

DRAFT BY-LAW ON THE CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES

SECTION ONE AIM, SCOPE, BASIS AND DEFINITIONS

Aim

ARTICLE 1 – (1) The purpose of this By-Law is to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and some articles placed on the market by defining administrative and technical rules and principles for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures.

Scope

ARTICLE 2 – (1) This By-law shall apply to;

- a) classification of substances and mixtures placed on the market, labelling and packaging of hazardous substances and mixtures;
- b) manufacturers, importers and downstream users to classify substances and mixtures placed on the market;
- c) suppliers to label and package substances and mixtures placed on the market;
- ç) manufacturers, producers of articles and importers to classify those substances not placed on the market that are subject to Sections 1, 3, 4 and 5 of Annex 8 of this By-law, except substances that are included in the headings 1, 2 and 3 of the Annex 1 of The By-law on Inventory and Control of Chemicals, published in Official Gazette no. 27092, dated 26/12/2008.
- d) establishing a list of substances with their harmonised classifications and labelling elements in Part 3 of Annex 6;
- e) notification of classification and labelling of hazardous substances,
- f) establishing a classification and labelling inventory of substances, which is made up of all notifications, submissions and harmonised classifications and labelling elements referred to in points (d) and (e).

(2) This By-law:

a) shall not apply to the following substances and mixtures, which are in the finished state, intended for the final user:

1) Medicinal products in the scope of The By-law On Packaging and Labelling of Medicinal Products for Human Use published in Official Gazette no. 25904, dated 12/8/2005.

2) Products in the scope of The By-law On Veterinary Medicinal Products published in Official Gazette no. 28152, dated 24/12/2012 or in the scope of The By-law on Non-medicinal Veterinary Health Products published in Official Gazette no 28145, dated 17/12/2012.

3) Products in the scope of “The By-law on Cosmetics” published in Official Gazette no25823, dated 23/05/2005.

4) Products in the scope of The By-law on Invasive Active Medical Devices” published in Official Gazette no 24693 dated 12/03/2002.

5) Products in the scope of By-law on Turkish Food Codex published in Official Gazette no 28157 dated 29/12/2011.

6) Products in the scope of By-law on Placing on The Market and Use of Animal Feeding Stuff published in the Official Gazette no. 28155 dated 27/12/2011.

b) shall not apply to:

1) Substances and mixtures in scope of The By-law on Safe Transport of Radioactive Substance published in the Official Gazette no. 25869 dated 08/07/2005.

- 2) substances and mixtures which are subject to customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit;
- 3) non-isolated intermediates;
- 4) substances and mixtures for scientific research and development, provided they are used under controlled conditions in accordance with workplace and environmental legislation in force in Türkiye.
- 5) Waste defined in The By-law on General Principles of Waste Management published in the Official Gazette no. 26927 dated 05/07/2008.
- 6) the transport of dangerous goods by air, sea, road, rail or inland waterways save where Article 35 applies;
- 7) Relevant institutions may allow for exemptions from this By-law in specific cases for certain substances or mixtures, where necessary in the interests of defence.

Basis

ARTICLE 3 – (1) This By-law is prepared on the ground of

- a) Environmental Law no.2872 dated 9/08/1983 and Decree Law on Organization and Duties of Ministry of Environment and Urbanization no. 644 dated 4/7/2011, Decree Law on Establishment and Duties of the Ministry of Health and Affiliated Institutions, General Hygiene Law no. 1593 dated 24/04/1930, Law on Establishment and Duties of Ministry of Labour and Social Security no. 3146 dated 9/01/1985, Decree Law on Establishment and Duties of Ministry of Food, Agriculture and Livestock no. 639 dated 3/6/2011, Law on Veterinary Services, Plant Health, Food and Feed Stuff no.5996 dated 11/6/2010, Regulation on Procedures and principles for manufacture, import, transport, conservation, storage, marketing, usage, disposal, inspection of unmonopolized explosive substances and hunting equipment and similar items which came into force by Cabinet Decree dated 14/8/1987 and numbered 87/12028 and Law on Preparation and Implementation of Technical Legislation Concerning Products no.4703 dated 29/6/2001.
- b) This By-law is prepared in parallel with the provisions of Regulation (EC) No 1272/2008 of The European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.

Definitions

ARTICLE 4 – For the purpose of this Regulation, the following definitions shall apply:

- a) ‘alloy’ means a metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means; alloys are considered to be mixtures for the purposes of this By-law,
- b) ‘downstream user’ means any natural or legal person established in Türkiye, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user.
- c) ‘package’ means the complete product of the packing operation, consisting of the packaging and its contents;
- ç) ‘packaging’ means one or more receptacles and any other components or materials necessary for the receptacles to perform their containment and other safety functions;
- d) ‘intermediate packaging’ means packaging placed between inner packaging, or articles, and outer packaging.
- e) ‘intermediate’ means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance;
- f) ‘notifier’ means the manufacturer or the importer, or group of manufacturers or importers notifying to the Competent Authority;

- g) 'scientific research and development' means any scientific experimentation, analysis or chemical research carried out under controlled conditions;
- ğ) CAS Number means the number given by Chemicals Abstract Service;
- h) 'distributor' means any natural or legal person established within Türkiye, including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties;
- i) EINECS means the European Inventory of Existing Commercial Substances. This inventory contains the definitive list of all substances deemed to be on the Community market on 18 September 1981;
- ı) ELINCS means the European List of Notified Chemicals Substances. It designate all new substances placed on the Community market as from 18 September 1981, which has been allocated an ELINCS number after their notification to the European Commission;
- j) 'cut-off value' means a threshold of any classified impurity, additive or individual constituent in a substance or in a mixture, above which threshold these shall be taken into account for determining if the substance or the mixture, respectively, shall be classified;
- k) 'article' means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;
- l) 'producer of an article' means any natural or legal person who makes or assembles an article within Türkiye;
- m) 'differentiation' means distinction within hazard classes depending on the route of exposure or the nature of the effects;
- n) IUPAC name means the name given to the substance by 'International Union of Pure and Applied Chemistry'.
- o) 'non-isolated intermediate' means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place
- ö) 'Related institutions' means Ministry of Health for biocidal products, detergents, air aromatizer products, cleaning products containing strong acids or bases and supplementary chemicals in pool cleaning, Ministry of Food, Agriculture and Livestock for plant protection products, Ministry of Science, Industry and Technology and Ministry for Internal Affairs for regulations concerning explosives and pyrotechnic substances and Ministry of Environment and Urbanization for all other hazardous chemicals and mixtures and for the coordination of studies which will be performed within the frame of this By-law.
- p) 'manufacturing' means production or extraction of substances in the natural state;
- r) 'manufacturer' means any natural or legal person established within Türkiye who manufactures a substance within Türkiye;
- s) 'import' means the physical introduction into the customs territory of Türkiye;
- ş) 'importer' means any natural or legal person established within Türkiye who is responsible for import;
- t) 'concentration limit' means a threshold of any classified impurity, additive or individual constituent in a substance or in a mixture that may trigger classification of the substance or the mixture, respectively;
- u) 'use' means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;
- ü) 'mixture' means a mixture or solution composed of two or more substances;
- v) 'M-factor' means a multiplying factor. It is applied to the concentration of a substance classified as hazardous to the aquatic environment acute category 1 or chronic category 1, and is used to derive by the summation method the classification of a mixture in which the substance is present;

- y) 'substance' means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
- z) 'monomer' means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process;
- aa) 'precautionary statement' means a phrase that describes recommended measure(s) to minimise or prevent adverse effects resulting from exposure to a hazardous substance or mixture due to its use or disposal;
- bb) 'placing on the market' means supplying or making available, whether in return for payment or free of charge, to a third party, or import;
- cc) 'polymer' means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:
- 1) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;
 - 2) less than a simple weight majority of molecules of the same molecular weight.
- çç) SMILES means Simplified Molecular Input Line Entry to represent chemical structure in linear showing form.
- dd) 'supplier' means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture;
- ee) 'UN RTDG' means the United Nations Recommendations on the Transport of Dangerous Goods;
- ff) 'signal word' means a word that indicates the relative level of severity of hazards to alert the reader to a potential hazard; the following two levels are distinguished:
- (a) 'Danger' means a signal word indicating the more severe hazard categories;
 - (b) 'Warning' means a signal word indicating the less severe hazard categories;
- gg) Competent Authority means Ministry of Environment and Urbanization;
- ğğ) 'hazard statement' means a phrase assigned to a hazard class and category that describes the nature of the hazards of a hazardous substance or mixture, including, where appropriate, the degree of hazard;
- hh) 'hazard pictogram' means a graphical composition that includes a symbol plus other graphic elements, such as a border, background pattern or colour that is intended to convey specific information on the hazard concerned;
- ıı) 'hazard category' means the division of criteria within each hazard class, specifying hazard severity;
- ii) 'hazard class' means the nature of the physical, health or environmental hazard.

SECTION TWO

GENERAL PROVISIONS ON CLASSIFICATION, LABELLING AND PACKAGING OF HAZARDOUS SUBSTANCES AND MIXTURES

Classification of Substances and Mixtures

ARTICLE 5- (1) The following principles apply for specification of the hazard classes and classifying dangerous substances and mixtures:

- a) A substance or a mixture fulfilling the criteria relating to physical hazards, health hazards or environmental hazards, laid down in Parts 2 to 5 of Annex 1 is hazardous and shall be classified in relation to the respective hazard classes provided for in that Annex.

b) Where, in Annex 1, hazard classes are differentiated on the basis of the route of exposure or the nature of the effects, the substance or mixture shall be classified in accordance with such differentiation.

General Principles of Classification, Labelling and Packaging of Hazardous Substances and Mixtures

ARTICLE 6 – (1) The principles of classification, labelling and packaging provisions of this By-law are as follows:

a) Manufacturers, importers and downstream users shall classify substances or mixtures in accordance with Section Three before placing them on the market.

b) Without prejudice to the requirements of paragraph 1 (a), manufacturers, producers of articles and importers shall classify those substances not placed on the market in accordance with Section Three.

c) If a substance is subject to harmonised classification and labelling in accordance with Section Six through an entry in Part 3 of Annex 6, that substance shall be classified in accordance with that entry, and a classification of that substance in accordance with Section Three shall not be performed for the hazard classes or differentiations covered by that entry. However, where the substance also falls within one or more hazard classes or differentiations not covered by an entry in Part 3 of Annex 6, classification under Section Three shall be carried out for those hazard classes or differentiations.

ç) Where a substance or mixture is classified as hazardous, suppliers shall ensure that the substance or mixture is labelled and packaged in accordance with Sections Four and Five, before placing it on the market.

d) In fulfilling their responsibilities under paragraph (1)(ç), distributors may use the classification for a substance or mixture derived in accordance with Section Three by an actor in the supply chain.

e) In fulfilling their responsibilities under paragraphs (1)(a) and (1)(c), downstream users may use the classification of a substance or mixture derived in accordance with Section Three by an actor in the supply chain, provided that they do not change the composition of the substance or mixture.

f) A mixture referred to in Part 2 of Annex 2 that contains any substance classified as hazardous shall not be placed on the market, unless it is labelled in accordance with Section Four.

g) For the purposes of this By-law, the articles referred to in section 2.1 of Annex 1 shall be classified, labelled and packaged in accordance with the rules for substances and mixtures before being placed on the market.

ğ) Suppliers in a supply chain shall cooperate to meet the requirements for classification, labelling and packaging in this By-law.

h) Substances and mixtures shall not be placed on the market unless they comply with this Regulation.

ı) Placing on the market of substances and mixtures which are classified, labelled and packaged according to the provisions of this By-law cannot be prohibited, restricted or impeded.

SECTION THREE HAZARD CLASSIFICATION

Identification and examination of available information on substances

ARTICLE 7-(1) Manufacturers, importers and downstream users of a substance shall identify the relevant available information for the purposes of determining whether the substance

entails a physical, health or environmental hazard as set out in Annex 1, and, in particular, the following:

- (a) data generated in accordance with any of the methods referred to in Article 10(3);
 - (b) epidemiological data and experience on the effects on humans, such as occupational data and data from accident databases;
 - (c) any other information generated in accordance with Annex 9 to this By-law;
 - (ç) any new scientific information;
 - (d) any other information generated under internationally recognised chemical programmes.
- (2) Manufacturers, importers and downstream users shall examine the information referred to in paragraph 1 to ascertain whether it is adequate, reliable and scientifically valid for the purpose of the evaluation pursuant to Articles (11) to (18).

Identification and examination of available information on mixtures

ARTICLE 8-(1) Manufacturers, importers and downstream users of a mixture shall identify the relevant available information on the mixture itself or the substances contained in it for the purposes of determining whether the mixture entails a physical, health or environmental hazard as set out in Annex 1, and, in particular, the following:

- (a) data generated in accordance with any of the methods referred to in Article 10(3) on the mixture itself or the substances contained in it;
- (b) epidemiological data and experience on the effects on humans, such as occupational data and data from accident databases;
- (c) any other information generated in accordance with Annex 9 to this By-law for the mixture itself or the substances contained in it;
- (ç) any new scientific information;
- (d) any other information on the mixture itself or the substances contained in it generated under internationally recognised chemical programmes.

(2) Subject to paragraphs 3 and 4, where the information referred to in paragraph 1 is available for the mixture itself, and the manufacturer, importer or downstream user has ascertained that information to be adequate and reliable and where applicable, scientifically valid, that manufacturer, importer or downstream user shall use that information for the purposes of the evaluation pursuant to Section Three.

(3) For the evaluation of mixtures pursuant to Articles (11) to (18) in relation to the ‘germ cell mutagenicity’, ‘carcinogenicity’ and ‘reproductive toxicity’ hazard classes referred to in sections 3.5.3.1, 3.6.3.1 and 3.7.3.1 of Annex 1, the manufacturer, importer or downstream user shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture. Further, in cases where the available test data on the mixture itself demonstrate germ cell mutagenic, carcinogenic or toxic to reproduction effects which have not been identified from the information on the individual substances, those data shall also be taken into account.

(4) For the evaluation of mixtures pursuant to Articles (11) to (18) in relation to the ‘biodegradation and bioaccumulation’ properties within the ‘hazardous to the aquatic environment’ hazard class referred to in sections 4.1.2.8 and 4.1.2.9 of Annex 1, the manufacturer, importer or downstream user shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture.

(5) Where no or inadequate test data on the mixture itself of the kind referred to in paragraph 1 are available, the manufacturer, importer or downstream user shall use other available information on individual substances and similar tested mixtures which may also be considered relevant for the purposes of determining whether the mixture is hazardous, provided that that manufacturer, importer or downstream user has ascertained that information to be adequate and reliable for the purpose of the evaluation pursuant to Article 11(4).

Animal and human testing

ARTICLE 9 - (1) Where new tests are carried out for the purposes of this By-law, tests on animals within the meaning of By-law on Protection of Test Animals Used in Experimental and Other Scientific Purposes published in Official Gazette no.25464 and dated 16/5/2004 and The By-law on Procedures and Principles of Establishing, Operating and Inspection of Laboratories which generates Testing Animal Livestock or which perform tests on Animals shall be undertaken only where no other alternatives, which provide adequate reliability and quality of data, are possible.

(2) Tests on non-human primates shall be prohibited for the purposes of this By-law.

(3) Tests on humans shall not be performed for the purposes of this By-law. Data obtained from other sources, such as clinical studies, can however be used for the purposes of this By-law.

Generating new information for substances and mixtures

ARTICLE 10 - (1) For the purposes of determining whether a substance or a mixture entails a health or environmental hazard as set out in Annex 1 to this Regulation, the manufacturer, importer or downstream user may, provided that he has exhausted all other means of generating information including by applying the rules provided for in Annex 9 of this By-law perform new tests.

(2) For the purposes of determining whether a substance or a mixture entails any of the physical hazards referred to in Part 2 of Annex 1, the manufacturer, importer or downstream user shall perform the tests required in that Part, unless there is adequate and reliable information already available.

(3) The tests referred to in paragraph 1 shall be conducted in accordance with one of the following methods:

(a) the test methods referred to in

or

(b) sound scientific principles that are internationally recognised or methods validated according to international procedures.

(4) Where the manufacturer, importer or downstream user carries out new ecotoxicological or toxicological tests and analyses, these shall be carried out in compliance with The By-law on Principles of Good Laboratory Practices and Certification of Testing Laboratories published in Official Gazette no. 24796 and dated 25/6/2002.

(5) Where new tests for physical hazards are carried out for the purposes of this By-law, they shall be carried out, at the latest from 1 January 2015, in laboratories which is certificated in compliance with The By-law on Principles of Good Laboratory Practices and Certification of Testing Laboratories or by laboratories complying with a relevant internationally recognised standard.

(6) Tests that are carried out for the purposes of this By-law shall be carried out on the substance or on the mixture in the form(s) or physical state(s) in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used.

Evaluation of hazard information for substances and mixtures

ARTICLE 11 - (1) Manufacturers, importers and downstream users of a substance or a mixture shall evaluate the information identified in accordance with Articles 7 to 10 by applying to it the criteria for classification for each hazard class or differentiation in Parts 2 to 5 of Annex 1, so as to ascertain the hazards associated with the substance or mixture.

(2) In evaluating available test data for a substance or a mixture which have been obtained from test methods other than those referred to in Article 10(3), manufacturers, importers and downstream users shall compare the test methods employed with those indicated in that Article in order to determine whether the use of those test methods affects the evaluation referred to in paragraph 1 of this Article.

(3) Where the criteria cannot be applied directly to available identified information, manufacturers, importers and downstream users shall carry out an evaluation by applying a weight of evidence determination using expert judgement in accordance with section 1.1.1 of Annex 1 to this By-law, weighing all available information having a bearing on the determination of the hazards of the substance or the mixture, and in accordance with Annex 9.

(4) Where only the information referred to in Article 8(5) is available, manufacturers, importers and downstream users shall apply the bridging principles referred to in section 1.1.3 and in each section of Parts 3 and 4 of Annex 1 for the purposes of the evaluation. However, where that information permits the application neither of the bridging principles nor the principles for using expert judgement and weight of evidence determination as described in Part 1 of Annex 1, manufacturers, importers and downstream users shall evaluate the information by applying the other method or methods described in each section of Parts 3 and 4 of Annex 1.

(5) When evaluating the available information for the purposes of classification, the manufacturers, importers and downstream users shall consider the forms or physical states in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used.

Concentration limits and M-factors for classification of substances and mixtures

ARTICLE 12 - (1) Specific concentration limits and generic concentration limits are limits assigned to a substance indicating a threshold at or above which the presence of that substance in another substance or in a mixture as an identified impurity, additive or individual constituent leads to the classification of the substance or mixture as hazardous.

Specific concentration limits shall be set by the manufacturer, importer or downstream user where adequate and reliable scientific information shows that the hazard of a substance is evident when the substance is present at a level below the concentrations set for any hazard class in Part 2 of Annex 1 or below the generic concentration limits set for any hazard class in Parts 3, 4 and 5 of Annex 1.

In exceptional circumstances specific concentration limits may be set by the manufacturer, importer or downstream user where he has adequate, reliable and conclusive scientific information that a hazard of a substance classified as hazardous is not evident at a level above the concentrations set for the relevant hazard class in Part 2 of Annex 1 or above the generic concentration limits set for the relevant hazard class in Parts 3, 4 and 5 of that Annex.

(2) M-factors for substances classified as hazardous to the aquatic environment, acute category 1 or chronic category 1, shall be established by manufacturers, importers and downstream users.

(3) Notwithstanding paragraph 1, specific concentration limits shall not be set for harmonised hazard classes or differentiations for substances included in Part 3 of Annex 6.

(4) Notwithstanding paragraph 2, M-factors shall not be set for harmonised hazard classes or differentiations for substances included in Part 3 of Annex 6 for which an M-factor is given in that Part.

However, where an M-factor is not given in Part 3 of Annex 6 for substances classified as hazardous to the aquatic environment, acute category 1 or chronic category 1, an M-factor based on available data for the substance shall be set by the manufacturer, importer or downstream user. When a mixture including the substance is classified by the manufacturer, importer or downstream user using the summation method, this M-factor shall be used.

(5) In setting the specific concentration limit or M-factor manufacturers, importers and downstream users shall take into account any specific concentration limits or M-factors for that substance which have been included in the classification and labelling inventory.

(6) Specific concentration limits set in accordance with paragraph 1 shall take precedence over the concentrations in the relevant sections of Part 2 of Annex 1 or the generic

concentration limits for classification in the relevant sections of Parts 2, 3, 4 and 5 of Annex 1.

Cut-off values

ARTICLE 13 - (1) Where a substance contains another substance, itself classified as hazardous, whether in the form of an identified impurity, additive or individual constituent, this shall be taken into account for the purposes of classification, if the concentration of the identified impurity, additive or individual constituent is equal to, or greater than, the applicable cut- off value in accordance with section 1.1.2.2 of Annex 1.

2. Where a mixture contains a substance classified as hazardous, whether as a component or in the form of an identified impurity or additive, this information shall be taken into account for the purposes of classification, if the concentration of that substance is equal to or greater than its cut-off value in accordance with section 1.1.2.2 of Annex 1.

Specific cases requiring further evaluation

ARTICLE 14 – (1) Where, as a result of the evaluation carried out pursuant to Article 11, the following properties or effects are identified, manufacturers, importers and downstream users shall take them into account for the purposes of classification:

- (a) adequate and reliable information demonstrates that in practice the physical hazards of a substance or a mixture differ from those shown by tests;
- (b) conclusive scientific experimental data show that the substance or mixture is not biologically available and those data have been ascertained to be adequate and reliable;
- (c) adequate and reliable scientific information demonstrates the potential occurrence of synergistic or antagonistic effects among the substances in a mixture for which the evaluation was decided on the basis of the information for the substances in the mixture.

Decision To Classify Substances And Mixtures

ARTICLE 15- (1) If the evaluation undertaken pursuant to Article 11 and Article 14 shows that the hazards associated with the substance or mixture meet the criteria for classification in one or more hazard classes or differentiations in Parts 2 to 5 of Annex 1, manufacturers, importers and downstream users shall classify the substance or mixture in relation to the relevant hazard class or classes or differentiations in accordance with subparagraphs (a) and (b) of paragraph.

- a) one or more hazard categories for each relevant hazard class or differentiation;
- b) subject to Article 23, one or more hazard statements corresponding to each hazard category assigned in accordance with (a).

Specific Rules For The Classification Of Mixtures

ARTICLE 16- (1) The classification of a mixture shall not be affected where the evaluation of the information indicates any of the following:

- a) that the substances in the mixture react slowly with atmospheric gases, in particular oxygen, carbon dioxide, water vapour, to form different substances at low concentration;
- b) that the substances in the mixture react very slowly with other substances in the mixture to form different substances at low concentration;
- c) that the substances in the mixture may self-polymerise to form oligomers or polymers, at low concentration.

(2) A mixture need not be classified for explosive, oxidising, or flammable properties as referred to in Part 2 of Annex 1 provided that any of the following requirements are met:

- (a) none of the substances in the mixture possesses any of those properties and, on the basis of the information available to the supplier, the mixture is unlikely to present hazards of this kind;
- (b) in the event of a change in the composition of a mixture, scientific evidence indicates that an evaluation of the information on the mixture will not lead to a change in classification;

(c) where a mixture is placed on the market in the form of an aerosol dispenser, it satisfies the provisions of the By-law on Aerosol Containers published in Official Gazette no.24246 and dated 30/11/2000.

Review of classification for substances and mixtures

ARTICLE 17- (1) Manufacturers, importers and downstream users shall take all reasonable steps available to them to make themselves aware of new scientific or technical information that may affect the classification of the substances or mixtures they place on the market and carry out a new evaluation in accordance with this Section.

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

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

(b) a change in the composition involving the substitution or addition of one or more constituents in concentrations at or above the cut-off value referred to in Article 13.

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

(4) Manufacturers, importers and downstream users shall adapt the classification of the substance or the mixture in accordance with the results of the new evaluation except where there are harmonised hazard classes or differentiations for substances included in Part 3 of Annex 6.

(5) For paragraphs 1 to 4 of this Article, when the substance or mixture concerned is within the scope of By-law on Classification, Packaging and Labelling of Plant Protection Products published in Official Gazette no. 27885, dated 25/03/2011 and By-law on Biocidal Products published in Official Gazette 274449 (4th replica) dated 31/12/2009, , the requirements of those By-laws shall also apply.

Classification of substances included in the classification and labelling inventory

ARTICLE 18- (1) Manufacturers and importers may classify a substance differently from the classification already included in the classification and labelling inventory, provided they submit the reasons for the classification to the Competent Authority together with the notification in accordance with Article 42.

(2) Paragraph 1 shall not apply if the classification included in the classification and labelling inventory is a harmonised classification included in Part 3 of Annex 6.

SECTION FOUR HAZARD COMMUNICATION IN THE FORM OF LABELLING

Content of the label

ARTICLE 19 – (1) A substance or mixture classified as hazardous and contained in packaging shall bear a label including the following elements:

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

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

(c) product identifiers as specified in Article 20;

(ç) where applicable, hazard pictograms in accordance with Article 21;

(d) where applicable, signal words in accordance with Article 22;

(e) where applicable, hazard statements in accordance with Article 23;

(f) where applicable, the appropriate precautionary statements in accordance with Article 24;

(g) where applicable, a section for supplemental information in accordance with Article 27.

2. The label shall be written in Turkish where the substance or mixture is placed on the market in Turkey. Suppliers may use more languages on their labels than Turkish, provided that the same details appear in all languages used.

Product identifiers

ARTICLE 20-(1) The label shall include details permitting the identification of the substance or mixture (hereinafter referred to as ‘product identifiers’). The term used for identification of the substance or mixture shall be the same as that used in the safety data sheet drawn up in accordance with By-law on Compilation and Distribution of Safety Data Sheets of Dangerous Substances and Preparations published in Official Gazette no.27092, dated 26/12/2008, without prejudice to Article 19(2) of this By-law.

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

(a) if the substance is included in Part 3 of Annex 6, a name and EC and/or CAS number as given therein;

(b) if the substance is not included in Part 3 of Annex 6, but appears in the classification and labelling inventory, a name and EC and/or CAS number as given therein;

(c) if the substance is not included in Part 3 of Annex 6 nor in the classification and labelling inventory, the number provided by the CAS number, together with the name set out in the nomenclature provided by the , or the CAS number together with another international chemical name(s); or

(ç) if the CAS number is not available, the name set out in the IUPAC Nomenclature or another international chemical name(s). Where the name in the IUPAC nomenclature exceeds 100 characters, one of the other names (usual name, trade name, abbreviation) may be used provided that the notification in accordance with Article 42 includes both the name set out in the IUPAC Nomenclature and the other name used.

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

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

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

(4) Where, in the case referred to in paragraph (3)(b), that requirement leads to the provision of multiple chemical names, a maximum of four chemical names shall suffice, unless more than four names are needed to reflect the nature and the severity of the hazards. In the latter case, more than four chemical names may be used.

Hazard pictograms

ARTICLE 21-(1) The label shall include the relevant hazard pictogram(s), intended to convey specific information on the hazard concerned.

(2) Subject to Article 35, hazard pictograms shall fulfil the requirements laid down in section 1.2.1 of Annex 1 and in Annex 5.

(3) The hazard pictogram relevant for each specific classification is set out in the tables indicating the label elements required for each hazard class in Annex 1.

Signal words

ARTICLE 22-(1) The label shall include the relevant signal word in accordance with the classification of the hazardous substance or mixture.

(2) The signal word relevant for each specific classification is set out in the tables indicating the label elements required for each hazard class in Parts 2 to 5 of Annex 1.

(3) Where the signal word ‘Danger’ is used on the label, the signal word ‘Warning’ shall not appear on the label.

Hazard statements

ARTICLE 23-(1) The label shall include the relevant hazard statements in accordance with the classification of the hazardous substance or mixture.

(2) The hazard statements relevant for each classification are set out in the tables indicating the label elements required for each hazard class in Parts 2 to 5 of Annex 1.

(3) Where a substance is included in Part 3 of Annex 6, the hazard statement relevant for each specific classification covered by the entry in that Part shall be used on the label, together with the hazard statements referred to in paragraph 2 for any other classification not covered by that entry.

(4) The hazard statements shall be worded in accordance with Annex 3.

Precautionary statements

ARTICLE 24-(1) The label shall include the relevant precautionary statements.

(2) The precautionary statements shall be selected from those set out in the tables in Parts 2 to 5 of Annex 1 indicating the label elements for each hazard class.

(3) The precautionary statements shall be selected in accordance with the criteria laid down in Part 1 of Annex 4 taking into account the hazard statements and the intended or identified use or uses of the substance or the mixture.

(4) The precautionary statements shall be worded in accordance with Part 2 of Annex 4.

Derogations from Labelling Requirements for Special Cases

ARTICLE 25-(1) The specific provisions on labelling laid down in section 1.3 of Annex 1 shall apply in respect of the following:

a) Transportable gas cylinders;

b) Gas containers intended for propane, butane or liquefied petroleum gas;

c) Aerosols and containers fitted with a sealed spray attachment and containing substances or mixtures classified as presenting an aspiration hazard;

ç) Metals in massive form, alloys, mixtures containing polymers, mixtures containing elastomers;

d) Explosives, as referred to in section 2.1 of Annex 1, placed on the market with a view to obtaining an explosive or pyrotechnic effect.

Request for Use of an Alternative Chemical Name

ARTICLE 26-(1) The manufacturer, importer or downstream user of a substance or a mixture may submit a request to the Relevant Institution to use an alternative chemical name which refers to that substance either by means of a name that identifies the most important functional chemical groups or by means of an alternative designation, where the substance meets the criteria set out in Part 1 of Annex 1 and where he can demonstrate that disclosure on the label or in the safety data sheet of the chemical identity of that substance puts the confidential nature of his business, in particular his intellectual property rights, at risk.

(2) Any request referred to in paragraph 1 of this Article shall be made to the Relevant Institution in the format exists in the web page of the Competent Authority.

(3) The Relevant Institution may require further information from the manufacturer, importer or downstream user making the request if such information is necessary to take a decision. If the Relevant Institution raises no objection within six weeks of the request or the receipt of further required information, the use of the requested name shall be deemed to be allowed.

(4) If the Relevant Institution does not accept the request, manufacturer, importer or downstream user may waive an objection to the Competent Authority.

(5) The Relevant Institution shall inform Competent Authority about the outcome of the request in accordance with paragraph 3 or 4 and provide Competent Authority with the information submitted by the manufacturer, importer or downstream user.

(6) Where new information shows that an alternative chemical name used does not provide sufficient information for necessary health and safety precautions to be taken at the workplace

and to ensure that risks from handling the mixture can be controlled, the Relevant Institution shall review its decision on the use of that alternative chemical name. The Relevant Institution may withdraw its decision or amend it by a decision specifying which alternative chemical name is allowed to be used. If the Relevant Institution withdraws or amends its decision, it informs the Competent Authority together with its justifications within four weeks of the withdrawing or amendment.

(7) Where the use of an alternative chemical name has been allowed, but the classification of the substance in a mixture for which the alternative name is used no longer meets the criteria set out in section 1.4.1 of Annex 1, the supplier of that substance in a mixture shall use the product identifier for the substance in accordance with Article 20 on the label and in the safety data sheet, and not the alternative chemical name.

(8) The manufacturer, importer or downstream user may use the alternative name, accepted as valid by the Relevant Institution, on the label and in the safety data sheet for six years. The information concerning the substances in mixtures or in articles can be publicly available, free of charge, in accordance with Annex 10 Part 1 and Part 2 by Relevant Institution.

(9) Where the supplier of a mixture, before 01/06/2016, has demonstrated under Article 37 of By-Law on the Classification, Packaging and Labelling of Dangerous Substances and Preparations published in the Official Gazette dated 26/12/2008 and numbered 27092, that the disclosure of the chemical identity of a substance in a mixture puts the confidential nature of his business at risk, he can continue to use the agreed alternative name for the purposes of this By-Law.

(10) Manufacturer, importer or downstream user pay fee which is published in the website of the Competent Authority, to Relevant Institution for the alternative name presented in accordance with Article 26 (1) and 26(2).

Supplemental information on the label

ARTICLE 27-(1) Following provisions shall be applied for supplemental information on label:

a) Statements shall be included in the section for supplemental information on the label where a substance or mixture classified as hazardous has the physical properties or health properties referred to in sections 1.1 and 1.2 of Annex 2 and Part 2 of Annex 3.

b) Where a substance is included in Part 3 of Annex 6, any supplemental hazard statements given therein for the substance shall be included in the supplemental information on the label.

(2) A statement shall be included in the section for supplemental information on the label where a substance or mixture classified as hazardous falls within the scope of By-Law on the Classification, Packaging and Labelling of Plant Protection Products published in the Official Gazette dated 25/03/2011 and numbered 27885. The statement shall be worded in accordance with Part 4 of Annex 2 and Part 3 of Annex 3 to this By-Law.

(3) The supplier may include supplemental information in the section for supplemental information on the label other than that referred to in paragraphs 1 and 2, provided that that information does not make it more difficult to identify the label elements referred to in Article 19(1) (a) to (f) and that it provides further details and does not contradict or cast doubt on the validity of the information specified by those elements.

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

(5) Where a mixture contains any substance classified as hazardous,

a) It shall be labelled in accordance with Part 2 of Annex 2. The statements shall be worded in accordance with Part 3 of Annex 3 and shall be placed in the supplemental information section of the label.

b) The label shall also include the product identifier referred to in Article 20 and the name, address and telephone number of the supplier of the mixture.

Principles of precedence for hazard pictograms

ARTICLE 28- (1) Where the classification of a substance or mixture would result in more than one hazard pictogram on the label, the following rules of precedence shall apply to reduce the number of hazard pictograms required:

- a) if the hazard pictogram ‘GHS01’ applies, the use of the hazard pictograms ‘GHS02’ and ‘GHS03’ shall be optional, except in cases where more than one of these hazard pictograms are compulsory;
- b) if the hazard pictogram ‘GHS06’ applies, the hazard pictogram ‘GHS07’ shall not appear;
- c) if the hazard pictogram ‘GHS05’ applies, the hazard pictogram ‘GHS07’ shall not appear for skin or eye irritation;
- ç) if the hazard pictogram ‘GHS08’ applies for respiratory sensitisation, the hazard pictogram ‘GHS07’ shall not appear for skin sensitisation or for skin and eye irritation;
- d) if the hazard pictogram “GHS02” or “GHS06” applies, the use of the hazard pictogram “GHS04” shall be optional.’.

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

(3) For substances that are included in Part 3 of Annex 6 and also subject to classification pursuant to Part 3, the label shall include the hazard pictogram corresponding to the most severe hazard category for each relevant hazard class.

Principles of precedence for hazard statements

ARTICLE 29- (1) If a substance or mixture is classified within several hazard classes or differentiations of a hazard class, all hazard statements resulting from the classification shall appear on the label, unless there is evident duplication or redundancy.

Principles of precedence for precautionary statements

ARTICLE 30- (1) Where the selection of the precautionary statements results in certain precautionary statements being clearly redundant or unnecessary given the specific substance, mixture or packaging, such statements shall be omitted from the label.

(2) Where the substance or mixture is supplied to the general public, one precautionary statement addressing the disposal of that substance or mixture as well as the disposal of packaging shall appear on the label, unless not required under Article 24. In all other cases, a precautionary statement addressing disposal shall not be required, where it is clear that the disposal of the substance or mixture or the packaging does not present a hazard to human health or the environment.

(3) Not more than six precautionary statements shall appear on the label, unless necessary to reflect the nature and the severity of the hazards.

Exemptions from labelling and packaging requirements

ARTICLE 31- (1) Where the packaging of a substance or a mixture is either in such a shape or form or is so small that it is impossible to meet the requirements of Article 33 for a label in another language together with Turkish, the label elements in accordance with Article 19(2) shall be provided in accordance with section 1.5.1 of Annex 1.

(2) If the full label information cannot be provided in the way specified in paragraph 1 the label information may be reduced in accordance with section 1.5.2 of Annex 1.

(3) When a hazardous substance or mixture referred to in Part 5 of Annex 2 is supplied to the general public without packaging it shall be accompanied by a copy of the label elements in accordance with Article 19.

Updating information on labels

ARTICLE 32-(1) The supplier shall ensure that the label is updated, without undue delay, following any change to the classification and labelling of that substance or mixture, where the new hazard is more severe or where new supplemental labelling elements are required under Article 27, taking into account the nature of the change as regards the protection of human health and the environment. Suppliers shall cooperate in accordance with Article 6(1)(g) to complete the changes to the labelling without undue delay.

(2) Where labelling changes are required other than those referred to in paragraph 1, the supplier shall ensure that the label is updated within 18 months.

(3) The supplier of a substance or a mixture within the scope of “By-Law on the Classification, Packaging and Labelling of Plant Protection Products” published in the Official Gazette dated 25/03/2011 and numbered 27885 and” Biocidal Products By-Law” published in the Official Gazette dated 31/12/2009 and numbered 27449 (4th Repeting) shall update the label in accordance with those By-Laws.

General rules for the application of labels

ARTICLE 33-(1) Labels shall be firmly affixed to one or more surfaces of the packaging immediately containing the substance or mixture and shall be readable horizontally when the package is set down normally.

(2) The colour and presentation of any label shall be such that the hazard pictogram stands out clearly.

(3) The label elements referred to in Article 19(1) shall be clearly and indelibly marked. They shall stand out clearly from the background and be of such size and spacing as to be easily read.

(4) The shape, colour and the size of a hazard pictogram as well as the dimensions of the label shall be as set out in section 1.2.1 of Annex 1.

(5) A label shall not be required when the label elements referred to in Article 19(1) are shown clearly on the packaging itself. In such cases, the requirements of this Section applicable to a label shall be applied to the information shown on the packaging.

Location of Information on the Label

ARTICLE 34-(1) The hazard pictograms, hazard statements, precautionary statements and signal word shall be located together on the label.

(2) The supplier may decide the order of the hazard statements and precautionary statements on the label. However, subject to paragraph 4, all hazard statements and precautionary statements shall be grouped on the label by language.

(3) Groups of hazard statements and groups of precautionary statements referred to in paragraph 2 shall be located together on the label by language.

(4) The supplemental information shall be placed in the supplemental information section referred to in Article 27, and shall be located with the other label elements specified in Article 19(1)(a) to (f).

(5) In addition to its use in hazard pictograms, colour may be used on other areas of the label to implement special labelling requirements.

(6) Label elements resulting from the requirements provided for other legislation acts shall be placed in the section for supplemental information on the label referred to in Article 27.

Specific Rules for Labelling of Outer Packaging, Inner Packaging and Single Packaging

ARTICLE 35- (1) Where a package consists of an outer and an inner packaging, together with any intermediate packaging, and the outer packaging meets labelling provisions in accordance with the rules on the transport of dangerous goods, the inner and any intermediate packaging shall be labelled in accordance with this By-Law. The outer packaging may also be labelled in accordance with this By-Law. Where the hazard pictogram(s) required by this By-

Law relate to the same hazard as in the rules for the transport of dangerous goods, the hazard pictogram(s) required by this By-Law need not appear on the outer packaging.

(2) Where the outer packaging of a package is not required to meet labelling provisions in accordance with rules on the transport of dangerous goods, both the outer and any inner packaging, including any intermediate packaging, shall be labelled in accordance with this By-Law. However, if the outer packaging permits the inner or intermediate packaging labelling to be clearly seen, the outer packaging need not be labelled.

(3) Single packages that meet the labelling provisions in accordance with the rules on the transport of dangerous goods shall be labelled both in accordance with this By-Law and the rules on the transport of dangerous goods. Where the hazard pictogram(s) required by this By-Law relate to the same hazard as in rules on the transport of dangerous goods, the hazard pictogram(s) required by this By-Law need not appear on the outer packaging.

Hazard Communication

ARTICLE 36 –(1) Informations about the hazards of the hazardous substance and mixture are communicated via the label.

SECTION FIVE

Packaging

Requirements of Packaging

ARTICLE 37-(1) Packaging containing hazardous substances or mixtures shall satisfy the following requirements:

- a) the packaging shall be designed and constructed so that its contents cannot escape, except in cases where other more specific safety devices are prescribed,
- b) the materials constituting the packaging and fastenings shall not be susceptible to damage by the contents, or liable to form hazardous compounds with the contents,
- c) the packaging and fastenings shall be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling;
- ç) packaging fitted with replaceable fastening devices shall be designed so that it can be refastened repeatedly without the contents escaping.

(2) Packaging containing a hazardous substance or a mixture supplied to the general public shall satisfy the following requirements:

- a) Packaging shall not have either a shape or design likely to attract or arouse the active curiosity of children or to mislead consumers, or have a similar presentation or a design used for foodstuff or animal feeding stuff or medicinal or cosmetic products, which would mislead consumers.
- b) Where the packaging contains a substance or mixture which meets the requirements in section 3.1.1 of Annex 2 it shall have a child-resistant fastening in accordance with sections 3.1.2, 3.1.3 and 3.1.4 of Annex 2.
- c) Where the packaging contains a substance or mixture which meets the requirements in section 3.2.1 of Annex 2 it shall bear a tactile warning of danger in accordance with section 3.2.2 of Annex 2.

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

SECTION SIX
Harmonisation of Classification and Labelling of Substances and
the Classification and Labelling Inventory

Harmonisation of Classification and Labelling of Substances

ARTICLE 38-(1) A substance that fulfils the criteria set out in Annex 1 for the following shall normally be subject to harmonised classification and labelling in accordance with Article 39:

- a) respiratory sensitisation, category 1 (Annex 1, section 3.4),
- b) germ cell mutagenicity, category 1A, 1B or 2 (Annex 1, section 3.5);
- c) carcinogenicity, category 1A, 1B or 2 (Annex 1, section 3.6);
- ç) reproductive toxicity, category 1A, 1B or 2 (Annex 1, section 3.7).

(2) A substance that is an active substance in the meaning of By-Law on the Classification, Packaging and Labelling of Plant Protection Products published in the Official Gazette dated 25/03/2011 and numbered 27885 and Biocidal Products By-Law published in the Official Gazette dated 31/12/2009 and numbered 27449 shall normally be subject to harmonised classification and labelling. For such substances, the procedures set out in Article 39, paragraphs 1, 4, 5 and 6 shall apply.

(3) Where a substance fulfils the criteria for other hazard classes or differentiations than those referred to in paragraph 1 and does not fall under paragraph 2, a harmonised classification and labelling in accordance with Article 39 may also be added to Annex 6 on a case-by-case basis, if justification is provided demonstrating the need for such action.

Procedure for Harmonisation of Classification and Labelling of Substances

ARTICLE 39-(1) A relevant institution may submit to the Competent Authority a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits or M-factors, or a proposal for a revision thereof. The proposal shall follow the format set out in Part 2 of Annex 6 and contain the relevant information provided for in Part 1 of Annex 6.

(2) A manufacturer, importer or downstream user of a substance may submit to the Competent Authority a proposal for harmonised classification and labelling of that substance and, where appropriate, specific concentration limits or M-factors, provided that there is no entry in Part 3 of Annex 6 for such a substance in relation to the hazard class or differentiation covered by that proposal.

(3) Where the proposal of the manufacturer, importer or downstream user concerns the harmonised classification and labelling of a substance in accordance with Article 38(3), it shall be accompanied by the fee issued on the web site of the Competent authority annually which is determined in the unit price list of the revolving fund

(4) Competent Authority shall adopt an opinion on any proposal submitted pursuant to paragraphs 1 or 2 within 18 months of receipt of the proposal, giving the parties concerned the opportunity to comment.

(5) Where the Competent Authority finds that the harmonisation of the classification and labelling of the substance concerned is appropriate, it shall, without undue delay, submit a draft decision concerning the inclusion of that substance together with the relevant classification and labelling elements in Table 3.1 of Part 3 of Annex 6 and, where appropriate, the specific concentration limits or M-factors. A corresponding entry shall be included in Table 3.2 of Part 3 of Annex 6 subject to the same conditions,

(6) Manufacturers, importers and downstream users who have new information which may lead to a change of the harmonised classification and labelling elements of a substance in Part 3 of Annex 6 shall submit a proposal in accordance with the paragraph 2 to the competent authority.

Content of Opinions and Decisions for Harmonised Classification and Labelling and Accessibility of Information

ARTICLE 40- (1) Any opinion referred to in Article 39(4) and any decision according to Article 39(5) shall at least specify for each substance:

- a) Identification of the substance;
 - 1) Name(s) in the IUPAC nomenclature or other international chemical name(s)
 - 2) Usual name, trade name, abbreviation
 - 3) EINECS or ELINCS number (if available and appropriate)
 - 4) CAS name and CAS number (if available)
 - 5) Other identity code (if available)
 - 6) Molecular and structural formula (including SMILES notation, if available)
 - 7) Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)
 - 8) Molecular weight or molecular weight range
 - 9) Degree of purity (%)
 - 10) Nature of impurities, including isomers and by-products
 - 11) Percentage of (significant) main impurities
 - 12) Nature and order of magnitude (... ppm, ... %) of any additives (e.g. stabilising agents or inhibitors)
 - b) the classification of the substance referred to in Article 38, including a statement of reasons;
 - c) specific concentration limits or M-factors, where applicable;
 - ç) the label elements specified in points (ç), (d) and (e) of Article 19(1) for the substance, together with any supplemental hazard statements for the substance, determined in accordance with Article 27(1);
 - d) any other parameter enabling an assessment to be made of the health or environmental hazard of mixtures containing the hazardous substance in question or of substances containing such hazardous substances as identified impurities, additives and constituents, if relevant.
- (2) When making publicly available an opinion or a decision as referred to in Article 39(4) and (5) of this By-Law, the provisions stated in the third part of Annex 10 shall apply.

Classification and Labelling Inventory

ARTICLE 41- (1) Provisions related to the classification and labelling inventory included in the Article 42, 43 and 44 shall apply to:

- a) Substances specified in the first, second, third and fourth provisions of Annex 8,
- b) Substances within the scope of Article 2 which meet the criteria for classification as hazardous and are placed on the market either on their own or in a mixture above the concentration limits specified in this By-Law or By-law on the Classification, Packaging and Labelling of Dangerous Substances and Preparations, where relevant, which results in the classification of the mixture as hazardous.

Obligation to Notify

ARTICLE 42-(1) Any manufacturer or importer, or group of manufacturers or importers, who places on the market a substance referred to in Article 41, shall submit the following information in order for it to be included in the inventory referred to in Article 44, in the format that exists on the Competent Authority web site:

- a) The following information about the notifier responsible for placing the substance on the market in self notification or each manufacturer or importer in joint submission;
 - 1) Name, address, telephone number, fax number and e-mail address;
 - 2) Contact person;
 - 3) Location of the production;
- b) The identity of the substance as specified in point (a) of Article 40(1);

- c) The classification of the substance in accordance with Article 15;
- ç) Where a substance has been classified in some but not all hazard classes or differentiations, an indication of whether this is due to lack of data, inconclusive data, or data which are conclusive although insufficient for classification;
- d) Specific concentration limits or M-factors, where applicable, in accordance with Article 12 of this By-Law together with a justification using the relevant Parts of Annex 9;
- e) The label elements specified in points (ç), (d) and (e) of Article 19(1) for the substance together with any supplemental hazard statements for the substance, determined in accordance with Article 27(1).

(2) The information listed in paragraph 1 shall be updated and notified to the Competent Authority by the notifier(s) concerned when, pursuant to the review in Article 17(1), a decision to change the classification and labelling of the substance has been taken.

(3) Substances placed on the market before 01/01/2015 shall be notified in between 01/01/2014 and 01/01/2015. Substances placed on the market on or after 01/01/2015 shall be notified in accordance with paragraph 1 within one month after their placing on the market.

(4) In the case of import of substances on their own or in a mixture; importer, on the point of being responsible for the obligation, may fulfill the obligations of importers under the scope of paragraph (1) (2) and (3), through a representative that is established in Turkey and appointed with an agreement determined by the natural or legal persons settled abroad.

Agreed Entries

ARTICLE 43- Where the notification in Article 42(1) results in different entries on the inventory referred to in Article 44(1) for the same substance, the notifiers shall make every effort to come to an agreed entry to be included in the inventory. The notifiers shall inform the Competent Authority accordingly.

Establishing and Updating of the Classification and Labelling Inventory

ARTICLE 44- (1) The Competent Authority, shall establish and maintain a classification and labelling inventory in the form of a database and provide its persistence.

(2) Information in the inventory which corresponds to the information referred to in Part 1 of Annex 10 may be publicly accessible.

(3) The Competent Authority shall update the inventory when it receives updated information in accordance with Article 42(2) or Article 43.

SECTION SEVEN

Cooperation, Helpdesk, National Toxicology Information Centre

Cooperation Between Competent Authority and Relevant Institution

ARTICLE 45- (1) The Competent Authority and the relevant institutions shall cooperate with each other in the performance of their tasks under this By-Law.

Yardımlı Masası

ARTICLE 46- (1) The Competent Authority shall establish national helpdesk to provide advice to manufacturers, importers, distributors, downstream users, article manufacturers and any other interested parties on their respective responsibilities and obligations under this By-Law.

National Toxicology Information Centre

ARTICLE 47- (1) Within the meaning of this By-Law, manufacturers, importers and downstream users are obliged to inform Ministry of Health National Toxicology Information Centre about the substances in mixtures placed on the market and classified as hazardous on

the basis of their health or physical effects, including the chemical identity of substances in mixtures for which a request for use of an alternative chemical name has been accepted by the Competent Authority, in accordance with Article 26. Procedure and format for submission of this information is determined by Ministry of Health.

(2) The National Toxicology Information Centre shall provide all requisite guarantees for maintaining the confidentiality of the information received. Such information may only be used:

a) to meet medical demand by formulating preventative and curative measures, in particular in the event of an emergency;

b) where requested by Relevant Institution, to undertake statistical analysis to identify where improved risk management measures may be needed.

3) The National Toxicology Information Centre keeps all the information come from manufacturers, importers and downstream users under this scope.

Enforcement

ARTICLE 48-(1) Relevant Institution shall implement the required enforcement in accordance with legislation in Article (3) to ensure that substances and mixtures are not placed on the market, unless they have been classified, labelled, notified and packaged in accordance with this Regulation.

Inspection

ARTICLE 49-(1) Inspections related with provisions of this By-Law is carried out by Relevant Institutions within the framework of their own legislation.

SECTION EIGHT

Common and Final Provisions

Advertisement

ARTICLE 50- (1) Without prejudice to the “By-Law on Distance Selling Contracts” published in the Official Gazette dated 06/03/2011 and numbered 27866, any advertisement for a substance classified as hazardous shall mention the hazard classes or hazard categories concerned.

(2) Any advertisement for a mixture classified as hazardous or covered by Article 27(6) which allows a member of the general public to conclude a contract for purchase without first having sight of the label shall mention the type or types of hazard indicated on the label.

Obligation to Maintain Information and Requests for Information

ARTICLE 51-(1) The supplier shall assemble and keep available all the information used by that supplier for the purposes of classification and labelling under this By-Law for a period of at least 10 years after the substance or the mixture was last supplied by that supplier.

(2) In the event of a supplier ceasing activity, or transferring part or all of his operations to a third party, the party responsible for liquidating the supplier's undertaking or assuming responsibility for the placing on the market of the substance or mixture concerned shall be bound by the obligation in paragraph 1 in place of the supplier.

(3) The competent authority may require the supplier to submit to it any information referred to paragraph 1. However, where that information is available to the Competent Authority as a notification pursuant to Article 42 of this By-Law, the Competent Authority shall use that information and the relevant institution may request these information from Competent Authority.

Safeguard Clause

ARTICLE 52-(1) Where a relevant institution has justifiable grounds for believing that a substance or a mixture, although satisfying the requirements of this By-Law, constitutes a serious risk to human health or the environment due to reasons of classification, labelling or

packaging, it may take appropriate provisional measures. The relevant institution shall inform the Competent Authority thereof, giving the reasons for its decision within 15 days.

Amendments to Directive By-Law on the Classification, Packaging and Labelling of Dangerous Substances and Preparations

ARTICLE 53 – (1) By-Law on the Classification, Packaging and Labelling of Dangerous Substances and Preparations published in the Official Gazette dated 26/12/2008 and numbered 27092 is amended as follows:

a) in Article 2(2), the subparagraph (c) shall be deleted;

b) Article 14(2) shall be amended as follows:

“Where there is information on harmonised classification and labelling for a particular substance has been included in Part 3 of Annex 6 to By-Law on Classification, Labelling and Packaging of Substances and Mixtures, the substance shall be classified in accordance with those information and Article 13(1) and Article 14(1) shall not be applied covered by that entry.”

c) Article 10(1), the subparagraph (d) shall be amended as follows:

“The measures in Article 20 and Article 24(1) shall apply until the substance is listed in Part 3 of Annex 6 to By-Law on Classification, Labelling and Packaging of Substances and Mixtures for the hazard categories covered by that entry or until a decision not to list it has been taken in accordance with the procedure laid down in Article 39 of the same By-Law.”

ç) Article 12 shall be replaced by the following:

“Manufacturers, importers and distributors of substances which appear in the EINECS but for which no entry has been included in Part 3 of Annex 6 to By-Law on Classification, Labelling and Packaging of Substances and Mixtures shall carry out an investigation to make themselves aware of the relevant and accessible data which exist concerning the properties of such substances. On the basis of this information, they shall package and provisionally label dangerous substances according to the rules laid down in Articles 20, 21, 24, 25,26,32 and 33 and the criteria in Annex 1 of this By-Law.”

d) Article 21(1), the sub paragraph (e) shall be deleted.

e) The words ‘Annex 2’ shall be replaced by ‘Part 3 of Annex 6 to By-Law on Classification, Labelling and Packaging of Substances and Mixtures’ existed in Article 14(3), 16(5), 24(1) and 28.

f) Annex 2 shall be deleted.

Repeal of By-Law

ARTICLE 54-(1)“By-Law on the Classification, Packaging and Labelling of Dangerous Substances and Preparations” published in the Official Gazette dated 26/12/2008 and numbered 27092 shall be repealed with effect from 01/06/2016.

Transitional provisions

TRANSITIONAL ARTICLE 1-(1) Substances and mixtures shall be classified, labelled and packaged until 01/01/2015 and until 01/06/2016 respectively, in accordance with “By-Law on the Classification, Packaging and Labelling of Dangerous Substances and Preparations”.

(2) By way of derogation from Article 55 of this Regulation and in addition to the requirements of paragraph 1 of this Article, substances and mixtures may, before 01/01/2015 and 01/06/2016 respectively, be classified, labelled and packaged in accordance with this By-Law. In that case, the provisions on labelling and packaging on “By-Law on the Classification, Packaging and Labelling of Dangerous Substances and Preparations” shall not apply.

(3) From 01/01/2015 until 01/06/2016, substances shall be classified in accordance with both “By-Law on the Classification, Packaging and Labelling of Dangerous Substances and Preparations” and this By-Law. They shall be labelled and packaged in accordance with this By-Law.

(4)By way of derogation from Article 55 of this By-Law, substances classified, labelled and packaged in accordance with “By-Law on the Classification, Packaging and Labelling of Dangerous Substances and Preparations” and already placed on the market before 01/01/2015, are not required to be relabelled and repackaged in accordance with this By-Law until 01/01/2017. By way of derogation from Article 55 of this Regulation, mixtures classified, labelled and packaged in accordance with “By-Law on the Classification, Packaging and Labelling of Dangerous Substances and Preparations” and already placed on the market before 01/06/ 2016 are not required to be relabelled and repackaged in accordance with this By-Law until 01/06/2018.

(5) Where a substance or mixture has been classified in accordance with “By-Law on the Classification, Packaging and Labelling of Dangerous Substances and Preparations” before 01/01/2015 or 01/06/2016 respectively, manufacturers, importers or downstream users may amend the classification of the substance or mixture using the conversion table in Annex 7 to this By-Law.

Entry into force

ARTICLE 55- (1) This By-law shall enter into force on the date of its publication.

Administration

ARTICLE 56-(1) The provisions of this By-law are administered by the Minister of Environment and Urbanization, Minister of Health and Minister of Food, Agriculture and Livestock.