

**REPUBLIC OF ALBANIA
ASSEMBLY**

**L A W
No.9108, dated 17.7.2003**

ON CHEMICAL SUBSTANCES AND PREPARATIONS

In reliance of Articles 78 and 83 paragraph 1 of the Constitutions, on the proposal of the Council of Ministers,

THE ASSEMBLY OF THE REPUBLIC OF ALBANIA

D E C I D E D:

CHAPTER I

GENERAL PROVISIONS

Article 1

Purpose

This law aims at regulating the management of chemical substances and preparations for the protection of life and health of people and animals as well as for the protection of environment from risks that may cause hazardous matters.

Article 2

Object

The object of this law is:

- a) Impose of rights and obligations to natural and juridical persons in determination of features and classification of chemical substances and preparations for their registration, inventory, announcement, management and commerce;
- b) Determination of the jurisdiction of the management offices for taking of measures for protection of life and health of people and animals as well as protection of environment against harmful effects of chemical substances and preparations on life and health, as well as to establish the jurisdiction of expert inspection organs in conformity with provisions of this law.

Article 3

This law shall not apply:

- a) On medical products, food for the livestock, cosmetics, mining raw materials, ammunitions, explosives, radio-nuclear radiators and nuclear matters, products for protection of plants, narcotics and psycotrops, chemical weapons and their precursors and substances that damage the ozone layer, which are object of separate laws;
- b) On obligations of the transport of hazardous chemical substances and preparations by rail, land, water and air routes, treatment of substances and preparations under the customs control, if a part of this transport does not deal with the treatment or processing of wastes and management of polluted and special waters.

Article 4

Definitions

Within the meaning of this law, the following terms have these meanings:

1. "Chemical substances", hereinafter called substances are the chemical elements and their components in a natural or obtained state by a production process including additives and main solvents to provide their durability as well as any impurity of a natural origin or obtained during the production process with exception of solvents that can be detached from the substance without changing its composition or without affecting its stability.
2. "Chemical preparations", hereinafter called preparations are mixtures or composed solutions by two or more chemical substances.
3. "Polymer" is the substance the molecules of which are formed by a string with one or more units of monomers that contain more than the half of their weight, from a fraction composed of molecules with at least three units of monomer, linked with covalent connections with at least one unit of monomer or an another reactive that contains less than its weight or a fraction with molecules of the same molecular weight.
4. "Unit of monomer" is the reactive form of the monomer in the molecule of polymer.
5. "Classification" is the evaluation according to which the substance or the preparation has one or more hazardous features and the further determination of individual danger.
6. "Distributor" is the juridical or natural person authorized for the commercial activity, which stores and distributes the substances of preparations to other persons and does not affect directly in the features of substances and preparations through its activity.
7. "Assessment" is the qualification of a hazardous feature according to the manner set forth in Article 5 of this law.
8. "Importer" is the juridical or natural person, local or foreigner, which imports in the territory of the Republic of Albania a chemical substance or preparation.
9. "Exporter" is the juridical or natural person, local or foreigner, which exports from the territory of the Republic of Albania a chemical substance or

preparation.

10. "Trade" is the passing of chemical substances and preparations to another natural and juridical person. Within the meaning of this law, transport is included in the trade.

11. "Transit" is any chemical substance or preparation that after entrance in the Albanian territory and until the exit from the Albanian territory is not subject of any kind of process or treatment.

12. "Management of substances and preparations" is an activity, object of which are substances and preparations, in particular the production, import, export, transit, use, storage, packing, labeling, transport within the territory of the subject and their demolitions.

13. "Registration of substances" is the registration of substances in the National Register that the Ministry of Environment keeps on basis of the data in writing about substances in compliance with this law.

14. "The technical safety regulation" is a summary of the identification data about the producer or importer of hazardous substances and preparations and the data required for the protection of the life and health of people and animals and of environment.

15. "The accredited laboratories system" is an international co-operation system for the safety and control of the quality of laboratory practice, verified and confirmed by a certificate.

16. "Hazardous substances and preparations" are substances and preparations that have one or more features that are hazardous classified according to the conditions set forth in this law.

CHAPTER II

Article 5

Classification of chemical substances and preparations

Chemical substances and preparations due to their features shall classify:

1. Explosives that may act in an ego-thermal manner without the presence of oxygen, with a rapid development of gases or that self-ignite and combust rapidly in certain conditions or that explode with heat when placed in non-hermetic containers.

2. As oxidizable that in the contact of other substances, in particular with flammable substances cause a powerful exo-thermal reaction.

3. As extremely inflammable that in the liquid condition have the ignition points lower than 0°C and the boiling point lower than 35°C or that are inflammable in the gaseous state in contact with air in normal temperature of the room and normal atmospheric pressure.

4. Very inflammable that:

a) May heat in a spontaneous manner and after to burn in contact with air in a normal room temperature, normal atmospheric pressure and without the presence of energy;

b) May burn easily in the solid state due to a short contact with a fire and ignition source and continue to burn or to smoke even after the removal of the fire source;

- c) Have an ignition point in the liquid state lower than 21°C and are not extremely inflammable;
- ç) Emit in contact with water or wet air very dangerous gases in a quantity of at least 1 liter/kg. per hour.
- 5. Inflammable that have the flaming point from 21°C up to 55°C.
- 6. Very poisoning that after inhaling swallow or infiltration into the skin even in small quantities may cause acute or chronic damages of the health or death.
- 7. Poisoning that after inhaling, swallow or infiltration into the skin even in small quantities may cause acute or chronic damages of the health or death.
- 8. Harmful to health that after inhaling, swallow or infiltration into the skin even in small quantities may cause acute or chronic damages of the health or death.
- 9. Corrosive, that in contact with lively tissues may destroy them.
- 10. Itching, that do not have the features of corrosive substances, but from the direct contact for a long time with the skin or the mucosal membranes may cause inflammations.
- 11. Sensitive, that after inhaling, swallows or infiltration into the skin may cause hyper-sensitiveness and consequently after another exposure its characteristic symptoms appear.
- 12. Cancerous that after inhaling, swallow or infiltration into the skin may cause or increase the frequency [potentiality] of cancer appearance.
- 13. Mutagenous that after inhaling, swallow or infiltration into the skin may cause or increase the frequency of genetic damages.
- 14. Harmful for reproduction that after inhaling, swallow or infiltration into the skin may cause or increase the frequency of the damages in the reproduction function or in the reproductive capacity of males or females.
- 15. Harmful to the environment that after introduction into environment constitutes or may constitute immediate or future danger to the environment.

Article 6

- 1. In the classification of the preparations should not be taken into consideration the components, mixtures, additives or impurities present in the following concentrations:
 - a) Less than 0,02 % in volume if there is a substance in gaseous preparations classified according to paragraph 6 of Article 5 of this law;
 - b) Less than 0,1 % in weight if there is a substance classified according to paragraphs 7, 11, 12, 13 and 14 of Article 5 of this law and in other preparations except those in gaseous state according to paragraph 2 of this Article;
 - c) Less than 1 % in weight if the substance has been classified according to paragraphs 8, 9, and 10 of Article 5 of this law.
- 2. The producer and the importer shall be obliged to make the new classification for preparations with known components:
 - a) If due to the absolute value of original concentration change of one or more hazardous components of the preparations shall be valid the unequal formula of the Appendix 1 of this law;
 - b) In relation to changes in the preparation composition due to adding of substances or replacement of some components of the preparation with another substance without taking into consideration the danger of the substance.

3. The producers and importers a substance shall be obliged to provide with all the required data for the classification of the new preparation another juridical or natural person authorized for a commercial activity, which uses this substance as component of a new preparation.

Article 7

Testing of chemical substances and preparations

1. Before releasing into the market an unclassified substance, the producer or importer is obliged to verify whether the substance or preparation has one or more hazardous features and on basis of this assessment to classify the substance or preparation in separate danger groups according to Article 5 of this law.

2. The features of substances and preparations are tested with methods complying with principles of protection of experimental animals. The methods for determination of hazardous features shall be determined by order of the following:

a) The Minister of Defense for substances that posses defined features in paragraphs 1 and 2 of Article 5 of this law;

b) The Minister of Health for substances that posses defined features in paragraphs 6 to 14 of Article 5 of this law;

c) The Minister of Industry and Energy for substances that posses defined features in paragraphs 3 to 5 of Article 5 of this law;

ç) The Minister of Environment for substances that posses defined features in paragraph 15 of Article 5 of this law.

3. The producer or the importer submits data on the features of hazardous substances and preparations after conduct of tests in the accredited laboratory.

4. The procedure for assessment of hazardous substances and preparations, classification, packing and labeling and the list of hazardous substances that will classify shall be determined by decision of the Council of Ministers.

Article 8

The system of accredited laboratories

1. Juridical or natural persons authorized and provided with certificate as accredited laboratory test the hazardous features of substances and preparations according to this law.

2. Juridical or natural persons authorized for exercise of the commercial activity in reliance with paragraph 1 of this Article shall be obliged to provide to the responsible ministry all the necessary data for meeting of the conditions, issued by the accredited laboratory on testing of the hazardous substances.

3. The General Directory of Standardization upon payment provides to the juridical or natural persons authorized for exercise of the commercial activity the certificate of the accredited laboratory on basis of an application and later verifies the conformity with requirements defined in paragraphs 4 and 5 of this Article.

4. The application contains:

a) Name, surname, name of the commercial activity, address, address of the commercial activity and the identification number of the applicant;

b) Name, surname and the number of birth certificate of the legal

representative of the testing center;

c) A certificate by the court of the legal representative of the testing center issued during the last three months;

ç) A declaration that the applicant permits to the responsible ministry to verify the certificate of the accredited laboratory.

5. Juridical or natural persons authorized for exercise of commercial activity according to paragraph 1 of this Article must submit to the relevant minister a program that ensures a quality system according to the principles of the accredited laboratory.

6. After verification of compliance with the practice of the accredited laboratory the relevant minister according to the definition of paragraph 2 of Article 7 of this law, shall issue the conformity certificate with the accredited laboratory within 30 days.

7. Juridical or natural persons authorized to exercise commercial activity according to paragraph 1 of this Article provided with the certificate of the accredited laboratory shall be obliged to permit the authorized persons to enter into the tests environs and buildings and to provide with the required data in the framework of the conformity control with the principles of the accredited laboratory practice.

8. Juridical or natural persons authorized to exercise commercial activity, which are provided with the conformity certificate with practice of the accredited laboratory shall be obliged to submit the tests results proving that tests have been conducted in conformity with the principles of the accredited laboratory.

9. The relevant minister shall reject the conformity certificate as an accredited laboratory to the juridical or natural person authorized to exercise this activity in case when this person does not meet even one of the conditions according to which the certificate has been issued.

10. The relevant minister shall decide by a regulation the conformity principles with the practice of the accredited laboratory, the procedure for verification of the conformity and the procedure of control of the conformity with the principles of the accredited laboratory.

11. The certificate of engagement of the accredited laboratory issued outside the territory of the Republic of Albania has equal value of the certificate issued inside this territory in case of meeting all the conditions set forth by this law and by other normative acts.

12. Ministries charged by this law shall keep a list of persons provided with the conformity certificate with the principles of the accredited laboratory and publish this list from 30 June to 31 December of each year in the Bulletin of the Ministry of Environment.

CHAPTER III

REGISTRATION OF SUBSTANCES

Article 9

Obligation of registration

1. The producer and importer shall be obliged to register the substances that release into the market even in cases when this substance is contained in another

substance as an additive, mixture or impurity or is contained in a preparation as one of its components.

2. For needs of the scientific research and development is not compulsory according to this law the registration of substances that:

a) Are been introduced into the market by the same producer or importer in quantities not exceeding ten kg in a calendar year registered according to the requirements for activity permit with the condition that the registration requirements are the same with the requirements of this law;

b) Are components of the preparations, mixtures, additives or impurities, the concentration of which does not exceed values given in paragraph 5 of Article 7 of this law;

c) Are been introduced into the market by the same producer and importer in quantities not exceeding 100 kg in a calendar year only for the needs of scientific research and development or only for laboratory use;

ç) Are been introduced into the market by the same producer and importer in quantities not exceeding 1000 kg in a calendar year only for the needs of applied research and development within a one year period;

d) Are intermediate products of production obtained by chemical reactions in closed technical systems that are not separated and disposed from the technological process;

dh) Are registered with the same conditions of this law, when the producer and importer of these substances notifies in writing the relevant ministry about the requirements of letters "a" and "ç" of paragraph 1 of Article 10 of this law.

3. If the quantity of the substance subject of the registration is less than 1000 kg in a calendar year, the producer and importer dependant of the quantity and the level of danger of the substance introduced into the market shall submit the registration documentation in a time limit placed in the ministry regulation designated by this law.

Article 10

Application for registration

1. Prior of introduction into the market of the substance to be registered, the producer and importer shall submit to the designated ministries by this law a written application in the Albanian language.

2. Application for registration contains:

a) Name, surname, civil status, and residence and identification number of the natural person authorized to exercise commercial activity;

b) The name and address of the trader, of the foreign producer of the imported substance compulsory for registration;

c) Basic data about substance and the registering quantity;

ç) Data about the technical safety of the registering substance.

3. Other details included in the application for registration and the way in which it is filled in shall be contained in the minister guidelines.

4. The producer and the importer shall be obliged to notify within ten days the relevant ministers about any change in the data of application for registration.

5. In case that conditions imposed in this Article are met, the relevant ministry registers the substance within 60 days from the application submission and notifies

the applicant. The ministry, within 60 days, rejects the application for registration if the registration conditions are not met.

6. The producers and importers of the substance to be registered shall submit protocols of tests required according to this law and prepared by other persons upon simultaneously receipt of the approval in writing by the mentioned persons to use these data.

7. The Ministry of Environment shall keep the National Register of substances and preparations. The ministries designated by this law shall provide the data of this register except of data that constitute a commercial secret.

8. The Council of Ministers shall approve by decision the organization and the structure of the office of chemicals registration. The Minister of Environment shall approve the regulation of functioning of this office.

9. The ministries shall publish the list of registered substances at least once a year in their Bulletin or in the Bulletin of the Ministry of Environment.

Article 11

Protection of commercial secret

1. The data publication of which damages the producer or importer on request of the producer or importer shall be considered during the process of the registration as a commercial secret and are obtained only upon request of the authorized persons.

2. The obligation for protection of the secret of data considered by the producer and importer as commercial secret is valid for all employees that perform the tests of substances features.

3. It shall not constitute a commercial secret the following:

- a) The trade name of the substance;
- b) Name and surname, name of the commercial activity, residence, address of trader and identification number of the producer and importer of the substance;
- c) Physical and chemical features of the substance;
- d) Guidelines for reduction of hazardous effects of the substance;
- e) Final results of toxicological and eco-toxicological tests of the substance;
- dh) Level of purity and identification of impurities or mixtures of hazardous features according to Article 7 of this law, applied in conformity with the requirements of the classification and naming of the substance;
- e) Guidelines in cases of substance leakage;
- ë) Data of technical safety;
- f) Analytical methods of hazardous substances that allow their determination in case of exposition in the environment and to people.

Article 12

Additional data

1. The relevant minister, according to definition of paragraph 2 of Article 7 of this law, shall require to the producers and importers additional data about features of the hazardous substance even if the quantity of the chemical substance or preparation introduced into the market by a producer or trader is equal to or higher

than ten tons per a calendar year.

2. These data are provided when the substance is contained in another substance as additional mixture or impurity or is contained in a preparation as its component.

CHAPTER IV

MANAGEMENT OF HAZARDOUS SUBSTANCES AND PREPARATIONS

Article 13

Assessment of risk of hazardous substances for the health of people and the environment

1. The Council of Ministers shall determine the list of hazardous substances that due to their nature constitute a serious risk to the life and health of man as well as to environment.

2. The Ministry of Environment together with other ministries designated by this law shall undertake measures for risk assessment to the life and health of man and to environment for substances included in the list according to paragraph 1 of this Article.

3. The procedure for risk assessment of hazardous substances to life and health of people shall be determined by order of the Minister of Health.

4. On the basis of the risk assessment results, at the national and international level, the Council of Ministers on the proposal of the relevant minister shall decide the conditions of introduction of these substances into the market.

Article 14

General conditions of management of hazardous substances and preparations

1. In the management of hazardous substances and preparations any person shall be obliged to protect the life of man and the environment, to place the danger precaution signs with expressions that describe the specific danger and with technical safety guidelines of their management.

2. Juridical or natural persons authorized to exercise commercial activity may manage hazardous substances and preparations that have one or more dangerous features according to paragraphs 1, 2, 3, 6, 12, 13, 14 and 15 of Article 5 of this law and treat these substances in quantities higher than ten tons per a calendar year, only on permit of the relevant ministry.

3. The management of hazardous substances shall be done after receipt of permit from the regional environmental agency.

4. Natural person over 18 years old and with juridical capacity to act may manage substances and preparations classified according to paragraphs 6, 7, 9, 12, 13 and 14 of Article 5 of this law.

5. Natural person from 15 up to 18 years old may manage substances and preparations classified according to paragraphs 6, 7, 9, 12, 13 and 14 of Article 5 of

this law only within the framework of a professional training and under supervision of professional qualification person according to paragraph 2 of Article 19 of this law.

6. Juridical or natural persons authorized to exercise commercial activity shall be obliged to allow authorized person by offices of control and inspection to enter in the environs and buildings and to get all the necessary data for their work.

CHAPTER V

INTRODUCTION INTO THE MARKET OF HAZARDOUS SUBSTANCES AND PREPARATIONS

Article 15

1. The producer, importer and distributor shall be prohibited to introduce into the market hazardous substances and preparations included in Appendix 2 of this law.

2. On the proposal of the Minister of Environment, the Council of Ministers shall approve the list of chemical substances and preparations, which production, introduction into the market and use are limited or prohibited.

Article 16

1. The juridical or natural person can't sell to the consumers or give to another person that has no relation with commercial activity, hazardous substances and preparations classified according to paragraphs 6, 12, 13 and 14 of Article 5 of this law.

2. Juridical or natural persons authorized to exercise commercial activity shall be prohibited to sell to the consumers or give to another person hazardous substances and preparations classified according to paragraphs 6, 7, 8 and 9 of Article 5 of this law:

- a) To persons under 18 years old;
- b) To persons to which has been removed or limited the juridical capacity to act.

3. Juridical or natural persons authorized to exercise commercial activity shall be prohibited to sell hazardous substances and preparations classified according to paragraphs 6, 7, 8 and 9 of Article 5 of this law, in parking places, in movement, in automatic selling machines and in containers determined by the buyer.

4. Juridical or natural persons authorized to exercise commercial activity shall be obliged to provide separate placement from other goods of hazardous substances and preparations classified according to paragraphs 6, 7, 8 and 9 of Article 5 of this law. These substances and preparations should be kept only in original packing, sealed and unbreakable. In cases of self-serve sale these goods shall be prohibited to expose in places where they can be easily taken, they must be given only by the salesperson.

Article 17

Juridical or natural persons authorized to exercise commercial activity as far

as the hazardous substances and preparations are concerned, classified according to paragraphs 6, 7, 9, 12, 13 and 14 of Article 5 of this law, shall be obliged to:

- a) To protect these substances and preparations from theft, loss or from exchange with other hazardous substances and preparations;
- b) To provide the storage environs with adequate measures for the first medical aid and protection of service personnel and decontamination of the environment in conformity with the technical safety regulation.

CHAPTER VI

AUTHORIZATION FOR MANAGEMENT OF HAZARDOUS SUBSTANCES AND PREPARATIONS

Article 18

1. Juridical or natural persons authorized to exercise commercial activity shall be permitted to manage the hazardous substances and preparations classified according to Article 5 of this law only if this activity is executed on basis of an authorization issued on their name, in compliance with this law.

2. The authorization is not issued if juridical or natural persons authorized to exercise commercial activity manage hazardous substances and preparations that have one or more dangerous features according to paragraphs 5, 8, 9, 10 and 11 of Article 5 of this law, in a quantity less than one tons per a calendar year.

Article 19

Conditions for authorization issuance

1. The relevant minister according to definition of paragraph 2 of Article 7 of this law, on basis of application in writing, shall issue the authorization in reliance with professional qualification criteria and health state to a juridical or natural person with full juridical capacity that is resident in the territory of the Republic of Albania and that has not committed a criminal offense.

2. The professional qualification for management of hazardous substances and preparations shall be proved with the following:

- a) With the document of university completion in the relevant field;
- b) With the document of secondary education completion in the relevant field;
- c) With the document of professional training completion.

3. Rules for qualification, verification procedure and issuance or rejection of the authorization shall be determined by order of relevant ministers.

4. The authorization is given for a period of two years. The authorization may be extended for one year, on the condition that the request is submitted three months prior of authorization expiration. The decision for time limit extension is issued within 90 days from the date of application submission. The request for time limit extension is rejected if conditions are not met.

5. The authorized persons are obliged to:

- a) Ensure that trained person executed the activity on which the authorization is issued;

- b) To ensure that equipments used for execution of activity on which authorization is issued meet conditions on protection and reliability;
 - c) To provide the inspection and control persons with data on execution of activity on which authorization is issued.
6. The authorization can not be used by other juridical or natural persons.
7. The relevant ministry lifts the authorization to the juridical or natural persons if repeatedly he does not meet obligations or if there is a change of the conditions based on which the authorization is issued.
8. The validity of the authorization expires:
- a) With elapse of time for which it is issued, if the time limit is not extended;
 - b) With authorization lift;
 - c) When the juridical persons dies;
 - ç) With loss of the right as a juridical person.

Article 20

1. When juridical or natural persons, authorized to execute the commercial activity herein expressed as the "Elimination of harmful organisms, plants and micro-organisms, elimination of other harmful factors using poisons including protection decontamination, control of bugs and rodents with exception of professional activities in the field of health care " do not report to the licensing office within a certain period defined by this office on the application of the authorization terms according to this law, the authorization for execution of commerce in this field becomes invalid.

2. The licensing office shall notify on the fact the juridical or natural persons authorized to execute commercial activity and simultaneously the administrative office when the licensing office possesses valid documents of professional qualification for a part of the commercial activity, it decides to change the issued license.

CHAPTER VII

IMPORT AND EXPORT OR HAZARDOUS SUBSTANCES AND PREPARATIONS

Article 21

1. The import and export of hazardous substances and preparations shall be performed only on permit of the relevant minister.

2. The importers and exporters shall be obliged to require to the relevant minister approval of permit for import and export of hazardous substances and preparations, no less than 60 days prior the date of import or export. The content of the application for permit issuance according to paragraph 1 of this Article shall be determined by order of the minister.

3. The permit issuance according to paragraphs 1 and 3 of this Article is not necessary on certain substances and preparations that are imported or exported in quantities lower than 1 kg per a calendar year by a juridical or natural person authorized to execute commercial activity for the purpose of scientific research and

development.

4. The office of chemicals registration based on the data of designated ministries by this law, shall register applications for import and export of certain hazardous substances and preparations, issued approvals and shall notify the Minister of Environment about the international exchange of data on these substances.

5. The management of hazardous substances and preparations eligible of commercial activity shall be executed according to conditions of Article 14 of this law.

6. The exporter shall be obliged to stick on the packing of the hazardous substances and preparations, eligible of commercial activity, labels in the language of country or area where these preparations are to be used.

7. Importers and exporters shall be obliged to present to the customs authorities for the purpose of control the enclosed documents of hazardous substances and preparations eligible of commercial activity.

8. The approval of the import and export of eligible hazardous substances and preparations, given according to this law, cannot replace the permit for import or export given by separate law.

CHAPTER VIII

REGISTRATION AND NOTIFICATION OF HAZARDOUS SUBSTANCES

Article 22

1. The producer, importer and distributor of hazardous substances and preparations shall be obliged to register type, quantity and features of the substance and the preparation. The registration shall be conducted separately for each commercial activity. Manner and details of registration and notification shall be determined by the chemicals registration office.

2. Producers and importers of hazardous substances in a higher quantity than ten tons per a calendar year only, shall be obliged to notify in writing the relevant ministry no later than 15 February of each year about the type of hazardous substance that they produce or import, the quantity and its features.

3. On the request of authorized persons, within the framework of the obligation of notice, the publication of data that might cause to the producer or importer damages in production or commerce may be written as a commercial secret.

4. Juridical or natural persons authorized to execute commercial activity shall be obliged to notify the regional environmental agency about the management of classified substances and preparations, to register entries of these substances and the maximal stored quantity. In addition, they must send to this agency the technical safety regulation on these substances. This obligation is invalid for substances used for scientific research and development.

5. Juridical and natural persons authorized to execute commercial activity of elimination of harmful organisms and micro-organisms shall be obliged to notify in writing, 48 hours prior to the operation, the regional environmental agency and the

relevant office of the municipality where such activity will take place, about the use of hazardous substances and preparations classified according to paragraphs 6 and 7 of Article 5 of this law. Within this period, days of official holidays and weekend are not calculated.

6. The regional environmental agency together with the local unit of health protection shall determine, 24 hours prior to operation about which notice is delivered, the special conditions of execution of this operation according to paragraph 5 of this Article.

Article 23

State Inspectorate of Environment

The State Inspectorate of Environment has the following duties and responsibilities:

a) Supervises the application of legal rules and guidelines of the Minister of Environment and of other administrative offices in the field of environmental protection during the management of hazardous substances and preparations by juridical or natural persons authorized to execute commercial activity;

b) Determines terms to avoid problems in the management of hazardous substances and preparations during the inspection visits;

c) Imposes penalties on the juridical and natural persons in cases of breaches of obligations in the field of environmental protection during the management of hazardous substances and preparations;

ç) Proposes to the relevant ministry interruption of the authorized person activity for a period of maximum 30 days if he does not meet the conditions of the authorization. If the conditions on basis of which authorization is issued are not met, proposes the lift of authorization;

d) Suggests to the Minister of Environment conduct of the high state inspection in the field of environment protection on the management of hazardous substances and preparations;

dh) Co-operates with custom authorities and provides them with assistance through specialists;

e) Designate inspectors in conducting the inspection visits. During the execution of the inspection visit, the inspectors verify their identity through the identification card of the inspector of the State Inspectorate of the Environment.

Article 24

State Sanitary Inspectorate

The State Sanitary Inspectorate has the following duties and responsibilities:

a) Controls application of legal rules and decisions in the field of man life and health protection during management of hazardous substances and preparations as well as fulfillment of defined obligations in the register of substances by juridical or natural persons;

b) Requires from juridical or natural persons authorized to execute commercial activity correction of irregularities in the field of management of substances and preparations having hazardous features for the life and health of

man, in conformity with the defined obligations in the substances register, as well as determined the deadline of irregularities correction;

* c) Imposes penalties on juridical or natural persons authorized to execute commercial activity;

ç) Gives opinions about issuing of authorization for management of classified substances according to paragraphs 6, 7, 8, 9, 10, 13 and 14 of Article 5 of this law,

d) Co-operates with State Inspectorate of Environment and with custom authorities and provides them with assistance through specialists.

Article 25

Custom Administration

1. The custom authorities shall control in the state border pass points the declared goods as hazardous substance and preparation on the import or export of which approval from the relevant ministry designated by this law is required.

2. In case of doubt or violation of this law, the custom authorities block the goods and notify the State Inspectorate of Environment about contravene and in case of doubt require to the inspectorates technical assistance.

3. Custom authorities register the lot of hazardous substances and preparations passing the state border.

4. Custom authorities allow to the employees of the Ministry of Environment and of inspectorates the review of registers in written copies or photocopies as well as digital transmission of data.

CHAPTER IX

ADMINISTRATIVE CONTRAVENES AND FINES

Article 26

The following breaches, when do not constitute criminal violations, shall constitute administrative contravene and punish with penalty as below following:

1. The State Inspectorate of Environment and State Sanitary Inspectorate impose penalties from 500 thousand up to one million ALL on the juridical or natural person authorized to execute commercial activity who:

a) Does not act in compliance with conditions of management of hazardous substances and preparations according to paragraphs 1, 4 and 5 of Article 14 of this law;

b) Sells or gives hazardous substances and preparations classified according to paragraphs 6, 12, 13 and 14 of Article 5 of this law.

2. The State Inspectorate of Environment and State Sanitary Inspectorate impose penalties from 50 thousand up to 500 thousand ALL on the importer and producer who:

a) Does not classify the substances and preparations prior to introduction into the market and does not fulfill obligations according to paragraphs 1 and 4 of Article 7 of this law;

b) Does not provide the required data for classification of a new preparation

according to paragraph 5 of Article 7 of this law;

3. The State Inspectorate of Environment imposes penalties from one million up to ten million ALL, dependant on the breach, on the juridical or natural person who:

a) Tests the features of hazardous substances and preparations in contrary with methods determined in Article 7 of this law;

b) Does not act in reliance of principles of accredited laboratories systems according to Article 8 of this law;

c) Does not act according to defined terms in the authorization for management of hazardous substances and preparations;

ç) Does not act according to all terms [conditions] for management of hazardous substances and preparations according to Article 14 of this law;

d) Does not register and provide data of hazardous substances and preparations.

4. The State Inspectorate of Environment imposes penalties from 500 thousand up to one million ALL on the juridical or natural person who introduces into the market an unregistered substance, which is compulsory to be registered according to Articles 9, 10, 11, 12, 13 and 14 of this law.

5. The State Inspectorate of Environment and State Sanitary Inspectorate impose penalties from ten million up to 50 million ALL on a producer or importer who:

a) Does not fulfill defined request of packing and labeling of hazardous substances and preparations;

b) Does not meet defined conditions for introduction into the market of hazardous substances and preparations according to Articles 15, 16 and 17 of this law;

c) Does not meet conditions for import or export of defined hazardous substances and preparations according to Article 21 of this law;

ç) Makes false declarations on compliance with certification of conformity of the accredited laboratory according to paragraph 8 of Article 8 of this law;

d) Gives incorrect data required by this law.

6. The relevant inspectorates, on repeated breaches, shall fine the juridical or natural person authorized to execute commercial activity with double of the amount defined above and in addition to with activity closure, license lift and sequestration of harmful products.

7. Repeated breach is the violation of obligations within a two years period from the effective date of the previous decision of penalty imposition.

8. The organ that initiates the process first shall impose the penalty. If the process initiates simultaneously on the same date by more than an administrative organ, the State Inspectorate of Environment shall execute the process of penalty imposition. The relevant financial office shall execute the penalty.

9. Against decision of punished with a penalty appeal may be filed, within ten days from notice of the decision, to the relevant minister, who must reply to the appeal within 15 days from the date of its filing.

10. Against the decision of the minister, or in cases when the latter does not reply within the 15 days deadline, appeal may be filed in court within 30 days.

11. Penalties imposed by inspectorates shall be deposited in the State Budget and shall be liquidated within 30 days of the final decision. For each day of delay, after elapse of this deadline, the contravener shall be obliged to pay, besides the penalty, an amount equal to 2 % of the penalty value.

CHAPTER X

TRANSITORY AND FINAL PROVISIONS

Article 27

1. Provisions of Chapters II, V, VI, VII and VIII shall apply within one year from the effective date of this law.

2. Provisions of Chapter III shall apply within two years from the effective date of this law.

3. Provisions of Chapter IX shall apply within one year from the effective date of this law.

4. Within two years from the effective date of this law, the Council of Ministers shall determine the list of hazardous substances according to Article 13, paragraph 1 of this law.

5. Natural persons, professionally qualified for management of poisons, according to existing legal rules shall be valid as such, according to paragraph 2 of Article 19, even for management of classified substances and preparations according to paragraphs 6 and 7 of Article 5, for a period of three years from the effective date of this law

6. Juridical or natural persons authorized to execute commercial activity that deal with the commerce qualified as "Production of poisons and corrosive substances with exception of special harmful poisons " or "Sale of poisons, corrosive substances and pesticides", based on the small business license issued prior of the effective date of this law shall be permitted to continue the commerce for a period of one year after the effective date of this law.

7. Juridical or natural persons authorized to execute commercial activity are obliged to prove the conformity with authorization conditions according to this law within one-year period from the effective date of this law

The licensing office, when conditions of professional qualification are missing shall make changes in the issued license.

8. When juridical or natural persons authorized to execute commercial activity do not prove to the licenses office that exercise of the activity is in conformity with the conditions, the issued authorization for exercise of their commercial activity expires on the date of completion of one-year period, from the effective date of this law.

Offices of licensing shall notify the juridical or natural persons authorized to execute commercial activity and the relevant administrative office about the completion of the period of their commercial activity exercise defined in the authorization.

9. Juridical or natural persons authorized to execute commercial activity that exercise the permitted commerce [referred as] "Elimination of harmful organisms, plants and micro-organisms and elimination of other damaging factors using poisons including the protective decontamination, the bugs and rodents control, with exception of professional activities in the field of health care " or [the commerce referred as] "Production of special hazardous poisons", based on the license issued prior of the effective date of this law may continue this commerce up to one year from the effective date of this law.

10. Juridical or natural persons authorized to execute commercial activity are

obliged that within one year from the effective date of this law to notify the licensing office about application of authorization conditions according to this law. With elapse of this deadline, the authorization is invalid.

The licensing office shall notify on the fact the juridical and natural persons authorized to execute commercial activity and simultaneously the administrative office.

If this office deems that conditions are met, shall decide to make changes in the issued license.

Article 28

Other necessary acts

The Council of Ministers shall be in charge of enacting by-laws in application of Articles 7 paragraph 4, 10 paragraphs 8, 13 paragraphs 1 and 5 and 15 paragraph 2 of this law.

Article 29

This law is effective 15 days after publication in the Official Journal

C H A I R M A N
Servet Pëllumbi

Appendix No.1

Limits for the change of Chemical Preparations Classification

The absolute value of the change of the original concentration expressed in percentage of weight for solid and liquid substances or in volume for gaseous substances is given:

$$|C2 - C1| > K \cdot C1$$

$|C2 - C1|$ - is the absolute value of the change of the component original concentration (in %)

K – The coefficient given in the below table

C1 – The original component concentration (in %)

C2 – The new component concentration (in %)

The original concentration C1	The coefficient K
$C1 \leq 2,5$	0,150
$2,5 < C1 \leq 10 \%$	0,100
$10\% < C1 \leq 25 \%$	0,060
$25\% < C1 \leq 50 \%$	0,050
$50\% < C1 \leq 100 \%$	0,025

Appendix No.2

Shall be prohibited in the Republic of Albania the production, import, export and distribution of these substances:

Name of the substance	CAS Number
Polychlorinated biphenyl (PCB) and preparations with content of this substance in quantity higher than 0,005 % (with exception of mono and bichlorinated biphenyls)	1336-36-3
Polychlorinated triphenyl (PTC) and preparations with content of this substance in quantity higher than 0,005 %	61788-88-8
Asbestos fibers	
a) crocidolite	12001-28-4
b) amazonite	12172-73-5
c) anthophyllite	77536-67-5
ç) actinolite	77536-66-4
d) tremolite	77536-68-6
Monomethyl tetrachlorbiphenyl methane (commercial name Ugilec 141)	75623-60-6
Monomethyl bichlorbiphenyl methane (commercial name Ugilec 141)	
Monomethyl bibrominebiphenyl methane (commercial name DBBT)	99688-47-8

Note: CAS – Chemical Abstract Service