Technical Assistance for Strengthening the Capacity of the Ministry of Environment, Forests and Water Administration in Albania for Law Drafting and Enforcement of National Environmental Legislation

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REPUBLIC OF ALBANIA
ASSEMBLY
DRAFT 2
Version 4

LAW
No. _____, dated _____

ON CHEMICALS MANAGEMENT [1]

Based on articles 78 and 83, item 1 of Albanian Constitution, at the proposal of Council of Ministers,

ASSEMBLY OF REPUBLIC OF ALBANIA

DECIDED:

Chapter 1
General Provisions
Article 1
Purpose

1. The purpose of this Law is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation through the classification, labelling, packaging, registration, evaluation, authorization and restriction of chemicals.

Article 2
Scope

[1] *This law transposes the Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishment of a European Chemicals Agency*.

1. This Law lays down provisions on substances and mixtures within the meaning of Article 3 "Definitions". These provisions shall apply to the manufacture, placing on the market or use of such substances on their own, in mixtures or in articles and to the placing on the market of mixtures
2. This Law is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.
3. This Law shall apply without prejudice to:
   a. the workplace and environmental legislation, including legislation on, safety and health at work, on environmental permits, on the limit values of air pollution, chemical substances, noises and vibrations at the work, on integrated water management and on the protection of workers from the risks related to exposure to carcinogens or mutagens at work;
   b. the specific legislation on cosmetic products as regards testing involving vertebrate animals.
4. This Law shall not apply to:
   a. Radioactive substances according to the legislation on safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation;
   b. Substances, on their own, in a preparation or in an article, which are subject to customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit;
   c. Non-isolated intermediates;
   d. The carriage of dangerous substances and dangerous substances in dangerous preparations by rail, road, inland waterway, sea or air.
5. The provisions of this Law shall not apply to the extent that a substance is used:
   a. in medicinal products for human or veterinary use according to the specific legislation, on Albania code relating to veterinary medicinal products and specific legislation on medicaments and pharmaceutics service;
   b. in food or feeding stuffs in accordance with specific legislation on food including use:
      (i) as a food additive in foodstuffs according to the specific legislation on sweeteners for use in foodstuffs;
      (ii) as a flavouring in foodstuffs according to the specific legislation on flavourings for use in foodstuffs and to source materials for their production and the register of flavouring substances used in or on foodstuffs;
      (iii) as an additive in feeding stuffs according to the specific legislation on additives for use in animal nutrition;
      (iv) in animal nutrition according to the specific legislation on marketing of compound feeding stuffs intended for livestock.
6. The provisions of this Law shall not apply to the following preparations in the finished state, intended for the final user:

   a. medicinal products for human or veterinary use, according to the specific legislation and on community code relating to veterinary medicinal products (draft regulation) and as defined in specific legislation on medicaments and pharmaceutics services;
   b. cosmetic products as defined in the specific legislation on cosmetic products;
   c. medical devices which are invasive or used in direct physical contact with the human body in so far as measures lay down provisions for the classification and labelling of dangerous substances and preparations which ensure the same level of information provision and protection according to the specific legislation on registration and assessment of criteria of PPPs;
   d. food or feeding stuffs in accordance with specific legislation on food including use:
      i. as a food additive in foodstuffs in accordance with specific legislation on sweeteners for use in foodstuffs;
      ii. as a flavouring in foodstuffs in accordance with specific legislation on flavourings for use in foodstuffs and to source materials for their production and the register of flavouring substances used in or on foodstuffs;
      iii. as an additive in feeding stuffs according to the legislation on additives for use in animal nutrition;
      iv. in animal nutrition in accordance to the legislation on marketing of compound feeding stuffs intended for livestock.
7. Waste as defined in the specific law on integrated management of waste, is not a substance, preparation or article within the meaning of this Law.
8. The Minister may allow for exemptions from this Law in specific cases for certain substances, on their own, in a preparation or in an article, where necessary in the interests of defence.
9. Council of Ministers, upon proposal of the Minister, approves a Decision on the definition of substances which shall be exempted from the provisions of this Law when they are considered to cause minimum risk because of their intrinsic properties or do not prejudice the objectives of this Law.
10. Council of Ministers, upon proposal of the Minister, may grant exemptions on on-site isolated intermediates and transported isolated intermediates as well as on polymers.

Definitions
Article 3
Definitions

For the purposes of this Law:

1. **"Substance"** means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent

which may be separated without affecting the stability of the substance or changing its composition;

2. **"Mixture"** means a mixture or solution composed of two or more substances;
3. **"Article"** means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;
4. **"Producer of an article"** means any natural or legal person who makes or assembles an article;
5. **"Polymer"** means a substance consisting of molecules characterized by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:
   a. a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;
   b. less than a simple weight majority of molecules of the same molecular weight.

   c. In the context of this definition a "monomer unit" means the reacted form of a monomer substance in a polymer;
6. **"Monome**r" means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process;
7. **"Registrant"** means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance;
8. **"Manufacturing"** means production or extraction of substances in the natural state;
9. "**Manufacturer**" means any natural or legal person established in accordance to the Albanian legislation;, who manufactures a substance;
10. **"Import"** means the physical introduction into the customs territory of Albania;
11. **"Importer"** means any natural or legal person established who is responsible for import;
12. "**Placing on the market"** means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market;
13. **"Downstream user"** means any natural or legal person, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user
14. **"Distributor"** means any natural or legal person, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties;
15. **"Intermediate"** means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as "synthesis"):
    a. non-isolated intermediate: means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other

vessels in which the substance(s) are stored after the manufacture;

b. on-site isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;

c. transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites;

16. **"Site"** means a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared;
17. **"Actors in the supply chain"** means all manufacturers and/or importers and/or downstream users in a supply chain;
18. Phase-in substance: means a substance which meets at least one of the following criteria:
    a. it is listed in the European Inventory of Existing Commercial Chemical Substances

    (EINECS);
    b. it was manufactured in the Republic of Albania, or in the European Union, provided the manufacturer or importer has documentary evidence of this;
    c. it was placed on the market in the Republic of Albania, or in the European Union, before entry into force of this Law by the manufacturer or importer and was considered as having been notified in accordance with the specific legislation, provided the manufacturer or importer has documentary evidence of this;
19. **"Notified substance"** means a substance for which a notification has been submitted and which could be placed on the market in accordance the specific legislation;
20. **"Product and process orientated research and development"** means any scientific development related to product development or the further development of a substance, on its own, in mixtures or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance;
21. **'Scientific research and development**" means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year;
22. **"Use**" means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;
23. **"Registrant's own use**" means an industrial or professional use by the registrant;
24. **"Identified use**" means a use of a substance on its own or in a mixtures , or a use of a mixtures, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;
25. "**Full study report"** means a complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test house describing the study performed;

26. **"Robust study summary"** means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report;
27. **"Study summary"** means a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study;
28. **"Per year"** means per calendar year, unless stated otherwise, for phase-in substances that have been imported or manufactured for at least three consecutive years, quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years;
29. **"Restriction**" means any condition for or prohibition of the manufacture, use or placing on the market;
30. **"Supplier of a substance or a mixture"** means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture;
31. **"Supplier of an article"** means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market;
32. **"Recipient of a substance or a mixture"** means a downstream user or a distributor being supplied with a substance or a mixture;
33. **"Recipient of an article"** means an industrial or professional user, or a distributor, being supplied with an article but does not include consumers;
34. **"Exposure scenario"** means the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate;
35. **"Use and exposure category"** means an exposure scenario covering a wide range of processes or uses, where the processes or uses are communicated, as a minimum, in terms of the brief general description of use;
36. **"Substances which occur in nature"** means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means;
37. **"Not chemically modified substance**" means a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities;
38. **"Alloy**" means a metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means.
39. **"Law on environment protection"** shall mean Law No. 10 431 of 09.06.2011, "On Environment Protection";
40. **"Environment Permit"** shall have the same meaning as provided for by relevant law no.10448, dated 14.7.2011 "On environmental permitting" ;

41. **"State environmental Inspectorate" "SEI",** shall have the same meaning as provided by Law no.10433, dated 16.6.2011 "On Inspection in the Republic of Albania" and the specific DCM "On establishment, organization, functioning of state inspectorate, on environment, forest and water";
42. **"NEA"** shall have the same meaning as provided by Law no. 10 431 of 09.06.2011, "On Environment Protection" and is the authority or authorities or bodies established according to this Law to carry out the obligations arising from this Law;
43. **"National Licensing Centre (NLC)"** shall have the same meaning as in Law No. 10 081 of 23.2.2009 "On Licenses, Authorizations and Permits in Republic of Albania".
44. **"Minister"** shall mean the Minister responsible for environment;
45. **"Ministry"** shall mean the Ministry responsible for environment.

CHAPTER 2

Competent Authorities

Article 4
Competent Authorities

1. The Ministry and NEA shall be responsible for coordinating the substance and mixture evaluation process and ensuring that substances according to this Law are evaluated with particular attention on import and export evaluation process. In carrying out an evaluation of a substance, the Ministry and NEA may appoint by contracting another licensed or registered body qualified in this field to act on their behalf.
2. The Ministry is the competent authority for:
   a. inter-institutional coordination on different issues regarding integrated chemicals management;
   b. international cooperation on different issues regarding integrated chemicals management, .
   c. granting the Authorizations
3. NEA is the competent authority for
   a. the classification, labelling, packaging of chemicals substances and mixtures;
   b. Assessment, registration, evaluation, authorization and restriction of chemicals;
   c. Publication of information on evaluation
   d. establishment of an information service office (help desk) to assist the market operators and inform the stakeholders.
4. The SEI is the competent authority for ensuring the monitoring and assessment of the implementation of the present Law.
5. The Minister shall place adequate resources at the disposal of NEA to enable it, in conjunction with any other available resources, to fulfil its tasks under this Law and the sub laws in a timely and effective manner.

Article 5
Cooperation between competent authorities

1. NEA shall cooperate with other State authorities, and public entities in the performance of their tasks under this Law and shall give the competent authorities of

other States all the necessary and useful support to this end.

Article 6
Duties of NEA

1. NEA shall assign a submission number to each registration, which is to be used for all correspondence regarding the registration until the registration is deemed to be complete, and a submission date, which shall be the date of receipt of the registration at NEA

2. NEA shall undertake a completeness check of each registration in order to ascertain that all the elements required as well as the registration fee under the present Law and under the by-laws to be established according to this Law. The completeness check shall not include an assessment of the quality or the adequacy of any data or justifications submitted.

3. NEA shall undertake the completeness check within three weeks of the submission date, or within three months of the relevant deadline foreseen in this law, as regards registrations of phase-in substances submitted in the course of the two-month period immediately preceding that deadline.

4. If a registration is incomplete, NEA shall inform the registrant, before expiry of the three-week or three-month period referred to in the paragraph 3, as to what further information is required in order for the registration to be complete, while setting a reasonable deadline for this. The registrant shall complete his registration and submit it to NEA within the deadline set. NEA shall confirm the submission date of the further information to the registrant. NEA shall perform a further completeness check, considering the further information submitted.

5. NEA shall reject the registration if the registrant fails to complete his registration within the deadline set. The registration fee shall not be reimbursed in such cases.

6. Once the registration is complete, NEA shall assign a registration number to the substance concerned and a registration date, which shall be the same as the submission date. NEA shall without delay communicate the registration number and registration date to the registrant concerned. The registration number shall be used for all subsequent correspondence regarding registration.

7. NEA shall notify the interested parties within 30 days of the submission date, that the following information is available in NEA database:

a. the registration dossier together with the submission or registration number;

b. the submission or registration date;

c. the result of the completeness check; and

d. any request for further information and deadline set in accordance with the paragraph 4.

8. An appeal may be brought, against NEA decisions under this Article based on the administrative procedures law.

9. Where additional information for a particular substance is submitted to NEA by a new registrant, NEA shall notify the existing registrants that this information is available on the database.

10. The Minister may establish instructions/guidelines in order to define additional details and criteria to the present article.

Article 7
Communication to the public of information on risks of substances

1. NEA shall inform the general public about the risks arising from substances where this is considered necessary for the protection of human health or the environment. NEA, in consultation with stakeholders and drawing as appropriate on relevant best practice, shall provide guidance for the communication of information on the risks and safe use of chemical substances, on their own, in mixtures or in articles, with a view to coordinating States in these activities.

Article 8
Other responsibilities

1. NEA shall submit electronically to the Ministry any available information that they hold on substances registered in accordance with the decision refered in article 8 whose dossiers do not contain the full information referred to in this Law or specific by-laws, in particular whether enforcement or monitoring activities have identified suspicions of risk. NEA shall update this information as appropriate.
2. NEA shall establish national and regional helpdesks to provide advice to manufacturers, importers, downstream users and any other interested parties on their respective responsibilities and obligations under this Law.

CHAPTER III
CLASSIFICATION, LABELLING, PACKAGING OF SUBSTANCES

Article 9
General criteria and obligations

1. Council of Ministers, upon proposal of the Minister, approves a Decision on defining the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures in particular defining obligations for manufacturers, suppliers, importers, and downstream users to classify substances and mixtures placed on the market.

CHAPTER IV
ASBESTOS

Article 10
General criteria and obligations

1. Council of Ministers, upon proposal of the Minister, approves a Decision on the prevention and reduction of environmental pollution by asbestos .

CHAPTER V
REGISTRATION OF SUBSTANCES

SECTION 1
General obligation to register and information requirements

Article 11
No data, no market

1. Substances on their own, in mixtures or in articles shall not be manufactured in Albania or placed on the market unless they have been registered in accordance with the relevant provisions of the present Law and under the by-laws to be established according to this Law.

Article 12
General obligation to register substances on their own or in mixtures

1. Except where this Law or the by-laws established according to this Law provide otherwise, any manufacturer or importer of a substance, either on its own or in one or more mixtures, in quantities of 1 tonne or more per year shall submit a registration to NEA.

2. Any manufacturer, importer, or where relevant downstream user, may, whilst retaining full responsibility for complying with his obligations under this Law, appoint a third party representative for all proceedings under the present Law and under the by-laws to be established according to this Law, involving discussions with other manufacturers, importers, or where relevant downstream users. In these cases, the identity of a manufacturer or importer or downstream user who has appointed a representative shall not normally be disclosed by NEA to other manufacturers, importers, or, where relevant, downstream users.

3. Provisions on registration by manufacturers or importers and exemptions concerning Monomers and polymers that are used as on-site isolated intermediates or transported isolated intermediates or any other substance(s) that have not already been registered by an actor up the supply chain shall be established by Decision of Council of Ministers upon proposal of the Minister.

Article 13
Registration and notification of substances

1. Any producer or importer of articles shall submit a registration to NEA for any substance contained in those articles, if both the following conditions are met:

a. the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;
b. the substance is intended to be released under normal or reasonably foreseeable conditions of use.
c. The fee required in accordance with this law shall accompany a submission for registration.

2. Any producer or importer of articles shall notify NEA in accordance with paragraph 4 of this Article, if a substance is identified in the list of substances subject to authorization and meets the criteria foreseen there if both the following conditions are met:

a. the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year; accordance in to be included in the list of substances

b. the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w).

3. Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.

4. Këshilli i Ministrave, me propozim të Ministrit, miraton një vendim për listen e substancave qe jane subject i autorizimit si dhe kriteret per identifikimin e substancave biokumulative, te qendrueshme dhe toksike dhe shume te qendrueshme, shume te rrezikshme dhe shume biokumulative.

5. Council of Ministers, upon proposal of the Minister, approves a Decision on the information to be notified, which shall include as minimum requirements the following:

a. the identity and contact details of the producer or importer, with the exception of their own use sites;

b. the registration number(s);

c. the identity of the substance;

d. the classification of the substance(s);

e. a brief description of the use(s) of the substance(s) and of the uses of the article(s);

f. the tonnage range of the substance(s), such as 1-10 tonnes, 10-100 tonnes and so on.

6. NEA may take decisions requiring producers or importers of articles to submit a registration, in accordance with this Title, for any substance in those articles, if all the following conditions are met:

a. the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;

b. NEA has grounds for suspecting that:

c. the substance is released from the articles, and

d. the release of the substance from the articles presents a risk to human health or the environment;

e. the substance is not subject to paragraph 1.

f. A submission for registration shall be accompanied by the fee required in accordance with this law.

7. Paragraphs 1 to 5 shall not apply to substances that have already been registered for that use.

8. From ----------paragraphs 2, 3 and 4 of this Article shall apply 6 months after a substance is identified in accordance with this law.

Article 14
Representative of a foreigner manufacturer

1. A natural or legal person established outside Albania who manufactures a substance on its own, in mixtures or in articles, formulates a mixture or produces an article that is

imported into Albania may by mutual agreement appoint a natural or legal person established in Albania to fulfil, as his only representative, the obligations on importers under this Title.

2. The representative shall also comply with all other obligations of importers under this Law. To this end, he shall have a sufficient background in the practical handling of substances and the information related to them and shall keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in this law.

3. If a representative is appointed in accordance with paragraphs 1 and 2, the non-Albanian manufacturer shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Law.

Article 15
Exemption from the general obligation to register for product and process orientated research and development (PPORD)

1. Articles 11,12, 13, and 24, 25 shall not apply for a period of five years to a substance manufactured in the Republic of Albania or imported for the purposes of product and process orientated research and development by a manufacturer or importer or producer of articles, by himself or in cooperation with listed customers and in a quantity which is limited to the purpose of product and process orientated research and development.

2. For the purpose of paragraph 1, the manufacturer or importer or producer of articles shall notify NEA of the following information:

- **a.** the identity of the manufacturer or importer or producer of articles;
- **b.** the identity of the substance,;
- **c.** the classification of the substance, if any;
- **d.** the estimated quantity;
- **e.** the list of customers referred to in paragraph 1, including their names and addresses.

The fee required in accordance with this law shall accompany the notification. The period set out in paragraph 1 shall begin at receipt of the notification at NEA.

3. NEA shall check the completeness of the information supplied by the notifies and shall apply adapted as necessary. NEA shall assign a number to the notification and a notification date, which shall be the date of receipt of the notification at NEA, and shall forthwith communicate that number and date to the manufacturer, or importer, or producer of articles concerned. NEA shall also communicate this information to all interested parties.

4. NEA may decide to impose conditions with the aim of ensuring that the substance or the mixture or article in which the substance is incorporated will be handled only by staff of listed customers as referred to in paragraph 2(e) in reasonably controlled

- **a.** Conditions, in accordance with the requirements of legislation for the protection of workers and the environment, and will not be made available to the general public at any time

b. Either on its own or in a mixture or article and that remaining quantities will be re-collected for disposal after the exemption period.
c. In such cases, NEA may ask the notifies to provide additional necessary information.

5. In the absence of any indication to the contrary, the manufacturer or importer of the substance or the producer or importer of articles may manufacture or import the substance or produce or import the articles not earlier than two weeks after the notification.
6. The manufacturer or importer or producer of articles shall comply with any conditions imposed by NEA in accordance with paragraph 4.
7. NEA may decide to extend the five-year exemption period by a further maximum of five years or, in the case of substances to be used exclusively in the development of medicinal products for human or veterinary use, or for substances that are not placed on the market, for a further maximum of ten years, upon request if the manufacturer or importer or producer of articles can demonstrate that such an extension is justified by the research and development programme.
8. NEA shall always keep confidential the information submitted in accordance with paragraphs 1 to 7.
9. An appeal may be brought, in accordance with this Article against NEA decisions under paragraphs 4 and 7 of this Article.

Article 16
Information to be submitted for general registration purposes

1. A registration required by Article 12 or by Article 13 shall include all the following information:
a. a technical dossier including:
i. the identity of the manufacturer(s) or importer(s);
ii. the identity of the substance;
iii. information on the manufacture and use(s) of the substance; this information shall represent all the registrant's identified use(s). This information may include, if the registrant deems appropriate, the relevant use and exposure categories;
iv. the classification and labelling of the substance;
v. guidance on safe use of the substance;
vi. study summaries of the information derived from the application;
vii. robust study summaries;
viii. an indication as to which of the information submitted under (iii), (iv), (vi), (vii) or subparagraph (b) has been reviewed by an assessor chosen by the manufacturer or importer and having appropriate experience;
ix. proposals for testing;
x. for substances in quantities of 1 to 10 tonnes, exposure information;
xi. a request as to which of the information in paragrafit (iii) the manufacturer or importer considers should not be made available on the Internet including a justification as to why publication could be harmful for his or any other concerned party's commercial interests.

xii. Except in cases covered under this law Article 31, Article 33 or Article 58(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (vi) and (vii) for the purpose of registration;

b. a chemical safety report when required under Article 20, according to a specific format to be defined by instructions of the Minister. The relevant sections of this report may include, if the registrant considers appropriate, the relevant use and exposure categories.

Article 17
Joint submission of data by multiple registrants

1. Provisions and information concerning a substance, which is intended to be manufactured in Albania by one or more manufacturers and/or imported by one or more importers, and/or is subject to registration under Article 12 or13, shall be established by Decision of Council of Ministers upon proposal of the Minister.

2. A submission for registration shall be accompanied by the fee required in accordance with this law.

Article 18
Information to be submitted depending on tonnage

1. Information and minimum requirements concerning all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant to be included in the technical dossier referred to in Article 16 shall be established by Decision of Council of Ministers upon proposal of the Minister.

2. This Article shall apply to producers of articles adapted as necessary.

Article 19
General requirements for generation of information on intrinsic properties of substances

1. Information on intrinsic properties of substances may be generated by means other than tests, provided that certain conditions are met. In particular for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods, for example, in vitro methods or qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across). Testing, when in accordance with certain conditions may be omitted where justified by information on exposure and implemented risk management measures according to the conditions to be specified by by-laws.

2. These methods shall be regularly reviewed and improved with a view to

reducing testing on vertebrate animals and the number of animals involved.

3. Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down in specific legislation or in accordance with other international test methods recognized by the NEA as being appropriate.

4. Information on intrinsic properties of substances may be generated in accordance with other test methods provided that specific conditions to be further defined are met.

5. Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in the specific legislation or other international standards recognised as being equivalent and with the provisions of other specific legislation, if applicable.

6. If a substance has already been registered, a new registrant shall be entitled to refer to the study summaries or robust study summaries, for the same substance submitted earlier, provided that he can show that the substance that he is now registering is the same as the one previously registered, including the degree of purity and the nature of impurities, and that the previous registrant(s) have given permission to refer to the full study reports for the purpose of registration.

Article 20
Chemical safety report and duty to apply and recommend risk reduction measures

1. Without prejudice of any other specific legislation, a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter in quantities of 10 tonnes or more per year per registrant.

2. The chemical safety report shall document the chemical safety assessment which shall be conducted in accordance with paragraphs 2 to 7 and with additional specifications to be further established for either each substance on its own or in a mixture or in an article or a group of substances.

3. A chemical safety assessment in accordance with paragraph 1 need not be performed for a substance which is present in a mixture if the concentration of the substance in the mixture is less than the lowest of any of the following:

a. the applicable concentrations defined in the specific legislation related to dangerous preparations;
b. the concentration limits given in the specific legislation related to dangerous substances;
c. the concentration limits given in the specific legislation related to dangerous preparations;
d. the concentration limits given in the specific legislation related to dangerous preparations;
e. the concentration limits given in an agreed entry in the classification and labelling inventory established under this Law;
f. 0,1 % weight by weight (w/w), if the substance meets the criteria to be further defined in specific by-laws.

4. A chemical safety assessment of a substance shall include the following steps:

a. human health hazard assessment;
b. physicochemical hazard assessment;

c. environmental hazard assessment;
d. persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment.

5. If, as a result of carrying out steps (a) to (d) of paragraph 3, the registrant concludes that the substance meets the criteria for classification as dangerous in accordance with the specific legislation related to dangerous substances or is assessed to be a PBT or vPvB, the chemical safety assessment shall include the following additional steps:

a. exposure assessment including the generation of exposure scenario(s) (or the identification of relevant use and exposure categories if appropriate) and exposure estimation;

b. risk characterisation.

The exposure scenarios (where appropriate the use and exposure categories), exposure assessment and risk characterisation shall address all identified uses of the registrant.

6. The chemical safety report need not include consideration of the risks to human health from the following end uses:

a. in food contact materials within the scope of the specific legislation on materials and articles intended to come into contact with food;

b. in cosmetic products within the scope of the specific legislation.

7. Any registrant shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets which he supplies in accordance with Article 37.

8. Any registrant required to conduct a chemical safety assessment shall keep his chemical safety report available and up to date.

Article 21
Additional criteria and specifications

1. Council of Ministers, upon proposal of the Minister, approves a Decision on information to be notified, defining the additional information, criteria, conditions, specifications and specific conditions to the information and procedures established in this Section.

SECTION 2
Substances regarded as being registered

Article 22
Substances in plant protection and biocidal products

1. Active substances and co-formulants manufactured or imported for use in plant protection products only and included in the specific legislation shall be regarded as being registered and the registration as completed, for manufacture or import for the use as a plant protection product and therefore as fulfilling the requirements of this Section.

2. Active substances manufactured or imported for use in biocides products only and included in the specific legislation concerning the placing of biocides products on the market, shall be regarded as being registered and the registration as completed for manufacture or import for the use in a biocides

product and therefore as fulfilling the requirements of this Section.

Article 23
Duties of the NEA and registrants of substances regarded as being registered

1. NEA shall make information equivalent to that required by this Law available for substances regarded as registered according to Article 12, 13. NEA shall include this information or a reference thereto in its databases and notify the interested parties thereof by ----------.
2. Articles 9, 10 and 11 shall not apply to uses of substances regarded as registered according to this law.

SECTION 3
Obligation to register and information requirements for certain types of isolated intermediates

Article 24
Registration of on-site isolated intermediates

1. Any manufacturer of an on-site isolated intermediate in quantities of 1 tonne or more per year shall submit a registration to NEA for the on-site isolated intermediate.
2. Description on information as well as additional specification to be included in a registration for an on-site isolated intermediate shall be established by Decision of Council of Minister upon proposal of the Minister.

Article 25
Registration of transported isolated intermediates

1. Any manufacturer or importer of a transported isolated intermediate in quantities of 1 tonne or more per year shall submit a registration to NEA for the transported isolated intermediate.
2. A registration for a transported isolated intermediate shall include information additional specification, for which requirements will be approved by Decision of Council of Minister upon proposal of the Minister.

Article 26
Joint submission of data on isolated intermediates by multiple registrants

1. Description on information as well as additional specification to be included in a joint submission for isolated intermediates by multiple registrants shall be established by Decision of Council of Minister upon proposal of the Minister.
2. A submission for registration shall be accompanied by the fee required in accordance with this law.

Article 27
Manufacturing and import of substances

1. Decision of Council of Ministers shall establish provisions on manufacturing and importing substances as well as on indications and deadlines to be decided by NEA to the registrant upon proposal of the Minister.

Article 28
Further duties of registrants

1. Following registration, a registrant shall be responsible on his own initiative for updating his registration without undue delay with relevant new information and submitting it to NEA in the following cases:
- **a.** any change in his status, such as being a manufacturer, an importer or a producer of articles, or in his identity, such as his name or address;
- **b.** any change in the composition of the substance;
- **c.** changes in the annual or total quantities manufactured or imported by him or in the quantities of substances present in articles produced or imported by him if these result in a change of tonnage band, including cessation of manufacture or import;
- **d.** new identified uses and new uses advised against for which the substance is manufactured or imported;
- **e.** new knowledge of the risks of the substance to human health and/or the environment of which he may reasonably be expected to have become aware which leads to changes in the safety data sheet or the chemical safety report;
- **f.** any change in the classification and labelling of the substance;
- **g.** any update or amendment of the chemical safety report;
- **h.** the registrant identifies the need to perform a test, in which cases a testing proposal shall be developed;
- **i.** any change in the access granted to information in the registration.

NEA shall communicate this information to all interested parties.

2. Information to be submitted to NEA by a registrant updating his registration shall be established by Decision of Council of Ministers upon proposal of the Minister.

3. An update shall be accompanied by the relevant part of the fee required and additional specifications established by by-laws.

SECTION 4
Transitional provisions applicable to phase-in substances and notified substances

Article 29
Specific provisions for phase-in substances

1. Decision of Council of Ministers shall establish specific provisions for phase-in substances upon proposal of the Minister.

Article 30
Notified substances

1. A notification in accordance with the specific legislation related to the classification, packaging and labeling of dangerous substances should be regarded, as a registration for the purposes of this Chapter and NEA shall assign a registration number by ----------.
2. If the quantity of a notified substance manufactured or imported per manufacturer or importer reaches the next tonnage threshold under Article 16, the additional required information corresponding to that tonnage threshold, as well as to all the lower tonnage thresholds, shall be submitted in accordance with Articles 16 and 18, unless it has already been submitted in accordance with those Articles.

CHPTER VI

DATA SHARING AND AVOIDANCE OF UNNECESSARY TESTING

SECTION 1
Objectives and general rules

Article 31
Objectives and general rules

1. In order to avoid animal testing, testing on vertebrate animals for the purposes of this Law shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests.
2. The sharing and joint submission of information in accordance with this Law shall concern technical data and in particular information related to the intrinsic properties of substances. Registrants shall refrain from exchanging information concerning their market behaviour, in particular as regards production capacities, production or sales volumes, import volumes or market shares.
3. Any study summaries or robust study summaries of studies submitted in the framework of a registration under this Law at least 12 years previously can be used for the purposes of registration by another manufacturer or importer.

SECTION 2

Rules for non-phase-in substances and registrants of phase-in substances who have not pre-registered

Article 32
Duty to inquire prior to registration

1. Every potential registrant of a non-phase-in substance, or potential registrant of a phase-in substance who has not pre-registered in accordance with Article 34, shall inquire from NEA whether a registration has already been submitted for the same substance. He shall submit all the following information to NEA with

the inquiry:

a. his identity, with the exception of the use sites;

b. the identity of the substance;

c. which information requirements would require new studies involving vertebrate animals to be carried out by him;

d. which information requirements would require other new studies to be carried out by him.

2. If the same substance has previously not been registered, NEA shall inform the potential registrant accordingly.

3. If the same substance has previously been registered less than 12 years earlier, NEA shall inform the potential registrant without delay of the names and addresses of the previous registrant(s) and of the relevant summaries or robust study summaries, as the case may be, already submitted by them. Studies involving vertebrate animals shall not be repeated.NEA shall simultaneously inform the previous registrants of the name and address of the potential registrant. The available studies shall be shared with the potential registrant in accordance with Article 33.

4. If several potential registrants have made an inquiry in respect of the same substance, NEA shall inform all potential registrants without delay of the name and address of the other potential registrants.

5. Additional information and procedures concerning the duties defined in the present article may be established by Order of Minister.

Article 33
Sharing of existing data in the case of registered substances

1. The Council of Minister upon proposal of the Minister shall establish criteria on sharing of existing data in the case of registered substances.

SECTION 3
Rules for phase-in-substances

Article 34
Duty to pre-register for phase-in substances

1. In order to benefit from the transitional regime provided for in Article 23 each potential registrant of a phase-in substance in quantities of 1 tonne or more per year, including without limitation intermediates, shall submit all necessary information to NEA.

2. The Council of Minister upon proposal of the Minister shall define detailed information required to the registrant.

CHAPTER VII
INFORMATION
IN THE SUPPLY CHAIN

Article 35
Requirements for Safety Data Sheets

1. The supplier of a substance or a mixture shall provide the recipient of the substance or mixture with a safety data sheet:
   a. where a substance meets the criteria for classification as dangerous in accordance with the specific legislation related to dangerous substances or dangerous preparations; or
   b. where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria defined in by-laws; or
   c. where a substance is included in the list established in accordance with article 13(2) approved by by-laws for reasons other than those referred to in points (a) and (b).

2. The Council of Minister upon proposal of the Minister shall approve a Decision on the detailed information required in the safety data sheet, including the classification requirements as well as the criteria for the identification of persistent, bio accumulative and toxic substances, and very persistent and very bioaccumulative substances.

Article 36

Duty to communicate information down the supply chain for substances on their own or in mixtures for which a safety data sheet is not required

1. Any supplier of a substance on its own or in a **mixture** who does not have to supply a safety data sheet in accordance with Article 35 shall provide the recipient with the information down the supply chain for substances on their own or in mixtures for which a safety data sheet is not required.
2. Additional information and criteria may be established by instructions of the Minister.

Article 37
Duty to communicate information on substances in articles

1. Any supplier of an article containing a substance meeting the criteria defined as per article 13(2) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.
2. On request by a consumer any supplier of an article containing a substance meeting the criteria set in the Decision refered in article 13.4 and identified in accordance with identification of substances in a concentration above 0,1 % weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

The relevant information shall be provided, free of charge, within 45 days of receipt of the request.

Article 38

Duty to communicate information on substances and mixtures up the supply chain

1. Any actor in the supply chain of a substance or a **mixture** shall communicate the following information to the next actor or distributor up the supply chain:
   a. new information on hazardous properties, regardless of the uses concerned;
   b. any other information that might call into question the appropriateness of the risk management measures identified in a safety data sheet supplied to him, which shall be communicated only for identified uses.

2. Distributors shall pass on that information to the next actor or distributor up the supply chain.

Article 39
Access to information for workers

1. Workers and their representatives shall be granted access by their employer to the information provided in accordance with Articles 35 and 36 in relation to substances or mixtures that they use or may be exposed to in the course of their work.

Article 40
Obligation to keep information

1. Each manufacturer, importer, downstream user and distributor shall assemble and keep available all the information he requires to carry out his duties under this Law for a period of at least 10 years after he last manufactured, imported, supplied or used the substance or mixture. That manufacturer, importer, downstream user or distributor shall submit this information or make it available without delay upon request to NEA.

2. In the event of a registrant, downstream user or distributor ceasing activity, or transferring part or all of his operations to a third party, the party responsible for liquidating the registrant, downstream user or distributor's undertaking or assuming responsibility for the placing on the market of the substance or mixture concerned shall be bound by the obligation in paragraph 1 in place of the registrant, downstream user or distributor.

Article 41
Additional criteria and specifications

1. Council of Ministers, upon proposal of the Minister, approves a Decision on defining the additional information, criteria, conditions, specifications and specific conditions for the implementation of this Chapter.

CHAPTER VIII
DOWNSTREAM USERS

Article 42
Downstream user chemical safety assessments and Duty to identify, apply and recommend risk

reduction measures

1. A downstream user or distributor may provide information to assist in the preparation of a registration.
2. Any downstream user shall have the right to make a use, as a minimum the brief general description of use, known in writing (on paper or electronically) to the manufacturer, importer, downstream user or distributor who supplies him with a substance on its own or in a preparation with the aim of making this an identified use. In making a use known, he shall provide sufficient information to allow the manufacturer, importer or downstream user who has supplied the substance, to prepare an exposure scenario, or if appropriate a use and exposure category, for his use in the manufacturer, importer or downstream user's chemical safety assessment.

   Distributors shall pass on such information to the next actor or distributor up the supply chain. Downstream users in receipt of such information may prepare an exposure scenario for the identified use(s), or pass the information to the next actor up the supply chain.
3. For registered substances, the manufacturer, importer or downstream user shall comply with the obligations laid down in Article 20 either before he next supplies the substance on its own or in a preparation to the downstream user making the re quest referred to in paragraph 2 of this Article, provided that the request was made at least one month before the supply, or within one month after the request, whichever is the later.

   For phase-in substances, the manufacturer, importer or downstream user shall comply with this request and with the obligations laid down in Article 20 before the relevant deadline in Article 29 has expired, provided that the downstream user makes his request at least12 months before the deadline in question.

   Where the manufacturer, importer or downstream user, having assessed the use in accordance with Article 20, is unable to include it as an identified use for reasons of protection of human health or the environment, he shall provide NEA and the downstream user with the reason(s) for that decision in writing without delay and shall not supply downstream user(s) with the substance without including these reason(s) in the information referred to under Articles 35 or 36. The manufacturer or importer shall include the specifications of the above use according to by-laws based on this Law.
4. A downstream user of a substance on its own or in a preparation shall prepare a chemical safety report in accordance with specific by-laws to be established according to this Law. Any use outside the conditions described in an exposure scenario or if appropriate a use and exposure category shall be communicated to him in a safety data sheet or for any use his supplier advises against.

   A downstream user need not prepare such a chemical safety report in any of the following cases:

   a. a safety data sheet is not required to be communicated with the substance or preparation in accordance with Article 35;
   b. a chemical safety report is not required to be completed by his supplier in accordance with Article 20;
   c. (c) the downstream user uses the substance or preparation in a total quantity of less than1 tonne per year;
   d. the downstream user implements or recommends an exposure scenario which includes as a minimum the conditions described in the exposure scenario communicated to him in the safety data sheet;

e. the substance is present in a preparation in a concentration lower than any of the concentrations set out in Article 20;
f. the downstream user is using the substance for the purposes of product and process oriented research and development, provided that the risks to human health and the environment are adequately controlled in accordance with the requirements of legislation for the protection of workers and the environment.

5. Any downstream user shall identify, apply and where suitable, recommend, appropriate measures to adequately control risks identified in any of the following:
a. the safety data sheet(s) supplied to him;
b. his own chemical safety assessment;
c. any information on risk management measures supplied to him in accordance with Article 38.

6. Where a downstream user does not prepare a chemical safety report in accordance with paragraph 4(b), he shall consider the use(s) of the substance and identify and apply any appropriate risk management measures needed to ensure that the risks to human health and the environment are adequately controlled. Where necessary, this information shall be included in any safety data sheet prepared by him.

7. Downstream users shall keep their chemical safety report up to date and available.

8. A chemical safety report prepared in accordance with paragraph 4 of this Article need not include consideration of the risks to human health from the end uses set out in Article 20(6).

Article 43
Obligation for downstream users to report information

1. Before commencing or continuing with a particular use of a substance that has been registered by an actor up the supply chain in accordance with Articles 12 or 35, the downstream user shall report to NEA all necessary information, in some cases to be specified in a Decision of the Council of Minister upon proposal of the Minister.

Article 44
Application of downstream user obligations

1. Downstream users shall be required to comply with the requirements of Article 42 at the latest 12 months after receiving a registration number communicated to them by their suppliers in a safety data sheet.

2. Downstream users shall be required to comply with the requirements of Article 43 at the latest six months after receiving a registration number communicated to them by their suppliers in a safety data sheet.

Article 45
Additional criteria and specifications

1. Council of Ministers, upon proposal of the Minister, approves a Decision on

defining the additional information, criteria, conditions and specific conditions to the information and procedures established in this Chapter.

CHAPTER IX
EVALUATION

SECTION 1
Dossier evaluation

Article 46
Examination of testing proposals

1. The Council of Minister upon proposal of the Minister shall establish criteria on the examination of testing proposals

2. The registrant or downstream user shall submit the information required to NEA by the deadline set.

Article 47
Compliance check of registrations

1. NEA may examine any registration in order to verify any of the following:
   a. that the information in the technical dossier(s) submitted pursuant to Article 16 complies with the requirements of this law;
   b. that the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in specific by-laws;
   c. that any required chemical safety assessment and chemical safety report comply with the present article and that the proposed risk management measures are adequate;
   d. that any explanation(s) submitted have an objective basis.

2. The list of dossiers being checked for compliance by NEA shall be made available to all interested parties.

3. On the basis of an examination made pursuant to paragraph 1, NEA may, within 12 months of the start of the compliance check, prepare a draft decision requiring the registrant(s) to submit any information needed to bring the registration(s) into compliance with the relevant information requirements and specifying adequate time limits for the submission of further information.

4. The registrant shall submit the information required to NEA by the deadline set.

5. To ensure that registration dossiers comply with this Law, NEA shall select a percentage of those dossiers, no lower than 5 % of the total received by NEA for each tonnage band, for compliance checking. NEA shall give priority, but not exclusively, to dossiers meeting at least one of the following criteria:
   a. the dossier contains information in Article 16(a)(iv), (vi) and/or (vii) submitted separately; or
   b. the dossier is for a substance manufactured or imported in quantities of 1 tonne or more per year and does not meet the requirements of the specific by-laws to be established according to this Law; or

6. Any third party may electronically submit information to NEA relating to

substances referred to in Article 34(1). NEA shall consider this information together with the information submitted according to the other informations.

Article 48
Check of information submitted and follow-up to dossier evaluation

1. Inspectorate shall examine any information submitted in consequence of a decision taken under Articles 46 or 47, and draft any appropriate decisions in accordance with these Articles, if necessary.
2. Once the dossier evaluation is completed, Inspectorate shall notify the Ministry and NEA of the information obtained and any conclusions made. NEA shall use the information obtained from this evaluation for the purposes of application of this law. NEA shall use the information obtained from this evaluation for the purposes of Article 50.

Article 49
Procedure and time periods for examination of testing proposals

1. In the case of non phase-in substances, NEA shall prepare a draft decision in accordance with Article 47(3) within 180 days of receiving a registration or downstream user report containing a testing proposal.
2. In the case of phase-in substances, NEA shall prepare the draft decisions by 1 December 20xx for all registrations received by 1 December 20yy containing proposals for testing;
3. The list of registration dossiers being evaluated under Article 47(2) shall be made available to the interested parties.

SECTION 2
Substance evaluation
Article 50
Criteria for substance evaluation

1. In order to ensure a harmonised approach, NEA shall develop criteria for prioritising substances with a view to further evaluation. Prioritisation shall be on a risk-based approach. The criteria shall consider:
   a. hazard information, for instance structural similarity of the substance with known substances of concern or with substances which are persistent and liable to bio-accumulate, suggesting that the substance or one or more of its transformation products has properties of concern or is persistent and liable to bio-accumulate;
   b. exposure information;
   c. tonnage, including aggregated tonnage from the registrations submitted by several registrants.

Article 51
Requests for further information and check of information submitted

1. If NEA considers that further information is required, it shall prepare a draft

decision, stating reasons, requiring the registrant(s) to submit the further information and setting a deadline for its submission.

2. The registrant shall submit the information required to NEA by the deadline set.

3. NEA shall examine any information submitted, and shall draft any appropriate decisions in accordance with this Article, if necessary, within 12 months of the information being submitted.

4. NEA shall finish its evaluation activities within 12 months of the start of the evaluation of the substance or within 12 months of the information being submitted under paragraph 2, and notify the Minister accordingly. If this deadline is exceeded, the evaluation shall be deemed to be finished.

Article 52
Coherence with other activities

1. An evaluation of a substance shall be based on all relevant information submitted on that particular substance and on any previous evaluation under this Law. Where information on intrinsic properties of a substance has been generated by reference to structurally related substance(s), the evaluation may also cover these related substances. In cases where a decision on an evaluation has been previously taken in accordance with Article 56 or Article 57, any draft decision requiring further information under Article 51 may be justified only by a change of circumstances or acquired knowledge.

2. In order to ensure a harmonised approach to requests for further information, NEA shall monitor draft decisions under Article 51 and shall develop criteria and priorities.

Article 53
Follow-up to substance evaluation

1. Once the substance evaluation has been completed, NEA shall consider how to use the information obtained from this. NEA shall inform the Minister of its conclusions as to whether or how to use the information obtained.

SECTION 3
Evaluation of intermediates

Article 54
Further information on on-site isolated intermediates

1. For on-site isolated intermediates that are used in strictly controlled conditions, neither dossier nor substance evaluation shall apply. However, where NEA considers that a risk to human health or the environment, equivalent to the level of concern arising from the use of substances meeting the criteria foreseen on DCM refered in article 13(4) arises from the use of an on-site isolated intermediate and that risk is not properly controlled, it may:
   a. require the registrant to submit further information directly related to the risk identified. This request shall be accompanied by a written justification;

b. examine any information submitted and, if necessary, recommend any appropriate risk reduction measures to address the risks identified in relation to the site in question.

The procedure provided for in the first paragraph may be undertaken only by NEA referred to therein. NEA shall inform the Minister of the results of such an evaluation.

SECTION 4
Common provisions

Article 55
Registrants' and downstream users' rights

1. NEA shall notify any draft decision under Articles 46, 47 or 51 to the registrant(s)

2. or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt. If the concerned registrant(s) or downstream user(s) wish to comment, they shall provide their comments to NEA. NEA shall take any comments received into account and may amend the draft decision accordingly.

3. If a registrant has ceased the manufacture or import of the substance, or the production or import of an article, or the downstream user the use, he shall inform NEA of this fact with the consequence that the registered volume in his registration, if appropriate, shall be put to zero and no further information may be requested with respect to that substance, unless the registrant notifies the restart of the manufacture or import of the substance or the production or import of the article, or the downstream user notifies the restart of the use. .

4. The registrant may cease the manufacture or import of the substance or the production or import of the article, or the downstream user the use, upon receipt of the draft decision. In such cases, the registrant, or downstream user, shall inform NEA of this fact with the consequence that his registration, or report, shall no longer be valid, and no further information may be requested with respect to that substance, unless he submits a new registration or report.

Article 56
Adoption of decisions under dossier evaluation

5. NEA shall notify its draft decision in accordance with Articles 46, or 47, together with the comments of the registrant, to the Minister.

6. Within 30 days of circulation, the Minister may propose amendments to the draft decision to NEA.

7. If NEA does not receive any proposals, it shall take the decision in the version notified under paragraph 1.

8. If NEA receives a proposal for amendment, it may modify the draft decision. NEA shall refer the decision reflecting the amendments proposed by the Minister within 15 days of the end of the 30-day period referred to in paragraph 2.

9. NEA shall forthwith communicate any proposal for amendment to any registrants or downstream users concerned and allow them to comment within 30 days.

10. An appeal may be brought, against Agency decisions in accordance to the Albanian legislation.

Article 57
Adoption of decisions under substance evaluation

1. NEA shall circulate its draft decision in accordance with Article 56, together with any comments by the registrant or downstream user, to the Minister.
2. The provisions of Article 56(2) to (6) shall apply *mutatis mutandis*.

Article 58
Cost sharing for tests without an agreement between registrants and/or downstream users

1. Where registrants or downstream users are required to perform a test as a result of a decision taken under this Chapter those registrants or downstream users shall make every effort to reach an agreement as to who is to carry it out on behalf of the other registrants or downstream users and to inform NEA accordingly within 90 days. If NEA is not informed of such agreement within such 90 days, it shall designate one of the registrants or downstream users to perform the test on behalf of all of them.
2. If a registrant or downstream user performs a test on behalf of others, they shall all share the cost of that study equally.
3. In the case referred to in paragraph 1, the registrant or downstream user who performs the test shall provide each of the others concerned with a copy of the full study report.
4. The person performing and submitting the study shall have a claim against the others accordingly. Any person concerned shall be able to make a claim in order to prohibit another person from manufacturing, importing or placing the substance on the market if that other person either fails to pay his share of the cost or to provide security for that amount or fails to hand over a copy of the full study report of the study performed. All claims shall be enforceable in the national courts. Any person may choose to submit their claims for remuneration to an arbitration board and accept the arbitration order.

Article 59
Publication of information on evaluation

1. By 28 February of each year, NEA shall publish on its website a report on the progress made over the previous calendar year towards discharging the obligations incumbent upon it in relation to evaluation. This report shall include, in particular, recommendations to potential registrants in order to improve the quality of future registrations.

Article 60
Additional criteria and specifications

1. Council of Ministers, upon proposal of the Minister, approves a Decision on defining the additional information, criteria, conditions, specifications and

specific conditions to the information and procedures established in Chapter IX.

CHAPTER X
AUTHORISATION/PERMITTING

Section 1
Authorization/permitting requirement

Article 61
Aim of authorization and considerations for substitution

1. The aim of this Chapter is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable.
2. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.
3. Any procedure regarding the Authorization/permitting shall be done in accordance to the Law No. 10 081 of 23.2.2009 "On Licenses, Authorizations and Permits in Republic of Albania".

Article 62
General provisions

1. A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in this Law and specific by-laws.
2. Council of Ministers, upon proposal of the minister and the minister responsible for health, approves a decision with the list of hazardous substances that from their nature represent a serious danger to life, human health and environment.

SEKSIONI 2
Granting of authorisations

Article 63
Granting of authorisations

1. The Minister shall be responsible for taking decisions on applications for authorizations in accordance with this Title.
2. The information and details requested by applicants in order to be issued an authorisation shall be established by Order of Minister.

Article 64
Applications and review of authorisations

1. The information and details concerning the applications, procedures and review of authorisation granted in accordance with Article 63 shall be established by Order of Minister.

SECTION 3
Authorisations in the supply chain

Article 65
Obligation of holders of authorisations

1. Holders of an authorisation, as well as downstream users referred to in Article 61(2) including the substances in a mixture, shall include the authorisation number on the label before they place the substance or a mixture containing the substance on the market for an authorised use. This shall be done without delay once the authorisation number has been made publicly available in accordance with procedures foreseen in this law and the other sub laws.

Article 66
Downstream users

1. Downstream users using a substance in accordance with Article 62 shall notify the NEA within three months of the first supply of the substance.
2. NEA shall establish and keep up to date a register of downstream users who have made a notification in accordance with paragraph 1. NEA shall grant access to this register to all interested parties.

CHAPTER XI

RESTRICTIONS ON THE MANUFACTURING, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES

Article 67
General provisions

1. A substance on its own, in a mixture or in an article, for which this Law or specific by-laws contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction.
2. Council of Ministers is in charge to approve the restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles.

CHAPTER XII
FEES AND CHARGES

Article 68
Fees and charges

1. The fees that are required according to this law shall be stipulated by a separate sublegal act issued by minister and the minister responsible for finance.
2. A fee need not be paid for a registration of a substance in a quantity of between 1 and

10 tonnes where the registration dossier contains the full information in this Law or specific by-laws.

3. The structure and amount of the fees referred to in paragraph 1 shall take account of the work required by this Law to be carried out by NEA and shall be fixed at such a level as to ensure that the revenue derived from them when combined with other sources of NEA's revenue is sufficient to cover the cost of the services delivered. In the case of Article 13(4), Article 15(1) and (5), Article 17(2), Article 24 and Article 25, the structure and amount of fees shall take account of the tonnage range of the substance being registered.
4. In all cases, a reduced fee shall be set for SMEs.
5. In the case of Article 17(1), the structure and amount of fees shall take into account whether information has been submitted jointly or separately.
6. In the case of a request made under Article 16, the structure and amount of fees shall take into account the work required by NEA in assessing the justification.
7. NEA may collect charges for other services it provides.
8. Incomes from the fees goes to the account of the ministry.

CHAPTER XIII
INFORMATION

Article 69
Reporting

1. Every five years, ---------- shall submit to NEA a report on the implementation of this Law in their respective territories, including sections on evaluation and enforcement. The first report shall be submitted by ----------.
2. Every five years, NEA shall submit to Ministry an overall report on the implementation of this Law. NEA shall include in its report information on the joint submission of information in accordance with Article 17 and an overview of the explanations given for submitting information separately.
3. The first report shall be submitted by ----------.
4. Every three years the ----------, in accordance with the objective of promoting non-animal testing methods, shall submit to NEA a report on the status of implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment to meet the requirements of this Law.
5. The first report shall be submitted by ----------.
6. Every five years, NEA shall publish a general report on
   a. the experience acquired with the operation of this Law, including the information referred to in paragraphs 1, 2 and 3 and
   b. the amount and distribution of funding made available by NEA for the development and evaluation of alternative test methods.
7. The first report shall be published by ----------

Article 70
Access to information

1. Access to information is regulated by Albanian legislation in power.

Article 71

Cooperation with third countries and international organisations

1. Information received by NEA under this Law may be disclosed to any third country or an international organization in accordance with an agreement concluded with them, provided that both the following conditions are met:
   a. the purpose of the agreement is cooperation on the implementation or management of legislation concerning chemicals covered by this Law;
   b. the third party protects the confidential information as mutually agreed.

Article 72
Additional criteria and specifications

1. Council of Ministers, upon proposal of the Minister, approves a Decision on defining the additional information, criteria, conditions, specifications and specific conditions to the information and procedures established in this Chapter.

CHAPTER XIV
PROHIBITIONS, SANCTIONS AND PENALTIES

Article 73
Prohibitions

1. The following are prohibited:
   a. Placed on the market or manufactured in Albania of the substances on their own, in mixtures or in articles which are unregistered in accordance with this law.
   b. Placed on the market or manufactured in Albania by a natural or legal person established outside Albania without an mutual agreement for appointment a natural or legal person established in Albania to fulfil, as his only representative, the obligations on importers.
   c. Placed on the market or manufactured in Albania of the substance on its own, in a mixture or in an article, for which this Law or specific by-laws contains a restriction or used unless it complies with the conditions of that restriction.

Article 74
Contraventions and Sanctions

The following infringements that do not comprise criminal offences comprise administrative contraventions:

1. Placing on market of the substances and mixtures, in contrary with the criteria and procedures on labelling and packaging for hazardous substances and mixtures shall constitute administrative contravention and shall be punished by fine in the amount from ---------- lek to ----------lek.
2. Any registrant who fails to conduct a chemical safety assessment and keep his chemical safety report available and updated in compliance with the requirement of the article 20, of this law, shall constitute administrative contravention and shall be punished by fine in the amount from ---------- lek to ----------lek.
3. Any manufacturer, who fails to submit a registration to NEA for an on-site isolated intermediate in quantities of 1 tonne or more per year in compliance with the requirement of the article 24 of this law, shall be liable to an administrative fine from ---------- lek to ----------_lek.

4. Any manufacturer or importer of a transported isolated intermediate in quantities of 1 tonne or more per year who fails to submit a registration to NEA for the transported isolated intermediate with the requirement of the article 25 of this law, shall be liable to an administrative fine from --------- lek to ----------_lek.
5. Any registrant who fails to conduct the manufacturing and importing substances in compliance with the requirement of the article 27 of this law shall be liable to an administrative fine from --------- lek to ----------_lek.
6. Any registrant who fails to conduct the following registration, for updating his registration without undue delay in compliance with the requirement of the article 28 of this law shall be liable to an administrative fine from --------- lek to ----------_lek.
7. Each manufacturer, importer, downstream user and distributor who fails to keep available all the information under this Law for a period of at least 10 years after the last manufactured, imported, supplied or used the substance or mixture, in compliance with the requirement of the article 40 of this law shall be liable to an administrative fine from --------- lek to ----------_lek.
8. Each downstream user who fails to prepare a chemical safety report and keep their chemical safety report up to date and available in compliance with the requirement of the article 42 of this law shall be liable to an administrative fine from --------- lek to ----------_lek.
9. The infringer, to whom is imposed the administrative fine has the right of appeal in accordance with the legislation in force.
10. The enforcement of the administrative contraventions does not release the subject to whom it is directed from the other obligations foreseen by this law and the civil responsibility for the damage caused in accordance with the legislation in force.

Article 75
Bylaws

1. Within 2 years from entry into force of this law, Council of Ministers shall issue the bylaws for application of article 2/8, 2/9, 9, 10, 12/3, 13/4, 17/1, 18/1, 21/1, 24/2, 25/3, 26/1, 27, 28/4, 29, 34/2, 35/2, 41, 43, 45, 46, 60, 62/2, 67/2, 68, and article 72.

2. Within 2 years from entry into force of this law, the Minister shall issue the bylaws for application of article 6/10, 16/b, 32/5, 36/2, 63/2, and article 64.

Article 76
Repeals

With the entry into force of this law, law No. 9108, dated 17.7.2003 "On Chemical Substances and Preparations" and every other bylaw that is contrary to this law, are invalidated.

Article 77
Entry into force

This law enters into force ..... years following its publication in the Official Journal.

The legal effects _____

CHAIRMAN

ILIR META