

**LAW NO. 04/L-197****ON CHEMICALS**

**Assembly of Republic of Kosovo,**

Based on Article 65 (1) of Constitution of the Republic of Kosovo,

Approves

**LAW ON CHEMICALS****CHAPTER I****GENERAL PROVISIONS****Article 1  
Purpose**

The purpose of this Law is sustainable management of hazardous chemicals, protection and reduction of possible risk from chemicals that may affect harmful consequences for human health and environment.

**Article 2  
Scope**

1. This law sets out the conditions for placing on the market of dangerous substances and mixtures and determination of their controlling manner; defining and assessing risks that may adversely affect human health and the environment; review and issuing the permits for the circulation, treatment and use of chemicals; maintaining the register of chemicals; register of natural and legal persons who trade and use chemicals; requirements for classification, labelling, packaging, import, export and transit of hazardous chemicals and responsibilities of competent authority for the implementation and monitoring of this Law.

2. This law also sets out the conditions for the placing on the market of detergents, issuing the permits and maintaining the register of detergents.

3. The provisions of this Law are based on the precautionary principle of the risks from chemicals.

**Article 3  
Definitions**

1. Terms used in this Law shall have the following meanings:

1.1. **Chemicals** – substances and mixture / chemical preparation;

1.2. **Substance** - chemical elements or their mixtures in the natural state or obtained by any manufacturing process, including any additive necessary substance to preserve their stability, respectively any impurity deriving from the process of manufacture, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

1.3. **Mixture** - mixture or solution composed of two or more substances; the word "Preparation" used so far has the same meaning and should be replaced with the word "mixture" according to EC Regulation 1272/2008;

- 1.4. **Monomer** - molecule which is capable to be linked with other molecules by forming Polymer;
- 1.5. **Polymer**- substance consisting of molecules characterized by the sequence of one or more types of monomer units;
- 1.6. **Producer** - any natural or legal person producing chemicals;
- 1.7. **Production** – production or issuing of chemical substances in natural state;
- 1.8. **Exporter** - any natural or legal person dealing with the export of chemicals who is responsible for their export from the territory of the republic of Kosovo;
- 1.9. **Importer** - any natural or legal person importing chemicals within the territory of Kosovo who is responsible for their import;
- 1.10. **Distributor** - any natural or legal person, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties;
- 1.11. **Supplier** - any manufacturer, importer, downstream user or distributor placing on the market a substance or mixtures;
- 1.12. **Downstream user** - any natural or legal person, differently from the manufacturer or the importer, uses a substance or the mixture, either on its own or in a preparation within its industrial or professional field of activities. A distributor or a consumer is not a downstream user;
- 1.13. **Registrant** - the manufacturer or the importer of a substance or the producer or importer of a product submitting this product for a registration as a substance;
- 1.14. **Packaging** - one or more receptacles and any other components or materials necessary for the receptacles to perform the function of protection, saving together with other necessary safety functions in order to provide safety of the good;
- 1.15. **Labelling /label** - putting a paper, metal, plastic, leather or other material or packaging of a printing / engraving direct in the product, explaining the identification information of the product;
- 1.16. **Pictogram** - graphical composition that includes a symbol plus other graphic elements, such as the frame background pattern or colour that is intended to convey specific information on the hazard concerned;
- 1.17. **Toxic** – substance or chemical mixture that is poisonous for human health and the environment;
- 1.18. **Intermediates substances** - substance in transforming process, before transformation into final product;
- 1.19. **Hazardous chemicals** - substances or mixtures with one or more hazardous characteristics classified under the conditions specified in this Law:
- 1.20. **Good Laboratory Practices (GLP)** - a quality system built with organizational process and under conditions where nonclinical studies for safety of health and environmental are planned, monitored, recorded, archived and reported;
- 1.21. **Movement of chemicals** – any activity related to substances or mixtures, in particular with production, import or export, placing on the market, keeping, protection, transport, use or transposition of chemicals;
- 1.22. **Scientific researches and developments** - scientific researches, analysis of chemical substances with the aim of determining main properties, effects and impacts of existing marketed substances as well as scientific investigation related to the product development;

- 1.23. **Chemical name under IUPAC denomination** – chemical name set out by International Union of Pure and Applied Chemistry – (IUPAC);
- 1.24. **CAS Number** – the number of chemicals registered in the International Register of Chemical Abstract Service;
- 1.25. **Detergents for use in industry or professional use** – detergents used for washing and cleaning outside households, used by professional persons;
- 1.26. **Detergents** - substances or mixtures that contain soap, tension-active substances and other ingredients that are used for cleaning and washing;
- 1.27. **Tension-active Substance** - organic substances or mixtures which are compounds of detergents, operating in surface and consist of one or more hydrophilic and hydrophobic groups, and have the ability to reduce the surface tension of water and form layers or mono-molecular suckling distribution on the surface air-water contact, forming emulsions or micro-emulsions or micelle inhalers in contact with water and solid surfaces;
- 1.28. **Primary biological decomposition** – the structural change of tension-active substances under the action of micro-organisms, in which lose their ability to operate at the surface level due to the decomposition of their structure;
- 1.29. **Full biological decomposition in the presence of oxygen (aerobic)** - the rate of biological decomposition in which tension-active substances, under the influence of microorganisms, under the presence of oxygen, making their complete decomposition into carbon dioxide, water and mineral salts;
- 1.30. **PIC - Prior Informed Consent** - the procedure by which the chemicals that are prohibited or restricted in the exporting country may be exported only if they are notified in advance and is issued the consent by the importing country;
- 1.31. **Placing on the market** - the importing, ordering or giving in use the chemicals to a third person, with or without payment;
- 1.32. **Revocation from the market** – any activity or measure which prevents further supply or termination of access to or possession of chemicals that were previously placed on the market;
- 1.33. **Exposure scenario** - a variety of measures and conditions, including conditions of work, measures to manage risk during the production of chemicals and their use during their life cycle, and the way of control of chemicals whether they affect the human health and the environment;
- 1.34. **Use** - processing, handling, storage, filling and emptying of reservoirs, mixtures, manufacturing of products, packaging and other ways of the use of chemicals;
- 1.35. **Cleaning** - is a definition according to ISO 862 standard - Glossary of terms for tensio-active substances;
- 1.36. **Ministry** - Ministry of Environment and Spatial Planning;
- 1.37. **Minister** - Minister of Environment and Spatial Planning;
- 1.38. **REACH** - Registration, Evaluation, Authorization and Restriction of Chemicals according to (EC) Regulation No 1907/2006;
- 1.39. **Information office / “help desk”** – information office for help and advice about the provisions of this Law;
- 1.40. **Person** - any natural or legal person who is involved directly or indirectly in chemicals management processes.

#### **Article 4**

#### **Safety management of chemicals**

1. Natural or legal persons who import, manufacture, trade and use hazardous chemicals should manage them safely; in accordance with legal provisions, guidelines for proper use of chemicals in order to protect the human health and the measures to be taken to provide first aid, and in accordance with the guidelines for the management of waste from used chemicals, empty packaging.
2. Persons referred to in paragraph 1 of this Article shall manage and undertake the measures for environmental protection, fire protection, as defined in Safety Data Sheet for Chemicals, as well as in accordance with other available data.
3. Persons who use hazardous chemicals must provide and use guidelines for fair use of hazardous chemicals without endangering personal life or others.

#### **Article 5**

#### **Exemptions**

1. This provisions of this Law shall not apply to:
  - 1.1. substances in customs stores and which are subject to customs supervision, or in a free custom areas with the aim of exporting or transiting and not processing or handling;
  - 1.2. radioactive substances;
  - 1.3. non isolated intermediate products;
  - 1.4. chemicals that might be used for production of narcotic substances and psychotropic substances (precursors);
  - 1.5. foods and additives in foodstuff;
  - 1.6. animal foodstuff and additives for these foods;
  - 1.7. drugs for human use and veterinary;
  - 1.8. medical/medicinal equipments;
  - 1.9. narcotic/drug substances;
  - 1.10. chemicals that are considered waste;
  - 1.11. munitions and explosive substances;
  - 1.12. chemical weapons and foregoing substances/precursors of chemical weapons.
2. The provisions of the Law shall not apply to chemicals that are placed in the market as available products, as:
  - 2.1. products for plant protection;
  - 2.2. biocide products
  - 2.3. cosmetic products.
3. The provisions of this Law regulating the classification, packaging and labelling of chemicals does not apply to chemicals that are used for study and scientific researches which are not for sale and are used in a controlled manner.

4. This Law does not regulate the transportation of hazardous chemicals with air, land and rail transport, and by mail.

## **CHAPTER II**

### **HAZARDOUS CHEMICALS**

#### **Article 6**

##### **Hazardous chemicals and their properties**

1. Hazardous chemicals are considered the chemicals in accordance with Regulation (EC) 1272/2008.

2. Classification of chemicals is based on data for:

- 2.1. physical properties;
- 2.2. hazards properties for health;
- 2.3. environmentally hazards properties;
- 2.4. hazards properties for ozone layer.

#### **Article 7**

##### **Hazardous physical properties**

1. Substances and mixtures which have one of the following properties are considered as substances with hazardous physical properties:

- 1.1. explosives;
- 1.2. flammable gases;
- 1.3. flammable aerosols;
- 1.4. gasses under pressure;
- 1.5. flammable liquids;
- 1.6. flammable solids;
- 1.7. self-reactive substances and mixtures;
- 1.8. pyrophoric liquids;
- 1.9. pyrophoric solids;
- 1.10. self-heating substances and mixtures;
- 1.11. substances and mixtures which in contact with water emit flammable gasses;
- 1.12. oxidizing liquids;
- 1.13. oxidizing solids;
- 1.14. organic peroxides;
- 1.15. corrosive to metals;

### **Article 8**

#### **Hazardous properties to health**

1. Substances and mixtures are considered hazardous to health if they have one of the following properties:

- 1.1. acute toxicity;
- 1.2. skin corrosive/irritation;
- 1.3. serious eye damage/eye irritation;
- 1.4. respiratory or skin sensitization;
- 1.5. germ cell mutagenicity;
- 1.6. carcinogenic;
- 1.7. reproductive toxicity;
- 1.8. specific target organ toxicity-single exposure (STOT);
- 1.9. specific target organ toxicity-repeated exposure (STOT);
- 1.10. aspiration hazard.

### **Article 9**

#### **Environmentally hazardous properties**

1. Substances and mixtures which have hazardous properties to the environment impose:

- 1.1. hazardous to the aquatic environment;
- 1.2. hazardous to the non-aquatic environment.

2. Substances and mixtures have hazardous properties to the environment, if they present immediate or delayed danger for one or more components of the environment. These chemicals can be persistent, bio-accumulative and toxic.

3. Substances are considered persistent bio-accumulative and toxic (PBT) if they meet the criteria laid down in Chapter 1 of Annex XIII of (EC) Regulation No. 1907/2006.

4. Substances are considered very persistent and very bio-accumulative (vPvB) if they meet the criteria set out in Chapter 2 of Annex XIII of (EC) Regulation No. 1907/2006.

### **Article 10**

#### **Dangerous to the ozone layer properties**

Substances and mixtures which are hazardous to the ozone layer are those that harm the ozone layer.

## CHAPTER III

### COMPETENT AUTHORITY

#### Article 11 Competent authority

1. The competent authority for the management of chemicals in the context of this Law is the Ministry of Environment and Spatial Planning.
2. The Ministry shall establish the requirements for the management and supervision of; detergents, dangerous chemicals used in the mining industry / extraction and colours, hazardous substances and mixtures used for scientific research and studies in the laboratories for coordination and supervision of scientific research which will be carried out under the provisions of this Law.
3. The Ministry according to this Law is the competent authority for cooperation with the European Commission and the European Chemicals Agency.

#### Article 12

1. According to this Law, Ministry shall:

- 1.1. draft legislation and secondary legislation for the management of chemicals in the Republic of Kosovo;
- 1.2. publish the List of harmonised classification and labelling of hazardous substances list of substances classified as hazardous;
- 1.3. publish the list of substances of high risk (which cause concern) - list of cancerogenic, mutagenic , azocolorants substances;
- 1.4. publish the list of prohibitions and restrictions on the use of hazardous chemicals;
- 1.5. keep the register of general chemicals in Republic of Kosovo;
- 1.6. issue permits for the manufacture, import, export, placing on the market and use of dangerous chemicals;
- 1.7. issue permits for the use of tensio-active substances in detergents;
- 1.8. removal of chemicals from the market or restriction of their use if they are danger to human health and the environment;
- 1.9. cooperate with the European Chemicals Agency (ECHA), agencies of other countries and the Secretariat of the International Convention, dealing with other aspects of chemicals management;
- 1.10. conducts preliminary approval notice procedure and the procedure for obtaining consent on the basis of prior notification for the import and export of certain dangerous chemicals;
- 1.11. perform other activities set out by this Law, and harmonization with other applicable laws;
- 1.12. inform the wider public about the impact of chemicals on human health and the environment and implements measures to reduce the risk of danger during the use of chemicals;
- 1.13. keep data on the hazardless of chemicals;

1.14. with sub- legal act establish information office for assistance “helpdesk”;

1.15. through the Kosovo Environmental Protection Agency, prepare the report on the state of chemicals in accordance with Article 14 of this Law, keeps records for manufacturers, importers and users of chemicals and detergents, collects data on chemicals and detergents, processes, assess, and made their distribution.

## CHAPTER IV

### INTEGRATED MANAGEMENT OF CHEMICALS

#### Article 13

##### Measures and restrictions for chemicals

1. For chemicals that do not meet all the requirements under the provisions of this law, endangering human health and the environment, the Ministry in collaboration with the Ministry of Health, orders:

- 1.1. temporarily prohibition of chemicals to manufacture, import, placing on the market and use;
- 1.2. removal of chemical from circulation in the market;
- 1.3. other measures necessary to limit the use of the chemical.

2. For the imposing the restrictions under sub-paragraph 1.2 of paragraph 1 of this Article, the Ministry takes into account the impact of the negative effects of the chemicals to human health and the environment, and if necessary replace the chemical for which it is suspected.

3. It is prohibited the sale of chemicals for persons under eighteen (18) years old and the placing on the market and use of chemicals by persons under eighteen (18) years old.

4. The Ministry, by a special act, describes the limitations in relation with the prohibition of certain chemical production, placing on the market and its use.

#### Article 14

##### Drafting of the annual report on chemicals

1. The Ministry shall draft annual report on the state of chemicals.
2. The report on chemicals under the paragraph 1 of this Article will be part of the report on the state of environmental approved by the Government of the Republic of Kosovo.
3. The report referred to in paragraph 2 of this Article contains mainly: data on the types of chemicals, information about the issued permits for the chemicals that are produced, imported, exported, information about researches conducted for chemicals, information about accredited laboratories and the implementation of the strategy and action plan for the management of chemicals.

#### Article 15

##### Chemicals information system

1. The exchange of information with EU and international institutions on chemicals is based on the provisions of the documents ratified by the competent authority of the Republic of Kosovo.

2. Collection, processing, storage and exchange of information with local institutions about the chemicals is the responsibility of the Ministry based on the provisions of this Law relating to obligations for information on chemicals.



3. The Ministry shall inform the public and the relevant authorities for the risks that may be arise by the use of hazardous substances and mixtures, and recommend measures necessary to reduce the risk.
4. The Ministry shall issue and publish technical guidelines in order to inform the public and publish the registers of substances and mixtures that are necessary for the implementation of this Law.

**Article 16**  
**Information office Helpdesk**

The Ministry with sub-act act shall establish information office for assistance “helpdesk”; which informs and gives advices to manufacturers, importers, suppliers, users and any other interested party concerning their responsibilities and obligations under this Law.

**Article 17**  
**Chemicals management strategy**

1. The Ministry shall draft the strategy for the management of chemicals in the Republic of Kosovo.
2. Strategy shall be drafted for a period of ten (10) years, which will be approved by the Government.
3. The strategy includes:
  - 3.1. assessment of the situation and problems in the field of chemicals management;
  - 3.2. priority activities to be undertaken, the measures for chemicals management;
  - 3.3. protection of the environment and human health;
  - 3.4. main tasks for chemical safety;
  - 3.5. action plan for implementing the strategy; and
  - 3.6. financial resources available.
4. The Ministry shall draft annual report for the implementation of the Strategy and Action Plan for the management of chemicals, under paragraph 2, 3, 4 of Article 14 of this Law.

**CHAPTER V**

**CLASSIFICATION, PACKAGING AND LABELLING OF CHEMICALS**

**Article 18**  
**General rules for the classification, packaging and labelling of chemicals**

1. It is prohibited the placing on the market and use of dangerous chemicals, if they are not classified, packaged and labelled in accordance with this Law and sub legal acts arising from this law.
2. Manufacturer, importer and supplier, who places chemicals into the market, is obliged to classify, package and label them in accordance with this Law and the sub legal acts arising from this Law.
3. The exporter is obliged for the chemicals that exports to pack and label them in accordance with this Law and sub legal acts that arise from it, unless it is necessary that the chemicals be packaged and labelled in another way in accordance with international standards, with the request of the exporting country.
4. Classification, packaging and labelling are used for risk communication derived from chemicals and as a result, management and reduction of risk from dangerous chemicals.

## **Article 19**

### **Classification**

1. Hazardous chemicals, according to sub-paragraph 1.19 of Article 3 of this Law, are chemicals that are classified at least at one risk class.
2. The classification of chemicals is made in order to assess their hazardous properties such as: physical properties, properties that affect health and the properties that affect the environment, as well as certain other criteria to classify certain classes' risk.

## **Article 20**

### **General liabilities for the classification of chemicals**

1. Any natural or legal person who places dangerous chemicals on the market is obliged to make their classification in accordance with the provisions of this Law.
2. Manufacturer, importer and user of a substance or mixture should evaluate the information identified under the criteria for the classification of chemicals for each risk class, in order to determine the risks associated with the substance or mixture.
3. The Ministry, through sub-legal acts shall determine the way of classification, labelling and packaging of hazardous substances and mixtures.
4. The Ministry with sub legal act shall determine the requirements / criteria for the classification and labelling of dangerous substances and mixtures according to Regulation (EC) No.1272/2008 by Annex I; Part 1, Part 2, Part 3 and Part 4 which contains: Key principles for classification and labelling, physical properties, risk for health and environment.
5. Hazardous chemicals, when necessary, should be classified under the allowed concentration limit values or according to other parameters that enable the assessment of the risks of substances and mixtures containing hazardous substances to human health and the environment.
6. The Ministry, by sub-legal acts shall publish the List of harmonized classification and labelling of hazardous substances under Regulation 1272/208/EC for CLP, Annex VI, and its updates.
7. The Ministry updates the Register of chemicals classified under this Law and the Register of hazardous chemicals placed on the market of the Republic of Kosovo.

## **Article 21**

### **Classification of hazardous substances**

1. Substances are classified according to the classification of substances with similar chemical composition, from the "List of harmonized classification and labelling of hazardous substances".
2. If the substance is not on the List of harmonized classification and labelling of hazardous substances, or when such a substance that is on this list is not classified as hazardous for all classes, the classification of this substance shall be performed based on analysis of existing data for the properties of this substance, based on the results of the new analysis for its properties, and comparison of these data.
3. Classification in accordance with Regulation (EC) No. 1272/2008, Articles 8 and 10-15, is included in the Safety data sheet for chemicals, as defined in paragraph 4 of Article 33 and paragraph 1 of Article 36 of this Law.

## **Article 22**

### **Classification of hazardous mixtures**

1. Hazardous mixtures are classified based on their hazardous properties and the categorization set out in Articles 6,7,8,9 and 10 of this Law, taking into account their priorities.

2. The mixtures classified as hazardous are specified depending on the content of one or more constituent substances which are contained in the list of substances classified as hazardous based on EU legislation.

3. Classification of mixtures shall be made according to risk assessment of mixtures on the basis of data on the properties of ingredients that contain a mixture, based on the analysis of existing data for the risk posed the mixture, respectively with the review of the properties through direct experiments and data comparisons, respectively the verified results by the criteria for the classification of chemicals.

### **Article 23**

#### **Packaging of chemicals and packaging characteristics**

1. Natural and legal persons should pack chemicals in such a way that the substances and mixtures within the packaging do not pose a risk to humans and the environment during the use, saving, storage or transport.

2. Packaging of hazardous chemicals and products that are not hazardous, but containing at least one substance classified as hazardous, should contain chemical trade name, name of hazardous substance contained in the mixture, name and address of the supplier of the chemical, the amount of chemical contained in the packaging, signs of risk and the text describing the hazardous properties of the chemical.

### **Article 24**

#### **Requirements for packaging**

1. Hazardous chemicals, according to sub-paragraph 1.19 of Article 3 of this Law shall be placed on the market only if they are packaged according to the following requirements:

1.1. packaging must prevent spilling or leaking of the substance;

1.2. packaging must consist of durable materials, in order to avoid risks when they come into contact with the substance;

1.3. packaging must be solid / strong and stable;

1.4. packaging must be well closed, have constringent enclosure;

1.5. packaging must contain a label with information statements, and the necessary data.

2. Constringent closure and touch distinct signs, for some chemicals are required for the protection of children and blind peoples.

3. Packaging unit with the destination for retail sale containing hazardous chemicals should not have:

3.1. shape and appearance that may be attractive to children or to draw their curiosity, and / or appearance that confuses the consumer;

3.2. shapes, images and signs that are commonly used for food, animal food, medicine and cosmetic products.

4. Detailed provisions for the implementation of packaging conditions under CPL Regulation 1272/208/EC will be determined by the sub-legal acts issued by Minister.

5. Requirements set out in paragraphs 2 and 3 of this Article shall also apply in cases where the packaging is done in accordance with the rules for rail, road, and air transport and through lines of pipes and postal transport.

6. Ministry, by sub-legal act, establishes rules for the packaging of hazardous chemicals.

**Article 25**  
**Labelling and presentation of risk through labelling**

1. Substances and mixtures classified as hazardous should be labelled and packaged in accordance with their classification, to ensure adequate protection from hazards and to provide adequate information.
2. Manufacturer, importer and suppliers ensure that the packaging of substances or mixtures that are placed on the market or distributed to a third party, be clearly labelled and in accordance with Article 27 of this Law.

**Article 26**  
**Ways of noting and communication**

1. The Labels and Safety data sheet - SDS are two tools provided for information that should be used to highlight the risks arising from the use of hazardous substances and mixtures.
2. The label is the only direct tool for information and communication with customers that serves to attract the attention of users and guide them towards comprehensive information on the properties of certain substances or mixtures.

**Article 27**  
**Content of the label**

1. A substance or mixture classified as hazardous, in its packaging shall contain label which must include the following elements:
  - 1.1. name, address and telephone number of natural or legal person that places on the market hazardous substances in the Republic of Kosovo;
  - 1.2. the exact amount of the substance or mixture in a package that is intended for use in retail, unless this quantity is specified elsewhere on the package;
  - 1.3. identification of the chemical or product;
  - 1.4. pictograms / symbols of danger;
  - 1.5. words of warning / signal "Danger" or "Warning";
  - 1.6. statements of risk / risk phrases such as "Fire", "Comprehensive Risk", "Fatal if swallowed" and so on.;
  - 1.7. respective statements;
  - 1.8. a section for additional information.
2. Manufacturers and importers who deals with supply of hazardous substance or mixtures to third parties, ensure that each package be labelled clearly and permanently and contain the following information:
  - 2.1. the name of the substance or mixture. If the substance is not registered, then its name shall be done according to internationally accepted descriptions;
  - 2.2. the name, full address and telephone number of the person responsible for the circulation of the chemical, which may be the manufacturer, importer or distributor / dealer;
  - 2.3. pictograms and hazard symbols, showing the effects of risks that may come through the use of the substance, in accordance with the secondary legislation adopted by the Ministry.

3. For substances with hazardous properties such as irritant, flammable and oxidizing, it is not necessary to put the statements of the risk in the package, if the package contains no more than one hundred and twenty-five millilitres (125 ml); This shall also apply in cases where the same amount of harmful substances is not intended for widespread use.
4. According to this Law the indicators, such as “non-toxic ‘,’ non-harmful’, or other similar indicators are not allowed to be placed on the packaging of dangerous chemical substances.
5. The Ministry with sub-legal act shall determine the provisions for the application of labelling requirements under CPL Regulation EC 1272/2008 for CLP.
6. In the Republic of Kosovo, each packing unit with hazardous chemicals should be attached to the instructions for use in the official languages, in accordance with the conditions set out by this Law.
7. If the substances or mixtures are classified in accordance with paragraph 3 of Article 27 of this Law, they shall be labelled in accordance with Articles 17 to 33 of Regulation (EC) No. 1272/2008 and should be packed in accordance with Article 35 of Regulation (EC) No 1272/2008.
8. The Ministry by sub-legal act shall determine the way of labelling of hazardous chemicals.

#### **Article 28** **Advertising dangerous chemicals**

1. With this law, it is prohibited the advertisement of chemical substances belonging to one or more of the categories specified as hazardous by Article 6 of this law, as there is not clearly stated risk categories under Article 7, 8, 9 and 10 of this Law.
2. For chemicals that can be bought without a label, the data for their hazardous properties should be known in advance in written form, with a specific sheet, understandable, clear and legible.
3. Advertisement of chemicals should not hide the risks they may pose to human health and the environment, also should not encourage their use, handling or disposing improperly.
4. Terms such as “degrading”, “ecologically harmless”, “environmentally friendly” and “water-friendly” might be used in advertising only if the described properties are explained in detail.
5. Suppliers of hazardous chemicals or mixtures classified as hazardous, but their contents have at least one substance classified as hazardous during the advertisement should be shown hazardous properties of chemicals. In advertising is not allowed to be hidden from users and the public hazardous properties of chemicals.
6. The Ministry by sub-legal act shall determine the conditions for advertising of chemicals.

#### **Article 29** **Tests and requirements for testing in humans and animals**

1. Producers of hazardous substances and mixtures shall conduct testing and evaluation of chemicals according to modern methods, in accordance with scientific and technical knowledge.
2. Testing in animals for the evaluation of new chemicals under Directive 86 / 609/EEC replaced by the Directive 2010/63/EU, shall be conducted only when no other alternative exists, for the classification of chemicals in scientific basis.
3. According to this Law it is prohibited testing in people, but when it is needed, the Ministry can use data from other sources, from clinical studies, in collaboration with the Ministry of Health, National Institute of Public Health of Kosovo and Veterinary Institute.

### **Article 30**

#### **Testing Methods**

1. Tests to determine the properties of substances and mixtures shall be carried out according to the test methods laid down in Regulation (EC) No. 440/2008.
2. Other test methods may be used if none of the methods is specified in paragraph 1 of this Article.
3. If there are used other methods for testing, the manufacturer shows and proves that these methods:
  - 3.1. produce valid results; and
  - 3.2. take into account the protection of animals in the case of their tests.
4. Non-clinical tests aimed at determining the properties of chemicals hazardous to health or the environment should be conducted in accordance with the principles of Good Laboratory Practice (GLP), as defined in Directive 2004/10/EC.
5. If the tests are not done according to the principles of GLP or not fully comply with them, the person who submits test reports should evidence the reasons for such a selection.
6. New studies or testing of new hazardous chemicals on animals, aimed at collecting data for the classification of substances or mixtures, shall be made only if there is no other way to provide the necessary information, to enable assessment of chemicals. For these cases, tests on animals shall be made with special permits by the Ministry in cooperation with the European Commission under special conditions.
7. For the classification of substances and mixtures shall be used other data obtained from tests performed on humans, such as; court needs analysis or clinical tests that are done for other purposes.
8. The Ministry shall decide on the acceptance of test results as valid, after consultation with the European Chemicals Agency (ECHA) for evaluation.
9. For the assessment of physical, toxicological and eco-toxicological properties of chemicals, the Minister by sub-legal acts shall specify the methods for testing the hazardous substances and mixtures:
  - 9.1. the Ministry by sub legal act shall determine the methods for determination of physical properties;
  - 9.2. the Ministry by sub-legal act shall determine the methods for determining the toxicity and other health effects;
  - 9.3. the Ministry by sub-legal act shall determine the methods for determining the eco-toxicity.

### **Article 31**

#### **Non-clinical testing of chemicals**

1. The aim of non-clinical testing of chemicals is evaluating and assessing potential risk to human health and the environment.
2. Non-clinical testing of chemicals shall be performed in laboratories working under Good Laboratory Practices (GLP).
3. GLP certificate issued by the competent authority of the Member State of GLP Working Group, within the frame of the Organization for Economic Cooperation and Development (OECD), is also acceptable in the Republic of Kosovo.
4. The Ministry or the Ministry of Health, shall determine the conditions and criteria for the implementation of Good Laboratory Practices system – GLP by sub-legal act.

**Article 32**  
**Removing chemicals from circulation / market**

1. A chemical shall temporarily or permanently be removed from the market if it is proved that the same impose unacceptable risk to human health or the environment, even if the chemical meets the conditions laid down in this Law and acts arising from this Law.

2. In order to implement paragraph 1 of this Article, the Ministry shall immediately inform the competent authority the European Chemicals Agency and the state where this hazardous chemical is produced, giving the reasons for the decision to remove the chemical from the market.

**CHAPTER VI**

**INFORMATION FOR SALES NETWORK**

**Article 33**  
**Requirements for the Safety data sheet for chemicals**

1. The Safety data sheet for chemicals shall be provided by the manufacturer, importer or supplier and enable the users to take the necessary measures relating to protection of human health and safety in the workplace and protect the environment.

2. The person who fulfils the Safety data sheet for chemicals shall take into account that the Safety data sheet for chemicals informs its user to risks that can cause a substance or mixture and provide information on handling, storage and safe disposal of the substance or mixture.

3. Supplier who puts dangerous substances and mixtures on the market, must be provided free of charge to any distributor or next user of safety data sheet on paper or in electronic form.

4. Safety data sheet for chemicals shall contain the following data:

- 4.1. identification of chemicals and natural or legal persons;
- 4.2. hazards identification;
- 4.3. information on ingredients;
- 4.4. first aid measures;
- 4.5. fire-fighting measures;
- 4.6. accidental release measures;
- 4.7. handling and storage;
- 4.8. exposure control / personal protection;
- 4.9. physical and chemical properties;
- 4.10. stability and reactivity;
- 4.11. toxicological information;
- 4.12. ecological information;



- 4.13. use of waste;
- 4.14. transport information;
- 4.15. regulatory information;
- 4.16. other information.

5. Information provided in Safety data sheet for chemicals should correspond to the information in the chemical Safety report and the exposure scenario.

6. The Ministry by sub-legal act shall determine the content of Safety data sheet for chemicals.

7. Data on Safety data sheet for chemicals shall be provided in the official language.

8. The Ministry, through a sub legal act shall issue Safety data sheet for chemicals meeting the requirements of REACH and its updates according to requirements and amendments by European legislation EU/453/2010.

#### **Article 34** **Requirements for Safety data sheet for chemicals**

1. Manufacturer, importer, exporter, supplier or distributor is obliged to provide the recipient or users of chemicals with the specific requirements in Safety data sheet for chemicals and if the chemical does not meet the criteria for classification as dangerous, but contains:

1.1. an individual concentration of  $\geq 1\%$  by weight for non-gaseous mixtures and  $\geq 0.2\%$  by the volume of gaseous mixtures, in which at least one substance posing human health or environmental hazards;

1.2. an individual concentration of  $\geq 0.1\%$  by weight for non-gaseous mixtures, at least one substance that is PBT or vPvB; such substances as those features can interrupt the functioning of the endocrine system, as well as substances which are classified as carcinogenic category 1 or 2 (or carcinogenic category 1A or 1B), mutagenic category 1 or 2 (or mutagenic category 1A or 1B), or toxic to the reproductive system, the category 1 or 2 (or toxic for reproductive system, category 1A or 1B) or other substances of concern;

1.3. for the substances that are defined maximum concentrations are allowed in working areas.

#### **Article 35** **Exceptions**

Safety data sheet for chemicals is not required when information on chemicals for wide use is sufficient in relation to safety, protection of human health and the environment, unless requested by the user or supplier.

#### **Article 36** **Updates of Safety data sheet for chemicals**

1. Manufacturer, importer, exporter or supplier, updates the contents of the Safety data sheet for chemicals, whenever new information on chemicals are obtained, particularly for risk reduction and control or new information on the risk of chemical including the cases when it is stopped or limited production, introduction to the market or their use.

2. Manufacturer, importer, exporter or supplier in accordance with paragraph 1 of this Article, shall inform and submit the updated Safety data sheet for chemicals to all users who have sold / distributed chemicals within twelve (12) months.

3. Changes in technical security sheet for chemicals shall contain the remark "updated", updated records and date when changes are made in the Safety data sheet for chemicals.



**Article 37**  
**Keeping of technical safety sheet of chemicals**

Professional users or merchants are obliged to keep the Safety data sheet for chemicals, as long as certain chemicals continue to be used in the workplace.

**Article 38**  
**Chemicals safety report**

1. Persons who place on the market hazardous chemicals are obliged to draft chemicals safety report, which contains the chemical safety assessment in accordance with the requirements of Annex I of Regulation (EC) No. 1907/2006, for each substance separately in the mixture or a group of substances.

2. Chemicals safety report includes the results from:

- 2.1. human health risk assessment;
- 2.2. physical risk assessment;
- 2.3. environmental risk assessment;
- 2.4. Risk assessment for the ozone layer;

**Article 39**  
**Implementation and recommendation of risk reduction measures**

Notwithstanding Article 4 of Directive 98/24/EC, people who register the substances in quantities of ten (10) tones or more per year per registrant, shall make and develop risk assessment for chemicals safety report.

**Article 40**  
**Excepts for the risk evaluation**

1. The chemical safety report does not include consideration of the risks to human health from the following uses:

- 1.1. foods in contact materials within the scope of Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food;
- 1.2. in cosmetic products within the scope of Directive 76/768/ EEC.

**Article 41**  
**Risk control and limit save of Safety report of chemicals**

1. Any person as registrant of hazardous substance shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and supplies the users for the safety data sheets in accordance with Article 33 and 34 of this Law.

2. Any person as registrant of hazardous substance required to conduct a chemical safety assessment shall keep available his chemical safety report ten (10) years after the use of the chemical.

**Article 42**  
**General Register of chemicals**

1. Chemicals produced, imported or placed on the market shall be registered in the general register of chemicals.

2. The Ministry shall keep the general register of chemicals in printed and electronic form.

**Article 43**  
**General rules for the registration of substances and mixtures**

1. New substances and mixtures are allowed to be produced, placed on the market or used if they are registered in accordance with the provisions of this Law.
2. Any manufacturer or importer of substances and mixtures is obliged to inform the Ministry and submit an application for registration to the Ministry.

**Article 44**  
**Registration of chemicals in the general register of chemicals**

1. Registration of chemicals in the general register of chemicals is based on reports from manufacturers, importers or users, who are obliged to send the information to the Ministry, by 31 March of the following year for the produced or imported amount of chemicals for the past year.
2. Polymers shall be registered in the register of chemicals.
3. In the general register of chemicals there shall be registered even the substances and mixtures containing substances which cause concern.
4. The request for registration in the register of chemicals includes: name, address, personal number of manufacturer, importer, data on the quantity of the chemical produced or imported, and dedication of use and business registration number.
5. Attached with the application for registration of chemicals according to paragraph 1 of this Article are given the business registration certificates, dossier for each chemical, Safety data sheet for chemicals that possess.
6. The dossier from paragraph 5 of this Article shall contain:
  - 6.1. chemical trade name and chemical name under the nomenclature of chemicals IUPAC, and other chemicals identifier names;
  - 6.2. data on the amount of chemicals in circulation;
  - 6.3. data on the use of chemicals;
  - 6.4. information on chemical content;
  - 6.5. classification and labelling of chemicals;
  - 6.6. data on physical and chemical properties of the chemical;
  - 6.7. data on the effects of the chemical in the environment;
  - 6.8. results of toxicological and eco-toxicological tests;
  - 6.9. possible ways of converting hazardous substances into harmless;
  - 6.10. data on the degree of purity and content of hazardous substance supplements if they are dangerous and if necessary for the classification and labelling of hazardous chemicals.
7. Contents of the dossier with documents for chemicals and chemicals Registry shall be set out by the Ministry in cooperation with the Ministry of Health.

**Article 45**  
**Register of hazardous substances that cause concern**

1. Substances that are carcinogen, mutagenic, toxic for the reproductive system substances shall be included in the register of substances that cause concern.
2. The register of substances that cause concern shall contain the following data:
  - 2.1. the identity of the substance;
  - 2.2. classification of the substance;
  - 2.3. use method, for which there is a not needed the description of additional measures to reduce the risk.
3. Register of substances that cause concern shall be set out and maintained by the Ministry, in collaboration with the Ministry of Health.

**Article 46**  
**Professional evaluation**

1. The Ministry in collaboration with the Ministry of Health made the professional evaluation of data for the chemicals registry presented in the dossier for the substance or mixture which possesses the substance which causes concern, risk reduction measures and systematic monitoring method for use of the substance that cause concern;
2. If the Ministry considers that risk reduction measures are not adequate, is obliged to determine other appropriate measures and specify the period for the implementation of certain measures.
3. Manufacturer, importer and user, are obliged to implement the measures referred to in paragraph 2 of this Article.
4. Registration of substances that cause concern, in the register of chemicals, shall be made with the decision, after verifying the presentation of data in the dossier, within thirty (30) days of receiving the request for registration of the substance in the register of chemicals.

**Article 47**  
**Changing of Data**

1. Manufacturers or importers are obliged to inform the Ministry for any changes on the data entered in the register of chemicals and which consists of:
  - 1.1. changing the legal status of the manufacturer or importer - name or place, address;
  - 1.2. changing of the composition of the substance or mixture;
  - 1.3. changing of annual production or import, changes in the quantity of the substance;
  - 1.4. changes and new knowledge about hazard to human health and the environment that may come from substances. These changes impose change of the content of the Safety Data Sheet for Chemicals;
  - 1.5. changes in the classification and marking of chemicals;
  - 1.6. changes in chemicals safety report.
2. To change the data from paragraph 1 of this Article, the notice must be presented to the Ministry no more than thirty (30) days after the changing day.

**Article 48**  
**Keeping of evidence and obligation to save the data**

1. Manufacturers or importers are obliged to keep evidence for hazardous chemicals, for:
  - 1.1. identity of the chemicals;
  - 1.2. distributors and users, as well as the ordered quantities of chemicals or distributed or stored;
  - 1.3. all quantities of chemicals that are sold to users during the calendar year;
2. The evidenced data according to paragraph 1 of this Article should be kept for at least ten (10) years after cessation of production, placing on the market and use of certain chemical.
3. Manufacturers or importers are obliged within the legal term to submit the evidenced data to the Ministry.
4. The method of keeping evidences of chemicals shall be determined by sub-legal act by the Ministry.

**Article 49**  
**Data for publication from the register of hazardous chemicals**

1. Data from the registry of chemicals and other records, which will be available to the public are:
  - 1.1. chemical name according to IUPAC Nomenclature for dangerous substances;
  - 1.2. trade name;
  - 1.3. classification and labelling / marking of chemicals;
  - 1.4. data for physical and chemical properties of the chemical;
  - 1.5. data on the effects of the chemical in the environment;
  - 1.6. results from toxicological and eco-toxicological tests;
  - 1.7. possible ways of conversion of substances on non-hazardous;
  - 1.8. data on the degree of purity and content of hazardous substance supplements if they are dangerous and if they are necessary for classification and labelling of hazardous chemicals.
2. Any person who considers that there is a need to keep confidential data, may require that the information provided in the Ministry be kept confidential, in order not to be damaged. In this case it is required to give full justification to the Ministry.
3. Any person may apply to the Ministry, to take available information for dangerous chemicals.
4. For the person who requires certain records for dangerous chemicals, the Ministry will provide the data, unless they are confidential and stored at the request of the person referred to in paragraph 2 of this Article.
5. Before the Ministry takes a decision to give the confidential records, the Ministry is obliged to consult with the person referred to in paragraph 2 of this Article who asked to keep confidential the data.
6. Officials after the extraction of the labour contract with the Ministry are obliged to keep confidential information according to paragraph 2 of this Article.
7. In the decision under paragraph 5 of this Article may be appealed at the Ministry.
8. The decision under paragraph 6 of this Article shall be final and for its contradiction there should be initiated the administrative dispute at the basic court, within thirty (30) days from the day of receipt the final decision.

**Article 50**  
**Alternative chemical name of chemicals**

1. In the Safety data sheet for chemicals or in the data placed in packaging of hazardous substance or hazardous substances or substance in a mixture can be used an alternative chemical name, so that it can be used the name which identifies the most important functional chemical groups or other appropriate orientation.
2. Manufacturer, importer or user of hazardous chemicals shall notify the Ministry for the use of an alternative chemical name of hazardous substance found in the mixture.
3. Alternative chemical name of chemicals can be used in cases where the name of the substance can reveal confidentiality of the work or violate intellectual property right, under the terms that an alternative chemical name will provide sufficient information relating to safety of hazardous chemical.
4. The Ministry describes the properties of a substance for which can be used an alternative chemical name and the contents of the information under paragraph 2 of this Article.
5. The Ministry shall decide whether or not to allow the use of alternative chemical name, if there is convincing information that the alternative chemical name does not provide enough information to take the necessary action of chemical safety within working environments to human health and the environment during its use.
6. In the decision according to paragraph 5 of this Article may be appealed at the Ministry.
7. The decision under paragraph 6 of this Article shall be final and for its contradiction there should be initiated the administrative dispute at the basic court, within thirty (30) days from the day of receipt the final decision.

**CHAPTER VII**

**PLACING ON THE MARKET, PRODUCTION, USE AND STORAGE PROHIBITIONS AND RESTRICTIONS OF HAZARDOUS CHEMICALS**

**Article 51**  
**Restrictions and prohibitions**

1. For chemicals that pose unacceptable risk to human and the environment, the Ministry by sub legal act shall determine restrictions, prohibition for manufacture, placing on the market and their use.
2. If, for technical, economic and social reasons the prohibitions and restrictions in accordance with paragraph 1 of Article 13 of this Law, for certain chemical cannot be implemented, the Ministry shall determine mandatory deadlines for the implementation of the prohibition, restriction.

**Article 52**  
**Application of restrictions and prohibitions**

Manufacturer, importer and user of substances, mixtures and products are obliged respect the procedures of restriction and prohibition under the provisions issued by the Ministry or the competent authority of the EU.

**Article 53**  
**Permit for circulation of hazardous chemicals**

1. Placed of hazardous chemicals on the market can only be done by persons who are equipped with movement permit (manufacture, placing on the market, use, store / and storage) of these chemicals.
2. Permit for movement of hazardous chemicals shall be issued to person who meets the requirements for safe manage of dangerous chemicals.

3. Permit for the use of hazardous chemicals can be issued and for natural or legal persons carrying out activities that use hazardous chemicals such as art activity, scientific research activities and other specific activities.

4. Permit for supply, use of hazardous chemicals in accordance with paragraph 1 of this Article shall be issued if the rationality for their use is based on, if the chemicals are used safely, if they are used for reasons of reaching effects on the quality or unable to other alternatives.

5. Basic conditions for the storage of hazardous chemicals are to: possess an building prepared for storage of chemicals, to ensure that this building does not have access for unauthorized persons, have conditions for physical protection and fire protection as well as if necessary, other risk preventive conditions.

6. The Ministry prepares the register of hazardous and very hazardous chemicals form human health and the environment for which will be issued the permit, as well as for chemicals that will not be issued the permit for circulation.

#### **Article 54** **Request for permit**

1. The request for Permit according to paragraph 1, 2, 3, and 4 of Article 53 of this Law, shall contain the name of the person the address of the person, information about hazardous chemical, the intended use of the chemical, the amount of chemical intended to be circulated.

2. With the request for Permit shall be attached the documents and records:

2.1. Environmental permit or Environmental consent for the facility and equipment where are produced or stored hazardous chemicals;

2.2. presentation of Permit by the competent authority for emergency situations when is necessary for the possession;

2.3. description of the manufacturing process for manufacturers;

2.4. Safety data sheet for chemicals;

2.5. business registration certificate;

2.6. the list of chemicals with custom number;

2.7. contract between sellers and buyers, for importers or pro bill;

2.8. prove of qualified staff;

2.9. CV of professional person for chemicals- responsible for professional issues.

3. The Ministry will describe:

3.1. permit application form;

3.2. decision for Permit for development of circulation with hazardous chemicals;

3.3. guidelines for establishing preventive measures for storage and safe storage of hazardous chemicals and their use.

#### **Article 55** **Commission for reviewing the application for permit**

1. The request shall be reviewed by the committee consisting of five (5) qualified members of the branches of natural sciences, at least two (2) of them in the field of chemistry or chemical engineer.

2. In the permit for the movement of chemicals according to paragraph 1, 2, 3, and 4 of Article 53 of this Law, it should be noted the name of the person receiving the permit, the purpose why is issued the permit, the deadline of the validity of the Permit, legal name of responsible person.

3. The review of Application for permit and issuing the Permit shall be done within thirty (30) working days.

#### **Article 56** **Duration of Permit**

1. The permission for circulation of hazardous chemicals shall be issued by Ministry for importation, manufacture, storage and use.

2. For the circulation of hazardous chemicals the Permit shall be issued for:

2.1. import or export of certain hazardous chemicals in determined quantities for one (1) calendar year;

2.2. production of hazardous chemicals shall be issued for a period not more than ten (10) years;

2.3. storage of certain chemicals shall be issued for five (5) years;

2.4. the use and treatment of chemicals shall be issued for two (2) years.

#### **Article 57** **Administrative fee for Permits**

1. In order to get the Permit and for any amendment or supplementation of the issued permit there should be applied with the documentation in accordance with Article 54 of this Law:

1.1. to get the Permit for import and export of chemicals there should be paid the administrative fee of ten (10) Euros;

1.2. to get the Permit for the production of chemicals there should be paid the administrative fee of fifty (50) Euros;

1.3. to get the permit for storage of chemicals there should be paid the administrative fee of twenty (20) Euros;

1.4 to get the Permit for the use of chemicals there should be paid the administrative fee of ten (10) Euros;

2. Administrative fee in accordance with paragraph 1 of this Article shall be paid to the budget of the Republic of Kosovo.

#### **Article 58** **Issuing and cancellation of permit**

1. The permit will be issued if all the conditions prescribed by this Law and other applicable laws are fulfilled.

2. The Ministry, through the Permit may impose special conditions for the placing on the market and use of hazardous chemicals.

3. The Permit shall be cancelled if by the person are presented inaccurate documents and records and found that the conditions laid down in the permit issued earlier are not fulfilled.

4. The holder of the Permit is obliged to comply with conditions specified in the permit for the circulation of chemicals.

5. For the decision under paragraph 2 and 3 of this Article may be appealed to the Ministry.

6. Against the response with decision from paragraph 5 this Article, there may be initiated the administrative dispute at the basic court, within thirty (30) days from the day of receipt the final decision.

#### **Article 59** **Keeping of date for permit**

1. The holder of Permit for the circulation of hazardous chemicals is required to keep the evidence for chemicals, for users to whom it has been sold or given for use the dangerous chemical, and report the data to the Ministry.

2. Ministry, by a special act will describe the method of keeping the evidence records for Permits under paragraph 1 of this Article regarding hazardous chemicals.

#### **Article 60** **Keeping and storage of hazardous chemicals**

1. Hazardous substances and mixtures should be kept and maintained well in accordance with the type of risk that may be caused. In particular, it must be:

1.1. protected against dangerous influences from outside;

1.2. protected and not accessible by unauthorized parties;

1.3. kept or stored in such a way as to prevent any risk, to not cause confusion for similarities with general consumer goods, especially with foods, or use them wrongly.

2. When substances and mixtures are stored in warehouses, there should be taken into account the advices and instructions given on the packaging and Safety data sheet for chemicals.

3. Hazardous substances and mixtures and their packaging should be protected from dangerous influences, particularly from those of mechanical nature.

4. Hazardous substances and mixtures should be clearly identifiable and during storage in warehouses must be kept separated from other goods.

5. Paragraphs 1 to 3 of this Article shall also apply to buildings from where the substances or mixtures are released on the market in quantities that could endanger human health or the environment.

6. Substances and mixtures that can react with each other and create risk should be stored separately.

7. Hazardous substances and mixtures must be stored in containers that meet the following requirements:

7.1. chemical packaging must not resemble or create confusion because of the similarity of the packaging, such as products like food packaging, cosmetic, or therapeutic products for animal feed;

7.2. name of the substance or mixture should be provided in the labelling, and

7.3. packaging should be consistent with requirements of Article 23 and 24 of this Law.

8. Chemical substances and mixtures that meet the conditions to be assessed as waste shall be treated according to the Law on Wastes.



## CHAPTER VIII

### EXPORT AND IMPORT OF CERTAIN HAZARDOUS CHEMICALS

#### Article 61 General Principles

1. In order to advance the distribution of responsibility and cooperation for the circulation and marketing of hazardous chemicals in accordance with the Rotterdam Convention, the consent process for export and import of certain substances for which is defined prohibition and restriction of production, and for certain mixtures containing hazardous substance, shall be applied the procedures for information and prior consent, respectively procedure of issuing the permit based on information for prior consent (hereinafter - PIC procedure).
2. Restrictions and prohibitions from paragraph 1 of this Article are based on prohibitions and restrictions under the Rotterdam Convention and Article 51 and 52 of this Law, such restrictions and prohibitions, are verified based on the legal provisions under which is allowed the placing on the market of hazardous chemicals, the applicable Law on plant protection products, respectively Law on biocide products.
3. Register of chemical for PIC procedure shall contain the name of the chemical, number which identifies the tariff number and category of the chemical.
4. Register of chemicals for PIC procedure shall contains chemicals from the Registry of the Rotterdam Convention.
5. Ministry, by a special act will describe the procedure for import, export and transit hazardous chemicals.

#### Article 62 Export

1. Exports of chemicals from the register of chemicals subject to the notification procedure for prior consent is based on the announcement of the Ministry for the state in where will be exported.
2. Notification from paragraph 1 of this Article shall be made for:
  - 2.1. chemicals from the register of chemicals for prior notification procedure;
  - 2.2. chemicals containing substance from the register of chemicals subject to notification procedure for prior consent by such concentration that represent risk, and
  - 2.3. products or mixtures possess the substance that are in the registry of PIC procedure.
3. Notification from paragraph 1 of this Article shall be prepared by exporter of the chemical who will submit it to the Ministry.
4. The notification from paragraph 3 of this Article shall contain the following information:
  - 4.1. name and address of the exporter and importer;
  - 4.2. identity of the substance or mixture;
  - 4.3. chemical properties;
  - 4.4. risk reduction measures.
5. The Ministry shall do the verification of information during the notification, and then after the verification it shall submit that information to the state that the chemical will be exported.

6. Upon notification the Ministry shall issue the evidence for the exporter of the chemical.

7. The contents of notification under paragraph 1 of this Article, the procedures and deadlines for implementation of PIC procedure shall be drafted by the Ministry with a sub-legal act.

### **Article 63**

#### **Import**

1. The imports of chemicals from the register of chemicals subject to the notification procedure for prior consent is based on the notification of the Ministry by the competent authority of the State that exports chemicals.

2. Ministry upon receiving the export notification of the chemical by the competent authority under paragraph 1 of this Article then will notify that body for receiving the notification.

### **Article 64**

#### **Circulation of chemicals according to PIC procedure**

1. PIC procedure shall be developed for export or import of chemicals registered in the register of chemicals for PIC procedure of the Rotterdam Convention registry on Chemicals.

2. PIC procedure shall be developed based on the announcement made by exporter to the Ministry.

3. The notification under paragraph 2 of this Article shall contain the following information:

3.1. the name and address of the exporter and importer;

3.2. identity of the substance or mixture;

3.3. physical and chemical, toxicological and eco-toxicological properties of the chemical;

3.4. name according to IUPAC;

3.5. CAS number of the chemical.

4. The Ministry shall made the verification of data from notification and after the verification submit the notification for prior consent of the competent authority of the exporting country to issue the consent.

5. Once the competent authority of exporting country notifies the Ministry that has allowed the export of hazardous chemical, the Ministry shall issue written consent for the importer of the chemical.

6. The Ministry is obliged to give consent in relation to the export of chemicals from Kosovo and to inform the Secretariat of the Rotterdam Convention.

7. The Ministry by special act shall draft the content of the notification referred to in paragraph 3 of this Article, the procedures and timetable for the development of PIC procedure.

8. The Ministry shall draft the register of chemicals subject to PIC procedure.

9. Registry of chemicals subject to the PIC procedure shall be published in Official Gazette of the Republic of Kosovo.

### **Article 65**

#### **Information on the exported and imported quantities of chemicals**

1. Exporters and importers of chemicals from Articles 63, 64 and 65 of this Law are obliged to submit information to the Ministry for exported and imported quantities of certain chemicals for countries from where are imported or exported and data for the exporter and importer of chemicals.

2. Data from paragraph 1 of this Article shall be submitted to the Ministry by 31 March of the following year, for the previous year.
3. Based on the data from paragraph 1 of this Article, the Ministry keeps records for exported and imported chemicals.
4. Exporters and importers of chemicals are obliged to inform the Ministry with information on the amount of import and export of chemicals within thirty (30) days from the date of the export or import.
5. Data from paragraph 3 of this Article shall be kept in electronic form.
6. Ministry with special act shall draft the way of submitting the data from paragraph 1 of this Article.

#### **Article 66** **Transit of chemicals**

1. The exporter of chemicals is obliged to submit information to the Ministry with the information required by the competent authority of the state in the territory of which there is organized the transit of chemicals from the Rotterdam Convention Registry no later than thirty (30) days prior to transit.
2. The Ministry provides information for the competent authority of the state in whose territory is organized the transit of chemicals no later than fifteen (15) days prior to transit.

#### **Article 67** **Register of hazardous chemicals prohibited for export and import**

1. Substances and mixtures, the use of which is prohibited in order to protect the human health and the environment should not be exported.
2. Dangerous chemicals prohibited for use by the list of the Rotterdam Convention are prohibited to be imported.
3. Chemicals that have the expired date less than six (6) months are not allowed to be exported or imported.
4. Register of hazardous chemicals that are prohibited for export and import shall be drafted by the Ministry.
5. The register from paragraph 4 of this Article shall contain: Name of the hazardous chemical, the number by which is identified the chemical and its tariff number.
6. Customs through phyto-sanitary inspection verifies the application of information procedure for preliminary consent of PIC procedure for substances and mixtures from the register under paragraph 4 of this Article.

### **CHAPTER IX**

#### **INFORMATION**

#### **Article 68** **Access to information on hazardous chemicals**

1. The data that the Ministry has, in chemical registers and other data are available to the public:
  - 1.1. chemical name:
    - 1.1.1. according to IUPAC nomenclature for hazardous substances;
    - 1.1.2. by CAS number;

- 1.1.3. the number of EC.
  - 1.2. alternative chemical name of the substance;
  - 1.3. trade name;
  - 1.4. classification and labelling of chemical;
  - 1.5. data on physical and chemical properties of the chemical;
  - 1.6. data on the effects of the chemical in the environment;
  - 1.7. results of toxicological and eco-toxicological tests;
  - 1.8. possible ways of sawing hazardous substances in safe;
  - 1.9. data on the degree of purity and content of hazardous substance supplements.
2. Any person who submits data in the Ministry and consider that there is a need to keep them confidential data, may require the Ministry that the information to be kept confidential. In this case he is obliged to give full justification.
  3. Any person may apply to the Ministry to take data for hazardous chemicals by the Ministry.
  4. For the person who requires certain data for hazardous chemicals, the Ministry shall provide these data, unless they are stored at the request of the person referred to in paragraph 2 of this Article.
  5. Before the Ministry decides to give the stored data is obliged to consult with the person who has put the data for storage.
  6. Against the decision from paragraph 5 of this Article may be appealed to the Ministry.
  7. Against the decision of the Ministry, the dissatisfied party has the right to initiate the administrative dispute at the basic court, within thirty (30) days from the day of receipt the final decision.

## **CHAPTER X**

### **DETERGENTS**

#### **Article 69 General Requirements**

1. Detergents and detergents for use in industry or for professional use shall be placed on the market by the manufacturer, if the active substance (hereinafter -tensio-active substances) that is present in detergent meets the criteria for full biological dissolution and other conditions determined by this Law.
2. Manufacturer of detergents from paragraph 1 of this Article is a natural or legal person who places the detergents on the market, which manufactures, imports or changes the characteristics of the detergent.
3. Exception from paragraph 1 of this Article are detergents – tensio-active substances in their composition does not meet the criteria for full biological dissolution shall be placed on the market if the Ministry issue the permission for the use of certain tensio-active substance, already permitted by the provisions of the EU legislation.
4. Data for the content of detergents that must be marked on the packaging, as well as general and special rules of the data, shall be determined by the Ministry by a special act.

5. Manufacturer of detergent from paragraph 3 of this Article shall be obliged to inform the Ministry for EU legislation provisions that allow the use of respective tensio-active substance.

6. The Ministry by sub-legal act describes the conditions and criteria for issuing permission for the production of detergents.

#### **Article 70**

##### **Permission for detergents**

1. Manufacturer and importer of detergents must apply for permission before placing on the market the detergent that contains certain tensio-active substance.

2. If the Ministry determines that in the detergent are used tensio-active substances that do not meet the legal requirements, then issues a decision to prohibit the validity of the permission granted in advance, and in this case there shall be determined the deadline for removing from the market the detergent that contains inappropriate tensio-active substances.

3. A decision under paragraph 2 of this Article may be appealed to the Ministry.

4. Against the decision of the Ministry according to paragraph 3 this Article, the dissatisfied party has the right to initiate the administrative dispute at the basic court, within thirty (30) days from the day of receipt the final decision.

#### **Article 71**

##### **Deadline for issuing the permit**

1. The respond for the permit for detergents production shall be issued by the Ministry, within four (4) months after the application with complete dossier of necessary documentation.

2. The permit will be issued if all the conditions prescribed by this Law and other legal acts in force are fulfilled.

3. The Ministry through the Permit sets conditions for the placing on the market of detergents.

4. The holder of the permit is obliged to comply with the conditions for which the permit has been issued for placing detergents on the market.

#### **Article 72**

##### **Register of tensio-active substances**

The register of tensio-active substances to be used in detergents, for which is issued the permit according EU legal acts, as well as the register of tensio-active substances that are forbidden to be used for detergents in the EU should be published in the Official Gazette of the Republic of Kosovo.

#### **Article 73**

##### **Evaluation of Detergents**

1. The Ministry with special acts shall describe the criteria and methods for evaluating the detergents and analyzing primary decomposition and complete biological decomposition of tensio-active substance in accordance with required standards and EU legislative for detergents.

2. The Laboratory in which are made the determination and certification of the characteristics of detergents and tensio-active substances must be accredited at the respective Ministry.

#### **Article 74**

##### **Specific obligations for the manufacturer of detergents**

1. The manufacturer of detergents is obliged to keep verified results from the laboratory.

2. The manufacturer and importer of detergents, except the provisions on the classification, labeling and packaging of chemicals is obliged to mark the detergents in accordance with the provisions of this Law.
3. The manufacturer and importer of detergents is obliged to maintain a register of components containing the certain detergent and make it public.
4. The manufacturer of detergents is obliged to maintain the data from the registry in accordance with paragraph 3 of this Article, for ten (10) years.
5. The Ministry with special act shall describe the way for marking of detergents, detergent composition registry content, and data by the Registry should be public pursuant to paragraph 3 of this Article.

## **CHAPTER XI**

### **SYSTEMATIC SUPERVISION OF CHEMICALS**

#### **Article 75**

##### **Systematic supervision of hazardous chemicals**

1. The Ministry is responsible to develop and implement continuous supervision of the management of chemicals, placing on the market and use of chemicals, supervision and control of the state of chemicals and their impact on human health and the environment.
2. For development of from paragraph 1 of this Article, the Ministry may engage professional organizations for scientific research.

#### **Article 76**

##### **Poison control centres from dangerous chemicals**

1. Poison control centres from dangerous chemicals are the Kosovo National Institute for Public Health and Agency of Food and Veterinary (AFV).
2. National Institute for Public Health of the Republic of Kosovo and Agency of Food and Veterinary are obliged to submit the collected data for poisoning by chemicals to the Ministry.
3. The Ministry shall use the data to maintain the control regarding the harmful effects of chemicals on human health and the environment.

#### **Article 77**

##### **Information on hazardous chemicals poisoning**

1. The National Institute of Public Health and AFV as control centres are obliged to collect and provide information about the poisonings that occur in the Republic of Kosovo.
2. The National Institute of Public Health and AFV should provide information on preventive measures and treatment of poisoning from dangerous chemicals, and recommend appropriate measures to prevent the risk from poison.
3. The National Institute of Public Health and AFV has right to access the registry data for chemicals in the Ministry and the right to request the needed data, directly from the manufacturer and importer of hazardous chemicals, in order to provide any additional information for hazardous substances and mixtures.
4. The Ministry shall provide data available to control centres in accordance with paragraph 2 and 3 of this Article and, if necessary, also for confidential data in accordance with paragraph 2 and 5 of Article 49 of this Law.

5. The Ministry in collaboration with the National Institute of Public Health and AFV, in order to prevent any risk to human health and the environment, with special act determines the conditions and measures for the management of information on poisoning.

#### **Article 78**

##### **Professional person responsible for chemicals**

1. The manufacturer and importer of hazardous chemicals is obliged by the contract to provide a professional person responsible for the implementation of legal rules and technical standards for the management of chemicals, in accordance with the provisions of this Law and sub legal acts issued by this Law.

2. The user of hazardous chemicals is obliged by the contract to provide a professional person responsible for the application of legal rules and technical standards for the management of chemicals, in accordance with the provisions of this Law and sub legal acts issued by this Law.

3. The Professional person for chemicals should be qualified and have university degree in the field of sciences of chemistry, chemical-engineering technology, pharmacology, pharmacy.

4. The Ministry with sub-legal act shall define the conditions, sectors and areas that are exemption from the obligation under paragraph 1 and 2 of this Article.

## **CHAPTER XII**

### **SUPERVISION INSPECTION AND IMPLEMENTATION**

#### **Article 79**

##### **Supervision and inspection**

1. The supervision for implementation of the provisions of this Law and provisions issued by the Law shall be done by the Ministry.

2. Inspection supervision for the implementation of the provisions of this law shall be carried out by the inspectorate for environmental protection and phyto-sanitary inspectorate.

3. Inspection supervision of chemicals in Kosovo Customs shall be carried by phyto-sanitary Inspectorate.

#### **Article 80**

##### **Inspectorate obligations**

Environmental Inspectorate is obliged to inspect the state of chemicals and to act on the basis of the annual inspection report and submit an annual report for the implementation of the provisions of this Law and sub legal acts issued by this Law.

#### **Article 81**

##### **Providing free access for the inspector**

1. Natural and legal persons are obliged that for the inspector to:

1.1. enable inspection and free access to data and information required regarding the inspection;

1.2. create access for the purpose of performing the inspection, control of space, building, equipments, facilities and documentation;

1.3. allow sampling to verify that the chemical meets the criteria under the provisions of this Law concerning the placing on the market.

2. Costs for examinations of the properties of substances and mixtures shall be compensated by the manufacturer, importer or other supplier of chemicals.

### **Article 82** **Supervision of import, export and transit of chemicals**

1. Prior to approve the entry of hazardous chemical in circulation, the Kosovo customs (Customs further) through phyto- sanitary inspectorate is authorized to perform the verification of the characteristics of hazardous chemicals that entering in the territory of the Republic of Kosovo, pursuant to this Law.

2. The Custom temporarily stop further implementation of the customs procedures required with aim to allow the chemicals in circulation, if during the verification referred to in paragraph 1 of this Article it is proved that:

2.1. hazardous chemicals have features that lead to the suspicion that they may pose a serious threat to safety, of the human health and environment.

2.2. hazardous chemicals under subparagraph it's not accompanied by documentation required under the provisions of this Law;

2.3. hazardous chemicals are not marked, packed and labelled in accordance with the provisions of this Law;

3. Provisions of this Law shall be implemented by the Customs without bringing into question the application of laws that regulates the specific control systems that should be implemented by the Customs.

4. In the process of supervision of dangerous chemicals, environmental protection inspector is authorized to:

4.1. prohibit the import of hazardous chemicals, the circulation of which is prohibited in Republic of Kosovo and order it to be returned to the sender;

4.2. prohibit the transit of hazardous chemicals that are not packaged or labelled in accordance with the provisions and regulations adopted pursuant to this Law and order to return the hazardous chemicals to the sender;

4.3. Order the implementation of other measures to protect human health and the environment during the import, export and transit of chemicals.

### **Article 83** **Obligations of inspector**

1. During the inspection, the inspector is obliged to verify the following:

1.1. chemical that is placed on the market is classified, labelled and packaged according to the conditions laid down by this Law and provisions issued by this Law;

1.2. are declared the hazardous chemicals and mixtures that are not hazardous but containing at least one substance that is qualified as hazardous under the provisions of this Law;

1.3. keep evidence and data prescribed by this Law, and data are kept for a determined term;

1.4. obligations are fulfilled according to the legal provisions regarding the content of the Safety data sheet for chemicals;

1.5. are provided appropriate and sufficient data related to the properties of chemicals, especially the name or alternatively name of chemicals;

1.6. waste from chemicals and their packaging are treated properly and securely in accordance with the provisions of the legislation regulating waste management;



- 1.7. chemicals are stored and maintained safely and do not risk the health and environment;
- 1.8. hazardous chemicals placed on the market for sale as good for the general consume are soled according to legal provisions;
- 1.9. it is provided professional person with preparation and qualifications required by this Law;
- 1.10. information and reporting for hazardous chemicals are made in a timely, accurate and in accordance with the provisions of this Law;
- 1.11. for hazardous chemicals are respected prohibitions and restrictions under the provisions of this Law;
- 1.12. prior the export of hazardous chemicals under the Rotterdam Convention, are implemented the procedures for information on prior consent and information is done in a timely manner;
- 1.13. it is made the request for the implementation of PIC procedure;
- 1.14. very hazardous chemicals are placed on the market and used by persons who possess a permit for their circulation;
- 1.15. persons who possess the permit to manufacture, import and use of very hazardous chemicals, have stores and places suitable for their safe keeping, and respect safety preventive measures for chemicals;
- 1.16. the detergent is treated in the manner as set out in the provisions of this Law.

#### **Article 84** **Authorizations of inspector**

1. In performing its duties according to Article 83 of this Law, the environmental protection inspector is authorized to:

- 1.1. order that the chemicals in circulation be classified, labelled and packaged in accordance with the provisions of this Law and provisions derived from this Law;
- 1.2. prohibit circulation of chemicals classified, labelled and packaged in contradiction with the provisions of this Law and the provisions derived from this Law;
- 1.3. order that dangerous substances and mixtures that are not hazardous but contains substance assessed as hazardous to be declared and assessed in accordance with the provisions of this Law and the provisions derived from this Law;
- 1.4. prohibit declaration and assessment of hazardous substances and mixtures which are not hazardous but on itself contain a substance regarded as hazardous in accordance with the provisions of this Law and the provisions derived from this Law;
- 1.5. order to keep the prescribed data on chemicals and the same to be stored within the deadline set out by this Law;
- 1.6. order to meet legal obligations regarding the issuing Safety data sheet for chemicals;
- 1.7. prohibit for circulation the hazardous chemicals defined as prohibited substances;
- 1.8. order mixtures containing substances with certain properties and concentrations to be given information which are necessary for their safety use;

- 1.9. prohibit the use of alternative chemical name for substances for which no prior notification is provided to the Ministry;
- 1.10. order that dangerous chemicals to be stored safely and waste, empty packages of chemicals save and treated according to the legislation on waste;
- 1.11. prohibit the storage of hazardous chemicals and waste, as well as empty packages improperly;
- 1.12. order that chemicals placed on the market as goods of consumer for wider use to be sold under the provisions of this Law;
- 1.13. prohibit that chemicals placed on the market as goods of consumer for wider use are sold, contrary to the provisions of this Law;
- 1.14. order the manufacturer, importer and user to provide the professional person for chemicals qualified as required by this Law;
- 1.15. prohibit the work of producers, importers and users until it provides the qualified professional person required by this Law;
- 1.16. order to report within the deadline prescribed by this Law for the chemicals included in the register of chemicals;
- 1.17. order that for substances which cause concern to be taken the necessary measures to put in the register of chemicals;
- 1.18. to prohibit substances that cause concern until the measures to put in the register of chemicals are implemented;
- 1.19. order to implement the prohibitions and restrictions on hazardous chemicals in accordance with this Law;
- 1.20. prohibit the manufacture, placing on the market and use of substances, which are treated in contradictions with the provisions of this Law on the prohibition and restrictions;
- 1.21. order the removal of chemical from the market for those that are not implemented prohibitions and restrictions under this Law;
- 1.22. order that before exporting the chemicals is given specific information on time, in accordance with the provisions of this Law relating to the procedure of prior information;
- 1.23. order to be done the request for implementation of PIC procedure;
- 1.24. prohibit the placing on the market of hazardous chemicals by the persons who do not hold a permit;
- 1.25. order that for very hazardous chemicals to ensure safe storage and to create conditions and apply preventive measures set out in this Law;
- 1.26. order to act in accordance with the provisions that define the obligations for detergents;
- 1.27. prohibit the placing on the market of detergents, if they are not treated in accordance with the provisions of this Law and the provisions issued by this Law for detergents;
- 1.28. prohibit the production, circulation and use of hazardous chemicals and, where necessary order their destruction, if it determines that even if it is used in the right way the chemicals can cause adverse effects on human health and the environment;

1.29. order other measures for which is authorized by this Law and other regulations issued by this Law.

#### **Article 85** **Decision of Inspector**

1. Measures to be taken during the inspection shall be determined with the decision by the inspector.
2. In the case of taking prompt measures to avoid direct risk to human health and the environment, the inspector with a decision under paragraph 1 of this Article may also impose orally and order its execution immediately.
3. Inspector takes immediate decisions and gives order only in the following cases:
  - 3.1. when the risk to the environment and human health needs immediate action and without delay;
  - 3.2. when there is a risk of hidden, changing or destruction of evidences, if it is not acted immediately.
4. The inspector is obliged that decision imposed by paragraph 2 of this Article, to issue a written decision within a period of three (3) days from the day of oral imposes decision.

#### **Article 86** **The right to appeal**

1. Against the decision of inspector it can be appealed to the Ministry within fifteen (15) days from the day of receiving the Inspector decision.
2. The appeal against the decision of inspector does not prevent his execution.
3. The appeal against the decision of the Ministry in accordance with paragraph 1 of this Article may be appealed in the court.

#### **Article 87** **Free access for inspector**

Any natural or legal person managing the chemicals is obliged to enable the inspector to carry out the inspection supervision, and provide the available documentation that is required and necessary for supervision.

#### **Article 88** **Cooperation with other inspectorates**

If the inspector during the supervision, finds that are broken the provisions of other laws, that deal with the impacts on human health, the environment, security and safety at work is obliged that for these cases to inform the other competent authorities and in cooperation to carry out the inspection supervision and take necessary measures.

### **CHAPTER XIII**

## **OFFENCES AND PUNITIVE MEASURES**

#### **Article 89** **Offences and punitive measures**

1. According to this Law, there shall be fined, for offence, in the amount of money from:
  - 1.1. one hundred (100) to five hundred (500) Euro, if there are placed or sold on the market the hazardous chemicals by persons under the age of eighteen (18) and if the chemicals are sold to people under eighteen (18) years old according to paragraph 3 of Article 13 of this Law;

1.2. five hundred (500) to two thousand (2.000) Euro, if the manufacturer, importer, seller and user of chemicals does not implement the prohibition or restriction of chemicals according to paragraph 4 of Article 13 of this Law;

1.3. one thousand (1.000) to five thousand (5.000) Euro, if persons place the hazardous substances and mixtures on the market and they are not classified, packaged and labelled in accordance with the provisions of this Law and the sub-legal acts arising from this Law, according to paragraph 1 of Article 18 and paragraph 1 of Article 20 of this Law;

1.4. five hundred (500) to two thousand (2.000) Euro, if the manufacturer, importer and user of a substance or mixture does not assess the identified information in accordance with the criteria for classification and determining the risk associated with the substance or the respective mixture according to paragraph 2 of Article 20 of this Law;

1.5. five hundred (500) to two thousand (2.000) Euro, if the packaging of chemicals is not done appropriately, so that substances and mixtures within the packaging do not pose any risk to human health and the environment during the keeping, storage or transport according to paragraph 1 of Article 23 of this Law;

1.6. one thousand (1.000) to two thousand (2.000) Euro, if the hazardous chemicals are placed on the market and which are not packed in appropriate packaging specified in the provisions of this Law according to paragraph 1 of Article 24 of this Law;

1.7. one thousand (1.000) to two thousand (2.000) Euro, if there is not done the tight closing and there are not emplaced tangible signs for hazardous chemicals to protect children and blind persons according to paragraph 2 of Article 24 of this Law;

1.8. one thousand (1.000) to two thousand and five hundred (2.500) Euro, if in the packaging unit intended for retail sale, which contains hazardous chemicals, is given the shape, appearance which causes curiosity and attraction to children or customer, or resembles with the appearance and shape of food for people, animals or medical medicaments or cosmetics according to paragraph 3 of Article 24 of this Law;

1.9. one thousand (1.000) to two thousand (2.000) Euro, if the manufacturer, importer, supplier has not ensured that the packaging of substances or mixtures which are to be sold or distributed to third parties, are not clearly labelled and according to the Article 27 of this Law and paragraph 2 of Article 25 of this Law;

1.10. one thousand (1.000) to two thousand (2.000) Euro, if the producer and importer during the supply of hazardous substances or mixture to the third persons, does not provide that each package to be labelled clearly and permanently and contain the information specified according to paragraph 2 of Article 27 of this Law;

1.11. five hundred (500) to one thousand and five hundred (1.500) Euro, if the indicators, such as 'non-toxic', 'non-harmful', or other similar indicators are placed on the packaging of hazardous substances or mixtures in accordance with paragraph 4 of Article 27 of this Law;

1.12. one thousand (1.000) to two thousand (2.000) Euro, if for each unit of hazardous chemical packaging, along with it, are not provided instructions for use in official languages according to paragraph 6 of Article 27 of this Law;

1.13. one thousand (1.000) to three thousand (3.000) Euro, if labelling of substances does not comply with the requirements specified in paragraph 8 of Article 27 of this Law;

1.14. two thousand (2.000) to five thousand (5.000) Euro, if the person makes any advertising of chemical substances belonging to one or more of the categories specified as hazardous by Articles 6 of this Law, and not clearly stated the risk categories according to Article 7,8,9,10 of this Law as well as paragraph 1 of Article 28 of this Law;

- 1.15. five hundred (500) to three thousand (3.000) Euro, if for chemicals that can be bought without a label by the general public, during their advertising, are not previously provided and shown with a separate sheet or by words the data for their hazardous properties understandably, clearly and readable, according to paragraph 2 of Article 28 of this Law;
- 1.16. five hundred (500) to three thousand (3.000) Euro, if during the advertising of chemicals are given wrong impressions about the risks that they pose to human health and the environment or their environmental acceptability, and will encourage the use, handling or disposing improperly according to paragraph 3 of Article 28 of this Law;
- 1.17. one thousand (1.000) to three thousand (3.000) Euro, if the person will use terms such as “degradable“, “ecologically harmless“, “environmentally friendly“ and “water-friendly” in the advertisement about the properties described so, they are not at the same time explained in details according to paragraph 4 of Article 28 of this Law;
- 1.18. five hundred (500) to three thousand (3.000) Euro, if the suppliers of certain hazardous substances and mixtures, which are not hazardous, but that contain at least one substance classified as hazardous, have not emphasizes its hazardous properties when it is advertised, and its advertising is done in such a way to hide the hazardous properties of that substance by users and public according to paragraph 5 of Article 28 of this Law;
- 1.19. five thousand (5.000) to fifteen thousand (15.000) Euro, if manufacturers of hazardous substances and mixtures do not ensure that the development of tests, testing methods and evaluation of test results are consistent with the current state of scientific and technical knowledge according to paragraph 1 of Article 29 of this Law;
- 1.20. five thousand (5.000) to fifteen thousand (15.000) Euro, if the person develops tests of hazardous chemicals that are prohibited for animals according to paragraph 3 of Article 29 of this Law;
- 1.21. five thousand (5.000) to ten thousand (10.000) Euro, if the person develops tests on humans that are prohibited according to paragraph 3 of Article 29 of this Law;
- 1.22. five thousand (5.000) to ten thousand (10.000) Euro, if the tests for determining the properties of substances and mixtures are not performed in accordance with test methods laid down in Regulation (EC) No 440/2008 according to paragraph 1 of Article 30 of this Law, with the exception of paragraph 2 of Article 30 of this Law;
- 1.23. five thousand (5.000) to ten thousand (10.000) Euro, if certain tests do not comply with GLP principles, the person who represents the test reports and does not declare the reasons in accordance with paragraph 5 of Article 30 of this Law;
- 1.24. five thousand (5.000) to ten thousand (10.000) Euro, if the laboratory does tests of hazardous chemicals without fulfilling the conditions for the implementation of GLP in accordance with paragraph 2 of Article 31 of this Law;
- 1.25. five thousand (5.000) to twenty thousand (20.000) Euro, if there is not provided the Safety data sheet for chemicals from the manufacturer, importer and supplier, according to paragraph 1 of Article 33 of this Law;
- 1.26. ten thousand (10.000) to thirty thousand (30.000) Euro, if the person that fulfils the Safety data sheet for chemicals, does not provide adequate information to inform its users about the risk that can be caused by a substance or mixture, and do not provide information on handling, storage and secure disposal of the substance or mixture according to paragraph 2 of Article 33 of this Law;
- 1.27. one thousand (1.000) to three thousand (3.000) Euro, if the data of Safety data sheet for chemicals does not correspond to the data on chemical safety report with those of exposure scenario according to paragraph 5 of Article 33 of this Law;

- 1.28. five hundred (500) to one thousand (1.000) Euro, if the data of Safety data sheet for chemicals do not appear in the official languages of the Republic of Kosovo, according to paragraph 7 of Article 33 of this Law;
- 1.29. ten thousand (10.000) to thirty thousand (30.000) Euro, if the producer, exporter or supplier does not provide for the recipient or user the Safety data sheet for chemicals, and when the mixture does not meet the criteria for classification as hazardous, according to the Article 34 of this Law;
- 1.30. one thousand (1.000) to three thousand (3.000) Euro, if the producer, exporter or supplier does not update the contents of the Safety data sheet for chemicals, where it is necessary, including also cases when it is prohibited or limited the production, placing on the market or their use, does not inform all users, and does not indicate the date of changing in accordance with Article 36 of this Law;
- 1.31. one thousand (1.000) to two thousand (2.000) Euro, if professional user or dealer does not keep the Safety data sheet for chemicals, as long as certain substances or mixtures continue to be treated and used in the workplace in accordance with Article 37 of this Law;
- 1.32. one thousand (1.000) to three thousand (3.000) Euro, if the persons who place hazardous chemicals on the market do not draft the chemicals safety report, which contains the chemical safety assessment in accordance with the requirements of Annex I of Regulation (EC) No. 1907/2006, for each substance on its own, or mixtures, or to a group of substances referred to in paragraph 1 of Article 38 of this Law;
- 1.33. one thousand (1.000) to eight thousand (8.000) Euro, if the producer, importer of substances and mixtures does not notify the Ministry and does not submit the request for registration of substances and mixtures in the Ministry according to Article 43 of this Law;
- 1.34. one thousand (1.000) to three thousand (3.000) Euro, if the manufacturer, importer or user who is obliged to submit the information to the Ministry, do not submit these information by 31 March of the following year for the amount of produced, imported chemicals for the past year according to paragraph 1 of Article 44 of this Law;
- 1.35. three thousand (3.000) to eight thousand (8.000) Euro, if the manufacturer, importer, and the user does not comply with measures to reduce the risk from paragraphs 2 and 3 of Article 46 of this Law;
- 1.36. one thousand (1.000) to three thousand (3.000) Euro, if the manufacturers or importers do not notify the Ministry of any change to the data included in the register of chemicals in accordance with Article 47 of this Law;
- 1.37. one thousand (1.000) to three thousand (3.000) Euro, if the manufacturers or importers do not keep the evidence on hazardous chemicals in accordance with Article 48 of this Law;
- 1.38. one thousand (1.000) to three thousand (3.000) Euro, if the manufacturer, importer or user of hazardous chemicals does not notify the Ministry for the use of the alternative name of hazardous substance contained in the mixture according to paragraph 2 of Article 50 of this Law;
- 1.39. three thousand (3.000) to eight thousand (8.000) Euro, if the manufacturer, importer and user of substances, mixtures and products does not comply with the restrictions and prohibitions according to the provisions issued by the competent body in accordance with Article 51 and 52 of this Law;
- 1.40. three thousand (3.000) to eight thousand (8.000) Euro, if placing of hazardous chemicals on the market is carried out by persons who are not equipped with permit for circulation of chemicals according to paragraph 1, 2, 3 and 4 of Article 53 of this Law;
- 1.41. one thousand (1.000) to three thousand (3.000) Euro, if there are not met the basic requirements for storage of hazardous chemicals in a building prepared for storage of chemicals according to paragraph 5 of Article 53 of this Law;



- 1.42. one thousand (1.000) to three thousand (3.000) Euro, if the holder of the permit does not apply the conditions for which the permit has been issued for circulation of chemicals in accordance with paragraph 1, 2, 3 and 4 of Article 58 of this Law;
- 1.43. one thousand (1.000) to three thousand (3.000) Euro, if the holder of the permit for circulation of hazardous chemicals does not keep the evidence for hazardous chemicals and does not report to MESP according to paragraph 1 of Article 59 of this Law;
- 1.44. one thousand (1.000) to three thousand (3.000) Euro, if hazardous substances and mixtures are not well kept and maintained in accordance with the type of risk that may be caused by external influences, by unauthorized parties, or cause confusion for similarities with general consumption goods, especially food according to paragraph 1 of Article 60 of this Law;
- 1.45. one thousand (1.000) to three thousand (3.000) Euro, if hazardous substances and mixtures are not clearly identifiable and during storages in warehouses are not kept separately from other goods according to paragraph 4 of Article 60 of this Law;
- 1.46. five hundred (500) to three thousand (3.000) Euro, if the hazardous substances and mixtures which are supplied are stored in containers or packages that cause confusion because of the similarity with the packaging of food products, cosmetics, therapeutic products or animal feed according to paragraph 7 of Article 60 of this Law;
- 1.47. one thousand (1.000) to three thousand (3.000) Euro, if the exporters and importers of chemicals or mixtures under Articles 63, 64 and 65 of this Law do not submit to the Ministry the data on time about the exported and imported quantities of chemicals and certain mixtures for states from where are imported or exported and data for the exporters and importers of chemicals according to paragraph 1, 2 and 4 of Article 65 of this Law;
- 1.48. one thousand (1.000) to three thousand (3.000) Euro, if the exporter of chemicals and mixtures does not send the information to the Ministry for the needs of the competent body of the state in the territory of which there is developed the transit of substances and mixtures within the time specified in paragraph 1 of Article 66 of this Law;
- 1.49. twenty thousand (20.000) to thirty thousand (30.000) Euro, if the persons import and export substances and mixtures, the use of which is prohibited in order to protect the human health and the environment according to paragraph 1 and 2 of Article 67 of this Law;
- 1.50. seven thousand (7.000) to twenty thousand (20.000) Euro, if there are exported hazardous chemicals that the deadline use is expired six (6) months after being exported or imported according to paragraph 3 of Article 67 of this Law;
- 1.51. five thousand (5.000) to eight thousand (8.000) Euro, if the producer and importer of detergents does not possess a permit before placing the detergent on the market that fulfils the conditions from paragraph 1 of Article 69 and paragraph 1 of Article 70 of this Law;
- 1.52. five thousand (5.000) to ten thousand (10.000) Euro, if there is not removed from the market, in the deadline, the detergent or tensio-active substance for which there shall be required prohibition of use according to paragraph 2 of Article 70 of this Law;
- 1.53. five thousand (5.000) to ten thousand (10.000) Euro, if the holder of the permit does not apply the conditions for which the permit has been issued for the placing the detergents on the market according to paragraph 4 of Article 71 of this Law;
- 1.54. two thousand (2.000) to five thousand (5.000) Euro, if the manufacturer of detergents does not keep the results of the reviews conducted in the laboratory according to paragraph 1 of Article 74 of this Law;

1.55. five thousand (5.000) to ten thousand (10.000) Euro, if the manufacturer of detergents does not maintain a register of components contained by a certain detergent and does not keep records for a determined time and does not make them public according to paragraph 3 of Article 74 of this Law;

1.56. two thousand (2.000) to five thousand (5.000) Euro, if the manufacturer, importer and user of hazardous chemicals does not appoint / provide the professional person for chemicals through the contract, to ensure a natural or legal person responsible for giving advice about legal rules and technical standards for the management of chemicals according to paragraph 1 and 2 of Article 78 of this Law;

1.57. two thousand (2.000) to five thousand (5.000) Euro, if the professional person for chemicals does not have university-level qualifications of specific branches and areas according to paragraph 3 of Article 78 of this Law;

1.58. three thousand (3.000) to ten thousand (10.000) Euro, if natural and legal persons do not enable the inspector the supervision without interference for taking data and information , required or requested, and the samples according to paragraph 1 of Article 81 and Article 87 of this Law.

2. Responsible persons of legal persons shall be punished, for offence from paragraph 1 of this Article, with a fine in the amount of one hundred (100) to one thousand (1.000) Euro.

3. Persons who violate the principle of confidentiality, according to paragraph 6 of Article 49 of this Law, even after the employment has ended, will be fined for offence in the amount of one hundred (100) to one thousand (1.000) Euro.

4. For offence from paragraph 1 of this Article, together with the penalty on money in order to take the measures for Chemical Safety, there may also be prohibited the activity of the legal person for up to five (5) years.

5. For offence from paragraph 1 of this Article, for the purpose of taking measures for chemical safety, the activity of the responsible person of legal person shall be prohibited up to ten (10) years.

## CHAPTER XIV

### TRANSITIONAL AND FINAL PROVISIONS

#### Article 90

##### Adoption of the strategy for management of chemicals

The strategy for the management of chemicals shall be drafted by the Ministry and approved by the Government.

#### Article 91

##### Adoption of the Plan for Chemical Safety

The Government of Kosovo upon the proposal of the Ministry shall approve the National plan of safety from chemicals within four (4) years from the date of entry into force of this Law.

#### Article 92

##### Adoption of sub-legal acts

The Government and the Ministry are obliged that all sub-legal acts arising from this Law, to be issued in a period of three (3) years from the date of entry into force of this Law.

#### Article 93

##### Harmonization of activities

All persons who produce circulate or use hazardous chemicals, should harmonize their actions with the provisions of this Law, within twelve (12) months from the date of adoption of this Law.



#### **Article 94**

##### **Repeal**

1. Upon entry into force of this Law, there shall be repealed the Law on Chemicals No. 02/L-116 promulgated with the UNMIK Regulation No. 2008/8 and every other provision regulating the field of hazardous chemicals and that is in contradictions with the provisions of this Law.

2. Exception from paragraph 1 of this Article shall be: the Administrative Instruction No.10/2010 on safety data sheet for chemicals and the way of its supplementation, which remains into force until the issuance of a new act.

#### **Article 95**

##### **Application of administrative procedure**

For the implementation of this Law there shall be applied the provisions of the Law on Administrative Procedure.

#### **Article 96**

##### **Entry into force**

This Law shall enter into force fifteen (15) days after publication in the Official Gazette of the Republic of Kosovo.

**Law No. 04/L-197**  
**27 February 2014**

**Promulgated by Decree No. DL-005-2014, dated 14.03.2014, President of the Republic of Kosovo Atifete Jahjaga.**

