BY-LAW ON REGISTRATION, EVALUATION, AUTHORIZATION AND RESTRICTION OF CHEMICALS

FIRST PART
General Issues
FIRST SECTION
Aim, Scope and Basis

Aim

ARTICLE 1 - (1) The purpose of this Bylaw is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances while enhancing competitiveness and innovation.

Scope

ARTICLE 2 - (1) This Bylaw covers manufacturing, placing on the market or use of the substances on their own, in a mixture or in an article and placing the mixtures on the market.
(2) This Bylaw;
(a) shall not apply to the substances and mixtures below
1) Radioactive substances and mixtures within the scope of Bylaw on the Safe Transportation of Radioactive Substances published in the Official Gazette dated 08/07/2005 and numbered 25869;
2) Substances, on their own, in a mixture or in an article, 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) The carriage of hazardous substances and hazardous mixtures by rail, road, inland waterway, sea or air;
5) Wastes in the scope of the Bylaw on Waste Management published in the Official Gazette dated 02/04/2015 and numbered 29314 and Bylaw on Radioactive Waste Management published in the Official Gazette dated 09/03/2013 and numbered 28882.
6) Substances and mixtures which are manufactured or imported for the purpose of defense
(3) of this Bylaw
a) The provisions of Second Part, Fifth Part, Sixth and Seventh Part shall not apply to the substances manufactured or imported in order to use in the products below:
1) Medicinal products for human or veterinary use within the scope of Bylaw on the Licencing of Medicinal Products for Human Use published in the Official Gazette dated 19/01/2005 and numbered 25705, Bylaw on the Packaging and Labelling of Medicinal Products for Human Use published in the Official Gazette dated 12/08/2005 andnumbered 25904 and Bylaw on Veterinary Medicinal Products published in the Official Gazette dated 24/12/2012 and dated and numbered 28152;
2) Food within the scope of the Bylaw on Turkish Food Codex published in the Official Gazette dated 29/12/2011 and numbered 28157;
3) Feeding stuffs within the scope of the Bylaw on Placing on the Market and Use of Feeding Stuffs published in the Official Gazette dated 27/12/2011 and numbered 28155;
(4) of this Bylaw:
(a) The provisions of Fourth Part shall not apply to the extent the following mixtures in the finished state, intended for the final user:
1) Medicinal products for human or veterinary use within the scope of Bylaw on the Licencing of Medicinal Products for Human Use published in the Official Gazette dated

19/01/2005 and numbered 25705, Bylaw on the Packaging and Labelling of Medicinal Products for Human Use and published in the Official Gazette dated 12/08/2005 and numbered 25904 and Bylaw on Veterinary Medicinal Products published in the Official Gazette dated 24/12/2012 and numbered 28152;
2) Cosmetic products within the scope of Bylaw on Cosmetics published in the Official Gazette dated 23/05/2005 and numbered 25823;
3) Invasive medical devices or medical devices which can be used in direct physical contact with the human body ;
4) Feeding stuffs within the scope of the Bylaw on Placing on the Market and Use of Feeding Stuffs published in the Official Gazette dated 27/12/2011 and numbered 28155.
5) Food within the scope of the Bylaw on Turkish Food Codex published in the Official Gazette dated 29/12/2011 and numbered 28157;
(5) of this Bylaw:
(a) The following shall be exempted from Second Part, Fifth Part and Sixth Part:
1) Substances included in Annex 4,
2) Substances included in Annex 5,
3) Substances on their own or in mixtures, registered in accordance with Second Part , exported from Turkey by an actor in the supply chain and re-imported into Turkey by the same or another actor in the same supply chain who proofs that:
a) The substance being re-imported is the same as the exported substance;
b) He has been provided with the information in accordance with Articles 27 or 28 relating to the exported substance.
4) Substances, on their own, in mixtures or in articles, which have been registered in accordance with Second Part and which are recovered in Turkey if:
a) The substance that results from the recovery process is the same as the substance that has been registered in accordance with Second Part; and
b) The information required by Articles 27 or 28 relating to the substance that has been registered in accordance with Second Part is available to the establishment undertaking the recovery.
(6) of this Bylaw:
(a) Section 1 of Second Part , with the exception of Articles 9 and 10; and Seventh Part shall not be applied to the on-site isolated intermediates and transported isolated intermediates.
(7) of this Bylaw:
(a) the provisions of the Second and Sixth Part shall not apply to the polymers.

Legal Basis
ARTICLE 3 - (1) This By-law is prepared
a) Based on the grounds of 09/08/1983 dated 2872 numbered Environmental Law, 04/07/2011 dated 644 numbered Decree Law on Establishment and Duties of Ministry of Environment and Urbanization, 11/10/2011 dated 663 numbered Decree Law on Establishment and Duties of Ministry of Health and Related Authorities, 24/04/1930 dated 1593 numbered General Hygiene Law, 09/01/1985 dated 3146 numbered Law on Establishment and Duties of Ministry of Labour and Social Security, 03/06/2011 dated 639 numbered Decree Law on Establishment and Duties of Ministry of Food, Agriculture and Livestock, 11/06/2010 dated 5996 numbered Law on Veterinary Services, Plant Health, Food and Feeding Stuff, 14/08/1987 dated 87/12028 numbered Regulation Promulgated by the Cabinet of Ministers Decision on Production, Import, Transportation, Storing, Warehousing, Sale, Use, Disposing, Control of Explosives, Hunting Materials and Similar Materials Outside the Scope of the Monopoly and 29/06/2001 dated and 4703 numbered Law on Preparation and Application of Technical Regulations on Products.

SECOND SECTION
Definitions and General Provision

Definitions

ARTICLE 4 - (1) For the purposes of this Bylaw:

a) Alloy: means a metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means;

b) Downstream user: means any natural or legal person established within Turkey, 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) Intermediate: means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance

ç) Ministry: means the Ministry of Environment and Urbanization;

d) Identified use: means a use of a substance on its own or in a mixture, or a use of a mixture, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by a downstream user;

e) Scientific research and development: means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year;

f) CAS Number: the number given by the “Chemical Abstract Service”;

g) Study summary: means a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study;

ğ) Distributor: means any natural or legal person established within Turkey, including a retailer, who only stores and places on the market a substance, on its own or in a mixture , for third parties;

h)Substances which occur in nature: means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means;

ı) EINECS: European Inventory of Existing Commercial Chemical Substances is the definer of all substances existing in the European Community Market since 18th of September, 1981;

i) ELINCS: means all the new substances which are put on European Community Market and have an ELINCS number by sending a notice to European Inventory of Existing Commercial Chemical Substances after 18th of September, 1981;

j) 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;

k) Recipient of an article: means an industrial or professional user, or a distributor, being supplied with an article but does not include consumers;

l) Supplier of an article: means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market;

m) Manufacturer of an article: Natural or legal person established in Turkey who manufacture or assembly the article;

n) IUPAC name: the name of the substance given by “International Union and Pure Applied Chemistry”;

o) Relevant authority: means Ministry of Health for biocidal products, Ministry of Customs and Trade for detergents and surface active agents used in detergents, air aromatizing products, cleaning products with strong acid or base and chemicals used in pool water,

Ministry of Food, Agriculture and Livestock for plant protection products, Ministry of Science, Industry and Technology and Ministry of Internal Affairs for explosives and pyrotechnic substances, Ministry of Environment and Urbanization for all other substances and mixtures and for the coordination of all the activities within the framework of this Bylaw; Ministry of Health, Ministry of Customs and Trade, Ministry of Food, Agriculture and Livestock, Ministry of Science, Industry and Technology, Ministry of Economy, Ministry of Work and Social Security, Ministry of Energy and Natural Resources andMinistry of Environment and Urbanization are responsible for inspection and enforcement of restricted and prohibited substances in the scope of Annex 17..

ö) Manufacturing: means production or extraction of substances in the natural state;

p) Manufacturer: means any natural or legal person established within Turkey who manufactures a substance within Turkey;

r) Import: means the physical introduction into the customs territory of Turkey;

s) Importer: means any natural or legal person established within Turkey who is responsible for import;

ş) 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.

t) Robust study summary: means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report;

u) Mixture : means a mixture or solution composed of two or more substances;

ü) Registrant: means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance;

v) Registrant's own use: means an industrial or professional use by the registrant;

y) Restriction: means any condition for or prohibition of the manufacture, use or placing on the market;

z) Not chemically modified substance: means a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities;

aa) SME: means small and medium-sized enterprises as defined in Bylaw on Definition, Qualifications and Classification of Small and Medium-sized Enterprises published in the Official Gazette dated 18/11/2005 numbered 25997;

bb) 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,

1) **(Annex:RG-29/11/2019-30963)** Industrial use: means using a substance or a mixture in industry,

2) **(Annex: RG-29/11/2019-30963)** Professional use: means using a substance or a mixture outside industry in areas such as education, health,

cc) Use and exposure category: means an exposure scenario covering a wide range of processes or uses, where the processes or uses are communicated, as a minimum, in terms of the brief general description of use;

çç) Substance: means chemicals elements and their composition which occur naturally or with a production including the additives in order to keep the stability and impurities of production but excluding the dissolvers removed without affecting the stability and the structure;

dd) Recipient of a substance or a mixture : means a downstream user or a distributor being supplied with a substance or a mixture;

ee) Supplier of a substance or a mixture: means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture , or a mixture;

ff) Exposure scenario: means the set of conditions, including operational conditions and risk management measures, 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 exposure scenarios may cover one specific process or use or several processes or uses as appropriate;
gg) 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;
ğğ) Placing on the market: means supplying or making available, whether in return for payment or free of charge, to a third party or import;
hh) Polymer: means a substance consisting of molecules characterised by the sequence of one or more types of monomer units,distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units and 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; and
2) Less than a simple weight majority of molecules of the same molecular weight.

ıı) Full study report: means a complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test laboratory describing the study performed;
ii) Transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites;
jj) 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;
kk) Actors in the supply chain: means all manufacturers and/or importers and/or downstream users in a supply chain;
ll) Product and process orientated research and development: means any scientific development related to product development or the further development of a substance, on its own, in mixtures or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance;
mm) On-site: means a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared;
nn) On-site isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;
oo) Competent authority: means Ministry of Environment and Urbanization;
öö) Amount per year: means the avarege amount of manufacture or import in the previous consecutive three calendar years, for the substances that have been imported or manufactured for at least three consecutive years; the amount of manufacture or import in the year of which the highest quantity is imported or manufactured, for the substances that have not been imported or manufactured for at least three consecutive years;

General provisions

ARTICLE 5 – (1) Any manufacturer, importer and downstream users are responsible with the production, placing on the market or use of the substance without any negative effect to the human health or the environment.
(2) Any manufacturer, importer, or where relevant downstream user, may, whilst retaining full responsibility for complying with his obligations under this Bylaw, appoint a third party

representative for all proceedings under Article 12, Article 19, Article 44 and Third Part involving discussions with other manufacturers, importers, or where relevant downstream users. In these cases, the identity of a manufacturer or importer or downstream user who has appointed a representative shall not be disclosed by the Ministry to other manufacturers, importers, or, where relevant, downstream users.

SECOND PART
Registration of Substances

FIRST SECTION
Information Requirements and General Obligation to Register

Placing of the substances on the market

ARTICLE 6 – (1) Subject to Articles 7, 8 and 21, substances on their own, in mixtures or in articles shall not be manufactured or placed on the market unless they have been registered in accordance with the relevant provisions of this Part where this is required.

General obligation to register substances on their own or in mixtures

ARTICLE 7 – (1) Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more mixture (s), in quantities of one tons or more per year shall submit a registration to the Ministry through Chemicals Registration System in the website of Ministry.

(2) For monomers that are used as on-site isolated intermediates or transported isolated intermediates, Articles 17 and 18 shall not apply.

(3) Any manufacturer or importer of a polymer shall submit a registration to the Ministry for the monomer substance(s) or any other substance(s), that have not already been registered by an actor up the supply chain, if both the following conditions are met:

a) The polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);

b) The total quantity of such monomer substance(s) or other substance(s) makes up one ton or more per year.

Registration and notification of substances in articles

ARTICLE 8 – (1) Any producer or importer of articles shall submit a registration to the Ministry through Chemicals Registration System in the website of Ministry for any substance contained in those articles, if both the following conditions are met:

a) The substance is present in those articles in quantities totaling over one ton per producer or importer per year;

b) The substance is intended to be released under normal or reasonably foreseeable conditions of use.

(2) Any producer or importer of articles shall notify the Ministry through Chemicals Registration System in the website of Ministry, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 47 and defined in the article 49 if both the following conditions are met:

a) The substance is present in those articles in quantities totaling over one ton per producer or importer per year;

b) The substance is present in those articles above a concentration of 0,1 % weight by weight (w/w);

(3) Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.
(4) The information to be notified shall include the following:
a) The identity and contact details of the producer or importer as specified in section 1 of Annex 6, with the exception of their own use sites;
b) The registration number(s) referred to in Article 20(1), if available;
c) The identity of the substance as specified in sections 2.1 to 2.3.4 of Annex 6;
ç) Classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex 6;
d) A brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex 6 and of the uses of the article(s);
e) The tonnage range of the substance(s) (1-10 tonnes; 10-100 tonnes; 100-1000 tonnes and more than 1000 tonnes)
(5) The Ministry may take decisions requiring producers or importers of articles to submit a registration, for any substance in those articles, if all the following conditions are met:
a) The substance is present in those articles in quantities totalling over one ton per producer or importer per year;
b) The Ministry has grounds for suspecting that:
1) The substance is released from the articles, and
2) The release of the substance from the articles presents a risk to human health or the environment;
c) the substance is not subject to paragraph 1
(6) Paragraphs 1 to 5 shall not apply to substances that have already been registered for that use.
(7) Paragraphs 2, 3 and 4 of this Article shall apply six months after a substance is identified in accordance with Article 49(1).

Only representative
ARTICLE 9 – (1)A natural or legal person established outside Turkey who manufactures a substance on its own, in mixtures or in articles, formulates a mixture or produces an article that is imported into the Turkey may by mutual agreement appoint a natural or legal person established in the Turkey to fulfil, as his only representative, the obligations on importers under the scope of this Bylaw. Only representative shall also comply with all obligations of importers under this Regulation.
(2) The representative shall have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 32, shall keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 27.
(3) If a representative is appointed in accordance with paragraphs 1 and 2, the non-resident manufacturer in Turkey shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Bylaw.

Exemption from the general obligation to register for product and process orientated research and development (PPORD)
ARTICLE 10 – (1) Articles 6, 7, 8, 17, 18 and 21 shall not apply for a period of five years to a substance manufactured in the Turkey or imported for the purposes of product and process orientated research and development by a manufacturer or importer or producer of articles, by

himself or in cooperation with listed customers and in a quantity which is limited to the purpose of product and process orientated research and development.
(2) For the purpose of paragraph 1, the manufacturer or importer or producer of articles shall notify the Ministry of the following information:
a) The identity of the manufacturer or importer or producer of articles as specified in section 1 of Annex 6 ;
b) The identity of the substance, as specified in section 2 of Annex 6 ;
c) The classification of the substance as specified in section 4 of Annex 6 , if any;
ç) The estimated quantity as specified in section 3.1 of Annex 6 ;
d) The list of customers referred to in paragraph 1, including their names and addresses.
(3) The Ministry shall check the completeness of the information supplied by the notifier and Article 20 (2) shall apply adapted as necessary. The Ministry shall assign a number to the notification and a notification date, which shall be the date of receipt of the notification at the Ministry and shall forthwith communicate that number and date to the manufacturer, or importer, or producer of articles concerned.
(4) The Ministry may decide to impose conditions with the aim of ensuring that the substance or the mixture or article in which the substance is incorporated will be handled only by staff of listed customers as referred to in paragraph 2(d) in reasonably controlled conditions, in accordance with the requirements of legislation for the protection of workers and the environment, and will not be made available to the general public at any time either on its own or in a mixture or article and may ask the notifier to provide additional necessary information. Also, The Ministry may re-collect remaining quantities following the exemption period.
(5) In the absence of any indication to the contrary, the manufacturer or importer of the substance or the producer or importer of articles may manufacture or import the substance or produce or import the articles not earlier than two weeks after the notification.
(6) The Ministry may decide to extend the five-year exemption period by a further maximum of five years or, in the case of substances to be used exclusively in the development of medicinal products for human or veterinary use, or for substances that are not placed on the market, for a further maximum of ten years, upon request if the manufacturer or importer or producer of articles can demonstrate that such an extension is justified by the research and development program.

Information to be submitted for general registration purposes
ARTICLE 11 – (1) A registration required by Article 7 or by Article 8(1) or (5) shall include all the following information:
a) A technical dossier including:
1) The identity of the manufacturer(s) or importer(s) as specified in section 1 of Annex 6 ;
2) The identity of the substance as specified in section 2 of Annex 6 ;
3) Information on the manufacture and use(s) of the substance as specified in section 3 of Annex 6; this information shall represent all the registrant's identified use(s). This information may include, if the registrant deems appropriate, the relevant use and exposure categories;
4) The classification and labelling of the substance as specified in section 4 of Annex 6 ;
5) Guidance on safe use of the substance as specified in Section 5 of Annex 6 ;
6) Study summaries of the information derived from the application of Annexes 7 to 11;
7) Robust study summaries of the information derived from the application of Annexes 7 to 11,
8) an indication as to which of the information submitted under (3), (4), (6), (7) or subparagraph (b) has been reviewed by an chemical assessment expert chosen by the manufacturer or importer and certified according to Annex 18 of this Bylaw;

9) Proposals for testing where listed in Annexes 9 and 10;
10) For substances in quantities of 1 to 10 tons, exposure information as specified in section 6 of Annex 6 ;
11) A request as to which of the information in Article 61(2) the manufacturer or importer considers should not be made available on the Internet including a justification as to why publication could be harmful for his or any other concerned party's commercial interests.
b) A chemical safety report when required under Article 15, in the format specified in Annex 1. The relevant sections of this report may include, if the registrant considers appropriate, the relevant use and exposure categories.
c) Save the cases in the scope of Article 23(3), Article 24(7) or Article 26(3), the registrant shall have the legal ownership or the right to refer to the summarised full study report intended for registration according to paragraphs (1)(a)(6) and (1)(a)(7).

Joint submission of data by multiple registrants
ARTICLE 12 – (1)When a substance is intended to be manufactured by one or more manufacturers and/or imported by one or more importers, and/or is subject to registration under Article 8, the following shall apply:
a) Being subject to the paragraph 3 of this article, the information specified in Article 11 (1) (a) (4), (6), (7) and (9), and any relevant indication under Article 11 (1) (a) 8) is firstly presented by the lead registrant. After this, each registrant will separately present the information specified in Article 11 (1) (a) (1), (2), (3) and (10) and the indication under Article 11 (1) (a) 8).
b) Each registrant may decide themselves whether to submit the information specified in Article 11 (1) (a) 5) and any relevant indication under Article 11 (1) (a) (8) separately himself or whether by the lead registrant.
(2) Each registrant need only comply with paragraph 1 for items of information specified in Article 11 (1) (a) (4), (6), (7) and (9) that are required for the purposes of registration within his tonnage band in accordance with Article 13.
(3) A registrant may submit the information referred to in Article 11 (1) (a) (4), (6), (7) or (9) separately if:
a) It would be disproportionately costly for him to submit this information jointly; or
b) Submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or
c) He disagrees with the lead registrant on the selection of this information.
(4) If the registrant complies with the provisions under paragraph 3, he submits his justification with the register file.

Information to be submitted depending on tonnage
ARTICLE 13 – (1) The technical dossier referred to in Article 11 (1) (a) shall include under points (6) and (7) of that provision all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant and as a minimum the following:
a) The information specified in Annex 7 for substances meeting at least one of the criteria specified in Annex 3, manufactured or imported in quantities of one ton or more per year per manufacturer or importer;
b) The information on physicochemical properties specified in Annex 7, section 7 for substances manufactured or imported in quantities of one ton or more per year per manufacturer or importer which do not meet either of the criteria specified in Annex 3;
c) The information specified in Annexes 7 and 8 for substances manufactured or imported in quantities of 10 tons or more per year per manufacturer or importer;

ç) The information specified in Annexes 7 and 8 and testing proposals for the provision of the information specified in Annex 9 for substances manufactured or imported in quantities of 100 tons or more per year per manufacturer or importer;
d) The information specified in Annexes 7 and 8 and testing proposals for the provision of the information specified in Annexes 9 and 10 for substances manufactured or imported in quantities of 1 000 tons or more per year per manufacturer or importer.
(2) As soon as the quantity of a substance per manufacturer or importer that has already been registered reaches the next tonnage threshold, the manufacturer or importer shall inform the Ministry in twenty working days of the additional information he would require under paragraph 1.
(3) This Article shall apply to producers of articles adapted as necessary.

General requirements for generation of information on intrinsic properties of substances
ARTICLE 14 – (1) Information on intrinsic properties of substances may be generated by means other than tests, provided that the conditions set out in Annex 11 are met. In particular for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods, for example, in vitro methods or qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across). Testing in accordance with Annex 8, Sections 8.6 and 8.7, Annex 9 and Annex 10 may be omitted where justified by information on exposure and implemented risk management measures as specified in Annex 11.
(2) These methods shall be regularly reviewed and improved with a view to reducing testing on vertebrate animals and the number of animals involved.
(3) Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the Bylaw on the Test Methods to Apply on Specifying the Physico-Chemical, Toxicological, and Eco-Toxicological Properties of the Substances and the Mixtures published in the Official Gazette dated 11/12/2013 and numbered 28848 (bis). The information on the intrinsic properties of chemical substances can be provided by the other test methods provided that the conditions are met under Annex 11.
(4) Ecotoxicological and toxicological tests shall be carried out in compliance with Bylaw on the Principles of Good Laboratory Practice, Harmonization of Test Units, Inspection of Good Laboratory Practice and Work published in the Official Gazette dated 9/3/2010 and numbered 27516.
(5) If a substance has already been registered, a new registrant shall be entitled to refer to the study summaries or robust study summaries, for the same substance submitted earlier, provided that he can show that the substance that he is now registering is the same as the one previously registered, including the degree of purity and the nature of impurities, and that the previous registrant(s) have given permission to refer to the full study reports for the purpose of registration. A new registrant shall not refer to such studies in order to provide the information required in Section 2 of Annex 6.

Chemical safety report and duty to apply and recommend risk reduction measures
ARTICLE 15 – (1) Without prejudice to the Article 6 of Bylaw on Safety and Security Measures related to Works with Chemical Substances published in the Official Gazette dated 12/08/2013 and numbered 28733, a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with

this Chapter in quantities of 10 tons or more per year per registrant. The chemical safety report shall document the chemical safety assessment which shall be conducted in accordance with paragraphs 2 to 7 and with Annex I for either each substance on its own or in a mixture or in an article or a group of substances.
(2) A chemical safety assessment in accordance with paragraph 1 need not be performed for a substance which is present in a mixture if the concentration of the substance in the mixture is less than the lowest of any of the following:
a) The concentration threshold values that have been set Article 13 of Bylaw on Classification, Labelling and Packaging of Substances and Mixtures published in the Official Gazette dated 11/12/2013 and numbered 28848.

b) 0,1 % weight by weight (w/w), if the substance meets the criteria in Annex 13 of this Bylaw.
(3) A chemical safety assessment of a substance shall include the following steps:
a) Human health hazard assessment;
b) Physicochemical hazard assessment;
c) Environmental hazard assessment;
ç) Persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment.
(4) If, as a result of carrying out steps (a) to (ç) of paragraph 3, the registrant concludes that the substance fulfils the criteria of PBT or vPvB or any of the following hazard classes or categories set out in Annex 1 to the Bylaw on Classification, Labelling and Packaging of Substances and Mixtures, the substance includes chemical safety assessment exposure scenarios or exposure scenario assessment including specifying the exposure scenario categories and exposure scenario assumptions and the risk characterization. The exposure scenarios (where appropriate the use and exposure categories), exposure assessment and risk characterisation shall address all identified uses of the registrant.
a) Hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
b) Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
c) Hazard class 4.1;
ç) Hazard class 5.1,
(5)The chemical safety report need not include consideration of the risks to human health from the following end uses:
a) In food contact materials within the scope Bylaw on the Turkish Food Codex Substances and Materials in Contact with Food published in the Official Gazette dated 29/12/2011 and numbered 28157;
b) In cosmetic products within the scope of Bylaw on Cosmetics.

(6) Any registrant shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the Safety Data Sheets which he supplies in accordance with Article 27.
(7)Any registrant required to conduct a chemical safety assessment shall keep his chemical safety report available and up to date.

SECOND SECTION
Substances Regarded as Being Registered

Substances in plant protection and biocidal products

ARTICLE 16 – (1) Active substances and co-formulants manufactured or imported for use in plant protection products only and included the Bylaw on Licensing of Plant Protection Products published in the Official Gazette dated 25/03/2011 numbered 27885 and Bylaw on the Classification, Packaging and Labelling of Plant Protection Products published in the Official Gazette dated 23/03/2010 and numbered 27530 shall be regarded as being registered and the registration as completed for manufacture or import for the use as a plant protection product and therefore as fulfilling the requirements of Section 1 of Part 2.

(2) Active substances manufactured or imported for use in biocidal products only and included in Bylaw on Biocidal Products published in the Official Gazette dated 31/12/2009 numbered 27449 (4th bis) on the placing of biocidal products on the market, shall be regarded as being registered and the registration as completed for manufacture or import for the use in a biocidal product and therefore as fulfilling the requirements of Section 1 of this Part.

THIRD SECTION
Obligation to Register and Information Requirements for Certain Types of Isolated Intermediates

Registration of on-site isolated intermediates

ARTICLE 17 – (1) Any manufacturer of an on-site isolated intermediate in quantities of one ton or more per year shall submit a registration to the Ministry through Chemicals Registration System in the website of Ministry for the on-site isolated intermediate.

(2) A registration for an on-site isolated intermediate shall include all the following information, to the extent that the manufacturer is able to submit it without any additional testing:

a) The identity of the manufacturer as specified in Section 1 of Annex 6 ;

b) The identity of the intermediate as specified in Sections 2.1 to 2.3.4 of Annex 6 ;

c) The classification of the intermediate as specified in Section 4 of Annex 6 ;

ç) Any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted;

d) A brief general description of the use, as specified in Section 3.5 of Annex 6 ;

e) Details of the risk management measures applied.

(3) Paragraph 2 shall apply only to on-site isolated intermediates if the manufacturer confirms that the substance is only manufactured and used under strictly controlled conditions in that it is rigorously contained by technical means during its whole lifecycle. Control and procedural technologies shall be used to minimise emission and any resulting exposure. If these conditions are not fulfilled, the registration shall include the information specified in Article 11.

(4) Save the cases in the scope of Article 23(3), 24 (7) or 26 (3), according to the paragraph (2)(ç) registrant shall have permission to the ownership or the right to refer to the full study report for purpose of registration.

Registration of transported isolated intermediates

ARTICLE 18 – (1) Any manufacturer or importer of a transported isolated intermediate in quantities of one ton or more per year shall submit a registration to the Ministry through Chemicals Registration System in the website of Ministry for the transported isolated intermediate.
(2) A registration for a transported isolated intermediate shall include all the following information:
a) The identity of the manufacturer or importer as specified in Section 1 of Annex 6 ;
b) The identity of the intermediate as specified in Sections 2.1 to 2.3.4 of Annex 6 ;
c) The classification of the intermediate as specified in Section 4 of Annex 6 ;
ç) Any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted;
d) A brief general description of the use, as specified in Section 3.5 of Annex 6;
e) Information on risk management measures applied and recommended to the user in accordance with paragraph 4.
(3) A registration for a transported isolated intermediate in quantities of more than 1 000 tons per year per manufacturer or importer shall include the information specified in Annex 7 in addition to the information required under paragraph 2. For the generation of this information, Article 14 shall apply.
(4) Paragraphs 2 and 3 shall apply only to transported isolated intermediates if the manufacturer or importer confirms himself or states that he has received confirmation from the user that the synthesis of (an)other substance(s) from that intermediate takes place on other sites under the following strictly controlled conditions:
a) The substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage. If these conditions are not fulfilled, the registration shall include the information specified under Article 11
b) Procedural and control technologies shall be used that minimize emission and any resulting exposure;
c) Only properly trained and authorized personnel handle the substance;
ç) In the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;
d) In cases of accident and where waste is generated, procedural and/or control technologies are used to minimize emissions and the resulting exposure during purification or cleaning and maintenance procedures;
e) Substance-handling procedures are well documented and strictly supervised by the site operator.
(5) Save the cases in the scope of Article 23(3), 24 (7) or 26 (3), according to the paragraph (2)(ç) registrant shall have permission to the ownership or the right to refer to the full study report for purpose of registration.

Joint submission of data on isolated intermediates by multiple registrants
ARTICLE 19 – (1) When an on-site isolated intermediate or transported isolated intermediate is intended to be manufactured by one or more manufacturers and/or imported by one or more importers, the following shall apply.
Subject to paragraph 2 of this Article, the information specified in Article 17(2)(c) and (ç) and Article 18(2) (c) and (ç) shall first be submitted by one manufacturer or importer acting with the agreement of the other assenting manufacturer(s) or importer(s) (hereinafter referred to as

'the lead registrant'). Each registrant shall subsequently submit separately the information specified in Article 17(2) (a), (b), (d) and (e) and Article 18(2) (a), (b), (d) and (e).

(2) A manufacturer or importer may submit the information referred to in Article 17(2)(c) or (ç) and Article 18 (2) (c) or (ç) separately if:

a) It would be disproportionately costly for him to submit this jointly; or

b) Submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or

c) He disagrees with the lead registrant on the selection of this information.

3) If paragraph 2apply, the manufacturer or importer shall submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment, or the nature of the disagreement, as the case may be.

FOURTH SECTION
Common Provisions for All Registrants

Duties of Ministry

ARTICLE 20 – (1) The Ministry shall assign a submission number to each registration, which is to be used for all correspondence regarding the registration until the registration is deemed to be complete, and a submission date, which shall be the date of receipt of the registration at the Ministry.

(2) In respect to registration dossier

(a) The Ministry shall undertake a completeness check of each registration in order to ascertain that all the elements required under Articles 11 and 13 or under Articles 17 or 18 as well as the registration fee referred to in Article 59 have been provided. The completeness check shall not include an assessment of the quality or the adequacy of any data or justifications submitted.

(b)The Ministry shall undertake the completeness check within three weeks of the submission date. If a registration is incomplete, the Ministry shall inform the registrant, before expiry of the three-week period, as to what further information is required in order for the registration to be complete, while setting a deadline for this.

(c)The registrant shall complete his registration and submit it to the Ministry within the deadline set. The Ministry shall confirm the submission date of the further information to the registrant. The Ministry shall perform a further completeness check, considering the further information submitted.

(ç)The Ministry shall reject the registration if the registrant fails to complete his registration within the deadline set. The registration fee shall not be reimbursed in such cases.

(3) Once the registration is complete, the Ministry shall assign a registration number to the substance concerned and a registration date, which shall be the same as the submission date. The Ministry shall communicate the registration number and registration date to the registrant concerned. The registration number shall be used for all subsequent correspondence regarding registration.

(4) Where additional information for a particular substance is submitted to the Ministry by a new registrant, the Ministry shall notify the existing registrants that this information is available on the database for the purposes of Article 22.

Manufacturing and import of substances

ARTICLE 21- (1)A registrant may start or continue the manufacture or import of a substance or production or import of an article, if there is no indication to the contrary from the Ministry

in accordance with Article 20(2) within the three weeks after the submission date, without prejudice to Article 24(8).
In the case of an update of a registration according to Article 22, a registrant may continue the manufacture or import of the substance, or the production or import of the article, if there is no indication to the contrary from the Ministry in accordance with Article 20(2) within the three weeks after the update date, without prejudice to Article 24(8).
(2) If the Ministry has informed the registrant that he is to submit further information the registrant may start the manufacture or import of a substance or production or import of an article if there is no indication to the contrary from the Ministry within the three weeks after receipt by the Ministry of the further information necessary to complete his registration, without prejudice to Article 24 (8).
(3) If a lead registrant submits parts of the registration on behalf of one or more other registrants, as provided for in Articles 12 or 19, any of the other registrants may manufacture or import the substance or produce or import the articles only after the expiry of the time-limit laid down in paragraph 1 or 2 of this Article and provided that there is no indication to the contrary from the Ministry in respect of the registration of the lead registrant acting on behalf of the others and his own registration.

Further duties of registrants
ARTICLE 22 – (1) Following registration, a registrant shall be responsible on his own initiative for updating his registration without undue delay with relevant new information and submitting it to the Ministry in the following cases:
a) Any change in his status, such as being a manufacturer, an importer or a producer of articles, or in his identity, such as his name or address;
b) Any change in the composition of the substance as given in Section 2 of Annex 6 ;
c) Changes in the annual or total quantities manufactured or imported by him or in the quantities of substances present in articles produced or imported by him if these result in a change of tonnage band, including cessation of manufacture or import;
ç) New identified uses and new uses advised against as in Section 3.7 of Annex 6 for which the substance is manufactured or imported;
d) New knowledge of the risks of the substance to human health and/or the environment of which he may reasonably be expected to have become aware which leads to changes in the safety data sheet or the chemical safety report;
e) Any change in the classification and labelling of the substance;
f) Any update or amendment of the chemical safety report or Section 5 of Annex 6 ;
g) The registrant identifies the need to perform a test listed in Annex 9 or Annex 10, in which cases a testing proposal shall be developed;
ğ) Any change in the access granted to information in the registration.
(2) A registrant shall submit to the Ministry an update of the registration containing the information required by the decision made in accordance with Articles 36, 37, 41 or 50 within the deadline specified in that decision.
(3) The Ministry shall undertake a completeness check of each updated registration according to Article 20(2) (a) and 20 (2) (b). In cases where the update is in accordance with Article 13(2) and with paragraph 1(c) of this Article then the Ministry shall check the completeness of the information supplied by the registrant and Article 20(2) shall apply adapted as necessary.
(4) In cases covered by Articles 12 or 19, each registrant shall submit separately the information specified in paragraph 1(c) of this Article.

THIRD PART
Data Sharing and Avoidance of Unnecessary Testing

FIRST SECTION
Data Sharing Rules

ARTICLE 23 – (1) In order to avoid animal testing, testing on vertebrate animals for the purposes of this Bylaw shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests.
(2) The sharing and joint submission of information in accordance with this Bylaw shall concern technical data and in particular information related to the intrinsic properties of substances. Registrants shall refrain from exchanging information concerning their market behaviour, in particular as regards production capacities, production or sales volumes, import volumes or market shares.
(3) Any study summaries or robust study summaries of studies submitted in the framework of a registration at least 12 years previously can be used for the purposes of registration by another manufacturer or importer.

SECOND SECTION
Sharing the Existing Data

Sharing the existing data for registered substances
ARTICLE 24 – (1) Every potential registrant of a substance shall inquire from the Ministry through Chemicals Registration System in the website of Ministry from 31/12/2023 whether a registration has already been submitted for the same substance. He shall submit all the following information to the Ministry with the inquiry:
a) his identity as specified in Section 1 of Annex 6, with the exception of the use sites;
b) the identity of the substance, as specified in Sections 2.1 to 2.3.4 of Annex 6;
c) which information requirements would require studies involving vertebrate animals to be carried out by him;
(2)Where a substance has previously been registered less than 12 years earlier, potential registrant shall require nessessary information with respect to the Article 11 (a) (6) and (7) from the previous registrant(s) in order to register
a) Shall, in the case of information involving tests on vertebrate animals; and
b) May, in the case of information not involving tests on vertebrate animals.
(3) When a request for information has been made according to paragraph 1, the potential and the previous registrant(s) as referred to in paragraph 1 shall make every effort to reach an agreement on the sharing of the information requested by the potential registrant(s) with respect to Article 11 (a) (6) and (7).
(4) The previous registrant and potential registrant(s) shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way. Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.
(5) On agreement on the sharing of the information, the previous registrant shall make available to the new registrant the agreed information and shall give the new registrant the permission to refer to the previous registrant's full study report.

(6) If there is failure to reach such an agreement, the potential registrant(s) shall inform the Ministry and the previous registrant(s) thereof at the earliest one month after receipt, from the Ministry, of the name and address of the previous registrant(s).
(7) Within one month from the receipt of the information referred to in paragraph 5, the Ministry shall give the potential registrant permission to refer to the information requested by him in his registration dossier, subject to the potential registrant providing, upon request by the Ministry, proof that he has paid the previous registrant(s) for that information a share of cost incurred. The previous registrant(s) shall have a claim on the potential registrant for a proportionate share of the cost incurred by him. Calculation of the proportionate share may be facilitated by the guidance adopted by the Ministry. Provided he makes the full study report available to the potential registrant, the previous registrant(s) shall have a claim on the potential registrant for an equal share of the cost incurred by him, which may be enforceable in the national courts.
(8) The registration waiting period in accordance with Article 21(1) for the new registrant shall be extended by a period of four months, if the previous registrant so requests.

THIRD SECTION
Rules for the Substances

Substance Information Exchange Forums
ARTICLE 25 – (1) All potential registrants, downstream users and third parties of substance who have submitted pre-substance information exchange forum (pre SIEF) to the Ministry, or registrants who have submitted a registration for that substance before 31/12/2023 shall be participants in a substance information exchange forum (SIEF).
(2) The aim of each SIEF shall be to:
a) Facilitate, for the purposes of registration, the exchange of the information specified in Article 11 (1) (a) (6) and (7) between potential registrants, thereby avoiding the duplication of studies; and
b) Agree classification and labelling where there is a difference in the classification and labelling of the substance between potential registrants.
(3)SIEF participants shall provide other participants with existing studies, react to requests by other participants for information, collectively identify needs for further studies for the purposes of paragraph 2(a) and arrange for such studies to be carried out. Each SIEF shall be operational until 31/12/2025.

Sharing of data involving tests
ARTICLE 26 – (1) Before testing is carried out in order to meet the information requirements for the purposes of registration, a SIEF participant shall inquire whether a relevant study is available by communicating within his SIEF. If a relevant study involving tests on vertebrate animals is available within the SIEF, a participant of that SIEF shall request that study. If a relevant study not involving tests on vertebrate animals is available within the SIEF, a SIEF participant may request that study. Within one month of the request, the owner of the study shall provide proof of its cost to the participant(s) requesting it. The participant(s) and the owner shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way. The calculation of the proportional cost sharing may be facilitated by the Ministry's advice. If they cannot reach such an agreement, the cost shall be shared equally. The owner shall give permission to refer to the full study report for the purpose of registration within two weeks of receipt of payment. Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.

(2) If a relevant study involving tests is not available within the SIEF, only one study shall be conducted per information requirement within each SIEF by one of its participants acting on behalf of the others. They shall take all reasonable steps to reach an agreement within a deadline set by the Ministry as to who is to carry out the test on behalf of the other participants and to submit a summary or robust study summary to the Ministry. If no agreement is reached, the Ministry shall specify which registrant or downstream user shall perform the test. All participants of the SIEF who require a study shall contribute to the costs for the elaboration of the study with a share corresponding to the number of participating potential registrants. Those participants that do not carry out the study themselves shall have the right to receive the full study report within two weeks following payment to the participant that carried out the study.
(3) If the owner of a study as referred to in paragraph 1 which involves testing on vertebrate animals refuses to provide either proof of the cost of that study or the study itself to (an) other participant(s), he shall not be able to proceed with registration until he provides the information to the other participants(s). The other participant(s) shall proceed with registration without fulfilling the relevant information requirement, explaining the reason for this in the registration dossier. The study shall not be repeated unless within 12 months of the date of registration of the other participant(s), the owner of this information has not provided it to them and the Ministry decides that the test should be repeated by them. However, if a registration containing this information has already been submitted by another registrant, the Ministry shall give the other participant(s) permission to refer to the information in his registration dossier(s). The other registrant shall have a claim on the other participant(s) for an equal share of the cost, provided he makes the full study report available to the other participant(s), which may be enforceable in the national courts.
(4) If the owner of a study as referred to in paragraph 1 which does not involve testing on vertebrate animals refuses to provide either proof of the cost of that study or the study itself to (an)other participant(s), the other SIEF participants shall proceed with registration as if no relevant study was available in the SIEF.
(5) The owner of the study who has refused to provide either proof of the cost or the study itself, as referred to in paragraph 3 or 4 of this Article, shall be penalized in accordance with Article 63.

FOURTH PART
Information in the Supply Chain

Requirements for safety data sheets
ARTICLE 27 – (1) The supplier of a substance or a mixture shall provide the recipient of the substance or mixture with a safety data sheet compiled in accordance with Annex 2 and prepared by a certified chemicals assessment expert according to Annex 18:
a) Where a substance or a mixture meets the criteria for classification as hazardous in accordance with the Bylaw on Classification, Labelling and Packaging of Substances and Mixtures or
b) Where a substance is persistent, bio accumulative and toxic or very persistent and very bio accumulative in accordance with the criteria set out in Annex 13; or
c) Where a substance is included in the list established in accordance with Article 49 for reasons other than those referred to in points (a) and (b).
(2) Any actor in the supply chain who is required, under Articles 15 or 33 to carry out a chemical safety assessment for a substance shall ensure that the information in the safety data sheet is consistent with the information in this assessment. If the safety data sheet is developed for a mixture and the actor in the supply chain has prepared a chemical safety

assessment for that mixture, it is sufficient if the information in the safety data sheet is consistent with the chemical safety report for the mixture instead of with the chemical safety report for each substance in the mixture.

(3) The supplier shall provide the recipient at his request with a safety data sheet compiled in accordance with Annex 2, where a mixture does not meet the criteria for classification as hazardous in accordance with Bylaw on Classification, Labelling and Packaging of Substances and Mixtures, but contains:

a) In an individual concentration of ≥ 1 % by weight for non-gaseous mixtures and ≥ 0,2 % by volume for gaseous mixtures at least one substance posing human health or environmental hazards; or

b) In an individual concentration of ≥ 0,1 % by weight for non-gaseous mixtures at least one substance that is carcinogenic category 2 or toxic to reproduction category 1, respiratory sensitiser category 1 or is persistent, bio accumulative and toxic or very persistent and very bio accumulative in accordance with the criteria set out in Annex 13 or has been included for reasons other than those referred to in point (a) in the list established in accordance with Article 49(1);

c) A substance for which there is workplace exposure limits.

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

(5) The safety data sheet shall be supplied in Turkish.

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

a) Identification of the substance/ mixture and of the company/undertaking;
b) Hazards identification;
c) Composition/information on ingredients;
ç) First-aid measures;
d) Fire-fighting measures;
e) Accidental release measures;
f) Handling and storage;
g) Exposure controls/personal protection;
ğ) Physical and chemical properties;
h) Stability and reactivity;
ı) Toxicological information;
i) Ecological information;
j) Disposal considerations;
k) Transport information;
l) Regulatory information;
m) Other information.

(7) Any actor in the supply chain who is required to prepare a chemical safety report according to Articles 15 or 33 shall place the relevant exposure scenarios (including use and exposure categories where appropriate) in an annex to the safety data sheet covering identified uses and including specific conditions resulting from the application of Section 3 of Annex 11.

Any downstream user shall include relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for identified uses.

Any distributor shall pass on relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for uses for which he has passed on information according to Article 33(2).

(8) A safety data sheet shall be provided free of charge on paper or electronically.
(9) Suppliers shall update the safety data sheet without delay on the following occasions:
a) As soon as new information which may affect the risk management measures, or new information on hazards becomes available;
b) Once an authorization has been granted or refused;
c) Once a restriction has been imposed.
(10) The new, dated version of the information, shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or mixture within the preceding 12 months. Any updates following registration shall include the registration number.
(11) The safety data sheets for substances shall contain the classification according to Bylaw on Classification, Labelling and Packaging of Substances and Mixtures.

Duty to communicate information down the supply chain for substances on their own or in mixtures for which a safety data sheet is not required
ARTICLE 28 – (1) Any supplier of a substance on its own or in a mixture who does not have to supply a safety data sheet in accordance with Article 27 shall provide the recipient with the following information:
a) The registration number(s) referred to in Article 20(3), if available, for any substances for which information is communicated under this paragraph;
b) If the substance is subject to authorization and details of any authorization granted or denied under Part 7 in this supply chain;
c) Details of any restriction imposed under Part 8;
ç) Any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied including specific conditions resulting from the application of Section 3 of Annex 11.
(2) The information referred to in paragraph 1 shall be communicated free of charge on paper or electronically at the latest at the time of the first delivery of a substance on its own or in a mixture after the enforcement date.
(3) Suppliers shall update this information without delay on the following occasions:
a) As soon as a new information which may affect the risk management measures, or new information on hazards becomes available;
b) Once an authorization has been granted or refused;
c) Once a restriction has been imposed.
(4)In addition, the updated information shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or mixture within the preceding 12 months. Any updates following registration shall include the registration number.

Duty to communicate information on substances in articles
ARTICLE 29 – (1) Any supplier of an article containing a substance meeting the criteria in Article 47 in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance with respect to the Article 49 (1).
(2) On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 47 in a concentration above 0,1 % weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance with respect to the Article 49 (1).The relevant information shall be provided, free of charge, within 45 days of receipt of the request.

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

ARTICLE 30 – (1) Any actor in the supply chain of a substance or a mixture shall communicate the following information to the next actor or distributor up the supply chain. Distributors shall pass on that information to the next actor or distributor up the supply chain:

a) New information on hazardous properties, regardless of the uses concerned;

b) Any other information that might call into question the appropriateness of the risk management measures identified in a safety data sheet supplied to him, which shall be communicated only for identified uses.

Access to information for workers

ARTICLE 31 – (1) Workers and their representatives shall be granted access by their employer to the information provided in accordance with Articles 27 and 28 in relation to substances or mixtures that they use or may be exposed to in the course of their work.

Obligation to keep information

ARTICLE 32 – (1) Each manufacturer, importer, downstream user and distributor shall assemble and keep available all the information he requires to carry out his duties under this Bylaw for a period of at least 10 years after he last manufactured, imported, supplied or used the substance or mixture. That manufacturer, importer, downstream user or distributor shall submit this information or make it available without delay upon request to the Ministry without prejudice to Parts 2 and 6.

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

FIFTH PART
Downstream Users

Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures

ARTICLE 33 – (1) A downstream user or distributor may provide information to assist in the preparation of a registration.

(2) In respect to communication of information

(a) Any downstream user shall have the right to make a use, as a minimum the brief general description of use, known in writing (on paper or electronically) to the manufacturer, importer, downstream user or distributor who supplies him with a substance on its own or in a mixture with the aim of making this an identified use.

(b) In making a use known, he shall provide sufficient information to allow the manufacturer, importer or downstream user who has supplied the substance, to prepare an exposure scenario, or if appropriate a use and exposure category, for his use in the manufacturer, importer or downstream user's chemical safety assessment.

(c) Distributors shall pass on such information to the next actor or distributor up the supply chain. Downstream users in receipt of such information may prepare an exposure scenario for the identified use(s), or pass the information to the next actor up the supply chain.

(3) For registered substances, the manufacturer, importer or downstream user may request the manufacturer, importer or downstream user,to add the substance on identified use in

accordance with paragraph 2. Provided that the request was made at least one month before the supply, either before he next supplies or within one month after the request, whichever is the later, shall apply the duties of Article 15.

(4) A downstream user of a substance on its own or in a mixture shall prepare a chemical safety report in accordance with Annex 12 for any use outside the conditions described in an exposure scenario or if appropriate a use and exposure category communicated to him in a safety data sheet or for any use his supplier advises against.

A downstream user need not prepare such a chemical safety report in any of the following cases:

a) A safety data sheet is not required to be communicated with the substance or mixture in accordance with Article 27;

b) A chemical safety report is not required to be completed by his supplier in accordance with Article 15;

c) The downstream user uses the substance or mixture in a total quantity of less than one ton per year;

ç) The downstream user implements or recommends an exposure scenario which includes as a minimum the conditions described in the exposure scenario communicated to him in the safety data sheet;

d) The substance is present in a mixture in a concentration lower than any of the concentrations set out in Article 15(2);

e) The downstream user is using the substance for the purposes of product and process oriented research and development, provided that the risks to human health and the environment are adequately controlled in accordance with the requirements of legislation for the protection of workers and the environment.

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

a) The safety data sheet(s) supplied to him;

b) His own chemical safety assessment;

c) Any information on risk management measures supplied to him in accordance with Article 28.

(6) Where a downstream user does not prepare a chemical safety report in accordance with paragraph 4(c), he shall consider the use(s) of the substance and identify and apply any appropriate risk management measures needed to ensure that the risks to human health and the environment are adequately controlled. Where necessary, this information shall be included in any safety data sheet prepared by him.

(7) Downstream users shall keep their chemical safety report up to date and available.

(8)A chemical safety report prepared in accordance with paragraph 4 of this Article need not include consideration of the risks to human health from the end uses set out in Article 15(5).

Obligation for downstream users to report information

ARTICLE 34 – (1) Before commencing or continuing with a particular use of a substance that has been registered by an actor up the supply chain in accordance with Articles 7 or 18, the downstream user shall report to the Ministry the information specified in paragraph 2 of this Article, in the following cases:

a) The downstream user has to prepare a chemical safety report in accordance with Article 33(4); or

b) The downstream user is relying on the exemptions in Article 33(4)(c) or (e).

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

a) His identity and contact details as specified in Section 1.1 of Annex 6 ;

b) The registration number(s) referred to in Article 20(3), if available;
c) The identity of the substance(s) as specified in Section 2.1 to 2.3.4 of Annex 6 ;
ç) The identity of the manufacturer(s) or the importer(s) or other supplier as specified in Section 1.1 of Annex 6;
d) A brief general description of the use(s), as specified in Section 3.5 of Annex 6 , and of the conditions of use(s);
e) Except where the downstream user is relying on the exemption in Article 33(4)(c), a proposal for additional testing on vertebrate animals, where this is considered necessary by the downstream user to complete his chemical safety assessment.
(3) The downstream user shall update this information without delay in the event of a change in the information reported in accordance with paragraph 1.
(4) A downstream user shall report to the Ministry if his classification of a substance is different to that of his supplier.
(5) Except where a downstream user is relying on the exemption in Article 33(4)(c), reporting in accordance with paragraphs 1 to 4 of this Article shall not be required in respect of a substance, on its own or in a mixture, used by the downstream user in quantities of less than one ton per year for that particular use.

Application of downstream user obligations
ARTICLE 35 – (1) Downstream users shall be required to comply with the requirements of Article 33 at the latest 12 months after receiving a registration number communicated to them by their suppliers in a safety data sheet.
(2) Downstream users shall be required to comply with the requirements of Article 34 at the latest six months after receiving a registration number communicated to them by their suppliers in a safety data sheet.

SIXTH PART
Evaluation

FIRST SECTION
Dossier Evaluation

Examination of testing proposals
ARTICLE 36 – (1) The Ministry shall examine any testing proposal set out in a registration or a downstream user report for provision of the information specified in Annexes 9 and 10 for a substance. Priority shall be given to registrations of substances which have or may have PBT, vPvB, sensitising and/or carcinogenic, mutagenic or toxic for reproduction (CMR) properties, or substances above 100 tonnes per year with uses resulting in widespread and diffuse exposure, provided they fulfil the criteria for any of the following hazard classes or categories set out in Annex 1 of Bylaw on Classification, Labelling and Packaging of Substances and Mixtures.
a) Hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
b) Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
c) Hazard class 4.1;
ç) Hazard class 5.1.
(2) Information relating to testing proposals involving tests on vertebrate animals shall be published on the Ministry website. The Ministry shall publish on its website the name of the substance, the hazard end-point for which vertebrate testing is proposed, and the date by

which any third party information is required. It shall invite third parties to submit, using the format provided by the Ministry, scientifically valid information and studies that address the relevant substance and hazard end-point, addressed by the testing proposal, within 45 days of the date of publication. All such scientifically valid information and studies received shall be taken into account by the Ministry in preparing its decision in accordance with paragraph 3.

(3) On the basis of the examination under paragraph 1, the Ministry shall draft one of the following decisions and that decision shall be taken in accordance with the procedure laid down in Articles 43:

a) A decision requiring the registrant(s) or downstream user(s) concerned to carry out the proposed test and setting a deadline for submission of the study summary, or the robust study summary if required by Annex 1;

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

c) A decision in accordance with subparagraphs (a), (b) or (ç) but requiring registrant(s) or downstream user(s) to carry out one or more additional tests in cases of non-compliance of the testing proposal with Annexes 9, 10 and 11;

ç) A decision rejecting the testing proposal;

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

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

Compliance check of registrations

ARTICLE 37 – (1) The Ministry may examine any registration in order to verify any of the following:

a) That the information in the technical dossier(s) submitted pursuant to Article 11 complies with the requirements of Articles 11, 13 and 14 and with Annex 3, Annex 6, Annex 7, Annex 8, Annex 9 and Annex 10;

b) That the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in Annexes 7 to 10 and with the general rules set out in Annex 11;

c) That any required chemical safety assessment and chemical safety report comply with the requirements of Annex 1 and that the proposed risk management measures are adequate;

ç) That any explanation(s) submitted in accordance with Article 12(3) or Article 19(2) has an objective basis.

(2) On the basis of an examination made pursuant to paragraph 1, the Ministry may, within 12 months of the start of the compliance check, prepare a draft decision requiring the registrant(s) to submit any information needed to bring the registration(s) into compliance with the relevant information requirements and specifying adequate time limits for the submission of further information. Such a decision shall be taken in accordance with the procedure laid down in Article 43.

(3) The registrant shall submit the information required to the Ministry by the deadline set.

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

a) The dossier contains information in Article 11(1)(a), (4), (6) and/or (7) submitted separately as per Article 12(3); or
b) The dossier is for a substance manufactured or imported in quantities of one tonne or more per year and does not meet the requirements of Annex 7 applying under either Article 13(1)(a) or (b), as the case may be.

Check of information submitted and follow-up to dossier evaluation
ARTICLE 38 – (1) The Ministry shall examine any information submitted in consequence of a decision taken under Articles 36 or 37, and draft any appropriate decisions in accordance with these Articles, if necessary.
(2) The Ministry shall use the information obtained from this evaluation for the purposes of Article 40.

Procedure and time periods for examination of testing proposals
ARTICLE 39 –(1) The Ministry shall prepare the draft decisions in accordance with the Article 36 (3) in order to fulfil the information requirements in Annexes 9 and 10 by 31/12/2025 for the proposals received by 31/12/2023 including the testing proposals.

SECOND SECTION
Substance Evaluation

Criteria for substance evaluation
ARTICLE 40 – (1) Prioritization shall be made by the Ministry on a risk-based approach:
a) Hazard information, for instance structural similarity of the substance with known substances of concern or with substances which are persistent and liable to bio-accumulate, suggesting that the substance or one or more of its transformation products has properties of concern or is persistent and liable to bio-accumulate;
b) Exposure information;
c) Tonnage, including aggregated tonnage from the registrations submitted by several registrants.

Requests for further information and check of information submitted
ARTICLE 41 – (1) Ministry may require further information from the registrants defined in Annex 7, Annex 8, Annex 9 and Annex 10 including the ones not defined there.
(2) The registrant shall submit the information required to the Ministry by the deadline set.
(3) The Ministry shall examine any information submitted, and shall draft any appropriate decisions in accordance with this Article, if necessary, within 12 months of the information being submitted.

(4) The Ministry shall finish its evaluation activities within 12 months of the start of the evaluation of the substance or within 12 months of the information being submitted under paragraph 2.

THIRD SECTION
Evaluation of Intermediates

Further information on on-site isolated intermediates

ARTICLE 42 – (1) For on-site isolated intermediates that are used in strictly controlled conditions, neither dossier nor substance evaluation shall apply. However, the Ministry considers that a risk to human health or the environment, equivalent to the level of concern arising from the use of substances meeting the criteria in Article 47, arises from the use of an on-site isolated intermediate and that risk is not properly controlled, it may:

a) Require the registrant to submit a written justification on further information directly related to the risk identified,

b) Examine any information submitted and, if necessary, recommend any appropriate risk reduction measures to address the risks identified in relation to the site in question.

FOURTH SECTION
Common Provisions

Registrants' and downstream users' rights

ARTICLE 43 – (1) The Ministry shall notify any draft decision under Articles 36, 37 or 41 to the registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt. If the concerned registrant(s) or downstream user(s) wish to comment, they shall provide their comments to the Ministry in 30 days. The Ministry may amend the draft decision accordingly. In the case that registrants and downstream users don't notify their potential comments to the Ministry in 30 days from the date of notification, notification decision is deemed to be accepted.

(2) If a registrant has ceased the manufacture or import of the substance, or the production or import of an article, or the downstream user the use, he shall inform the Ministry of this fact with the consequence that the registered volume in his registration, if appropriate, shall be put to zero and no further information may be requested with respect to that substance, unless the registrant notifies the restart of the manufacture or import of the substance or the production or import of the article, or the downstream user notifies the restart of the use.

(3) The registrant may cease the manufacture or import of the substance or the production or import of the article, or the downstream user the use, upon receipt of the decision. In such cases, the registrant, or downstream user, shall inform the Ministry of this fact with the consequence that his registration, or report, shall no longer be valid, and no further information may be requested with respect to that substance, unless he submits a new registration or report.

(4) Notwithstanding paragraphs 2 and 3, further information may be required in accordance with Article 41 in either or both of the following cases:

(a) Where a dossier has been prepared in accordance with Annex 15 concluding that there is a potential long-term risk to human health or the environment justifiying the need for further information;

b) where the exposure to the substance manufactured or imported by the registrant(s), or to the substance in the article produced or imported by the registrant(s), or to the substance used by the downstream user(s) contributes significantly to that risk.

Cost sharing for tests without an agreement between registrants and/or downstream users

ARTICLE 44 – (1) Where registrants or downstream users are required to perform a test as a result of a decision taken under this Part, those registrants or downstream users shall make every effort to reach an agreement as to who is to carry it out on behalf of the other registrants or downstream users and to inform the Ministry accordingly within 90 days. If the Ministry is not informed of such agreement within 90 days, it shall designate one of the registrants or downstream users to perform the test on behalf of all of them.

(2) If a registrant or downstream user performs a test on behalf of others, they shall all share the cost of that study equally.

(3) In the case referred to in paragraph 1, the registrant or downstream user who performs the test shall provide each of the others concerned with a copy of the full study report.

(4) The person performing and submitting the study shall have a claim against the others accordingly. Any person concerned shall be able to make a claim in order to prohibit another person from manufacturing, importing or placing the substance on the market if that other person either fails to pay his share of the cost or to provide security for that amount or fails to hand over a copy of the full study report of the study performed.

SEVENTH PART
Authorization

FIRST SECTION
Authorization Requirement

Authorization and Substitution

ARTICLE 45 – (1) All manufacturers, importers and downstream users applying for authorizations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.

General provisions

ARTICLE 46 – (1) A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex 14, unless:

a) The use(s) of that substance on its own or in a mixture or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been authorized in accordance with Articles 50, 51, 52, 53, 54 or ;

b) The use(s) of that substance on its own or in a mixture or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been exempted from the authorization requirement in Annex 14 itself in accordance with Article 48(2); or

c) The date referred to in Article 48(1)(c)(1) has not been reached; or

ç) The date referred to in Article 48(1)(c)(1) has been reached and he made an application 18 months before that date but a decision on the application for authorization has not yet been taken; or

d) In cases where the substance is placed on the market, authorization for that use has been granted to his immediate downstream user.

(2) A downstream user may use a substance meeting the criteria set out in paragraph 1 provided that the use is in accordance with the conditions of an authorization granted to an actor up his supply chain for that use.

(3) Paragraphs 1 and 2 shall not apply to the use of substances in scientific research and development. Annex 14 shall specify if paragraphs 1 and 2 apply to product and process orientated research and development as well as the maximum quantity exempted.
(4) Paragraphs 1 and 2 shall not apply to the following uses of substances:
a) Uses in plant protection products within the scope of Bylaw on the Classification, Packaging and Labelling of Plant Protection Products;
b) Uses in biocidal products within the scope of Bylaw on Biocidal Products;
c) Use as motor fuels covered by Bylaw on Environmental Effects of Motor Fuels and Diesel Fuels Types; published in the Official Gazette dated 01/04/2017 and numbered 30025;
ç) Uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems.
(5) In the case of substances that are subject to authorization only because they meet the criteria in Article 47 (1) (a), (b) or (c) or because they are identified in accordance with Article 47 (1) (e) only because of hazards to human health, paragraphs 1 and 2 of this Article shall not apply to the following uses:
a) Uses in cosmetic products within the scope of Bylaw on Cosmetics ;
(6) Uses in food contact materials within the scope of Bylaw on the Turkish Food Codex Substances and Materials in Contact with Food Paragraphs 1 and 2 shall not apply to the use of substances when they are present in mixtures:
a) For substances referred to in Article 47 (1) (ç), (d) and (e), below a concentration limit of 0,1 % weight by weight (w/w);
b) For all other substances, below the lowest of the concentration limits specified in Annex 6, Section 3 of Bylaw on Classification, Labelling and Packaging of Substances and Mixtures which result in the classification of the mixture as hazardous.

Substances to be included in Annex XIV
ARTICLE 47 – (1) The following substances defined as the substances of high concern may be included in Annex 14 in accordance with the procedure laid down in Article 48:
a) Substances meeting the criteria for classification in the hazard class carcinogenicity category 1A or 1B in accordance with title 3.6 of Annex 1 of Bylaw on Classification, Labelling and Packaging of Substances and Mixtures;
b) Substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B in accordance with title 3.5 of Annex 1 of the Bylaw on Classification, Labelling and Packaging of Substances and Mixtures ;
c) Substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B in accordance with title 3.7 of Annex 1 to Bylaw on Classification, Labelling and Packaging of Substances and Mixtures;
ç) Substances which are persistent, bio accumulative and toxic in accordance with the criteria set out in Annex 13 of this Bylaw;
d) Substances which are very persistent and very bio accumulative in accordance with the criteria set out in Annex 13 of this Bylaw;
e) Substances — such as those having endocrine disrupting properties or those having persistent, bio accumulative and toxic properties or very persistent and very bio accumulative properties, which do not fulfill the criteria of subparagraphs (ç) or (d) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in this paragraph and which are identified on a case-by-case basis in accordance with the procedure set out in Article 49.

Inclusion of substances in Annex 14

ARTICLE 48 – (1) Whenever a decision is taken by the Ministry to include the substances referred to in Article 47 in Annex 14, such a decision shall specify for each substance:

a) The identity of the substance as specified in Section 2 of Annex 6 ;

b) The intrinsic property (properties) of the substance referred to in Article 47;

c) Transitional arrangements:

1) The date(s) from which the placing on the market and the use of the substance shall be prohibited unless an authorization is granted, the sunset date, which should take into account, where appropriate, the production cycle specified for that use;

2) A date or dates at least 18 months before the sunset date(s) by which applications must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s); these continued uses shall be allowed after the sunset date until a decision on the application for authorization is taken;

ç) Review periods for certain uses, if appropriate;

d) Uses or categories of uses exempted from the authorization requirement, if any, and conditions for such exemptions, if any.

(2) Uses or categories of uses may be exempted from the authorization requirement provided that, on the basis of the existing specific related legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled. In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and the environment related to the nature of the substance, such as where the risk is modified by the physical form.

(3) Prior to a decision to include substances in Annex 14, the Ministry shall, determine priority substances to be included specifying for each substance the items set out in paragraph 1. Priority shall normally be given to substances with:

a) PBT or vPvB properties; or

b) Wide dispersive use; or

c) High volumes.

The number of substances included in Annex 14 and the dates specified under paragraph 1 shall also take account of the Ministry’s capacity to handle applications in the time provided for.

(4) Before the Ministry adopts a decision it shall make it publicly available on its website in accordance with Article 60 and 61, clearly indicating the date of publicationand all interested parties may submit comments within three months of the date of publication, in particular on uses which should be exempt from the authorization requirement. The Ministry shall make its decision according to the received comments. In the event that the substance proposed to be included in Annex 14 concerns the Relevant Authorities other than the Ministry, the Ministry shall first obtain the written opinion of such Relevant Authorities.

(5) Subject to paragraph 6, after inclusion of a substance in Annex 14, this substance shall not be subjected to new restrictions under the procedure outlined in Part 8 covering the risks to human health or the environment from the use of the substance on its own, in a mixture or incorporation of a substance in an article arising from the intrinsic properties specified in Annex 14.

(6) A substance listed in Annex 14 may be subjected to new restrictions under the procedure outlined in Part 8 covering the risks to human health or the environment from the presence of the substance in (an) article(s).

(7) Substances for which all uses have been prohibited under Part 8 or by other relevant legislation shall not be included in Annex 14 or shall be removed from it.

(8) Substances which as a result of new information no longer meet the criteria of Article 47 shall be removed from Annex 14 by the Ministry.

Defining the substances in Article 47

ARTICLE 49- (1) The procedure mentioned in this article is applied in order to define the substances compliant with the criteria mentioned in Article 47 and the substances to be included in Annex 14.

(2) Before starting the procedures for the substances in Article 47, the Ministry shall specify the substances in this Article in order to prepare dossier under Annex 15 and announce that the dossier is prepared under Annex 15 through website. The Ministry shall invite all releted parties to send their opinions to the Ministry.

(3) Any Relevant Authority prepares a dossier for the substances for which he thinks they are compliant with the criteria under Article 47 according to Annex 15 and send it to the Ministry. The Ministry shall forward the dossier to the relevant entities within 30 days after receiving if it is in accordance with Annex 15 .

(4) Beginning from the forward of the dossier within 60 days, all relevant entities will send their comments to the Ministry.

(5) After the 60 day period mentioned in paragraph 4, , the Ministry shall decide on adding or not the substance in paragraph 1 to the list.

(6)After the decision on adding the substance, the Ministry shall announce and update the list under paragraph 1 through website.

SECOND SECTION
Authorization

Granting of authorizations

ARTICLE 50 – (1) The Ministry shall be responsible for taking decisions on applications for authorizations in accordance with this Section.

(2) Without prejudice to paragraph 3 provisions of this Article an authorization shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex 14 is adequately controlled in accordance with Section 6.4 of Annex 1 and as documented in the applicant's chemical safety report. When granting the authorization, and in any conditions imposed therein, the Ministry shall take into account all discharges, emissions and losses, including risks arising from diffuse or dispersive uses, known at the time of the decision.

(3) Paragraph 2 shall not apply to:

a) Substances meeting the criteria in Article 47 (1) (a), (b), (c) or (e) for which it is not possible to determine a threshold in accordance with Section 6.4 of Annex 1;

b) Substances meeting the criteria in Article 47 (1) (ç) or (d);

c) Substances identified under Article 47 (1) (e) having persistent, bio accumulative and toxic properties or very persistent and very bio accumulative properties.

(4) If an authorisation cannot be granted under paragraph 2 or for substances listed in paragraph 3, an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. This decision shall be taken after consideration of all of the following elements and taking into account the opinions of the Risk Assessment and the Socio-economic Analysis referred to in Article 54 (4)(a) and (b):

a) The risk posed by the uses of the substance, including the appropriateness and effectiveness of the risk management measures proposed;

b) The socio-economic benefits arising from its use and the socio- economic implications of a refusal to authorize as demonstrated by the applicant or other interested parties;

c) the analysis of the alternatives submitted by the applicant under Article 52(4)(d) or any substitution plan submitted by the applicant under Article 52(4)(e), and any third party contributions submitted under Article 54 (2);
ç) Available information on the risks to human health or the environment of any alternative substances or technologies.
(5) When assessing whether suitable alternative substances or technologies are available, all relevant aspects shall be taken into account by the Ministry including:
a) Whether the transfer to alternatives would result in reduced overall risks to human health and the environment, taking into account the appropriateness and effectiveness of risk management measures;
b) The technical and economic feasibility of alternatives for the applicant.
(6) A use shall not be authorized if this would constitute a relaxation of a restriction set out in Annex 17.
(7) The authorization shall specify:
a) The person(s) to whom the authorization is granted;
b) The identity of the substance(s);
c) The use(s) for which the authorization is granted
ç) Any conditions under which the authorization is granted;
d) The time-limited review period;
e) Any monitoring arrangement.
(8) Notwithstanding any conditions of an authorization, the holder shall ensure that the exposure is reduced to as low a level as is technically and practically possible.

Review of authorizations
ARTICLE 51 – (1) Authorizations granted in accordance with Article 50 shall be regarded as valid until the Ministry decides to amend or withdraw the authorization in the context of a review, provided that the holder of the authorization submits a review report at least 18 months before the expiry of the time-limited review period. Rather than re-submitting all elements of the original application for the current authorization, the holder of an authorization may submit only the number of the current authorization, subject to the second, third and fourth subparagraphs.
A holder of an authorization granted in accordance with Article 50 shall submit an update of the analysis of alternatives referred to in Article 52(4)(d), including information about any relevant research and development activities by the applicant, if appropriate, and any substitution plan submitted under Article 52(4)(e). If the update of the analysis of alternatives shows that there is a suitable alternative available taking into account the elements in Article 50(5), he shall submit a substitution plan, including a timetable for proposed actions by the applicant. If the holder cannot demonstrate that the risk is adequately controlled, he shall also submit an update of the socio- economic analysis contained in the original application.
If he can now demonstrate that the risk is adequately controlled, he shall submit an update of the chemical safety report.
If any other elements of the original application have changed, he shall also submit updates of these element(s).
When any updated information is submitted in accordance with this paragraph, any decision to amend or withdraw the authorization in the context of the review shall be taken in accordance with the procedure referred to in Article 54 applied mutatis mutandis.
(2) The Ministry shall set a reasonable deadline by which the holder(s) of the authorization may submit further information necessary for the review and indicate by when it will take a decision in accordance with Article 54. Authorizations may be reviewed at any time if:

a) The circumstances of the original authorization have changed so as to affect the risk to human health or the environment, or the socio- economic impact; or
b) New information on possible substitutes becomes available.
(3) In its review decision the Ministry may, if circumstances have changed and taking into account the principle of proportionality, amend or withdraw the authorization, if under the changed circumstances it would not have been granted or if suitable alternatives in accordance with Article 50(5) become available. In the latter case the Ministry shall require the holder of the authorization to present a substitution plan if he has not already done so as part of his application or update.
In cases where there is a serious and immediate risk for human health or the environment, the Ministry may suspend the authorization pending the review, taking into account the principle of proportionality.
(4) If an environmental quality standard referred to in relevant legislation on IPPC is not met, the authorizations granted for the use of the substance concerned may be reviewed.
(5) If the environmental objectives as referred to in Article 4 of Bylaw on Water Pollution Control published in Official Gazette dated 31/12/2004 and numbered 25687 are not met, the authorizations granted for the use of the substance concerned in the relevant river basin may be reviewed.
(6) If a use of a substance is subsequently prohibited or otherwise restricted in regulations on persistent organic pollutants, the Ministry shall withdraw the authorization for that use.

Applications for authorizations
ARTICLE 52 – (1) An application for an authorization shall be made to the Ministry through Chemicals Registration System in the website of Ministry.
(2) Applications for authorization may be made by the manufacturer(s), importer(s) and/or downstream user(s) of the substance. Applications may be made by one or several persons.
(3) Applications may be made for one or several substances that meet the definition of a group of substances in Section 1.5 of Annex 11, and for one or several uses. Applications may be made for the applicant's own use(s) and/or for uses for which he intends to place the substance on the market.
(4) An application for authorization shall include the following information:
a) The identity of the substance(s), as referred to in Section 2 of Annex 6 ;
b) The name and contact details of the person or persons making the application;
c) A request for authorization, specifying for which use(s) the authorization is sought;
ç) Unless already submitted as part of the registration, a chemical safety report in accordance with Annex 1 covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex 14;
d) An analysis of the alternatives considering their risks and the technical and economic feasibility of substitution and including, if appropriate information about any relevant research and development activities by the applicant;
e) Where the analysis referred to in paragraph (d) shows that suitable alternatives are available, taking into account the elements in Article 50(5), a substitution plan including a timetable for proposed actions by the applicant.
(5) The application may include:
a) A socio-economic analysis conducted in accordance with Annex 16;
b) A justification for not considering risks to human health and the environment arising either from:
1) Emissions of a substance from an installation for which a permit was granted; or
2) Discharges of a substance from a point source governed by the requirement for prior regulation.

(6) The application shall not include the risks to human health arising from the use of a substance in a medical device in the scope of Bylaw on Medical Devices published in the Official Gazette dated 07/06/2011 and numbered 27957, Bylaw on Invasive Active Medical Devices published in the Official Gazette dated 07/06/2011 and numbered 27957 and Bylaw on Medical Diagnosis Devices Which Are Used Outside The Body (In vitro) published in the Official Gazette dated 09/01/2007 and numbered 26398.

Subsequent applications for authorization

ARTICLE 53 – (1) If an application has been made for a use of a substance, a subsequent applicant may refer to the appropriate parts of the previous application submitted in accordance with Article 52(4)(ç), (d), (e) and (5)(a), provided that the subsequent applicant has permission from the previous applicant to refer to these parts of the application.

(2) If an authorization has been granted for a use of a substance, a subsequent applicant may refer to the appropriate parts of the previous application submitted in accordance with Article 52(4)(ç), (d) and (e) and (5)(a), provided that the subsequent applicant has permission from the holder of the authorization to refer to these parts of the application.

(3) Before referring to any previous application in accordance with paragraphs 1 and 2, the subsequent applicant shall update the information of the original application as necessary.

Procedure for authorization

ARTICLE 54 – (1) The Ministry shall acknowledge the date of receipt of the application. Following the receipt of application, the Ministry shall conduct the Risk Assessment and Socio-economic Analysis referred to in this Article and shall give its draft opinions within ten months of the date of receipt of the application.

(2) The Ministry shall make available on its website broad information on uses, taking into account Articles 60 and 61 on access to information, for which applications have been received and for reviews of authorizations, with a deadline by which information on alternative substances or technologies may be submitted by interested third parties.

(3) During the process for adoption of authorization decisions in paragraph 1, the Ministry shall first check that the application includes all the information specified in Article 52 that is relevant to its remit. If necessary, the Ministry shall, request to the applicant for additional information to bring the application into conformity with the requirements of Article 52. The Ministry may, if it deems it necessary, require the applicant or request third parties to submit, within a specified time period, additional information on possible alternative substances or technologies. The Ministry shall also take into account any information submitted by third parties.

(4) The draft opinions shall include the following elements:

a) Risk Assessment: an assessment of the risk to human health and/or the environment arising from the use(s) of the substance, including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives;

b) Socio-economic Analysis: an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application, when an application is made in accordance with Article 52 and of any third party contributions submitted under paragraph 2 of this Article.

(5) The Ministry shall send these draft opinions to the applicant by the end of the deadline set out in paragraph 1. Within 60 days of receipt of the draft opinion, the applicant may provide written notice that he wishes to comment.

If the applicant does not send comment to the Ministry in 60 days, the draft opinion will be finalized. After the Ministry takes the written opinion in 60 days, it will finalize its draft opinion in 60 days.
(6) The Ministry shall determine which parts of its opinions and parts of any attachments thereto should be made publicly available on its website.
(7) In cases covered by Article 53(1), the Ministry shall treat the applications together, provided the deadlines for the first application can be met.
(8) The Ministry shall prepare a draft authorization decision within 90 days of the issuance of its opinions. A final decision granting or refusing the authorization shall be taken.
(9) Summaries of the Ministry decisions, including the authorization number and the reasons for the decision, in particular where suitable alternatives exist, shall be published in the web-site of the Ministry.
(10) In cases covered by Article 53(2), the deadline set out in paragraph 1 of this Article shall be shortened to five months.

THIRD SECTION
Authorizations in the Supply Chain

Obligation of holders of authorizations
ARTICLE 55 – (1) Holders of an authorization, as well as downstream users referred to in Article 46(2) including the substances in a mixture, shall include the authorization number on the label before they place the substance or a mixture containing the substance on the market for an authorised use without prejudice to Bylaw on the Classification, Labelling and Packaging of Substances and Mixtures.

Downstream users
ARTICLE 56 – (1) Downstream users using a substance in accordance with Article 46(2) shall notify the Ministry within 90 days of the first supply of the substance.
(2) The Ministry shall establish and keep up to date a register of downstream users who have made a notification in accordance with paragraph 1.

EIGHTH PART
Restrictions on the Manufacturing, Placing on the Market and Use of Certain Hazardous Substances, Mixtures and Articles

FIRST SECTION
Restrictions

Placing Restriction
ARTICLE 57 – (1) A substance on its own, in a mixture or in an article, for which Annex 17 contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. This shall not apply to the manufacture, placing on the market or use of a substance in scientific research and development. Annex 17 shall specify if the restriction shall not apply to product and process orientated research and development, as well as the maximum quantity exempted.
(2) Paragraph 1 shall not apply to the use of substances in cosmetic products, as defined by Bylaw on Cosmetics with regard to restrictions addressing the risks to human health within the scope of that Bylaw.

SECOND SECTION
Restrictions Process

Introducing new and amending current restrictions
ARTICLE 58 – (1) When there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, Annex 17 shall be amended by the Ministry by adopting new restrictions, or amending current restrictions in Annex 17, for the manufacture, use or placing on the market of substances on their own, in mixtures or in articles. Any amendment shall take into account the socio- economic impact of the restriction, including the availability of alternatives.
(2) The first subparagraph shall not apply to the use of a substance as an on-site isolated intermediate.
(3) Ministry shall conduct risk assessment and socio-economic analysis to evaluate the risk to human health or the environment and the socio-economic impact of restriction during the restriction process. Ministry may use the services of third parties or compose committees consisting of experts in order to conduct or help to conduct such Risk Assessments and socio-economic analysis.
(4) Any relevant entity may prepare a restriction proposal dossier under Annex 15 and can submit this to the Ministry.

NINETH PART
Fees

FIRST SECTION
Circulation Capital Costs

Circulation capital costs
ARTICLE 59 – (1) The processes in the scope of Article 7(1), Article 8(1) and (5), Article 10(2), Article 12, Article 17(2), Article 18(2), Article 19, Article 22(1), Article 51, Article 52 and Article 61(2) are subject to fees.

(2) The fees that shall be paid in the scope of this Bylaw, is determined annually and published at the website of the Ministry in the circulating capital enterprise unit price list.
(3) No fee shall be taken for the substances in the 1-10 tonnage band which have all of the information according to Annex 7 in their registration dossier.

TENTH PART
Information

FIRST SECTION
Access to Information

Access to information
ARTICLE 60– (1) Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests of the concerned person:
a) details of the full composition of a mixture ;
b) without prejudice to Article 8(6) and Article 54 (2), the precise use, function or application of a substance or mixture , including information about its precise use as an intermediate;
c) the precise tonnage of the substance or mixture manufactured or placed on the market;
ç) links between a manufacturer or importer and his distributors or downstream users.

(2)Where urgent action is essential to protect human health, safety or the environment, such as emergency situations, the Ministry may disclose the information referred to in this paragraph.

Public access

ARTICLE 61 – (1) The following information held by the Ministry on substances whether on their own, in mixtures or in articles, shall be made publicly available, free of charge, over the Internet:

a) Without prejudice to paragraph 2(e) of this Article, the name in the IUPAC nomenclature for substances fulfilling the criteria for any of the following hazard classes or categories set out in Annex 1 to Bylaw on the Classification, Labelling and Packaging of Substances and Mixtures

1) 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;

2) 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;

3) Hazard class 4.1;

4) Hazard class 5.1;

b) If applicable, the name of the substance as given in EINECS;

c) The classification and labelling of the substance;

ç) Physicochemical data concerning the substance and on pathways and environmental fate;

d) toxicological and eco toxicological information;

e) Any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC);

f) The guidance on safe use provided in accordance with Sections 4 and 5 of Annex 6 ;

g) Analytical methods if requested in accordance with Annexes 9 or 10 which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.

(2) The following information on substances whether on their own, in mixtures or in articles, shall be made publicly available, free of charge, over the Internet except where a party submitting the information submits a justification in accordance with Article 11(a)(11), accepted as valid by the Ministry, as to why such publication is potentially harmful for the commercial interests of the registrant or any other party concerned:

a) If essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be hazardous;

b) The total tonnage band (i.e. 1 to 10 tons, 10 to 100 tons, 100 to 1 000 tons or over 1 000 tons) within which a particular substance has been registered;

c) The study summaries or robust study summaries of the information referred to in paragraph 1(ç) and (d);

ç) Information, other than that listed in paragraph 1, contained in the safety data sheet;

d) The trade name(s) of the substance;

e) Subject to Article 26 of Bylaw on the Classification, Labelling and Packaging of Substances and Mixtures , the name in the IUPAC nomenclature for substances that are only used as one or more of the following:

1) As an intermediate;

2) In scientific research and development

3) In product and process orientated research and development.

ELEVENTH PART
Inspectıon and Enforcement

FIRST SECTION
Inspection and Enforcement

Inspection
ARTICLE 62 – (1) Of this Bylaw:

a) Inspections regarding Article 46 and 57 shall be conducted according to the Law numbered 4703, Law on Occupational Health and Safety published in the Official Gazette dated 13/07/2012 and numbered 6331, Law on Provincial Administration published in the Official Gazette dated 10/06/1949 and numbered 5442 and Law numbered 5996 by Relevant Institutions.
b) Inspections regarding the other provisions shall be conducted according to Law numbered 2872 and Law numbered 4703 by the Ministry.

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Enforcement
ARTICLE 63 – (1) In case the breech of the provisions of this Bylaw, enforcement and penalties indicated in Article 12 ,13 and (20)(1) (y) of Law numbered 2872, Article 11 and 12 of Law numbered 4703, Articles 36 to 42 of Law numbered 5996 and Article 66 of Law numbered 5442 shall be applied.

TWELVETH PART
Miscellaneous and Final Provisions

FIRST SECTION
Miscellaneous Provisions

Repeals
ARTICLE 64 – (1) Following Bylaws shall be repealed upon the entry into force of this Bylaw:
a) Bylaw on Safety Data Sheets Concerning Hazardous Substances and Mixtures published in the Turkish Official Gazette dated 13/12/ 2014 numbered 29204
b) Bylaw on Inventory and Control of Chemicals published in the Turkish Official Gazette dated 26/12/ 2008 numbered27092 (bis)
c) Bylaw on Restriction and Ban of Hazardous Substances and Mixtures published in the Official Gazette dated 26/12/ 2008 numbered 27092 (bis)

Harmonisation of European Union Legislation
Madde 65- (1) This Bylaw was prepared taking into account Regulation of European Parliament and Council numbered 1907/2006/EC on Registration, Evaluation, Authorization and Restriction of Chemicals in the framework of harmonization of European Union acquie.

Transitional provision
TRANSITIONAL ARTICLE 1- (1) All registrants, shall send a pre-SIEF including below mentioned information to the Ministry through Chemicals Registration System in the website of Ministry until 31/12/2020:
a) substance identity according to Annex-6;

b) Role in the supply chain

TRANSITIONAL ARTICLE 2- (1) If substances on their own or in a mixture are manufactured or imported before 31/12/2023 and equal to or more than 1tonne/year, Articles 7 and/or 8 or 17 or 18 are executed between dates 31/12/2020 and 31/12/2023.
(2) Safety Data Sheets shall be prepared according to the Bylaw on Safety Data Sheets Concerning Hazardous Substances and Mixtures until 31/12/2023.
(3) Safety Data Sheets can be prepared according to this Bylaw from the execution date of Article 27 until 31/12/2023. In these cases, provisions of Bylaw on Safety Data Sheets Concerning Hazardous Substances and Mixtures will not be applied.
(4) Chemicals Assessment Specialist can prepare a safety data sheet also according to the Bylaw on Safety Data Sheets Concerning Hazardous Substances and Mixtures.

Entry into Force
ARTICLE 66- (1) Of this Bylaw;
a) Articles 6, 40-56 will enter into force on 31/12/2023,
b) Article 57(1);
(1) Entries 28, 29, 30, 31, 32, 34, 35, 36, 37, 38, 40, 41, 45, 48,49, 54, 55,57, 58, 60 of Annex 17 will enter into force on 31/12/2018,
(2) Entry 62 of Annex 17 will enter into force on 31/12/2019
(3) Entries 46a, paragraphs 1 to 4 of 47 and 65 of Annex 17 will enter into force on 31/12/2021
(4) Enty 66 of Annex 17 will enter into force on 31/12/2022
(5) All other entries of Annex 17 will enter into force 6 months later the date of its publication on the Official Gazette.
c) Article 64(1)(a) will enter into force on 31/12/2023, Article 64(1)(b) will enter into force on the published day,
ç) All other provisions will enter into force 6 months later the date of its publication on the Official Gazette.

Execution
ARTICLE 67 – (1) Of this Bylaw;
a) Article 58 (1) shall be executed by the Minister of Environment and Urbanization and Minister of Health jointly.
b) Other provisions shall be executed by the Minister of Environment and Urbanization.