

Pursuant to Article 95 item 3 of the Constitution of Montenegro I hereby issue the

DECREE
PROMULGATING THE LAW ON CHEMICALS

I hereby promulgate the Law on Chemicals passed by the 24th Parliament of Montenegro at the third sitting of the first ordinary session in 2012 on 21 March 2012.

No 01-372/2

Podgorica, 26 March 2012

The President of Montenegro

Filip Vujanovic, m.p.

Pursuant to Article 82, paragraph 1, item 2 and Article 91, paragraph 1 of the Constitution of Montenegro, the 24th Parliament of Montenegro at the third sitting of the first ordinary (spring) session in 2012 on 21 March 2012 passed the

LAW ON CHEMICALS

I. GENERAL PROVISIONS

General Provisions

Article 1

This Law shall regulate the classification, packaging and labeling of chemicals, transport, import and export of dangerous chemicals, as well as other issues of importance to the protection of life and health of people and the environment from harmful effects of chemicals.

The chemical is a substance or mixture.

Article 2

This law shall not apply to:

- 1) Radioactive chemicals;
- 2) Substances which are under customs supervision in a customs warehouse or free zone, either for re-export or transit, if these chemicals are not processed or treated;
- 3) Non-insulated intermediates;
- 4) Chemical substances that can be used in the manufacture of narcotic drugs and psychotropic compounds (precursors);
- 5) Food and food additives;
- 6) Animal feed and animal feed additives;
- 7) Drugs for human and veterinary use;
- 8) Medical Devices;
- 9) Drugs;
- 10) Chemicals that are considered waste in accordance with the law regulating waste management;
- 11) Ammunition and explosives;
- 12) Chemical weapons and precursors for chemical weapons;
- 13) Items of general use, as well as chemicals that come into direct contact with food;

14) Chemicals used for scientific research and development in quantities that do not affect human health and the environment, not exceeding 10 kg for each chemical and for each import.

The provisions of this Law relating to the registration of chemicals in the Register of Chemicals shall not apply to the chemicals that are put in final shape on the market, such as:

- 1) Biocidal products;
- 2) Plant protection products;
- 3) Beauty products.

The provisions of this Law relating to the classification, packaging and labeling of chemicals shall not apply to chemicals:

- 1) Which are used for scientific research and development and which are not put into circulation, and are used under controlled conditions where the exposure is reduced;
- 2) Which are in the final form placed on the market as cosmetic products.

This Law shall not apply to the transportation of hazardous chemicals in air, sea, road, rail and postal transport and inland waterways.

Definition of Terms

Article 3

Terms used in this Law shall have the following meanings:

- 1) **Packaging** is an appropriate container for packaging chemicals made of materials providing the safety of the chemical composition;
- 2) **CAS number** is a characteristic number of chemical substances under which the chemical is listed on the list of the International Chemical Abstract Service;
- 3) **Future user** is a legal entity or entrepreneur who is not a manufacturer or importer of chemicals, distributor and consumer, and who uses a chemical alone or in mixture for industrial or professional purposes;
- 4) The **distributor** is a legal entity or entrepreneur, including a retailer, who only stores and distributes chemicals to a third party;
- 5) **Good Laboratory Practice (GLP)** is a quality system that applies to the organizations, processes, and the conditions under which non-clinical tests are performed in relation to risk assessment of dangers to life and human health and the environment, in accordance with international standards;
- 6) **Detergents** are chemical substances or chemical mixtures that contain soap, or other surface-active substances which are used for washing and cleaning;
- 7) **Chemical name according to IUPAC chemical nomenclature** is the name of the chemical specified under the nomenclature of the International Union of Pure and Applied Chemistry - IUPAC);
- 8) **Industrial detergents and detergents for professional use** are detergents for outdoor washing and cleaning, conducted by professional staff;
- 9) **Exporter** is a legal entity or entrepreneur that exports chemicals in the territory of another state;
- 10) **Intermediate** is a chemical substance that is produced for use in processing and obtaining other substances;
- 11) **Monomer** is a substance that is able to build covalent bonds with a series of other similar or different molecules in the reaction conditions, creating a polymer that is used in a specific process;
- 12) **Non-isolated intermediate** is an intermediate that during synthesis is not intentionally removed from the equipment in which the synthesis takes place (except for sampling);
- 13) **Polymer** is a substance consisting of molecules characterized by a sequence of one or several types of monomeric units, in which the molecular weight must be distributed within the area in which the difference in molecular weight are primarily related to differences in the number of monomer units, which contains more than 50% of weight of molecules with at least three monomer units which are covalently linked with at least one other monomer unit or other reactant or less than 50% of weight of molecules of

the same molecular weight;

14) **Product** is an item which is, during production, given a certain shape or design that further determines its function, more specifically than the chemical composition;

15) **Producer** is a legal entity or entrepreneur who produces, finishes, processes or uses chemicals to obtain the final product, performs repackaging or changing the name of the chemical for further use;

16) **Production** is making and finishing, shaping, processing, filling, decanting, mixing chemicals into intermediate and final products, using chemical, physical or biological processes and procedures, as well as transmission and storage within manufacturing sites;

17) **Packaging** is packaging chemicals and its contents in the container;

18) **Surface-active substances** are organic substances or mixtures which have surface-active properties and which contain one or more hydrophilic and hydrophobic groups that are able to reduce the surface tension of water, forming a widespread or absorbing monolayer at the point of contact between water and air, which creates emulsion or a microemulsion or micelle and that are absorbed when touching water and solid surfaces;

19) **Primary biodegradability** is a structural change (transformation) of surface-active substances under the action of microorganisms, resulting in loss of its surface-active capacity due to the decomposition of its structure;

20) **Ultimate aerobic biodegradability** is the level of biodegradability where the surface-active substance with the help of microorganisms in the presence of oxygen completely breaks down to carbon dioxide, water and mineral salts (mineralization);

21) **PIC - Prior Informed Consent** is a procedure by which the chemicals that are banned or restricted in the exporting country may be exported only upon prior notification and obtaining the consent of the importing country;

22) **Handling** is the production, processing, packing, storage, circulation, transport and use of chemicals, pollution and other activities with chemicals;

23) **Mixture** is a mixture or solution of two or more chemical substances;

24) **Circulation** is the import of chemicals, supplying or making them available for use by third persons with or without a charge;

25) **Exposure scenario** is a set of measures and conditions, including working conditions, measures of risk management in the production and use of chemicals during the entire life cycle, as well as a way of controlling chemicals when the people and the environment are exposed their influence;

26) **Substance** is a chemical element or compound in its natural state or obtained in the production process, including supplements (additives) that are essential for maintaining its stability, or byproducts (impurities) that are the result of the process of obtaining the chemicals, except for solvents that may be extracted without affecting the stability of the substance and changing its composition,

27) **Importer** is a legal entity or entrepreneur who imports chemicals in the territory of Montenegro;

28) **Use** is processing, consumption, storage, fabrication, keeping, filling the tank, transfer from one tank to another, mixing, production, or other use of chemicals.

II. CLASSIFICATION, PACKAGING AND MARKING

Method of Classification of Chemicals and Specific Products

Article 4

Classification of chemicals and products containing hazardous chemicals (hereinafter referred to as a specific product) is made on the basis of assessment of their physical and chemical properties, properties that affect the lives and health and the environment, in accordance with the criteria for the classification into certain classes of danger.

Dangerous chemicals are classified into the following classes: explosive, oxidizing, extremely inflammable, very flammable, flammable, very toxic, toxic, harmful, corrosive, irritant, chemicals that cause hypersensitivity, carcinogenic, mutagenic, reproductive toxic, and chemicals threatening the environment.

Hazard classification of chemicals is determined on the basis of chemical properties that affect life and human health and the environment or based on the nature of the effects of chemicals.

The criteria and method of classification of chemicals and a specific product in hazard classes shall be set by the state administration authority in charge of environmental protection (hereinafter: the Ministry), with the consent of the state administration authority responsible for health.

Method of Labeling and Packaging Chemicals

Article 5

The producer, importer, distributor and future user, who distributes chemicals and specific products (hereinafter referred to as: the supplier) shall classify, label and pack chemicals in accordance with this Law.

The exporter shall label and pack the chemical for export in accordance with this Law, unless it is necessary that the chemical is packed and marked in a different manner, in accordance with international standards, and is requested by the country to which the chemical is exported.

A future user who does not change the composition of chemicals in use, may use the classification, labeling and packaging of chemicals of one of the entities in the supply chain.

Classification of chemicals may use data from epidemiological studies, statistical data on occupational diseases, the data on the effects of chemicals on people who were exposed to the chemical in chemical accidents, as well as data obtained by other internationally accepted methods for determining the properties of chemicals.

Information on Substances

Article 6

The producer, importer and future user of chemical substances shall determine relevant information available for this substance to determine the degree of danger to human health and the environment.

A substance shall be classified in accordance with the classification of substances of the same chemical composition in the lists of classified substances.

If the substance is not on the list of substances classified or is not classified for all hazard classes, classification is based on:

- 1) existing data on the properties of this substance;
- 2) the results of new tests of its properties and comparison of these data;
- 3) results identified based on the criteria for classification of chemicals.

The list of classified substances shall be established by the Ministry, with the consent of the state administration authority responsible for health.

Information about Mixtures

Article 7

The producer, importer and future user shall establish relevant information which is available for the mixture or substance which it contains in order to determine the degree of danger to human health and the environment.

Classification of mixtures shall be performed by estimating the danger of the mixture on the basis of:

- 1) Data on the properties of substances contained in the mixture;
- 2) Analysis of existing data on the risk posed by a mixture;
- 3) Experimental investigations of properties of the mixture and comparison of such data or the results identified on the basis of criteria for the classification of chemicals.

Chemicals Testing

Article 8

When no data for classification are available for the chemical or data were not obtained in the manner determined by this Law, to avoid research on vertebrates, in each specific case the need for new testing of chemicals shall be assess.

It is forbidden to test chemicals on primates for the purpose of classification.

Methods of Testing Chemicals

Article 9

New testing of chemicals for the purpose of classification shall be performed according to prescribed methods.

Toxicological and ecotoxicological tests shall be conducted by the laboratory whose work conforms to the guidelines of good laboratory practice (hereinafter DLP), authorized by the Ministry.

Methods for testing the hazardous properties of chemicals shall be regulated by the Ministry, with the consent the state administration authority responsible for health.

Packaging

Article 10

Containers for packaging dangerous chemicals shall conform to the characteristics, purpose and manner of using chemicals which prevents any loss of packed products.

The material that the packaging is made of and closures shall not be susceptible to contact with the content, nor induce reaction with the content.

Containers and closures shall be firm and stable throughout the area not to cause leakage and to safely undergo normal loads to which they are exposed due to handling.

Packaging containing hazardous chemicals in retail sales shall be safe with security gates and shall not have a form that may attract children or cause misapprehension of consumers.

A detailed manner of packaging and labeling of chemicals and specific products shall be regulated by the Ministry, with the consent of the state administration authority responsible for health.

Method of classification, packaging and labeling of chemicals and specific products in accordance with the UN Globally Harmonized System for Classification and Labeling shall be specified by the Ministry.

Labeling

Article 11

Packaging into which a substance or mixture is packed, which is classified as dangerous, shall be marked as dangerous with written warnings.

The warning shall be printed clearly and prominently.

The written warning label shall be in the Montenegrin language.

The written warning label shall be in addition printed in the Braille system.

Suppliers may use written warning labels in multiple languages, provided that the same information is listed in all languages.

Suppliers of hazardous chemicals and mixtures that are not dangerous, but contain at least one substance that is classified as hazardous, shall indicate on the label any supplemental information about such dangerous properties and safety measures in a way that its users shall not be misled about the hazardous properties of chemicals.

Identification Marks of Products

Article 12

The label shall include information on identification of substances and mixtures, which shall be the same as in the safety sheet.

An identification label of a product containing the chemical substance shall consist of a name and identification number, CAS number, name established under the IUPAC nomenclature.

An identification label of a product containing the chemical mixture shall consist of trade name or trademark of the mixture, the identity of all substances in the mixture based on which the mixture classification is done.

Alternative Chemical Names of Chemicals

Article 13

An alternative name of the chemical may be used if the use of chemical name of the substance may lead to a violation of trade secrets or intellectual property rights, and if an alternative chemical name provides enough information to take measures relating to health, safety and control of occupational risk in handling the mixture.

In safety data sheet or when labeling the packaging containing dangerous substances in the mixture, an alternative chemical name for this substance may be used, so that the name which is used will identify the most important chemical functional groups or other alternative specifications may be used.

An alternative chemical name for chemicals may be used for a substance that has certain characteristics.

An alternative chemical name may be used under the authorization for the use of alternate chemical name, issued by the competent administration authority for environmental protection (hereinafter: the Agency).

The properties of a substance for which an alternative chemical name may be used, and the content of application for the use of alternate chemical name shall be regulated by the Ministry, with prior consent of the state administration authority responsible for health.

Approval for Use of Alternate Chemical Names

Article 14

Approval for use of alternate chemical name shall be issued upon request submitted by the producer, importer and future user to the Agency.

The authorization referred to in paragraph 1 of this Article shall be issued with prior approval of the state administration authority responsible for health.

The Agency may, within one month from the date of application referred to in paragraph 1 of this Article request more information from the applicant necessary for the decision to use an alternative chemical name.

If the conditions referred to in Article 13 paragraphs 1 and 3 are met, the Agency shall issue an authorization for the use of alternate chemical names.

The Agency may revoke approval for the use of alternate chemical name if on the basis of new information, it is determined that an alternative chemical name does not provide enough information to take measures relating to safety and occupational health and risk control when handling the mixture.

In the case referred to in paragraph 5 of this Article, the Agency may approve other alternative chemical name for that substance.

Storage

Article 15

The Supplier shall store hazardous chemicals in a manner that does not endanger life and human health and the environment.

The person referred to in paragraph 1 shall collect, store and safely dispose of the remains of dangerous chemicals and empty containers in accordance with the regulations governing the management of waste.

Safety Data Sheet

Article 16

Dangerous chemical, a chemical that contains a substance identified as persistent - bioaccumulable - toxic (hereinafter referred to as PBT) or very persistent - very bioaccumulable (hereinafter referred to as vPvB) and other chemicals that have the characteristics referred to in Article 26 paragraph 2 of this Law that are placed on the market shall be accompanied by safety data sheet.

Safety Data Sheet contains specifically: chemical name of the chemical, information about the properties of the chemical, usage patterns, preventive measures, risk mitigation measures and data on the chemical supplier.

The supplier shall provide the Safety Data Sheet to each distributor or future user in the supply chain, in the Montenegrin language, in printed or electronic form.

Exporter of chemicals referred to in paragraph 1 of this Article shall submit a Safety Data Sheet to the importer, in the language of the country of export or in English.

Criteria for identifying a substance such as PBT or vPvB and detailed content of the Safety Data Sheet shall be prescribed by the Ministry, with the consent of the state administration authority responsible for health.

Safety Data Sheet for Mixtures Not Classified as Dangerous

Article 17

The Supplier shall, at the request of other distributors or future users in the chain of supply, provide Safety Data Sheet for the mixture that is not classified as dangerous and containing:

- 1) at least one hazardous substance, based on the risk posed by this substance for human health and the environment in a quantity of at least 1% by weight of the mixture that is not in gas aggregate condition, or at least 0.2% by volume of the mixture in gas aggregate condition;
- 2) at least one substance in a quantity of at least 0.1% by weight of the mixture that meet the criteria for identification as PBT or vPvB, or other substances that have properties referred to in Article 26 paragraph 2 of this Law;
- 3) a substance for which the maximum allowable concentrations in workspaces are prescribed.

Modifying Safety Data Sheet

Article 18

The supplier referred to in Article 17 paragraph 1 of this Law shall be required to modify the content of Safety Data Sheet in accordance with new findings on the chemical, especially knowledge that may affect the measures to reduce and control risks and hazards of the chemical, as well as restrictions or bans on production, marketing and use of chemicals.

The supplier referred to in paragraph 1 shall deliver the amended Safety Data Sheet to each distributor or future user in the supply chain where the chemical was delivered in the preceding 12 months.

The amended Safety Data Sheet shall contain the note "Revised" and date of modification.

Chemical Safety Assessment

Article 19

The supplier that distributes chemicals shall deliver to the Agency, in addition to the Safety Data Sheet, a Chemical Safety Report.

The Chemical Safety Report shall be prepared on the basis of chemical safety assessment with measures to reduce and control the risks of substance.

Chemical safety assessment shall include:

- 1) Assessment of risks to human health;

- 2) Evaluation of physical and chemical hazards;
- 3) Assessment of risks to the environment;
- 4) Evaluation of PBT (steady, bioaccumulative and toxic) and vPvB properties (very persistent and very bioaccumulative).

If following the safety assessment of chemicals referred to in paragraph 3 of this Article it is established that the chemical meets the criteria by which chemicals are classified as hazardous or if it is a chemical with PBT or vPvB properties, the following shall be applied:

- Assessment of exposure, including the creation of one or more exposure scenarios (i.e., determining relevant categories of use and exposure) and exposure assessment, and
- Risk characterization.

The exposure scenarios, exposure assessment and risk characterization shall also include the method of use or the use of chemicals.

Report on Chemical Safety

Article 20

The data in the Chemical Safety Report shall match the data in the Safety Data Sheet.

The scenario of risk exposure shall be an integral part of the Safety Data Sheet.

The report referred to in paragraph 1 of this Article shall be submitted in the Montenegrin or English.

Method of preparation and content of the Chemical Safety Report shall be regulated by the Ministry.

Other Data on Chemicals

Article 21

The producer, importer or distributor of the product containing a substance that has the characteristics of the substance referred to in Article 26 of this Law in a concentration greater than 0.1%, shall provide to the distributor or future user in the supply chain, and each consumer, at his request, sufficient information for the safe use of this product, but at least the name of the substance.

The data referred to in paragraph 1 of this Article shall be delivered free of charge, within 45 days following the request.

Handling of Chemicals

Article 22

The Supplier shall take precautionary measures for chemicals produced and marketed, or used, in order to prevent or reduce their harmful effect on human health and the environment.

Exchange of Information

Article 23

The suppliers of chemicals shall exchange new information on the hazardous properties of chemicals as well as other information relating to the use of these chemicals, which are included in the Safety Data Sheet.

III. REGISTRATION OF CHEMICALS

Register of Chemicals

Article 24

Chemicals produced or put into circulation shall be entered in the Register of Chemicals. Register of Chemicals shall be maintained by the Agency, in electronic form. Register of Chemicals shall include chemicals that are used in scientific research purposes in quantities less than 100 kg.

Listing of Chemicals in the Register of Chemicals

Article 25

Listing of chemicals in the Register of Chemicals shall be done on the basis of application of the producer, importer or future user, submitted to the Agency not later than by 31 March of the current year for the chemicals produced or imported in the previous year in excess of 100 kg.

On behalf of foreign producers and importers of chemicals, application for chemicals registration may be submitted by the proxy, or authorized person.

The polymer shall be entered in the Register of Chemicals, if:

- It contains at least 2% by weight of such monomer substances or other substances in the form of monomeric units and chemically tied substances;
- The total amount of such monomer substances, or other substances is least 100 kg per year.

In addition, the substance or mixture containing a substance that causes a high concern shall be entered in the Register of Chemicals.

Application for registration of chemicals shall in particular contain: name, address, or name and address and registration number of the producer or importer, the data on the quantity of chemicals produced and imported, purpose of using chemicals, tax identification number.

The application referred to in paragraph 1 of this Article shall be enclosed with evidence of registration in the Central Registry of Commercial Entities (hereinafter referred to as CRPS), or proof of registration with the competent authority of the home country for foreign legal person, a file for each chemical, Safety Data Sheet for each chemical which is required to have a Safety Data Sheet according to the regulations.

The file referred to in paragraph 6 of this Article shall contain in particular:

- 1) chemical trade name and chemical name according to IUPAC nomenclature, and other identification of the chemical;
- 2) information on the amount of chemicals put into circulation;
- 3) data on the use of chemicals;
- 4) information about the chemical composition.

Detailed contents of the file of chemicals and registry of chemicals shall be regulated by the Ministry, with prior approval of the state administration authority responsible for health.

The List of Substances that Cause a High Concern

Article 26

Substances that are carcinogenic, mutagenic, toxic for reproduction and identified as a PBT or vPvB substances are entered into the list of substances that cause a high concern.

The list of substances that cause high concern shall also include the substances that lead to disorders of the endocrine system or have PBT or vPvB properties, but do not meet the criteria to be identified as PBT or vPvB, and science found them to cause significant effects on human health and the environment.

The list of substances that cause high concern include the following information:

- 1) The identity of the substance;
- 2) Classification of the substance;
- 3) Methods of use that require no additional measures to reduce risk.

The list of substances that cause high concern shall be determined by the Ministry, with the consent the state administration authority responsible for health.

File of a Substance that Causes a High Concern

Article 27

The file for a substance that causes a high concern, or a mixture containing the substance, in addition to the data referred to in Article 26 paragraph 3 of this Act, shall include:

- 1) The method of using such substances or mixtures containing such substances,
- 2) Measures to reduce risks during use;
- 3) A systematic way of monitoring the use of substances or mixtures containing such substances.

The file referred to in paragraph 1 of this Article shall contain the information, if available, on possible alternative substances, the dangers and risks that may be posed by alternative substances to human health and the environment, as well as data that are important to replace these substances by alternative substances.

Professional Assessment

Article 28

The Agency, in cooperation with the competent state administration authority responsible for health, shall perform a professional assessment of the information contained in the file for a substance or mixture containing a substance causing high concern, measures to reduce risk and way of systematic monitoring of the use of a substance which causes concern.

If the Agency considers that measures to reduce risk, or way of systematic monitoring the use of a substance that causes high concern are not appropriate, it shall order amendment of the proposed measures to reduce risk, or ways of systematic monitoring the use of a substance that causes concern and set the deadline for the execution of the measures imposed.

The producer, importer and future user shall adhere to the measures imposed in paragraph 2 of this Article.

Registration of substances that cause high concern in the Register of Chemicals shall be done by decision after checking the completeness of data from the file, within 20 days of receipt of application for registration in the register of chemical substances.

Change of Data

Article 29

Producers and importers shall submit to the Agency any change of data entered in the register of chemicals, which relate to:

- 1) change of legal status of the producer or importer (name or registered office of the producer or importer);
- 2) change of the composition of the substance;
- 3) change of the yearly or the total production or imports, or change in the amount of substances present in the products produced or imported;
- 4) new knowledge about the risks of substances on human health and the environment which is realistic to obtain and which leads to modification of the Safety Data Sheet or Chemical Safety Report;
- 5) changes in the classification and labeling of substances;
- 6) changes of the chemical safety report.

Change of data referred to in paragraph 1 of this Article shall be submitted no later than 30 days after the change occurred.

The Records of Chemicals and Recordkeeping Obligations

Article 30

The supplier shall keep records of chemicals, which shall in particular contain information on:

- 1) the identity of chemicals;
- 2) distributors and future users, and quantities of chemicals delivered to them;
- 3) aggregate quantities of chemicals that are sold to consumers in a calendar year.

The records referred to in paragraph 1 of this Article shall be kept at least 10 years after the last production, marketing and use of chemicals.

The supplier shall submit data from the records to the Agency at its request.

The manner of keeping records of chemicals shall be regulated by the Ministry.

IV. CIRCULATION OF HAZARDOUS CHEMICALS

License for Circulation of Dangerous Chemicals

Article 31

Hazardous chemicals may be circulated by the supplier only if licensed by the Agency.

The license referred to in paragraph 1 of this Article shall be issued at the request of a supplier that puts the chemical into circulation.

The license for carrying out trade in hazardous chemicals may be issued to the supplier who has adequate space for storage and safekeeping of hazardous chemicals in a way that prevents access to individuals for use in unauthorized purposes.

An Application for a License

Article 32

An application for a license under Article 31 of this Law shall contain in particular:

- 1) the name and address or name and address of the supplier, trade name of the chemical and name and address of the producer of chemicals;
- 2) information on the method of packaging and labeling of chemicals;
- 3) information on the purpose and use of chemicals;
- 4) information on the quantity of chemicals;
- 5) information on the method of storage (location, description of premises);
- 6) measures to be implemented for safe keeping and storage of chemicals;
- 7) other information at the Agency's request.

The application referred to in paragraph 1 shall be attached to the contract of insurance against liability for any damage that may result from the use of chemicals.

Further requirements for the storage and measures for safe keeping or use of hazardous chemicals shall be prescribed by the Ministry.

Keeping Records on Transport of Dangerous Chemicals

Article 33

Record of licenses issued for carrying out trade in hazardous chemicals shall be kept by the Agency.

Manner of keeping records referred to in paragraph 1 of this Article shall be prescribed by the Ministry.

Restrictions and Prohibition of Certain Chemicals

Article 34

Chemicals that represent an unacceptable risk to human health and the environment may be used in a manner and under conditions prescribed by the Ministry, and in accordance with time limits when the restrictions and prohibitions become mandatory for the application, with the consent of the state administration authority responsible for health.

The regulation referred to in paragraph 1 of this Article shall contain prohibited, or permitted methods of use, as well as other requirements for the production, marketing, reporting and use of a substance, mixture, or a particular product.

V. IMPORT AND EXPORT OF CHEMICALS

Export

Article 35

Exports of chemicals from the List of Chemicals subject to the prior notification procedure shall be done on the basis of information supplied by the Agency in the country of export of chemicals.

The notice referred to in paragraph 1 of this Article shall be submitted for:

- 1) chemicals included in the list of chemicals for the procedure of prior notice;
- 2) chemicals that contain a substance from the List of Chemicals for the procedure of prior notice in a concentration that is dangerous;
- 3) products that contain chemicals from the list of chemicals for the PIC procedure.

The notice referred to in paragraph 1 of this Article shall be prepared by the exporter of chemicals and submitted to the Agency.

The notice referred to in paragraph 3 of this Article, shall especially contain information on:

- 1) the exporter or importer (title and address or name and address);
- 2) the identity of the chemicals or products;
- 3) the properties of these chemicals;
- 4) measures to reduce risk.

The Agency shall verify the data from the notice and after testing notify the country of export of chemicals.

After the notification the Agency shall issue a certificate to the exporter of chemicals.

Detailed contents of the notification referred to in paragraph 1 of this Article, the procedure and timetable for implementing the procedure of prior notification shall be regulated by the Ministry.

The list of chemicals for the prior notification procedure shall be determined by the Ministry.

The list of chemicals for the procedure of prior notification shall be published in the "Official Gazette of Montenegro".

Import

Article 36

Import of chemicals from the List of chemicals subject to the prior notification procedure is performed when the Agency is notified of export by the competent authority of the exporting country that exports the chemicals.

The Agency after receiving notification of export shall inform the authority referred to in paragraph 1 of this Article that it has been notified.

Exports of Chemicals in the PIC Procedure

Article 37

The PIC procedure is carried out for the import or export of chemicals that are found in the List of Chemicals for the PIC procedure and for the chemicals listed under the Rotterdam Convention.

The PIC procedure shall be carried out based on information submitted to the Agency by the exporter of chemicals.

The notice referred to in paragraph 2 of this Article shall contains information about:

- 1) the exporter or importer (title and address or the name and address);
- 2) the identity of chemicals;
- 3) physical-chemical, toxicological and ecotoxicological properties of chemicals;
- 4) name according to the IUPAC;
- 5) CAS number of the chemical.

The Agency shall verify the data from the notice and after the verification notify the competent authority of the importing country to obtain consent.

If the competent authority of the country of import informs the Agency that it agrees with the import, or agrees to import under certain conditions, the Agency shall issue an approval to the exporter of chemicals.

The Agency shall deliver a decision in connection with the import of chemicals listed under the Rotterdam Convention to the Secretariat of the Rotterdam Convention.

Detailed contents of the notification referred to in paragraph 3 of this Article, the procedure and timetable for implementing the PIC procedure shall be regulated by the Ministry.

The list of chemicals for the PIC procedure shall be determined by the Ministry.

The list referred to in paragraph 8 of this Article shall be published in the "Official Gazette of Montenegro".

Imports of Chemicals according to the PIC procedure

Article 38

For the import of chemicals from the List of chemicals in the PIC procedure and the chemicals listed under the Rotterdam Convention, approval shall be given by the Agency based on prior notification of the competent authority of the exporting country.

Information on Quantities Imported and Exported

Article 39

Exporters and importers of chemicals from Articles 35, 36, 37 and 38 of this Law shall submit to the Agency information on imported and exported quantities of chemicals and certain of products, about the countries of export or import of chemicals, as well as data on the importer or exporter of chemicals.

The data referred to in paragraph 1 of this Article shall be submitted by 31 March of the current for the previous year.

Based on data from paragraph 1 of this Article, the Agency shall keep records of imported and exported chemicals, or certain products.

The records referred to in paragraph 3 of this Article shall be kept in electronic form.

Method of delivery of the data referred to in paragraph 1 of this Article shall be prescribed by the Ministry.

Report on Actual Quantities

Article 40

An exporter or importer of a chemical or a specific product shall submit a report to Agency on the actual quantities of exported and imported chemicals or particular products, within 30 days of realized export or import.

Method of delivery of the report referred to in paragraph 1 of this Article shall be prescribed by the Ministry.

The Transit of Chemicals

Article 41

The exporter of chemicals shall submit to the Agency information required by the competent authority of the transit country for the chemicals listed under the Rotterdam Convention, at least 30 days prior to transit.

The Agency shall notify the competent authority of the transit country of the chemicals in transit referred to in paragraph 1 of this Article, at least 15 days prior to the transit.

List of Hazardous Chemicals and Products whose Export is Banned

Article 42

Chemicals and products whose use is banned to protect human health and the environment shall not be exported.

Chemicals whose term expires six months after the export shall not be exported.

The list of hazardous chemicals and products whose export is prohibited shall be determined by the Ministry.

The list referred to in paragraph 3 of this Article shall contain in particular: the name of the hazardous chemicals or products, numbers that identify the chemical or product and the tariff number of the hazardous chemical or product.

VI. DETERGENTS

Marketing of Detergents

Article 43

Detergents can be traded only if they fulfill the conditions of ultimate aerobic biodegradability and if chemical and surface-active substances contained in detergents meet the conditions relating to the classification, packaging and labeling required by this law.

Limitations of Biodegradability of Surface-Active Substances

Article 44

Industrial detergents and detergents for professional use containing surface-active substances that do not meet the requirements of the aerobic biodegradability may be marketed on the basis of a license for the use of surface-active substances issued by the Agency or a document approving the use of surface-active substances in detergents in the EU.

Methods of test for biodegradability of surface active substances shall be prescribed by the Ministry, with the consent of the state administration authority responsible for health.

Application for Licensing

Article 45

The license under Article 44 of this Law shall be issued based on application submitted to the Agency by the producer of detergent.

The following shall be enclosed with the application referred to in paragraph 1:

- 1) Technical file of the surface-active substances, in particular containing identification of the surface-active substances;
- 2) Results of tests of biodegradability of surface active substances;
- 3) Information about the surface-active substances and metabolites of biodegradation;
- 4) Data on the amount of surface active substances in detergents that has been put into circulation;
- 5) Anticipated use of detergent;
- 6) Draft risk assessment for the surface-active substance.

Conditions for Approval

Article 46

Based on the application data referred to in Article 45, paragraph 2 of this Law, the Agency shall verify whether:

- 1) the detergent is used in a way that the minimum surface-active substance is released to the environment;
- 2) the detergent from the surface-active substance is used for industrial or professional purposes;

- 3) the risk posed by the surface-active substance to human health and the environment is minimal, taking into account the amount of surface active substances in the detergent put into circulation and usage of such detergent, in addition to the requirements for food safety and maintaining hygiene;
- 4) surface-active substance contained in the detergent meet the criteria of primary biodegradability.

Licensing

Article 47

The license under Article 44 of this Law shall be issued within six months from the date of filing an application.

By the license referred to in paragraph 1 of this Article the Agency may specify conditions for the marketing and use of surface-active substances as a detergent ingredient.

License for the Surface Active Substance

Article 48

The holder of a license under Article 44 of this Law shall, if the amount of surface-active substances in detergents change, or the usage of detergents is altered, submit to the Agency a technical dossier of the surface-active substance including updated information.

Based on data from paragraph 1 of this Article, the Agency may issue a:

- New license setting the conditions for using the surface-active substance;
- Decision revoking the license, which determines the period in which the detergent-containing surface-active substance shall be withdrawn from the market.

The list of surface-active substances that may be used in detergents, in addition to the list of surface-active substances which are prohibited for use in detergents shall be specified by the Ministry.

The lists referred to in paragraph 3 of this Article shall be published in the "Official Gazette of Montenegro".

Investigation of Surface-Active Substances

Article 49

Aerobic biodegradability of surface active substances shall be performed by the laboratory authorized to apply relevant testing method whose activity shall comply with GLP guidelines.

The detergent manufacturer shall keep the test results referred to in paragraph 1 of this Article confirming that the criterion of ultimate aerobic biodegradability of surface active substances is met and deliver them to the Agency at its request.

The manufacturer of any detergent intended for medical use shall list the composition of the detergent and keep the list for five years, as confidential, and use it for medicinal purposes.

Method of marking and content of the detergent composition list shall be specified by the Ministry, with prior approval of the state administration authority responsible for health.

VII. GOOD LABORATORY PRACTICE

Non-Clinical Testing of Chemicals

Article 50

Non-clinical chemical tests are performed to evaluate the chemicals and assess the risk of their potential danger to life and human health and the environment.

Non-clinical testing of chemicals shall be performed by laboratories whose work is compliant with the GLP guidelines.

Guidelines and requirements for the GLP shall be prescribed by the Ministry.

Application for GLP Certificate

Article 51

Compliance with GLP requirements shall be determined by the Agency that issues GLP certificates.

GLP certificate is issued on the basis of application submitted by the laboratory.

The application shall contain the name and address of the laboratory, name and surname of responsible person, chemical to be tested by the laboratory, and types of methods by which testing will be performed.

More detailed content of the application and GLP certification form shall be specified by the Ministry.

GLP certificate issued by the competent authority of the country which is a member of the Working Group for GLP Organization for Economic Cooperation and Development (OECD) shall be recognized in Montenegro.

Authorization

Article 52

A GLP certified laboratory may conduct non-clinical tests based on authorization issued by the Ministry in the form of a decision.

The decision referred to in paragraph 1 shall be issued on the basis of public call announced by the line Ministry.

Revocation of the GLP Certificate

Article 53

If the authorized laboratory ceases to perform non-clinical tests in accordance with the GLP guidelines, it shall notify the Ministry accordingly, in writing.

On the basis of the notification referred to in paragraph 1 of this Article, the Ministry shall issue a decision on the withdrawal of authorization and GLP certificate.

VII. MANAGEMENT OF CHEMICALS

Measures and Restrictions on Chemicals

Article 54

If it is suspected that a certain chemical that meets all the requirements prescribed by this Law causes serious and irreparable consequences for life and human health and the environment, the Agency, in cooperation with the competent state administration authority for health, may order:

1) a temporary prohibition or restriction of production, import, placing on the market or use of such

chemicals;

2) withdrawal of chemicals from the market;

3) other measures to limit or reduce the effects of negative impacts of chemicals to an acceptable level.

When deciding on the measures referred to in paragraph 1 of this Article, the Agency takes into account the seriousness and consequences of potential effects on human health and the environment, the availability of chemicals and technologies that may replace existing chemicals, in addition to new scientific knowledge about the effects and functioning of the chemicals .

Control of Marketing and Use of Chemicals

Article 55

In order to protect human health and the environment from harmful effects of chemicals, chemicals shall be monitored from the point of placing on the market to the point of use by end users.

Monitoring of chemicals shall be carried out to study the mode of use of substances that cause a high concern and those subject to the measures of restrictions on use in force.

Based on the monitoring of chemicals the Agency shall prepare an annual report and submit it to the Ministry, until 31 March of the current for the previous year.

The report referred to in paragraph 3 of this Article shall constitute an integral part of the report on the state of the environment adopted by the Government.

The report referred to in paragraph 3 of this Article shall contain in particular: data on chemicals produced, imported, exported and marketed, the information on issued permits for the import, export and marketing, information about the tests performed, information on accredited laboratories and issued GLP certificates.

Detailed contents and method of making the report referred to in paragraph 3 of this Article shall be prescribed by the Ministry.

Information System for Chemicals

Article 56

Exchange of information on chemicals with international organizations and foreign states, in accordance with the ratified international treaties and agreements, and with relevant bodies and organizations of the EU, shall be performed by the Agency.

Confidentiality and Data Availability

Article 57

Information provided in the process of registration of chemicals in the register of chemicals, in the process of issuing licenses for carrying out operations and licenses for the use of hazardous chemicals and other procedures that are marked as confidential shall be kept by the Agency, in accordance with the law.

The National Strategy for Managing Chemicals

Article 58

For adequate management of chemicals, from the point of manufacture or import to the point of storage, which contributes to sustainable development of Montenegro, the National Strategy for Managing Chemicals shall be adopted (hereinafter referred to as the National Strategy).

The National Strategy for a period of four years shall be adopted by the Government.

The National Strategy shall in particular contain:

- 1) An assessment of the situation and issues in the field of chemicals management;
- 2) Priority activities and measures for the preservation of the environment and human health;
- 3) Medium and long-term national strategic objectives;
- 4) The priority tasks in all areas of chemical safety;
- 5) Action plans for implementing the National Strategy, identifying the priorities and potential sources of funding.

Annual report on implementing the National Strategy shall be prepared by the Ministry and submitted to the Government for approval by 31 March of the current for the previous year.

X. SUPERVISION

The Competent Authority

Article 59

Supervision over the implementation of this Law and regulations adopted pursuant thereto shall be performed by the Ministry.

Inspection supervision over the enforcement of this Law and secondary legislation adopted pursuant to this Law shall be performed by the Agency, through the Environmental Inspector, in accordance with this Law and the law regulating inspection supervision.

Powers of Environmental Inspector

Article 60

In carrying out environmental inspections, environmental inspector shall have the authority to determine whether:

- 1) the chemicals and certain products that are put into circulation are classified, labeled and packed in accordance with this Law and the regulations passed under this Law;
- 2) the label of dangerous chemicals, and certain mixture that is not dangerous, but it contains at least one substance that is classified as hazardous, is in accordance with this Law;
- 3) the prescribed records on the chemical are kept and prescribed data collected, and whether the records and data are kept for the prescribed period;
- 4) the obligations are met in connection with the contents, updating and delivering the Safety Data Sheet;
- 5) for a product that contains a substance of prescribed characteristics and concentrations, information shall be provided sufficient for the safe use of this product, especially the name of the substance;

- 6) a permit is issued for the use of alternate chemical name of the substance, and whether that name is used in accordance with the approval;
- 7) the hazardous chemicals are stored so as not to endanger the life or health of people and the environment, i.e. whether the residues of these chemicals and empty packaging comply with the regulations regulating waste management;
- 8) a certain dangerous chemical is marketed in accordance with prescribed conditions;
- 9) a chemical which is subject to the obligation of entering in the register of chemicals is reported in a timely manner, and whether the required data are provided every following year at a particular time;
- 10) measures entered in the file on registration of a chemical in the register of chemicals are applied for the substance that causes high concern;
- 11) the prohibitions and restrictions are complied with;
- 12) prior to export the prescribed information is delivered for the prior notification procedure and whether this information is submitted within the prescribed period;
- 13) an application for conducting the PIC procedure is submitted;
- 14) the marketing or use of hazardous chemicals is done by a licensed person;
- 15) A person who is licensed for the transport or use of hazardous chemicals ensured proper storage, and whether the prescribed conditions and preventive measures are complied with;
- 16) actions are taken in accordance with the prescribed obligations for detergents.

Responsibilities of the Environmental Inspector

Article 61

In carrying out activities under Article 60 of this Law, environmental inspector shall:

- 1) order the chemicals and certain products that are marketed to be classified, marked and packed in accordance with this Law and the regulations passed under this Law;
- 2) prohibit putting into circulation a chemical or certain product classified, labeled and packed contrary to this Law and the regulations passed under this Law;
- 3) order to label hazardous chemicals and certain mixtures that are not dangerous, yet contain at least one substance classified as dangerous, in accordance with the Law and regulations passed under this Law;
- 4) prohibit to mark hazardous chemicals and certain mixtures that are not dangerous, yet contain at least one substance classified as dangerous, contrary to this Law and the regulations passed under this Law;
- 5) order to keep the prescribed records and collect the prescribed data on the chemical, and to keep the records and data stored within the prescribed period;
- 6) order to fulfill the prescribed obligations in connection with the content, update and delivery of the Safety Data Sheet;
- 7) prohibit trade in hazardous chemicals, chemicals containing a substance identified as a PBT or vPvB, and other chemicals with properties referred to in Article 26 paragraph 2 of this Law, if the obligations laid down in connection with the content, update and submission of the Safety Data Sheet are not met;
- 8) order to provide information on the product that contains a substance of prescribed characteristics and concentration sufficient for the safe use of this product, especially the name of the substance;
- 9) prohibit the use of alternate chemical name of a substance, if not approved, or order that the name shall be used in accordance with the approval;
- 10) order that the dangerous chemicals are stored so as not to endanger the life or health of people and the environment, or ordered handling of the remains of these chemicals and empty packaging in accordance with regulations regulating waste management;
- 11) prohibit the storage of dangerous chemicals to endanger life and human health and the environment, or handling the remains of these chemicals and empty packaging safely in a way contrary to the regulations on waste management;

- 12) order marketing of certain dangerous chemicals in accordance with prescribed conditions;
- 13) order reporting any chemical that is subject to the obligation of registration in the register of chemicals in a timely manner, or providing the prescribed information every within a particular deadline;
- 14) order for the substances that cause high concern application of measures registered in the file on entering chemicals in the register of chemicals;
- 15) prohibit the use of a substance that causes high concern until the measures entered in the file on entering the chemical in the register of chemicals are applied;
- 16) order to comply with the restrictions and prohibitions;
- 17) prohibit the manufacture, marketing and use of substances, mixtures and products, if handled contrary to the restrictions and prohibitions;
- 18) order to withdraw from the market a substance, mixture and product, if it does not comply with the restrictions and prohibitions;
- 19) order that the substance, mixture and product which is not handled in accordance with the restrictions and prohibitions is returned to the country of origin or to handle them in accordance with the regulations on waste management;
- 20) order to deliver prior to export information required for the prior notification procedure and to submit such information within the prescribed deadline;
- 21) order to submit an application to carry out the PIC procedure;
- 22) prohibit the marketing or use of hazardous chemicals by any person who has no license;
- 23) order to ensure proper storage of hazardous chemicals and apply the prescribed preventive measures and conditions;
- 24) order to act in accordance with the prescribed obligations of the detergent industry;
- 25) prohibit placing detergents on the market which do not comply with the prescribed obligations of the detergent industry.

X. PENAL PROVISIONS

Article 62

A fine of 2,000-40,000 Euros shall be imposed on a legal entity, if:

- 1) chemical and products are put into circulation, and the same is not classified, labeled, and packed in accordance with this Law (Article 5, paragraph 1);
- 2) containers in which hazardous chemical are packed does not match the properties, purpose and method of utilization of the chemical which prevents the loss of packaged content (article 10 paragraph 1);
- 3) the packaging of a substance or mixture classified as dangerous (Article 11 paragraph 1) is not marked with a hazard warning label;
- 4) the label fails to contain additional information on hazardous properties and precautionary measures for dangerous chemicals and mixtures that are not dangerous, yet those contain at least one substance that is classified as a hazardous, in a way that its users are not misled about the hazardous properties of chemicals (Article 11, paragraph 4);
- 5) the remains of hazardous chemicals and empty packaging are not collected, stored and safely disposed of in the prescribed manner (Article 15, paragraph 2);
- 6) the Safety Data Sheet is not provided with a chemical that is put on the market in the prescribed manner (Article 16);
- 7) the Safety Data Sheet is not amended in accordance with new findings on the chemical, particularly any knowledge that may affect the measures to reduce and control risk, or chemical hazard, and

- restrictions or banning the production, circulation and use of chemicals (Article 18, paragraph 1);
- 8) an amended Safety Data Sheet is not provided to each distributor or future user in the supply chain to which the chemical was supplied in the previous 12 months (Article 18, paragraph 2);
- 9) a report on the safety of chemicals is not enclosed with the Safety Data Sheet (Article 19, paragraph 1) and submitted to the Agency;
- 10) the data given in the chemical safety report do not correspond to the data given in the Safety Data Sheet (Article 20, paragraph 1);
- 11) failing to submit an application for registration of chemicals in the register of chemicals produced or imported in the previous year in excess of 100 kg (Article 25 paragraph 1);
- 12) failing to comply with measures to reduce risk, and systematic ways of monitoring the use of substance that causes high concern imposed by the Agency (Article 28 paragraphs 2 and 3);
- 13) failing to submit any change of data entered in the register of chemicals to the Agency (Article 29 paragraph 1);
- 14) failing to keep records of chemicals (Article 30, paragraph 1);
- 15) failing to submit data from the records to the Agency upon request (Article 30, paragraph 3);
- 16) performing transport of hazardous chemicals without a license from the Agency (Article 31 paragraph 1);
- 17) putting into circulation and using chemicals contrary to the prescribed prohibitions and restrictions (Article 34, paragraph 2);
- 18) failing to notify the Agency prior to exporting the chemicals from the List of chemicals subject to the prior notification procedure (Article 35, paragraphs 1 and 3);
- 19) failing to notify the Agency prior to export of chemicals that are on the list of chemicals for the PIC procedure and the chemicals listed under the Rotterdam Convention (Article 37, paragraphs 1 and 2);
- 20) failing to submit to the Agency data on imported and exported quantities of chemicals and products, the countries from which those were exported, or imported chemicals, and data on the importer or exporter of chemicals (Article 39 paragraph 1);
- 21) failing to submit to the Agency a report on the actual quantities exported or imported chemicals or particular products, within 30 days after commission of exports and imports (Article 40 paragraph 1);
- 22) failing to provide the Agency with the information required by the competent authority of the transit country for a chemical listed under the Rotterdam Convention, at least 30 days prior to actual transit (Article 41, paragraph 1);
- 23) distributing detergents that do not meet the requirements of the aerobic biodegradability and if the chemicals and surface active substances contained in detergents do not meet the conditions relating to the classification, packaging and labeling (Article 43);
- 24) industrial detergents and detergents for professional use containing surface-active substances that do not meet the requirements of full aerobic biodegradability are placed on the market without a license for use provided with the detergent and surface active substances, which is issued by the Agency (Article 44 paragraph 1);
- 25) failing to submit to the Agency a technical file of the surface-active substance and up to date information about changes in the quantity of surface active substances in detergents, and how to use detergents (Article 48 paragraph 1);
- 26) non-clinical tests are performed contrary to the GLP guidelines (Article 50, paragraph 2);
- 27) non-clinical tests are performed with no authorization of the Ministry (Article 52, paragraph 1).

For the offense referred to in paragraph 1 of this Article, the responsible person in a legal person shall be subject to a pecuniary penalty of 500-4,000 Euros.

For the offense referred to in paragraph 1 of this Article, an entrepreneur shall be subject to a pecuniary penalty of 1,000-12,000 Euros

XI. TRANSITIONAL AND FINAL PROVISIONS

Secondary Legislation

Article 63

Secondary legislation for the implementation of this Law shall be passed within one year from the date of entry into force of this Law.

Until passing the regulations referred to in paragraph 1 of this Article, secondary legislation adopted on the basis of the Law on the Production and Transport of Toxic Substances ("Official Gazette of FRY", 15/95) shall apply, unless contrary to this Law.

Adoption of the National Strategy

Article 64

The National Strategy for Chemicals Management shall be adopted within two years of the entry into force of this Law.

Termination of the Law

Article 65

On the day of application of this Law, the Law on Chemicals ("Official Gazette of Montenegro", 11/07), the Law on the Manufacture and Sale of Poisons ("Official Gazette of the Socialist Republic of Montenegro", 31/77, 17/82 and 20/88), and the Law on the Production and Trade of Poisonous Substances ("Official Gazette of the FRY" 15/95) shall cease to apply.

Entry into Force

Article 66

This Law shall enter into force eight days after its publication in the "Official Gazette of Montenegro", and apply from 1 March 2013.

Number 27-8/11-2/10

EPA 765 XXIV

Podgorica, 21 March 2012

The 24th Parliament of Montenegro

President,
Ranko Krivokapic, m.p.