

**LAW NO. 02/L-116**

**ON CHEMICAL**

The Kosovo Assembly,

Based on Chapter 5.1 (i) and 9.1. 26 (a), of the Constitutional Framework of Provisional Self-Government in Kosovo (UNMIK Regulation No. 2001/9 of 15 May 2001),  
Aiming to create Legislative Framework, mechanisms and conditions in compliance with European Union standards for Chemical Administration in Kosovo,

Hereby adopts as follows:

**LAW ON CHEMICAL**

**CHAPTER I**

**GENERAL PROVISIONS**

**Article 1  
Aims and Scope**

1.1. The purpose of this law is also to regulate sustainable administration of chemicals including measures for environmental protection and the exposure of man to the substance.

1.2. This law regulates regulates:

- a) the rights and obligations of legal and natural persons;
- b) requirements and procedures for chemical registration;
- c) proof of content, accessibility of information, classification, packaging and labelling of chemicals;

**Article 2  
Exemptions**

2.1. This Law shall not apply to the following preparations in the finished state, intended for the final user:

- a) medicinal products for human or veterinary use;
- b) cosmetic products;
- c) mixtures of substances in the form of waste;
- d) foodstuffs;
- e) animal feedingstuffs;
- f) plant protection products;
- g) biocides;
- h) radioactive substances.

2.2. In addition, this Law shall not apply to:

- a) the carriage of dangerous substances by rail, road, inland waterway, sea or air,
- b) chemicals in transit into the Kosovo territory, which should be under customs supervision, provided that they do not stored or processing in Kosovo.
- c) chemicals foreseen by the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction.

**Article 3**

## Definitions

3.1. For the purpose of this Law:

a) **Chemicals** - means substances, chemical elements and their compounds, or materials in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

b) **Polymer** - means a substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. In the context of this definition a "monomer unit" means the reacted form of a monomer in a polymer.

c) **Chemical administration** - means implementation of measures and activities used on chemicals within their expiry date, to optimally manage production, import, export, transit, use, protection, packaging and labelling of chemicals and environment and human protection in compliance with new development trends and measures for oversight.

d) **Putting into the market** – means manufacture of chemicals or prepares available for third party including here importing in Kosovo territory ,

e) **Notifier** - means manufacturer, importer, and distributor or authorized dealer that is the person, which through the attached documentation with the application, gives the information required by law for the notification of new substances.

f) **Preparations** - means mixtures or solutions composed of two or more substances;

g) **Existing substances** - means substances listed in EINECS.

h) **New substances** - means substances not listed in EINECS. These substances might be listed into ELINCS.

i) **Dangerous chemicals** - means substances with one or more characteristics regarded dangerous in accordance with this law:

*i. explosive chemicals* - solid, liquid, pasty or gelatinous substances and preparations which may also react exothermically without atmospheric oxygen, thereby quickly evolving gases, and which, under defined test conditions, detonate, quickly deflagrate or upon heating explode when partially confined;

*ii. oxidizing chemicals* - substances and preparations which give rise to a highly exothermic reaction in contact with other substances, particularly flammable substances;

*iii. extremely chemicals* - liquid substances and preparations having an extremely low flash-point and a low boiling-point and gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure;

*iv. highly flammable chemicals* - are :

-Substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy, or

-Solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition, or

-Liquid substances having a very low flash-point and are not extremely flammable, or

-Substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities;

**v. flammable chemicals** - liquid substances and preparations having a low flash-point;

**vi. very toxic chemicals** - substances and preparations which in very low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

**vii. toxic chemicals** - substances and preparations which in low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

**viii. harmful chemicals** - substances and preparations which may cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

**ix. corrosive chemicals** - substances and preparations which may, on contact with living tissues, destroy them;

**x. irritant chemicals** - non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, may cause inflammation;

**xi. sensitizing chemical** - substances and preparations which, if they are inhaled or if they penetrate the skin, are capable of eliciting a reaction of hypersensitization such that on further exposure to the substance or preparation, characteristic adverse effects are produced;

**xii. carcinogenic chemicals** - and preparations: substances or preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence;

**xiii. mutagenic chemicals** - substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce heritable genetic defects or increase their incidence;

**xiv. toxically reproduction chemicals** - are substances or preparations which if they are inhaled or ingested or if they penetrate the skin, may produce, or increase the incidence of, non-heritable adverse effects in the progeny and/or an impairment of male or female reproductive functions or capacity;

**xv. dangerous chemicals for environment** - substances and preparations which, were they to enter the environment, should be harmful for environment, human health, flora and fauna, in particular for biological and landscape diversity.

j) **Notification** - means the information given to MESP by the notifier which aims to put into the market the new chemicals, notification respectively represent the announcement, information or presentation of the new substance through the documentation which content the required (needed) notes before to put it in circulation. In general, the notification includes information for the substance identity (it will be used to identify the new substance and to confirm its status), for the capacity production, producer identity and making public of the information and analyses of data for the new substances.

k) **Scientific research** - means scientific experimentation, analysis or chemical research carried out under controlled conditions; it includes the determination of intrinsic properties, performance and efficacy as well as scientific investigation related to product development;

l) **EINECS** - means the European Inventory of Existing Commercial Substances, and represent the register of trade existing substances, which contains the list of all substances in market until 18 September 1980, while is accomplished as European registration of existing substances on Official Gazzete EUC 146/4 of 15.6.1990;

m) **ELINCS** - means European List of Notified Commercial Chemical Substances and presents the European registry of new substances,

n) **Ministry** - means the Ministry of Environment and Spatial Planning;

o) **Minister** - means the Minister of Environment and Spatial Planning;

p) **EC** - is now preferred number issued by "EINECS / ELINCS number" designations, but this is not to be confused with the EC number of European Commission legislation in force.

q) **Researching and developemtn oriented processes** – are further developemtns of substances which during the pilot plans and experimental production shall be used to prove the application field of chemical substances.

## **CHAPTER II**

### **NOTIFICATION, PLACING IN THE MARKET AND USING OF NEW SUBSTANCES**

#### **Article 4 Full notification**

4.1. Any person which aims to import or manufacture a new substance or preparation shall present the notification into the Ministry. The notification shall include these information:

- a) a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for man and the environment, and containing all available relevant data for this purpose. As a minimum, the dossier shall contain the information and results of the studies, referred to in secondary legislation adopted on the basis of paragraph 2 of this article, together with a detailed and full description of the studies conducted and of the methods used or a bibliographical reference to them;
- b) a declaration concerning the unfavourable effects of the substance in terms of the various foreseeable uses, and based on technical briefing from European office for chemicals;
- c) the proposed classification and labelling of the substance in accordance with this Law;
- d) in case of dangerous substanc, a proposal safety data sheet as provided for in article 21 of this law.

4.2. The content of the notification and the notification process shall be determined by subordinate legal acts passed by the Minister.

#### **Article 5 Exemption of notification requirments**

5.1. Provisions of article 4, 7, 9 and article 10 of this Law, shall not apply to:

- a) substances which appear in the EINECS inventory;
- b) additives and substances for exclusive use in animal feedstuffs;
- c) substances used exclusively as additives in foodstuffs and substances used exclusively as flavourings in foodstuffs;
- d) active ingredients used exclusively in the medicinal products; this does not, however, include chemical intermediates;
- e) substances for exclusive use in other product sectors, in which similar notification or approval procedures exist, and for which requirements for data submission are equivalent to those laid down by this Law.

5.2. The following substances shall be considered as notified within the meaning of this Law:

- a) polymers, with the exception of those which contain in combined form 2% or more of any substance which is not on EINECS;
- b) substances placed on the market in quantities of less than 10 kg per year per manufacturer, provided the manufacturer or importer satisfies all the conditions imposed by a country in which the substance is placed on the market;
- c) substances placed on the market in limited quantities, and in any case not exceeding 100 kg per manufacturer per year, and intended solely for purposes of scientific research and development carried out under controlled conditions;
- d) substances placed on the market for the purposes of process oriented research and development with a limited number of registered customers in quantities which are limited to their purpose under conditions set out in secondary legislation adopted by the Ministry under paragraph 4 of this article.

5.3. Any manufacturer or importer making use of the exception referred to in paragraph 2 point (c) must maintain written records containing the identity of the substance, labelling data, quantities and list of customers; this information shall be made available to the Minister upon request.

5.4. Minister basen on enforced EU legislation shall adopt secondary legislation prescribing conditions for packaging and labelling of substances referred to in paragraph 2 of this article as well as detailed conditions of use of the exemption described in paragraph 2 point (d) of this article.

## **Article 6**

### **Additional tests for substances already notified**

6.1. Without prejudice to article 9 of this Law any notifier of a substance already notified shall inform the Ministry:

- a) when the quantity of the substance placed on the market reaches 10 tonnes per year per manufacturer or when the total quantity placed on the market reaches 50 tonnes per manufacturer, in which case the Ministry may require some or all of the additional tests/studies to be carried out, in accordance with secondary legislation adopted on the basis of paragraph 3 of this article, to be carried within the time limit he will determine;
- b) when the quantity of the substance placed on the market reaches 100 tonnes per year per manufacturer or when the total quantity placed on the market reaches 500 tonnes per manufacturer, in which case the Ministry shall require the additional tests/studies to be carried out, in accordance with secondary legislation adopted on the basis of paragraph 3 of this article, within the time limit it will determine, unless the notifier can give good reasons why a given test/study is not appropriate or and alternative scientific test/study would be preferable;
- c) when the quantity of a substance placed on the market reaches 1000 tonnes per year per manufacturer or when the total quantity placed on the market reaches 5000 tonnes per manufacturer, in which case the Ministry shall draw up a programme of tests/studies to be carried out, in accordance with secondary legislation adopted on the basis of paragraph 3 of this article, within the time limit it will determino.

6.2. When additional testing is carried out in accordance with paragraph 1 of this article, the notifier shall provide the Ministry with the results of the studies carried out.

6.3. Minister will adopt secondary legislation concerning additional tests and studies to be carried out by the notifier in situations determined in this article.

## **Article 7**

### **Reduced notification**

7.1. Any notifier intending to place a substance on the market in Kosovo in quantities of less than one tonne per year per manufacturer shall be required to submit to the Ministry a notification including:

- a) a technical dossier supplying information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for man and the environment, and containing all relevant data for this purpose, in accordance with the secondary legislation adopted on the basis of paragraph 3 of this article , together with a detailed an full description of the studies conducted and of the methods used or a bibliographical reference to them;
- b) a declaration concerning the unfavorable effects of the chemicals substance in terms of the various foreseeable uses;
- c) the proposed classification and labeling of the substance in accordance with this Law and accompanying secondary legislation, basen on the enforced EU legislation;
- d) in the case of dangerous substances, a proposal for a technical safety data sheet, as provided for in article 21 of this Law.

7.2. When the quantities to be placed on the market are below 100 kg per year per manufacturer, the notifier may restrict the information in the technical dossier of the said notification to the minimum provided for in the secondary legislation adopted on the basis of paragraph 3 of this article.

7.3. Ministry will lay down the minimum requirements for the dossiers referred to in paragraph 1 (a) and paragraph 2 of this article, with regard to the information and results of the conducted studies that it shall contain.

7.4. In the case of a notifier, who has submitted a reduced notification in conformity with paragraph 3, of this article, he shall, before the quantity of the substance placed on the market reaches 100 kg per year per manufacturer or before the total quantity placed on the market reaches 500 kg per manufacturer, provide the Ministry with the additional information necessary to complete the technical dossier to the level required by paragraph 1(a) of this article.

7.5. In the case of a notifier, who has submitted a reduced notification in conformity with paragraph 1, point (a) of this article, he shall, before the quantity of the substance placed on the market reaches 1 tonne per year per manufacturer or before the total quantity placed on the market reaches 5 tonnes per manufacturer, submit the full notification in accordance with article 4 of this Law.

7.6. The substances notified in conformity with paragraph 1 and 3 of this article, must in so far as the notifier may reasonably be expected to be aware of their dangerous properties, be packaged and labeled in accordance with the rules and criteria laid down in this law and accompanying secondary legislation.

7.7. Where it is not possible to label them accordingly, the label should bear, in addition to the label deriving from the tests already carried out, the warning: "Caution – substance not yet fully tested".

## **Article 8** **Placing of notified substances on the market and using**

8.1. Substances notified in accordance with article 4 of this law, should in the absence of any indication to the contrary from the competent authority, be placed on the market no sooner than 60 days after receipt by the authority of the dossier in conformity with this Law and secondary legislation based upon it.

8.2. If the Ministry considers that the dossier is not in conformity with the Law and secondary legislation based upon this law, the substance may be placed on the market and use only 60 days after receipt by the Ministry of the information necessary to bring the notification into conformity with the requirements of this Law and secondary legislation based upon it.

8.3. Substances placed on the market under, paragraph 1 and 2 of article 7, in the absence of any indication to the contrary from the competent authority, be placed on the market no sooner than 30 days after receipt by the authority of the dossier in conformity with this Law and secondary legislation based upon it.

8.4. If the Ministry considers that the dossier is not in conformity with the Law and secondary legislation based upon it and advises the notifier accordingly, the substance may be placed on the market only 30 days after receipt by the Ministry of the information necessary to bring the notification into conformity with the requirements of this Law and secondary legislation based upon it.

## **Article 9** **Follow-up information**

Any notifier of a substance already notified in conformity with article 4 paragraph 1 or article 7 paragraph 1 of this Law, shall be responsible on his own initiative for informing the Ministry of:

- a) changes in the annual or total quantities placed on the market;
- b) new knowledge of the effects of the substance on man and/or the environment of which Ministry may reasonably be expected to become aware;
- c) new uses for which the substance is placed on the market of which Ministry may reasonably be expected to have become aware;
- d) any change in the composition of the substances;
- e) any change in his status (manufacturer or importer).

## **Article 10**

### **Renotification of the same substance**

10.1. In case of a substance which has already been notified in conformity with article 4 paragraph 1 or article 7 paragraph 1 of this Law, the Ministry may agree that the subsequent notifier of that substance may refer to the results of the test/studies forwarded by the first notifier, in so far as the subsequent notifier can provide evidence that the substance renotified is the same as the one previously notified, including the degree of purity and the nature of impurities.

10.2. Before such reference can be made, the first notifier must give his agreement in writing to the reference to the results of tests/studies he has forwarded.

10.3. Before carrying out tests on vertebrate animals for the purpose of submitting a notification in accordance with article 4 paragraph 1 or article 7 paragraph 1 of this Law, and without prejudice to paragraph 1 of this article, prospective notifier shall enquire of the Ministry as to:

- a) whether or not the substance they intend to notify has already been notified; and
- b) the name and address of the notifier, providing evidence that he has intention to place the substance on the market and of the quantities he intends to place on the market and use.

10.4. If the Ministry consider that by the evidence provided for in paragraph 3 of this article, and the substance has previously been notified, while the first notifier has not requested and been granted temporary exception from the provisions of this article, the Minister shall provide the prospective notifier with the name and address of the first notifier and shall inform the first notifier of the name and address of the prospective notifier.

10.5. The first notifier and the prospective notifier shall take all appropriate steps to reach agreement on the sharing of information so as to avoid the duplication of testing on vertebrate animals, as well as on sharing information derived from testing on vertebrate animals submitted in accordance with article 6 of this Law.

## **Article 11**

### **Confidentiality of data**

11.1. Any notifier, who considers that there is a confidentiality problem, may indicate the information provided for in articles 4, 7 and 9 of this Law which he considers commercially sensitive and disclosure of which might harm him industrially or commercially, and which he therefore wishes to be kept secret from all persons other than the competent authorities. In such cases he is obliged to give full justification.

11.2. With regard to notifications and information submitted in conformity with articles 4 paragraph 1, article 6 paragraph 1, article 7 paragraph 1, 2 and 4 of this Law, industrial secrecy shall not apply to:

- a) the trade name of the substance;
- b) the name of the manufacturer and the notifier;
- c) physico-chemical data concerning the substance, referred to in the secondary legislation passed on the basis of article 4 paragraph 3 of this Law;
- d) the possible ways of rendering the substance harmless;
- e) the summary results of the toxicological and ecotoxicological tests;
- f) data for the degree of purity and content of hazardous covering into the substance, whether they are dangerous or needful for classification and labelling of hazardous chemicals within the meaning of Article 3 point (i) of this Law with the purpose of introducing the substance into the list referred to in article 17 paragraph 3, of this Law;
- g) the recommended measures, emergency measures and precautions referred to in the secondary legislation passed on the basis of article 4, paragraph 1 of this Law;
- h) the information contained in the safety data sheet;
- i) in case of substances registered in the list referred to in article 17 paragraph 3 of this Law, analytical methods that make it possible to detect a dangerous substance when discharged into environment as well as to determine the direct exposure of humans.

11.3. If the notifier should himself later disclose previously confidential information, he shall inform the competent authority accordingly.

11.4. The Ministry after receiving the notification/ information shall decide on his own responsibility which information is covered by industrial and commercial secrecy in accordance with paragraph 1 of this article, and such information accepted as confidential, shall be treated accordingly by other authorities and shall be kept secret.

11.5. Information referred to in paragraph 4 of this article, may, however, be divulged to persons directly involved in administrative or legal proceedings involving sanctions which are undertaken for the purpose of controlling substances placed on the market and to persons who are to participate or be heard in legal and administrative proceedings.

## **Article 12 Duty to store data**

The notifier is obliged to store the dossier and all other documents containing data on the substance for at least five years after the production or putting into the market the substance has ceased.

## **CHAPTER III EVALUATION OF THE NEW SUBSTANCES**

### **Article 13 Duties of the Ministry**

13.1. Upon the receipt of a notification made in accordance with article 4 paragraph 1 and article 7 paragraph 1 and 2 the Ministry shall carry out an assessment of the risks in accordance with methods and principles laid down in secondary legislation, issued basen on the EU legislation.

13.2. The assessment shall include recommendations on the most appropriate method of testing the substance and, where appropriate, also include recommendations on measures which will nable the risk for man and the environment connected with the marketing of the substance to be lessened; such assessment shall be regularly updated in the light of additional information provided on the basis of article 6, article 7 paragraph 4 and article 9 of this Law.

13.3. In case of notifications made under article 4 of this Law, within 60 days following the receipt of the notification Ministry shall inform notifier in writing as to whether the notification has or has not been accepted.

13.4. If the dossier is accepted, Ministry shall inform the notifier of the official number allocated to his notification.

13.5. In case of notifications made under article 7 of this Law, within 30 days following the receipt of the notification Ministry shall inform notifier in writing as to whether the notification ahs or has not been accepted.

13.6. Ministry will keep register of new registered substances and notifiers for there substance.

13.7. Minister based on the e EU legislation will adopt a subordinate legal act laying down general principles of testing chemicals, as well as detailed methods for testing physico-chemical proprieties of substances, their toxicity and ecotoxicity, and laboratory test, in accordance with good laboratory practice, which shall be carried out in execution of provisions of this Law.

## **Article 14**



### **Legal entities appointed by the Ministry for carrying out technical evaluation**

14.1. Technical evaluation of the substance shall be done in accordance with this Law and secondary legislation based thereon, by legal entities authorized by the Ministry.

14.2. The legal entities referred to in paragraph 1 of this article shall evaluate the real or potential risks of the substance to man and environment in accordance with new scientific research based on principles of Good Laboratory Practice.

14.3. Register of legal entities referred to in paragraph 1 of this article shall be kept by the Ministry; it shall be published as a subordinate legal act, and regularly updated.

14.4. Detailed requirements for the legal entities by paragraph 1 of this article and evaluation methods referred to in this article shall be laid down in a subordinate legal acts issued by the Minister, basen on the EU legislation, standards, requirmentsa and instructions.

### **Article 15 International cooperation and ELINCS and EINECS registers**

15.1. At the international level, Ministry will work towards cooperation and exchange of data about new substances listed in ELINCS register and substances listed in EINECS register.

15.2. By means of subordinate legal act, the Minister will publish and regularly update the registers mentioned in paragraph 1 of this article.

## **CHAPTER IV**

### **CLASSIFICATION, PACKAGING AND LABELLING OF DANGEROUS CHEMICALS**

#### **Article 16 General rules**

Dangerous substances cannot be placed on the market and use unless they are properly classified, packaged and labelled, in accordance with this law and secondary legislation based upon it.

#### **Article 17 Classification of substances**

17.1. Substances shall be classified on the basis of their intrinsic proprieties according to the categories laid down in article 3 point (i) of this Law, taking into account impurities as far as their concentrations exceed the concentration limits referred to in paragraph 3 of this article.

17.2. General principles of the classification and labelling of substances and preparations shall be adopted by the Ministry by means of secondary legislation.

17.3. Minister, by means of a secondary legislative act, will publish a list of substances classified according to the principles referred to in paragraphs 1 and 2 of this article, together with their harmonised classification and labelling.

17.4. The dangerous substances listed in accordance with paragraph 3 of this article shall, where appropriate, be characterised by concentration limits or any other parameter enabling an assessment to be made to the health or environmental hazard of preparations containing the said dangerous substances or substances containing other dangerous substances as impurities.

#### **Article 18 Packaging of substances**

18.1. Dangerous substances cannot be placed on the market and use unless their packaging satisfies the following requirements:

- a) it shall be so designed and constructed that its contents cannot escape; however, this requirement shall not apply where special safety devices are prescribed;
- b) the materials constituting the packaging and fastenings must not be susceptible to adverse attack by the contents, or liable to form dangerous chemical compounds with their contents;
- c) packaging and fastening must be strong throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling;
- d) containers fitted with replaceable fastening devices shall be so designed that the packaging can be refastened repeatedly without the content escaping;
- e) Every container of whatever capacity, containing substances sold or made available to the general public and labelled "very toxic", "toxic", or "corrosive", as defined by this Law, must have a child-resistant fastening and a tactile warning of danger.

18.2. Containers for dangerous preparations, including containers for chemicals for general usage that can be found in the market, cannot resemble of ordinary food or general usage goods containers.

18.3. Technical specifications relating to devices referred to in paragraph 1 point (e) of this article shall be laid down by the Minister in a subordinate legislative act.

## **Article 19 Labelling of substances**

19.1. Dangerous substances cannot be placed on the market and use unless the labelling on their packaging satisfies the following requirements.

19.2. Every package shall show clearly and indelibly the following:

- a) the name of the substance under one of the designations given in the list referred to in article 17, paragraph 3 of this Law or, if the substance is not the list, the name must be given using an internationally recognized designation;
- b) the name and full address including the telephone number of the person responsible for placing the substance on the market whether it be the manufacturer, the importer or the distributor;
- c) danger symbols, when laid down, and indication of the danger involved in the use of the substance, in accordance with the secondary act adopted by the Minister;
- d) standard mark (R-mark ) indicating the special risks arising from the dangers involved in using the substance, in accordance with the secondary act adopted by the Minister;
- e) standard mark relating to the safe use of the substance (S-mark), in accordance with the secondary act adopted by the Minister;
- f) The EC number obtained from the EINECS list, when allocated.

19.3. In case of irritant, highly flammable, flammable and oxidising substances, an indication of R-phrases and S-phrases need not be given when the package does not contain more than 125 ml; this shall also apply in the case of the same volume of harmful substances not retailed to the general public.

19.4. Indications such as "non-toxic", "non-harmful" or any other similar indications must not appear on the label or packaging of substances subject to this Law.

19.5. Detailed provisions on the implementation of labelling requirements, as well as danger symbols and indications, and use of "R"-phrases and "S"-phrases of danger shall be laid down in a subordinate legal act adopted by the Minister.

19.6. Each unit of dangerous chemical packaging should be provided with instructions for usage in all official languages, harmonized with conditions as set by this Law.

## **Article 20**

## **Advertisement**

Any advertisement for a substance which belongs to one or more of the categories referred to in article 3 (i) of this Law shall be prohibited if no mention is made therein of the category or categories concerned of this article.

### **Article 21 Safety data sheet**

21.1. To enable professional users in particular to take the necessary measures as regards the protection of the environment and health and safety at the workplace, at, or if appropriate, before the putting into the circulation of a dangerous substance. Any manufacturer, importer or distributor shall communicate to the recipient a safety data sheet, which must contain the information necessary for protection of the environment and human health.

21.2. The safety data sheet may be communicated on paper or electronically.

21.3. The manufacturer, importer or distributor shall forward to the recipient of the safety data sheet any new relevant information on the substance which has become known to him.

21.4. Detailed rules for elaboration, distribution, contents and format of the safety data sheet referred to in paragraph 1 of this article will be laid down in a subordinate legal act adopted by the Minister in accordance with EU legislation.

## **CHAPTER V**

### **TRADING AND USING OF HAZARDOUS SUBSTANCE**

#### **Article 22 Conditions for production placing on market and use of chemicals**

22.1. Any entity which is put into the market or use chemicals or dangerous preparates is obliged to fulfil the specific conditions determined by the Government through subordinate legislation based on EU legislation.

22.2. Specific conditions determined in paragraph 1 of this article means:

- a) conditions under which shall be putted into the market and used dangerous chemicals;
- b) conditions under which dangerous chemicals and preparatiosn shall be stored in a safety way by making the verification through their assessment.
- c) conditions under which shall be done the importing and exporting of dangerous chemicalas and preparations in and from Kosovo
- d) compiling lists for dangerous chemicals and preparatiosn which shall be introduced in determined restrictions (clearly defined).

#### **Article 23 National Plan for Chemical Safety**

23.1. For sustainable national policy management in the field of protection from dangerous chemicals, the Government of Kosovo, upon the proposal of Ministry will issue the National Plan for Chemical Safety.

23.2. Content, procedure term for adaption and update of National Plan for Chemical Safety, shall set out the Ministry by subordinate legislation.

## **CHAPTER VI**

## **SUPERVISION AND CONTROL**

### **Article 24 Responsible Body for chemicals**

24.1. Minister with subordinate legislation will appoint a Responsible Body for notification of chemicals, which under the provisions of this law shall accomihs these duties:

- a) receive and review notifications;
- b) keep evidence of new registered substances and applicants for these substances;
- c) keep evidence of data collection from legal or physical entities;
- d) keep evidence of data from safety data sheets;
- e) keep register of poisoning cases;
- f) control and verify the declarations and instructions for use of chemicals;
- g) plan and organize trainings on protection from dangerous chemicals, in connection with those trainings it may issue certificates for acquired knowledge on safety of dangerous chemicals for environment and human health.
- h) accomplish other tasks for which minister shall consider that are necessary for implementation and appropriate controlling of the Law.

24.2. Financial resources for functioning of the Body of paragraph 1 of this article will be provided by the Budget of the Ministry.

24.3. Budget from paragraph 2 of this article will include as well resources for legal entities which will be appointed by the Ministry to perform some technical and laboratory functions.

### **Article 25 Official control bodies**

25.1. Administrative supervision of implementation of the provisions of this Law and secondary legislation based upon it will be performed, by the Ministry.

25.2. Practical supervision and official control will be carried out by respective environmental inspectors.

25.3. Legal or physical entities bound by provisions of this Law are obliged to enable the performance of supervision functions by environmental inspectors and to make available required data and documents.

25.4. Environmental inspector, for the purpose of performing of supervision tasks, will have a right to control spaces, buildings, equipments and documentations.

### **Article 26 Rights of the inspector**

In performance of his functions, the environmental inspector has a right to:

- a) prohibit production, circulation and use of dangerous chemicals, and, in some cases order their destruction, if certain that even if it is used in required manner, the chemicals may have harmful consequences for environment and human health;
- b) prohibit all activities which do not fulfill the conditions for production, circulate and use of dangerous chemicals;
- c) order elimination of consequences of unlawful production, circulation, and use of dangerous chemicals, if these consequences cause risk for environment and human health;
- d) order examination of dangerous chemicals to re-evaluate their risks and characteristics if there are doubts relating to them;
- e) if there exist any doubt for the change of chemical characteristics, should be taken the samples for verification;
- f) prohibit circulation of dangerous chemicals which are not classified, packaged or labeled in accordance with this law this Law;

- g) prohibit circulation of dangerous chemicals if according to the opinion of the department of chemicals; documentation of dangerous chemicals is not in accordance with this Law;
- h) order other measures authorized by this Law and other sublegal acts.

**Article 27**  
**Importation, exportation and transit of chemicals**

In the supervision process of dangerous chemicals referred to in article 3 (i) (iv)-(xv) of this Law, the environmental inspector is authorized to:

- a) prohibit the importing of dangerous chemicals, which circulation is not allowed in Kosovo, and order it to be returned back to the sender;
- b) In cooperation and in assistance with customs official to prohibit transit of dangerous chemicals which, covering, packaging and labeling are not in accordance with the provisions of this Law and secondary legislation based upon it, and will order that the dangerous chemicals be returned back to the sender;
- c) Order the implementation of other measures in interest of man and environment protection during the importation, exportation and transit of chemicals.

**Article 28**  
**Decisions of environmental inspector**

28.1. Environmental inspector issues his decisions in writing.

28.2. Environmental inspector may take immediate decisions and issue oral orders in the following cases:

- a) when the protection of environment, human health and life requires undertaking actions immediately and without delay;
- b) when there is a risk of hiding, changing or destroying evidence, if action is not undertaken immediately.

**Article 29**  
**Right to appeal**

Legal and physical entities unsatisfied by decisions of supervisory body, issued based on the provisions of this Law, have a right of plaint upon the procedure determined with the Low of Administrative Procedure.

**CHAPTER VII**  
**ADMINISTRATIVE SANCTIONS**

**Article 30**  
**Fines**

30.1. Any legal or physical entity will be liable of breach of this Law and will be ordered a fine amounting to 5,000 to 50,000 €, in the following cases:

- a) production or placing on the market of new substance without proper notification of the Minsitry, as in articles 4,5,6,7 and 10 of this Law;
- b) failing to inform the Ministry about any case of changes or new scientific knowledge about the characteristics and the risks caused by a new substance;
- c) failing to provide the Ministry with necessary information under article 6, 9 and 10 of this Law,
- d) failing to save and store the data and test results in accordance with article 12;

- e) placing on the market of dangerous chemicals which are not classified, packaged or labeled in accordance with this Law and secondary legislation;
- f) advertises dangerous substances against the provision of article 20 of this Law.
- g) fails to provide the safety data sheet or provides an inadequate data sheet;

30.2. Breach of confidentiality, referred to in article 11, of this Law by any person bound by it, even after termination of their employment, is an offence and will be ordered a fine amounting to 1,000 to 10,000 €.

30.3. Responsible persons of juridical persons will be punished with fine amounting from 300 – 1,500 €.

## **CHAPTER VIII**

### **TRANSITIONAL AND FINAL PROVISIONS**

#### **Article 31 Approval of the National Plan**

The Government of Kosovo upon a proposal of the Ministry will approve the Kosovo Plan for Chemical within two years from the date of adoption of this Law.

#### **Article 32 Adoption of secondary legislation**

The Government and Minister are obliged to issue all subsidiary legal acts based upon this law within 24 months from the date of adoption of this Law.

#### **Article 33 Harmonization of Activities**

The legal and physical entities which produce, circulate and use dangerous chemicals upon article 3 point (i) of this law, should harmonize their actions with the provisions of this Law within a period of 24 months, from the adoption of this Law.

#### **Article 34 Repeal of contrary provisions**

With the entry into force of this Law, all other provisions regulating this field shall be considered contrary to it and are thereby repealed.

#### **Article 35 Application of administrative procedure**

For the implementation of this Law, and provisions upon this Law shall be applied the provisions of Law on Administrative Procedure, unless otherwise determined by this Law.

#### **Article 36 Entry into force**

This law shall enter into force after approval by Kosovo Assembly and promulgation by Special Representative of Secretary General.

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