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This law partially transposes: art. 191 of the Treaty on the Functioning of the European Union of 25 March 1957, published in the Official Journal of the European Union C 326 of 26 October 2012 (consolidated version); art. 1, 2, 4-6, 8, 35, 43, 46, 47 and 49 of Regulation (EC) no. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548 / EEC and 1999/45 / EC, as well as amending Regulation (EC) no. 1907/2006 (text with EEA relevance), published in the Official Journal of the European Union L 353 of 31 December 2008; art. 1–3, 5–7, 14, 31, 32, 34, 35, 56, 60–62, 68, 118, 119, 121, 123, 125 and 126, Annex IV and point 18a (Mercury) of Annex XVII of Regulation (EC) no. 1907/2006 of the European Parliament and of the Council of 18 December 2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45 / EC and repealing the Regulation (EEC) no. 793/93 of the Council and of Regulation (EC) no. 1488/94, as well as Council Directive 76/769 / EEC and Directives 91/155 / EEC, 93/67 / EEC, 93/105 / EC and 2000/21 / EC (text relevant to EEA), published in the Official Journal of the European Union L 396 of

30 December 2006; art. 1–4, 18 and 28 of Regulation (EU) no. 649/2012 of the European Parliament and of the Council of 4 July 2012 on the export and import of hazardous chemicals (recast) (text with EEA relevance), published in the Official Journal of the European Union L 201 of 27 July 2012; art. 1, 2, 4-6 and 10 of Regulation (EC) no. 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (text with EEA relevance), published in the Official Journal of the European Union L 104 of 8 April 2004; art. 1–3, 28, 29, 31, 33, 40 and 44 of Regulation (EC) no. 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing on the market of plant protection products and repealing Council Directives 79/117 / EEC and 91/414 / EEC, published in the Official Journal of the European Union L 309 of 24 November 2009; art. 1, 3, 17, 19, 20, 22, 25, 48 and Annex V of Regulation (EU) no. 528/2012 of the European Parliament and of the Council of 22 May 2012 on the placing on the market and use of biocidal products (text with EEA relevance), published in the Official Journal of the European Union L 167 of 27 June 2012; art. 1, 3 and 8 of Regulation (EC) no. 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117 / EEC, published in the Official Journal of the European Union L 158 of 30 April 2004; art. 1 of Directive 2004/9 / EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (codified version) (text with EEA relevance), published in the Official Journal of the European Union L 50 from February 20, 2004; art. 1 and the notion "Good laboratory practice" in point 2.1, section I of Annex 1 to Directive 2004/10 / EC of the European Parliament and of the Council of 11 February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practices and verification of their application to chemical tests (codified version) (text with EEA relevance), published in the Official Journal of the European Union L 50 of 20 February 2004; art. 1 of Directive 2006/66 / EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157 / EEC (Text with EEA relevance), published in the Official Journal of the European Union L 266 of September 26, 2006; art. 1 of Directive 2011/65 / EU of the European Parliament and of the Council of 8 June 2011 on the restrictions on the use of certain dangerous substances in electrical and electronic equipment (text with EEA relevance), published in the Official Journal of the European Union L 174 of 1 July 2011; art. 11 of Directive 94/62 / EC of the European Parliament and of the Council of 20 December 1994 on packaging and packaging waste, published in the Official Journal of the European Communities L 365 of 31 December 1994.

Considering the need to ensure the compatibility of the national legislative and normative acts with the European Union legislation through the harmonization procedure, the elimination of contradictions and the establishment of the legal framework necessary to promote a set of legal regulations harmonized with the Community legislation, pursuant to art. 72 paragraph (3) lit. r) of the Constitution of the Republic of Moldova, Parliament adopts this organic law.

Chapter I

GENERAL DISPOSITIONS

Article 1. The object of the law

(1) This law regulates the obligations of natural and legal persons producing or placing chemical substances or mixtures, prohibitions and restrictions on the production, placing on the market, import, export and use of hazardous chemical substances and mixtures, the conditions of classification, labeling and packaging. of chemical substances and mixtures, creation and maintenance of a chemical register, chemical reporting procedure, hazardous chemical authorization procedure, reporting obligations, control and other aspects of chemical substances and

mixtures.

(2) The provisions of the present law also apply to microorganisms, including viruses, as active substances in the composition of plant protection products and biocidal products.

Article 2. Purpose of the law

(1) The purpose of this law is to protect human life and health, the environment and the property from the harmful effects of chemical substances and mixtures.

(2) In order to achieve the purpose stipulated in par. (1):

a) the legal and institutional framework regarding chemical substances and mixtures is strengthened;

b) the public authority in the field of chemicals is established, establishing its attributions, rights and obligations.

Article 3. Domains of law enforcement

(1) The provisions of this Law shall apply to manufacturers, importers, exporters, traders and users of substances as such and in chemical mixtures or articles.

(2) The provisions of this law and the measures adopted pursuant to it shall be without prejudice to:

a) environmental legislation, including pollution prevention and integrated pollution control, regulation of industrial emissions in the environment, management, protection and efficient use of surface and groundwater;

b) legislation on safety and health at work.

(3) Substances, mixtures or articles within the meaning of art. 4 of this law are not considered waste, as defined in Law no. 209/2016 on waste.

(4) The provisions of this law do not apply:

a) radioactive substances regulated by Law no. 132/2012 regarding the safe conduct of nuclear and radiological activities;

b) substances as such, in mixtures or in articles, which are subject to customs supervision and are in temporary storage, in a free zone or in a free warehouse, with the purpose of being re-exported or transited, provided they are not be subjected to any treatment or transformation;

c) to the non-isolated intermediates, presenting the substances which, during the synthesis, intentionally are not removed from the equipment in which the synthesis takes place (except for sampling). Such equipment includes the reaction vessel, its auxiliary equipment and any equipment through which the substance (s) pass (s) during a continuous or discontinuous process, as well as the pipelines through which the transfer from one reaction vessel to another occurs. carrying out the next stage of the reaction, but exclude vats or other containers in which the substance (s) is stored (s) after production;

d) the transport of dangerous goods by air, sea, road, rail, by post or by inland waterways, which are regulated by special legislation.

(5) The provisions of this Law on the registration, authorization and evaluation of substances, intermediaries and dossiers, on downstream users, and on information within the supply chain shall not apply if a substance is used:

1) in medicines for human and veterinary use;

2) in food or feed, including when used:

a) as a food additive in food products;

b) as flavors in food;

c) as an additive in animal feed;

d) in animal feed.

(6) The provisions of the present law on information within the supply chain shall not apply to the following finite state mixtures intended for the end user:

1) medicinal products for human and veterinary use;

2) cosmetic products;

3) invasive medical devices or used in direct physical contact with the human body, insofar as

the classification and labeling of dangerous substances and mixtures correspond to the Regulation on the classification, labeling and packaging of substances and mixtures, approved by the Government;

4) food or feed, including when used:

- a) as a food additive in food products;
- b) as flavors in food;
- c) as an additive in animal feed;
- d) in animal feed.

(7) The substances included in the annex no. Are exempted from the provisions of the present law regarding the registration and evaluation. 6.

(8) The provisions regarding the export and import of dangerous chemicals, stipulated in art. 18, does not apply:

- a) the radioactive substances mentioned in par. (4) lit. a) of this article;
- b) food and food additives;
- c) narcotic and psychotropic substances;
- d) waste;
- e) feed;
- f) genetically modified organisms;
- g) chemical weapons;
- h) patented medicinal products and medicinal products for human and veterinary use, except those regulated by art. 4 pt. 14) lit. c).

(9) The provisions of the present law regarding the classification and labeling of chemical substances and mixtures do not apply:

- 1) the substances and mixtures mentioned in par. (4);
- 2) substances and mixtures intended for scientific research and development, which are not placed on the market, if they are used under controlled conditions, in accordance with the legislation regarding the workplace and the environment;
- 3) substances and mixtures in the following forms which are in the finite state and intended for the end user:
 - a) medicines for human use;
 - b) veterinary medicinal products;
 - c) cosmetic products;
 - d) invasive medical devices or used in direct physical contact with the human body;
 - e) food or feed, including when used as additives and flavors in foodstuffs, as feed additives, in feed.

Article 4. Main concepts

For the purpose of this law, the following main notions apply:

- 1) *mixture* - mixture or solution of two or more substances (components);
- 2) *packaging* - one or more receivers and any other components or materials necessary for the receivers to perform their containment or other security functions;
- 3) *article* - object to which, during manufacture, it is given a special shape, surface or appearance, which determines its function to a greater degree than does its chemical composition;
- 4) *authorization for dangerous chemicals* - permissive act by which the public authority in the field of chemical substances or other authority authorized by this law authorizes the placing on the market and the use of a dangerous chemical, with potential serious effects on health and the environment, mentioned in art. 23 paragraph (1), indicating the chemical name of the substance or constituent substances of the chemical mixture according to the nomenclature system of the International Union of Pure and Applied Chemistry (IUPAC) and the CAS registration number;
- 5) *informed consent prior to importation* - permissive act of import of the dangerous chemical, which is issued by the national authority designated for the Rotterdam Convention of the

importing country following the examination of the export notification of the dangerous chemical, received from the national authority designated for the Rotterdam Convention in the exporting country;

6) *detergent* - any substance or mixture containing soaps and / or other surfactants intended for washing and cleaning processes, manufactured in different forms (liquid, powder, paste, pieces, blocks, castings, molded parts, etc.) and marketed for domestic and institutional or industrial purposes. Other products considered as detergents are:

a) auxiliary washing mixture, intended for soaking (washing), rinsing or bleaching clothes, household linen, etc .;

b) laundry conditioner, intended to modify the fabric fabric in the operations of completing the fabric washing;

c) cleaning mixture for general purpose household cleaning products and / or other surface cleaning products, including materials, products, machinery, mechanical installations, means of transport and related equipment, instruments, equipment, etc .;

d) other cleaning and washing mixtures intended for other washing and cleaning processes;

7) *distributor* - any natural or legal person, including a retailer, whose activity is exclusively for the storage and placing on the market of a substance, either as such or in a mixture, for the benefit of third parties;

8) *importer* - any natural or legal person who is responsible for the import;

9) *supplier of a substance or a mixture* - any manufacturer, importer, downstream user or distributor placing on the market a substance as such or in a mixture or a mixture;

10) *supplier of an item* - any manufacturer or importer of an item, distributor or other operator within the supply chain who places an item on the market;

11) *handling* - any activity or measure involving the production, processing, treatment, packaging, storage, transport, use, disposal, destruction, transformation, marketing, transfer and other similar procedures;

12) *supply chain operator* - producer and / or importer and / or downstream user within the supply chain;

13) *permit for the commercialization, distribution and / or other forms of transfer of particularly dangerous chemicals* - permissive act by which the public authority in the field of chemicals approves the conduct of the activities of commercialization, distribution and other forms of transfer of the particularly dangerous chemicals;

14) *pesticides* - chemicals that fall into one of the following subcategories:

a) pesticides used as plant protection products;

b) biocidal products;

c) disinfectants, insecticides and parasiticides for human use, regulated by Law no. 1409/1997 regarding medicines, or for veterinary use, regulated by Law no. 221/2007 regarding the sanitary-veterinary activity;

15) *placing on the market* - supply to a third party or making it available, either for a fee or free of charge. The importation into the national customs territory is considered as placing on the market;

16) *production* - production or extraction of substances in the natural state, as well as reprocessing, designing, reprocessing, filling, decanting, mixing of chemical substances and mixtures in intermediate products and articles in chemical, physical or biological processes and procedures, as well as transport and intermediate storage at the place of production;

17) *producer* - a natural or legal person who produces a chemical, as well as any other person who processes, repackages or changes its name for later use;

18) *chemical product* - substance present either as such, or in a manufactured or natural mixture or mixture, but which does not include any living organism, which belongs to one of the following categories:

a) pesticides, including pesticide formulations that present a severe risk;

b) industrial chemicals.

The chemical product with an expired term, which became waste within the meaning of art. 2 point 9) of Law no. 209/2016 regarding the waste, is regulated according to its provisions and according to the normative acts approved by the Government;

19) *chemical product that is subject to reporting* - a chemical substance and mixture that belongs to the List of chemical products that are subject to reporting, approved by Government decision;

20) *hazardous chemical* - a chemical substance and mixture that meets the criteria for physical, health or environmental hazards in the Regulation on classification, labeling and packaging of substances and mixtures, approved by the Government;

21) *Particularly dangerous chemical* - any chemical substance and mixture which, in accordance with the Regulation on classification, labeling and packaging of substances and mixtures, is classified in one or more of the following hazard classes:

a) acute toxicity, categories 1, 2 and 3;

b) carcinogenicity, category 1A or 1B;

c) mutagenicity of embryonic cells, category 1A or 1B;

d) reproductive toxicity, category 1A or 1B;

e) skin corrosion, category 1A;

f) toxicity on a specific target organ - a single exposure, category 1;

g) toxicity on a specific target organ - repeated exposure, category 1;

22) *industrial chemical product* - chemical product that belongs to one of the following sub-categories:

a) chemical products for professional use;

b) household chemicals;

23) *biocidal product* - any substance or mixture:

a) which is composed of / contains / generates one or more active substances, with the purpose of destroying, preventing, injuring harmful organisms, preventing their action or exerting a control effect on them any other way than by simple physical or mechanical action, in the form in which it is provided to the user;

b) which is composed of substances or mixtures, other than those provided in letter. a), whose use aims to destroy, prevent or harm the harmful organisms, prevent their action or exert an effect of control on them in any other way than by simple physical or mechanical action.

A treated article that has, first of all, a biocidal function is considered a biocidal product.

The types of biocidal products that are the subject of this law are indicated in the annex no. 5;

24) *plant protection product (also called plant protection product)* - a product consisting of / containing active substances, *plant protection* agents or synergistic agents, in the form in which they are presented to the user, and which is intended for one of the following uses:

a) the protection of plants or plant products against all harmful organisms or the prevention of the action of such organisms, unless it is considered that the main purpose of using these products is rather for hygiene than for the protection of plants or plant products;

b) the influence of the vital processes of the plants, such as the substances that influence their growth, other than the fertilizers;

c) preservation of plant products, insofar as these substances or products do not fall under special provisions on preservatives;

d) destruction of plants, other than algae, or unwanted parts thereof, unless the products are applied, on the ground or in water, for the protection of the plants;

e) the control or prevention of the unwanted growth of plants, except algae, unless the products are applied, on the ground or in water, for the protection of the plants;

25) *restriction* - any condition or prohibition regarding the production, use or placing on the market;

26) *registrant* - the manufacturer or importer of a substance or the manufacturer or importer

of an article, who submits an application for registration of a substance;

27) *substance* - a chemical element and its compounds, in their natural state or obtained by any production process, including any additive necessary to maintain stability and any impurity that derives from the process used, except for any solvent that can be separated without affecting the stability of the substance or without changing its composition;

28) *active substance* - a substance or microorganism that exerts an action on or against harmful organisms;

29) *substance with major risk for human health and the environment* - substance that is part of the List of substances of major risk for human health and the environment, approved by Government decision, which includes:

a) substances that meet the criteria for classification in the carcinogenic hazard class, category 1A or 1B;

b) substances that meet the criteria for classification in danger class mutagenicity of embryonic cells, category 1A or 1B;

c) substances that meet the classification criteria in the hazard class for reproductive toxicity, category 1A or 1B, with adverse effects on sexual function and fertility or on development;

d) substances that are persistent, bioaccumulative and toxic (PBT);

e) substances that are very persistent and very bioaccumulative (vPvB);

f) substances such as those that affect the endocrine system or those that have persistent, bioaccumulative and toxic or very persistent and very bioaccumulative properties, for which there is scientific evidence of probable serious effects on human health and the environment, which raises a level of concern equivalent to that for other substances listed in letter. a) –e) and which are individually identified, if necessary;

30) *use* - any processing, formulation, consumption, storage, storage, treatment, loading in containers, transfer from one container to another, mixing, manufacture of an article;

31) *downstream user* - natural or legal person, other than the producer or importer, who uses a substance, either alone or in a mixture, in his industrial or professional activities, including the legal person who uses the chemical substances to produce the mixtures. A distributor and a consumer are not a downstream user. A re-importer except in accordance with the requirements approved by the Government must be considered as a downstream user.

Article 5. Basic principles

In line with the principles of protection of health and the environment, this law is additionally based on the following principles:

a) the precautionary principle in the management of hazardous substances and chemical mixtures, in order to prevent the impact on human health, the environment and property;

b) the principle of transparency towards consumers, by ensuring access to information on the negative effects that dangerous chemical substances and mixtures can generate;

c) the principle of safety of operations for the management of hazardous chemical substances and mixtures;

d) the "green chemistry" principle, also called the "sustainable chemistry principle", by encouraging the design of products and processes that reduce or eliminate the use and generation of hazardous substances.

Chapter II

POWERS AND ATTRIBUTIONS OF THE AUTHORITIES CENTRAL PUBLIC ADMINISTRATION

Article 6. The powers of the Government

Government:

a) establishes the priority directions of the state policy in the field of chemicals;

b) approves the normative acts necessary for the execution of the present law;

- c) approves the national programs on the sustainable management of the chemical substances and the action plans for the implementation of the national programs on the sustainable management of the chemical substances;
- d) establishes the organization, structure and main directions of activity of the public authority in the field of chemicals.

Article 7. Jurisdiction and powers of the Ministry of Agriculture, Regional Development and the Environment

(1) The Ministry of Agriculture, Regional Development and the Environment is the competent authority, with powers and responsibilities for developing, promoting and coordinating the implementation of the single state policy and the normative framework in the field of integrated chemical management and constitutes the official contact point for the treaties and international agreements related to the present law to which the Republic of Moldova is a party.

(2) The Ministry of Agriculture, Regional Development and the Environment ensures:

- a) promoting the policy in the field of integrated management of substances and chemicals throughout their life cycle;
- b) elaboration and promotion of normative acts of ratification, acceptance, approval or accession to the international treaties related to the present law;
- c) elaboration and promotion of the proposals to modify, as necessary, the present law and other special normative acts related to the present law;
- d) organizing and coordinating the activities of elaboration of programs and action plans in the field of sustainable management of the chemical substances mentioned in art. 33-35;
- e) coordinating the updating activities, according to the provisions of art. 36, of the programs and action plans in the field of sustainable management of the chemicals mentioned in art. 33-35;
- f) to coordinate the activities of preparation of the reports regarding the fulfillment of the national programs and plans of actions in the field of sustainable management of chemical substances and their presentation to the Government, according to the provisions of art. 37;
- g) coordinating the implementation of international treaties and agreements related to the present law to which the Republic of Moldova is a party, with the involvement of other central public administration authorities mentioned in art. 11, within the limits of their competences;
- h) participation in the elaboration of the new international treaties related to the present law or of the amendments to the existing international treaties;
- i) cooperation with the European Commission and its institutions on the legislation on chemicals;
- j) collaboration, in the field of chemical management, with other states and their similar structures in accordance with national law, with the norms of international law and with the treaties to which the Republic of Moldova is a party.
- k) coordinating and monitoring the activities of the National Agency for the Regulation of Nuclear, Radiological and Chemical Activities, subordinated to the Ministry of Agriculture, Regional Development and the Environment, including by examining and approving its annual reports;
- l) organization and functioning of the integrated system for identifying and assessing the dangers and risks caused by the chemicals listed in art. 23 paragraph (1) for the environment, human health, animals, other living organisms and ecosystems, as well as risk management, including by regulating, streamlining, authorizing and registering substances and chemicals for placing on the market or restricting them;
- m) organization and functioning of the system of state control and supervision of the execution of the provisions of the present law and of the normative acts approved under it;
- n) public access to information in the field of chemicals, including through the automated information system "Register of chemicals placed on the market of the Republic of Moldova" and through other databases.

Article 8. National Agency for the Regulation of Nuclear Activities, Radiological and Chemical

(1) The National Agency for the Regulation of Nuclear, Radiological and Chemical Activities (hereinafter referred to as "*National Agency*") is an administrative authority established by the Government, subordinated to the Ministry of Agriculture, Regional Development and the Environment, with the status of legal entity, responsible for the integrated management of the chemicals.

(2) The activity of the National Agency is financed from the state budget, as well as from other sources not prohibited by the normative framework, including from technical and financial assistance projects offered by the development partners and from the international environmental treaties that regulate the chemical substances.

(3) The regulation, structure and limitation of the National Agency are approved by Government decision.

Article 9. Duties of the National Agency

The National Agency has the following basic tasks:

- a) ensures the exercise of the functions of management of the field of integrated management of chemical substances, the management of the application of the provisions of this law and of the regulations resulting from the present law, unless the law provides otherwise;
- b) constitutes the national authority designated for the Rotterdam Convention on the prior informed consent procedure, applicable to certain dangerous chemicals and pesticides that are subject to international trade, to which the Republic of Moldova acceded by Law no. 389/2004;
- c) constitutes the liaison point for communication and cooperation with the European Chemicals Agency with reference to the legislation on chemicals;
- d) participates in the drafting of normative acts that establish regulatory requirements of the activities related to the legislation on chemical substances;
- e) participates in the elaboration of the projects of national programs mentioned in art. 33 and 34 and elaborates the projects of the national action plans, mentioned in art. 35;
- f) issue, at the request of the economic agent, export notifications of chemicals in the case of their export from the Republic of Moldova, send them to the national authority designated for the Rotterdam Convention of the importing party or to the competent authorities of other importing countries and request, if necessary, issuing the prior import consent of the hazardous chemicals and / or the import response in accordance with the procedure regarding the import and export of the hazardous chemicals established by the Government;
- g) examines the export notifications of the chemical substances received from the national authority designated for the Rotterdam Convention by the exporting party and issues the prior informed consent of the dangerous chemicals and / or the import response in accordance with the import procedure; export of dangerous chemicals established by the Government;
- h) releases, based on Law no. 852/2002 for the approval of the Regulation on the commercial regime and the regulation of the use of halogenated hydrocarbons that destroy the ozone layer and of art. 24 of this law, authorizations for the import or export of ozone-depleting substances, equipment and products containing such substances;
- i) confirms the date of receipt of the application for authorization of the products mentioned in art. 24 paragraph (1) lit. a) –f) and, through the one-stop shop for issuing permits, ensures the use of the unique authorization platform for hazardous chemicals;
- j) issue the authorizations mentioned in art. 24 paragraph (1) lit. a), c) –f);
- k) releases, based on art. 27 and 28, permits for the commercialization, distribution and / or other forms of transfer of particularly dangerous chemicals;
- l) insures, based on art. 29 and 30, collecting reports on the chemicals being subjected to reporting, maintaining the automated information system "Register of chemicals placed on the market of the Republic of Moldova" and other databases, as well as placing in the register the

substances as such, in mixtures or subject articles. registration;

m) withdraw the authorization or the permit in case of violation by the holder of the provisions of the legislation in force and of the conditions of the authorization according to Law no. 235/2006 regarding the basic principles of regulating the entrepreneurial activity and Law no. 160/2011 regarding the regulation by authorization of the entrepreneur activity;

n) ensures the assessment of the dangers and risks for the environment within the procedure of registration and authorization of plant protection products, biocidal products and other chemicals mentioned in art. 23 paragraph (1) lit. a) –f) of the present law, as well as in other cases where the scientific assessment of the dangers and risks for the environment is necessary;

o) cooperates with the Inspectorate for Environmental Protection under the subordination of the Ministry of Agriculture, Regional Development and the Environment in the process of supervision and control of compliance with this law and the regulations approved under it;

p) cooperates with other states, institutions and international bodies in the aspects related to risk management associated with chemicals;

q) informs the general public about the provisions of this law, information about the risks posed by chemicals and their use under safe conditions;

r) creates and maintains the National System of Support of Economic Agents in the field of chemicals (Helpdesk), ensuring the provision of advisory and informational assistance to economic agents and individuals who carry out activities of production, placing on the market or use of chemical substances and mixtures, in view the fulfillment by them of the obligations incumbent upon them from this law and from the normative acts approved under it;

s) ensures the establishment and maintenance of the System and inventory of classification and labeling in accordance with the Regulation on classification, labeling and packaging of substances and mixtures;

t) organizes, separately or jointly with other competent authorities, the training and training of subordinate staff or of other ministries and institutions, as well as of the chemical consultants involved in the application of the legislation in the field of chemical substances;

u) organizes, within the limits of competence, seminars, conferences and exhibitions at republican, regional and international level to promote an integrated management of chemical substances;

v) presents to the central environmental body of the public administration annual reports on its activity and arranges their publication.

Article 10. Rights and obligations of the National Agency

(1) The National Agency has the right:

- a) to request the producers, importers, distributors and downstream users to comply with the provisions of the legal acts and other normative acts in force and the conditions of authorization;
- b) to request the manufacturers or importers to submit the safety data sheet for hazardous chemicals and mixtures for professional use and for other chemicals necessary for the protection of health and the environment;
- c) to request the manufacturers or importers to present the data on the hazardous properties and the possible risks associated with the chemicals they place on the market, in accordance with the requirements regarding the classification, labeling and packaging of the substances and mixtures and the safety data sheet, approved by the Government;
- d) require producers or importers to carry out additional tests to evaluate the hazardous properties of chemical substances and mixtures in the manner established by the Government;
- e) to request the manufacturers, importers, distributors, users and holders of authorizations or permits to keep records of chemical substances and mixtures in the form established by the Government and to verify this record;

f) to request the manufacturers or importers and holders of authorizations or permits to present the reports and information in the form provided in the annexes no. 1, 2 and 4;

g) to organize and carry out, at the request of the economic agents, consultancy visits in order to familiarize the operators in the supply chain with the requirements of the normative acts regarding the classification, labeling and packaging of the chemical substances and mixtures and with the requirements of registration, evaluation, authorization and restriction of chemical substances, in accordance with the functions assigned by this law.

(2) The National Agency has the following obligations:

a) to ensure the annual updating of the automated information system "Register of chemicals placed on the market of the Republic of Moldova" and other databases;

b) to ensure, in accordance with the present law and with the legislation in force, the confidentiality of the commercial information obtained in the process of fulfilling the service obligations, except in cases of emergency or other cases provided by law or in cases where such commercial information is already publicly disclosed;

c) to inform operationally the relevant central bodies regarding the detection of violations that can lead to the triggering of the exceptional situation, to the pollution of the environment or to cause harm to the human health and the environment.

Article 11. Powers of other central public administration authorities

(1) Ministry of Health, Labor and Social Protection:

a) initiates and promotes, together with the other competent authorities, the normative acts regarding the protection of human health, including the workers who carry out activities or are in places of work in which dangerous substances or chemical mixtures are present, and in the assessment and control of the risk on which presents to man the dangerous chemical substances and mixtures;

b) identifies, evaluates and manages the risks for human health related to the chemical substances and mixtures placed on the market of the Republic of Moldova;

c) evaluates the dangers and risks for human health in the procedure of authorization of plant protection products, biocidal products and other chemicals mentioned in art. 23 paragraph (1) lit. a) –e), as well as in other cases where it is necessary to evaluate the dangers and risks for human health;

d) organizes toxic-hygienic investigations of dangerous chemical substances and mixtures;

e) ensures the evaluation of the effectiveness in the authorization procedure of the biocidal products mentioned in art. 23 paragraph (1) lit. b);

f) authorizes the biocidal products mentioned in art. 23 paragraph (1) lit. b), using the unique authorization platform for dangerous chemicals, established in accordance with this law;

g) ensures the monitoring, recording, reporting and research of poisoning cases with dangerous chemicals, taking measures to prevent them;

h) ensures the information and awareness of the public and economic agents about the dangers and risks presented by the products mentioned in art. 23 paragraph (1) lit. a) –e) for human health;

i) cooperates, through the National Agency for Public Health, with the Ministry of Agriculture, Regional Development and the Environment in the process of implementing the international environmental treaties related to the present law;

j) cooperates, through the National Agency for Public Health, with the Inspectorate for Environmental Protection in the process of supervision and control of the execution of the provisions of the present law and the regulations approved under it;

k) notifies, through the National Agency for Public Health, the National Agency for the Regulation of Nuclear, Radiological and Chemical Activities and the Inspectorate for Environmental Protection regarding the violations of the provisions of this law and of the regulations approved under it, which are detected in accordance with the control carried out with the powers conferred by special laws in the field of public health and labor protection.

(2) The General Inspectorate for Emergency Situations of the Ministry of Internal Affairs:

- a) Provides specialized assistance to the Customs Service and other institutions empowered with responsibilities in combating the illicit trafficking and use of dangerous chemical substances and mixtures;
- b) cooperates with the Inspectorate for Environmental Protection in the process of supervision and control of the execution of the provisions of this law and of the regulations approved under it;
- c) notifies the Inspectorate for Environmental Protection of the violations of the provisions of this law and of the regulations approved under it, which are detected within the control carried out in accordance with the competences assigned by the special laws in the field of civil protection;
- d) cooperates with the National Agency in the process of implementing the international environmental treaties related to the present law;
- e) has a mandate with the right to receive data from the automated information system "Register of chemicals placed on the market of the Republic of Moldova".

(3) Customs Service of the Ministry of Finance:

- a) performs the control and admission of the introduction / removal from the territory of the Republic of Moldova of chemical substances and mixtures based on the permissive acts issued by the National Agency in accordance with the provisions of the present law and according to the procedure mentioned in art. 18 paragraph (2);
- b) cooperates with the Inspectorate for Environmental Protection in the process of supervision and control of the execution of the provisions of this law and of the regulations approved under it;
- c) notifies the Inspectorate for Environmental Protection about the cases of violation of the provisions of this law and of the regulations approved under it, which are detected within the control carried out in accordance with the competences assigned by the Customs Code of the Republic of Moldova;
- d) cooperates with the National Agency in the process of implementing the international environmental treaties related to the present law;
- e) has a mandate with the right to receive data from the automated information system "Register of chemicals placed on the market of the Republic of Moldova".

(4) National Agency for Food Safety:

- a) performs the supervision and control of the production, import, marketing, use and storage of plant protection products in accordance with the legislation in the field of plant protection;
- b) cooperates with the Inspectorate for Environmental Protection in the process of supervision and control of the execution of the provisions of this law and of the regulations approved under it;
- c) notifies the Inspectorate for Environmental Protection about the cases of violation of the provisions of this law and of the regulations approved under it, which are detected in the control carried out in accordance with the competences assigned by the special legislation in the field of plant protection products;
- d) has a mandate with the right to receive data from the automated information system "Register of chemicals placed on the market of the Republic of Moldova".

Chapter III

GENERAL RESPONSIBILITIES AND OBLIGATIONS OF OPERATORS IN THE SUPPLY CHAIN

Article 12. General obligations of operators in the supply chain

(1) Manufacturers and importers of chemical substances and mixtures are obliged:

- a) to identify and evaluate the hazardous properties and possible human and environmental

risks of the chemicals they supply;

b) to have information on the identification, dangerous properties and possible risks of the chemicals they supply;

c) to provide users and other persons handling the chemical with information on the evaluation results and other available and relevant information on the hazardous properties of the chemical, on the risks and safety measures;

d) to constantly update the available information on chemicals.

(2) In order to evaluate the hazardous properties of chemical substances and mixtures, manufacturers and importers of chemical substances and mixtures are required to carry out tests in laboratories that comply with the principles of good laboratory practice, established by the Government, in the following cases:

a) the chemical substance or mixture placed on the market constitutes a new domestic product;

b) the producers and importers do not have the necessary information according to par. (1) lit. b) and there is no data available for the proper evaluation of the chemical substance or mixture without carrying out laboratory tests;

c) in the scientific literature specialized data have appeared regarding the potential dangerous properties of the substance or the constituent substances of the chemical mixture;

d) there are no other means of obtaining the information needed to evaluate the substance or mixture without performing the tests.

(3) The tests mentioned in par. (2) shall be carried out in accordance with the methods indicated in the Regulation on the establishment of methods for testing chemical substances and in other normative acts approved by the Government.

(4) Any operator in the supply chain of a substance or mixture shall:

a) to transmit to the operator or distributor immediately upstream of the supply chain the information provided by producers and importers;

b) inform the operator or distributor immediately upstream of the supply chain about the new information he has identified regarding the dangers and risks of the chemicals and the safety measures.

(5) For the purpose of preventing or avoiding damage to human health and the environment, all natural or legal persons handling chemicals must take the necessary protective measures that they have identified themselves or have been notified in accordance with. with this article.

Article 13. Information on the danger and risk of substances and mixtures
chemical

(1) Depending on the danger it presents, the chemical substances and mixtures must be classified and labeled with data on the identity of the economic agent placing the chemical on the market, the name of the substance or product, the dangerous properties, the name of the component elements that contribute to the classification. substance, as well as the safety measures for use, in accordance with the requirements set out in the Regulation on classification, labeling and packaging of substances and mixtures.

(2) The supplier of a chemical for professional use that meets the criteria for classification as a hazardous chemical, a particularly dangerous chemical or as a substance with a major risk to human health and the environment must submit to the recipient a safety data sheet, in the established form by the Government, with detailed information such as components, physico-chemical properties, ecological and toxicological data, information on hazards, exposure and personal protection, first aid and response measures in case of unintended spread in the environment and with other information necessary to protect health and the environment.

(3) The safety data sheet mentioned in par. (2) is provided free of charge in the supply chain, on paper or in electronic format, no later than the date on which the substance or mixture is first delivered.

(4) The safety data sheet is drawn up in Romanian.

Article 14. Packaging of chemical substances and mixtures

(1) The packaging of the chemical substances and mixtures shall be carried out before being placed on the market in such a way as to ensure their safe delivery and not to endanger the environment, life and health of humans and other living organisms.

(2) Chemical substances and mixtures shall be placed on the market only when they are packaged in accordance with the provisions of this law and of the Regulation on classification, labeling and packaging of substances and mixtures.

(3) The packaging of hazardous substances and mixtures must meet the following requirements:

a) the materials for making the packaging and the closing systems are not likely to be attacked by the contents and do not form dangerous compounds with it;

b) the packages and the closing systems must be strong and robust, so that any possibility of product loss is excluded, and meet the safety criteria under normal handling conditions.

(4) The packaging of hazardous substances or mixtures delivered to the general public shall not have a form or aspect which will attract or provoke the active curiosity of the children, or mislead the consumers, and also will not have a similar presentation or appearance. used for food, feed or cosmetics or medicines to mislead consumers.

(5) The packaging of dangerous substances or mixtures shall be provided with a child-resistant closing system and a tactile hazard warning device, in accordance with the Regulation on classification, labeling and packaging of substances and mixtures.

Article 15. Presentation of information on chemicals

(1) The natural and legal persons who import / export and / or those who use chemicals for professional purposes provide, at the request of the National Agency, within 90 days, information about the chemicals and their handling, necessary for the assessment of the health risks. or for the environment associated with the product and its handling, as well as for the implementation of risk reduction measures.

(2) The natural and legal persons who produce, import and / or market a chemical must inform the National Agency immediately, but not later than 10 days, of any new information that becomes available after the issuance of an authorization or a permit and which indicates that the chemical or residues of an active substance in the product could have adverse effects on human health, groundwater or the environment in general.

(3) The provisions of para. (2) also applies to chemicals that are not subject to authorization or permit requirements if new information becomes available that the product may have carcinogenic, mutagenic or toxic properties for reproduction, information that may influence classification or its labeling.

(4) The information requested according to par. (1) is presented in the form established in the annex no. 1.

(5) New information on the dangers and risks of the chemical products mentioned in par. (2) is presented in accordance with annex no. 2.

Article 16. Qualification of personnel - chemical consultant

(1) Natural and legal persons engaged in activities with dangerous chemicals must have access to the expertise necessary to comply with the provisions of the legislation on chemicals and to assume responsibility. The economic agents employ a qualified person (hereinafter referred to as a chemical consultant) who ensures the management of chemical substances and mixtures.

(2) The chemistry consultant shall pass the qualification test every 3 years.

(3) The Ministry of Agriculture, Regional Development and the Environment, in collaboration with the Ministry of Education, Culture and Research and with the Ministry of Health, Labor and Social Protection, coordinates the development of training programs and testing of chemical consultants involved in placing chemicals on the market. , in order to ensure a high

level of protection of human health and the environment against the risks that may arise from the use of chemicals.

(4) The training and testing for obtaining the qualification certificate of a chemical consultant shall be carried out by the institution or the company that fulfills the conditions regarding the teaching staff, the technical equipment and has the necessary spaces for training. The training is carried out against payment.

(5) In order to carry out the training of professional skills development in the field of chemical management, the Ministry of Agriculture, Regional Development and the Environment shall cooperate with the institution or enterprise accredited in accordance with Law no. 235/2011 regarding accreditation and conformity assessment activities.

Chapter IV

PROHIBITIONS AND RESTRICTIONS

Article 17. Prohibitions and restrictions for some substances and mixtures
chemical

(1) For the protection of health and the environment, some particularly dangerous chemical substances and mixtures may be prohibited or restricted to production, placing on the market and use by natural and legal persons.

(2) In the context of para. (1) and for the execution of the provisions of the international treaties to which the Republic of Moldova is a party, the production, placing on the market and use of mercury and its compounds are prohibited:

1) in medical thermometers;

2) in other measuring devices intended for marketing to the general public, such as:

a) barometer;

b) pressure gauges;

c) sphygmomanometers;

d) thermometers, other than medical ones;

3) in measuring devices intended for industrial and professional uses, such as:

a) barometer;

b) hygrometer;

c) pressure gauges;

d) sphygmomanometers;

e) deformation measuring devices, used in plethysmographs, tensiometers, thermometers and other non-electric thermometric applications.

The restriction also applies to those devices which are placed on the market empty if they are intended to be filled with mercury.

The restriction does not apply to sphygmomanometers used as reference standards in clinical validation studies of mercury-free sphygmomanometers and mercury-based cells for triple point measurement, which are used in calibrating platinum-resistant thermometers;

4) in measuring devices intended for industrial and professional uses, such as mercury-based pycnometers and mercury-containing measuring devices for determining the softening point;

5) in pesticides used as plant protection products;

6) in biocidal products;

7) in local antiseptics, which are antimicrobial agents used to destroy, inhibit or reduce the number of microorganisms on the skin;

8) in cosmetic products (with mercury content exceeding 1 ppm), including in soaps and skin whitening creams, except those intended for the eye area, where mercury is used as a preservative and there is no effective preservative to replace it;

9) in dental amalgams.

(3) The detailed list of prohibited and restricted chemical substances and mixtures is approved

by the Government.

(4) The list of chemical substances and mixtures prohibited and restricted to production, import, placing on the market, export and other types of uses or manipulations, including their use in articles, will be adjusted in accordance with internationally modified changes.

(5) Requirements for the use of hazardous chemicals, including persistent organic pollutants, such as mercury, lead, cadmium, organic tin compounds, hexavalent chromium, phthalates, ozone-depleting substances, including hydrochlorofluorocarbons, in electrical equipment and electronic, in vehicles, accumulators and batteries, packaging or packaging components and in other articles or devices manufactured or placed on the market, are established by special legislation.

(6) Natural and legal persons may place detergents on the market if the surfactants contained in them meet the criteria for final aerobic biodegradation and if the chemicals and surfactants contained in the detergents meet the conditions set out in this regulation and the regulation of Government.

(7) The Ministry of Agriculture, Regional Development and the Environment ensures the implementation of international environmental treaties ratified by the Republic of Moldova, which include prohibitions and restrictions.

Chapter V

EXPORT AND IMPORT OF PRODUCTS DANGEROUS CHEMICALS

Article 18. Export and import of hazardous chemicals

(1) In the context of this law, the provisions of this article do not apply to chemicals exported for research or analysis in quantities where there is no likelihood of affecting human health or the environment and which do not exceed 10 kg per exporter to each country per year. calendar.

(2) Exporters and importers of chemicals must comply with the procedure for the import and export of hazardous chemicals, based on the Rotterdam Convention on Prior Informed Consent, applicable to certain hazardous chemicals and pesticides that are the subject of international trade. .

(3) The procedure regarding the import and export of dangerous chemicals mentioned in par. (2) is provided in the Regulation on the export and import of dangerous chemicals approved by the Government and applies:

a) certain hazardous chemicals subject to the prior informed consent procedure, in accordance with the Rotterdam Convention also referred to as the "PIC procedure";

b) certain dangerous chemicals that are banned or subject to severe restrictions in the Republic of Moldova;

c) exported chemicals, in terms of their classification, labeling and packaging.

(4) The Ministry of Agriculture, Regional Development and the Environment is responsible for the implementation of the Rotterdam Convention and, in accordance with the provisions of art. 7 paragraph (1) of this law, ensures the fulfillment of the functions of the official contact point for this Convention.

(5) The National Agency is the national authority designated for the administrative tasks related to the implementation and management of the Rotterdam Convention.

Article 19. Prior informed consent of import

(1) Prior consent of import in the knowledge of the case shall be issued by the National Agency in accordance with the provisions of art. 9 lit. g) and with the procedure provided for in the Regulation on the export and import of dangerous chemicals.

(2) Prior informed consent of the case, mentioned in par. (1), shall be issued at the request re-

ceived from the designated national authority of the Party of the Rotterdam Convention or another exporting country, accompanied by the export notification for the substance, and shall be sent to it in the format set out in the Regulation on export and import of hazardous chemicals.

(3) The prior import consent in the knowledge of the case shall be issued free of charge, until the import is carried out.

Chapter VI

THE PRINCIPLES OF GOOD LABORATORY PRACTICE

Article 20. Principles of good laboratory practice

(1) In the context of the present law, good laboratory practice presents a quality system that deals with the way of organization and the conditions under which the non-clinical safety studies related to health and the environment are planned, conducted, verified, archived and reported. .

(2) Testing the dangerous properties of chemical substances and mixtures, mentioned in art. 12 paragraph (2) of the present law, is carried out in laboratories that are accredited by the national accreditation body in accordance with the provisions of Law no. 235/2011 regarding the activities of accreditation and conformity assessment and respecting the principles of good laboratory practice established by the Government.

(3) Manufacturers and importers of chemical substances and mixtures may submit test results for the evaluation of hazardous properties carried out in international laboratories that comply with the principles of good laboratory practice.

Chapter VII

REGISTRATION AND AUTHORIZATION

Section 1

Registration of chemicals

Article 21. Main requirements for the registration of chemicals

(1) Substances as such, in mixtures or in articles, are not placed on the market unless they are registered in accordance with this law and with the normative acts approved by the Government.

(2) The substances are registered in the automated information system "Register of chemicals placed on the market of the Republic of Moldova", provided in art. 30 and held by the National Agency.

(3) The registration of the chemical substances shall be carried out against payment.

(4) In the case of placing on the market of the substance which, at the time of the entry into force of this law, has already been registered at European level by the Chemicals Agency, the producer or importer shall present the proof of registration, together with the registration dossier submitted to National Agency, for inclusion in the automated information system "Register of chemicals placed on the market of the Republic of Moldova".

(5) For the registration in the Automated Information System "Register of chemicals placed on the market of the Republic of Moldova", any manufacturer or importer of a substance as such or in a mixture or mixtures, in annual quantities of 100 kg or greater, shall submit To the National Agency a request for registration accompanied by the technical file.

(6) For the registration of monomer substances contained in polymers, any manufacturer or importer of a polymer shall submit to the National Agency a registration application, together with the technical file, for the monomer / monomer or any other / other non-substance / substances. a / were still registered by an operator upstream of the supply chain, in the following cases:

- a) the polymer contains at least 2% by weight of the monomer substance / substances or other / other substances in the form of monomer units and chemically bound substance (s);
- b) the total quantity of such substance (s) monomer / monomers or other / other substance (s) is at least 100 kg / year.

(7) For the registration of the substances in the composition of the articles, any producer or importer of articles shall submit to the National Agency a registration application, together with the technical file, for any substance in the composition of the respective articles, in the following cases:

- a) the substance is present in the respective articles in quantities exceeding 100 kg / year for a producer or importer;
- b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.

(8) In the registration process, if the substance meets the classification criteria provided in art. 4 point 29) according to the Regulation on the classification, labeling and packaging of substances and mixtures, any manufacturer or importer of articles notifies the National Agency about it, in accordance with par. (10) of this article, in the following cases:

- a) the substance is present in the respective articles in quantities exceeding 100 kg / year for a producer or importer;
- b) the substance is present in the respective articles in a concentration of more than 0,1% by weight.

(9) The provisions of para. (8) does not apply if the manufacturer or importer excludes exposure of humans or the environment under conditions of use, including disposal, of the substance present in the articles. In such cases, the manufacturer or importer shall provide the beneficiary of the article with appropriate instructions.

(10) In the cases provided in par. (8), any manufacturer or importer must provide the following information:

- a) the name / name and contact details of the manufacturer or importer;
- b) the registration number (s);
- c) the name of the substance (s);
- d) classification of the substance (s);
- e) a brief description of the use of the substance;
- f) the quantity of the substance (s).

(11) The National Agency requests the producers or importers of articles to submit a registration application, accompanied by the technical file, in the following cases:

- a) the substance is present in the respective articles in quantities exceeding 100 kg / year for a producer or importer;
- b) The National Agency has reason to suspect that the substance is emitted from the respective articles and the emission of the substance presents a risk to human health or the environment;
- c) the substance is not subject to par. (7).

(12) The provisions of para. (7) - (11) do not apply to substances previously registered for that use.

(13) The procedure for registration and notification of substances and products is established by Government decision.

Article 22. Chemical safety assessment and report preparation security

1. Any manufacturer or importer requesting registration of the substance in quantities of at least 10 t per year shall be required to carry out a chemical safety assessment and to draw up a chemical safety report for all substances subject to registration in accordance with this Article.

(2) The chemical safety assessment of a chemical substance includes the stages of the assessment of the dangers to human health and the environment, of the physico-chemical properties, of the classification as persistent, bio-accumulative and toxic and very persistent and very bio-accumulative. Depending on the results, the chemical safety assessment may include additional steps that include:

a) exposure assessment, including the elaboration of an exposure scenario (s) (or, where appropriate, identification of the relevant types of use and exposure) and exposure estimation, as well as the assessment of the danger to human health;

b) risk characterization.

(3) Exposure scenarios (or, as appropriate, types of use and exposure), exposure assessment and risk characterization referred to in par. (2) refers to all identified uses of the registrant.

(4) The chemical safety report does not need to take into account the risks posed to human health by the following end uses:

a) in the materials destined to come in contact with the food products;

b) in cosmetic products.

(5) Any applicant for the registration of the substance:

a) identify and apply appropriate risk control measures identified in the chemical safety assessment and, where appropriate, recommend them in the safety data sheets they provide;

b) who has the obligation to carry out a chemical safety assessment, he / she ensures that his / her chemical safety report is made available to the public and is updated.

Section 2

Authorization of hazardous chemicals

Article 23. Chemicals subject to authorization

(1) The following chemicals may not be produced, imported, placed on the market and used without following the authorization procedure:

a) plant protection products;

b) biocidal products;

c) detergents containing surfactants that do not meet the criteria for final aerobic biodegradation;

d) substances with major risk for human health and environment;

e) hazardous industrial chemicals;

f) chemicals that destroy the ozone layer, equipment and products containing such substances.

(2) The chemical products mentioned in par. (1) lit. a) –e) may be authorized by a simplified procedure if the applicant confirms the approval and / or authorization of the chemical for the types of uses requested in one of the Member States of the European Union.

(3) The simplified authorization procedure mentioned in par. (2) is a procedure for recognizing the authorizations granted by a Member State of the European Union and is provided by Government decision.

(4) The chemical substances that destroy the ozone layer, the equipment and products containing such substances are authorized by the National Agency in accordance with the provisions of Law no. 852/2002 for the approval of the Regulation on the commercial regime and the regulation of the use of halogenated hydrocarbons that destroy the ozone layer.

Article 24. Issue of authorization

(1) Authorizations for hazardous chemicals shall be issued as follows:

a) the authorization for the plant protection products indicated in art. 23 paragraph (1) lit. a) - according to art. 9 lit. j);

b) the authorization for the biocidal products indicated in art. 23 paragraph (1) lit. b) - according to art. 11 paragraph (1) lit. f);

c) the authorization for detergents containing surfactants that do not meet the criteria for final

aerobic biodegradation indicated in art. 23 paragraph (1) lit. c) - according to art. 9 lit. j);
d) the authorization for the chemical products with major risk for human health and the environment indicated in art. 23 paragraph (1) lit. d) - according to art. 9 lit. j);
e) the authorization for hazardous industrial chemicals indicated in art. 23 paragraph (1) lit. e) - according to art. 9 lit. j);
f) the authorization for the import, export or re-export of ozone-depleting chemicals, equipment and products containing such substances - in accordance with art. 9 lit. h) and art. 23 paragraph (4).

(2) The authorizations mentioned in par. (1) lit. a) –e) are issued through the unique platform created within the National Agency, based on the authorization decisions adopted by the inter-ministerial council mentioned in par. (3), specifies the terms and conditions of placing on the market and use of the product and includes a summary of its characteristics.

(3) The decision to approve or refuse the authorization of the substances and chemicals mentioned in art. 23 paragraph (1) lit. a) –e) is adopted by the inter-ministerial council, constituted by the Government from representatives of the central public administration authorities provided in art. 7–11, of scientific institutions and non-governmental organizations. The decision is adopted following the examination of the results of the assessment of the dangers and risks for the health of humans, animals, other living organisms and the environment.

(4) In order to obtain the authorization, the applicant submits the following documents to the National Agency:

a) the request for authorization;

b) the technical file, which will contain data on the name, characteristics and properties of the chemicals for which authorization is requested, the results of the evaluation of the risks related to the product and its handling, the intended use of the product, the expected product quantity to be placed on the market in the form approved by the Government. Content of the technical file that is annexed to the application for authorization of the chemical products mentioned in par. (1) is established by the Government.

(5) In the case of the simplified procedure referred to in art. 23 paragraph (2), the authorizations provided in par. (1) of this article shall be issued without payment, within 10 working days from the date of receipt of the complete file.

(6) In the case of the applicant's submission of the application for authorization of a chemical for which the simplified authorization procedure does not apply, the examination of the application and the technical file shall be paid.

(7) The name and address of the authorization holder, the number and the date of issue of the authorization, as well as the term of validity of the authorization are specified in its contents. The term of issue and the term of validity of the authorizations mentioned in par. (1) shall be established at the time of receipt of the complete file, in accordance with the annex no. 3.

Article 25. Conditions for issuing and extending the authorization

1. The authorization may be granted if:

a) when using the chemical for the intended purpose and in a way that reflects the known and accepted practices of risk management, the effects on the health and the environment are acceptable;

b) the chemical is necessary for the purpose specified in the authorization application and cannot be replaced by chemicals or safer alternative technologies.

(2) In the context of art. 17 and para. (1) lit. a) from this article, the authorizations mentioned in art. 24 paragraph (1) lit. a) and b) if the plant protection product or the biocidal product:

1) is composed of or contains:

a) mercury and / or its compounds;

b) persistent organic pollutants;

2) being intended for placing on the market for use by the general public, in accordance with the requirements regarding the classification, labeling and packaging of the substances and

mixtures approved by the Government, it fulfills the criteria to be classified:

- a) toxic or very toxic;
- b) carcinogen category 1 or 2;
- c) category 1 or 2 mutagen;
- d) toxic for reproduction category 1 or 2;
- e) in the hazard class acute oral toxicity category 1, 2 or 3;
- f) in the hazard class acute skin toxicity category 1, 2 or 3;
- g) in the hazard class acute toxicity by inhalation (gases and dust / mist) category 1, 2 or 3;
- h) in the hazard class acute toxicity by inhalation (vapors) category 1 or 2;
- i) in the hazard class carcinogenicity category 1A or 1B;
- j) in the hazard class mutagenicity category 1A or 1B; or
- k) in the hazard class reproductive toxicity category 1A or 1B;

or

3) being intended for placing on the market for use by the general public, it fulfills the criteria to be identified as:

- a) a product that is composed of / contains / generates a substance that meets the criteria to be identified as persistent, bioaccumulative and toxic or very persistent and very bioaccumulative;
- b) product with properties that affect the endocrine system or have neurotoxic or immunotoxic effects on development.

(3) The special conditions for issuing authorizations for each of the chemicals mentioned in art. 23 are stipulated by regulation approved by the Government.

(4) The authorization applicant must meet the following conditions:

- a) confirm the employment of at least one chemical consultant in accordance with the provisions of art. 16;
- b) has internal instructions regarding the own control of the chemical products, approved by the General Inspectorate for Emergency Situations and necessary for the prevention and mitigation of the consequences of incidents and accidents involving dangerous chemicals that could adversely affect the life and health of their own personnel, of the population and the environment;
- c) has environmental insurance, which could recover possible damages in the size established by special law;
- d) establishes and maintains its own control and emergency preparedness system in the event of incidents or accidents involving dangerous chemicals, approved by the General Inspectorate for Emergency Situations;
- e) establishes and maintains in its activity the record of the production, import, marketing and use of dangerous chemicals in the Register of Records, in the form established by the Government;
- f) establish and maintain a public information system in exceptional situations, in accordance with the special law.

(5) After the expiry of the term of validity of the authorization, the extension of its validity shall be carried out in accordance with the provisions of art. 6 of Law no. 160/2011 regarding the regulation by authorization of the entrepreneur activity.

Article 26. Withdrawal or suspension of the authorization

(1) The authorization shall be suspended pursuant to art. 10 paragraph (2) lit. a) of Law no. 160/2011 regarding the regulation by authorization of the entrepreneur activity.

(2) The authorization is withdrawn pursuant to art. 11 of Law no. 160/2011 regarding the regulation by authorization of the entrepreneur activity, as well as in all cases where it is found that:

- a) the authorization holder, during the activity, did not comply with the provisions of this law

and the normative acts approved under it or not complied with the conditions set out in the authorization and / or used the chemical for purposes other than those specified in the authorization;

b) false or misleading information was provided about the data on which the authorization was granted;

c) new information, unknown at the time of issuing the authorization, regarding the risk of the use of substances and mixtures that may affect human health or the environment appear.

Chapter VIII

MARKETING, DISTRIBUTION AND OTHER

FORMS OF TRANSFER OF SPECIFIC DANGEROUS CHEMICALS

Article 27. Permission for the commercialization, distribution and / or other forms of transfer of particularly dangerous chemicals

(1) In order to initiate and carry out the activities of commercialization, distribution and other forms of transfer of particularly dangerous chemicals, the entrepreneur needs a permit .

(2) Particularly dangerous chemicals may be marketed, distributed and / or transferred only:

a) for professional use;

b) to the legal and natural persons who carry out business as an entrepreneur and hold a permit in accordance with par. (1).

(3) The legal and natural persons who act as an entrepreneur and who market, distribute and / or transfer very dangerous chemicals in accordance with par. (2) it must keep records of the operations of commercialization, distribution and / or transfer of particularly dangerous chemicals in the register of records, in the form established by the Government. The register shall include:

a) the name of the chemical;

b) the quantity of chemical product sold, distributed and / or transferred;

c) the name and contact details of the client, as the case may be;

d) purpose of use (production or direct use);

e) the date of the marketing, distribution and / or transfer operation.

(4) It is forbidden to commercialize particularly dangerous chemicals on the basis of the entrepreneurial patent.

Article 28. Issuance, extension, suspension and withdrawal of the permit

(1) The permit for the commercialization, distribution and / or other forms of transfer of particularly dangerous chemicals may be issued if the applicant:

a) confirms the access to the necessary expertise according to with the provisions of art. 16;

b) has internal instructions regarding the own control of the chemicals, necessary for the prevention and mitigation of the consequences of incidents and accidents with the involvement of chemicals that could adversely affect the life and health of the personnel, the population and the environment;

c) keeps records of the operations of commercialization, distribution and / or transfer of particularly dangerous chemicals in the register of records.

(2) The permit shall be issued by the National Agency for a term of 5 years.

(3) In order to obtain the permit, the applicant submits to the National Agency a request for issuing the permit, which will include the following data on the chemical for which the permit is requested:

a) the name of the substance or constituents of the hazardous chemical mixture;

b) the quantity of chemical product expected to be marketed, distributed and / or transferred by the applicant;

c) the expected way of using the chemical;

d) confirmation of the employment of at least one chemical consultant.

(4) The National Agency shall issue the permit for the commercialization, distribution and / or other forms of transfer of the particularly dangerous chemicals free of charge, within 10 working days from the date of submission of the application, if the conditions provided in par. (1).

(5) After the expiry of the term of validity of the permit, the extension of its validity shall be carried out in accordance with the provisions of art. 6 of Law no. 160/2011 regarding the regulation by authorization of the entrepreneur activity.

(6) The permit is suspended pursuant to art. 10 paragraph (2) lit. a) of Law no. 160/2011 regarding the regulation by authorization of the entrepreneur activity.

(7) The withdrawal of the permit for the commercialization, distribution and / or transfer of particularly dangerous chemicals shall be carried out under the conditions of art. 11 of Law no. 160/2011 regarding the regulation by authorization of the entrepreneur activity, in the following cases:

a) the holder does not respect the conditions of the present law;

b) in the process of the control carried out by the Inspectorate for Environmental Protection, there are negative effects on the environment or human health as a result of the activity of commercialization, distribution and / or transfer of the particularly dangerous chemical product;

c) the holder does not keep the record of the operations of commercialization, distribution and / or transfer in accordance with art. 27 paragraph (3) of the present law.

Capitolul IX

RAPORTAREA PRODUSELOR CHIMICE

Article 29. Obligation to report chemicals

(1) Any legal entity that initiates or carries out an activity of production or import of a chemical in a volume of at least 100 kg per year shall report to the National Agency. The report is to be issued within one month from the date of commencement of the activity and must include data on the identity of the rapporteur, the name of the chemical product (s), other data on the chemical product (s) according to the form reporting of a chemical provided in annex no. 4.

(2) The list of chemicals that are subject to reporting, with the indication of tariff codes, is approved by the Government.

(3) The rapporteur shall update the reporting data and submit annually, by March 31, to the National Agency information on chemicals manufactured or imported in the last calendar year.

(4) The reporting form of a chemical is completed and presented in electronic form or in paper format.

(5) The manufacturer or importer of chemicals may delegate to another person the responsibility to report the chemicals.

(6) The manufacturer or importer of chemical products must inform the National Agency in writing, by November 1 of the year for which the report will be made, about the delegation of a person, indicating his name and contact details, with the attachment of the copy of the contract. mandate. Otherwise, the manufacturer or importer of chemicals is required to report the chemical product (s) on its own.

Article 30. The automated information system "Product Register chemicals placed on the market of the Republic of Moldova "

(1) The automated information system "Register of chemicals placed on the market of the Republic of Moldova" forms the specialized information resource regarding the chemicals placed on the market of the Republic of Moldova.

(2) The holder of the automated information system "Register of chemicals placed on the market of the Republic of Moldova" is the Ministry of Agriculture, Regional Development

and the Environment.

(3) The automated information system "Register of chemicals placed on the market of the Republic of Moldova" is formed on the basis of the registration record according to art. 21, of the authorization according to art. 24 and the reporting provided for in art. 15 and 29.

(4) The National Agency is the holder of the automated information system "Register of chemicals placed on the market of the Republic of Moldova" and the data recorder within this system.

(5) Any legal entity that carries out an activity of production or import of a chemical product is obliged to submit information in accordance with this law and with the Regulation on the way of keeping the Register of chemicals placed on the market of the Republic of Moldova approved by the Government.

(6) The creation, operation and operation of the automated information system "Register of chemicals placed on the market of the Republic of Moldova" shall be carried out in accordance with the provisions of the legislation in force in the field of resources and state information systems.

Chapter X

STORAGE, STORAGE AND TRADE RETAIL OF CHEMICALS

Article 31. Storage and storage of chemicals

(1) Manufacturers, importers, distributors and downstream users store and store chemicals in such a way that they do not endanger the environment, life and health of humans, animals and other living organisms.

(2) The natural and legal persons mentioned in par. (1) of this article have the obligation to collect, store and safely dispose of hazardous chemical waste and packaging waste used for hazardous chemicals, in accordance with the provisions of Law 209/2016 on waste and regulatory acts approved by Government.

(3) The storage of hazardous chemicals is allowed only in warehouses designed, constructed and arranged in accordance with the norms in constructions established by the Government or reconstructed for this purpose and destined exclusively for the storage of these products.

(4) The chemical products shall be stored and stored only in the manufacturer's packaging, which corresponds to the provisions of the Regulation on the classification, labeling and packaging of substances and mixtures.

(5) The storage, storage and trade of dangerous non-packaged chemicals shall be prohibited.

(6) The normative acts regarding the storage and storage of chemicals are approved by the Government.

Article 32. Retail trade of chemicals

(1) Chemicals that are marketed as household products and which can be sold in specialty stores for chemicals and other stores must be kept separate from other items so as not to come in contact with them, not to it is within the reach of children, and consumers should not be misled about their purpose. Incompatible chemicals are not stored side by side.

(2) The requirements for storing chemicals in the marketing area and the marking of the area are established by the Government.

Chapter XI

PROGRAMS AND ACTION PLANS ON SUSTAINABLE MANAGEMENT OF CHEMICALS

Article 33. Sustainable management programs and action plans of chemicals

The programs and action plans on the sustainable management of chemicals will target:

- a) creating the normative and institutional framework to ensure the sustainable management of chemicals;
- b) the application of the provisions of the present law, of the strategic acts of national development, of the National Strategy regarding the reduction and elimination of persistent organic pollutants and of other relevant policy documents;
- c) creating the specialized capacities and infrastructure necessary to ensure environmentally safe chemical management;
- d) implementation of the provisions of the international treaties to which the Republic of Moldova is a party;
- e) assessing the impact of the use of chemical substances on the environment and establishing measures to reduce the risks caused by dangerous chemicals;
- f) the criteria for evaluating the results of the implementation of the measures provided for in the respective programs and plans.

Article 34. National program on the sustainable management of substances chemical

(1) The National Program for the Sustainable Management of Chemicals (hereinafter referred to as the *National Program*) is the main long-term strategic planning document, which determines the state's policies and the specific objectives for the development of the sustainable chemical management system in the country and is approved, by Government decision, for a term of 10 years.

(2) The national program sets goals, objectives and actions designed to create an integrated system of chemical management, efficient from a technical, economic, social and ecological point of view, as well as the record of the coordinated implementation of the provisions of the international policy documents and treaties. in the given field to which the Republic of Moldova is a party.

(3) The national program is elaborated by the Ministry of Agriculture, Regional Development and the Environment, with the participation of the National Agency. When elaborating the National Program, the central and local public administration authorities provide the necessary informational and organizational assistance, within the limits of their functional competence.

Article 35. National action plan on the sustainable management of substances chemical

(1) The National Action Plan on the Sustainable Management of Chemicals (hereinafter referred to as the *National Plan*) provides for the implementation of policies for the sustainable management of chemicals, in accordance with the National Program, and is approved, by Government Decision, as a document. planning for a period of 5 years.

(2) The national plan shall be elaborated by the National Agency in collaboration with the authorities of the central and local public administration, which shall provide the necessary assistance within the limits of their functional competence.

Article 36. Update of the National Program and the National Plan

(1) The national program and the National Plan shall be evaluated by the Ministry of Agriculture, Regional Development and the Environment every 2 years and shall be reviewed, if necessary, at least every 5 years, in accordance with art. 34 of this law and with its obligations under the international treaties to which the Republic of Moldova is a party.

(2) The Ministry of Agriculture, Regional Development and the Environment and the National Agency offer the public the opportunity to participate in the updating of the National Program and of the National Plan, in accordance with the provisions of the Convention on ac-

cess to information, justice and public participation in making decisions in the field of environment in which The Republic of Moldova is a party, as well as with the legislation and procedures in force.

Article 37. Report on the implementation of the National Program and a National plan

(1) The report on the implementation of the National Program and of the National Plan shall be prepared by the National Agency in collaboration with other central and local public authorities and shall be submitted to the Government for examination by April 10 of the year following the management year.

(2) The report mentioned in par. (1) includes the analysis of the results obtained in the management year, highlighting the degree of achievement of the general and specific objectives established in the National Program and the degree of accomplishing the activities envisaged in the National Plan and, in case of significant deviations from the planned objectives, the draft amendments to The national program.

Chapter XII

CONFIDENTIALITY

Article 38. Confidentiality of information

(1) Information that is commercially confidential, obtained by the authorities in accordance with this law, shall not be made public.

(2) Except as provided in par. (3) from this article or other cases provided by law or to the extent that commercial information is not already publicly disclosed, the authorities consider the following information to be confidential and inaccessible to the public:

- a) details on the complete composition of the mixture;
- b) the exact use, function or application of a substance or mixture, including information on its precise use as an intermediate;
- c) the links between the producer or importer and their distributors or downstream users;
- d) the exact quantity of the substance or mixture manufactured or placed on the market.

(3) In cases where it is imperative to act urgently for security reasons or for the protection of human health or the environment, the National Agency shall disclose the information mentioned in par. (2) from this article to other central public administration authorities mentioned in art. 7–11, respecting the confidentiality of information by their officials.

Article 39. Exceptions to confidentiality requirements

The following information held by the National Agency regarding the substances as such, in mixtures or in articles may not be treated as confidential:

- a) the name from the IUPAC nomenclature for hazardous substances;
- b) the commercial name of the chemical;
- c) the name of the manufacturer / importer and the notifier;
- d) classification and labeling of the substance;
- e) physico-chemical data regarding the substance;
- f) the procedures to prevent the adverse effects of the dangerous substances or to remove the dangerous properties of the substances;
- g) data on the ways of contamination of the environment and of the human body with chemicals and the ways of their transformation into the environment and into biological objects;
- h) results of toxicological and ecotoxicological studies;
- i) the calculated level without effect or the predictable concentration without effect;
- j) the degree of purity of the substance and the quantitative analysis of the additives known as dangerous, if such information is essential for classification and labeling;
- k) indications of safe use;
- l) the information specified in the safety data sheet of a substance or chemical mixture;

- m) analytical methods that make it possible to identify a dangerous substance when released into the environment, as well as to determine the direct exposure of humans;
- n) methods for determining the hazardous properties of chemical substances.

Chapter XIII

CONTROL AND SURVEILLANCE OF THE STATE

Article 40. State control and surveillance

(1) The state control and supervision of the execution of the provisions of the present law and of the regulations approved under it shall be entrusted to the administrative authorities subordinated to the authorities of the central public administration indicated in art. 7–11, within the limits of the assigned competences.

(2) The control regarding the compliance with the requirements of this law and of the regulations approved under it shall be carried out by the Environmental Protection Inspectorate, in accordance with the principles of Law no. 131/2012 regarding the state control over the entrepreneurial activity.

(3) The Inspectorate for Environmental Protection cooperates with the authorities of the central public administration mentioned in art. 11 in the process of control and supervision of the execution of the provisions of this law and of the regulations approved under it.

(4) Inspectors from the Environmental Protection Inspectorate may carry out preliminary sampling and control of the content of the chemical and of the article in order to determine whether the conditions for placing on the market or use of the chemical and the article are met.

(5) Natural and legal persons are obliged:

a) to allow the control and supervision to be carried out;

b) to provide the necessary truthful information and notifications;

c) to allow the inspector to take the required amount of samples for testing the chemical and article.

(6) The instructions regarding the control of the execution of the provisions of the present law and of the regulations approved under it are established by the Government.

Article 41. Inspectors' rights

(1) During the inspection, the inspector, within the limits of his competence, has the right:

a) to access, according to Law no. 131/2012 regarding the state control over the entrepreneurial activity, in the places of activity of the natural and legal persons who produce, place on the market and use chemicals, in order to control the application and compliance with the requirements of this law and the conditions of the authorizations mentioned in art. 24 paragraph (1) of the present law;

b) to draw up a control document, accompanied by a prescription, including a suspension of the activity of production, import, marketing or use of chemicals if this creates an imminent danger to the life and health of people, as well as to environment, with addressing within 3 working days in the court;

c) to issue a prescription regarding the removal of the violations of the legislation in the field of chemical substances in accordance with Law no. 131/2012 regarding the state control over the entrepreneurial activity;

d) to draw up a report on the application of the contravention sanction after issuing the control act in case of the existence of danger to human life and health or to the environment.

(2) The challenge of the inspector's prescription, provided in par. (1) lit. b), does not exempt the natural or legal person from the obligation to execute the prescription established until the moment the final decision is issued by the court.

Article 42. Qualification of inspectors

(1) The inspectors who control the compliance with the requirements of the present law and

the regulations approved under it may be persons with higher education in the field of chemistry, toxicology, ecotoxicology, hazard and environmental risk assessment, risk management and / or technology that meet the general conditions provided. of Law no. 158/2008 regarding the civil service and the status of the civil servant.

(2) The National Agency organizes, separately or together with other competent authorities, training seminars for the inspectors responsible for the implementation of the provisions of this law and of the regulations approved under it, in order to develop their professional competences in the field of chemical control and Familiarity with the new regulations in the field of chemical substances at international and national level.

Chapter XIV

LIABILITY FOR BREACH OF THE LEGISLATION CONCERNING CHEMICAL SUBSTANCES

Article 43. Liability for violation of the legislation on substances
chemical

Failure to comply with the provisions of the present law and of the normative acts approved pursuant to it shall result in disciplinary, contravention, criminal or, as the case may be, civil liability, according to the law.

Article 44. Liability for harm caused to human health
and the environment

The harm caused to human health or, as a result of pollution, the environment during the activities of chemical substances shall be repaired in accordance with the provisions of the Civil Code.

Chapter XV

TRANSITIONAL AND FINAL PROVISIONS

Article 45. Transitional provisions

(1) The natural or legal person who, at the date of entry into force of the present law, carries out activities with the chemical products mentioned in art. 23 paragraph (1) lit. c) shall request, within 60 days from the date of its entry into force, the authorization of the chemical in accordance with Chapter VII, Section 2.

(2) The natural or legal person who, at the date of entry into force of this law, carries out activities of commercialization, distribution and / or other forms of transfer of the particularly dangerous chemicals that correspond to the requirements provided in art. 27 paragraph (2) shall request, within 60 days from the date of its entry into force, the issuance of the permit for the sale, distribution and / or transfer of particularly dangerous chemicals in accordance with Chapter VIII.

(3) The natural or legal person who, at the date of entry into force of the present law, carries out activities with the substances mentioned in art. 23 paragraph (1) lit. d) –e) shall request, within 60 days from the date of its entry into force, the authorization of the chemical in accordance with Chapter VII, Section 2.

(4) The natural or legal person who, at the date of entry into force of the present law, carries out activities with substances that destroy the ozone layer, with equipment and products containing such substances, activities regulated by Law no. 852/2002 for the approval of the Regulation on the commercial regime and the regulation of the use of halogenated hydrocarbons that destroy the ozone layer, will request, within 60 days from the date of entry into force of this law, the authorization for the import, export or re-export of the substances. which destroy the ozone layer, equipment and products containing such substances in accordance with Chapter VII, Section 2 of this Law.

(5) The provisions regarding the issuing of the authorization for biocidal products, mentioned in art. 24 paragraph (1) lit. b), shall enter into force 1 year after the date of establishment of the National Agency.

(6) The natural or legal person who, at the date of entry into force of this law, carries out activities with biocidal products, registered in accordance with the Sanitary Regulation regarding the establishment of the conditions for placing on the market of the biocidal products, will request the authorization of biocidal products according to chapter VII section 2 of this law within 60 days from the date of entry into force of the provisions of par. (5) of this article.

(7) The provisions regarding the issuance of the authorization for plant protection products, mentioned in art. 24 paragraph (1) lit. a), shall enter into force 2 years after the date of establishment of the National Agency.

(8) The natural or legal person who, at the date of entry into force of the provisions of par. (7), carrying out activities with the involvement of plant protection products will request the authorization of these products in accordance with Chapter VII section 2, within 60 days from the date of entry into force of the provisions of para. (7) of this article.

Article 46. Organizing the execution and strengthening of the institutional framework and normative

(1) The Government:

1) within 12 months from the publication of this law:

a) will ensure the creation under the subordination of the Ministry of Agriculture, Regional Development and Environment of the public authority in the field of chemical substances, based on the reorganization of the National Agency for the Regulation of Nuclear and Radiological Activities and of consolidating its capacity, taking into account the provisions of art. 8, 9 and 10 of this law;

b) elaborate the normative framework related to the present law;

2) within 12 months from the entry into force of this law:

a) will elaborate and present to the Parliament proposals for bringing the legal acts in force in accordance with the present law;

b) will bring its normative acts in accordance with the present law;

c) will create the automated information system "Register of chemicals placed on the market of the Republic of Moldova".

(2) The Government, within 3 years from the entry into force of the present law, will ensure the gradual establishment of the System and inventory of classification and labeling.

(3) The requirements stipulated in art. 25 paragraph (4) lit. c) of this law is applied after 3 years from the date of entry into force of this law.

(4) The restrictions provided in art. 17 paragraph (2) points 3), 4) and 8) of this law shall apply from 1 January 2021.

Article 47. Entry into force

(1) This law shall enter into force 12 months from the date of its publication in the Official Gazette of the Republic of Moldova.

(2) At the date of entry into force of this law, Law no. 1236/1997 regarding the regime of harmful products and substances.

THE PRESIDENT OF THE PARLIAMENT Andrian CANDU

Nr. 277. Chisinau, November 29, 2018.

[annex no.1](#)

[annex no.2](#)

[annex no.3](#)

[annex no.4](#)

[Annex no.5](#)

[annex no.6](#)