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No. 9108, date 17.7.2003

ON CHEMICAL SUBSTANCES AND PREPARATIONS

Based on the articles 78 and 83, point 1 of the Constitution, with proposal of the Council of Ministers,

THE ASSEMBLY OF THE REPUBLIC OF ALBANIA

HAS DECIDED:

CHAPTER I

GENERAL PROVISIONS

Article 1

The Scope

The scope of this law is to regulate the administration of the chemical substances and preparations concerning the health and life protection for humans, animals as well as the environment protection from the risks eventually caused from the dangerous substances.

Article 2

The objective

The objective of this law is the following:

- a) Establishing the respective rights and obligations related to the juristic and/or physical persons for establishing the characteristics and the classification of the chemical substances and preparations with the purpose of their registration, inventory, announcement, management and commercialising;
- b) Determining the jurisdiction of the administration offices for taking appropriate measures concerning the health and life protection for people and animals, as well as the environment protection, against the dangerous effects of the destructive chemical substances and preparations to the health and life. Moreover, it aims to establish the jurisdiction of the expert inspection organisms in accordance with the provisions of this law.

Article 3

This law does not apply to:

- a) the medicinal products, alimentary products, animals food, cosmetic preparations, mineral raw materials, munitions, explosives, radio nuclear radiators and nuclear materials, plant protection products, narcotic and psychotropic substances, chemical weapons and

their precursors as well as the substances that harm the land ozone layer, which are object of the particular laws;

b) the obligations related to the transportation of the dangerous chemical substances and preparations via railway, ground transportation, water transportation, and air transportation, the treatment of the substances and preparations under the customs' inspection, with the condition that a part of this transportation does not have anything to do with the treatment and the processing of the residues and the management of the sludgy waters and special waters.

Article 4

Definitions

The definitions and denominations used in this law are determined as follows:

1. "The Chemical substances", which, in this law will be called substances, include the chemical elements and their components in the natural state or obtained from a production process, including the principal additives and solvents in order to obtain their stability, as well as any other impurity of natural origin or obtained during the production process, excluding the solvents that can be separated from the substance without changing its composition or without influencing its stability.
2. "The Chemical Preparations", which, in this law will be called Preparations, include the mixtures or dissolutions composed of two or more chemical substances.
3. "Polymer" is the substance, whose molecules are formed by a chain of one or more monomers, which constitute more than half of their weight, from one fraction composed of molecules with at least three units of monomers, connected with covalent connection with at least one unit of monomers or another reactive, which constitutes less than half of its weight, or one fraction of molecules with the same molecular weight.
4. "Monomer unit" is the reactive form of the monomer in the polymers.
5. "The classification" is the evaluation, based on which the substance or the preparation has one or more dangerous characteristics. It also establishes the further establishment of the individual danger categories.
6. "The distributor" is the juristic or physical person authorized for performing commercial activities who protects and distributes the substances and preparations to the other persons and does not have direct influence, through its activity, on the characteristics of the substances and preparations.
7. "The assessment" is the specification of the dangerous characteristics, based on the methods foreseen in article 5 of this law.
8. "Importer" is the juristic or physical person, local or foreigner, who introduces to the Republic of Albania territory one substance or chemical preparation.
9. "Exporter" is the juristic or physical person, local or foreigner, who takes out of the Republic of Albania territory one substance or chemical preparation.

10. As "Commerce" is considered the passage of chemical substances or chemical preparations to another juristic or physical person. In the meaning of this law, the importing is included in the commerce.

11. As "Transit" is considered every substance or chemical preparation, which, after entering the Albanian territory and until it leaves it, does not undergo to any processing or treatment.

12. "The Administration of the substances and preparations" is an activity, whose object are substances and preparations, especially the production, import, export, transition, usage, storage, packaging, labelling, transportation within the territory of the subject, as well as their liquidation.

13. "Registration of the substances" is the registration of the substances in the National Register, maintained by the Ministry of Environment Protection, based on the written data for the substances, in accordance with this law.

14. "Regulation of the technical security" is a summary of the identification data for the producer or importer for the dangerous substances or preparations and the data requested for the life and health protection of people, animals, and environment security.

15. "Accredited laboratory system" is an international collaboration system for ensuring the quality control of the laboratory practice, which is verified and its approval is confirmed by a certificate.

16. As "Dangerous substances and preparations" are considered the substances and preparations that have one or more dangerous characteristics, classified based on the conditions established by this law.

CHAPTER II

Article 5

Classification of the chemical substances and preparations

Based on their characteristics, the chemical substances and preparations are classified as follows:

1. Explosives, which can operate in an exothermic way, without the presence of oxygen, with a quick development of gases or self-starters that burn quickly in established conditions or explosives in warm conditions when placed in no-hermetic containers.
2. Oxygenate that in contact with other substances, especially with inflammable substances, causes powerful exothermic reaction.
3. Extremely inflammable. In liquid state, they have the flammable point lower than 0°C and the boiling point lower than 35°C or are inflammables in gaseous form, in contact with the air in the normal room temperature and normal atmospheric pressure.

4. Highly flammable, which:

a) they can be heated in spontaneous way and then burn in contact with the air in the normal room temperature, normal atmospheric pressure and without the presence of the energy;

b) they can be easily burned in the solid form, as a consequence of a short contact with a source of fire, inflammation and continue to burn or to smoke even after the recession of the fire source;

c) they have an inflammable point in the liquid form lower than 21°C and they are not extremely inflammable;

d) in contact with the water or the liquid air, they release very dangerous gases at least 1 litre/kg.h

5. Inflammables. They have the inflammation point from 21°C to 55°C.

6. Very poisonous. After the absorption, swallow or skin penetration, even in small quantities, they can cause acute or chronic health damages or death.

7. Poisonous. After the absorption, swallow or skin penetration, even in small quantities, they can cause acute or chronic health damages or death.

8. Harmful for the health. After the absorption, swallow or skin penetration, even in small quantities, they can cause acute or chronic health damages or death.

9. Corrosive. In contact with the vivid vital tissues, they can destroy them.

10. Exasperating. They do not have the characteristics of the corrosive substances. However, if in direct contact for a long time with the skin or mucosal membranes, they can cause inflammations.

11. Susceptible. After the absorption, swallow or skin penetration, they can cause hypersensitivity and, as a consequence, after another exposure, it displays its characteristic symptoms.

12. Cancerous. After the absorption, swallow or skin penetration, it can cause or increase the frequency of the cancer appearance.

13. Mutagens. After the absorption, swallow or skin penetration, it can cause or increase the frequency of the appearance of the genetic damages.

14. Reproduction detrimental. After the absorption, swallow or skin penetration, it can cause or increase the frequency of the damages in the reproduction function or in the reproduction ability for the males or females.

15. Dangerous for the environment security. After entering the environment, they constitute or may constitute an immediate or ulterior danger for the environment security.

Article 6

1. During the classification of the preparations, there shall be disregarded the components, the mixtures, the additives or the inherited impurities in the concentrations:

- a) less than 0,02 per cent of the volum, if we have to do with substances of gas preparations, classified based on point 6 of the article 5 of this law;
 - b) less than 0,1 per cent of the weight, if we have to do with the substances classified based on the points 7, 11, 12, 13 and 14 of the article 5 of this law, as well as other preparations, except the gas ones, based on the point 2 of this article;
 - c) less than 1 per cent of the weight, if the substance is classified based on the points 8, 9, 10 of the article 5 of this law.
2. The producer and the importer are obliged to perform the new classification for the preparations with known components:
- a) if due to the absolute value of the modification for the original concentration of one or more dangerous components of the preparations, it is valid the inequality formula in the annex no.1 of this law;
 - b) with regard to the modifications of the preparation composition, due to the addition of the substances or to the substitution of some components of the preparation with another substance, without taking into account the dangerousness of the substance.
3. The producers and the importers of a substance are obliged to supply all the data requested for the classification of the new preparation to another juristic or physical person authorized for performing a commercial activity, if he/she uses this substance as a component of the new preparation.

Article 7

Testing of the chemical substances and preparations

1. Before launching into the market an unclassified substance, the producer or the importer is obliged to verify if the substance or the preparation have more than one dangerous characteristic and, based on this assessment, the substance or the preparation shall be classified in special danger groups, based on article 5 of this law.
2. The characteristics of the substances or preparations are tested only with the methods that fulfil the principles of the protection for the experimental animals. The methods for the determination of the dangerous activities are established with an order of:
 - a) the Defence Minister, for the substances that possess the characteristics described in the points 1 and 2 of the article 5 this law;
 - b) the Minister of Health, for the substances that possess the characteristics described in the points 6 – 14 of the article 5 of this law;
 - c) the Minister of Industry and Energetic, for the substances that possess the characteristics described in the points 3 – 5 of the article 5 of this law;
 - d) the Minister of Environment Protection, for the substances that possess the characteristics described in the point 15 of the article 5 of this law.
3. The producer or the importer presents the data related to the characteristics of the dangerous substances and the preparations after the tests performed in one accredited laboratory.

4. The procedure for the assessment of the dangerous substances and preparations, the classification method, packaging and labelling, and the list of the dangerous substances to be classified shall be established with a decision by the Council of Ministers.

Article 8

The system of the accredited laboratories

1. Based on this law, the dangerous characteristics of the substances and preparations shall be tested only by authorized juristic or physical persons supplied with the certificate by the accredited laboratory of this purpose.

2. The juristic or physical persons authorized for performing the commercial activity, based on the point 1 of this article, are obliged to supply the respective industry with all the data necessary for fulfilling the conditions released by a laboratory accredited for testing the dangerous substances.

3. The General Directorate of Standardization, after the payment, supplies the juristic or physical persons authorized for performing commercial activity with the certificate of the accredited laboratory, based on one application and then verifies the conformity of the requirements described in the points 4 and 5 of this article.

4. The application contains:

a) the name, the last name, the title of the commercial activity, and the identification number of the applicant;

b) the name, the last name and number of the birth certificate for the legal representative of the testing centre;

c) one confirmation from the court for the legal representative of the testing centre, received within the last three months;

d) a declaration with which the applicant allows the respective ministry to verify the certificate of the accredited laboratory.

5. The juristic and physical persons authorized for performing the commercial activity, based on the point 1 of this article, shall present to the respective minister one program that ensures the quality system based on the principles of the accredited laboratory.

6. After the verification of the conformity with the practice of the accredited laboratory, the respective minister, in accordance with the establishment of the point 2 of the article 7 of this law, within 30 days shall provide the conformity certificate according to the accredited laboratory.

7. The juristic and physical persons authorized for performing the commercial activity, based on the point 1 of this article, supplied with the certificate of the accredited laboratory, are obliged to allow the authorized persons to enter the premisses and the buildings that serve for testing purposes. Moreover, they shall give to these authorized persons all the data required during the process of conformity assessment with the principles of the practice of the accredited laboratory.

8. The juristic and physical persons authorized for performing the commercial activity, who are supplied with the conformity certificate with the principles of the activity of the accredited laboratory, are obliged to present the test results that verify the fact that the tests have been performed in accordance with the principles of the accredited laboratory.

9. The respective minister shall remove the conformity certificate as an accredited laboratory to the juristic or physical person authorized to perform this activity, if this person does not fulfil at least one of the conditions for receiving this certificate.

10. The respective minister establishes, through the regulation, the principles of the conformity with the practice of the accredited laboratory, the procedure for the conformity assessment, the procedure for giving or removing the certificates, and the procedure for controlling of the conformity with the principles of accredited laboratory.

11. The conformity certificate for the accredited laboratory, given outside the Republic of Albania, has the same validity as the certificate given inside this territory when the conditions established by this law and other normative acts are fulfilled.

12. The Ministries charged by this law maintain a list of the people supplied with the conformity certificate with the principles of the accredited laboratory and publish this list from the 30th of June until the 31st of December of every year in the Buletin of the Ministry of Environment Protection.

CHAPTER III

REGISTRATION OF THE SUBSTANCES

Article 9

The obligation for registration

1. The producer and the importer are obliged to register the substances they put into the market even in the cases when this substance is included in another substance as additives, mixtures or impurities, or is included as preparation or as one of its components.

2. Regarding the needs of scientific research and development, based on this law, it is not obligatory the registration of the substances that:

a) they have been placed into the market from the same producer and importer in quantities that do not exceed 10 kilograms in a calendarian year, registered based on the specific requirements for obtaining the permission of the activity, with the condition that the registration requirements are the same with the requirements of this law;

b) they are components of the preparations, mixtures, additives or impurities, whose concentration does not exceed the values given in the point 5 of article 7 of this law;

c) they have been placed into the market from the same producer and importer, in quantities that do not exceed 100 kilograms within a calendarian year, only for scientific research and development reasons, only for laboratory use;

d) they have been placed into the market from the same producer and importer, in quantities that do not exceed 1000 kilograms within a calendarian year, only for the reasons of applied research and development;

e) they are intermediate products, obtained from the chemical reactions in closed technical systems, which are not separated or devived from the technological process;

f) they have been registered under conditions similar to this law, when the producer and importer of this substances notifies by writing the respective ministry about the letters "a" and "d" of point 1 of article 10 of this law.

3. If the quantity of the substances to be registered from a producer or importer is less than 1000 kilograms within a calendarian year, the producer and the importer, depending from the quantity and the degree of risk of the substance placed into the market, shall present the registration documentation within a period established by the regulation of the ministry put in charge by this law.

Article 10

Application for registration

1. Before the entrance into the market of the substances to be registered, the producer and the importer shall present to the respective ministry charged by this law one written application, in Albanian language.

2. The application for the registration shall contain:

a) the name, the last name, the civil status, address and the identification number of the physical person, authorized for performing the commercial activity;

b) the name and the address of the marketer, the foreign producer of the imported substances obliged to be registered;

c) the basic data and the quantity of the substance to be registered;

d) the basic data regarding the technical insurance of the dangerous substance to be registered.

3. Other details, which include the application for registration and the ways of filling it up, are foreseen in the guidance of the minister.

4. The producer and importer are obliged to notify within 10 days the respective minister for any changes on the data related to the application for registration.

5. When the conditions established by this law are fulfilled, the respective ministry registers the substance within 60 days from the presentation of the application and informs the applicant. Within 30 days, the Ministry refuses the application for the registration if the conditions for registration are not fulfilled.

6. The producers and the importers of the substance that needs to be registered, present the protocols of the tests required from this law, performed from other people, when they, in the same time, receive the written approval of the interested person to use these data.

7. The Ministry of Environment Protection maintains the National Register for the substances and chemical preparations. The data for this registers shall be ensured by the ministers charged by this law, with the exception of the data that constitute commercial secret.

8. The organisation and the structure of the office for the registration of the chemicals shall be approved with a decision of the Council of Ministers. The functioning regulation for this office shall be approved from the Ministry of Environment Protection.

9. The ministries shall publish the list of the substances registered at least one year in advance, on their Bulletin or on a bulletin of the Ministry of the Environment Protection.

Article 11

Protection of the commercial secret

1. The data, whose publication damages the producer and the importer, with the producer's or importer's request, are considered as commercial secret during the registration process. These data shall be received only with a special request from the authorized persons.

2. The obligation for protecting the secret of the data considered by the producer and the importer as a commercial secret is valid for all the employees involved in the testing of the characteristics of the substances.

3. The following data do not constitute a commercial secret:

a) the commercial name of the substance;

b) the name, the surname, the nomination of the commercial activity, the residence, the commercial address, and the identification number of the producer and importer of the substance;

c) the physical – chemical characteristics of the substance;

d) the instructions for the limitation of the dangerous effects of the substance;

e) the final results of the toxicological and ecotoxicological tests of the substance;

f) the purity degree and the identification of the impurities or mixtures with dangerous characteristics, based on the article 7 of this law, realized in accordance with the requirements of the classification and the nomination of the substance;

g) the instructions given in the cases of leakages of the substance;

h) the technical safety data;

i) the analytical method for the dangerous substances that allows their establishment in cases of environment and people exposure.

Article 12

Complementary data

1. The respective minister, based on the articles 2 and 7 of this law, shall require the producer and the importer for complementary data regarding the characteristics of the dangerous substance even in the cases when the quantity of the substances or the chemical preparation placed into the market from this producer or importer is not less than 10 tons for a calendarian year.

2. These data shall be given in the cases when the substance is included within another substance as an additional mixture or impurity or is included in a preparation as its ingredient.

CHAPTER IV THE ADMINISTRATION OF THE DANGEROUS SUBSTANCES AND PREPARATIONS

Article 13

The risk assessment for the dangerous substances related to human health
and environment security.

1. The list of the dangerous substances, that due to their nature constitute a serious risk regarding the life and health of people and environment security, shall be established from the Council of Ministers.
2. The Ministry of Environment Protection, together with the other ministries charged by this law, shall undertake some measures regarding the assessment of risk related to human life and environment security for the substances included in the list, as described by the point 1 of this article.
3. The procedure for the assessment of the risk for the dangerous substances related to life and health of people shall be established with an order of the Minister of Health.
4. The procedure for the assessment of the risk from the dangerous substances related to environment security shall be established with an order of the Minister of Environment Protection.
5. Based on the results of the risk assessment for the dangerous substances, in national and international level, the Council of Ministers, with a proposal from the respective minister, shall establish conditions for launching of these substances into the market.

Article 14

General condition regarding the management of the dangerous substances and chemicals

1. During the management of the dangerous substances and preparations, every person is obliged to protect the human health and the environment security, to place the risk warning signs with the expressions that describe the specific risk and the respective technical safety instructions for their management.
2. The juristic or physical persons, authorized for performing commercial activity, can manage the dangerous substances and preparations that have one or more dangerous characteristics, in accordance with the points 1, 2, 3, 6, 12, 13, 14 and 15 of article 5 of this law and treat these substances in quantities more than 10 tons in a calendarian year, only with a permission of the respective ministry.
3. The management of the dangerous substances shall be done only after receiving the permission from the regional environment agency.

4. The physical persons over 18 years old and with juristic capability to act, can manage the substances and the preparations classified in accordance with points 6, 7, 9, 12, 13 and 14 of article 5 of this law.

5. The physical persons between 15 and 18 years old can manage the substances and preparations in accordance with the points 6, 7, 9, 12, 13 and 14 of article 5 of this law, only in the conditions of the professional qualifications based on the point 2 of article 19 of this law.

6. The juristic or physical persons, authorized for performing commercial activity, are obliged to allow the authorized persons from the control and inspection office to enter the areas and buildings that are being used for the management of the substances and preparations and receive all the necessary data for their work.

CHAPTER V

LAUNCHING INTO THE MARKET THE DANGEROUS SUBSTANCES AND PREPARATIONS

Article 15

1. The producer, the importer and distributor are not allowed to launch into the market the dangerous substances and preparations, included in the annex 2 of this law.

2. With a proposal of the Minister of Environment Protection, the Council of Ministers approves the list of the substances and chemical preparations, whose production, launching into the market and usage is restrained or prohibited.

Article 16

1. The juristic or physical persons cannot sell to the consumers or give to another person, not related to the commercial activity, dangerous substances and preparations, classified in accordance with the points 6, 12, 13 and 14 of article 5 of this law.

2. The juristic or physical persons, authorised to perform commercial activity, are not allowed to sell to the consumers or give to another person, not related to the commercial activity, dangerous substances and preparations, classified in accordance with the points 6, 7, 8 and 9 of article 5 of this law:

a) to the persons under the age of 18 years;

b) to the persons whose juristic ability to act has been removed or restrained.

3. The juristic or physical persons, authorised to perform commercial activity, are not allowed to sell to the consumers or give to another person, not related to the commercial activity, dangerous substances and preparations, classified in accordance with the points 6, 7, 8 and 9 of article 5 of this law, in emplacements, in movements, in automatic selling vehicles and the containers determined from the customer.

4. The juristic or physical persons, authorised to perform commercial activity, are obliged that for selling the dangerous substances or preparations, classified in accordance with the points 6, 7, 8 and 9 of article 5 of this law, to ensure the separate placement of these

substances and preparations from the other merchandises. These substances and preparations shall be kept only in original, closed, and unbreakable packages. In cases when they are sold in self-service areas, these merchandises are not allowed to be exposed in places where they can be taken away freely; they shall be given only from the seller.

Article 17

The juristic or physical persons, authorised to perform commercial activity are obliged, concerning the dangerous substances and preparations, classified in accordance with the points 6, 7, 9, 12, 13 and 14 of article 5 of this law:

- a) to protect these substances and preparations from being stolen, lost or exchanged with other dangerous substances and preparations;
- b) to ensure the equipment of the storage areas with the appropriate means for the first medical help, the protection of the service people and environment decontamination, in accordance with the technical security regulation.

CHAPTER VI

AUTHORIZATION FOR THE MANAGEMENT OF THE DANGEROUS SUBSTANCES AND PREPARATIONS

Article 18

1. The juristic or physical persons, who perform commercial activity, are allowed to manage dangerous substances and preparations, classified in accordance with the article 5 of this law, only if this activity is been performed based on the authorisation, received in their name, in compliance with this law.
2. The authorisation shall not be issued if the juristic or physical persons, authorised for performing commercial activity, manage dangerous substances and preparations that have one or more dangerous characteristics, in compliance with the points 5, 8, 9, 10 and 11 of article 5 of this law, in quantities less than 1 ton for a calendarian year.

Article 19

The conditions for giving the authorization

1. The respective minister, in compliance with the definitions of the point 2 of article 7 of this law, based on the written application, issues the authorization, sustained by the professional qualification and health status criteria, for a juristic or physical person, with complete juristic capability, whose residence or emplacement is within the territory of the Republic of Albania and has not carried out penal offence.
2. The professional qualification for managing dangerous substances and preparation shall be verified through:
 - a) the certificate of the completion of the university education in the respective field;
 - b) the certificate of the completion of high school education in the respective field;

c) the certificate of the completion of the professional qualification.

3. The regulations for the qualification, the procedure for the verification and issuing or removing of the authorisation shall be established through an order from the respective ministers.

4. The authorisation shall be given for a period of two years. The authorisation can be prorogued for one more year, with the condition that the request is presented three months before the expiration of the term. The decision for proroguing of the authorisation term shall be given within 90 days from the day of presenting the application. If the conditions are not fulfilled, the request for proroguing the term shall be refused.

5. The authorised persons are obliged:

a) to ensure that the activity, for which they have received the authorisation, is performed by trained people;

b) to ensure that the equipment used for the performance of the activity, for which they have received the authorisation, fulfils the conditions for protection and credibility;

c) to provide the inspection and controlling people the data related for the performance of the activity, for which they have received the authorisation.

7. The respective Ministry calls off the authorisation for one juristic or physical person, if he/she, repeatedly, has not fulfilled the obligation or has had change of the conditions, based on which the authorisation has been issued.

8. The validity of the authorisation ends:

a) with the termination of the time period of the authorisation validity, if it is not prorogued;

b) with the elimination of the authorisation;

c) when the physical person dies;

d) with the loss of the rights of a juristic person.

Article 20

1. When the juristic or physical person, authorised for performing commercial activity "Extermination of the dangerous organisms, plants and micro-organisms and the elimination of the other damaging factors by using poisons, including protecting disinfestations, the control for insects and gnawers, excluding the professional activities in the field of medical safeguard " do not report near the licensing office within a period of time established by this office, regarding the fulfilment of the conditions of the authorisation based on this law, the authorisation for performing the commercial activity in this field becomes non-valid.

2. The licensing office notifies for this fact the juristic or physical persons, authorised to perform commercial activity as well as the administrative office. When the licensing office has valid documents for the professional qualification for one part of the commercial activity, it decides regarding changing the issued license.

CHAPTER VII
IMPORTING AND EXPORTING OF THE DANGEROUS SUBSTANCES AND
PREPARATIONS

Article 21

1. The import and the export of the dangerous substances and preparations shall be done only with permission from the respective minister.
2. The importers and the exporters are obliged to request to the minister the approval of the permission for importing and exporting of the dangerous substances and preparations, not earlier than 60 days before the day of the implementation of the import and export. The content of the application for issuing the permission, based on the point 1 of this article, shall be established with an order of the minister.
3. It is not necessary to give the permission, based on the points 1 and 2 of this article, for the specific substances and preparations imported or exported from one juristic or physical person, authorised for performing commercial activity, in quantities less than 1 kg for one calendarian year, and used for the purpose of scientific research and development.
4. The registration office for the chemicals, based on the data of the respective ministries charged by this law, registers the applications for importing and exporting of the specific dangerous substances and preparations, the permissions given, and also notifies the Ministry of Environment Protection for the international exchange of the data for these substances.
5. The management of the dangerous substances and preparations, established for commercial activity, shall be performed in compliance with the conditions of the article 14 of this law.
6. The exporter is obliged to label the packaging of the dangerous substances and preparations decided to be used for commercial activities in the language of the expectant country or area where these substances and preparations will be used.
7. The importers and the exporters are obliged to present to the custom authorities, for controlling purposes, the accompanying documents for the dangerous substances and preparations decided to be used for commercial activity.
8. The approval for the importing and exporting of the specific dangerous substances and preparations, issued in compliance with this law, cannot substitute the permission for import or export given with a special law.

CHAPTER VIII
REGISTRATION AND THE ANNUNCIATION FRO THE DANGEROUS
SUBSTANCES AND PREPARATIONS

Article 22

1. The producer, the importer and the distributor of the dangerous substances and preparations are obliged to register the type, the quantity, the characteristics of the substance and the preparation. The registration shall be made separately for every business. The method and the details of the registration and the announcement shall be established from the registration office for the chemicals.
2. The producer and the importer only for the dangerous substances or substances contained in one preparation in quantities less than 10 tons in a calendarian year are obliged to notify by writing the respective ministry within the 15th of February of every year concerning the type of the dangerous substance they produce or import, its quantity, and its characteristics.
3. With the request of the authorized persons, regarding the obligation for notification, it can be signed as commercial secret the proclamation of the data that can cause to the producer or the importer damages during the production or the trading process.
4. The juristic or physical persons, authorised to performe commercial activity, are obliged that for the management of the classified substances and preparations, in accordance with the points 6 and 7 of article 5 of this law, to notify the regional environment agency, to register the entrances of these substances and the maximal quantity stored. Moreover, they shall send to this agency the regulation of the technical security for these substances. This obligation is not valid for the substances used with the purposes of scientific research and development.
5. The juristic or physical persons authorized to perform commercial activities, for the liquidation of the dangerous organisms and micro-organisms, are obliged that, for using the dangerous substances and preparations classified in compliance with the points 6 and 7 of article 5 of this law, to notify by writing the regional environment agency and the respective municipality office where this activity will be performed, 48 hours before the activity starts. The holidays, weekends and vacation days shall not be included within this period of time.
6. The regional environment agency together with the local government unit responsible for the health protection shall establish, 24 hours before the related activity starts, the specific conditions for the performance of the activity in accordance with the point 5 of this article.

Article 23

National Environment Inspectorate

The National Environment Inspectorate has the following tasks and responsibilities:

- a) it shall supervise the implementation of the juristic regulations and the instructions prepared by the Minister of Environment Protection and the other administrative offices in the field of environment protection during the management of the dangerous substances and preparations, from juristic or physical persons authorised for performing commercial activities;
- b) it shall establish the conditions for avoiding the deficiencies during the management of the dangerous substances and preparations during the inspection tasks;

- c) it shall give penalties to the juristic or physical persons in the cases of violations of the obligations in the field of environment protection, during the management of the dangerous substances and preparations;
- d) it shall propose to the respective ministry the suspension of the activity for the authorised person, for a maximum of 30 days, if he/she does not fulfil the conditions of the authorisation. If he/she does not respect the conditions, based on which it has had the authorisation, it shall propose to the respective ministry the privation from the authorisation of the respective juristic or physical person;
- e) it shall suggest to the Minister of Environment Protection the accomplishment of the high national level inspection in the field of environment protection, for the management of the dangerous substances and preparations;
- e) it shall collaborate with the custom authorities and ensure them assistance with the respective specialists.
- f) it shall charge the inspectors to implement their inspecting task. During the fulfilment of their task, the inspectors certify their identity through the respective inspector document from the National Environment Inspectorate.

Article 24

National Sanitarian Inspectorate

The National Sanitarian Inspectorate has the following tasks and responsibilities:

- a) it shall control the fulfilment of the juristic regulations and the decisions in the field of human health and life protection during the management of the dangerous substances and preparations, as well as the accomplishment of the established obligations for the registration of the substances from the juristic or physical persons;
- b) it requires from the juristic or physical persons authorised for performing commercial activities, the adjustment of the irregularities in the field of management of the substances and preparation with dangerous characteristics for the health and life of people in accordance with the obligations established for the registration of the substances. Moreover, it shall determine the deadline for the regulations;
- c) it shall emplace penalties for the juristic or physical persons authorised for the performance of the commercial activity;
- d) it shall give ideas for issuing the authorisation for the management of the classified substances in compliance with the points 6, 7, 8, 9, 10, 13 and 14 of article 5 of this law;
- e) it shall collaborate with the National Environment Inspectorate as well as the custom authorities and ensures them appropriate assistance with the specialists.

Article 25

Customs administration

1. The custom authorities shall control at the points of the national frontier passage the merchandise declared as a dangerous substance or preparation if for its importing or exporting is required an approval from the respective ministry charged by this law.

2. In cases of suspicion, the custom authorities shall block the merchandise and notify the National Environment Inspectorate or the National Sanitarian Inspectorate regarding the violation and, if in doubt, they shall request to these inspectorates for technical assistance.

3. The custom authorities shall register the batch of the dangerous substances and preparations that pass the national frontier.

4. The custom authorities shall allow the employees of the Ministry of Environment Protection and of the inspectorates to examine the registers in written copies or photocopies as well as the digital transmissions of the data.

CHAPTER IX

ADMINISTRATIVE VIOLATIONS AND PENALTIES

Article 26

The following violations, when they do not constitute penal offence, constitute administrative violations and shall be punished with penalties as follows:

1. The National Environment Inspectorate and the National Sanitarian Inspectorate shall give penalties from 500 000 to 1 000 000 lek for the juristic or physical person authorised for the performance of the commercial activity if:

a) he/she does not act in accordance with the required conditions for the management of the dangerous substances and preparations in compliance with the points 1, 4 and 5 of article 14 of this law;

b) he/she sells or gives dangerous substances and preparations classified in compliance with the points 6, 12, 13 and 14 of article 5 of this law.

2. The National Environment Inspectorate and the National Sanitarian Inspectorate shall give penalties from 50 000 to 500 000 lek for the importer and the producer if:

a) he/she does not classify the substances and preparations before been launched into the market and if he/she does not fulfil the obligations in accordance with the points 1 and 4 of article 7 of this law;

b) he/she does not give the required data for the classification of a new preparation, in accordance with the point 5 of article 7 of this law.

3. The National Environment Inspectorate shall give penalties from 1 000 000 to 10 000 000 lek, depending from the type of the violation for the juristic or physical person if:

a) he/she tests the characteristics of the dangerous substances and preparations in violation with the methods established by the article 7 of this law;

b) he/she does not act in accordance with the principles of the accredited laboratory systems, in compliance with the article 8 of this law;

c) he/she does not act in compliance with the conditions established in the authorisation for the management of the dangerous substances and preparations;

d) he/she does not act in compliance with all the established conditions for the management of the dangerous substances and preparations, based on article 14 of this law;

e) he/she does not register and does not give the required data for the dangerous substances and preparations.

4. The National Environment Inspectorate shall give penalties from 500 000 to 1 000 000 lek for the juristic or physical person that launch into the market unregistered substances that are required to be registered in compliance with the articles 9, 10, 11, 12, 13 and 14 of this law.

5. The National Environment Inspectorate or the National Sanitarian Inspectorate shall give penalties from 10 000 000 to 50 000 000 lek for a producer of importer if:

a) he/she does not comply with the established requirements regarding the packaging and labelling of the dangerous substances and preparations;

b) he/she does not comply with the established conditions for placing into the market of the dangerous substances and preparations in accordance with the articles 15, 16 and 17 of this law;

c) he/she does not fulfil the conditions for importing or exporting of the specific dangerous substances and preparations in accordance with the article 21 of this law;

d) he/she makes fake declaration concerning the conformity of the certificate of compliance for the accredited laboratory in accordance with the point 8 of the article 8 of this law;

e) he/she gives incorrectly the data required by this law.

6. The respective inspectorates, for repeated violations, assign penalties to the juristic or physical person authorized for the performance of the commercial activity with the double of the value established above as well as the closure of the activity, the call off of the license and the sequestration of the dangerous products.

7. As repeated violations shall be considered the violations of the obligations realised within a period of two years from the empowering date of the previous decision for assigning the penalty.

8. The penalty shall be assigned from the administrative organism that first starts the process. If the process starts contemporary, in the same date, from more than one administrative organism, the process of assigning the penalty shall be carried out from the National Environment Inspectorate. The penalty shall be executed from the respective financial office.

9. Against the decision of the punishment with a penalty, the involved party can fill a written complaint within 10 days from the notification of the decision near the respective minister who shall respond to the complaint within 15 days from its deposition.

10. Against the decision of the minister or in case when the minister does not answer within 15 days, the involved party can fill a complaint in the court within 30 days.

11. The penalties assigned from the inspectorates shall go in favour of the State Budget and shall be paid within 30 days from the date of the final decision. For every day of delay, after the completion of this deadline, the violator is obliged to pay in addition to the penalty another amount equal to 2 % of the penalty.

CHAPTER X
TRANSITORY AND FINAL DISPOSITIONS

Article 27

1. The dispositions of the chapter II, V, VI, VII and VIII shall be implemented within one year from the date of the empowering of this law.
2. The dispositions of chapter III shall be implemented within two years from the date of the empowering of this law.
3. The dispositions of chapter IX shall be implemented within one year from the date of the empowering of this law.
4. Within two years from the date of the empowering of this law, the Council of Ministers shall determine the list of the dangerous substances in compliance with the point 1 of article 13 of this law.
5. The physical persons professionally qualified for managing the poisons in accordance with the existing juristic regulations, shall be evaluated as such in compliance with point 2 of article 19, and for managing the classified substances and preparations in compliance with the points 6 and 7 of article 5, for a period of three years from the date of empowering of this law.
6. The juristic or physical persons authorized for the performance of the commercial activity which are involved with the trade specified as the "Production of poisons and corrosive substances, excluding the specially dangerous poisons" or the "Selling of the poisons, corrosive substances and pesticides", based on the licence for the small trade issued before the date of the empowering of this law, are allowed to continue the activity for a period of one year from the date of the empowering of this law.
7. The juristic or physical persons authorized for the performance of the commercial activity, are obliged to certify the accordance with the authorisation conditions, based on this law, within a period of one year from the date of the empowering of this law.
The licensing office, in cases of the deficiencies of the conditions of the professional qualification, makes the appropriate changes in the license issued.
8. When the juristic or physical persons authorised for the performance of the commercial activity do not certify near to the licensing office the performance of the activity in accordance with the conditions, the issued authorisation for the performance of their commercial activity ends on the last date of the period of one year from the date of empowering of this law.
The licensing offices notify the juristic or physical persons authorised for the performance of the commercial activity and the respective administrative office concerning the termination of the exercising period for their commercial activity established in the authorisation.
9. The juristic or the physical persons, authorised to perform commercial activity which exercise the permitted activity "Extermination of the organisms, plants and dangerous micro-organisms, and the elimination of other damaging factors by using poisons, including the protecting disinfection, controlling for insects or gnawers, excluding the

professional activity in the field of the medical safeguard " or the "Production of the special dangerous poisons", in compliance with the license issued before the date of empowering of this law, can continue this activity until one year from the date of the empowering of this law.

10. The juristic or physical persons authorised for the performance of the commercial activity are obliged that within one year from the date of empowering of this law to notify the licensing office concerning the implementation of the authorisation conditions in compliance with this law. With the termination of this term, the authorisation is invalid.

The licensing office notifies about this fact the juristic or physical persons authorised for the performance of the commercial activity and also the administrative office.

If this office does not consider that the conditions have been accomplished, it decides about changes in the license issued.

Article 28

Additional necessary acts

The Council of Ministers is responsible for issuing the by-laws concerning the implementation of the point 4 of article 7, point 8 of article 10, points 1 and 5 of article 13, and point 2 of article 15 of this law.

Article 29

This law enters into power 15 days after its publication on the Official Bulletin.

Declared with the decree no. 3922, date 30.7.2003
from the President of the Republic of Albania,

Alfred Moisiu

Annex no.1

The limits for the changes on the classification of the chemical preparations

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

$$|C2-C1| > K.C1$$

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

K – coefficient given by the table below

C1- the original concentration of the component (in %)

C2 – the new concentration of the component (in %)

The original concentration C1 Coefficient K

C1 ? 2,5

2,5 < C1 ? 10 %

10% < C1 ? 25 %

25% < C1 ? 50 %

50% < C1 ? 100 % 0,150

0,100

0,060

0,050

0,025

Annex no.2

In the Republic of Albanian is not allowed:

The production, importing, exporting and distribution of the following substances

Name of the substance - Cas Number

Policlorined bifeniles (PCB) and preparations with the content of this substance in quantities larger than 0,005 % (excluding the monidiclorined) 1336-36-3

Policlorined trifeniles (PTC) and preparations with the content of this substance in quantities larger than 0,005 % 61788-88-8

Azbest Fibres

a) crocidolit

b) amozit

c) antrofilit

d) actonolit

e) tremolit

12001-28-4

12172-73-5

77536-67-5

77536-66-4

77536-68-6

Monometil tetraklordifenil metan

(commercial name Ugilec 141) 75623-60-6

Monometil diklordifenil metan

(commercial name Ugilec 141)

Monometil dibromdifenil metan

(commercial name DBBT) 99688-47-8

Note: CAS – Chemical Abstract Service