification, Labelling and Packaging of Substances and Mixtures shall be presented and justified.

### **3. ENVIRONMENTAL HAZARD ASSESSMENT**

#### **3.0. Introduction**

3.0.1. The objective of the environmental hazard assessment shall be to determine the classification of a substance in accordance with By-law on Classification, Labelling and Packaging of Substances and Mixtures and to identify the concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur. This concentration is known as the Predicted No- Effect Concentration (PNEC).

3.0.2. The environmental hazard assessment shall consider the potential effects on the environment, comprising the (1) aquatic (including sediment), (2) terrestrial and (3) atmospheric compartments, including the potential effects that may occur (4) via food-chain accumulation. In addition, the potential effects on the (5) microbiological activity of sewage treatment systems shall be considered. The assessment of the effects on each of these five environmental spheres shall be presented under the relevant heading of the Chemical Safety Report (Section 7) and where required and in accordance with Article 27, summarised in the Safety Data Sheet under headings 2 and 12.

3.0.3. For any environmental sphere, for which no effect information is available, the relevant section of the chemical safety report shall contain the sentence: 'This information is not available'. The justification, including reference to any literature research carried out, shall be included in the technical dossier. For any environmental sphere for which information is available, but the manufacturer or importer believes that it is not necessary to conduct the hazard assessment, the manufacturer or importer shall present a justification, with reference to pertinent information, under the relevant heading of the Chemical Safety Report (Section 7) and where required and in accordance with Article 27, summarised in the Safety Data Sheet under heading 12.

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

Step 1: Evaluation of information.

Step 2: Classification and Labelling.

Step 3: Derivation of the PNEC.

#### **3.1. Step 1: Evaluation of information**

3.1.1. The evaluation of all available information shall comprise:

— the hazard identification based on all available information,

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

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

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

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

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

### **3.2. Step 2: Classification and Labelling**

3.2.1. The appropriate classification developed in accordance with the criteria in By-law on Classification, Labelling and Packaging of Substances and Mixtures shall be presented and justified. Any M- factor resulting from the application of Article 12 of the same By-law shall be presented and, if it is not included in Part 3 of Annex VI to the same By-law, justified.

3.2.2. If the information is inadequate to decide whether a substance should be classified for a particular hazard class or category, the registrant shall indicate and justify the action or decision he has taken as a result.

### **3.3. Step 3: Identification of the PNEC**

3.3.1. Based on the available information, the PNEC for each environmental sphere shall be established. The PNEC may be calculated by applying an appropriate assessment factor to the effect values (e.g. LC50 or NOEC). An assessment factor expresses the difference between

effects values derived for a limited number of species from laboratory tests and the PNEC for the environmental sphere<sup>1</sup>.

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

## **4. PBT AND vPvB ASSESSMENT**

### **4.0. Introduction**

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

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

Step 1: Comparison with the Criteria.

Step 2: Emission Characterisation.

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

#### **4.1. Step 1: Comparison with the criteria**

This part of the PBT and vPvB assessment shall entail the comparison of the available information with the criteria given in Section 1 of Annex XIII and a statement of whether the substance fulfils or does not fulfil the criteria. The assessment shall be conducted in accordance with the provisions laid down in the introductory part of Annex XIII as well as Sections 2 and 3 of that Annex.

#### **4.2. Step 2: Emission Characterisation**

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

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<sup>1</sup> Genel olarak, veriler ne kadar fazlaysa ve testlerin süresi ne kadar uzunsa, belirsizlik derecesi ve değerlendirme faktörü o kadar küçük olur. Tipik olarak, farklı trofik düzeylerini temsil eden türlerden elde edilen en düşük üç kısa dönemli L(E)C<sub>50</sub> değerine değerlendirme faktörü olarak 1 000 uygulanır ve farklı trofik düzeylerini temsil eden türlerden elde edilen en düşük üç uzun dönemli NOEC değerine değerlendirme faktörü olarak 10 uygulanır.

## 5. EXPOSURE ASSESSMENT

### 5.0. Introduction

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

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

Step 2: Exposure Estimation.

Where required and in accordance with Article 27, the exposure scenario shall also be included in an annex to the Safety Data Sheet.

### 5.1. Step 1: Development of exposure scenarios

5.1.1. Exposure scenarios as described in Sections 0.7 and 0.8 shall be generated. Exposure scenarios are the core of the process to carry out a chemical safety assessment. The chemical safety assessment process may be iterative. The first assessment will be based on the required minimum and all available hazard information and on the exposure estimation that corresponds to the initial assumptions about the operating conditions and risk management measures (an initial exposure scenario). If the initial assumptions lead to a risk characterisation indicating that risks to human health and the environment are not adequately controlled, then it is necessary to carry out an iterative process with amendment of one or a number of factors in hazard or exposure assessment with the aim to demonstrate adequate control. The refinement of hazard assessment may require generation of additional hazard information. The refinement of exposure assessment may involve appropriate alteration of the operational conditions or risk management measures in the exposure scenario or more precise exposure estimation. The exposure scenario, resulting from the final iteration (a final exposure scenario), shall be included in the chemical safety report and attached to the safety data sheet in accordance with Article 27.

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

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

a) *Operational conditions*

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

- the activities of workers related to the processes and the duration and frequency of their exposure to the substance,
- the activities of consumers and the duration and frequency of their exposure to the substance,
- the duration and frequency of emissions of the substance to the different environmental compartments and sewage treatment systems and the dilution in the receiving environmental compartment.

*b) Risk management measures*

- the risk management measures to reduce or avoid direct and indirect exposure of humans (including workers and consumers) and the different environmental compartments to the substance,
- the waste management measures to reduce or avoid exposure of humans and the environment to the substance during waste disposal and/or recycling.

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

## **5.2. Step 2: Exposure Estimation**

5.2.1. The exposure shall be estimated for each exposure scenario developed and shall be presented under the relevant heading of the Chemical Safety Report and where required and in accordance with Article 27, summarised in an annex to the safety data sheet. The exposure estimation entails three elements: (1) emission estimation; (2) assessment of chemical fate and pathways; and (3) estimation of exposure levels.

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

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

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

- adequately measured, representative exposure data,
- any major impurities and additives in the substance,
- the quantity in which the substance is produced and/or imported,
- the quantity for each identified use,

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

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

## **6. RISK CHARACTERISATION**

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

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

6.3. The risk characterisation consists of:

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

6.4. For any exposure scenario, the risk to humans and the environment can be considered to be adequately controlled, throughout the lifecycle of the substance that results from manufacture or identified uses, if:

- the exposure levels estimated in Section 6.2 do not exceed the appropriate DNEL or the PNEC, as determined in Sections 1 and 3, respectively, and,

— the likelihood and severity of an event occurring due to the physicochemical properties of the substance as determined in Section 2 is negligible.

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

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

## 7. CHEMICAL SAFETY REPORT FORMAT

The Chemical Safety Report shall include the following headings:

<b>CHEMICAL SAFETY REPORT FORMAT</b>	
<b>PART A</b>	
1. SUMMARY OF RISK MANAGEMENT MEASURES	
2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED	
3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED	
<b>PART B</b>	
1.	IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES
2.	MANUFACTURE AND USES
	2.1. Manufacture
	2.2. Identified uses
	2.3. Uses advised against
3.	CLASSIFICATION AND LABELLING
4.	ENVIRONMENTAL FATE PROPERTIES
	4.1. Degradation
	4.2. Environmental distribution
	4.3. Bioaccumulation
	4.4. Secondary poisoning
5.	HUMAN HEALTH HAZARD ASSESSMENT
	5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)
	5.2. Acute toxicity
	5.3. Irritation
	5.4. Corrosivity
	5.5. Sensitisation
	5.6. Repeated dose toxicity
	5.7. Germ cell mutagenicity
	5.8. Carcinogenicity
	5.9. Toxicity for reproduction
	5.10. Other effects
	5.11. Derivation of DNEL(s)
6.	HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES
	6.1. Explosivity
	6.2. Flammability
	6.3. Oxidising potential

7. ENVIRONMENTAL HAZARD ASSESSMENT
  - 7.1. Aquatic compartment (including sediment)
  - 7.2. Terrestrial compartment
  - 7.3. Atmospheric compartment
  - 7.4. Microbiological activity in sewage treatment systems
  
8. PBT AND vPvB ASSESSMENT
  
9. EXPOSURE ASSESSMENT
  - 9.1. (Title of exposure scenario 1)
    - 9.1.1. Exposure scenario
    - 9.1.2. Exposure estimation
  - 9.2. (Title of exposure scenario 2)
    - 9.2.1. Exposure scenario
    - 9.2.2. Exposure estimation
 (etc.)
  
10. RISK CHARACTERISATION
  - 10.1. (Title of exposure scenario 1)
    - 10.1.1. Human health
      - 10.1.1.1. Workers
      - 10.1.1.2. Consumers
      - 10.1.1.3. Indirect exposure to humans via the environment
    - 10.1.2. Environment
      - 10.1.2.1. Aquatic compartment (including sediment)
      - 10.1.2.2. Terrestrial compartment
      - 10.1.2.3. Atmospheric compartment
      - 10.1.2.4. Microbiological activity in sewage treatment systems
  - 10.2. (Title of exposure scenario 2)
    - 10.2.1. Human health
      - 10.2.1.1. Workers
      - 10.2.1.2. Consumers
      - 10.2.1.3. Indirect exposure to humans via the environment
    - 10.2.2. Environment
      - 10.2.2.1. Aquatic compartment (including sediment)
      - 10.2.2.2. Terrestrial compartment
      - 10.2.2.3. Atmospheric compartment
      - 10.2.2.4. Microbiological activity in sewage treatment systems
 (etc.)
  - 10.x. Overall exposure
    - 10.x.1. Human health (combined for all exposure routes)
      - 10.x.1.1.
    - 10.x.2. Environment (combined for all exposure routes)
      - 10.x.2.1.

## ANNEX-2

### REQUIREMENTS FOR THE COMPILATION OF SAFETY DATA SHEETS

#### PART A

##### **0.1. Introduction**

0.1.1. This Annex sets out the requirements that the supplier shall fulfil for the compilation of a safety data sheet that is provided for a substance or a mixture in accordance with Article 27.

0.1.2. The information provided in the safety data sheet shall be consistent with the information in the chemical safety report, where one is required. Where a chemical safety report has been completed, the relevant exposure scenario(s) shall be placed in an annex to the safety data sheet.

##### **0.2. General requirements for compiling a safety data sheet**

0.2.1. The safety data sheet shall enable users to take the necessary measures relating to protection of human health and safety at the workplace, and protection of the environment. The writer of the safety data sheet shall take into account that a safety data sheet must inform its audience of the hazards of a substance or a mixture and provide information on the safe storage, handling and disposal of the substance or the mixture.

0.2.2. The information provided by safety data sheets shall also meet the requirements set out in By-law on Health and Safety Precautions for Working with Chemical Substances. In particular, the safety data sheet shall enable employers to determine whether any hazardous chemical agents are present in the workplace and to assess any risk to the health and safety of workers arising from their use.

0.2.3. The information in the safety data sheet shall be written in a clear and concise manner. The safety data sheet shall be prepared by a competent person who shall take into account the specific needs and knowledge of the user audience, as far as they are known. Suppliers of substances and mixtures shall ensure that such competent persons have received appropriate training, including refresher training.

0.2.4. The language used in the safety data sheet shall be simple, clear and precise, avoiding jargon, acronyms and abbreviations. Statements such as 'may be dangerous', 'no health effects', 'safe under most conditions of use' or 'harmless' 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 be used.

0.2.5. The date of compilation of the safety data sheet shall be given on the first page. When a safety data sheet has been revised and the new, revised version is provided to recipients, the changes shall be brought to the attention of the recipients in Section 16 of the safety data sheet, unless the changes have been indicated elsewhere. For the revised safety data sheets, the date of compilation, identified as 'Revision: (date)', as well as a version number, revision number, supersedes date or some other indication of what version is replaced shall appear on the first page.

### **0.3. Safety Data Sheet Format**

0.3.1. A safety data sheet is not a fixed length document. The length of the safety data sheet shall be commensurate with the hazard of the substance or mixture and the information available.

0.3.2. All pages of a safety data sheet, including any annexes, shall be numbered and shall bear either an indication of the length of the safety data sheet (such as 'page 1 of 3') or an indication whether there is a page following (such as 'Continued on next page' or 'End of safety data sheet').

### **0.4. Safety Data Sheet Content**

The information required by this Annex shall be included in the safety data sheet, where applicable and available, in the relevant subsections set out in Part B. The safety data sheet shall not contain blank subsections.

### **0.5. Other information requirements**

The inclusion of additional relevant and available information in the relevant subsections may be necessary in some cases in view of the wide range of properties of substances and mixtures.

### **0.6. Units**

The units of measurements as set out in By-law on International Unit System published in Official Gazette dated 21/6/2002 and numbered 24792 shall be used.

### **0.7. Special cases**

Safety data sheets shall also be required for the special cases listed in paragraph 1.3 of Annex I to By-law on Classification, Labelling and Packaging of Substances and Mixtures for which there are labelling derogations.

## **1. SECTION 1: Identification of the substance/mixture and of the company/undertaking**

This section of the safety data sheet shall prescribe how the substance or mixture shall be identified and how the identified relevant uses, the name of the supplier of the substance or mixture and the contact detail information of the supplier of the substance or mixture, including an emergency contact, shall be provided in the safety data sheet.

### **1.1. Product identifier**

The product identifier shall be provided in accordance with Article 20 of By-law on Classification, Labelling and Packaging of Substances and Mixtures, and in Turkish. For substances subject to registration, the product identifier shall be consistent with that provided in the registration and the registration number assigned under Article 20(3) of this Regulation shall also be indicated.

Without affecting the obligations of downstream users laid down in Article 35 of this Regulation, the part of the registration number referring to the individual registrant of a joint submission may be omitted by a supplier who is a distributor or a downstream user provided that:

(a) this supplier assumes the responsibility to provide the full registration number upon request for enforcement purposes or, if the full registration number is not available to him, to forward the request to his supplier, in line with point (b); and

(b) this supplier provides the full registration number to the Member State authority responsible for enforcement (the enforcement authority) within 7 days upon request, received either directly from the enforcement authority or forwarded by his recipient, or, if the full registration number is not available to him, this supplier shall forward the request to his supplier within 7 days upon request and at the same time inform the enforcement authority thereof.

A single safety data sheet may be provided to cover more than one substance or mixture where the information in that safety data sheet fulfils the requirements of this Annex for each of those substances or mixtures.

#### *Other means of identification*

Other names or synonyms by which the substance or mixture is labelled or commonly known, such as alternative names, numbers, company product codes, or other unique identifiers may be provided.

#### **1.2. Relevant identified uses of the substance or mixture and uses advised against**

At least the identified uses relevant for the recipient(s) of the substance or mixture shall be indicated. This shall be a brief description of what the substance or mixture is intended to do, such as 'flame retardant', 'antioxidant'.

The uses which the supplier advises against and the reasons why shall, where applicable, be stated. This need not be an exhaustive list.

Where a chemical safety report is required, the information in this subsection of the safety data sheet shall be consistent with the identified uses in the chemical safety report and the exposure scenarios from the chemical safety report set out in the annex to the safety data sheet.

#### **1.3. Details of the supplier of the safety data sheet**

The supplier and/or only representative shall be identified. The full address and telephone number of the supplier shall be given as well as an e-mail address for a competent person responsible for the safety data sheet.

For registrants, the information shall be consistent with the information on the identity of the manufacturer or importer provided in the registration.

Where an only representative has been appointed, details of the manufacturer or formulator outside Turkey may also be provided.

#### **1.4. Emergency telephone number**

References to emergency information services shall be provided. Emergency situation telephone number of the Ministry of Health National Poison Center shall be given. If availability of such services is limited for any reasons, such as hours of operation, or if there are limits on specific types of information provided, this shall be clearly stated.

## **2. SECTION 2: HAZARDS IDENTIFICATION**

This section of the safety data sheet shall describe the hazards of the substance or mixture and the appropriate warning information associated with those hazards.

### **2.1. Classification of the substance or mixture**

The classification of the substance or the mixture which results from the application of the classification criteria in By-law on Classification, Labelling and Packaging of Substances and Mixtures shall be given. Where the supplier has notified information regarding the substance to the classification and labelling inventory in accordance with Article 41 of the same By-law, the classification given in the safety data sheet shall be the same as the classification provided in that notification.

Classification of the mixture shall be given according to By-law on Classification, Labelling and Packaging of Substances and Mixtures. If the mixture does not meet the criteria for classification in accordance with the By-law, this shall be clearly stated. Information on the substances in the mixture is provided under subsection 3.2.

If the classification, including the hazard statements, is not written out in full, reference shall be made to Section 16 where the full text of each classification, including each hazard statement, shall be given.

The most important adverse physical, human health and environmental effects shall be listed in accordance with Sections 9 to 12 of the safety data sheet, in such a way as to allow non-experts to identify the hazards of the substance or mixture.

### **2.2. Label elements**

Based on the classification, at least the following elements appearing on the label in accordance with By-law on Classification, Labelling and Packaging of Substances and Mixtures shall be provided: hazard pictogram(s), signal word(s), hazard statement(s) and precautionary statement(s). A graphical reproduction of the full hazard pictogram in black and white or a graphical reproduction of the symbol only may be substituted for the colour pictogram provided in the same By-law.

The applicable label elements of the same By-law shall be provided.

### **2.3. Other hazards**

Information shall be provided on other hazards which do not result in classification but which may contribute to the overall hazards of the substance or mixture (such as formation of air contaminants during hardening or processing, dustiness, dust explosion hazards, cross-sensitisation, suffocation, freezing, high potency for odour or taste, or environmental effects like hazards to soil-dwelling organisms, or photochemical ozone creation potential). The statement 'May form explosible dust-air mixture if dispersed' is appropriate in the case of a dust explosion hazard.

## **3. SECTION 3: Composition/information on ingredients**

This section of the safety data sheet shall describe the chemical identity of the ingredient(s) of the substance or mixture, including impurities and stabilising additives as set out below. Appropriate and available safety information on surface chemistry shall be indicated.

### **3.1. Substances**

The chemical identity of the main constituent of the substance shall be provided by providing at least the product identifier or one of the other means of identification given in subsection 1.1. The chemical identity of any impurity, stabilising additive, or individual constituent other than the main constituent, which is itself classified and which contributes to the classification of the substance shall be provided as follows:

- (a) the product identifier in accordance with Article 20 of By-law on Classification, Labelling and Packaging of Substances and Mixtures;
- (b) if the product identifier is not available, one of the other names (usual name, trade name, abbreviation) or identification numbers.

Suppliers of substances may choose to list in addition all constituents including non-classified ones. This subsection may also be used to provide information on multi-constituent substances.

### **3.2. Mixtures**

The product identifier, the concentration or concentration ranges and the classifications shall be provided for at least all substances referred to in points 3.2.1 or 3.2.2. Suppliers of mixtures may choose to list in addition all substances in the mixture, including substances not meeting the criteria for classification. This information shall enable the recipient to identify readily the hazards of the substances in the mixture. The hazards of the mixture itself shall be given in Section 2.

The concentrations of the substances in a mixture shall be described as either of the following:

- (a) exact percentages in descending order by mass or volume, if technically possible;
- (b) ranges of percentages in descending order by mass or volume, if technically possible.

When using a range of percentages, the health and environmental hazards shall describe the effects of the highest concentration of each ingredient.

If the effects of the mixture as a whole are available, this information shall be included under Section 2.

Where the use of an alternative chemical name is permitted in accordance with Article 26 of By-law on Classification, Labelling and Packaging of Substances and Mixtures, that name can be used.

3.2.1. For a mixture meeting the criteria for classification in accordance with By-law on Classification, Labelling and Packaging of Substances and Mixtures, the following substances shall be indicated, together with their concentration or concentration range in the mixture:

a) substances presenting a health or environmental hazard within the meaning of By-law on Classification, Labelling and Packaging of Substances and Mixtures, if those substances are present in concentrations equal to or greater than the lowest of any of the following:

ia) the generic cut-off values set out in Table 1.1 of Annex I to By-law on Classification, Labelling and Packaging of Substances and Mixtures;

ib) the generic concentration limits given in parts 3 to 5 of Annex I to By-law on Classification, Labelling and Packaging of Substances and Mixtures, taking into account the concentrations specified in the notes to certain tables in part 3 in relation to the obligation to make available a safety data sheet for the mixture upon request, and for aspiration hazard (Section 3.10 of Annex I to same By-law)  $\geq 10 \%$ ;

**List of hazard classes, hazard categories and concentration limits for which a substance shall be listed as a substance in a mixture in subsection 3.2**

<b>1.1 Hazard class and category</b>	<b>Concentration limit (%)</b>
Acute toxicity, category 1, 2 and 3	≥ 0,1
Acute toxicity, category 4	≥ 1
Skin corrosion/irritation, category 1, sub-categories 1A, 1B, 1C and category 2	≥ 1
Serious damage to eyes/eye irritation, category 1 and 2	≥ 1
Respiratory/skin sensitisation	≥ 0,1
Germ cell mutagenicity category 1A and 1B	≥ 0,1
Germ cell mutagenicity category 2	≥ 1
Carcinogenicity category 1A, 1B and 2	≥ 0,1
Reproductive toxicity, category 1A, 1B, 2 and effects on or via lactation	≥ 0,1
Specific target organ toxicity (STOT) — single exposure, category 1 and 2	≥ 1
Specific target organ toxicity (STOT) — repeated exposure, category 1 and 2	≥ 1
Aspiration hazard	≥ 10
Hazardous to the aquatic environment — Acute, category 1	≥ 0,1
Hazardous to the aquatic environment — Chronic, category 1	≥ 0,1
Hazardous to the aquatic environment — Chronic, category 2, 3 and 4	≥ 1
Hazardous for the ozone layer	≥ 0,1

(ii) the specific concentration limits given in Part 3 of Annex VI to By-law on Classification, Labelling and Packaging of Substances and Mixtures,

(iii) if an M-factor has been given in Part 3 of Annex VI to By-law on Classification, Labelling and Packaging of Substances and Mixtures, the generic cut-off value in Table 1.1 of Annex I to that By-law, adjusted using the calculation set out in Section 4.1 of Annex I to that By-law,

(iv) the specific concentration limits provided to the classification and labelling inventory established under By-law on Classification, Labelling and Packaging of Substances and Mixtures,

(v) the concentration limits set out in Annex II to By-law on Classification, Labelling and Packaging of Substances and Mixtures,

(vi) if an M-factor has been provided to the classification and labelling inventory established under By-law on Classification, Labelling and Packaging of Substances and Mixtures, the generic cut-off value in Table 1.1 of Annex I to that By-law, adjusted using the calculation set out in Section 4.1 of Annex I to that By-law.

b) substances for which there are Union workplace exposure limits which are not already included under point (a);

c) substances that are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, or substances included in the list established in accordance with Article 49(1) for reasons other than the hazards referred to in point (a), if the concentration of an individual substance is equal to or greater than 0,1 %.

3.2.2. For a mixture not meeting the criteria for classification in accordance with By-law on Classification, Labelling and Packaging of Substances and Mixtures, substances present in an individual concentration equal to or greater than the following concentrations shall be indicated, together with their concentration or concentration range:

(a) 1 % by weight in non-gaseous mixtures and 0,2 % by volume in gaseous mixtures for:

(i) substances which present a health or environmental hazard within the meaning of By-law on Classification, Labelling and Packaging of Substances and Mixtures; or

(ii) substances for which Union workplace exposure limits have been assigned;

(b) 0,1 % by weight for substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex 13, very persistent and very bioaccumulative in accordance with the criteria set out in Annex 13, or included in the list established in accordance with Article 49(1) for reasons other than the hazards referred to in point (a).

3.2.3. For the substances indicated in subsection 3.2, the classification of the substance according to By-law on Classification, Labelling and Packaging of Substances and Mixtures, including the hazard class(es) and category code(s) as provided in Table 1.1 of Annex VI to that Regulation as well as the hazard statements which are assigned in accordance with their physical, human health and environmental hazards, shall be provided. The hazard statements do not need to be written out in full in this section; their codes shall be sufficient. In cases where they are not written out in full, reference shall be made to Section 16, where the full text of each relevant hazard statement shall be listed. If the substance does not meet the classification criteria, the reason for indicating the substance in subsection 3.2 shall be described, such as 'non-classified vPvB substance' or 'substance with a workplace exposure limit'.

3.2.4. For the substances indicated in subsection 3.2 the name and, if available, the registration number, as assigned under Article 20(3) of this By-law, shall be given.

Without affecting the obligations of downstream users laid down in Article 35 of this By-law, the part of the registration number referring to the individual registrant of a joint submission may be omitted by the supplier of the mixture provided that:

(a) this supplier assumes the responsibility to provide the full registration number upon request for enforcement purposes or, if the full registration number is not available to him, to forward the request to his supplier, in line with point (b); and

(b) this supplier provides the full registration number to the related institution within seven days upon request, received either directly from the enforcement authority or forwarded by his recipient, or, if the full registration number is not available to him, this supplier shall forward the request to his supplier within seven days upon request and at the same time inform the enforcement authority thereof.

The EC number, if available, shall be given in accordance with By-law on Classification, Labelling and Packaging of Substances and Mixtures. The CAS number, if available, and the IUPAC name, if available, may also be given.

For substances indicated in this subsection by means of an alternative chemical name in accordance with Article 26 of By-law on Classification, Labelling and Packaging of Substances and Mixtures, the registration number, EC number and other precise chemical identifiers are not necessary.

#### **4. SECTION 4: First aid measures**

This section of the safety data sheet shall describe the initial care in such a way that an untrained responder can understand and provide it without the use of sophisticated equipment and without the availability of a wide selection of medications. If medical attention is required, the instructions shall state this, including its urgency.

##### **4.1. Description of first aid measures**

4.1.1. First aid instructions shall be provided by relevant routes of exposure. Subdivisions shall be used to indicate the procedure for each route, such as inhalation, skin, eye and ingestion.

4.1.2. Advice shall be provided as to whether:

- (a) immediate medical attention is required and if delayed effects can be expected after exposure;
- (b) movement of the exposed individual from the area to fresh air is recommended;
- (c) removal and handling of clothing and shoes from the individual is recommended; and
- (c) personal protective equipment for first aid responders is recommended.

##### **4.2. Most important symptoms and effects, both acute and delayed**

Briefly summarised information shall be provided on the most important symptoms and effects, both acute and delayed, from exposure.

##### **4.3. Indication of any immediate medical attention and special treatment needed**

Where appropriate, information shall be provided on clinical testing and medical monitoring for delayed effects, specific details on antidotes (where they are known) and contraindications. For some substances or mixtures, it may be important to emphasise that special means to provide specific and immediate treatment shall be available at the workplace.

#### **5. SECTION 5: Firefighting measures**

This section of the safety data sheet shall describe the requirements for fighting a fire caused by the substance or mixture, or arising in its vicinity.

### **5.1. Extinguishing media**

Suitable extinguishing media:

Information shall be provided on the appropriate extinguishing media.

Unsuitable extinguishing media:

Indications shall be given whether any extinguishing media are inappropriate for a particular situation involving the substance or mixture.

### **5.2. Special hazards arising from the substance or mixture**

Information shall be provided on hazards that may arise from the substance or mixture, like hazardous combustion products that form when the substance or mixture burns, such as ‘may produce toxic fumes of carbon monoxide if burning’ or ‘produces oxides of sulphur and nitrogen on combustion’.

### **5.3. Advice for firefighters**

Advice shall be provided on any protective actions to be taken during firefighting, such as ‘keep containers cool with water spray’, and on special protective equipment for firefighters, such as boots, overalls, gloves, eye and face protection and breathing apparatus.

## **6. SECTION 6: Accidental release measures**

This section of the safety data sheet shall recommend the appropriate response to spills, leaks, or releases, to prevent or minimise the adverse effects on persons, property and the environment. It shall distinguish between responses to large and small spills, in cases where the spill volume has a significant impact on the hazard. If the procedures for containment and recovery indicate that different practices are required, these shall be indicated in the safety data sheet.

### **6.1. Personal precautions, protective equipment and emergency procedures**

#### **6.1.1. For non-emergency personnel**

Advice shall be provided related to accidental spills and release of the substance or mixture such as:

- (a) the wearing of suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing;
- (b) removal of ignition sources, provision of sufficient ventilation, control of dust; and
- (c) emergency procedures such as the need to evacuate the danger area or to consult an expert.

#### **6.1.2. For emergency responders**

Advice shall be provided related to suitable fabric for personal protective clothing (such as ‘appropriate: Butylene’; ‘not appropriate: PVC’).

### **6.2. Environmental precautions**

Advice shall be provided on any environmental precautions to be taken related to accidental spills and release of the substance or mixture, such as keeping away from drains, surface and ground water.

### **6.3. Methods and material for containment and cleaning up**

6.3.1. Appropriate advice shall be provided on how to contain a spill. Appropriate containment techniques may include any of the following:

- (a) bunding, covering of drains;
- (b) capping procedures.

6.3.2. Appropriate advice shall be provided on how to clean-up a spill. Appropriate clean-up procedures may include any of the following:

- (a) neutralisation techniques;
- (b) decontamination techniques;
- (c) adsorbent materials;
- (d) cleaning techniques;
- (e) vacuuming techniques;
- (f) equipment required for containment/clean-up (include the use of non-sparking tools and equipment where applicable).

6.3.3. Any other information shall be provided relating to spills and releases, including advice on inappropriate containment or clean-up techniques, such as by indications like 'never use ...'.

### **6.4. Reference to other sections**

If appropriate Sections 8 and 13 shall be referred to.

## **7. SECTION 7: Handling and storage**

This section of the safety data sheet shall provide advice on safe handling practices. It shall emphasise precautions that are appropriate to the identified uses referred to under subsection 1.2 and to the unique properties of the substance or mixture.

Information in this section of the safety data sheet shall relate to the protection of human health, safety and the environment. It shall assist the employer in devising suitable working procedures and organisational measures according to Article 7 of By-law on Health and Safety Precautions for Working with Chemical Substances and Article 7 of By-law on Health and Safety Precautions for Working with Carcinogens and Mutagens.

Where a chemical safety report is required, the information in this section of the safety data sheet shall be consistent with the information given for the identified uses in the chemical safety report and the exposure scenarios showing control of risk from the chemical safety report set out in the annex to the safety data sheet.

In addition to information given in this section, relevant information may also be found in Section 8.

### **7.1. Precautions for safe handling**

7.1.1. Recommendations shall be specified to:

- (a) allow safe handling of the substance or mixture, such as containment and measures to prevent fire as well as aerosol and dust generation;

- (b) prevent handling of incompatible substances or mixtures;
- (c) draw attention to operations and conditions which create new risks by altering the properties of the substance or mixture, and to appropriate countermeasures; and
- (c) reduce the release of the substance or mixture to the environment, such as avoiding spills or keeping away from drains.

7.1.2. Advice on general occupational hygiene shall be provided, such as:

- (a) not to eat, drink and smoke in work areas;
- (b) to wash hands after use; and
- (c) to remove contaminated clothing and protective equipment before entering eating areas.

## **7.2. Conditions for safe storage, including any incompatibilities**

The advice provided shall be consistent with the physical and chemical properties described in Section 9 of the safety data sheet. If relevant, advice shall be provided on specific storage requirements including:

- (a) how to manage risks associated with:
  - (i) explosive atmospheres;
  - (ii) corrosive conditions;
  - (iii) flammability hazards;
  - (iv) incompatible substances or mixtures;
  - (v) evaporative conditions; and
  - (vi) potential ignition sources (including electrical equipment);
- (b) how to control the effects of:
  - (i) weather conditions;
  - (ii) ambient pressure;
  - (iii) temperature;
  - (iv) sunlight;
  - (v) humidity; and
  - (vi) vibration;
- (c) how to maintain the integrity of the substance or mixture by the use of:
  - (i) stabilisers; and
  - (ii) antioxidants;
- (d) other advice including:
  - (i) ventilation requirements;
  - (ii) specific designs for storage rooms or vessels (including retention walls and ventilation);
  - (iii) quantity limits under storage conditions (if relevant); and
  - (iv) packaging compatibilities.

## **7.3. Specific end use(s)**

For substances and mixtures designed for specific end use(s), recommendations shall relate to the identified use(s) referred to in subsection 1.2 and be detailed and operational. If an exposure scenario is attached, reference to it may be made or the information as required in subsections 7.1 and 7.2 shall be provided. If an actor in the supply chain has carried out a chemical safety assessment for the mixture, it is sufficient that the safety data sheet and the exposure scenarios are consistent with the chemical safety report for the mixture, rather than with the chemical

safety reports for each substance in the mixture. If industry- or sector-specific guidance is available, detailed reference to it (including source and issuing date) may be made.

## **8. SECTION 8: Exposure control/personal protection**

This section of the safety data sheet shall describe the applicable occupational exposure limits and necessary risk management measures.

Where a chemical safety report is required, the information in this section of the safety data sheet shall be consistent with the information given for the identified uses in the chemical safety report and the exposure scenarios showing control of risk from the chemical safety report set out in the annex to the safety data sheet.

### **8.1. Control parameters**

8.1.1. Where available, the following national limit values, including the legal basis of each of them, shall be listed for the substance or for each of the substances in the mixture. When listing occupational exposure limit values, the chemical identity as specified in Section 3 shall be used:

8.1.1.1. The occupational exposure limit values in accordance with By-law on Health and Safety Precautions for Working with Chemical Substances;

8.1.1.2. The occupational exposure limit values in accordance with By-law on Health and Safety Precautions for Working with Carcinogens and Mutagens,

8.1.1.3. If available, any other national occupational exposure limit values,

8.1.1.4. Biological limit values in accordance with By-law on Health and Safety Precautions for Working with Chemical Substances,

8.1.1.5. If available, any other biological limit values.

8.1.2. Information on currently recommended monitoring procedures shall be provided at least for the most relevant substances

8.1.3. If air contaminants are formed when using the substance or mixture as intended, applicable occupational exposure limit values and/or biological limit values for these shall also be listed.

8.1.4. Where a chemical safety report is required or where a DNEL as referred to in Section 1.4 of Annex I or a PNEC as referred to in Section 3.3 of Annex I is available, the relevant DNELs and PNECs for the substance shall be given for the exposure scenarios from the chemical safety report set out in the annex to the safety data sheet.

8.1.5. Where a control banding approach is used to decide on risk management measures in relation to specific uses, sufficient detail shall be given to enable effective management of the risk. The context and limitations of the specific control banding recommendation shall be made clear.

### **8.2. Exposure controls**

The information required in the present subsection shall be provided, unless an exposure scenario containing that information is attached to the safety data sheet.

Where the supplier has waived a test under Section 3 of Annex XI, he shall indicate the specific conditions of use relied on to justify the waiving.

Where a substance has been registered as an isolated intermediate (on-site or transported), the supplier shall indicate that this safety data sheet is consistent with the specific conditions relied on to justify the registration in accordance with Article 17 or 18.

### **8.2.1. Appropriate engineering controls**

The description of appropriate exposure control measures shall relate to the identified use(s) of the substance or mixture as referred to in subsection 1.2. This information shall be sufficient to enable the employer to carry out an assessment of risk to the safety and health of workers arising from the presence of the substance or mixture in accordance with By-law on Health and Safety Precautions for Working with Chemical Substances and By-law on Health and Safety Precautions for Working with Carcinogens and Mutagens, where appropriate.

This information shall complement that already given under Section 7.

### **8.2.2. Individual protection measures, such as personal protective equipment**

8.2.2.1. The information on use of personal protective equipment shall be consistent with good occupational hygiene practices and in conjunction with other control measures, including engineering controls, ventilation and isolation. Where appropriate, Section 5 shall be referred to for specific fire/chemical personal protective equipment advice.

8.2.2.2. Taking into account By-law on Personal Protective Equipment published in the Official Gazette dated 29/11/2006 and numbered 26361 and referring to the appropriate CEN standards, detailed specifications shall be given on which equipment will provide adequate and suitable protection, including:

#### **(a) Eye/face protection**

The type of eye/face protection equipment required shall be specified based on the hazard of the substance or mixture and potential for contact, such as safety glasses, safety goggles, face-shield.

#### **(b) Skin protection**

##### **(i) Hand protection**

The type of gloves to be worn when handling the substance or mixture shall be clearly specified based on the hazard of the substance or mixture and potential for contact and with regard to the amount and duration of dermal exposure, including:

— the type of material and its thickness,

— the typical or minimum breakthrough times of the glove material,

If necessary, any additional hand protection measures shall be indicated.

##### **(ii) Other**

If it is necessary to protect a part of the body other than the hands, the type and quality of protection equipment required shall be specified, such as gauntlets, boots, bodysuit based on the hazards associated with the substance or mixture and the potential for contact.

If necessary, any additional skin protection measures and specific hygiene measures shall be indicated.

#### **(c) Respiratory protection**

For gases, vapours, mist or dust, the type of protective equipment to be used shall be specified based on the hazard and potential for exposure, including air-purifying respirators, specifying

the proper purifying element (cartridge or canister), the adequate particulate filters and the adequate masks, or self-contained breathing apparatus.

(d) Thermal hazards

When specifying protective equipment to be worn for materials that represent a thermal hazard, special consideration shall be given to the construction of the personal protective equipment.

### **8.2.3. Environmental exposure controls**

The information required by the employer to fulfil his commitments under environmental protection legislation shall be specified.

Where a chemical safety report is required, a summary of the risk management measures that adequately control exposure of the environment to the substance shall be given for the exposure scenarios set out in the annex to the safety data sheet.

## **9. SECTION 9: Physical and chemical properties**

This section of the safety data sheet shall describe the empirical data relating to the substance or mixture, if relevant. Article 10(2) of By-law on Classification, Labelling and Packaging of Substances and Mixtures shall apply. The information in this section shall be consistent with the information provided in the registration and/or in the chemical safety report where required, and with the classification of the substance or mixture.

### **9.1. Information on basic physical and chemical properties**

The following properties shall be clearly identified including, where appropriate, a reference to the test methods used and specification of appropriate units of measurement and/or reference conditions. If relevant for the interpretation of the numerical value, the method of determination shall also be provided (for example, the method for flash point, the open-cup/closed-cup method):

(a) Appearance:

The physical state (solid (including appropriate and available safety information on granulometry and specific surface area if not already specified elsewhere in this safety data sheet), liquid, gas) and the colour

(b) Odour:

If odour is perceptible, a brief description of it shall be given;

(c) Odour threshold;

(ç) pH:

The pH of the substance or mixture as supplied or of an aqueous solution shall be indicated; in the case of an aqueous solution, the concentration shall also be indicated;

(d) Melting point/freezing point;

(e) Initial boiling point and boiling range;

(f) Flash point;

(g) Evaporation rate;

(ğ) Flammability (solid, gas);

(h) Upper/lower flammability or explosive limits;

(i) Vapour pressure;

(i) Vapour density;

- (j) Relative density;
- (k) Solubility(ies);
- (l) Partition coefficient: n-octanol/water;
- (m) Auto-ignition temperature;
- (n) Decomposition temperature;
- (o) Viscosity;
- (ö) Explosive properties;
- (p) Oxidising properties.

If it is stated that a particular property does not apply or if information on a particular property is not available, the reasons shall be given.

To enable proper control measures to be taken, all relevant information on the substance or mixture shall be provided. The information in this section shall be consistent with the information provided in a registration where one is required.

In the case of a mixture, the entries shall clearly indicate to which substance in the mixture the data apply, unless it is valid for the whole mixture.

## **9.2. Other information**

Other physical and chemical parameters shall be indicated as necessary, such as miscibility, fat solubility (solvent — oil to be specified), conductivity, or gas group. Appropriate and available safety information on redox potential, radical formation potential and photocatalytic properties shall be indicated.

## **10. SECTION 10: Stability and reactivity**

This section of the safety data sheet shall describe the stability of the substance or mixture and the possibility of hazardous reactions occurring under certain conditions of use and also if released into the environment, including, where appropriate, a reference to the test methods used. If it is stated that a particular property does not apply or if information on a particular property is not available, the reasons shall be given.

### **10.1. Reactivity**

10.1.1. The reactivity hazards of the substance or mixture shall be described. Specific test data shall be provided for the substance or mixture as a whole, where available. However, the information may also be based on general data for the class or family of substance or mixture if such data adequately represent the anticipated hazard of the substance or mixture.

10.1.2. If data for mixtures are not available, data on substances in the mixture shall be provided. In determining incompatibility, the substances, containers and contaminants that the substance or mixture might be exposed to during transportation, storage and use shall be considered.

### **10.2. Chemical stability**

It shall be indicated if the substance or mixture is stable or unstable under normal ambient and anticipated storage and handling conditions of temperature and pressure. Any stabilisers which are, or may need to be, used to maintain the chemical stability of the substance or mixture shall

be described. The safety significance of any change in the physical appearance of the substance or mixture shall be indicated.

### **10.3. Possibility of hazardous reactions**

If relevant, it shall be stated if the substance or mixture will react or polymerise, releasing excess pressure or heat, or creating other hazardous conditions. The conditions under which the hazardous reactions may occur shall be described.

### **10.4. Conditions to avoid**

Conditions such as temperature, pressure, light, shock, static discharge, vibrations or other physical stresses that might result in a hazardous situation shall be listed and if appropriate a brief description of measures to be taken to manage risks associated with such hazards shall be given.

### **10.5. Incompatible materials**

Families of substances or mixtures or specific substances, such as water, air, acids, bases, oxidising agents, with which the substance or mixture could react to produce a hazardous situation (like an explosion, a release of toxic or flammable materials, or a liberation of excessive heat), shall be listed and if appropriate a brief description of measures to be taken to manage risks associated with such hazards shall be given.

### **10.6. Hazardous decomposition products**

Known and reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating shall be listed. Hazardous combustion products shall be included in Section 5 of the safety data sheet.

## **11. SECTION 11: Toxicological information**

This section of the safety data sheet is meant for use primarily by medical professionals, occupational health and safety professionals and toxicologists. A concise but complete and comprehensible description of the various toxicological (health) effects and the available data used to identify those effects shall be provided, including where appropriate information on toxicokinetics, metabolism and distribution. The information in this section shall be consistent with the information provided in the registration and/or in the chemical safety report where required, and with the classification of the substance or mixture.

### **11.1. Information on toxicological effects**

The relevant hazard classes, for which information shall be provided, are:

- (a) acute toxicity;
- (b) skin corrosion/irritation;
- (c) serious eye damage/irritation;
- (d) respiratory or skin sensitisation;
- (e) germ cell mutagenicity;
- (f) carcinogenicity;
- (g) reproductive toxicity;

- (h) STOT-single exposure;
- (i) STOT-repeated exposure;
- (j) aspiration hazard.

For substances subject to registration, brief summaries of the information derived from the application of Annexes VII to XI shall be given, including, where appropriate, a reference to the test methods used. For substances subject to registration, the information shall also include the result of the comparison of the available data with the criteria given in By-law on Classification, Labelling and Packaging of Substances and Mixtures for CMR, categories 1A and 1B, following point 1.3.1 of Annex I to this By-law.

11.1.1 Information shall be provided for each hazard class or differentiation. If it is stated that the substance or mixture is not classified for a particular hazard class or differentiation, the safety data sheet shall clearly state whether this is due to lack of data, technical impossibility to obtain the data, inconclusive data or data which are conclusive although insufficient for classification; in the latter case the safety data sheet shall specify 'based on available data, the classification criteria are not met'.

11.1.2 The data included in this subsection shall apply to the substance or mixture as placed on the market. In the case of a mixture, the data should describe the toxicological properties of the mixture as a whole, except if Article 8(3) of By-law on Classification, Labelling and Packaging of Substances and Mixtures applies. If available, the relevant toxicological properties of the hazardous substances in a mixture shall also be provided, such as the LD50, acute toxicity estimates or LC50.

11.1.3. Where there is a substantial amount of test data on the substance or mixture, it may be necessary to summarise results of the critical studies used, for example, by route of exposure.

11.1.4. Where the classification criteria for a particular hazard class are not met, information supporting this conclusion shall be provided.

11.1.5. Information on likely routes of exposure

Information shall be provided on likely routes of exposure and the effects of the substance or mixture via each possible route of exposure, that is, through ingestion (swallowing), inhalation or skin/eye exposure. If health effects are not known, this shall be stated.

11.1.6. Symptoms related to the physical, chemical and toxicological characteristics:

Potential adverse health effects and symptoms associated with exposure to the substance or mixture and its ingredients or known by-products shall be described. Available information shall be provided on the symptoms related to the physical, chemical, and toxicological characteristics of the substance or mixture following exposure. The first symptoms at low exposures through to the consequences of severe exposure shall be described. (For example 'headaches and dizziness may occur, proceeding to fainting or unconsciousness; large doses may result in coma and death').

11.1.7. Delayed and immediate effects as well as chronic effects from short and long-term exposure:

Information shall be provided on whether delayed or immediate effects can be expected after short- or long-term exposure. Information on acute and chronic health effects relating to human exposure to the substance or mixture shall also be provided. Where human data are not available, animal data shall be summarised and the species clearly identified. It shall be indicated whether toxicological data is based on human or animal data.

11.1.8. Interactive effects:

Information on interactions shall be included if relevant and available.

11.1.9. Absence of specific data:

It may not always be possible to obtain information on the hazards of a substance or mixture. In cases where data on the specific substance or mixture are not available, data on similar substances or mixtures, if appropriate, may be used, provided the relevant similar substance or mixture is identified. Where specific data are not used, or where data are not available, this shall be clearly stated.

11.1.10. Mixtures:

For a given health effect, if a mixture has not been tested for its health effects as a whole, relevant information on relevant substances listed under Section 3 shall be provided.

11.1.11 Mixtures versus substance information

11.1.11.1. The substances in a mixture may interact with each other in the body, resulting in different rates of absorption, metabolism and excretion. As a result, the toxic actions may be altered and the overall toxicity of the mixture may be different from that of the substances in it. This shall be taken into account when providing toxicological information in this section of the safety data sheet.

11.1.11.2. It is necessary to consider whether the concentration of each substance is sufficient to contribute to the overall health effects of the mixture. The information on toxic effects shall be presented for each substance, except for the following cases:

(a) if the information is duplicated, it shall be listed only once for the mixture overall, such as when two substances both cause vomiting and diarrhoea;

(b) if it is unlikely that these effects will occur at the concentrations present, such as when a mild irritant is diluted to below a certain concentration in a non-irritant solution;

(c) where information on interactions between substances in a mixture is not available, assumptions shall not be made and instead the health effects of each substance shall be listed separately.

11.1.12. Other information:

Other relevant information on adverse health effects shall be included even when not required by the classification criteria.

## **12. SECTION 12: Ecological information**

This section of the safety data sheet shall provide information to enable evaluation of the environmental impact of the substance or mixture where it is released to the environment. Subsections 12.1, 12.2, 12.3, 12.4, 12.5 and 12.6 of the safety data sheet shall provide a short summary of the data including, where available, relevant test data and clearly indicating species, media, units, test duration and test conditions. This information may assist in handling spills, and evaluating waste treatment practices, control of release, accidental release measures and transport. If it is stated that a particular property does not apply or if information on a particular property is not available, the reasons shall be indicated.

Some properties are substance specific, i.e. bioaccumulation, persistence and degradability, and that information shall be given, where available and appropriate, for each relevant substance in the mixture. Information shall also be provided for hazardous transformation products arising from the degradation of substances and mixtures.

The information in this section shall be consistent with the information provided in the registration and/or in the chemical safety report where required, and with the classification of the substance or mixture.

### **12.1. Toxicity**

Information on toxicity using data from tests performed on aquatic and/or terrestrial organisms shall be provided when available. This shall include relevant available data on aquatic toxicity, both acute and chronic for fish, crustaceans, algae and other aquatic plants. In addition, toxicity data on soil micro- and macroorganisms and other environmentally relevant organisms, such as birds, bees and plants, shall be included when available. Where the substance or mixture has inhibitory effects on the activity of microorganisms, the possible impact on sewage treatment plants shall be mentioned.

For substances subject to registration, summaries of the information derived from the application of Annexes VII to XI of this Regulation shall be included.

### **12.2. Persistence and degradability**

Persistence and degradability is the potential for the substance or the appropriate substances in a mixture to degrade in the environment, either through biodegradation or other processes, such as oxidation or hydrolysis. Test results relevant to assess persistence and degradability shall be given where available. If degradation half-lives are quoted it must be indicated whether these half-lives refer to mineralisation or to primary degradation. The potential of the substance or certain substances in a mixture to degrade in sewage treatment plants shall also be mentioned. This information shall be given where available and appropriate, for each individual substance in the mixture which is required to be listed in Section 3 of the safety data sheet.

### **12.3. Bioaccumulation potential**

Bioaccumulative potential is the potential of the substance or certain substances in a mixture to accumulate in biota and, eventually, to pass through the food chain. Test results relevant to assess the bioaccumulative potential shall be given. This shall include reference to the octanol-water partition coefficient (K<sub>ow</sub>) and bioconcentration factor (BCF), if available.

This information shall be given where available and appropriate, for each individual substance in the mixture which is required to be listed in Section 3 of the safety data sheet.

#### **12.4. Mobility in soil**

Mobility in soil is the potential of the substance or the components of a mixture, if released to the environment, to move under natural forces to the groundwater or to a distance from the site of release. The potential for mobility in soil shall be given where available. Information on mobility in soil can be determined from relevant mobility data such as adsorption studies or leaching studies, known or predicted distribution to environmental compartments, or surface tension. For example, Koc values can be predicted from octanol/water partition coefficients (Kow). Leaching and mobility can be predicted from models.

This information shall be given where available and appropriate, for each individual substance in the mixture which is required to be listed in Section 3 of the safety data sheet.

Where experimental data is available, that data shall, in general, take precedence over models and predictions.

#### **12.5. Results of PBT ve vPvB assessment**

Where a chemical safety report is required, the results of the PBT and vPvB assessment as set out in the chemical safety report shall be given.

#### **12.6. Other adverse effects**

Information on any other adverse effects on the environment shall be included where available, such as environmental fate (exposure), photochemical ozone creation potential, ozone depletion potential, endocrine-disrupting potential and/or global warming potential.

### **13. SECTION 13: Disposal considerations**

This section of the safety data sheet shall provide information for proper waste management of the substance or mixture and/or its container to assist in the determination of safe and environmentally preferred waste management options, consistent with the requirements of waste management legislation. Information relevant for the safety of persons conducting waste management activities shall complement the information given in Section 8.

Where a chemical safety report is required and where a waste stage analysis has been performed, the information on the waste management measures shall be consistent with the identified uses in the chemical safety report and the exposure scenarios from the chemical safety report set out in the annex to the safety data sheet.

#### **13.1. Waste treatment methods**

This subsection of the safety data sheet shall:

- (a) specify waste treatment containers and methods including the appropriate methods of waste treatment of both the substance or mixture and any contaminated packaging (for example, incineration, recycling, landfilling);
- (b) specify the physical/chemical properties that may affect waste treatment options;
- (c) discourage sewage disposal;

(c) Identify, where appropriate, any special precautions for any recommended waste treatment option.

Any relevant waste management legislation in force shall be referred to.

#### **14. SECTION 14: Transport Information**

This section of the safety data sheet shall provide basic classification information for the transport/shipment of substances or mixtures mentioned in Section 1 by road, rail, sea, inland waterways or air. Where such information is not available or relevant this shall be stated.

Where relevant, this section shall provide information on the transport classification for each of the UN Model Regulations: the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) and the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN), the International Maritime Dangerous Goods (IMDG) Code (sea) and the Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO)(air).

##### **14.1. UN number**

The UN number (i.e. the four-figure identification number of the substance, mixture or article preceded by the letters 'UN') from the UN Model Regulations shall be provided.

##### **14.2. UN proper shipping name**

The UN proper shipping name from the UN Model Regulations shall be provided, unless it was used as the product identifier in subsection 1.1.

##### **14.3. Transport hazard class(es)**

The transport hazard class (and subsidiary risks) assigned to the substances or mixtures on the basis of the predominant hazard that they present according to the UN Model Regulations shall be provided.

##### **14.4. Packing group**

The packing group number from the UN Model Regulations shall be provided, if applicable. The packing group number is assigned to certain substances in accordance with their degree of hazard.

##### **14.5. Environmental hazards**

It shall be indicated whether the substance or mixture is environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID and ADN) and/or a marine pollutant according to the IMDG Code. If the substance or mixture is authorised or intended for carriage by inland waterways in tank-vessels, it shall be indicated whether the substance or mixture is environmentally hazardous in tank-vessels only according to the ADN.

##### **14.6. Special precautions for user**

Information shall be provided on any special precautions which a user should or must take or be aware of in connection with transport or conveyance either within or outside his premises.

#### **14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

This subsection only applies when cargoes are intended to be carried in bulk according to the following IMO instruments: Annex II of International Convention for the Prevention of Pollution from Ships (MARPOL 73/78) and the International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk (IBC Code).

The product name shall be provided (if different from that given in subsection 1.1) as required by the shipment document and in accordance with the name used in the lists of product names given in chapters 17 or 18 of the IBC Code or the latest edition of the IMO's Maritime Environment Protection Committee (MEPC).2/Circular. Ship type required and pollution category shall be indicated.

### **15. SECTION 15: Regulatory information**

This section of the safety data sheet shall describe the other regulatory information on the substance or mixture that is not already provided in the safety data sheet (such as whether the substance or mixture is subject to by-law on substances that deplete the ozone layer, legislation on persistent organic pollutants or legislation concerning the export and import of dangerous chemicals).

#### **15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Information shall be provided regarding relevant safety, health and environmental provisions (for example, By-law on Prevention of Major Industrial Accidents and Reduction of Their Impact published in the Official Gazette dated 31/12/2013 and numbered 28867), including advice on action that should be taken by the recipient as a result of these provisions.

If the substance or mixture covered by this safety data sheet is the subject of specific provisions in relation to the protection of human health or the environment (such as authorisations or restrictions) these provisions shall be mentioned.

#### **15.2. Chemical Safety Assessment**

This subsection of the safety data sheet shall indicate whether the supplier has carried out a chemical safety assessment for the substance or the mixture.

### **16. SECTION 16: Other information**

This section of the safety data sheet shall contain other information that is not included in Sections 1 to 15, including information on the revision of the safety data sheet such as:

(a) in the case of a revised safety data sheet, a clear indication of where changes have been made to the previous version of the safety data sheet, unless such indication is given elsewhere in the safety data sheet, with an explanation of the changes, if appropriate. A supplier of a substance or mixture shall be able to provide an explanation of the changes upon request;

- (b) a key or legend to abbreviations and acronyms used in the safety data sheet;
- (c) key literature references and sources for data;
- (ç) in the case of mixtures, an indication of which of the methods of evaluating information referred to in Article 11 of By-law on Classification, Labelling and Packaging of Substances and Mixtures was used for the purpose of classification;
- (d) a list of relevant hazard statements and/or precautionary statements. Write out the full text of any statements which are not written out in full under Sections 2 to 15;
- (e) advice on any training appropriate for workers to ensure protection of human health and the environment.

## **PART B**

The safety data sheet shall include the following 16 headings in accordance with Article 27(5) and in addition the subheadings also listed except Section 3, where only subsections 3.1 or 3.2 need to be included as appropriate:

- SECTION 1: Identification of the substances/mixture and of the company/undertaking
  - 1.1. Product identifier
  - 1.2. Relevant identified uses of the substances or mixture and uses advised against
  - 1.3. Details of the supplier of the safety data sheet
  - 1.4. Emergency telephone number
- SECTION 2: Hazards identification
  - 2.1. Classification of the substance or mixture
  - 2.2. Label elements
  - 2.3. Other hazards
- SECTION 3: Composition/information on ingredients
  - 3.1. Substances
  - 3.2. Mixtures
- SECTION 4: First aid measures
  - 4.1. Description of first aid measures
  - 4.2. Most important symptoms and effects, both acute and delayed
  - 4.3. Indication of any immediate medical attention and special treatment needed
- SECTION 5: Firefighting measures
  - 5.1. Extinguishing media
  - 5.2. Special hazards arising from the substance or mixture
  - 5.3. Advice for firefighters
- SECTION 6: Accidental release measures
  - 6.1. Personal precautions, protective equipment and emergency procedures
  - 6.2. Environmental precautions
  - 6.3. Methods and material for containment and cleaning up
  - 6.4. Reference to other sections
- SECTION 7: Handling and storage
  - 7.1. Precautions for safe handling
  - 7.2. Conditions for safe storage, including any incompatibilities

- 7.3. Specific end use(s)
- SECTION 8: Exposure controls/personal protection
  - 8.1. Control parameters
  - 8.2. Exposure controls
- SECTION 9: Physical and chemical properties
  - 9.1. Information on basic physical and chemical properties
  - 9.2. Other information
- SECTION 10: Stability and reactivity
  - 10.1. Reactivity
  - 10.2. Chemical stability
  - 10.3. Possibility of hazardous reactions
  - 10.4. Conditions to avoid
  - 10.5. Incompatible materials
  - 10.6. Hazardous decomposition products
- SECTION 11: Toxicological information
  - 11.1. Information on toxicological effects
- SECTION 12: Ecological information
  - 12.1. Toxicity
  - 12.2. Persistence and degradability
  - 12.3. Bioaccumulative potential
  - 12.4. Mobility in soil
  - 12.5. Results of PBT and vPvB assessment
  - 12.6. Other adverse effects
- SECTION 13: Disposal considerations
  - 13.1. Waste treatment methods
- SECTION 14: Transport information
  - 14.1. UN number
  - 14.2. UN proper shipping name
  - 14.3. Transport hazard class(es)
  - 14.4. Packing group
  - 14.5. Environmental hazards
  - 14.6. Special precautions for user
  - 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code
- SECTION 15: Regulatory information
  - 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
  - 15.2. Chemical safety assessment
- SECTION 16: Other information.

### **ANNEX III**

#### **CRITERIA FOR SUBSTANCES REGISTERED IN QUANTITIES BETWEEN 1 AND 10 TONNES**

Criteria for substances registered between 1 and 10 tonnes, with reference to Article 13(1)(a) and (b):

a) substances for which it is predicted (i.e. by the application of (Q)SARs or other evidence) that they are likely to meet the criteria for category 1A or 1B classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity or the criteria in Annex XIII;

(b) substances:

(i) with dispersive or diffuse use(s) particularly where such substances are used in consumer 3 mixtures or incorporated into consumer articles; and

(ii) for which it is predicted (i.e. by application of (Q)SARs or other evidence) that they are likely to meet the classification criteria for any health or environmental hazard classes or differentiations under By-law on Classification, Labelling and Packaging of Substances and Mixtures.

## ANNEX IV

### EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(5)(a)

Einecs no	Name/Group	CAS No
200-061-5	D-glucitol C <sub>6</sub> H <sub>14</sub> O <sub>6</sub>	50-70-4
200-066-2	Ascorbic acid C <sub>6</sub> H <sub>8</sub> O <sub>6</sub>	50-81-7
200-075-1	Glucose C <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	50-99-7
200-233-3	Fructose C <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	57-48-7
200-294-2	L-lysine C <sub>6</sub> H <sub>14</sub> N <sub>2</sub> O <sub>2</sub>	56-87-1
200-334-9	Sucrose, pure C <sub>12</sub> H <sub>22</sub> O <sub>11</sub>	57-50-1
200-405-4	α-tocopheryl acetate C <sub>31</sub> H <sub>52</sub> O <sub>3</sub>	58-95-7
200-416-4	Galactose C <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	59-23-4
200-432-1	DL-methionine C <sub>5</sub> H <sub>11</sub> NO <sub>2</sub> S	59-51-8
200-559-2	Lactose C <sub>12</sub> H <sub>22</sub> O <sub>11</sub>	63-42-3
200-711-8	D-mannitol C <sub>6</sub> H <sub>14</sub> O <sub>6</sub>	69-65-8
201-771-8	L-sorbose C <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	87-79-6
204-664-4	Glycerol stearate, pure C <sub>21</sub> H <sub>42</sub> O <sub>4</sub>	123-94-4
204-696-9	Carbon dioxide CO <sub>2</sub>	124-38-9
205-278-9	Calcium pantothenate, D-form C <sub>9</sub> H <sub>17</sub> NO <sub>5</sub> ·1/2Ca	137-08-6
205-756-7	DL-phenylalanine C <sub>9</sub> H <sub>11</sub> NO <sub>2</sub>	150-30-1
208-407-7	Sodium gluconate C <sub>6</sub> H <sub>12</sub> O <sub>7</sub> ·Na	527-07-1
215-665-4	Sorbitan oleate C <sub>24</sub> H <sub>44</sub> O <sub>6</sub>	1338-43-8
231-098-5	Krypton Kr	7439-90-9
231-110-9	Neon Ne	7440-01-9
231-147-0	Argon Ar	7440-37-1
231-168-5	Helium He	7440-59-7

<b>Einecs no</b>	<b>Name/Group</b>	<b>CAS No</b>
231-172-7	Xenon Xe	7440-63-3
231-783-9	Nitrogen N <sub>2</sub>	7727-37-9
231-791-2	Water, distilled, conductivity or of similar purity H <sub>2</sub> O	7732-18-5
232-307-2	Lecithins  The complex combination of diglycerides of fatty acids linked to the choline ester of phosphoric acid Lesitinler	8002-43-5
232-436-4	Syrups, hydrolyzed starch  A complex combination obtained by the hydrolysis of cornstarch by the action of acids or enzymes. It consists primarily of d-glucose, maltose and maltodextrins	8029-43-4
232-442-7	Tallow, hydrogenated	8030-12-4
232-675-4	Dextrin	9004-53-9
232-679-6	Starch  High-polymeric carbohydrate material usually derived from cereal grains such as corn, wheat and sorghum, and from roots and tubers such as potatoes and tapioca. Includes starch which has been pregelatinised by heating in the presence of water	9005-25-8
232-940-4	Maltodextrin	9050-36-6
238-976-7	Sodium D-gluconate C <sub>6</sub> H <sub>12</sub> O <sub>7</sub> .xNa	14906-97-9
248-027-9	D-glucitol monostearate C <sub>24</sub> H <sub>48</sub> O <sub>7</sub>	26836-47-5
262-988-1	Fatty acids, coco, Me esters	61788-59-8
265-995-8	Cellulose pulp	65996-61-4

<b>Einecs no</b>	<b>Name/Group</b>	<b>CAS No</b>
266-948-4	Glycerides, C <sub>16-18</sub> and C <sub>18</sub> -unsaturated. C <sub>16</sub> -C <sub>18</sub> ve C <sub>18</sub> trialkyl glyceride	67701-30-8
268-616-4	Syrups, corn, dehydrated	68131-37-3
269-658-6	Glycerides, tallow mono-, di- and tri-, hydrogenated	68308-54-3
270-312-1	Glycerides, C <sub>16-18</sub> and C <sub>18</sub> -unsaturated, mono- and di-  This substance is identified by SDA Substance Name: C <sub>16</sub> - C <sub>18</sub> and C <sub>18</sub> unsaturated alkyl and C <sub>16</sub> -C <sub>18</sub> and C <sub>18</sub> unsaturated dialkyl glyceride and SDA Reporting Number: 11-002-00	68424-61-3
288-123-8	Glycerides, C <sub>10-18</sub>	85665-33-4

## ANNEX V

### EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(5)(b)

1. Substances which result from a chemical reaction that occurs incidental to exposure of another substance or article to environmental factors such as air, moisture, microbial organisms or sunlight.
2. Substances which result from a chemical reaction that occurs incidental to storage of another substance, mixture or article.
3. Substances which result from a chemical reaction occurring upon end use of other substances, mixtures or articles and which are not themselves manufactured, imported or placed on the market.
4. Substances which are not themselves manufactured, imported or placed on the market and which result from a chemical reaction that occurs when:
  - (a) a stabiliser, colorant, flavouring agent, antioxidant, filler, solvent, carrier, surfactant, plasticiser, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, desiccant, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutraliser, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended; or
  - (b) a substance solely intended to provide a specific physicochemical characteristic functions as intended.
5. By-products, unless they are imported or placed on the market themselves.
6. Hydrates of a substance or hydrated ions, formed by association of a substance with water, provided that the substance has been registered by the manufacturer or importer using this exemption.
7. The following substances which occur in nature, if they are not chemically modified: Minerals, ores, ore concentrates, raw and processed natural gas, crude oil, coal.
8. Substances which occur in nature other than those listed under paragraph 7, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to By-law on Classification, Labelling and Packaging of Substances and Mixtures or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 49(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 47(1)(f).
9. The following substances obtained from natural sources, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to By-law Classification, Labelling and Packaging of Substances and Mixtures with the exception of those classified as flammable liquid and vapour (H224, H225, H226), skin irritant (H315) or eye irritant (H319) or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were

identified in accordance with Article 49(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 47(1)(e):

Vegetable fats, vegetable oils, vegetable waxes; animal fats, animal oils, animal waxes; fatty acids from C<sub>6</sub> to C<sub>24</sub> and their potassium, sodium, calcium and magnesium salts; glycerol.

10. The following substances if they are not chemically modified:

Liquefied petroleum gas, natural gas condensate, process gases and components thereof, coke, cement clinker, magnesia.

11. The following substances unless they meet the criteria for classification as hazardous according to By-law on Classification, Labelling and Packaging of Substances and Mixtures and provided that they do not contain constituents meeting the criteria as hazardous in accordance with By-law on Classification, Labelling and Packaging of Substances and Mixtures present in concentrations above the lowest of the applicable concentration limits or concentration limits set out in Annex 2 to same By-law, unless conclusive scientific experimental data show that these constituents are not available throughout the lifecycle of the substance and those data have been ascertained to be adequate and reliable:

Glass, ceramic frits.

12. Compost and biogas.

13. Hydrogen and oxygen.

## ANNEX VI

### INFORMATION REQUIREMENTS REFERRED TO IN ARTICLE 10

#### Guidance Note On Fulfilling The Requirements Of Annexes VI To XI

Annexes VI to XI specify the information that shall be submitted for registration and evaluation purposes according to Articles 11, 13, 14, 36, 37 and 41. For the lowest tonnage level, the standard requirements are in Annex VII, and every time a new tonnage level is reached, the requirements of the corresponding Annex have to be added. For each registration the precise information requirements will differ, according to tonnage, use and exposure. The Annexes shall thus be considered as a whole, and in conjunction with the overall requirements of registration, evaluation and the duty of care.

#### STEP 1 – GATHER AND SHARE EXISTING INFORMATION

The registrant should gather all existing available test data on the substance to be registered, this would include a literature search for relevant information on the substance. Wherever practicable, registrations should be submitted jointly, in accordance with Articles 12 or 19. This will enable test data to be shared, thereby avoiding unnecessary testing and reducing costs. The registrant should also collect all other available and relevant information on the substance regardless whether testing for a given endpoint is required or not at the specific tonnage level. This should include information from alternative sources (e.g. from (Q)SARs, read-across from other substances, in vivo and in vitro testing, epidemiological data) which may assist in identifying the presence or absence of hazardous properties of the substance and which can in certain cases replace the results of animal tests.

In addition, information on exposure, use and risk management measures in accordance with Article 10 and this Annex should be collected. Considering all this information together, the registrant will be able to determine the need to generate further information.

#### STEP 2 – CONSIDER INFORMATION NEEDS

The registrant shall identify what information is required for the registration. First, the relevant Annex or Annexes to be followed shall be identified, according to tonnage. These Annexes set out the standard information requirements, but shall be considered in conjunction with Annex XI, which allows variation from the standard approach, where it can be justified. In particular, information on exposure, use and risk management measures shall be considered at this stage in order to determine the information needs for the substance.

#### STEP 3 – IDENTIFY INFORMATION GAPS

The registrant shall then compare the information needs for the substance with the information already available and identify where there are gaps. It is important at this stage to ensure that the available data is relevant and has sufficient quality to fulfil the requirements.

## STEP 4 – GENERATE NEW DATA/PROPOSE TESTING STRATEGY

In some cases it will not be necessary to generate new data. However, where there is an information gap that needs to be filled, new data shall be generated (Annexes VII and VIII), or a testing strategy shall be proposed (Annexes IX and X), depending on the tonnage. New tests on vertebrates shall only be conducted or proposed as a last resort when all other data sources have been exhausted.

In some cases, the rules set out in Annexes VII to XI may require certain tests to be undertaken earlier than or in addition to the standard requirements.

### NOTES

Note 1: If it is not technically possible, or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated, in accordance with the relevant provisions.

Note 2: The registrant may wish to declare that certain information submitted in the registration dossier is commercially sensitive and its disclosure might harm him commercially. If this is the case, he shall list the items and provide a justification.

## **INFORMATION REFERRED TO IN ARTICLE 11(1)(a) (1) TO (5)**

### 1. GENERAL REGISTRANT INFORMATION

#### 1.1. Registrant

1.1.1. Name, address, telephone number, fax number and e-mail address

1.1.2. Contact person

1.1.3. Location of the registrant's production and own use site(s), as appropriate

#### 1.2. Joint submission of data

Articles 12 or 19 foresee that parts of the registration may be submitted by a lead registrant on behalf of other registrants.

In this case, the lead registrant shall identify the other registrants specifying:

- their name, address, telephone number, fax number and e-mail address,
- parts of the present registration which apply to other registrants.

Mention the number(s) given in this Annex or Annexes VII to X, as appropriate.

Any other registrant shall identify the lead registrant submitting on his behalf specifying:

- his name, address, telephone number, fax number and e-mail address,
- parts of the registration which are submitted by the lead registrant.

Mention the number(s) given in this Annex or Annexes VII to X, as appropriate.

### 1.3 Third party appointed under Article 4

1.3.1. Name, address, telephone number, fax number and e-mail address

1.3.2. Contact person

## 2. IDENTIFICATION OF THE SUBSTANCE

For each substance, the information given in this section shall be sufficient to enable each substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items below, the reasons shall be clearly stated.

2.1. Name or other identifier of each substance

2.1.1. Name(s) in the IUPAC nomenclature or other international chemical name(s)

2.1.2. Other names (usual name, trade name, abbreviation)

2.1.3. EINECS or ELINCS number (if available and appropriate)

2.1.4. CAS name and CAS number (if available)

2.1.5. Other identity code (if available)

2.2. Information related to molecular and structural formula of each substance

2.2.1. Molecular and structural formula (including SMILES notation, if available)

2.2.2. Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)

2.2.3. Molecular weight or molecular weight range

2.3. Composition of each substance

2.3.1. Degree of purity ( %)

2.3.2. Nature of impurities, including isomers and by-products

2.3.3. Percentage of (significant) main impurities

2.3.4. Nature and order of magnitude (... ppm, ... %) of any additives (e.g. stabilising agents or inhibitors)

2.3.5. Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)

2.3.6. High-pressure liquid chromatogram, gas chromatogram

2.3.7. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance and, where appropriate, for the identification of impurities and additives. This information shall be sufficient to allow the methods to be reproduced.

### 3. INFORMATION ON MANUFACTURE AND USE(S) OF THE SUBSTANCE(S)

3.1. Overall manufacture, quantities used for production of an article that is subject to registration, and/or imports in tonnes per registrant per year in:

the calendar year of the registration (estimated quantity)

3.2. In the case of a manufacturer or producer of articles: brief description of the technological process used in manufacture or production of articles.

Precise details of the process, particularly those of a commercially sensitive nature, are not required.

3.3. An indication of the tonnage used for his own use(s)

3.4. Form (substance, mixture or article) and/or physical state under which the substance is made available to downstream users. Concentration or concentration range of the substance in mixtures made available to downstream users and quantities of the substance in articles made available to downstream users.

3.5. Brief general description of the identified use(s)

3.6. Information on waste quantities and composition of waste resulting from manufacture of the substance, the use in articles and identified uses

3.7. Uses advised against (see Section 1.2 of the safety data sheet)

Where applicable, an indication of the uses which the registrant advises against and why (i.e. non-statutory recommendations by supplier). This need not be an exhaustive list.

### 4. CLASSIFICATION AND LABELLING

4.1 The hazard classification of the substance(s), resulting from the application of By-law on Classification, Labelling and Packaging of Substances and Mixtures,

In addition, for each entry, the reasons why no classification is given for a hazard class or differentiation of a hazard class should be provided (i.e. if data are lacking, inconclusive, or conclusive but not sufficient for classification),

4.2 The resulting hazard label for the substance(s), resulting from the application of By-law on Classification, Labelling and Packaging of Substances and Mixtures,

4.3 Specific concentration limits, where applicable, resulting from the application of Article 12 of By-law on Classification, Labelling and Packaging of Substances and Mixtures.

## 5. GUIDANCE ON SAFE USE CONCERNING:

This information shall be consistent with that in the Safety Data Sheet, where such a Safety Data Sheet is required according to Article 31.

- 5.1. First-aid measures (Safety Data Sheet heading 4)
- 5.2. Fire-fighting measures (Safety Data Sheet heading 5)
- 5.3. Accidental release measures (Safety Data Sheet heading 6)
- 5.4. Handling and storage (Safety Data Sheet heading 7)
- 5.5. Transport information (Safety Data Sheet heading 14)

Where a Chemical Safety Report is not required, the following additional information is required:

- 5.6. Exposure controls/personal protection (Safety Data Sheet heading 8)
- 5.7. Stability and reactivity (Safety Data Sheet heading 10)
- 5.8. Disposal considerations
  - 5.8.1. Disposal considerations (Safety Data Sheet heading 13)
  - 5.8.2. Information on recycling and methods of disposal for industry
  - 5.8.3. Information on recycling and methods of disposal for the public..8.3. Geri dönüşüm ve halka yönelik bertaraf yöntemleri ile ilgili bilgiler

## 6. INFORMATION ON EXPOSURE FOR SUBSTANCES REGISTERED IN QUANTITIES BETWEEN 1 AND 10 TONNES PER YEAR PER MANUFACTURER OR IMPORTER

### 6.1. Main use category:

#### 6.1.1.

- (a) industrial use; and/or
- (b) professional use; and/or
- (c) consumer use.

### 6.1.2. Specification for industrial and professional use:

- (a) used in closed system; and/or
- (b) use resulting in inclusion into or onto matrix; and/or
- (c) non-dispersive use; and/or
- (ç) dispersive use.

6.2. Significant route(s) of exposure:

6.2.1. Human exposure:

(a) oral; and/or

(b) dermal; and/or

(c) inhalatory.

6.2.2. Environmental exposure:

(a) water; and/or

(b) air; and/or

(c) solid waste; and/or

(ç) soil.

6.3. Pattern of exposure:

(a) accidental/infrequent; and/or

(b) occasional; and/or

(c) continuous/frequent.

## ANNEX VII

### STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF ONE TONNE OR MORE

Column 1 of this Annex establishes the standard information required for substances manufactured or imported in quantities of 1 tonne or more.

Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided. For substances not meeting the criteria in Annex III only the physicochemical requirements as set out in section 7 of this Annex are required.

Column 2 of this Annex lists specific rules according to which the required standard information may be omitted, replaced by other information, provided at a different stage or adapted in another way. If the conditions are met under which column 2 of this Annex allows adaptations, the registrant shall clearly state this fact and the reasons for each adaptation under the appropriate headings in the registration dossier.

In addition to these specific rules, a registrant may adapt the required standard information set out in column 1 of this Annex according to the general rules contained in Annex XI with the exception of Section 3 on substance-tailored exposure waiving. In this case as well, he shall clearly state the reasons for any decision to adapt the standard information under the appropriate headings in the registration dossier referring to the appropriate specific rule(s) in column 2 or in Annex XI.

Before new tests are carried out to determine the properties listed in this Annex, all available in vitro data, in vivo data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. In vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be consulted in addition to this Annex.

When, for certain endpoints, information is not provided for other reasons than those mentioned in column 2 of this Annex or in Annex XI, this fact and the reasons shall also be clearly stated.

<b>7. INFORMATION ON THE PHYSICOCHEMICAL PROPERTIES OF THE SUBSTANCE</b>	
<b>COLUMN 1 STANDARD INFORMATION REQUIRED</b>	<b>COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1</b>
7.1. State of the substance at 20 °C and 101,3 kPa	
7.2. Melting/freezing point	7.2. The study does not need to be conducted below a lower limit of - 20 °C.
7.3. Boiling point	7.3. The study does not need to be conducted: — for gases, or — for solids which either melt above 300 °C or decompose before boiling. In such cases the boiling point under reduced pressure may be estimated or measured, or — for substances which decompose before boiling (e.g. auto- oxidation, rearrangement, degradation, decomposition, etc.).

7.4. Relative density	7.4. The study does not need to be conducted if: — the substance is only stable in solution in a particular solvent and the solution density is similar to that of the solvent. In such cases, an indication of whether the solution density is higher or lower than the solvent density is sufficient, or — the substance is a gas. In this case, an estimation based on calculation shall be made from its molecular weight and the Ideal Gas Laws.
7.5. Vapour pressure	7.5. The study does not need to be conducted if the melting point is above 300 °C. If the melting point is between 200 °C and 300 °C, a limit value based on measurement or a recognised calculation method is sufficient.
7.6. Surface tension	7.6. The study need only be conducted if: — based on structure, surface activity is expected or can be predicted, or — surface activity is a desired property of the material. If the water solubility is below 1 mg/l at 20 °C the test does not need to be conducted.
7.7. Water solubility	7.7. The study does not need to be conducted if: — the substance is hydrolytically unstable at pH 4, 7 and 9 (half-life less than 12 hours), or — the substance is readily oxidisable in water. If the substance appears 'insoluble' in water, a limit test up to the detection limit of the analytical method shall be performed.
7.8. Partition coefficient (n-octanol/water)	7.8. The study does not need to be conducted if the substance is inorganic. If the test cannot be performed (e.g. the substance decomposes, has a high surface activity, reacts violently during the performance of the test or does not dissolve in water or in octanol, or it is not possible to obtain a sufficiently pure substance), a calculated value for log P as well as details of the calculation method shall be provided.
7.9. Flash-point	7.9. The study does not need to be conducted if: — the substance is inorganic, or — the substance only contains volatile organic components with flash-points above 100 °C for aqueous solutions, or — the estimated flash-point is above 200 °C, or — the flash-point can be accurately predicted by interpolation from existing characterised materials.
7.10. Flammability	7.10. The study does not need to be conducted:

	<ul style="list-style-type: none"> <li>— if the substance is a solid which possesses explosive or pyrophoric properties. These properties should always be considered before considering flammability, or</li> <li>— for gases, if the concentration of the flammable gas in a mixture with inert gases is so low that, when mixed with air, the concentration is all time below the lower limit, or</li> <li>— for substances which spontaneously ignite when in contact with air.</li> </ul>
7.11. Explosive properties	<p>7.11. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— there are no chemical groups associated with explosive properties present in the molecule, or</li> <li>— the substance contains chemical groups associated with explosive properties which include oxygen and the calculated oxygen balance is less than -200, or</li> <li>— the organic substance or a homogenous mixture of organic substances contains chemical groups associated with explosive properties, but the exothermic decomposition energy is less than 500 J/g and the onset of exothermic decomposition is below 500 °C, or</li> <li>— for mixtures of inorganic oxidising substances (UN Division 5.1) with organic materials, the concentration of the inorganic oxidising substance is: <ul style="list-style-type: none"> <li>— less than 15 %, by mass, if assigned to UN Packaging Group I (high hazard) or II (medium hazard),</li> <li>— less than 30 %, by mass, if assigned to UN Packaging Group III (low hazard).</li> </ul> </li> </ul> <p>Note: Neither a test for propagation of detonation nor a test for sensitivity to detonative shock is required if the exothermic decomposition energy of organic materials is less than 800 J/g.</p>
7.12. Self-ignition temperature	<p>7.12. The study does not need to be conducted:</p> <ul style="list-style-type: none"> <li>— if the substance is explosive or ignites spontaneously with air at room temperature, or</li> <li>— for liquids non flammable in air, e.g. no flash point up to 200 °C, or</li> <li>— for gases having no flammable range, or</li> <li>— for solids, if the substance has a melting point <math>\leq 160</math> °C, or if preliminary results exclude self-heating of the substance up to 400 °C.</li> </ul>
7.13. Oxidising properties	<p>7.13. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— the substance is explosive, or</li> <li>— the substance is highly flammable, or</li> <li>— the substance is an organic peroxide, or</li> </ul>

	<p>— the substance is incapable of reacting exothermically with combustible materials, for example on the basis of the chemical structure (e.g. organic substances not containing oxygen or halogen atoms and these elements are not chemically bonded to nitrogen or oxygen, or inorganic substances not containing oxygen or halogen atoms).</p> <p>The full test does not need to be conducted for solids if the preliminary test clearly indicates that the test substance has oxidising properties.</p> <p>Note that as there is no test method to determine the oxidising properties of gaseous mixtures, the evaluation of these properties must be realised by an estimation method based on the comparison of the oxidising potential of gases in a mixture with that of the oxidising potential of oxygen in air.</p>
7.14. Granulometry	7.14. The study does not need to be conducted if the substance is marketed or used in a non solid or granular form.
<b>8. TOXICOLOGICAL INFORMATION</b>	
8.1. Skin corrosion/irritation	<p>8.1. The study/ies do(es) not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— the substance is a strong acid (<math>\text{pH} \leq 2,0</math>) or base (<math>\text{pH} \geq 11,5</math>) and the available information indicates that it should be classified as skin corrosion (Category 1), or</li> <li>— the substance is spontaneously flammable in air or in contact with water or moisture at room temperature, or</li> <li>— the substance is classified as acute toxicity by the dermal route (Category 1), or</li> <li>— an acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (2 000 mg/kg body weight).</li> </ul> <p>If results from one of the two studies under point 8.1.1 or 8.1.2 already allow a conclusive decision on the classification of a substance or on the absence of skin irritation potential, the second study need not be conducted.</p>
8.1.1 Skin corrosion, in vitro 8.1.2 Skin irritation, in vitro	
8.2. Serious eye damage/eye irritation	<p>8.2. The study/ies do(es) not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— the substance is classified as skin corrosion, leading to classification as serious eye damage (Category 1), or</li> </ul>

	<ul style="list-style-type: none"> <li>— the substance is classified as skin irritation and the available information indicates that it should be classified as eye irritation (Category 2), or</li> <li>— the substance is a strong acid (<math>\text{pH} \leq 2,0</math>) or base (<math>\text{pH} \geq 11,5</math>) and the available information indicates that it should be classified as serious eye damage (Category 1), or</li> <li>— the substance is spontaneously flammable in air or in contact with water or moisture at room temperature.</li> </ul>
8.2.1 Serious eye damage/eye irritation, in vitro	8.2.1. If results from a first in vitro study do not allow a conclusive decision on the classification of a substance or on the absence of eye irritation potential, (an)other in vitro study(ies) for this endpoint shall be considered.
<p>8.3. Skin sensitisation Information allowing:</p> <ul style="list-style-type: none"> <li>— a conclusion whether the substance is a skin sensitiser and whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A), and</li> <li>— risk assessment, where required.</li> </ul>	<p>The study(ies) under point 8.3.1 and 8.3.2 do not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— the substance is classified as skin corrosion (Category 1), or</li> <li>— the substance is a strong acid (<math>\text{pH} \leq 2,0</math>) or base (<math>\text{pH} \geq 11,5</math>), or</li> <li>— the substance is spontaneously flammable in air or in contact with water or moisture at room temperature.</li> </ul>
<p>8.3.1. Skin sensitisation, in vitro/in chemico</p> <p>Information from in vitro/in chemico test method(s) recognised according to Article 14(3), addressing each of the following key events of skin sensitisation:</p> <ul style="list-style-type: none"> <li>(a) molecular interaction with skin proteins;</li> <li>(b) inflammatory response in keratinocytes;</li> <li>(c) activation of dendritic cells.</li> </ul>	<p>The(se) test(s) do not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— an in vivo study according to point 8.3.2 is available, or</li> <li>— the available in vitro/in chemico test methods are not applicable for the substance or are not adequate for classification and risk assessment according to point 8.3.</li> </ul> <p>If information from test method(s) addressing one or two of the key events in column 1 already allows classification and risk assessment according to point 8.3, studies addressing the other key event(s) need not be conducted.</p>
8.3.2 Skin sensitisation, in vivo	<p>An in vivo study shall be conducted only if in vitro/in chemico test methods described under point 8.3.1 are not applicable, or the results obtained from those studies are not adequate for classification and risk assessment according to point 8.3.</p> <p>The murine local lymph node assay (LLNA) is the first-choice method for in vivo testing. Only in exceptional circumstances should another test be used. Justification for the use of another in vivo test shall be provided.</p>

	In vivo skin sensitisation studies that were carried out or initiated before 11 November 2016, and that meet the requirements set out in Article 14(3) and Article 14(4) shall be considered appropriate to address this standard information requirement.
8.4. Mutagenicity	8.4. Further mutagenicity studies shall be considered in case of a positive result.
8.4.1. In vitro gene mutation study in bacteria	
8.5. Acute toxicity	8.5. The study/ies do(es) not generally need to be conducted if: — the substance is classified as corrosive to the skin.
8.5.1. By oral route	The study need not be conducted if a study on acute toxicity by the inhalation route (8.5.2) is available.
<b>9. ECOTOXICOLOGICAL INFORMATION</b>	
9.1. Aquatic toxicity	
9.1.1. Short-term toxicity testing on invertebrates (preferred species <i>Daphnia</i> ) The registrant may consider long-term toxicity testing instead of short-term.	9.1.1. The study does not need to be conducted if: — there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes, or — a long-term aquatic toxicity study on invertebrates is available, or — adequate information for environmental classification and labelling is available.  The long-term aquatic toxicity study on <i>Daphnia</i> (Annex IX, section 9.1.5) shall be considered if the substance is poorly water soluble.
9.1.2. Growth inhibition study aquatic plants (algae preferred)	9.1.2. The study does not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes.
9.2. Degradation	
9.2.1. Biotic	
9.2.1.1. Ready biodegradability	9.2.1.1. The study does not need to be conducted if the substance is inorganic.

Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided.

## ANNEX VIII

### STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 10 TONNES OR MORE

Column 1 of this Annex establishes the standard information required for all substances manufactured or imported in quantities of 10 tonnes or more in accordance with Article 13(1)(c). Accordingly, the information required in column 1 of this Annex is additional to that required in column 1 of Annex VII. Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided. Column 2 of this Annex lists specific rules according to which the required standard information may be omitted, replaced by other information, provided at a different stage or adapted in another way. If the conditions are met under which column 2 of this Annex allows adaptations, the registrant shall clearly state this fact and the reasons for each adaptation under the appropriate headings in the registration dossier.

In addition to these specific rules, a registrant may adapt the required standard information set out in column 1 of this Annex according to the general rules contained in Annex XI. In this case as well, he shall clearly state the reasons for any decision to adapt the standard information under the appropriate headings in the registration dossier referring to the appropriate specific rule(s) in column 2 or in Annex XI.

Before new tests are carried out to determine the properties listed in this Annex, all available in vitro data, in vivo data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. In vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be consulted in addition to this Annex.

When, for certain endpoints, information is not provided for other reasons than those mentioned in column 2 of this Annex or in Annex XI, this fact and the reasons shall also be clearly stated.

<b>8. TOXICOLOGICAL INFORMATION</b>	
<b>COLUMN 1 STANDARD INFORMATION REQUIRED</b>	<b>COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1</b>
8.1. Skin corrosion/ irritation	8.1. An in vivo study for skin corrosion/irritation shall be considered only if the in vitro studies under points 8.1.1 and 8.1.2 in Annex VII are not applicable, or the results of these studies are not adequate for classification and risk assessment. The study does not need to be conducted if: — the substance is a strong acid ( $\text{pH} \leq 2,0$ ) or base ( $\text{pH} \geq 11,5$ ), or — the substance is spontaneously flammable in air or in contact with water or moisture at room temperature, or

	<p>— the substance is classified as acute toxicity by the dermal route (Category 1), or</p> <p>— an acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (2 000 mg/kg body weight).</p>
8.2. Serious eye damage/eye irritation	<p>8.2. An in vivo study for eye corrosion/irritation shall be considered only if the in vitro study(ies) under point 8.2.1 in Annex VII are not applicable, or the results obtained from these study(ies) are not adequate for classification and risk assessment. The study does not need to be conducted if:</p> <p>— the substance is classified as skin corrosion, or</p> <p>— the substance is a strong acid (<math>\text{pH} \leq 2,0</math>) or base (<math>\text{pH} \geq 11,5</math>), or</p> <p>— the substance is spontaneously flammable in air or in contact with water or moisture at room temperature.</p>
8.4. Mutagenicity	
8.4.2. In vitro cytogenicity study in mammalian cells or in vitro micronucleus study	<p>8.4.2. The study does not usually need to be conducted</p> <p>— if adequate data from an in vivo cytogenicity test are available, or</p> <p>— the substance is known to be carcinogenic category 1A or 1B or germ cell mutagenic category 1A, 1B or 2.</p>
8.4.3. In vitro gene mutation study in mammalian cells, if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2.	<p>8.4.3. The study does not usually need to be conducted if adequate data from a reliable in vivo mammalian gene mutation test are available.</p>
	<p>8.4. Appropriate in vivo mutagenicity studies shall be considered in case of a positive result in any of the genotoxicity studies in Annex VII or VIII.</p>
8.5. Acute toxicity	<p>8.5. The study/ies do(es) not generally need to be conducted if:</p> <p>— the substance is classified as skin corrosion.</p> <p>In addition to the oral route (Annex VII, 8.5.1.), for substances other than gases, the information mentioned under 8.5.2 to 8.5.3 shall be provided for at least one other route. The choice for the second route will depend on the nature of the substance and the likely route of human exposure. If there is only one route of exposure, information for only that route needs to be provided.</p>
8.5.2. By inhalation	<p>8.5.2. Testing by the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size.</p>

<p>8.5.3. By dermal route</p>	<p>8.5.3. Testing by the dermal route is appropriate if:</p> <ul style="list-style-type: none"> <li>(1) inhalation of the substance is unlikely; and</li> <li>(2) skin contact in production and/or use is likely; and</li> <li>(3) the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin.</li> </ul> <p>Testing by the dermal route does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— the substance does not meet the criteria for classification as acute toxicity or STOT SE by the oral route and</li> <li>— no systemic effects have been observed in in vivo studies with dermal exposure (e.g. skin irritation, skin sensitisation) or, in the absence of an in vivo study by the oral route, no systemic effects after dermal exposure are predicted on the basis of non-testing approaches (e.g. read across, QSAR studies).</li> </ul>
<p>8.6. Repeated dose toxicity</p> <p>8.6.1. Short-term repeated dose toxicity study (28 days), one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure.</p>	<p>8.6.1. The short-term toxicity study (28 days) does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— a reliable sub-chronic (90 days) or chronic toxicity study is available, provided that an appropriate species, dosage, solvent and route of administration were used, or</li> <li>— where a substance undergoes immediate disintegration and there are sufficient data on the cleavage products, or</li> <li>— relevant human exposure can be excluded in accordance with Annex XI Section 3.</li> </ul> <p>The appropriate route shall be chosen on the following basis: Testing by the dermal route is appropriate if:</p> <ul style="list-style-type: none"> <li>(1) inhalation of the substance is unlikely; and</li> <li>(2) skin contact in production and/or use is likely; and</li> <li>(3) the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin.</li> </ul> <p>Testing by the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size.</p>

	<p>The sub-chronic toxicity study (90 days) (Annex IX, Section 8.6.2) shall be proposed by the registrant if: the frequency and duration of human exposure indicates that a longer term study is appropriate;</p> <p>and one of the following conditions is met:</p> <ul style="list-style-type: none"> <li>— other available data indicate that the substance may have a dangerous property that cannot be detected in a short- term toxicity study, or</li> <li>— appropriately designed toxicokinetic studies reveal accumulation of the substance or its metabolites in certain tissues or organs which would possibly remain undetected in a short-term toxicity study but which are liable to result in adverse effects after prolonged exposure.</li> </ul> <p>Further studies shall be proposed by the registrant or may be required by the Agency in accordance with Article 40 or 41 in case of:</p> <ul style="list-style-type: none"> <li>— failure to identify a NOAEL in the 28 or the 90 days study, unless the reason for the failure to identify a NOAEL is absence of adverse toxic effects, or</li> <li>— toxicity of particular concern (e.g. serious/severe effects), or</li> <li>— indications of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity), or</li> <li>— the route of exposure used in the initial repeated dose study was inappropriate in relation to the expected route of human exposure and route-to-route extrapolation cannot be made, or</li> <li>— particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity to humans may be expected), or</li> <li>— effects shown in substances with a clear relationship in molecular structure with the substance being studied, were not detected in the 28 or the 90 days study.</li> </ul>
<p>8.7. Reproductive toxicity</p> <p>8.7.1. Screening for reproductive/developmental toxicity, one species (OECD 421 or 422), if there is no evidence from available information on structurally related substances, from (Q)SAR estimates or from in vitro methods that the substance may be a developmental toxicant</p>	<p>8.7.1. This study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented, or</li> <li>— the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented, or</li> <li>— relevant human exposure can be excluded in accordance with Annex XI section 3, or</li> </ul>

	<p>— a pre-natal developmental toxicity study (Annex IX, 8.7.2) or, either an Extended One-Generation Reproductive Toxicity Study (B.56, OECD TG 443) (Annex IX, section 8.7.3) or a two-generation study (B.35, OECD TG 416), is available.</p> <p>If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for developmental toxicity must be considered.</p> <p>If a substance is known to cause developmental toxicity, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.</p> <p>In cases where there are serious concerns about the potential for adverse effects on fertility or development, either an Extended One-Generation Reproductive Toxicity Study (Annex IX, section 8.7.3) or a pre-natal developmental toxicity study (Annex IX, section 8.7.2) may, as appropriate, be proposed by the registrant instead of the screening study.</p>
<p>8.8. Toxicokinetics</p> <p>8.8.1. Assessment of the toxicokinetic behaviour of the substance to the extent that can be derived from the relevant available information</p>	

<b>9. ECOTOXICOLOGICAL INFORMATION</b>	
<b>COLUMN 1 STANDARD INFORMATION REQUIRED</b>	<b>COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1</b>
<p>9.1.3. Short-term toxicity testing on fish: the registrant may consider long-term toxicity testing instead of short-term.</p>	<p>9.1.3. The study does not need to be conducted if: — there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes, or — a long-term aquatic toxicity study on fish is available.</p> <p>Long-term aquatic toxicity testing as described in Annex IX shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further effects on aquatic organisms. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.</p>
<p>9.1.4. Activated sludge respiration inhibition testing</p>	<p>9.1.4. The study does not need to be conducted if: — there is no emission to a sewage treatment plant, or — there are mitigating factors indicating that microbial toxicity is unlikely to occur, for instance the substance is highly insoluble in water, or — the substance is found to be readily biodegradable and the applied test concentrations are in the range of concentrations that can be expected in the influent of a sewage treatment plant.</p> <p>The study may be replaced by a nitrification inhibition test if available data show that the substance is likely to be an inhibitor of microbial growth or function, in particular nitrifying bacteria.</p>
<p>9.2. Degradation</p> <p>9.2.1. Abiotic</p> <p>9.2.1.1. Hydrolysis as a function of pH.</p>	<p>9.2. Further degradation testing shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.</p> <p>9.2.2.1. The study does not need to be conducted if: — the substance is readily biodegradable, or — the substance is highly insoluble in water.</p>

<p>9.3. Fate and behaviour in the environment</p> <p>9.3.1. Adsorption/desorption screening</p>	<p>9.3.1. The study does not need to be conducted if:</p> <ul style="list-style-type: none"><li>— based on the physicochemical properties the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol water partition coefficient), or</li><li>— the substance and its relevant degradation products decompose rapidly.</li></ul>
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## ANNEX IX

### STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 100 TONNES OR MORE

At the level of this Annex, the registrant must submit a proposal and a time schedule for fulfilling the information requirements of this Annex in accordance with Article 13(1)(ç).

Column 1 of this Annex establishes the standard information required for all substances manufactured or imported in quantities of 100 tonnes or more in accordance with Article 13(1)(ç). Accordingly, the information required in column 1 of this Annex is additional to that required in column 1 of Annexes VII and VIII. Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided. Column 2 of this Annex lists specific rules according to which the registrant may propose to omit the required standard information, replace it by other information, provide it at a later stage or adapt it in another way. If the conditions are met under which column 2 of this Annex allows an adaptation to be proposed, the registrant shall clearly state this fact and the reasons for proposing each adaptation under the appropriate headings in the registration dossier.

In addition to these specific rules, a registrant may propose to adapt the required standard information set out in column 1 of this Annex according to the general rules contained in Annex XI. In this case as well, he shall clearly state the reasons for any decision to propose adaptations to the standard information under the appropriate headings in the registration dossier referring to the appropriate specific rule(s) in column 2 or in Annex XI.

Before new tests are carried out to determine the properties listed in this Annex, all available in vitro data, in vivo data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. In vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be consulted in addition to this Annex.

When, for certain endpoints, it is proposed not to provide information for other reasons than those mentioned in column 2 of this Annex or in Annex XI, this fact and the reasons shall also be clearly stated.

<b>7. INFORMATION ON THE PHYSICOCHEMICAL PROPERTIES OF THE SUBSTANCE</b>	
<b>COLUMN 1 STANDARD INFORMATION REQUIRED</b>	<b>COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1</b>
7.15. Stability in organic solvents and identity of relevant degradation products Only required if stability of the substance is considered to be critical.	7.15. The study does not need to be conducted if the substance is inorganic.
7.16. Dissociation constant	7.16. The study does not need to be conducted if: — the substance is hydrolytically unstable (half-life less than 12 hours) or is readily oxidisable in water, or

	— it is scientifically not possible to perform the test for instance if the analytical method is not sensitive enough.
7.17. Viscosity	
<b>8. TOXICOLOGICAL INFORMATION</b>	
<b>COLUMN 1 STANDARD INFORMATION REQUIRED</b>	<b>COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1</b>
	8.4. If there is a positive result in any of the in vitro genotoxicity studies in Annex VII or VIII and there are no results available from an in vivo study already, an appropriate in vivo somatic cell genotoxicity study shall be proposed by the registrant. If there is a positive result from an in vivo somatic cell study available, the potential for germ cell mutagenicity should be considered on the basis of all available data, including toxicokinetic evidence. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered.
8.6. Repeated dose toxicity  8.6.1. Short-term repeated dose toxicity study (28 days), one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure, unless already provided as part of Annex VIII requirements or if tests according to Section 8.6.2 of this Annex is proposed. In this case, Section 3 of Annex XI shall not apply.  8.6.2. Sub-chronic toxicity study (90-day), one species, rodent, male and female, most appropriate route of administration, having regard to the likely route of human exposure.	8.6.2. The sub-chronic toxicity study (90 days) does not need to be conducted if: — a reliable short-term toxicity study (28 days) is available showing severe toxicity effects according to the criteria for classifying the substance as R48, for which the observed NOAEL-28 days, with the application of an appropriate uncertainty factor, allows the extrapolation towards the NOAEL-90 days for the same route of exposure, or — a reliable chronic toxicity study is available, provided that an appropriate species and route of administration were used, or — a substance undergoes immediate disintegration and there are sufficient data on the cleavage products (both for systemic effects and effects at the site of uptake), or — the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day 'limit

	<p>test', particularly if such a pattern is coupled with limited human exposure.</p> <p>The appropriate route shall be chosen on the following basis:  Testing by the dermal route is appropriate if:  (1) skin contact in production and/or use is likely;  and  (2) the physicochemical properties suggest a significant rate of absorption through the skin;  and  (3) one of the following conditions is met:  — toxicity is observed in the acute dermal toxicity test at lower doses than in the oral toxicity test, or  — systemic effects or other evidence of absorption is observed in skin and/or eye irritation studies, or  — in vitro tests indicate significant dermal absorption, or  — significant dermal toxicity or dermal penetration is recognised for structurally-related substances.</p> <p>Testing by the inhalation route is appropriate if:  — exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size.</p> <p>Further studies shall be proposed by the registrant or may be required by the Ministry in accordance with Articles 36 or 37 in case of:  — failure to identify a NOAEL in the 90 days study unless the reason for the failure to identify a NOAEL is absence of adverse toxic effects, or  — toxicity of particular concern (e.g. serious/severe effects), or  — indications of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity), or  — particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity to humans may be expected).</p>
8.7. Reproductive toxicity	8.7. The studies do not need to be conducted if: — the substance is known to be a genotoxic

<p>8.7.2. Pre-natal developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure (B.31 of the By-law on Determination of Physico-Chemical, Toxicological and Ecotoxicological Properties of Substances and Mixtures or OECD 414).</p> <p>8.7.3. Extended One- Generation Reproductive Toxicity Study (B.56 of the By-law on Determination of Physico-Chemical, Toxicological and Ecotoxicological Properties of Substances and Mixtures or OECD 443), basic test design (cohorts 1A and 1B without extension to include a F2 generation), one species, most appropriate route of administration, having regard to the likely route of human exposure, if the available repeated dose toxicity studies (e.g. 28-day or 90-day studies, OECD 421 or 422</p>	<p>carcinogen and appropriate risk management measures are implemented, or  — the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented, or  — the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure.</p> <p>If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for developmental toxicity must be considered.</p> <p>If a substance is known to cause developmental toxicity, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.</p> <p>8.7.2. The study shall be initially performed on one species. A decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant available data.</p> <p>8.7.3. An Extended One-Generation Reproductive Toxicity Study with the extension of cohort 1B to include the F2 generation shall be proposed by the registrant or may be required by the Ministry in accordance with Article 36 or 37, if:</p> <p>(a) the substance has uses leading to significant exposure of consumers or professionals, taking into account, inter alia, consumer exposure from articles, and</p> <p>(b) any of the following conditions are met:</p>
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screening studies) indicate adverse effects on reproductive organs or tissues or reveal other concerns in relation with reproductive toxicity.

- the substance displays genotoxic effects in somatic cell mutagenicity tests in vivo which could lead to classifying it as Mutagen Category 2, or
- there are indications that the internal dose for the substance and/or any of its metabolites will reach a steady state in the test animals only after an extended exposure, or
- there are indications of one or more relevant modes of action related to endocrine disruption from available in vivo studies or non-animal approaches.

An Extended One-Generation Reproductive Toxicity Study including cohorts 2A/2B (developmental neurotoxicity) and/or cohort 3 (developmental immunotoxicity) shall be proposed by the registrant or may be required by the Ministry in accordance with Article 36 or 37, in case of particular concerns on (developmental) neurotoxicity or (developmental) immunotoxicity justified by any of the following:

- existing information on the substance itself derived from relevant available in vivo or non-animal approaches (e.g. abnormalities of the CNS, evidence of adverse effects on the nervous or immune system in studies on adult animals or animals exposed prenatally), or
- specific mechanisms/modes of action of the substance with an association to (developmental) neurotoxicity and/or (developmental) immunotoxicity (e.g. cholinesterase inhibition or relevant changes in thyroidal hormone levels associated to adverse effects), or
- existing information on effects caused by substances structurally analogous to the substance being studied, suggesting such effects or mechanisms/modes of action.

Other studies on developmental neurotoxicity and/or developmental immunotoxicity instead of cohorts 2A/ 2B (developmental neurotoxicity) and/or cohort 3 (developmental immunotoxicity) of the Extended One- Generation Reproductive Toxicity Study may be proposed by the registrant in order to clarify the concern on developmental toxicity.

Two-generation reproductive toxicity studies (B.35, OECD TG 416) that were initiated before 13 March 2015 shall be considered appropriate to address this standard information requirement. Çalışma tek tür üzerinde gerçekleştirilir.

The study shall be performed on one species. The need to perform a study at this tonnage level or the next on a second strain or a second species may be considered and a decision should be based on the outcome of the first test and all other relevant available data.

<b>9. ECOTOXICOLOGICAL INFORMATION</b>	
<p>9.1. Aquatic toxicity</p> <p>9.1.5. Long-term toxicity testing on invertebrates (preferred species <i>Daphnia</i>), (unless already provided as part of Annex VII requirements)</p> <p>9.1.6. Long-term toxicity testing on fish, (unless already provided as part of Annex VIII requirements) The information shall be provided for one of the Sections 9.1.6.1, 9.1.6.2 or 9.1.6.3.</p> <p>9.1.6.1. Fish early-life stage (FELS) toxicity test</p> <p>9.1.6.2. Fish short-term toxicity test on embryo and sac- fry stages</p> <p>9.1.6.3. Fish, juvenile growth test</p>	<p>9.1. Long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The choice of the appropriate test(s) depends on the results of the chemical safety assessment.</p>
<p>9.2. Degradation</p> <p>9.2.1. Biotic</p> <p>9.2.1.2. Simulation testing on ultimate degradation in surface water</p> <p>9.2.1.3. Soil simulation testing (for substances with a high potential for adsorption to soil)</p> <p>9.2.1.4. Sediment simulation testing (for substances with a high potential for adsorption to sediment)</p>	<p>9.2. Further biotic degradation testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) depends on the results of the chemical safety assessment and may include simulation testing in appropriate media (e.g. water, sediment or soil).</p> <p>9.2.1.2. The study need not be conducted if: — the substances is highly insoluble in water, or — the substance is readily biodegradable.</p> <p>9.2.1.3. The study need not be conducted: — if the substance is readily biodegradable, or — if direct and indirect exposure of soil is unlikely.</p> <p>9.2.1.4. The study need not be conducted: — if the substance is readily biodegradable, or — if direct and indirect exposure of sediment is unlikely.</p>

9.2.3. Identification of degradation products	9.2.3. Unless the substance is readily biodegradable
<p>9.3. Fate and behaviour in the environment</p> <p>9.3.2. Bioaccumulation in aquatic species, preferably fish</p> <p>9.3.3. Further information on adsorption/desorption depending on the results of the study required in Annex VIII</p>	<p>9.3.2. The study need not be conducted if:</p> <ul style="list-style-type: none"> <li>— the substance has a low potential for bioaccumulation (for instance a <math>\log K_{ow} \leq 3</math>) and/or a low potential to cross biological membranes, or</li> <li>— direct and indirect exposure of the aquatic compartment is unlikely.</li> </ul> <p>9.3.3. The study need not be conducted if:</p> <ul style="list-style-type: none"> <li>— based on the physicochemical properties the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol water partition coefficient), or</li> <li>— the substance and its degradation products decompose rapidly.</li> </ul>
<p>9.4. Effects on terrestrial organisms</p> <p>9.4.1. Short-term toxicity to invertebrates</p> <p>9.4.2. Effects on soil microorganisms</p> <p>9.4.3. Short-term toxicity to plants</p>	<p>9.4. These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely.</p> <p>In the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. The choice of the appropriate tests depends on the outcome of the chemical safety assessment.</p> <p>In particular for substances that have a high potential to adsorb to soil or that are very persistent, the registrant shall consider long-term toxicity testing instead of short-term.</p>

## 10. METHODS OF DETECTION AND ANALYSIS

Description of the analytical methods shall be provided on request, for the relevant compartments for which studies were performed using the analytical method concerned. If the analytical methods are not available this shall be justified.

## ANNEX X

### STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 1 000 TONNES OR MORE

At the level of this Annex, the registrant must submit a proposal and a time schedule for fulfilling the information requirements of this Annex in accordance with Article 13(1)(d).

Column 1 of this Annex establishes the standard information required for all substances manufactured or imported in quantities of 1 000 tonnes or more in accordance with Article 13(1)(d). Accordingly, the information required in column 1 of this Annex is additional to that required in column 1 of Annexes VII, VIII and IX. Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided. Column 2 of this Annex lists specific rules according to which the registrant may propose to omit the required standard information, replace it by other information, provide it at a later stage or adapt it in another way. If the conditions are met under which column 2 of this Annex allows an adaptation to be proposed, the registrant shall clearly state this fact and the reasons for proposing each adaptation under the appropriate headings in the registration dossier.

In addition to these specific rules, a registrant may propose to adapt the required standard information set out in column 1 of this Annex according to the general rules contained in Annex XI. In this case as well, he shall clearly state the reasons for any decision to propose adaptations to the standard information under the appropriate headings in the registration dossier referring to the appropriate specific rule(s) in column 2 or in Annex XI.

Before new tests are carried out to determine the properties listed in this Annex, all available in vitro data, in vivo data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. In vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be consulted in addition to this Annex.

When, for certain endpoints, it is proposed not to provide information for other reasons than those mentioned in column 2 of this Annex or in Annex XI, this fact and the reasons shall also be clearly stated.

<b>8. TOXICOLOGICAL INFORMATION</b>	
<b>COLUMN 1 STANDARD INFORMATION REQUIRED</b>	<b>COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1</b>
	<p>8.4. If there is a positive result in any of the in vitro genotoxicity studies in Annexes VII or VIII, a second in vivo somatic cell test may be necessary, depending on the quality and relevance of all the available data.</p> <p>If there is a positive result from an in vivo somatic cell study available, the potential for germ cell mutagenicity should be considered</p>

	<p>on the basis of all available data, including toxicokinetic evidence. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered.</p>
	<p>8.6.3. A long-term repeated toxicity study (<math>\geq</math> 12 months) may be proposed by the registrant or required by the Ministry in accordance with Articles 36 or 37 if the frequency and duration of human exposure indicates that a longer term study is appropriate and one of the following conditions is met:</p> <ul style="list-style-type: none"> <li>— serious or severe toxicity effects of particular concern were observed in the 28-day or 90-day study for which the available evidence is inadequate for toxicological evaluation or risk characterisation, or</li> <li>— effects shown in substances with a clear relationship in molecular structure with the substance being studied were not detected in the 28-day or 90-day study, or</li> <li>— the substance may have a dangerous property that cannot be detected in a 90-day study.</li> </ul>
<p>8.7. Reproductive toxicity</p>	<p>8.6.4. Further studies shall be proposed by the registrant or may be required by the Ministry in accordance with Articles 36 or 37 in case of:</p> <ul style="list-style-type: none"> <li>— toxicity of particular concern (e.g. serious/severe effects), or</li> <li>— indications of an effect for which the available evidence is inadequate for toxicological evaluation and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity), or</li> <li>— particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity is observed).</li> </ul> <p>8.7. The studies need not be conducted if:</p> <ul style="list-style-type: none"> <li>— the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented, or</li> </ul>

<p>8.7.2. Developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure (OECD 414).</p> <p>8.7.3. Extended One- Generation Reproductive Toxicity Study (B.56 of By-law on Determination of Physico-Chemical, Toxicological and Ecotoxicological Properties of Substances and Mixtures or OECD 443), basic test design (cohorts 1A and 1B without extension to include a F2 generation), one species, most appropriate route of</p>	<p>— the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented, or</p> <p>— the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure.</p> <p>M3 If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for developmental toxicity must be considered.</p> <p>If a substance is known to cause developmental toxicity, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.</p> <p>8.7.3. An Extended One-Generation Reproductive Toxicity Study with the extension of cohort 1B to include the F2 generation shall be proposed by the registrant or may be required by the Ministry in accordance with Article 36 or 37, if:</p> <p>(a) the substance has uses leading to significant exposure of consumers or professionals, taking</p>
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<p>administration, having regard to the likely route of human exposure, unless already provided as part of Annex IX requirements.</p>	<p>into account, inter alia, consumer exposure from articles, and</p> <p>(b) any of the following conditions are met:</p> <ul style="list-style-type: none"> <li>— the substance displays genotoxic effects in somatic cell mutagenicity tests in vivo which could lead to classifying it as Mutagen Category 2, or</li> <li>— there are indications that the internal dose for the substance and/or any of its metabolites will reach a steady state in the test animals only after an extended exposure, or</li> <li>— there are indications of one or more relevant modes of action related to endocrine disruption from available in vivo studies or non-animal approaches.</li> </ul> <p>An Extended One-Generation Reproductive Toxicity Study including cohorts 2A/2B (developmental neurotoxicity) and/ or cohort 3 (developmental immunotoxicity) shall be proposed by the registrant or may be required by the Ministry in accordance with Article 36 or 37, in case of particular concerns on (developmental) neurotoxicity or (developmental) immunotoxicity justified by any of the following:</p> <ul style="list-style-type: none"> <li>— existing information on the substance itself derived from relevant available in vivo or non-animal approaches (e.g. abnormalities of the CNS, evidence of adverse effects on the nervous or immune system in studies on adult animals or animals exposed prenatally), or</li> <li>— specific mechanisms/modes of action of the substance with an association to (developmental) neurotoxicity and/or (developmental) immunotoxicity (e.g. cholinesterase inhibition or relevant changes in thyroidal hormone levels associated to adverse effects), or</li> <li>— existing information on effects caused by substances structurally analogous to the substance being studied, suggesting such effects or mechanisms/modes of action.</li> </ul> <p>Other studies on developmental neurotoxicity and/or developmental immunotoxicity instead of cohorts 2A/2B (developmental</p>
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	<p>neurotoxicity) and/or cohort 3 (developmental immunotoxicity) of the Extended One-Generation Reproductive Toxicity Study may be proposed by the registrant in order to clarify the concern on developmental toxicity.</p> <p>Two-generation reproductive toxicity studies (B.35, OECD TG 416) that were initiated before 13 March 2015 shall be considered appropriate to address this standard information requirement.</p>
8.9.1. Carcinogenicity study	<p>8.9.1. A carcinogenicity study may be proposed by the registrant or may be required by the Ministry in accordance with Articles 36 or 37 if:</p> <ul style="list-style-type: none"> <li>— the substance has a widespread dispersive use or there is evidence of frequent or long-term human exposure, and</li> <li>— the substance is classified as germ cell mutagen category 2 or there is evidence from the repeated dose study(ies) that the substance is able to induce hyperplasia and/or pre-neoplastic lesions.</li> </ul> <p>If the substance is classified as germ cell mutagen category 1A or 1B, the default presumption would be that a genotoxic mechanism for carcinogenicity is likely. In these cases, a carcinogenicity test will normally not be required.</p>
<b>9. ECOTOXICOLOGICAL INFORMATION</b>	
9.2. Degradation	9.2. Further biotic degradation testing shall be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) depends on the results of the chemical safety assessment and may include simulation testing in appropriate media (e.g. water, sediment or soil).
9.2.1. Biotic	
9.3. Fate and behaviour in the environment	9.3.4. Further testing shall be proposed by the registrant or may be required by the Ministry

<p>9.3.4. Further information on the environmental fate and behaviour of the substance and/or degradation products</p> <p>9.4. Effects on terrestrial organisms</p> <p>9.4.4. Long-term toxicity testing on invertebrates, unless already provided as part of Annex IX requirements.</p> <p>9.4.6. Long-term toxicity testing on plants, unless already provided as part of Annex IX requirements.</p>	<p>in accordance with Articles 36 or 37 if the chemical safety assessment according to Annex I indicates the need to investigate further the fate and behaviour of the substance. The choice of the appropriate test(s) depends on the results of the chemical safety assessment.</p> <p>9.4. Long-term toxicity testing shall be proposed by the registrant if the results of the chemical safety assessment according to Annex I indicates the need to investigate further the effects of the substance and/or degradation products on terrestrial organisms. The choice of the appropriate test(s) depends on the outcome of the chemical safety assessment. These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely.</p>
<p>9.5.1. Long-term toxicity to sediment organisms</p>	<p>9.5.1 Long-term toxicity testing shall be proposed by the registrant if the results of the chemical safety assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on sediment organisms. The choice of the appropriate test(s) depends on the results of the chemical safety assessment.</p>
<p>9.6.1. Long-term or reproductive toxicity to birds</p>	<p>9.6.1. Any need for testing should be carefully considered taking into account the large mammalian dataset that is usually available at this tonnage level.</p>

## 10. METHODS OF DETECTION AND ANALYSIS

Description of the analytical methods shall be provided on request, for the relevant compartments for which studies were performed using the analytical method concerned. If the analytical methods are not available this shall be justified.

**ANNEX XI**  
**GENERAL RULES FOR ADAPTATION OF THE STANDARD TESTING REGIME**  
**SET OUT IN ANNEXES VII TO X**

Annexes VII to X set out the information requirements for all substances manufactured or imported in quantities of:

- one tonne or more in accordance with Article 13(1)(a),
- 10 tonnes or more in accordance with Article 13(1)(c),
- 100 tonnes or more in accordance with Article 13(1)(ç), and
- 1 000 tonnes or more in accordance with Article 13(1)(d).

In addition to the specific rules set out in column 2 of Annexes VII to X, a registrant may adapt the standard testing regime in accordance with the general rules set out in Section 1 of this Annex.

## **1. TESTING DOES NOT APPEAR SCIENTIFICALLY NECESSARY**

### **1.1. Use of existing data**

*1.1.1. Data on physical-chemical properties from experiments not carried out according to By-law on Principles of Good Laboratory Practices, Harmonisation of Test Units, Auditing of Good Laboratory Practices published in the Official Gazette dated 09/03/2010 and numbered 27516 or the test methods referred to in Article 14(3)*

Data shall be considered to be equivalent to data generated by the corresponding test methods referred to in Article 14(3) if the following conditions are met:

- (1) adequacy for the purpose of classification and labelling and/or risk assessment;
- (2) sufficient documentation is provided to assess the adequacy of the study; and
- (3) the data are valid for the endpoint being investigated and the study is performed using an acceptable level of quality assurance.

*1.1.2. Data on human health and environmental properties from experiments not carried out according to to By-law on Principles of Good Laboratory Practices, Harmonisation of Test Units, Auditing of Good Laboratory Practices or the test methods referred to in Article 14(3)*

Data shall be considered to be equivalent to data generated by the corresponding test methods referred to in Article 14(3) if the following conditions are met:

- (1) adequacy for the purpose of classification and labelling and/or risk assessment;
- (2) adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in By-law on Principles of Good Laboratory Practices, Harmonisation of Test Units, Auditing of Good Laboratory Practices or the test methods referred to in Article 14(3);
- (3) exposure duration comparable to or longer than the corresponding test methods referred to in By-law on Principles of Good Laboratory Practices, Harmonisation of Test Units, Auditing of Good Laboratory Practices or the test methods referred to in Article 14(3) if exposure duration is a relevant parameter; and
- (4) adequate and reliable documentation of the study is provided.

### 1.1.3. *Historical human data*

Historical human data, such as epidemiological studies on exposed populations, accidental or occupational exposure data and clinical studies, shall be considered.

The strength of the data for a specific human health effect depends, among other things, on the type of analysis and on the parameters covered and on the magnitude and specificity of the response and consequently the predictability of the effect. Criteria for assessing the adequacy of the data include:

- (1) the proper selection and characterisation of the exposed and control groups;
- (2) adequate characterisation of exposure;
- (3) sufficient length of follow-up for disease occurrence;
- (4) valid method for observing an effect;
- (5) proper consideration of bias and confounding factors; and
- (6) a reasonable statistical reliability to justify the conclusion.

In all cases adequate and reliable documentation shall be provided.

## **1.2. Weight of evidence**

There may be sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property, while the information from each single source alone is regarded insufficient to support this notion.

There may be sufficient weight of evidence from the use of newly developed test methods, not yet included in the test methods referred to in By-law on Principles of Good Laboratory Practices, Harmonisation of Test Units, Auditing of Good Laboratory Practices or in Article 14(3) or from an international recognised test method as being equivalent, leading to the conclusion that a substance has or has not a particular dangerous property.

Where sufficient weight of evidence for the presence or absence of a particular dangerous property is available:

- further testing on vertebrate animals for that property shall be omitted,
- further testing not involving vertebrate animals may be omitted.

In all cases adequate and reliable documentation shall be provided.

## **1.3. Qualitative or Quantitative structure-activity relationship ((Q)SAR)**

Results obtained from valid qualitative or quantitative structure-activity relationship models ((Q)SARs) may indicate the presence or absence of a certain dangerous property. Results of (Q)SARs may be used instead of testing when the following conditions are met:

- results are derived from a (Q)SAR model whose scientific validity has been established,
- the substance falls within the applicability domain of the (Q)SAR model,
- results are adequate for the purpose of classification and labelling and/or risk assessment, and
- adequate and reliable documentation of the applied method is provided.

#### **1.4. *In vitro* methods**

Results obtained from suitable *in vitro* methods may indicate the presence of a certain dangerous property or may be important in relation to a mechanistic understanding, which may be important for the assessment. In this context, 'suitable' means sufficiently well developed according to internationally agreed test development criteria (e.g. the European Centre for the Validation of Alternative Methods (ECVAM)) criteria for the entry of a test into the prevalidation process). Depending on the potential risk, information requiring testing beyond the information foreseen in Annexes VII or VIII needs approval of the Ministry. If the results obtained from the use of such *in vitro* methods do not indicate a certain dangerous property, the relevant test shall nevertheless be carried out at the appropriate tonnage level to confirm the negative result, unless testing is not required in accordance with Annexes VII to X or the other rules in this Annex.

Such confirmation may be waived, if the following conditions are met:

- (1) results are derived from an *in vitro* method whose scientific validity has been established by a validation study, according to internationally agreed validation principles;
- (2) results are adequate for the purpose of classification and labelling and/or risk assessment; and
- (3) adequate and reliable documentation of the applied method is provided.

#### **1.5. Grouping of substances and read-across approach**

Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or 'category' of substances. Application of the group concept requires that physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read- across approach). This avoids the need to test every substance for every endpoint.

The similarities may be based on:

- (1) a common functional group;
- (2) the common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals; or
- (3) a constant pattern in the changing of the potency of the properties across the category.

If the group concept is applied, substances shall be classified and labelled on this basis.

In all cases results should:

- be adequate for the purpose of classification and labelling and/or risk assessment,
- have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 14(3),
- cover an exposure duration comparable to or longer than the corresponding test method referred to in Article 14(3) if exposure duration is a relevant parameter, and
- adequate and reliable documentation of the applied method shall be provided.

## **2. TESTING IS TECHNICALLY NOT POSSIBLE**

Testing for a specific endpoint may be omitted, if it is technically not possible to conduct the study as a consequence of the properties of the substance: e.g. very volatile, highly reactive or unstable substances cannot be used, mixing of the substance with water may cause danger of fire or explosion or the radio-labelling of the substance required in certain studies may not be possible. The guidance given in the test methods referred to in Article 14(3), more specifically on the technical limitations of a specific method, shall always be respected.

### **3. SUBSTANCE-TAILORED EXPOSURE-DRIVEN TESTING**

3.1. Testing in accordance with Sections 8.6 and 8.7 of Annex VIII and in accordance with Annex IX and Annex X may be omitted, based on the exposure scenario(s) developed in the Chemical Safety Report.

3.2. In all cases, adequate justification and documentation shall be provided. The justification shall be based on a thorough and rigorous exposure assessment in accordance with section 5 of Annex I and shall meet any one of the following criteria:

(a) the manufacturer or importer demonstrates and documents that all of the following conditions are fulfilled:

(i) the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5;

(ii) a DNEL or a PNEC can be derived from results of available test data for the substance concerned taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes;

(iii) the comparison of the derived DNEL or PNEC with the results of the exposure assessment shows that exposures are always well below the derived DNEL or PNEC;

(b) where the substance is not incorporated in an article the manufacturer or importer demonstrates and documents for all relevant scenarios that throughout the life cycle strictly controlled conditions as set out in Article 18(4)(a) to (e) apply;

(c) where the substance is incorporated in an article in which it is permanently embedded in a matrix or otherwise rigorously contained by technical means, it is demonstrated and documented that all of the following conditions are fulfilled:

(i) the substance is not released during its life cycle;

(ii) the likelihood that workers or the general public or the environment are exposed to the substance under normal or reasonably foreseeable conditions of use is negligible; and

(iii) the substance is handled according to the conditions set out in Article 18(4)(a) to (e) during all manufacturing and production stages including the waste management of the substance during these stages.

3.3. The specific conditions of use must be communicated through the supply chain in accordance with Article 27 or 28, as the case may be.

## ANNEX XII

### GENERAL PROVISIONS FOR DOWNSTREAM USERS TO ASSESS SUBSTANCES AND PREPARE CHEMICAL SAFETY REPORTS

#### INTRODUCTION

The purpose of this Annex is to set out how downstream users are to assess and document that the risks arising from the substance(s) they use are adequately controlled during their use for a use not covered by the Safety Data Sheet supplied to them and that other users further down the supply chain can adequately control the risks. The assessment shall cover the life-cycle of the substance, from its receipt by the downstream user, for his own uses and for his identified uses further down the supply chain. The assessment shall consider the use of the substance on its own, in a mixture or in an article.

In carrying out the chemical safety assessment and producing the Chemical Safety Report, the downstream user shall take account of information received from the supplier of the chemical in accordance with Article 27 and 28 of this Regulation. Where available and appropriate, an assessment carried out (e.g. risk assessments) shall be taken into account in the chemical safety assessment and be reflected in the Chemical Safety Report. Deviations from such assessments shall be justified. Assessments carried out under other international and national programmes may also be taken into account.

The process which the downstream user goes through in carrying out the chemical safety assessment and in producing his Chemical Safety Report, involves three steps:

#### STEP 1: DEVELOPMENT OF EXPOSURE SCENARIO(S)

The downstream user shall develop exposure scenarios for uses not covered in a Safety Data Sheet supplied to him in accordance with Section 5 of Annex I.

#### STEP 2: IF NECESSARY, A REFINEMENT OF THE HAZARD ASSESSMENT BY THE SUPPLIER

If the downstream user considers the hazard and PBT assessments reported in the Safety Data Sheet supplied to him to be appropriate, then no further hazard assessment or PBT and vPvB assessment is necessary. In this case he shall use the relevant information reported by the supplier for the risk characterisation. This shall be stated in the Chemical Safety Report.

If the downstream user considers the assessments reported in the Safety Data Sheet supplied to him to be inappropriate, then he shall carry out the relevant assessments in accordance with Sections 1 to 4 of Annex I as appropriate to him.

In those cases where the downstream user considers that information in addition to that provided by the supplier is necessary for producing his Chemical Safety Report the downstream user shall gather this information. Where this information can only be obtained by testing on vertebrate animals, he shall submit a proposal for a testing strategy to the Ministry in accordance with Article 34. He shall explain why he considers that additional information is necessary. While waiting for results of further testing, he shall record in his chemical safety report the risk management measures intended to manage the risks being explored that he has put in place.

On completion of any additional testing, the downstream user shall revise the Chemical Safety Report, and his Safety Data Sheet if he is required to prepare one, as appropriate.

### STEP 3: RISK CHARACTERISATION

A risk characterisation shall be carried out for each new exposure scenario as prescribed in Section 6 of Annex I. The risk characterisation shall be presented under the relevant heading of the Chemical Safety Report and summarised in the Safety Data Sheet under the relevant heading(s).

When generating an exposure scenario it will be necessary to make initial assumptions about the operating conditions and risk managements measures. If the initial assumptions lead to a risk characterisation indicating inadequate protection of human health and the environment, then it shall be necessary to carry out an iterative process with amendment of one or a number of factors until adequate control can be demonstrated. This may require the generation of additional hazard or exposure information or appropriate alteration of the process, operating conditions or risk management measures. Therefore, iterations may be made between on the one hand developing and revising an (initial) exposure scenario, which includes developing and implementing risk management measures, and on the other hand generating further information to produce the definitive exposure scenario. The purpose of generating further information is to establish a more precise risk characterisation, based on a refined hazard assessment and/or exposure assessment.

The downstream user shall produce a Chemical Safety Report detailing his chemical safety assessment using Part B, Sections 9 and 10, of the format set out in Section 7 of Annex I and the other sections of this format, if appropriate.

Part A of the Chemical Safety Report shall include a declaration that the risk management measures outlined in the relevant exposure scenarios are implemented by the downstream user for his own uses and that the risk management measures outlined in the exposure scenarios for the identified uses are communicated down the supply chain.

## ANNEX XIII

### **CRITERIA FOR THE IDENTIFICATION OF PERSISTENT, BIOACCUMULATIVE AND TOXIC SUBSTANCES, AND VERY PERSISTENT AND VERY BIOACCUMULATIVE SUBSTANCES**

This Annex lays down the criteria for the identification of persistent, bioaccumulative and toxic substances (PBT substances), and very persistent and very bioaccumulative substances (vPvB substances) as well as the information that must be considered for the purpose of assessing the P, B, and T properties of a substance.

For the identification of PBT substances and vPvB substances a weight-of-evidence determination using expert judgement shall be applied, by comparing all relevant and available information listed in Section 3.2 with the criteria set out in Section 1. This shall be applied in particular where the criteria set out in Section 1 cannot be applied directly to the available information.

The approach to classification of mixtures to ensure that available information can be applied as much as possible to protect human health and the environment may involve the application of expert judgment in some areas. The expert judgement may also be necessary in interpretation of the data for classification of the hazardous substances, especially where the determination of the weight of evidence is necessary.

A weight-of-evidence determination means that all available information bearing on the identification of a PBT or a vPvB substance is considered together, such as the results of monitoring and modelling, suitable in vitro tests, relevant animal data, information from the application of the category approach (grouping, read-across), (Q)SAR results, human experience such as occupational data and data from accident databases, epidemiological and clinical studies and well documented case reports and observations. The quality and consistency of the data shall be given appropriate weight. The available results regardless of their individual conclusions shall be assembled together in a single weight-of-evidence determination.

The information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions.

The identification shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products.

This Annex shall apply to all organic substances, including organo-metals.

#### **1. CRITERIA FOR THE IDENTIFICATION OF PBT AND vPvB SUBSTANCES**

##### **1.1. PBT Substances**

A substance that fulfils the persistence, bioaccumulation and toxicity criteria of Sections 1.1.1, 1.1.2 and 1.1.3 shall be considered to be a PBT substance.

###### **1.1.1. Persistence**

A substance fulfils the persistence criterion (P) in any of the following situations:

- (a) the degradation half-life in marine water is higher than 60 days;
- (b) the degradation half-life in fresh or estuarine water is higher than 40 days;
- (c) the degradation half-life in marine sediment is higher than 180 days;
- (ç) the degradation half-life in fresh or estuarine water sediment is higher than 120 days;
- (d) the degradation half-life in soil is higher than 120 days.

#### 1.1.2. Bioaccumulation

A substance fulfils the bioaccumulation criterion (B) when the bioconcentration factor in aquatic species is higher than 2000.

#### 1.1.3. Toxicity

A substance fulfils the toxicity criterion (T) in any of the following situations:

- (a) the long-term no-observed effect concentration (NOEC) or EC10 for marine or freshwater organisms is less than 0,01 mg/l;
- (b) the substance meets the criteria for classification as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B, or 2) according to By-law on Classification, Labelling and Packaging of Substances and Mixtures;
- (c) there is other evidence of chronic toxicity, as identified by the substance meeting the criteria for classification: specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) according to By-law on Classification, Labelling and Packaging of Substances and Mixtures.

### 1.2. vPvB Substances

A substance that fulfils the persistence and bioaccumulation criteria of Sections 1.2.1 and 1.2.2 shall be considered to be a vPvB substance.

#### 1.2.1. Persistence

A substance fulfils the 'very persistent' criterion (vP) in any of the following situations:

- (a) the degradation half-life in marine, fresh or estuarine water is higher than 60 days;
- (b) the degradation half-life in marine, fresh or estuarine water sediment is higher than 180 days;
- (c) the degradation half-life in soil is higher than 180 days.

#### 1.2.2. Bioaccumulation

A substance fulfils the 'very bioaccumulative' criterion (vB) when the bioconcentration factor in aquatic species is higher than 5 000.

## **2. SCREENING AND ASSESSMENT OF P, vP, B, vB and T PROPERTIES**

### **2.1. Registration**

For the identification of PBT and vPvB substances in the registration dossier, the registrant shall consider the information as described in Annex I and in Section 3 of this Annex.

If the technical dossier contains for one or more endpoints only information as required in Annexes VII and VIII, the registrant shall consider information relevant for screening for P, B, or T properties in accordance with Section 3.1 of this Annex. If the result from the screening tests or other information indicate that the substance may have PBT or vPvB properties, the registrant shall generate relevant additional information as set out in Section 3.2 of this Annex. In case the generation of relevant additional information would require information listed in Annexes IX or X, the registrant shall submit a testing proposal. Where the process and use conditions of the substance meet the conditions as specified in Section 3.2(b) or (c) of Annex XI the additional information may be omitted, and subsequently the substance is considered as if it is a PBT or vPvB in the registration dossier. No additional information needs to be generated for the assessment of PBT/vPvB properties if there is no indication of P or B properties following the result from the screening test or other information.

### **2.2. Authorisation**

For dossiers for the purposes of identifying substances referred to in Article 47(c) and Article 47(d), relevant information from the registration dossiers and other available information as described in Section 3 shall be considered.

## **3. INFORMATION RELEVANT FOR THE SCREENING AND ASSESSMENT OF P, vP, B, vB and T PROPERTIES**

### **3.1. Screening Information**

The following information shall be considered for screening for P, vP, B, vB and T properties in the cases referred to in the second paragraph of Section 2.1 and may be considered for screening for P, vP, B, vB and T properties in the context of Section 2.2.

#### **3.1.1. Indication of P and vP properties**

- (a) Results from tests on ready biodegradation in accordance with Section 9.2.1.1 of Annex VII;
- (b) Results from other screening tests (tests on inherent biodegradability);
- (c) Results obtained from biodegradation (Q)SAR models in accordance with Section 1.3 of Annex XI;
- (c) Other information provided that its suitability and reliability can be reasonably demonstrated.

#### **3.1.2. Indication of B and vB Properties**

(a) Octanol-water partitioning coefficient experimentally determined in accordance with Section 7.8 of Annex VII or estimated by (Q)SAR models in accordance with Section 1.3 of Annex XI;

(b) Other information provided that its suitability and reliability can be reasonably demonstrated.

### 3.1.3. Indication of T properties

(a) Short-term aquatic toxicity in accordance with Section 9.1 of Annex VII and Section 9.1.3 of Annex VIII;

(b) Other information provided that its suitability and reliability can be reasonably demonstrated.

## 3.2. Assessment Information

The following information shall be considered for the assessment of P, vP, B, vB and T properties, using a weight-of-evidence approach.

### 3.2.1. Assessment of P or vP properties

(a) Results from simulation testing on degradation in surface water;

(b) Results from simulation testing on degradation in soil;

(c) Results from simulation testing on degradation in sediment;

(c) Other information, such as information from field studies or monitoring studies, provided that its suitability and reliability can be reasonably demonstrated.

### 3.2.2. B or vB properties

(a) Results from a bioconcentration or bioaccumulation study in aquatic species;

(b) Other information on the bioaccumulation potential provided that its suitability and reliability can be reasonably demonstrated, such as:

— Results from a bioaccumulation study in terrestrial species;

— Data from scientific analysis of human body fluids or tissues, such as blood, milk, or fat;

— Detection of elevated levels in biota, in particular in endangered species or in vulnerable populations, compared to levels in their surrounding environment;

— Results from a chronic toxicity study on animals;

— Assessment of the toxicokinetic behaviour of the substance;

(c) Information on the ability of the substance to biomagnify in the food chain, where possible expressed by biomagnification factors or trophic magnification factors.

### 3.2.3. Assessment of T properties

(a) Results from long-term toxicity testing on invertebrates as set out in Section 9.1.5 of Annex IX;

(b) Results from long-term toxicity testing on fish as set out in Section 9.1.6 of Annex IX;

(c) Results from growth inhibition study on aquatic plants as set out in Section 9.1.2 of Annex VII;

ç) The substance meeting the criteria for classification as carcinogenic in Category 1A or 1B (assigned hazard phrases: H350 or H350i), germ cell mutagenic in Category 1A or 1B (assigned hazard phrase: H340), toxic for reproduction in Category 1A, 1B and/or 2 (assigned hazard phrases: H360, H360F, H360D, H360FD, H360Fd, H360fD, H361, H361f, H361d or H361fd), specific target organ toxic after repeated dose in Category 1 or 2 (assigned hazard phrase: H372 or H373), according to By-law on Classification, Labelling and Packaging of Substances and Mixtures;

d) Results from long-term or reproductive toxicity testing with birds as set out in Section 9.6.1 of Annex X;

e) Other information provided that its suitability and reliability can be reasonably demonstrated.

## ANNEX XIV

### LIST OF SUBSTANCES SUBJECT TO AUTHORISATION

Entry Nr	Substance	Intrinsic property(ies) referred to in Article 47	Transitional arrangements		Exempted (categories of) uses	Review periods
			Latest application date	Sunset date		

Note: List of Substances subject to Authorisation shall be published in the Ministry's website.

## ANNEX XV

### DOSSIERS

#### 1. INTRODUCTION AND GENERAL PROVISIONS

This Annex lays down general principles for preparing dossiers to propose and justify:

- the identification of CMRs, PBTs, vPvBs, or a substance of equivalent concern in accordance with Article 49,
- restrictions of the manufacture, placing on the market or use of a substance

The relevant parts of Annex I shall be used for the methodology and format of any dossier according to this Annex.

For all dossiers any relevant information from registration dossiers shall be considered and other available information may be used. For hazard information which has not been previously submitted, a robust study summary shall be included in the dossier.

#### 2. CONTENT OF DOSSIERS

2.1. Dossier for the identification of a substance as a CMR, PBT, vPvB or a substance of equivalent concern according to Article 49

##### *Proposal*

The proposal shall include the identity of substance(s) concerned and whether it is proposed to be identified as a CMR according to Article 47(1)(a), (b) or (c), a PBT according to Article 47(1)(ç), a vPvB according to Article 47(1)(d), or a substance of equivalent concern according to Article 47(1)(e).

##### *Justification*

A comparison of the available information with the criteria in Annex XIII for PBT according to Article 47(1)(ç), and vPvBs according to Article 47(1)(d), or an assessment of the hazards and a comparison with Article 47(1)(e), according to the relevant parts of Sections 1 to 4 of Annex I shall be completed. This shall be documented in the format set out in Part B of the Chemical Safety Report in Annex I.

##### *Information on exposures, alternative substances and risks*

The available use and exposure information and information on alternative substances and techniques shall be provided.

2.2. Dossiers for restrictions proposal

##### *Proposal*

The proposal shall include the identity of the substance and the restriction(s) proposed for the manufacture, placing on the market or use(s) and a summary of the justification.

##### *Information on hazard and risk*

The risks to be addressed with the restriction shall be described based on an assessment of the hazard and risks according to the relevant parts of Annex I and shall be documented in the format set out in Part B of that Annex for the Chemical Safety Report.

Evidence shall be provided that implemented risk management measures (including those identified in registrations under Articles 11 to 15 to this By-law) are not sufficient.

#### *Information on alternatives*

Available information on alternative substances and techniques shall be provided, including:

- information on the risks to human health and the environment related to the manufacture or use of the alternatives,
- availability, including the time scale,
- technical and economical feasibility.

#### *Justification for Restrictions*

Justification shall be provided that:

- action is required,
- a restriction is the most appropriate measure which shall be assessed using the following criteria:
  - (i) effectiveness: the restriction must be targeted to the effects or exposures that cause the risks identified, capable of reducing these risks to an acceptable level within a reasonable period of time and proportional to the risk;
  - (ii) practicality: the restriction must be implementable, enforceable and manageable;
  - (iii) monitorability: it must be possible to monitor the result of the implementation of the proposed restriction.

#### *Socio-economic assessment*

The socio-economic impacts of the proposed restriction may be analysed with reference to Annex XVI. To this end, the net benefits to human health and the environment of the proposed restriction may be compared to its net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole.

#### *Information on stakeholder consultation*

Information on any consultation of stakeholders and how their views have been taken into account shall be included in the dossier.

## ANNEX XVI

### SOCIO-ECONOMIC ANALYSIS

This Annex outlines the information that may be addressed by those submitting a socio-economic analysis with an application for authorisation, as specified in Article 52(5)(a), or in connection with a proposed restriction, as specified in Article 58.

However, the level of detail and scope of the socio-economic analysis, or contributions to them, shall be the responsibility of the applicant for authorisation, or, in the case of a proposed restriction, the interested party. The information provided can address the socio-economic impacts at any level.

An SEA may include the following elements:

- impact of a granted or refused authorisation on the applicant(s), or, in the case of a proposed restriction, the impact on industry (e.g. manufacturers and importers). The impact on all other actors in the supply chain, downstream users and associated businesses in terms of commercial consequences such as impact on investment, research and development, innovation, one-off and operating costs (e.g. compliance, transitional arrangements, changes to existing processes, reporting and monitoring systems, installation of new technology, etc.) taking into account general trends in the market and technology,
- impacts of a granted or refused authorisation, or a proposed restriction, on consumers. For example, product prices, changes in composition or quality or performance of products, availability of products, consumer choice, as well as effects on human health and the environment to the extent that these affect consumers,
- social implications of a granted or refused authorisation, or a proposed restriction. For example job security and employment,
- availability, suitability, and technical feasibility of alternative substances and/or technologies, and economic consequences thereof, and information on the rates of, and potential for, technological change in the sector(s) concerned. In the case of an application for authorisation, the social and/or economic impacts of using any available alternatives,
- wider implications on trade, competition and economic development (in particular for SMEs and in relation to third countries) of a granted or refused authorisation, or a proposed restriction. This may include consideration of local, regional, national or international aspects,
- in the case of a proposed restriction, proposals for other regulatory or non-regulatory measures that could meet the aim of the proposed restriction (this shall take account of existing legislation). This should include an assessment of the effectiveness and the costs linked to alternative risk management measures,
- in the case of a proposed restriction or refused authorisation, the benefits for human health and the environment as well as the social and economic benefits of the proposed restriction.

For example, worker health, environmental performance and the distribution of these benefits, for example, geographically, population groups,

— an SEA may also address any other issue that is considered to be relevant by the applicant(s) or interested party.

ANNEX 17

RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES

If the substance is not restricted, restrictions in this Annex shall not be applied for export purposes in the case of storage, keeping, processing, filling of the containers or transfer from one container to another.

<p style="text-align: center;"><b>Column 1</b></p> <p style="text-align: center;"><b>Designation of the substance, of the group of substances or of the mixture</b></p>	<p style="text-align: center;"><b>Column 2</b></p> <p style="text-align: center;"><b>Conditions of restriction</b></p>
<p>1. Polychlorinated terphenyls (PCTs)</p>	<p>Shall not be placed on the market, or used:</p> <ul style="list-style-type: none"> <li>— as substances,</li> <li>— in mixtures, including waste oils, or in equipment, in concentrations greater than 50 mg/kg (0,005 % by weight).</li> </ul>
<p>2. Chloroethene (vinyl chloride) CAS No 75-01-4 EC No 200-831-0</p>	<p>1. Chloroethene shall not be used as propellant in aerosols for any use. Aerosols dispensers containing the substance as propellant shall not be placed on the market.</p>
<p>3. Liquid substances or mixtures which are fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Bylaw on Classification, Labelling and Packaging of Substances and Mixtures:</p> <p>(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;</p> <p>(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;</p> <p>(c) hazard class 4.1;</p> <p>(d) hazard class 5.1. ◀</p>	<p>1. Shall not be used in:</p> <ul style="list-style-type: none"> <li>a) ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,</li> <li>b) tricks and jokes,</li> <li>c) games for one or more participants, or any article intended to be used as such, even with ornamental aspects,</li> </ul> <p>2. Articles not complying with paragraph 1 shall not be placed on the market.</p> <p>3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they:</p> <ul style="list-style-type: none"> <li>a) can be used as fuel in decorative oil lamps for supply to the general public, and,</li> <li>b) present an aspiration hazard and are labelled with H304,</li> </ul> <p>4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the Turkish Standard on Decorative oil lamps-Safety Rules and Test Methods Standards (TS EN 14059) adopted by the Turkish Standardisation Institute.</p>

	<p>5. Without prejudice to the provisions of Bylaw on Classification, Labelling and Packaging of Substances and Mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:</p> <p>(a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: ‘Keep lamps filled with this liquid out of the reach of children’; and, ‘Just a sip of lamp oil — or even sucking the wick of lamps — may lead to life-threatening lung damage’;</p> <p>(b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked as follows: ‘Just a sip of grill lighter may lead to— or even sucking the wick of lamps — life threatening lung damage’;</p> <p>(c) lamp oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre.</p>
<p>4. Tris (2,3 dibromopropyl) phosphate CAS No 126-72-7</p>	<p>1. Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin and articles not complying with paragraph 1 shall not be placed on the market.</p>
<p>5. Benzene CAS No 71-43-2 EC No 200-753-7</p>	<p>1. Shall not be used in toys or parts of toys where the concentration of benzene in the free state is greater than 5 mg/kg (0,0005 %) of the weight of the toy or part of toy.</p> <p>2. Toys and parts of toys not complying with paragraph 1 shall not be placed on the market.</p> <p>3. Shall not be placed on the market, or used,</p> <ol style="list-style-type: none"> <li>a) as a substance,</li> <li>b) as a constituent of other substances, or in mixtures, in concentrations equal to, or greater than 0,1 % by weight.</li> </ol> <p>4. However, paragraph 3 shall not apply to:</p> <ol style="list-style-type: none"> <li>(a) motor fuels which are covered by Bylaw on Environmental Effects of Gasoline and Diesel Oil published in Official Gazette dated 01/04/2017 and numbered 30025;</li> <li>(b) substances and mixtures for use in industrial processes not allowing for the emission of benzene in quantities in excess of those laid down in Bylaw on Environmental Effects of Gasoline and Diesel Oil,</li> </ol>

	(c) natural gas placed on the market for use by consumers, provided that the concentration of benzene remains below 0,1 % volume/volume. ◀
<p>6. Asbestos fibres</p> <p>Crocidolite CAS No 12001-28-4</p> <p>Amosite CAS No 12172-73-5</p> <p>Anthophyllite CAS No 77536-67-5</p> <p>Actinolite CAS No 77536-66-4</p> <p>Tremolite CAS No 77536-68-6</p> <p>Chrysotile CAS No 12001-29-5 CAS No 132207-32-0</p>	<p>1. The manufacture, placing on the market and use of these fibres and of articles and mixtures containing these fibres added intentionally is prohibited.</p> <p>2. The use of articles containing asbestos fibres referred to in paragraph 1 which were already installed and/or in service before 26 December 2008 shall continue to be permitted until they are disposed of or reach the end of their service life and articles containing these fibres shall be labelled in accordance with Appendix VII of this Annex.</p> <p>3. Without prejudice to the application of Bylaw on Classification, Labelling and Packaging of Substances and Mixtures, the placing on the market and use of articles containing these fibres, as permitted according to the preceding derogations, shall be permitted only if suppliers ensure before the placing on the market that articles bear a label in accordance with Appendix 7 to this Annex.</p>
<p>7. Tris(aziridinyl)phosphinoxide CAS No 545-55-1 EC No 208-892-5</p>	<p>1. Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin.</p> <p>2. Articles not complying with paragraph 1 shall not be placed on the market.</p>
<p>8. Polybromobiphenyls; Polybrominatedbiphenyls (PBB) CAS No 59536-65-1</p>	<p>1. Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin.</p> <p>2. Articles not complying with paragraph 1 shall not be placed on the market.</p>
<p>9. (a) Soap bark powder (<i>Quillaja saponaria</i>) and its derivatives containing saponines CAS No 68990-67-0 EC 273-620-4</p> <p>(b) Powder of the roots of <i>Helleborus viridis</i> and <i>Helleborus niger</i></p> <p>(c) Powder of the roots of <i>Veratrum album</i> and <i>Veratrum nigrum</i></p> <p>(ç) Benzidine and/or its derivatives CAS No 92-87-5</p>	<p>1. Shall not be used, in jokes and hoaxes or in mixtures or articles intended to be used as such, for instance as a constituent of sneezing powder and stink bombs.</p> <p>2. Jokes and hoaxes, or mixtures or articles intended to be used as such, not complying with paragraph 1 shall not be placed on the market.</p> <p>3. However, paragraphs 1 and 2 shall not apply to stink bombs containing not more than 1,5 ml of liquid.</p>

<p>EC No 202-199-1</p> <p>(d) o-Nitrobenzaldehyde CAS No 552-89-6 EC No 209-025-3</p> <p>(f) Wood powder</p>	
<p>10. (a) Ammonium sulphide CAS No 12135-76-1 EC No 235-223-4</p> <p>(b) Ammonium hydrogen sulphide CAS No 12124-99-1 EC No 235-184-3</p> <p>(c) Ammonium polysulphide CAS No 9080-17-5 EC No 232-989-1</p>	<p>1. Shall not be used, in jokes and hoaxes or in mixtures or articles intended to be used as such, for instance as a constituent of sneezing powder and stink bombs.</p> <p>2. Jokes and hoaxes, or mixtures or articles intended to be used as such, not complying with paragraph 1 shall not be placed on the market.</p> <p>3. However, paragraphs 1 and 2 shall not apply to stink bombs containing not more than 1,5 ml of liquid.</p>
<p>11. Volatile esters of bromoacetic acids:</p> <p>(a) Methyl bromoacetate CAS No 96-32-2 EC No 202-499-2</p> <p>(b) Ethyl bromoacetate CAS No 105-36-2 EC No 203-290-9</p> <p>(c) Propyl bromoacetate CAS No 35223-80-4</p> <p>(ç) Butyl bromoacetate CAS No 18991-98-5 EC No 242-729-9</p>	<p>1. Shall not be used, in jokes and hoaxes or in mixtures or articles intended to be used as such, for instance as a constituent of sneezing powder and stink bombs.</p> <p>2. Jokes and hoaxes, or mixtures or articles intended to be used as such, not complying with paragraph 1 shall not be placed on the market.</p> <p>3. However, paragraphs 1 and 2 shall not apply to stink bombs containing not more than 1,5 ml of liquid.</p>
<p>12. 2-Naphthylamine CAS No 91-59-8 EC No 202-080-4 and its salts</p> <p>13. Benzidine CAS No 92-87-5 EC No 202-199-1 and its salts</p> <p>14. 4-Nitrobiphenyl CAS No 92-93-3 Einecs EC No 202-204-7</p> <p>15. 4-Aminobiphenyl xenylamine CAS No 92-67-1 Einecs EC No 202-177-1 and its salts</p>	<p>1. The following shall apply to entries 12 to 15: Shall not be placed on the market, or used, as substances or in mixtures in concentrations greater than 0,1 % by weight.</p>

<p>16. Lead carbonates:</p> <p>(a) Neutral anhydrous carbonate (PbCO<sub>3</sub>) CAS No 598-63-0 EC No 209-943-4</p> <p>(b) Trilead-bis(carbonate)-dihydroxide 2Pb CO<sub>3</sub>-Pb(OH)<sub>2</sub> CAS No 1319-46-6 EC No 215-290-6</p>	<p>1. Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint.</p> <p>2. However, the use of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors is exempted from these provisions.</p>
<p>17. Lead sulphates:</p> <p>(a) PbSO<sub>4</sub> CAS No 7446-14-2 EC No 231-198-9</p> <p>(b) Pb<sub>x</sub> SO<sub>4</sub> CAS No 15739-80-7 EC No 239-831-0</p>	<p>1. Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint.</p> <p>2. However, the use of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors is exempted from these provisions.</p>
<p>18. Mercury compounds</p>	<p>1. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use:</p> <p>(a) to prevent the fouling by micro-organisms, plants or animals of:</p> <ul style="list-style-type: none"> <li>— the hulls of boats,</li> <li>— cages, floats, nets and any other appliances or equipment used for fish or shellfish farming,</li> <li>— any totally or partly submerged appliances or equipment;</li> </ul> <p>(b) in the preservation of wood;</p> <p>(c) in the impregnation of heavy-duty industrial textiles and yarn intended for their manufacture;</p> <p>(ç) in the treatment of industrial waters, irrespective of their use.</p>
<p>18a. Mercury CAS No 7439-97-6 EC No 231-106-7</p>	<p>1. Shall not be placed on the market:</p> <p>(a) in fever thermometers;</p> <p>(b) in other measuring devices intended for sale to the general public (such as manometers, barometers, sphygmomanometers, thermometers other than fever thermometers).</p> <p>2. The restriction in paragraph 1(b) shall not apply to:</p> <p>(a) measuring devices more than 60 years old on the publication date of this Bylaw;</p> <p>(b) barometers (except barometers within point (a)) until 31 December 2018</p>

	<p>3. The following mercury-containing measuring devices intended for industrial and professional uses shall not be placed on the market after 31 December 2018:</p> <ul style="list-style-type: none"> <li>(a) barometers;</li> <li>(b) hygrometers;</li> <li>(c) manometers;</li> <li>(d) sphygmomanometers;</li> <li>(e) strain gauges to be used with plethysmographs;</li> <li>(f) tensiometers;</li> <li>(g) thermometers and other non-electrical thermometric applications.</li> </ul> <p>The restriction shall also apply to measuring devices under points (a) to (g) which are placed on the market empty if intended to be filled with mercury.</p> <p>4. The restriction in paragraph 3 shall not apply to:</p> <ul style="list-style-type: none"> <li>(a) sphygmomanometers to be used: <ul style="list-style-type: none"> <li>(i) in epidemiological studies which are ongoing on the publication date of this Bylaw;</li> <li>(ii) as reference standards in clinical validation studies of mercury-free sphygmomanometers;</li> </ul> </li> <li>(b) thermometers exclusively intended to perform tests according to standards that require the use of mercury thermometers until 31 December 2020;</li> <li>(c) mercury triple point cells which are used for the calibration of platinum resistance thermometers.</li> </ul> <p>5. The following mercury-using measuring devices intended for professional and industrial uses shall not be placed on the market after 31 December 2018:</p> <ul style="list-style-type: none"> <li>(a) mercury pycnometers;</li> <li>(b) mercury metering devices for determination of the softening point.</li> </ul> <p>6. The restrictions in paragraphs 3 and 5 shall not apply to:</p> <ul style="list-style-type: none"> <li>(a) measuring devices more than 60 years old on the date of publication of this Bylaw;</li> <li>(b) measuring devices which are to be displayed in public exhibitions for cultural and historical purposes.</li> </ul>
19. Arsenic compounds	<p>1. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use to prevent the fouling by micro-organisms, plants or animals of:</p> <ul style="list-style-type: none"> <li>a) the hulls of boats,</li> </ul>

	<p>b) cages, floats, nets and any other appliances or equipment used for fish or shellfish farming,</p> <p>c) any totally or partly submerged appliances or equipment.</p> <p>2. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use in the treatment of industrial waters, irrespective of their use.</p> <p>3. Shall not be used in the preservation of wood. Furthermore, wood so treated shall not be placed on the market.</p> <p>4. By way of derogation from paragraph 3:</p> <p>(a) Relating to the substances and mixtures for the preservation of wood: these may only be used in industrial installations using vacuum or pressure to impregnate wood if they are solutions of inorganic compounds of the copper, chromium, arsenic (CCA) type C. Wood so treated shall not be placed on the market before fixation of the preservative is completed.</p> <p>(b) Wood treated with CCA solution in accordance with point (a) may be placed on the market for professional and industrial use provided that the structural integrity of the wood is required for human or livestock safety and skin contact by the general public during its service life is unlikely:</p> <ul style="list-style-type: none"> <li>— as structural timber in public and agricultural buildings, office buildings, and industrial premises,</li> <li>— in bridges and bridgework,</li> <li>— as constructional timber in freshwater areas and brackish waters, for example jetties and bridges,</li> <li>— as noise barriers,</li> <li>— in avalanche control,</li> <li>— in highway safety fencing and barriers,</li> <li>— as debarked round conifer livestock fence posts,</li> <li>— in earth retaining structures,</li> <li>— as electric power transmission and telecommunications poles,</li> <li>— as underground railway sleepers.</li> </ul> <p>(c) Without prejudice to the Bylaw on Classification, Labelling and Packaging of Substances and Mixtures, suppliers shall ensure before the placing on the market that all treated</p>
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	<p>wood placed on the market is individually labelled 'For professional and industrial installation and use only, contains arsenic'. In addition, all wood placed on the market in packs shall also bear a label stating 'Wear gloves when handling this wood. Wear a dust mask and eye protection when cutting or otherwise crafting this wood. Waste from this wood shall be treated as hazardous by an authorised undertaking'.</p> <p>(ç) Treated wood referred to under point (a) shall not be used:</p> <ul style="list-style-type: none"> <li>— in residential or domestic constructions, whatever the purpose,</li> <li>— in any application where there is a risk of repeated skin contact,</li> <li>— in marine waters,</li> <li>— for agricultural purposes other than for livestock fence posts and structural uses in accordance with point (b),</li> <li>— in any application where the treated wood may come into contact with intermediate or finished products intended for human and/or animal consumption.</li> </ul> <p>5. Wood treated with arsenic compounds that was in use before 01 January 2014, or that was placed on the market in accordance with paragraph 4 may remain in place and continue to be used until it reaches the end of its service life.</p> <p>6. Wood treated with CCA type C that was in use before 01 January 2014, or that was placed on the market in accordance with paragraph 4:</p> <ul style="list-style-type: none"> <li>— may be used or reused subject to the conditions pertaining to its use listed under points 4(b), (c) and (ç),</li> <li>— may be placed on the market subject to the conditions pertaining to its use listed under points 4(b), (c) and (ç).</li> </ul> <p>7. Wood treated with other types of CCA solutions that was in use before 01 January 2014 shall be permitted to be used in the following conditions:</p> <ul style="list-style-type: none"> <li>— to be used or reused subject to the conditions pertaining to its use listed under points 4 (b), (c) and (ç),</li> <li>— to be placed on the market subject to the conditions pertaining to its use listed under points 4(b), (c) and (ç).</li> </ul>
20. Organostannic compounds	1. Shall not be placed on the market, or used, as substances or in mixtures where the substance or

	<p>mixture is acting as biocide in free association paint.</p> <p>2. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture acts as biocide to prevent the fouling by micro-organisms, plants or animals of:</p> <p>(a) all craft irrespective of their length intended for use in marine, coastal, estuarine and inland waterways and lakes;</p> <p>(b) cages, floats, nets and any other appliances or equipment used for fish or shellfish farming;</p> <p>(c) any totally or partly submerged appliance or equipment.</p> <p>3. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use in the treatment of industrial waters.</p> <p>4. Tri-substituted organostannic compounds:</p> <p>(a) Tri-substituted organostannic compounds such as tributyltin (TBT) compounds and triphenyltin (TPT) compounds shall not be used in articles where the concentration in the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin.</p> <p>(b) Articles not complying with point (a) shall not be placed on the market.</p> <p>5. Dibutyltin (DBT) compounds:</p> <p>(a) Dibutyltin (DBT) compounds shall not be used in mixtures and articles for supply to the general public where the concentration in the mixture or the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin.</p> <p>(b) Articles and mixtures not complying with point (a) shall not be placed on the market.</p> <p>(c) By way of derogation, points (a) and (b) shall not apply to the following articles and mixtures for supply to the general public:</p> <ul style="list-style-type: none"> <li>— one-component and two-component room temperature vulcanisation sealants (RTV-1 and RTV-2 sealants) and adhesives,</li> <li>— paints and coatings containing DBT compounds as catalysts when applied on articles, <ul style="list-style-type: none"> <li>— soft polyvinyl chloride (PVC) profiles whether by themselves or coextruded with hard PVC,</li> </ul> </li> <li>— outdoor rainwater pipes, gutters and fittings, as well as covering material for roofing and façades.</li> </ul>
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	<p>(d) By way of derogation, points (a) and (b) shall not apply to materials and articles regulated under Bylaw on Turkish Food Codex Substances and Materials In Contact With Food published in the Official Gazette dated 29/12/2011 and numbered 28157 (3<sup>rd</sup> bis).</p> <p>6. Dioctyltin (DOT) compound:  (a) Dioctyltin (DOT) compounds shall not be used in the following articles for supply to, or use by, the general public, where the concentration in the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin:</p> <ul style="list-style-type: none"> <li>— textile articles intended to come into contact with the skin,</li> <li>— gloves,</li> <li>— footwear or part of footwear intended to come into contact with the skin,</li> <li>— wall and floor coverings,</li> <li>— childcare articles,</li> <li>— female hygiene products,</li> <li>— nappies,</li> <li>— two-component room temperature vulcanisation moulding kits (RTV-2 moulding kits).</li> </ul> <p>(b) Articles not complying with point (a) shall not be placed on the market, except for articles that were already in use.</p>
<p>21. Di-<math>\mu</math>-oxo-di-n-butylstanniohydroxyborane/Dibutyltin hydrogen borate <math>C_8H_{19}BO_3Sn</math> (DBB)  CAS No 75113-37-0  EC No 401-040-5</p>	<p>1. Shall not be placed on the market, or used, as a substance, or in mixtures in a concentration equal to, or greater than 0,1 % by weight.</p> <p>2. However, the first paragraph shall not apply to this substance (DBB) or mixtures containing it if these are intended solely for conversion into articles, among which this substance will no longer feature in a concentration equal to or greater than 0,1 %.</p>
<p>22. Pentachlorophenol  CAS No 87-86-5  EC No 201-778-6 and its salts and esters</p>	<p>1. Shall not be placed on the market, or used,</p> <ul style="list-style-type: none"> <li>— as a substance,</li> <li>— as a constituent in other substances, or in mixtures, in a concentration equal to or greater than 0,1 % by weight.</li> </ul>
<p>23. Cadmium  CAS No 7440-43-9  EC No 231-152-8 and its compounds</p>	<p>For the purpose of this Bylaw, the codes and chapters indicated in square brackets are the codes and chapters of the tariff and statistical nomenclature of Common Customs Tariff (GTIP).</p> <p>1. Shall not be used in mixtures and articles</p>

	<p>produced from the following synthetic organic polymers (hereafter referred to as plastic material):</p> <ul style="list-style-type: none"> <li>— polymers or copolymers of vinyl chloride (PVC) [3904 10] [3904 21]</li> <li>— polyurethane (PUR) [3909 50]</li> <li>— low-density polyethylene (LDPE), with the exception of low-density polyethylene used for the production of coloured masterbatch [3901 10]</li> <li>— cellulose acetate (CA) [3912 11]</li> <li>— cellulose acetate butyrate (CAB) [3912 11]</li> <li>— epoxy resins [3907 30]</li> <li>— melamine-formaldehyde (MF) resins [3909 20]</li> <li>— urea-formaldehyde (UF) resins [3909 10]</li> <li>— unsaturated polyesters (UP) [3907 91]</li> <li>— polyethylene terephthalate (PET) [3907 60]</li> <li>— polybutylene terephthalate (PBT)</li> <li>— transparent/general-purpose polystyrene [3903 11]</li> <li>— acrylonitrile methacrylate (AMMA)</li> <li>— cross-linked polyethylene (VPE)</li> <li>— high-impact polystyrene</li> <li>— polypropylene (PP) [3902 10]</li> </ul> <p>(a) Mixtures and articles produced from plastic material as listed above shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight of the plastic material.</p> <p>(b) By way of derogation, point(a) of the first paragraph shall not apply to articles placed on the market before 21 May 2015.</p> <p>2. Shall not be used or placed on the market in paints with codes [3208 ] [3209 ] in a concentration (expressed as Cd metal) equal to or greater than 0,01 % by weight. For paints with codes [3208 ] [3209 ] with a zinc content exceeding 10 % by weight of the paint, the concentration of cadmium (expressed as Cd metal) shall not be equal to or greater than 0,1 % by weight. Painted articles shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,1 % by weight of the paint on the painted article.</p> <p>3. By way of derogation, paragraphs 1 and 2 shall not apply to articles coloured with mixtures containing cadmium for safety reasons.</p>
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4. By way of derogation, point(a) of the paragraph 1, shall not apply to:

- mixtures produced from PVC waste, hereinafter referred to as ‘recovered PVC’,
- mixtures and articles containing recovered PVC if their concentration of cadmium (expressed as Cd metal) does not exceed 0,1 % by weight of the plastic material in the following rigid PVC applications:

- a) profiles and rigid sheets for building applications;
- b) doors, windows, shutters, walls, blinds, fences, and roof gutters;
- c) decks and terraces;
- d) cable ducts;
- e) pipes for non-drinking water if the recovered PVC is used in the middle layer of a multilayer pipe and is entirely covered with a layer of newly produced PVC in compliance with paragraph 1 above.

Suppliers shall ensure, before the placing on the market of mixtures and articles containing recovered PVC for the first time, that these are visibly, legibly and indelibly marked as follows: ‘*Contains recovered PVC*’ or with the following pictogram:



5. For the purpose of this entry, ‘cadmium plating’ means any deposit or coating of metallic cadmium on a metallic surface.

Shall not be used for cadmium plating metallic articles or components of the articles used in the following sectors/applications:

(a) equipment and machinery for:

- food production [8210] [8417 20] [8419 81] [8421 11] [8421 22] [8422] [8435] [8437] [8438] [8476 11]
- agriculture [8419 31] [8424 81] [8432] [8433] [8434] [8436]

	<ul style="list-style-type: none"> <li>— cooling and freezing [8418]</li> <li>— printing and book-binding [8440] [8442] [8443]</li> </ul> <p>(b) equipment and machinery for the production of:</p> <ul style="list-style-type: none"> <li>— household goods [7321] [8421 12] [8450] [8509] [8516]</li> <li>— furniture [8465] [8466] [9401] [9402] [9403] [9404]</li> <li>— sanitary ware [7324]</li> <li>— central heating and air conditioning plant [7322] [8403] [8404] [8415]</li> </ul> <p>In any case, whatever their use or intended final purpose, the placing on the market of cadmium-plated articles or components of such articles used in the sectors/applications listed in points (a) and (b) above and of articles manufactured in the sectors listed in point (b) above is prohibited.</p> <p>6. The provisions referred to in paragraph 5 shall also be applicable to cadmium-plated articles or components of such articles when used in the sectors/applications listed in points (a) and (b) below and to articles manufactured in the sectors listed in (b) below:</p> <p>(a) equipment and machinery for the production of:</p> <ul style="list-style-type: none"> <li>— paper and board [8419 32] [8439] [8441] [8444] [8445] [8447] [8448] [8449] [8451] [8452]</li> </ul> <p>(b) equipment and machinery for the production of:</p> <ul style="list-style-type: none"> <li>— industrial handling equipment and machinery [8425] [8426] [8427] [8428] [8429] [8430] [8431]</li> <li>— road and agricultural vehicles [chapter 87]</li> <li>— rolling stock [chapter 86]</li> <li>— vessels [chapter 89]</li> </ul> <p>7. However, the restrictions in paragraphs 5 and 6 shall not apply to:</p> <ul style="list-style-type: none"> <li>— articles and components of the articles used in the aeronautical, aerospace, mining, offshore and nuclear sectors whose applications require high safety standards and in safety devices in road and agricultural vehicles, rolling stock and vessels,</li> <li>— electrical contacts in any sector of use, where that is necessary to ensure the reliability</li> </ul>
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	<p>required of the apparatus on which they are installed.</p> <p>8. Shall not be used in brazing fillers in concentration equal to or greater than 0,01 % by weight. Brazing fillers shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight. For the purpose of this paragraph brazing shall mean a joining technique using alloys and undertaken at temperatures above 450 °C.</p> <p>9. By way of derogation, paragraph 8 shall not apply to brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons.</p> <p>10. Shall not be used or placed on the market if the concentration is equal to or greater than 0,01 % by weight of the metal in:</p> <p>(i) metal beads and other metal components for jewellery making;</p> <p>(ii) metal parts of jewellery and imitation jewellery articles and hair accessories, including:</p> <ul style="list-style-type: none"> <li>— bracelets, necklaces and rings,</li> <li>— piercing jewellery,</li> <li>— wrist-watches and wrist-wear,</li> <li>— brooches and cufflinks.</li> </ul> <p>11. By way of derogation, paragraph 10 shall not apply to articles placed on the market before 21 May 2015 and jewellery more than 50 years old on 21 May 2015.</p>
<p>24. Monomethyl tetrachlorodiphenyl methane Trade name: Ugilec 141 CAS No 76253-60-6</p>	<p>—</p> <p>1. Shall not be placed on the market, or used, as a substance or in mixtures. Articles containing the substance shall not be placed on the market.</p> <p>2. By way of derogation, paragraph 1 shall not apply:</p> <p>(a) in the case of plant and machinery already in service on the date of entry into force of this entry, until such plant and machinery is disposed of.</p>
<p>25. Monomethyl-dichloro-diphenyl methane Trade name: Ugilec 121 Ugilec 21</p>	<p>1. Shall not be placed on the market, or used, as a substance or in mixtures. Articles containing the substance shall not be placed on the market.</p>
<p>26. Monomethyl-dibromo-diphenyl methane bromobenzylbromotoluene, mixture of isomers Trade name: DBBT CAS No 99688-47-8</p>	<p>1. Shall not be placed on the market, or used, as a substance or in mixtures. Articles containing the substance shall not be placed on the market.</p>

<p>27. Nickel CAS No 7440-02-0 EC No 231-111-4 and its compounds</p>	<p>1. Shall not be used:</p> <p>(a) in any post assemblies which are inserted into pierced ears and other pierced parts of the human body unless the rate of nickel release from such post assemblies is less than 0,2 µg/cm<sup>2</sup>/week (migration limit);</p> <p>(b) in articles intended to come into direct and prolonged contact with the skin such as:</p> <ul style="list-style-type: none"> <li>— earrings,</li> <li>— necklaces, bracelets and chains, anklets, finger rings,</li> <li>— wrist-watch cases, watch straps and tighteners,</li> <li>— rivet buttons, tighteners, rivets, zippers and metal marks, when these are used in garments,</li> </ul> <p>if the rate of nickel release from the parts of these articles coming into direct and prolonged contact with the skin is greater than 0,5 µg/cm<sup>2</sup>/week.</p> <p>(c) in articles referred to in point (b) where these have a non-nickel coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of such articles coming into direct and prolonged contact with the skin will not exceed 0,5 µg/cm<sup>2</sup>/week for a period of at least two years of normal use of the article.</p> <p>2. Articles which are the subject of paragraph 1 shall not be placed on the market unless they conform to the requirements set out in that paragraph.</p> <p>3. The standards adopted by the Turkish Standardisation Institute(TSE) and European Committee for Standardisation (CEN) shall be used as the test methods for demonstrating the conformity of articles to paragraphs 1 and 2.</p>
<p>28. Substances which appear in Part 3 of Annex VI to Bylaw on Classification, Labelling and Packaging of Substances and Mixtures classified as carcinogen category 1A or 1B (Table 3.1) and listed as follows:</p> <ul style="list-style-type: none"> <li>— Carcinogen category 1A (Table 3.1) listed in Appendix 1</li> <li>— Carcinogen category 1B (Table 3.1) listed in Appendix 2</li> </ul> <p>29. Substances which appear in Part 3 of Annex VI to Bylaw on Classification, Labelling and</p>	<p>Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30:</p> <p>1. Shall not be placed on the market, or used,</p> <ul style="list-style-type: none"> <li>— as substances,</li> <li>— as constituents of other substances, or,</li> <li>— in mixtures,</li> </ul> <p>for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:</p> <ul style="list-style-type: none"> <li>— either the relevant specific concentration limit specified in Part 3 of Annex VI to</li> </ul>

<p>Packaging of Substances and Mixtures classified as germ cell mutagen category 1A or 1B (Table 3.1) and listed as follows:</p> <ul style="list-style-type: none"> <li>— Mutagen category 1A (Table 3.1) listed in Appendix 3</li> <li>— Mutagen category 1B (Table 3.1) listed in Appendix 4</li> </ul> <p>30. Substances which appear in Part 3 of Annex VI to Bylaw on Classification, Labelling and Packaging of Substances and Mixtures classified as toxic to reproduction category 1A or 1B (Table 3.1) and listed as follows:</p> <ul style="list-style-type: none"> <li>— Reproductive toxicant category 1A adverse effects on sexual function and fertility or on development (Table 3.1) listed in Appendix 5</li> <li>— Reproductive toxicant category 1B adverse effects on sexual function and fertility or on development (Table 3.1) listed in Appendix 6</li> </ul>	<p>Bylaw on Classification, Labelling and Packaging of Substances and Mixtures, or,</p> <ul style="list-style-type: none"> <li>— the relevant generic concentration limit specified in Part 3 of Annex I of Bylaw on Classification, Labelling and Packaging of Substances and Mixtures.</li> </ul> <p>Without prejudice to the implementation of Bylaw on Classification, Labelling and Packaging of Substances and Mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows:</p> <p style="text-align: center;">‘Restricted to professional users’.</p> <p>2. By way of derogation, paragraph 1 shall not apply to:</p> <ul style="list-style-type: none"> <li>(a) medicinal or veterinary products as defined by Bylaw on Licensing of Human Medicinal Products published in the Official Gazette dated 19/01/2005 and numbered 25705, Bylaw on Packaging and Labelling of Human Medicinal Products published in the Official Gazette dated 12/08/2005 and numbered 25904, Bylaw on Veterinary Medicinal Products published in the Official Gazette dated 24/12/2012 and numbered 28152 ;</li> <li>(b) cosmetic products as defined by Bylaw on Cosmetics published in the Official Gazette dated 23/05/2005 and numbered 25823;</li> <li>(c) the following fuels and oil products: <ul style="list-style-type: none"> <li>— motor fuels which are covered by Bylaw on Control of Exhaust Gas Emission and Quality of Gasoline and Diesel Fuel published in the Official Gazette dated 30/11/2013 and numbered 28837,</li> <li>— mineral oil products intended for use as fuel in mobile or fixed combustion plants, <ul style="list-style-type: none"> <li>— fuels sold in closed systems (e.g. liquid gas bottles);</li> </ul> </li> </ul> </li> </ul>
<p>31. (a) Creosote; wash oil CAS No 8001-58-9 EC No 232-287-5</p> <p>(b) Creosote oil; wash oil CAS No 61789-28-4 EC No 263-047-8</p>	<p>1. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for the treatment of wood.</p> <p>2. By way of derogation from paragraph 1:</p> <ul style="list-style-type: none"> <li>(a) The substances and mixtures may be used for wood treatment in industrial installations or by professionals covered by legislation on the</li> </ul>

<p>(c) Distillates (coal tar), naphthalene oils; naphthalene oil CAS No 84650-04-4 EC No 283-484-8</p> <p>(ç) Creosote oil, acenaphthene fraction; wash oil CAS No 90640-84-9 EC No 292-605-3</p> <p>(d) Distillates (coal tar), upper; heavy anthracene oil CAS No 65996-91-0 EC No 266-026-1</p> <p>(e) Anthracene oil CAS No 90640-80-5 EC No 292-602-7</p> <p>(f) Tar acids, coal, crude; crude phenols CAS No 65996-85-2 EC No 266-019-3</p> <p>(g) Creosote, wood CAS No 8021-39-4 EC No 232-419-1</p> <p>(ğ) Low temperature tar oil, alkaline; extract residues (coal), low temperature coal tar alkaline CAS No 122384-78-5 EC No 310-191-5</p>	<p>protection of workers for in situ retreatment only if they contain:</p> <p>(i) benzo[a]pyrene at a concentration of less than 50 mg/kg (0,005 % by weight), and</p> <p>(ii) water extractable phenols at a concentration of less than 3 % by weight.</p> <p>Such substances and mixtures for use in wood treatment in industrial installations or by professionals:</p> <ul style="list-style-type: none"> <li>— may be placed on the market only in packaging of a capacity equal to or greater than 20 litres,</li> <li>— shall not be sold to consumers.</li> </ul> <p>Without prejudice to the application of Bylaw on Classification, Labelling and Packaging of Substances and Mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is visibly, legibly and indelibly marked as follows:</p> <p style="text-align: center;">‘For use in industrial installations or professional treatment only’.</p> <p>(b) Wood treated in industrial installations or by professionals according to subparagraph (a) which is placed on the market for the first time or retreated in situ may be used for professional and industrial use only, for example on railways, in electric power transmission and telecommunications, for fencing, for agricultural purposes (for example stakes for tree support) and in harbours and waterways.</p> <p>(c) The prohibition in paragraph 1 on the placing on the market shall not apply to wood which has been treated with substances listed in entry 31 (a) to (ğ) before 31 December 2018 and is placed on the second-hand market for re-use.</p> <p>3. Treated wood referred to under paragraph 2(b) and (c) shall not be used:</p> <ul style="list-style-type: none"> <li>— inside buildings, whatever their purpose,</li> <li>— in toys,</li> <li>— in playgrounds,</li> <li>— in parks, gardens, and outdoor recreational and leisure facilities where there is a risk of frequent skin contact,</li> <li>— in the manufacture of garden furniture such as picnic tables,</li> </ul>
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	<p>— for the manufacture and use and any re-treatment of:</p> <ul style="list-style-type: none"> <li>— containers intended for growing purposes,</li> <li>— packaging that may come into contact with raw materials, intermediate or finished products destined for human and/or animal consumption,</li> <li>— other materials which may contaminate the articles mentioned above.</li> </ul>
<p>32. Chloroform CAS No 67-66-3 EC No 200-663-8</p> <p>34. 1,1,2-Trichloroethane CAS No 79-00-5 EC No 201-166-9</p> <p>35. 1,1,2,2-Tetrachloroethane CAS No 79-34-5 EC No 201-197-8</p> <p>36. 1,1,1,2-Tetrachloroethane CAS No 630-20-6</p> <p>37. Pentachloroethane CAS No 76-01-7 EC No 200-925-1</p> <p>38. 1,1-Dichloroethene CAS No 75-35-4 EC No 200-864-0</p>	<p>Without prejudice to the other parts of this Annex, the following shall apply to entries 32 to 38.</p> <p>1. Shall not be placed on the market, or used,</p> <ul style="list-style-type: none"> <li>— as substances,</li> <li>— as constituents of other substances, or in mixtures in concentrations equal to or greater than 0,1 % by weight,</li> </ul> <p>where the substance or mixture is intended for supply to the general public and/or is intended for diffusive applications such as in surface cleaning and cleaning of fabrics.</p> <p>2. Without prejudice to the application Bylaw on Classification, Labelling and Packaging of Substances and Mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures containing them in concentrations equal to or greater than 0,1 % by weight is visibly, legibly and indelibly marked as follows:</p> <p style="text-align: center;">‘For use in industrial installations only’.</p> <p>By way of derogation this provision shall not apply to:</p> <p>(a) medicinal or veterinary products as defined by Bylaw on Veterinary Medicinal Products published in the Official Gazette dated 24/12/2012 and numbered 28152, Bylaw on Licensing of Human Medicinal Products published in the Official Gazette dated 19/01/2005 and numbered 25705, Bylaw on Packaging and Labelling of Human Medicinal Products published in the Official Gazette dated 12/08/2005 and numbered 25904;</p> <p>(b) cosmetic products as defined by Bylaw on Cosmetics published in the Official Gazette dated 23/05/2005 and numbered 25823.</p>
<p>40. Substances classified as flammable gases category 1 or 2,</p>	<p>1. Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended for supply to the general public for</p>

<p>flammable liquids categories 1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases, category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids category 1, regardless of whether they appear in Part 3 of Annex VI to Bylaw on Classification, Labelling and Packaging of Substances and Mixtures or not.</p>	<p>entertainment and decorative purposes such as the following:</p> <ul style="list-style-type: none"> <li>— metallic glitter intended mainly for decoration,</li> <li>— artificial snow and frost,</li> <li>— ‘whoopee’ cushions,</li> <li>— silly string aerosols,</li> <li>— imitation excrement,</li> <li>— horns for parties,</li> <li>— decorative flakes and foams,</li> <li>— artificial cobwebs,</li> <li>— stink bombs.</li> </ul> <p>2. Without prejudice to the application of Bylaw on Classification, Labelling and Packaging of Substances and Mixtures, suppliers shall ensure before the placing on the market that the packaging of aerosol dispensers referred to above is marked visibly, legibly and indelibly with:</p> <p style="text-align: center;">‘For professional users only’.</p> <p>3. By way of derogation, paragraphs 1 and 2 shall not apply to the aerosol dispensers referred to Article 8 of Bylaw on Aerosol Containers published in the Official Gazette dated 30/11/2000 and numbered 24246.</p> <p>4. The aerosol dispensers referred to in paragraphs 1 and 2 shall not be placed on the market unless they conform to the requirements indicated.</p>
<p>41. Hexachloroethane CAS No 67-72-1 EC No 200-666-4</p>	<p>1. Shall not be placed on the market, or used, as substance or in mixtures, where the substance or mixture is intended for the manufacturing or processing of non-ferrous metals.</p>
<p>43. Azocolourants and Azodyes</p>	<p>1. Azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in Appendix 8, in detectable concentrations, i.e. above 30 mg/kg (0,003 % by weight) in the articles or in the dyed parts thereof, according to the testing methods listed in Appendix 10, shall not be used, in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity, such as:</p> <p>a) clothing, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items, sleeping bags,</p>

	<p>b) footwear, gloves, wristwatch straps, handbags, purses/wallets, briefcases, chair covers, purses worn round the neck,</p> <p>c) textile or leather toys and toys which include textile or leather garments,</p> <p>ç) yarn and fabrics intended for use by the final consumer.</p> <p>2. Furthermore, the textile and leather articles referred to in paragraph 1 shall not be placed on the market unless they conform to the requirements set out in that paragraph.</p> <p>3. Azodyes, which are contained in Appendix 9, 'List of azodyes' shall not be placed on the market, or used, as substances, or in mixtures in concentrations greater than 0,1 % by weight, where the substance or the mixture is intended for colouring textile and leather articles.</p>
<p>45. Diphenylether, octabromo derivative  <math>C_{12}H_2Br_8O</math></p>	<p>1. Shall not be placed on the market, or used:</p> <ul style="list-style-type: none"> <li>— as a substance,</li> <li>— as a constituent of other substances, or in mixtures, in concentrations greater than 0,1 % by weight.</li> </ul> <p>2. Articles shall not be placed on the market if they, or flame-retardant parts thereof, contain this substance in concentrations greater than 0,1 % by weight.</p> <p>3. By way of derogation, paragraph 2 shall not apply:</p> <ul style="list-style-type: none"> <li>— to articles that were in use before 31 December 2018,</li> <li>— to electrical and electronic equipment within the scope of Bylaw on Control of Waste Electrical and Electronic Equipment published in the Official Gazette dated 22/05/2012 and numbered 28300.</li> </ul>
<p>46. (a) Nonylphenol  <math>C_6H_4(OH)C_9H_{19}</math>  CAS 25154-52-3  EC 246-672-0</p> <p>(b) Nonylphenol ethoxylates  <math>(C_2H_4O)_n C_{15}H_{24}O</math></p>	<p>Shall not be placed on the market, or used, as substances or in mixtures in concentrations equal to or greater than 0,1 % by weight for the following purposes:</p> <p>(1) industrial and institutional cleaning except:</p> <ul style="list-style-type: none"> <li>— controlled closed dry cleaning systems where the washing liquid is recycled or incinerated,</li> <li>— cleaning systems with special treatment where the washing liquid is recycled or incinerated.</li> </ul> <p>(2) domestic cleaning;</p>

	<p>(3) textiles and leather processing except:  — processing with no release into waste water,  — systems with special treatment where the process water is pre-treated to remove the organic fraction completely prior to biological waste water treatment (degreasing of sheepskin);</p> <p>(4) emulsifier in agricultural teat dips;</p> <p>(5) metal working except:  uses in controlled closed systems where the washing liquid is recycled or incinerated;</p> <p>(6) manufacturing of pulp and paper;</p> <p>(7) cosmetic products;</p> <p>(8) other personal care products except:  spermicides;</p> <p>(9) co-formulants in pesticides and biocides.</p>
<p>46a. Nonylphenol ethoxylates (NPE)  <math>(C_2H_4O)_n C_{15}H_{24}O</math></p>	<p>1. Shall not be placed on the market in textile articles which can reasonably be expected to be washed in water during their normal lifecycle, in concentrations equal to or greater than 0,01 % by weight of that textile article or of each part of the textile article.</p> <p>2. Paragraph 1 shall not apply to the placing on the market of second-hand textile articles or of new textile articles produced, without the use of NPE, exclusively from recycled textiles.</p> <p>3. For the purposes of paragraphs 1 and 2, ‘textile article’ means any unfinished, semi-finished or finished product which is composed of at least 80 % textile fibres by weight, or any other product that contains a part which is composed of at least 80 % textile fibres by weight, including products such as clothing, accessories, interior textiles, fibres, yarn, fabrics and knitted panels.</p>
<p>47. Chromium VI compounds</p>	<p>1. Cement and cement-containing mixtures shall not be placed on the market, or used, if they contain, when hydrated, more than 2 mg/kg (0,0002 %) soluble chromium VI of the total dry weight of the cement.</p> <p>2. If reducing agents are used, then without prejudice to the application of Bylaw on Classification, Labelling and Packaging of Substances and Mixtures, suppliers shall ensure before the placing on the market that the packaging of cement or cement-containing mixtures is</p>

	<p>visibly, legibly and indelibly marked with information on the packing date, as well as on the storage conditions and the storage period appropriate to maintaining the activity of the reducing agent and to keeping the content of soluble chromium VI below the limit indicated in paragraph 1.</p> <p>3. By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for, and use in, controlled closed and totally automated processes in which cement and cement-containing mixtures are handled solely by machines and in which there is no possibility of contact with the skin.</p> <p>4. The standard adopted by the European Committee for Standardization (CEN) for testing the water-soluble chromium (VI) content of cement and cement-containing mixtures shall be used as the test method for demonstrating conformity with paragraph 1.</p> <p>5. Leather articles coming into contact with the skin shall not be placed on the market where they contain chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of the leather.</p> <p>6. Articles containing leather parts coming into contact with the skin shall not be placed on the market where any of those leather parts contains chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of that leather part.</p> <p>7. Paragraphs 5 and 6 shall not apply to the placing on the market of articles which were placed on the market before the publication date of this Bylaw.</p>
<p>48. Toluene CAS No 108-88-3 EC No 203-625-9</p>	<p>1. Shall not be placed on the market, or used, as a substance or in mixtures in a concentration equal to or greater than 0,1 % by weight where the substance or mixture is used in adhesives or spray paints intended for supply to the general public.</p>
<p>49. Trichlorobenzene CAS No 120-82-1 EC No 204-428-0</p>	<p>1. Shall not be placed on the market, or used, as a substance or in mixtures in a concentration equal to or greater than 0,1 % by weight for any use except:</p> <ul style="list-style-type: none"> <li>— as an intermediate of synthesis, or,</li> <li>— as a process solvent in closed chemical applications for chlorination reactions, or,</li> <li>— in the manufacture of 1,3,5-triamino — 2,4,6-trinitrobenzene (TATB).</li> </ul>

<p>50. Polycyclic-aromatic hydrocarbons (PAH)</p> <p>(a) Benzo[a]pyrene (BaP) CAS No 50-32-8</p> <p>(b) Benzo[e]pyrene (BeP) CAS No 192-97-2</p> <p>(c) Benzo[a]anthracene (BaA) CAS No 56-55-3</p> <p>(d) Chrysen (CHR) CAS No 218-01-9</p> <p>(e) Benzo[b]fluoranthene (BbFA) CAS No 205-99-2</p> <p>(f) Benzo[j]fluoranthene (BjFA) CAS No 205-82-3</p> <p>(g) Benzo[k]fluoranthene (BkFA) CAS No 207-08-9</p> <p>(h) Dibenzo[a,h]anthracene (DBAhA) CAS No 53-70-3</p>	<p>1. Extender oils shall not be placed on the market, or used for the production of tyres or parts of tyres if they contain:</p> <ul style="list-style-type: none"> <li>— more than 1 mg/kg (0,0001 % by weight) BaP, or,</li> <li>— more than 10 mg/kg (0,001 % by weight) of the sum of all listed PAHs.</li> </ul> <p>The standard EN 16143:2013 (Petroleum products — Determination of content of Benzo(a)pyrene (BaP) and selected polycyclic aromatic hydrocarbons (PAH) in extender oils — Procedure using double LC cleaning and GC/MS analysis) shall be used as the test method for demonstrating conformity with the limits referred to in the first subparagraph. The limits referred to in the first subparagraph may be regarded as kept, if the polycyclic aromatics (PCA) extract is less than 3 % by weight as measured by the Institute of Petroleum standard IP 346:1998 (Determination of PCA in unused lubricating base oils and asphaltene free petroleum fractions — Dimethyl sulphoxide extraction refractive index method), provided that compliance with the limits of BaP and of the listed PAHs, as well as the correlation of the measured values with the PCA extract, is measured by the manufacturer or importer every six months or after each major operational change, whichever is earlier.</p> <p>2. Furthermore, tyres and treads for retreading manufactured after the date of entry into force of this entry shall not be placed on the market if they contain extender oils exceeding the limits indicated in paragraph 1.</p> <p>These limits shall be regarded as kept, if the vulcanised rubber compounds do not exceed the limit of 0,35 % Bay protons as measured and calculated by ISO 21461 (Rubber vulcanised — Determination of aromaticity of oil in vulcanised rubber compounds).</p> <p>3. By way of derogation, paragraph 2 shall not apply to retreaded tyres if their tread does not contain extender oils exceeding the limits referred to in paragraph 1.</p> <p>4. For the purpose of this entry ‘tyres’ shall mean tyres for vehicles covered by:</p> <ul style="list-style-type: none"> <li>— Bylaw on Type Authorisation of Motor Vehicles and Trailers published in the Official Gazette dated 28/06/2009 and numbered 27272 which establishes a framework for authorisation of motor vehicles and trailers,</li> <li>— Bylaw on Type Authorisation of Agricultural or Forestry Tractors and Their Trailers published in the Official Gazette dated 08/06/2008 and numbered 26900, and</li> </ul>
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	<p>— Bylaw on Type Authorisation of 2 or 3 Wheeled Motor Vehicles published in the Official Gazette dated 03/12/2004 and numbered 25679.</p> <p>5. Articles shall not be placed on the market for supply to the general public, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 1 mg/kg (0,0001 % by weight of this component) of any of the listed PAHs. Such articles include amongst others:</p> <ul style="list-style-type: none"> <li>— sport equipment such as bicycles, golf clubs, racquets</li> <li>— household utensils, trolleys, walking frames</li> <li>— tools for domestic use</li> <li>— clothing, footwear, gloves and sportswear</li> <li>— watch-straps, wrist-bands, masks, head-bands</li> </ul> <p>6. Toys, including activity toys, and childcare articles, shall not be placed on the market, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 0,5 mg/kg (0,00005 % by weight of this component) of any of the listed PAHs.</p> <p>7. By way of derogation from paragraphs 5 and 6, these paragraphs shall not apply to articles placed on the market before the date of entry into force of this entry.</p>
<p>51. The following phthalates (or other CAS and EC numbers covering the substance):</p> <p>(a) Bis (2-ethylhexyl) phthalate (DEHP) CAS No 117-81-7 EC No 204-211-0</p> <p>(b) Dibutyl phthalate (DBP) CAS No 84-74-2 EC No 201-557-4</p> <p>(c) Benzyl butyl phthalate (BBP) CAS No 85-68-7 EC No 201-622-7</p>	<p>1. Shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles.</p> <p>2. Toys and childcare articles containing these phthalates in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market.</p> <p>4. For the purpose of this entry ‘childcare article’ shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.</p>

<p>52. The following phthalates (or other CAS- and EC numbers covering the substance):</p> <p>(a) Di-‘isononyl’ phthalate (DINP) CAS No 28553-12-0 and 68515-48-0 EC No 249-079-5 and 271-090-9</p> <p>(b) Di-‘isodecyl’ phthalate (DIDP) CAS No 26761-40-0 and 68515-49-1 EC No 247-977-1 and 271-091-4</p> <p>(c) Di-n-octyl phthalate (DNOP) CAS No 117-84-0 EC No 204-214-7</p>	<p>1. Shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles which can be placed in the mouth by children.</p> <p>2. Such toys and childcare articles containing these phthalates in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market.</p> <p>4. For the purpose of this entry ‘childcare article’ shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.</p>
<p>54. 2-(2-methoxyethoxy)ethanol (DEGME) CAS No 111-77-3 EC No 203-906-6</p>	<p>Shall not be placed on the market, for supply to the general public, as a constituent of paints, paint strippers, cleaning agents, self-shining emulsions or floor sealants in concentrations equal to or greater than 0,1 % by weight.</p>
<p>55. 2-(2-butoxyethoxy)ethanol (DEGBE) CAS No 112-34-5 EC No 203-961-6</p>	<p>1. Shall not be placed on the market, for supply to the general public, as a constituent of spray paints or spray cleaners in aerosol dispensers in concentrations equal to or greater than 3 % by weight.</p> <p>2. Spray paints and spray cleaners in aerosol dispensers containing DEGBE and not conforming to paragraph 1 shall not be placed on the market for supply to the general public.</p>
<p>56. Methylenediphenyl diisocyanate (MDI) CAS No 26447-40-5 EC No 247-714-0 including the following specific isomers:</p> <p>(a) 4,4’-Methylenediphenyl diisocyanate: CAS No 101-68-8 EC No 202-966-0;</p> <p>(b) 2,4’-Methylenediphenyl diisocyanate: CAS No 5873-54-1 EC No 227-534-9;</p> <p>(c) 2,2’-Methylenediphenyl diisocyanate: CAS No 2536-05-2 EC No 219-799-4</p>	<p>1. Shall not be placed on the market, as a constituent of mixtures in concentrations equal to or greater than 0,1 % by weight of MDI for supply to the general public, unless suppliers shall ensure before the placing on the market that the packaging:</p> <p>(a) contains protective glove according to Bylaw on Personal Protection Equipment published in the Official Gazette dated 29/11/2006 and numbered 26361;</p> <p>(b) is marked visibly, legibly and indelibly as follows, and without prejudice to Bylaw on classification, packaging and labelling of substances and mixtures:</p> <p>‘— Persons already sensitised to diisocyanates may develop allergic reactions when using this product.</p>

	<p>— Persons suffering from asthma, eczema or skin problems should avoid contact, including dermal contact, with this product.</p> <p>— This product should not be used under conditions of poor ventilation unless a protective mask with an appropriate gas filter (i.e. type A1 according to standard EN 14387) is used.’</p> <p>2. By way of derogation, paragraph 1(a) shall not apply to hot melt adhesives.</p>
<p>57. Cyclohexane CAS No 110-82-7 EC No 203-806-2</p>	<p>1. Shall not be placed on the market, for supply to the general public, as a constituent of neoprene-based contact adhesives in concentrations equal to or greater than 0,1 % by weight in package sizes greater than 350 g.</p> <p>2. Neoprene-based contact adhesives containing cyclohexane and not conforming to paragraph 1 shall not be placed on the market for supply to the general public.</p> <p>3. Without prejudice to Bylaw on classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that neoprene-based contact adhesives containing cyclohexane in concentrations equal to or greater than 0,1 % by weight that are placed on the market for supply to the general public are visibly, legibly and indelibly marked as follows:</p> <p>‘— This product is not to be used under conditions of poor ventilation.</p> <p>— This product is not to be used for carpet laying.’.</p>
<p>58. Ammonium nitrate (AN) CAS No 6484-52-2 EC No 229-347-8</p>	<p>1. Shall not be placed on the market as a substance, or in mixtures that contain more than 28 % by weight of nitrogen in relation to ammonium nitrate, for use as a solid fertiliser, straight or compound, unless the fertiliser complies with the technical provisions for ammonium nitrate fertilisers of high nitrogen content set out in Bylaw on Chemical Fertilizers Used In Agriculture published in the Official Gazette dated 18/03/2004 and numbered 25452.</p> <p>2. Shall not be placed on the market as a substance, or in mixtures that contain 16 % or more by weight of nitrogen in relation to ammonium nitrate except for supply to:</p> <p>(a) downstream users and distributors, including natural or legal persons licensed or authorised in accordance with Bylaw on Licensing Placing on the</p>

	<p>Market and Inspection of Explosive Substances for Civil Use published in the Official Gazette dated 15/10/2002 and numbered 24907.</p> <p>(b) farmers for use in agricultural activities, either full time or part time and not necessarily related to the size of the land area.</p> <p>For the purposes of this subparagraph:</p> <p>(i) ‘farmer’ shall mean a natural or legal person, or a group of natural or legal persons, whatever legal status is granted to the group and its members by national law, whose holding is situated in Turkey who exercises an agricultural activity;</p> <p>(ii) ‘agricultural activity’ shall mean the production, rearing or growing of agricultural products including harvesting, milking, breeding animals and keeping animals for farming purposes, or maintaining the land in good agricultural and environmental condition ;</p> <p>(c) natural or legal persons engaged in professional activities such as horticulture, plant growing in greenhouses, maintenance of parks, gardens or sport pitches, forestry or other similar activities.</p>
<p>59. Dichloromethane CAS No 75-09-2 EC No: 200-838-9</p>	<p>1. Paint strippers containing dichloromethane in a concentration equal to or greater than 0,1 % by weight shall not be:</p> <p>(a) placed on the market for supply to the general public or to professionals after 31 December 2019;</p> <p>(b) used by professionals after 31 December 2021.</p>
<p>60. Acrylamide CAS No 79-06-1</p>	<p>Shall not be placed on the market or used as a substance or constituent of mixtures in a concentration, equal to or greater than 0,1 % by weight for grouting applications.</p>
<p>61. Dimethylfumarate (DMF) CAS No 624-49-7 EC 210-849-0</p>	<p>1. Shall not be used in articles or any parts thereof in concentrations greater than 0,1 mg/kg.</p> <p>Articles or any parts thereof containing DMF in concentrations greater than 0,1 mg/kg shall not be placed on the market.</p>
<p>62. (a) Phenylmercury acetate EC No: 200-532-5 CAS No: 62-38-4 (b) Phenylmercury propionate EC No: 203-094-3 CAS No: 103-27-5</p>	<p>1. Shall not be manufactured, placed on the market or used as substances or in mixtures if the concentration of mercury in the mixtures is equal to or greater than 0,01 % by weight.</p> <p>2. Articles or any parts thereof containing one or more of these substances shall not be placed on the market if the concentration of mercury in the</p>

<p>(c) Phenylmercury 2-ethylhexanoate EC No: 236-326-7 CAS No: 13302-00-6</p> <p>(d) Phenylmercury octanoate EC No: - CAS No: 13864-38-5</p> <p>(e) Phenylmercury neodecanoate EC No: 247-783-7 CAS No: 26545-49-3</p>	<p>articles or any part thereof is equal to or greater than 0,01 % by weight.</p>
<p>63. Lead CAS No 7439-92-1 EC No 231-100-4 and its compounds</p>	<p>1. Shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0,05 % by weight.</p> <p>2. For the purposes of paragraph 1:</p> <p>(a) 'jewellery articles' shall include jewellery and imitation jewellery articles and hair accessories, including:</p> <ul style="list-style-type: none"> <li>- bracelets, necklaces and rings;</li> <li>- piercing jewellery;</li> <li>- wrist watches and wrist-wear;</li> <li>- brooches and cufflinks;</li> </ul> <p>(b) 'any individual part' shall include the materials from which the jewellery is made, as well as the individual components of the jewellery articles.</p> <p>3. Paragraph 1 shall also apply to individual parts when placed on the market or used for jewellery-making.</p> <p>4. By way of derogation, paragraph 1 shall not apply to:</p> <p>(a) crystal glass (category 1,2,3 and 4) as defined in Annex-1 of Bylaw on Crystal Glass Products published in the Official Gazette dated 19/03/2002 and numbered 24700;</p> <p>(b) internal components of watch timepieces inaccessible to consumers;</p> <p>(c) non-synthetic or reconstructed precious and semiprecious stones unless they have been treated with lead or its compounds or mixtures containing these substances;</p> <p>(ç) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C.</p> <p>5. By way of derogation, paragraph 1 shall not apply to jewellery articles produced before 31 December 1970.</p> <p>7. Shall not be placed on the market or used in</p>

articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0,05 % by weight, and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children.

That limit shall not apply where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0,05 µg/cm<sup>2</sup> per hour (equivalent to 0,05 µg/g/h), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article.

For the purposes of this paragraph, it is considered that an article or accessible part of an article may be placed in the mouth by children if:

- it is smaller than 5 cm in one dimension or
- has a detachable or protruding part of that size.

8. By way of derogation, paragraph 7 shall not apply to:

- (a) jewellery articles covered by paragraph 1;
- (b) crystal glass (category 1,2,3 and 4) as defined in Annex-1 of Bylaw on Crystal Glass Products published in the Official Gazette dated 19/03/2002 and numbered 24700;
- (c) non-synthetic or reconstructed precious and semi-precious stones (those who have GTIP code of 7103) unless they have been treated with lead or its compounds or mixtures containing these substances;
- (ç) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of mineral melted at a temperature of at least 500 °C;
- (d) keys and locks, including padlocks;
- (e) musical instruments;
- (f) articles and parts of articles comprising brass alloys, if the concentration of lead (expressed as metal) in the brass alloy does not exceed 0,5 % by weight;
- (g) the tips of writing instruments;
- (ğ) religious articles;
- (h) portable zinc-carbon batteries and button cell

	<p>batteries;</p> <p>(1) articles within the scope of Bylaw on Control of Packaging Waste published in the Official Gazette dated 24/08/2011 and numbered 28035, Bylaw on Turkish Food Codex Substances and Materials in Contact With Food published in the Official Gazette dated 29/11/2011 and numbered 28157, Bylaw on Control of Waste Electrical and Electronic Equipment published in the Official Gazette dated 22/05/2012 and numbered 28300.</p> <p>10. By way of derogation paragraph 7 shall not apply to articles placed on the market for the first time before 31 December 2017.</p>
<p>64. 1,4-dichlorobenzene (p- dichlorobenzene) CAS No 106-46-7 EC No 203-400-5</p>	<p>1. Shall not be placed on the market or used, as a substance or as a constituent of mixtures in a concentration equal to or greater than 1 % by weight, where the substance or the mixture is placed on the market for use or used as an air freshener or deodoriser in toilets, homes, offices or other indoor public areas.</p>
<p>65. Inorganic ammonium salts</p>	<p>1. Shall not be placed on the market, or used, in cellulose insulation mixtures or cellulose insulation articles unless the emission of ammonia from those mixtures or articles results in a concentration of less than 3 ppm by volume (2,12 mg/m<sup>3</sup>) under the test conditions specified in paragraph 4.</p> <p>A supplier of a cellulose insulation mixture containing inorganic ammonium salts shall inform the recipient or consumer of the maximum permissible loading rate of the cellulose insulation mixture, expressed in thickness and density.</p> <p>A downstream user of a cellulose insulation mixture containing inorganic ammonium salts shall ensure that the maximum permissible loading rate communicated by the supplier is not exceeded.</p> <p>2. By way of derogation, paragraph 1 shall not apply to placing on the market of cellulose insulation mixtures intended to be used solely for the production of cellulose insulation articles, or to the use of those mixtures in the production of cellulose insulation articles.</p> <p>4. Compliance with the emission limit specified in the first subparagraph of paragraph 1 shall be demonstrated in accordance with Technical Specification CEN/TS 16516, adapted as follows:</p>

	<p>(a) the duration of the test shall be at least 14 days instead of 28 days;</p> <p>(b) the ammonia gas emission shall be measured at least once per day throughout the test;</p> <p>(c) the emission limit shall not be reached or exceeded in any measurement taken during the test;</p> <p>(ç) the relative humidity shall be 90 % instead of 50 %;</p> <p>(d) an appropriate method to measure the ammonia gas emission shall be used;</p> <p>(e) the loading rate, expressed in thickness and density, shall be recorded during the sampling of the cellulose insulation mixtures or articles to be tested.</p>
<p>66. Bisphenol A CAS No 80-05-7 EC No 201-245-8</p>	<p>Shall not be placed on the market in thermal paper in a concentration equal to or greater than 0,02 % by weight.</p>

*Explanation for Appendices 1 to 6 of Annex 17*

**FOREWORD**

**Explanations of column headings**

*Substances:*

The name corresponds to the International Chemical Identification used for the substance in Part 3 of Annex VI to Bylaw on Classification, Labelling and Packaging of substances and mixtures.

Whenever possible, substances are designated by their IUPAC names. Substances listed in EINECS (European Inventory of Existing Commercial Chemical Substances), ELINCS (European List of Notified Substances) or the list of 'No-longer-polymers' are designated using the names in these lists. Other names, such as usual or common names, are included in some cases. Whenever possible, plant protection products and biocides are designated by their ISO names.

*Entries for groups of substances:*

A number of group entries are included in Part 3 of Annex VI to Bylaw on Classification, Labelling and Packaging of Substances and Mixtures. In these cases, the classification requirements will apply to all substances covered by the description.

In some cases, there are classification requirements for specific substances that would be covered by the group entry. In such cases a specific entry is included in Part 3 of Annex VI to Bylaw on Classification, Labelling and Packaging of substances and mixtures for the substance and the group entry will be annotated with the phrase 'except those specified elsewhere in Annex VI of Bylaw on Classification, Labelling and Packaging of substances and mixtures.'

In some cases, individual substances may be covered by more than one group entry. In these cases, the classification of the substance reflects the classification for each of the two group entries. In cases where different classifications for the same hazard are given, the most severe classification will be applied.

*Index number:*

The Index number is the identification code given to the substance in Part 3 of Annex VI to Bylaw on Classification, Labelling and Packaging of substances and mixtures. Substances are listed in the Appendix according to this index number.

*EC numbers:*

The EC number, i.e. EINECS, ELINCS or NLP, is the official number of the substance within the European Union. The EINECS number can be obtained from the European Inventory of Existing Commercial Chemical Substances (EINECS). The ELINCS number can be obtained from the European List of Notified Substances. The NLP number can be obtained from the list of 'No-longer-polymers'.

The EC number is a seven-digit system of the type XXX-XXX-X which starts at 200-001-8 (EINECS), at 400-010-9 (ELINCS) and at 500-001-0 (NLP). This number is indicated in the column entitled 'EC No'.

*CAS number:*

Chemical Abstracts Service (CAS) numbers have been defined for substances to help in their identification.

*Notes:*

The full text of the notes can be found in Part 1 of Annex VI to Bylaw on Classification, Labelling and Packaging of substances and mixtures.

The notes to be taken into account for the purposes of this Bylaw are the following:

*Note A:*

Without prejudice to Article 19(2) of Bylaw on Classification, Labelling and Packaging of substances and mixtures, the name of the substance must appear on the label in the form of one of the designations given in Part 3 of Annex VI to that Bylaw.

In that Part, use is sometimes made of a general description such as '... compounds' or '... salts'. In this case, the supplier who places such a substance on the market is required to state on the label the correct name, due account being taken of Section 1.1.1.4 of Annex VI to Bylaw on Classification, Labelling and Packaging of substances and mixtures.

*Note B:*

Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations.

*Note C:*

Some organic substances may be marketed either in a specific isomeric form or as a mixture of several isomers.

*Note D:*

Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3 of Annex VI to Bylaw on Classification, Labelling and Packaging of substances and mixtures.

However, such substances are sometimes placed on the market in a non-stabilised form. In this case, supplier who places such a substance on the market must state on the label the name of the substance followed by the words 'non-stabilised'.

*Note J:*

The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0,1 % w/w benzene (EC No 200-753-7).

*Note K:*

The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0,1 % w/w 1,3-butadiene (EC No 203-450-8).

*Note L:*

The classification as a carcinogen need not apply if it can be shown that the substance contains less than 3 % DMSO extract as measured by IP 346.

*Note M:*

The classification as a carcinogen need not apply if it can be shown that the substance contains less than 0,005 % w/w benzo[a]-pyrene (EC No 200-028-5).

*Note N:*

The classification as a carcinogen need not apply if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen.

*Note P:*

The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0,1 % w/w benzene (EC No 200-753-7).

*Note R:*

The classification as a carcinogen need not apply to fibres with a length weighted geometric mean diameter, less two standard errors, greater than 6µm.

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Notes for translation:

1. Title of Appendix 7 to Annex 17 was changed as below:  
“Special provisions on the labelling of articles containing asbestos which installed and/or in use before 26/12/2008”
2. Appendices 1 to 10 to Annex 17 of this By-law are same as REACH.
3. Appendix 11 to Annex 17 of REACH is not included in this Bylaw.

## ANNEX 18

### CONDITIONS FOR RECEIVING CERTIFICATE OF COMPETENCY OF CHEMICAL ASSESSMENT EXPERT

#### Introduction

Persons who has attended training on subjects given in Section 2 of this Annex and received a certificate of competency that was given by an institution that has been accredited by Turkish Accreditation Institution (TÜRKAK) for personnel certification on chemical assessment or who has worked in the Ministry in the field of chemicals management for at least 10 years shall be defined as “chemical assessment expert” in the scope of this By-law.

#### SECTION ONE

##### Training, Certification, Exam of competency and certificate of competency for chemical assessment

##### 1- Training and training institution

- a) Period of training shall be at least 64 hours on subjects given in Section 2 of this Annex.
- b) Daily training period shall not exceed 8 hours and in this period max. 2 hours break may be given.
- c) Training shall be given by the experts who meet the criteria stated in Section 4 of this Annex.
- ç) Maximum participant number shall not exceed 30 persons per training.
- d) Trainings, shall conducted in an appropriate and efficient place which enables practices to be done.
- e) Training venues shall have appropriate thermal comfort conditions and adequate lightning.
- f) Equipment which will be used in the trainings, shall be up to date technology.
- g) Training institution, shall submit training programme, which is prepared according to Sections 2 and 4 of this Annex, for approval to the General Directorate of Environmental Management of the Ministry of Environment and Urbanisation.
- ğ) After taking approval from the Ministry, training institution shall start to give at least 64 hours of face-to-face training on the subjects given in Section 2 to the nominees who will take the chemical assessment expert competency examination.
- h) Trainings given by the training institutions shall be observed by the personnel of General Directorate of Environmental Management of Ministry of Environment and Urbanisation at least once in a year.
- ı) when during the observation referred in paragraph (h), in the case of nonconformity to the above stated training conditions, training institutions shall not resume trainings until nonconformity is removed. If nonconformity is not removed in 12 months, the approval certificate of training institution shall be revoked by the Ministry.

##### 2- Certification

- a) Certification institution;

- 1) Shall submit the certification programme prepared according to sections 3 and 5 of this Annex to the Ministry.
- 2) After receiving positive opinion of the Ministry, shall apply to the Turkish Accreditation Institution (TÜRKAK) for personnel certification on chemical assessment in the scope of ISO 17024.
- 3) After accreditation, may start to certify personnel on chemical assessment.
- 4) Shall send contact information, the date and number of competency certificate within in one month from the certification date to the Ministry in writing.
- b) Ministry, shall publish in its website certification institutions accredited by TÜRKAK.

### **3. Competency examination**

- a) Competency examination questions shall consist of two parts as multiple-choice and classic. Examination subjects and scoring is given in the section 5 of this annex.
- b) Examination duration is 180 minutes.
- c) Without prejudice to paragraph 4(c) in section 1, nominees who has taken the trainings according to paragraph 1 in section 1 and meet the requirements stated in section 3 may attend the examination.
- ç) Nominees who scored below 70 in the competency examination, shall have the right to attend the examination two more times in a year without training requirement.

### **4. Competency certificate**

- a) Nominees who scored 70 and above in the examination given by the certification institution shall have right to receive chemical assessment competency certificate.
- b) Validity period of the chemical assessment competency certificate is 5 years.
- c) Persons who want to renew their certificate shall attend the examination in the validity period of their certificate or in 2 years after the expiration date of their certificate without training requirement.
- ç) Competency certificate of persons, who has attended and succeeded the competency examination referred in paragraph (c), shall be revoked. These persons shall be certificated by given a new certificate number.
- d) Persons who documented that they worked in the Ministry on the chemicals management for 10 years shall be certificated by the certification institution without entering competency examination. In this case, the accreditation institution is responsible for the certificates given to these persons.

## SECTION 2

### TRAINING SUBJECTS AND DURATION

Training subject	Duration (hour)
Chemicals Management	At least 3
Legislation: <ul style="list-style-type: none"><li>• Bylaw on Classification, Labelling and Packaging of Substances and Mixtures,</li><li>• Transportation and Storage of Dangerous Goods</li><li>• Occupational health and safety</li><li>• Registration, Evaluation, Authorisation and Restriction of Chemicals</li></ul>	At least 5
Classification of substances and mixtures according to; <ul style="list-style-type: none"><li>• Physico-chemical properties</li><li>• Toxicological properties</li><li>• Ecotoxicological properties</li></ul>	At least 12
Chemicals-human health risk assessment	At least 12
Chemicals-environmental risk assessment	At least 8
Exposure scenarios	At least 8
Chemical Safety Assessment (CSA), Chemical Safety Report (CSR)	At least 8
Requirements for preparation of Safety Data Sheet	At least 8

## SECTION 3

### CRITERIA FOR ENTRY OF THE EXAMINATION

- Being attended at least 64 hours training and,
- Having a Bachelor degree from fields related to chemistry, biology or environmental sciences of Faculty of Science/Science and Literature or Faculty of Engineering or,
- Having a MSc or PhD related to chemistry science or,
- Having a Bachelor degree from other departments of the universities and working at least 5 years on manufacture, laboratory, quality control or chemicals management related in the field of chemicals.

## SECTION 4

### CRITERIA FOR TRAINERS

- Having a Bachelor degree from chemical engineering, environmental engineering, chemistry, biology, chemistry education or biology education departments and working at least 3 years on manufacture, laboratory, quality control or chemicals management related in the

field of chemicals and being trained on each subject of training subjects of Section 2 of this Annex for at least durations given in Section 2 and being able to document this.

b) Having a Bachelor degree from other departments of the universities and working at least 5 years on manufacture, laboratory, quality control or chemicals management related in the field of chemicals and being trained on each subject of training subjects of Section 2 of this Annex for at least durations given in Section 2 and being able to document this.

## SECTION 5

### EXAMINATION SUBJECTS AND SCORING

Examination shall consist of 25 multiple-choice question (with at least 4 choices) and 5 classic questions. Number of questions and scoring of the multiple-choice and classic questions according to subject headings is given in Table-1. In scoring, only right answers shall be taken into account, wrong answers will not affect the scoring of the right answers.

Table-1. Number of Competency examination test questions per subject heading and scoring.

Subject headings of test questions	Number of questions	Score	Total score
Legislation	15	2	30
Chemicals management	2	2	4
Classification knowledge	8	2	16
Classic:			
Human health risk assessment	1	10	10
Environmental risk assessment	1	10	10
Exposure scenarios	1	10	10
CSA/CSR	1	10	10
Preparation of SDS	1	5	5
Preparation of registration dossier	1	5	5
	6		50
<b>TOTAL SCORE</b>			<b>100</b>