MINISTRY OF HEALTH
BUREAU OF PHARMACEUTICALS

LAW ON CHEMICALS

SKOPJE, 2007

LAW ON CHEMICALS

I. GENERAL PROVISIONS

Article 1

This law shall regulate the conditions and the method or placing chemicals on the market, the conditions of production of chemicals, the rights and obligations of the legal entities which produce and market chemicals or use, test, assess, classify, mark and package chemicals, as well as supervise, with the objective of protecting the health of people and the environment.

The provisions of this law, with respect to assessment and classification shall also apply to biocides and detergents.

This law shall also regulate the requirements and procedure for registration of new substances and the assessment of new and existing substances, maintenance of a registry of chemicals, the procedures for notification, the procedure for mutual recognition of the certificates, the reporting obligations, the determination of the content, the method and conditions for exchanges of information about chemicals with respect to their degree of hazard, as well as the conditions, obligations and methods for safe operations with the chemicals.

Article 2

Certain terms used in this law shall have the following meaning:

1. “Chemicals” shall mean substances and preparations;

a.) “*Substances”* shall mean chemical elements and their compounds in the natural state or obtained through a production process, including the additions required to preserve their stability, and the impurities which occur during production, due to the applied process of production. The term shall also include the polymer compounds, as well as the solutions, where, when the solvent is removed, there can be a chemical change of the compound or an impact on its stability;

b.) “*Polymers”* shall mean substances comprising molecules, for which the order of one or more monomer units matters, where the most molecules contains at least three monomer units, interconnected with a covalent bond, or with one ore more other monomer units or some other reagents. Such molecules have to be with different molecular masses where the differences in the molecular masses are mainly due to the differences in the number of monomer units. In that context, the expression monomer unit shall be a reagent form of a monomer into a polymer;

c.) “*Preparations”* shall be mixtures or solutions comprising two or more substances;

2. "*Harmful chemicals"* shall mean:

a) "*explosive chemicals"* shall mean solid, liquid, paste form or gelatinous substances or preparations which react exothermally without atmospheric oxygen, creating gasses in the process, and which, in specific test conditions, detonate, degrade quickly or, when heated, explode, if placed in a constrained area;

b) "*oxidizing chemicals"* shall mean substances and preparations which cause highly exothermal reaction when in contact with other substances, especially with flammable substances;

c) "*very easily flammable chemicals"* shall mean liquid substances and preparations with an extremely liquid ignition temperature and low boiling point and gaseous substances and preparations which ignite when in contact with air during normal temperature and pressure;

d) "*easily flammable chemical"* shall mean

- Substances and preparations which may be heated and ignite when in contact with air during normal temperature and pressure, without any kind of energy change
- Solid substances and preparations which can ignite quickly and easily after a short contact with a ignition source and which continue to combust or become destroyed after the ignition source,
- Liquid substances and preparations with very low ignition temperature,
- Substances and preparations which, in contact with water or moist air, develop extremely flammable gasses in dangerous quantities;

e) "*flammable chemicals"* shall mean substances and preparations with a low ignition temperature;

f) "*very toxic chemicals"* shall mean substances and preparations which, in very small quantities cause death, or acute or chronic harm of the organism when swallowed, inhaled or absorbed through the skin;

g). "*toxic chemicals"* shall mean substances or preparations, which in small quantities cause death or an acute or chronic harm to the health when swallowed, inhaled or absorbed through the skin;

h). "*harmful chemicals*" shall mean substances or preparations which may cause death or an acute or chronic harm to the health when swallowed, inhaled or absorbed through the skin;

i) "*caustic chemicals"* shall be substances and preparations which, in contact with living tissues may damage or destroy them. Theses shall also be corrosive chemicals which, in contact with metal surfaces, rock or minerals may damage, destroy or degrade them through chemical or electro chemical processes;

j) "*irritant chemicals"* shall be non caustic substances and preparations which, through a direct or repetitive contact with the skin may cause inflammation or other adverse effects;

k) "*sensitizing chemicals"* shall be substances or preparations which, if inhaled or if they enter the skin, may cause an oversensitive reaction, so that any further exposure to the substance or the preparation causes a characteristic adverse effect;

l) "*carcinogenic chemicals"* shall be substances or preparation which if inhaled, swallowed, inserted through the skin or come into contact with the skin, may cause cancer or to increase its proliferation;

m) "*mutagenic chemicals*" shall be substances and preparations which, if swallowed, inhaled, inserted through the skin, or may cause modification of the genetic material, with inheritable genetic irregularities or increase their proliferation;

n) "*chemicals which are toxic for reproduction"* shall be substances and preparations which, if inhaled, swallowed or are inserted through the skin may cause or increase the proliferation of non inheritable adverse effects in the offspring and/or have adverse effects on the male or female reproductive functions;

o) "*environmentally harmful chemicals*" shall mean substances and preparations which, if inserted through the skin may represent a direct, momentary or continuing danger for one or multiple parts of the environment;

3. "*harmful products* " shall mean products which are not chemicals within the meaning of this law, but do contain some of the harmful chemicals specified in items from f) to o) of this article;

4. "*Biocides*" shall mean Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.
The plant protection products shall not be counted in the biocides, within the meaning of the provisions of this law;

5. "*Low risk biocides"* shall mean product which contains as active substance(s) only one or more of those listed in the List of active substances for inclusion in lows risk biocidal products and which does not contain any substance(s) of concern.

6. "*Controlled substances"* shall mean any substances, except active substances, which have a natural capacity to cause adverse effects on people, animals or the environment and are present or produced in a biocidal product is sufficient quantities to cause such an effect.

7. "harmful organism" shall mean any organism which has an unwanted presence or a detrimental effect for humans, their activities or the products they use or produce, or for animals or for the environment.

8. "*residues*" shall mean One or more of the substances present in a biocidal product which remains as a result of its use including the metabolites of such substances and products resulting from their degradation or reaction.

9. "*marketing authorization*" shall mean nn administrative act by which the competent authority of a Member State authorizes, following an application submitted by an applicant, the placing on the market of a biocidal product in its territory or in a part thereof
The same procedure shall apply for placing on the market of low risk biocidal products.

10. "*framework formulation*" shall mean specifications for a group of biocidal products having the same use and user type. This group of products must contain the same active substances of the same specifications, and their compositions must present only variations from a previously authorized biocidal product which do not affect the level of risk associated with them and their efficacy. A variation is the allowance of a reduction in the percentage of the active substance and/or an alteration in percentage composition of one or more non-active substances and/or the replacement of one or more pigments, dyes, perfumes by others presenting the same or a lower risk, and which do not decrease its efficacy.

11. **"***letter of access*" shall mean a document signed by the owner or owners of the relevant data which are protected, which states that these data may be used by the competent authority for the purposes of issuing a marketing authorization.

12. **"***Detergent*" shall mean any substance or preparation containing soaps and/or other surfactants intended for washing and cleaning processes. Detergents may be in any form (liquid, powder, paste, bar, cake, molded piece, shape, etc.) and marketed for or used in household, or institutional or industrial purposes.

Other products to be considered as detergents are:
-'Auxiliary washing preparation', intended for soaking (pre-washing), rinsing or bleaching cloths.
- 'Laundry fabric-softener', intended to modify the feel of fabrics in processes which are to complement the washing of fabrics
-'Cleaning preparation', intended for domestic all purposes cleaners and/or other cleaning of surfaces (e.g.: materials, products, machinery, mechanical appliances, means of transport and associated equipment, instruments, apparatus, etc.)
-'Other cleaning and washing preparations', intended for any other washing and cleaning processes

13. 'Surfactant' means any organic substance and/or preparation used in detergents, which has surface-active properties and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable of reducing

the surface tension of water, and of forming spreading or adsorption monolayers at the water- air interface, and of forming emulsions and/or microemulsions and/or micelles, and of adsorption at water-solid interfaces

14."*CAS"* shall mean a characteristic number of an already discovered substance according to the international list - Chemical Abstract Service ;

15."*EINECS*" shall mean a European list of existing commercial chemical substances. This list contains a finate list of chemical substances.

16."*ELINCS*" is a European list of newly published substances;

17. "*New Substances*" shall be the substances stipulated in the ELINCS list (European list of published chemical substances);

18. "EU Index" shall be a characteristic number of the harmful substance from the EU list of already classified substances;

19 "*Existing substances*" shall be substances which are contained within the EINECS list (European List of Existing Commercial Chemical Substances);

20. "*Life cycle of a chemical*" shall be a validity period of the chemical which shall include the overall process of prior investigations, production, marketing, use, manipulation with the waste and the packaging and their safe disposal and/or storage;

21. "*Production*" shall mean obtainment, manufacturing, processing, packaging, mixing of the chemicals in interim products and finished products using chemical, physical and biological processes and procedures as well as transportation and storage within the production location;

22. "*Producer* " shall mean any legal entity which produces or obtains chemicals, as well as every legal entity which processes, packs or changes the name of the chemical for further use;

23. "*Manipulation*" shall mean any activity that leads to a direct contact with the chemical;

24. "*Use* " shall mean preparation for use, storage and utilization;

25. "*Notification*" shall mean a notice about documentation and information necessary to be submitted to the competent authority.

26. "*Notifier*" shall mean a producer or his/her representative that places the chemical on the market and submits the notification to the state administration authority responsible for matters regarding with chemicals.

27. "*Placing of chemicals on the market*"shall mean any supply to third parties.

28. "*Trade*" shall be import, export, transport, transit, sales and/or manipulation with the chemicals as well as trade mediation on the domestic and foreign markets;

29. "*Scientific research and development*" shall mean scientific experimentation, analysis or chemical investigations conducted in a controlled environment; it shall include determination of the internal properties, performances and efficiency, as well as scientific research related to product development.

30. *"Process of orientated research and development"* shall mean further development of the substance in the direction in which a pilot facility or a production test are used to field test the application of the chemicals.

31. "*Proposing entity*" is a producer or his/her authorized representative that proposes the placing of the biocide on the market;

32. "Placing on the market of biocides" shall mean any supply, whether in return for payment or free of charge, or subsequent storage other than storage followed by consignment from the customs territory or disposal. Importation of a biocidal product into the customs territory shall be deemed to constitute placing on the market.

33. "Marketing authorization for biocides" shall mean an administrative act by which the competent authority authorizes, following an application submitted by an applicant, the placing on the market of a biocide.

34. "registration of biocides" shall mean an administrative act by which the competent authority following an application submittedby an applicant, after verification that the dossier meets the relevant requirements, allows the placing on the market of a low-risk biocidal product.

35**. "***Detergent producer***"**- shall mean the natural or legal person responsible for placing a detergent or a surfactant for a detergent on the market; in particular, a producer, an importer, a packager working for his own account, or any person changing the characteristics of a detergent or of a surfactant for a detergent, or creating or changing the labeling thereof, shall be deemed to be a manufacturer. A distributor who does not change the characteristics, labeling or packaging of a detergent, or of a surfactant for a detergent, shall not be deemed to be a manufacturer, except where
he acts as an importer

36. "Placing of detergents on the market**"** – making available to third parties, whether in exchange for payment or not. Import into the customs territory shall be deemed to be placing on the market.

37. "*Waste*" shall mean unused parts of chemicals, expired chemicals and waste packaging;

38. "*Active substances"* shall mean substances or micro-organisms including a virus or a fungus having general or specific action on or against harmful organisms;

39. "*Basic substance"* shall mean a substance included in the List of basic substances , whose major use is non-pesticidal but which has some minor use as a biocide either directly or in a product consisting of the substance and a simple diluent which itself is not a substance of concern and which is not directly marketed for this biocidal use;

40. "*Objects for general use"* shall be chemicals, which are placed on the market without the end user being knows, and the possibility to procure or use such chemicals is not restricted neither quantitatively nor with some special requirements with respect to the enc user or the buyer;

41. "*Professional use of chemicals"* is any use of the chemicals during the performance of registered activities, including trade of chemicals.

42."Primary biodegradation" shall mean the structural change (transformation) of a surfactant by micro-organisms resulting in the loss of its surface-active properties due to the degradation of the parent substance and consequential loss of the surface-active property as measured by test methods

43."*Ultimate aerobic degradation"* the level of biodegradation achieved when the surfactant is totally used by micro-organisms in the presence of oxygen resulting in its breakdown to carbon dioxide, water and mineral salts of any other elements present (mineralisation), and new microbial cellular constituents (biomass).

44. 'Industrial and institutional detergent' means a detergent for washing and cleaning outside the domestic sphere, carried out by specialised personnel using specific products.

45. 'Medical personnel' means a registered medical practitioner, or a person working under the direction of a registered medical practitioner, acting to provide patient care, make a diagnosis or administer treatment, and who is bound by professional confidentiality.

46. "*chemical form*" means the aggregate state of the chemical and the form in which it is placed on the market.

47. "ISO" - International Organization for Standardization и
48. "IUPAC" International Union of Pure and Applied Chemistry.

Article 3

The provisions of this law shall also apply to:

- production and marketing of chemical weapons and chemical for producing chemical weapons, unless otherwise regulated by a separate law,
- production and marketing of precursors stipulated in article 2, item 2 of this law,

- objects for general use if they contain some of the chemicals stipulated in article 2, item 2 of this law.

The provisions of this law which apply to the classification, packaging and labeling shall also apply to the plant protection products, explosive substances, radioactive substances and products containing radioactive substances, waste and impurities in the chemicals, if they contain some of the chemicals stipulated in article 2, item 2 of this law.

Article 4

The provisions of this law shall not apply to substances and preparation in their final form, in particular:

1. pharmaceutical products for humane and veterinarian use,
2. food and objects which come into contact with the food
3. objects for general use (with the exception of those containing toxic substances),
4. cosmetic products,
5. narcotic drugs and other psychotropic substances,
6. fodder products,
7. explosive substances,
8. plant protection products,
9. artificial fertilizers,
10. products containing radioactive substances,
11. transportation of harmful chemicals with rail, road, domestic water or air traffic,

Article 5

The administrative and professional matters with respect to the chemicals shall be performed by the Bureau for medicinal products, as an authority within the Ministry of Health (hereinafter in the text: Bureau for Medicinal Products).

The assessment of the risk of danger and classification of the chemicals shall be performed by the Ministry of Health upon a proposal from the Chemical Commission.

The inter sectoral cooperation for implementation of this Law shall be performed by an inter sectoral body for chemicals formed by the Government of the Republic of Macedonia.

Article 6

The Commission stipulated in article 5, paragraph 3 shall comprise a president and foru members appointed by the Minister of Health, from the pool of renowned professional and scientific persons from the field of pharmacy, medicine, veterinary medicine, chemistry, technology, biology, agriculture and forestry and environmental protection.

The assessment of the risk of danger, classification of chemicals as well as their safe use, shall be prescribed by the Minister of Health in agreement with the Minister of Environment and Physical Planning and the Minister of Agriculture, Forestry and Water Economy..

The commission shall be a professional, independent and advisory body.

The Minister of Health shall cover the operational costs of the commission.

The commission shall work on the basis of rules of procedure and shall be accountable for its work to the Minister of Health.

Article 7

The Minister of Health shall authorize a public health institution which shall perform the works of an information center for chemical poisoning (hereinafter in the text: The Center).
The center stipulated in paragraph 1 of this article shall collect, and process data about acute poisonings and other adverse effects and inform about the acute poisonings and other adverse effects, it shall also perform documentation, information and consultation activities, shall maintain a registry of accidental poisoning cases, shall participate in the formulation and control of the central base of antidotes in the Republic of Macedonia and shall perform other tasks in line with the law.

The producers, notifiers, and the proposing entities shall be obligated to submit data upon a request from the Center.

The content and the method of maintenance of the registry stipulated in paragraph 2 of this article, shall be prescribed by the Minister of Health.

Article 8

In order to provide for inter sectoral cooperation for monitoring of the implementation of this law, proposing changes and additions of the Law on the basis of the European and international recommendations referring to chemical management, providing recommendations and guidelines for the needs to strengthen the capacities on the central and local levels and of the industry in accordance with the European and international recommendations and cooperation with the relevant bodies, the Government of the Republic of Macedonia shall for an inter sectoral body for chemicals.

The inter sectoral body for chemicals shall comprise representatives from the Ministry of Health, the Ministry of Environment and Physical Planning, the Ministry of Agriculture, Forestry and Water Economy, the Ministry of Interior, the Ministry of Defense, the Ministry of Economy, the Ministry of Transport and Communication, the Ministry of Finance - the Customs Administration and a representative from the chemical industry.

The inter sectoral body shall be chaired by the representative proposed by the Minister of Environment and Physical Planning.

The inter sectoral body shall work in accordance with rules of procedures.

The professional and administrative and technical matters for the purposes of the intersectoral body shall be performed by the Bureau for medicinal products.

II. TESTING, ASSESSMENT AND CLASSIFICATION OF CHEMICALS

Article 9

The method of testing of the physical, chemical, toxic and ecotoxic properties of the chemicals shall be prescribed by the Minister of Health in agreement with the Minister of Environment and Physical Planning and the Minister of Agriculture, Forestry and Water Economy.

Article 10

The assessment of the hazardousness of the chemical shall be based on determining: the physical and chemical properties, the properties that have an impact on the health of people and the environmental impact.

The hazardous effects on the health of people shall be determined as:

1. acute, lethal effects,
2. non lethal irreversible effects after a one time exposure,
3. severe effects after a repeated or a prolonged exposure,
4. corrosive effects and effects which cause irritation,
5. sensitizing effects, and
6. carcinogenic, mutagen, teratogene, embriotoxic and toxic effects on the reproductive system.

In the assessment procedure, the Bureau for medicinal products shall determine the assessment of the risk on the basis of the data submitted by the notifier, or the proposing entity. The assessment of the submitted documentation shall be performed by the Bureau for medicinal products, based on an opinion from the Chemical Commission.

The assessment of the risk on the health of the people and the environment shall be prescribed by the Minister of Health in an agreement with the Minister of Environment and Physical Planning and the Minister of Agriculture, Forestry and Water Economy.

The real costs of the risk assessment shall be covered by the applicant.

The procedures for determining the hazardous properties shall be prescribed by the Minister of Health in an agreement with the Minister of Environment and Physical Planning and the Minister of Agriculture, Forestry and Water Economy.

Article 11

Chemicals shall be classified in accordance to the highest level of hazardousness.
If it is determined that a given chemical has some of the properties stipulated in article 2, item two of this law, it shall be classified as harmful.

The classification of the hazardous substances shall be based on the current EINECS list of classified substances marketed on the European Union, if the substances contained in the preparation are classified according to this list.

The national list of new and classified substances placed on the market on the territory of the Republic of Macedonia shall be determined by the Minister of Health in agreement with the Minister of Environment and Physical Planning and the Minister of Agriculture, Forestry and Water Economy.

If the hazardous substance is not contained within the lists stipulated in paragraphs 3 and 4 of this article, it shall be classified on the basis of:

1. the results from the testing of the properties of the substances in accordance with the provisions of this law, or
2. findings from already existing data.

The classification of hazardous preparations shall be performed on the basis of:
1. prescribed calculation method,
2. direct experimental investigations of the toxicological properties of the preparation according to prescribed measures and procedures,
3. findings about the properties of the substances contained in the preparation, using the existing data.

When some of the toxicological properties of the preparation have been confirmed using the methods listed in paragraph 6 of this article, items 1 and 2 the classification will make use of the results obtained using the method stipulated in paragraph 6, item 2 of this article, unless the substance is carcinogenic or toxic for the reproductive system, when the method stipulated in paragraph 5, item 1 should be used.

The need for testing shall be assessed for each individual case, if for a substance or a preparation there are not data, or if these data have been obtained using a different method, not in accordance with this law, in order to avoid testing on vertebrate animals.

The notifies that produces and places on the market hazardous substances from the lists stipulated in paragraphs 3 and 4 of this article, and which have not been classified as hazardous substances in the list of hazardous substances, as well as the notifier that produces and places on the market hazardous preparations, should use existing data for classification in order to avoid the unnecessary testing on experimental animals.

The methods for classification of hazardous substances shall be prescribed by the Minister of Health.

Article 12

The Minister of Health in an agreement with the Minister of Agriculture, Forestry and Water Economy and the Minister of Environment and Physical Planning shall prescribe the method for classification and labeling of the hazardous chemicals stipulated in article 2, item 2 of this Law.

The list of classified and marked chemicals shall be published in the "Official Gazette of the Republic of Macedonia"

The list stipulated in paragraph 2 of this article shall contain all classified and labeled chemicals produced and/or placed on the market on the territory of the Republic of Macedonia, with dosage or concentration limit in accordance with the classification and labeling.

III. NOTIFICATION OF NEW SUBSTANCES

Article 13

The notification for a new substance shall be submitted by the notifier. The procedure for notification can be full and abridged. The content of the application stipulated in paragraph 1 of this article shall be prescribed by the Minister of Health.

Article 14

The notifier shall be obligated to submit to the competent authority in the country where the substance is produced or in the country where the notifier has headquarters, a notification with:

- a technical dossier with all available relevant data necessary to evaluate the possible risks which the chemical may cause for the humans and the environment and which shall contain at least the information and the results from the performed studies for determination of the hazard, together with a comprehensive and detailed description of the performed tests, the applied methods and/or the reference data related to the performed tests and the applied methods;
- technical dossier with information necessary to evaluate the predictable risks irrespective of whether they occur immediately or their activity is delayed, which risks the substance may have for human health and the environment.
- A statement related to the unwanted effects of the substance during different predictable methods of use.
- Proposal classification and labeling
- Proposal safety list
- Contract for representation
- A request from the notifier for exemption of the notification from the application of article 21 of this law, for a period of at most one year after the submission of the notification, if the notifier requests this specially.

The Minister of Health, in an agreement with the Minister of Agriculture, Forestry and Water Economy and the Minister of Environment and Physical Planning, upon a proposal from the Chemical Commission shall prescribe the data which have to be contained in the technical dossier, as well as method for informing about notified chemicals by the notifier.

Article 15

The notifier that intends to place on the market chemicals on the territory of the Republic of Macedonia in quantities smaller than one ton per year per producer, shall be obligated to submit a notification to the Bureau for medicinal products, which will include the following:

- a technical dossier with all available relevant data necessary to evaluate the possible risks which the chemical may cause for the humans and the environment. The dossier shall contain minimal information and results from the performed studies for determination of the hazard, together with a comprehensive and detailed description of the performed tests, the applied methods and/or the reference data related to the performed tests and the applied methods; unless the Bureau for medicinal products decides otherwise;
- all other information stipulated in article 14, lines 3 to 7 of this Law

The data that have to be contained in the technical dossier shall differ depending on the quantities placed on the market.
The Minister of Health shall prescribe the data which have to be contained in the technical dossier, as well as the data required in the technical dossier for polymers.

If the notifier submitted a dossier for an abridged procedure, before the quantities placed on the market reach a level of 100 kg/year per producer or before the total quantity placed on the market reaches 500 kg/year per producer, the notifier should submit additional data to complete the technical dossier.

If the notifier submitted a dossier for an abridged procedure, before the quantities placed on the market reach a level of 1000 kg/year per producer or before the total quantity placed on the market reaches 5 tons/year per producer, the notifier should file an application for a full notification procedure.

Article 16

The procedures for notification and testing stipulated in Articles 14 and 15 of this law shall not apply to
-substances stipulated in the EINECS list,
-additives and substances used solely for fodder,
-substances used exclusively for food,
-active ingredients used exclusively for medicinal products, but not chemical byproducts

Article 17

The substances shall be considered to have been notified if they fulfill the following conditions:

- polymers, with the exception of those which contained a combined form 2% or more than 2% of some substance which is not stipulated in the EINECS list;
- substances on the market in quantities less than 10 kg per year per producer if the producer meets the criteria prescribed by this Law;
- substances in limited quantities which do not exceed 100 kg per year per producer and are intended exclusively for scientific research and development, under controlled conditions. The producers must keep written documents with data on the identity of the substance, data on labeling, quantities and the list of users and they have to be available to the competent authority in the country where they have been placed on the market;
- substances intended for process oriented scientific research and development with a limited number of registered users in quantities limited for the purposes of the research and development. For this substances, the derogation shall be valid for a period of one year, and the importer or the producer should submit to the competent authority the data about the identity, labeling, the quantity, the list of users and the program for research and development and the substance must not be accessible to the public. The one year period may be extended if the notifier submits data justifying this,
- If it is not possible to label the substances in accordance with the article 59 of this law, the marking next to the label which is derived from the already performed tests, must also contain the warning “ATTENTION – the substance is not fully tested”.

Article 18

Chemicals subject to the full notification procedure may be placed on the market upon submission of the required documentation to the Bureau for Medicinal Products by the notifier. The bureau for medicinal products shall be obligated within 60 days from day when the required documentation is submitted, to review the documentation and to issue an approval for placing the chemical on the market and to notify the notifier about the awarded number.

If the submitted documentation is not complete, the competent Bureau for medicinal products my ask the notifier in writing to submit further documentation.

Chemicals which are subject to the abridged procedure, may be placed in the market after the submission of the necessary documentation to the Bureau for medicinal products by the notifier. The bureau for medicinal products shall be obligated within 30 days to review the documentation and issue a marketing authorization for the chemical as well as to notify the nofier about the awarded number.

If the submitted documentation is not sufficient, the competent authority my ask the notifier in writing to submit further documentation.

The deadline stipulated in paragraph 2 of this article shall stop running from the day when the bureau asks the submitted to provide additional documents, information or clarifications which it deems necessary and the deadline shall continue to run from the day when the requirements of the bureau are met.

Against the decision for placing the chemical on the marker, an appeal may be submitted to the Minister of Health.

Article 19

If the substances are classified as very toxic, carcinogen, toxic to the reproductive system or mutagen, the producer or the importer must submit to the Bureau for medicinal products appropriate data related to the recommended methods and caution measures for manipulation, storage, transport, fire and other types of hazards, especially chemical reactions with water, and if applicable, information related to suspicion that the substance may explode when in powder form, as well as emergency measures in the event of spillage or injuries. If available, the data on acute toxicity must be submitted.

Article 20

The bureau for medicinal products shall issue a decision for placing new substances and preparations on the market, upon an opinion of the Chemical Commission, and based on the performed assessment of the application and the enclosed documentation for placement of a substance on the market, independently or as a part of a preparation.

The validity of the decision for placing a new substance on the market is up to ten years.

The notifier shall be obligated to submit a request for renewing the decision stipulated in paragraph 2 of this article, 120 days before the expiration of the validity.

Article 21

If a chemical had already been notifies in accordance with the provisions of this Law, the Bureau for medicinal products may agree to allow the next notifier to refer to the results for the physical, chemical, toxicological and ecotoxic investigations submitted by the initial notifier, if he/she can prove that the substance subject to re – notification is the same as the previously notified substance, including the degree of purity and the nature of the impurities.

For the utilization of the results from the testing of the notified substances, the next notifier must provide for a written agreement from the initial notifier.

In case of a notification of a new substance which has not been included in the ELINCS list, and which has been registered, approved and included in the national list of new and classified substances of the Bureau for medicinal products, the next notifier may request that the data about the substance and the proofs of the performed testing

submitted by the initial notifier be taken into account, if the previous notifier agrees to this in writing.
The next notifier is obligated to prove that this is the same substance which is identical with the previously notified substance, including the level of its purity and the impurities.

The notifier of the new substance shall be obligated to ask from the Bureau for medicinal products information about whether the substance had already been notifies and who is its first notifier, with the name and address of the first notifier.
Together with the request, the notifier must also submit proof of the intent of putting the substance on the market and to stipulate the quantities.

The notifiers of the same substance, shall be obligated to do everything in their power to reach an agreement for the joint use of the test data.

Article 22

The bureau for medicinal products shall inform the notifier whether the documentation submitted is complete and which notification procedure will be implemented, within 15 days from the day when the application is received.

When assessing new substances which have not been subject to registration, a complete notification procedure shall be implemented within 60 days counting from the day when the complete documentation was received.

For the substances which have been subject to registration by another applicant, an abridged registration procedure shall be implemented within 30 days. The bureau will inform, the writing, the next notifier, about the previously issued approval for the application for a new chemical, by quoting the number under which the chemical appears on the List stipulated in article 11, paragraph 3.

If there is any doubt, based on scientific findings that the substance is more dangerous than the documentation suggests, the Bureau may request additional documentation on additional tests on the substance which has already been notified.

In the event of paragraph 4 of this article, the Bureau may decide to temporarily ban the placement of the chemical on the market until the required documentation is submitted.

Against the decision of the Bureau temporarily banning the placement of the chemical on the market, an appeal may be lodged to the Ministry of Health. The appeal does not suspend the enforcement of the decision.

Article 23

The chemicals, in the form of substances or within preparations, which are explosive substances, waste and chemical impurities and others, if they have some of the chemical properties listed in article 2, item 2 of this law, after the assessment and classification by Bureau for medicinal products, shall be placed on the market by an appropriate competent administrative authority in accordance with the Law.

IV. PLACEMENT OF BIOCIDES ON THE MARKET

Article 24

The substances used for preparation of biocides (hereinafter in the text: active substances) may be placed on the market only if they comply with the requirements of this law.

The list of active substances for inclusion in biocidal products; for inclusion in low risk biocidal products; the list of basic substances; the type of biocidal products as well as their description shall be prescribed by the Minister of Health.

For the active substances which, on the basis of a statement by the notifier, shall be used exclusively for the production of biocides, the provisions of this law related to registration of new substances, shall not apply.

Article 25

The biocides may be placed on the market and be used if the Bureau for medicinal products, based on an opinion of the Chemical Commission, issues an approval for placement on the market through a procedure for authorization or registration and enters them in the Biocide registry.

The method for placement on the market through an authorization or registration procedure shall be prescribed by the Minister of Health.

The marketing authorization for biocides shall be issued for a period of at most ten years.

The marketing authorization may be conditioned with special limitations derived from the nature of the biocide and its envisaged application contained within the application for placement of the market stipulated in article 26, paragraph 2 of this law.

When issuing the marketing authorization, the competent authority shall take into account the other regulations related to the protection of the health of the population, workers, consumers, animals and the environment.

The real costs of the procedure for placing the biocides on the market shall be covered by the applicant.

Article 26

The application for placing biocides on the market shall be filed to the Bureau for medicinal products by a legal entity responsible for the first entry of the biocide the country, or its authorized representative.
Every applicant should have an office in the Republic of Macedonia.

Article 27

The marketing authorization may be modified at any time during its validity period, if the conditions under which it had been issued have changed.
The holder of the marketing authorization for the biocide shall be obligated, upon a request from the Bureau for medicinal products, to submit the data necessary for the modification.

Article 28

The application for issuance of the marketing authorization for biocides shall contain the following data:

1. applicant
2. producer of the biocide
3. data about the physical and chemical properties of the biocide
4. data on the laboratory and other tests based on which one can conclude the what harm can the biocide cause to humans and the environment
5. proposal declaration and instruction manual
6. decision for placement of the biocide on the market in the country of the producer,
7. a list of countries in which the biocide has been approved for use and has been placed on the market
8. the status of the biocide in the country of production,
9. instructions about disposing of the remnants and the packaging after the expiration of the biocide, as well as after the full use of the biocide,
10. A dossier or a letter of agreement for the biocidal product with data contained in the Collection of key data on the biocidal product and the active substance, as well as on the Collection of additional data on the biocidal product and the active substance, prescribed by the Minister of Health.
11. Other data prescribed by the minister of health

The more specific content of the application and conditions for the issuance of the authorization from paragraph 1 of this article, shall be prescribed by the minister of health.

If, because of the nature of the biocidal product or its proposed use, there are information which is not necessary to be submitted, such information shall not be submitted.

The provisions from paragraph 3 of this article shall also apply if it is not scientifically necessary or technically possible to submit the required information. In such cases the applicants shall submit confirmations acceptable to the Bureau for medicinal products, such as the existence of the framework formulation which the applicant has the right to access.

If after the evaluation of the documents, for the purposes of evaluating the risk from the biocidal product, it is demonstrated that it is necessary to submit additional data, the

applicant shall be obligated to submit such data, including the data from the necessary additional tests.
The time period for evaluation of the dossier shall be counted from the day of submission of the complete dossier.

The method of evaluation of the dossiers of biocidal products shall be prescribed by the minister of health.

Article 29

The name of the active substance must be in accordance to the stipulation ion the List of active substances from article 24 paragraph 2 of this Law, or in line with the stipulation in the EINECS list and the national list of classified substances on the market in the Republic of Macedonia
If the active substance is not included in the lists stipulated in paragraph 1 of this article, its usual ISO name shall be indicates , or if this is unavailable, it shall be indicated in line with the IUPAC nomenclature.

Article 30

The minister of health shall prescribe the procedure for inclusion of the active substances in the lists stipulated in article 24, paragraph 2 of this law.

Article 31

The testing of the biocides shall be conducted in accordance with article 9 of this law. If the testing is performed using methods different from those prescribed, the need to perform new tests shall be assessed in a case by case basis, taking into account the need to minimize the testing on vertebrate animals.

Article 32

In order to avoid repeating tests on vertebrate animals, the applicant for placing of the biocidal product on the market, before commencing the procedures involving experiments on vertebrate animals, shall be obligated to inform the Bureau for medicinal products about his/her intentions and to ask for data about performed tests for similar biocidal products, as well as the name and address of the holder of the marketing authorization for the biocide.
The application stipulated in paragraph 1 of this article must be accompanied by evidence that the applicant intends to submit an application for a marketing authorization for a biocide and that he/she possesses all other necessary data.
The Bureau for medicinal products shall be obligated to inform the holder of the marketing authorization for the biocides, about the name and the address of the holder of the authorization and shall also inform the holder of the authorization about the name and address of the new applicant in order to agree on the exchange of information in the interest of avoiding repetition of already performed tests involving vertebrate animals.

Article 33

The information included in the biocide marketing authorization request submitter's file for which marketing authorization has been issued may not be used by other biocide marketing authorization request submitters except in cases stipulated by the Minister of Health.

Article 34

The authorization holder is obligated to submit all the necessary information to the Bureau for medicinal products, regarding the following:
-the new findings or information on the active substance or biocide effects to the humans and to the environment,
-changes of the source or in the composition of the active substance,
-changes in the biocide product composition
-occurs resistance
-administrative changes such as modifications in the packaging.

Article 35

The Bureau for Medicinal Products shall maintain a Biocides Register based on the issued marketing authorizations.

The Register shall be published in the "Official Gazette of the Republic of Macedonia", once a year and shall contain the following data: biocide's brand name, the active substance, the manufacturer and the representative, the number and date of the marketing authorization and the validity period of the authorization.

Article 36

The biocides classified as poisonous, very poisonous, carcinogen, mutagen, as well as toxic for the reproductive system must not be given marketing authorization for public use.

Article 37

Notwithstanding the article 25 paragraph 1 of this Law, the Bureau for Medicinal Products may issue license to use the biocide for a period not exceeding 120 days, under certain conditions and in certain quantities.

Article 38

In case of extraordinary circumstances, in order to prevent the development of some unforeseen organism, when there are no available means or in case when other measures are impossible to be undertaken, the Bureau for Medicinal Products shall issue a license to use certain biocide products under special conditions and in specified quantities.

Article 39

The marketing authorization for the biocide shall be issued within than 60 days from the day of receipt of the complete documentation.

If the documentation is incomplete, the Bureau for Medicinal Products shall inform the submitter within 15 days from the day of receipt of the request.

The Bureau's decision can be appealed to the Second Minister of Health.

Article 40

The marketing authorization of the biocides shall be renewed before the end of its validity period, based on reassessment of the documentation stipulated in the articles 28 paragraph 2 and 26 paragraph 1 of this law.
In order to renew the marketing authorization, the holder of the marketing authorization should submit a request to the Bureau for medicinal products within 90 days before the end of the marketing authorization's validity period.

Article 41

The Bureau for medicinal products shall revoke or alter the marketing authorization renewal of the biocides in the following cases:

- there is a changes in the facts based on which the marketing authorization has been issued,
- the active substance has been banned,
- the conditions for issuing of the marketing authorization have been changed or are not met any more,
- there is a change in the entity proposing the biocide rights,
- the authorization has been issued based on wrong or incorrect data,
- additional data from the Center,
- the authorization holder submits explained request for revocation or alteration.

If the alteration is performed based on changes in the contents in the Active substances list, it shall be authorized after the evaluation of the active substance which is object of the request, in line with the procedure stipulated in paragraph 25 paragraph 1 of this law.

The Bureau for medicinal products shall inform the authorization holder about the alteration or the revocation of the marketing authorization.

Article 42

The Bureau for medicinal products may alter the authorized conditions for biocide use, especially of the manner and quantities of use, based on new scientific and technical findings, as well as in order to protect the health of people and the environment.

Article 43

The biocides should be used in accordance with the labeling and the instructions for use of the biocide.
The proper use of the biocide shall mean rational use of combination of physical, biological, chemical and other relevant measures, where the use of the biocide products is limited to the necessary minimum.
If the biocide is used at work, the use should be in line with the regulations for protection at work.

Article 44

Shortened procedure for marketing authorization on the territory of the Republic of Macedonia according to article 25 paragraph 2 of this Law shall be followed for biocides with marketing authorization in some of the EU member countries.

Article 45

If the Bureau for medicinal products determines that the biocide which is authorized in another country does not meet the conditions stipulated in article 28 of this Law and proposes to refuse the authorization or if limits the authorization, it shall inform the European Committee, the country where the authorization has been issued and the applicant and shall explain the reasons for the refusal or limitation.

Article 46

Notwithstanding the article 25 of this Law, the Bureau for medicinal producst may allow use of unauthorized biocide products and active substances for biocide products for the purpose of scientific researches and development and tests necessary for placing on the market.
The researches and tests stipulated in paragraph 1 of this article shall not be realized if the following data are submitted:
-in case of scientific researches and development –if written records are prepared and maintained with data on the biocide product and active substance identity, data on the labelling, procured quantities, the name and address of the end users of the biocide products or active substance and all data about the impact on the human health and on the environment,
-process oriented research and development the information shall be submitted to the competent authority in the country where the testing is going to be performed.

Article 47

Biocides or active substance which is used in biocide without marketing authorization may not be placed on the market for the purpose of experiments or tests which include or result with discharge in the environment, except if the Bureau for medicinal products has issued an approval for the experiments i.e. the tests and has determined the conditions for their implementation.

Notwithstanding the paragraph 1 of this article, Bureau for medicinal producst, based on assessment of the available data, may issue an approval to use the biocide for the required purpose, but it shall limit the used quantity and the treated area, and may impose additional requirements.

Article 48

If the experiment or the test takes place in a country where the biocide is not going to be placed on the market, the applicant should provide an authorization for their implementation from the competent authority in the country where it will take place.
If the experiments i.e. the tests may lead to harmful effect for the humans, animals or unacceptable undesired effects on the environment, the Bureau for medicinal products may ban or may approve them under certain conditions and limitations.

Article 49

The Minister of Health shall stipulate the method for classification, packaging and labeling of the biocide products.

Article 50

If the authorized biocide product is used as an insecticide, acaricide, rodenticide, avicide or molluscicide, the Bureau for medicinal products may authorize different manner of labeling and packaging.

V. PLACING OF DETERGENTS ON THE MARKET

Article 51

The detergents placed on the market should fulfill the conditions stipulated in this Law and which refer to biodegradability and labeling.

For surfactants which are also active substances for biocides and which are used as disinfectants, the tests for primary and final biodegradability, addition risk assessment and the method for testing and analysis of detergents, shall not apply if they are

- stipulated in the list of active substances for inclusion in biocidal products and in the list for inclusion in the low risk biocide products stipulated in article 24, paragraph 2 of this law and
- integral part of the biocide product approved in accordance with article 37 of this law

The detergent and/or surfactants manufacturer may be legal entity with registered in the Republic of Macedonia.

The manufacturer is responsible for the conformity of the detergents and/or surfactants for detergents with the provisions of this Law.

Article 52

Surfactants or the detergents which contain surfactants and which fulfill the criteria for final aerobe biodegradation stipulated in this Law may be placed on the market without further limitation regarding the biodegradability.

If the detergent contains surfactants for which the level or aerobic degradation is lower than that stipulated in this Law, manufacturers of detergents for application in the industry or institutions or of surfactants for the industrial or institutional detergents may ask for derogation in accordance with article 53 of this law.

The level of primary biodegradability shall be measured for all surfactants in detergents failing ultimate aerobic degradation tests.
Detergent surfactants, for which the level of primary biodegradability is lower than that stipulated in the Law, shall not be granted derogation.
The Minister of Health shall stipulate the methods for determination of the biodegradability of surfactants in detergents , as well as the referent methods for testing and analysis of the detergents.

Article 53

The request for derogation shall be submitted to the Bureau for Medicinal Products.
- with a technical file supplying all the information necessary for evaluating the safety aspects related to the specific use of surfactants in detergents failing to comply with the biodegradability limits.
The technical file shall also include information and results of tests for primary biodegradability and of the additional risk assessment, performed based on tiered approach and in compliance with the Good Laboratory Practice.
The decision for approval of the derogation shall be enacted by the Bureau for medicinal products on the basis of an opinion from a Commission for chemicals on the basis of the following criteria, if:
- the detergent of the surfactant for the detergent is not widely applied,
- it is used only in the industry or institutions and
- the risk for the health of people and the environment in accordance with the sales volume and the method of use is small as compared to the social and economic benefits, including food safety and hygienic standards.

The Minister of Health shall prescribe the content of the additional risk assessment.

Article 54

The manufacturer that places detergents or surfactants on the market is obligated to submit the following documents to the Bureau for medicinal products:
-information on one or more results from the biodegradability tests

-information for the surfactants which failed to pass the tests for final biodegradability and for which derogation has been requested:

-technical file of the primary biodegradability tests

-technical file of the test results and additional information on the risk assessment of the surfactants in the detergents.

Manufacturers are responsible for the correct testing of the detergents which are placed on the market.

The manufacturers should have available documentation for the tests in order to prove that they have been realized according to the regulations enacted based on this Law and that they may benefit from the property right on the test results, unlike the test results which are already available to the public.

The manufacturers which place detergents or surfactants for detergents on the market, upon request, free of charge and immediately, should submit to the medical personnel the data lists of the ingredients.

VI. PACKAGING AND LABELING OF CHEMICALS

Article 55

Any legal entity that manufactures or places chemicals on the market is obligated to pack and label them in accordance with the provision of the Law and the regulations enacted based on this Law.

Article 56

Dangerous chemicals, for which special safety devices are not stipulated, may be placed on the market only in packagings which fulfill the following conditions:

1. the packaging should be designed and constructed in a manner that prevents leakage of the contents, except in cases when special safety measures are stipulated,
2. the packaging and the closures should be made from strong materials which will not loosen and will not react with the contents of the packaging, and there is no possibility to form dangerous compounds with the contents,
3. the packaging and the closures should withstand the pressure and other loads during normal handling,
4. the containers equipped with changeable closing devices should be designed in a manner that allows repeated closing without leakage of the contents,
5. all packagings, regardless of their volume, which contain chemicals for sale labeled as “very toxic”, “toxic” and “corrosive” have to be equipped with child safety closures and tactile warning,

6. all packagings, regardless of their volume, which contain chemicals for sale labeled as “harmful”, “very easily flammable” and “easily flammable” have to have tactile warning,

The packaging should be sealed in a manner that allows permanent damage to the seal during the first opening.

Article 57

The packagings that contain dangerous chemicals, which are intended for general purpose, must not have:

1. shape or graphic decoration which easily attracts or encourage active curiosity in children or will deceive the consumers, or
2. presentation and/or label used for marking food or animal food products or medical or cosmetic products.

Article 58

During the selection of the packaging for placing the dangerous chemical on the market, the manufacturer must take care about the chemical’s properties, its purpose and way of use.
The dangerous chemical has to be labeled in a manner that allows the persons with special needs to realize the danger.
The dangerous chemicals have to be packed in packagings which cannot be easily opened by children.
The manufacturers shall be obligated to verify the appropriateness in an authorized laboratory.

Article 59

The chemicals which are placed on the market have to fulfill the following conditions regarding the labeling of the packaging:

1. The labeling of the dangerous chemical has to be visible, clear, indubitable and undeletable,

2. Any packaging of the dangerous chemical has to include the following minimum information:

- the trade name of the chemical,

- designation of the form of the chemical,

- the name of the substance as given in the EINECS list. If the substance is not included in the list yet, internationally recognizable name should be provided,

- name, address and telephone number of the entity responsible for placing the product on the market – manufacturer, importer or distributor,

- the danger symbols and the designation of danger in the use of the chemicals, the design of the danger symbols and the writings which point on danger should be in accordance with the international standards. The symbols should be printed in black on orange-yellow background. In cases when more than one sign or symbol should be applied on the chemical, then the obligation to place the T sign makes the X and S symbols conditional, if it is not determined otherwise the obligation to place the S sign makes the application of X sign voluntary and the obligation to place the E sign makes the application of F and O signs voluntary

- standardized text in accordance with the international standards which provides warning about the risks related to the use of the dangerous chemicals (R-phrases),

- standardized text in accordance with the international standards which provides information about safe storage and use of the dangerous chemicals (S-phrases)

- EEC number, if determined, (taken from EINECS or ELINCS).

3. In case of chemicals classified as irritating, easily flammable, flammable and oxidizing, in packagings not exceeding 125 ml, it is not necessary to label them with R-phrase and S-phrases. This also applies in case of same volume of harmful substances which are not for retail sale.

4. Labeling of the chemicals with the words “nontoxic”, “not harmful” or any other similar marks must not be placed on the label of the packagings of the chemicals which are object of this Law.

5. The label on the packaging should be tightly attached to one or several places on the packaging, in a way that enables horizontal reading of the data when the packaging stands normally. The dimensions of the label should be:
- at least 52x74 mm in case of packagings with volume not exceeding 3 l,
- at least 74x105 mm in case of packagings with volume between 3l and 50l;
- at least 105x148 mm in case of packagings with volume between 50l and 500l;
- at least 148x210 mm in case of packagings with volume over 500l;

Every symbol should cover at least one tenth of the area of the label, but not less than 1 cm^2. The complete surface of the label should be attached to the packaging immediately after the filling with the substance. Notwithstanding, marking of this kind shall not be necessary if all previously mentioned data are clearly visible on the packaging.
The color and the look of the label in the case of the derogation from the labeling of the packaging should be such as to provide clear visibility of the danger sign and its background.
The information which have to be included on the label should be clearly distinguished from the background and in such dimensions which enable easy reading.

6. nominal quantity (expressed as weight or volume) of the content in case of products for general purpose.

The clarification of the signs and symbols for danger on the chemicals and the cautionary and information marks shall be in Macedonian language and its Cyrillic alphabet using name which is commonly used (trivial name).

Notwithstanding the provisions of paragraph 2 of this article, if the dangerous chemicals are intended for industrial of laboratory use, they can be equipped with instructions in another language if all handlers of the chemicals are informed about the dangerous properties of the chemicals.

The provisions of this article regarding the language shall also apply to the biocide products.

Article 60

Notwithstanding the provisions of article 59 of this law it shall be considered that the requirements for marking shall be fulfilled in the following cases:

- external packagings which contain one ore more internal packagings if they are labeled according to the international transport rules for dangerous substances and of the internal packagings are labeled according to the requirements stipulated in article 59 of this law;
- single packagings if the packaging is labeled according to the international transport regulations for dangerous substances as well as in accordance with the requirements of article 59 item 2, lines 1, 2, 4, 6, 7 and 8 of this law;
- special types of packaging (mobile gas cylinders).

Article 61

Notwithstanding the provisions of article 59 item 5 of this law, the labeling may be in different manner:

- in packagings which are too small or in other way inappropriate for labeling;
- in packagings which contain very small quantities of dangerous substances which are not explosive, very toxic or toxic and which are not dangerous to the persons who handle them, or to other persons;
- in case when the packagings which contain explosive, very toxic and toxic substances are very small and there is not foundation for fear of any danger for the person who handles them or for other persons.

The exemption from paragraph 1 of this article does not allow different use of symbols, danger, risk and safety signs than the ones which are already determined in this Law.

Article 62

The dangerous chemicals have to be labeled with the highest degree of danger they pose.

If certain chemical is classified as dangerous, it is forbidden to be labeled as dangerous or not dangerous for the health people and for the environment.

It is forbidden to label the dangerous chemicals with marks such as “nontoxic”, “nonpolluting”, ‘environmentally friendly” or with any other term which says that the product is not dangerous i.e. term that can lead to underestimating of the dangers of the product.

Article 63

The instructions for use of the products for general purpose which contain substances stipulated in article 2 item 2 of this Law are necessary to include information on the handling safety, protection of the health of people, precaution measures and first aid measures in case of accident.

Article 64

The Minister of Health shall prescribe the labeling method and the manner of packaging of the dangerous chemicals.

Article 65

In order to enable the professional users to undertake the necessary measures for environmental protection and to protect the health of people and safety at work on or before the first shipment of the dangerous substance and biocide products, any manufacturer, importer or distributor should submit safety sheet to the end user.
The safety sheet may be submitted in hard copy or in electronic form and should contain information about the health of people and environment.

The Minister of Health and in an agreement with the Minister of environment and physical planning, the Minister of Labor and Social Policy and the Minister of Agriculture, Forestry and Water Economy shall prescribe the Safety Manual.

The legal entities which place chemicals on the market are obligated to keep up with the changes and new knowledge about the chemicals and to inform the end user and the Bureau of medicinal products.

Article 66

The manufacturers, distributors and importers of dangerous substances included in the ELINCS list, but not in the National List of New and Already Classified Substances which are on the Market on the Territory of the Republic of Macedonia are obligated to perform research in order to learn about the relevant and available data about the substance. The packaging and the conditional labeling of these substances should be realized based on the received information, according to article 59 of this Law.

Article 67

It is forbidden to advertise dangerous chemicals without including the danger category according to article 1 item 2 of this Law.

Article 68

The applicant who intends to advertise the biocide is obligated to attach an integral text of the advertisement to the application.

The following text “Use the biocide safely. Always read the label and the product information before use.” has to be used in the biocide advertisements.
These sentences have to be clearly separated of the advertisement.

In the advertisement, the word biocide may be replaced with the type of biocide.

In the advertisement, the consumer must not be deluded about the risk which the chemical poses for the health of people and for the environment.

The words “low risk biocide product”, “nontoxic”, “harmless” or similar expressions must not be used in the advertisements for biocide products.

Article 69

The packagings in which the detergents are placed on the market have to include the following readable, clear, visible and undeletable information:

1. the name and trade name of the product;
2. the name or trade name or trademark and address and telephone number of the party responsible for placing the product on the market;
3. the address, email address, (where available), and telephone number from which the datasheet can be obtained

The information stipulated in paragraph 1 of this article shall appear on all documents accompanying detergents transported in large packets.

The packaging of detergents shall indicate the content. The packaging shall indicate instructions for use and special precautions, if required.

Graphic symbols of fruit must not be used on the packagings in which the detergents are sold to the consumers and which may cause wrong impression regarding the use of liquid products.

The Minister of Health shall prescribe the data on the detergent content which have to be placed on the packaging, as well as the general and the special rules for labeling.

VII. CHEMICAL SAFETY

Article 70

The legal entities which perform manufacturing or sale of chemicals, according to this Law, as well as all entities that handle or use chemicals, are obligated to provide chemical safety.

All users of dangerous chemicals, during the procurement of the chemical, are necessary to be warned about its dangerous properties, with appropriate instructions for use, procedures for preservation of the health of people and of the environment, as well as the management of the waste of the chemical and of the packaging.

The Minister of Health in coordination with the Minister of Environment and the Minister for Agriculture, Forestry and Water Economy shall prescribe the content and the way of the warning for the users.

Article 71

The legal entities which manufacture or place chemicals on the market are obligated to provide instruction for proper use of dangerous chemicals, for handling without endangering of the own life and of the other persons' lives, not to cause harmful effects on the health of people or the environment, to handle with the waste according to the regulations, as well as to be responsible for any damage which may occur during their manufacturing or trade.

VIII. OBLIGATION TO INFORM

Article 72

The notifier has to inform the Bureau for Medicinal Products, in written, at last once a year, about the following:

- changes of the annual or total quantity of chemicals placed on the market,
- the new findings about the effects of the chemicals on the humans and/or the environment,
- about any new use for which it is placed on the market,
- about any change in the composition,
- about any change in the status of the manufacturer of importer,

The notifier is obligated to submit the data about the name and quantities of the chemicals which were placed on the market during the previous year, to the Bureau for Medicinal Products, until the end of the first trimester of the current year.

Article 73

If the quantity of the reported substance which was placed on the market by the notifier during one year or the total quantity from the commencement of the marketing exceeds the boundary values, the notifier is obligated to submit the Bureau the results of the additional investigations.

The Minister of Health shall prescribe the additional investigations.

The Bureau may recognize the investigations results of the same substance on the vertebrae reported by another notifier, if he/she has issued written consent.

If the notifier fails to submit additional investigations, the Bureau for Medicinal Products may temporary ban the substance of the market.

The Minister of Health shall prescribe the boundary quantities of the new substances for which additional investigations are required, the type and scope of investigations, as well as the methods and conditions for use of data received by another notifier.

Article 74

The Bureau for Medicinal Products shall exchange data on international level about the following:

- new substance included in the ELINCS list,
- data about the existing substances in order to prepare and assess the danger and about the individual classification of the existing substances from the EINECS list,
- data bout the biocides in order to prepare summary lists, and
- other data which come from this law, according from the international cooperation programs and the international agreements.

Article 75

If the notifier and the applicant prove that the revealing special data which are a trade secret may cause commercial losses, they may mark such data with degree of secrecy, and the Bureau has to treat them as such, except in cases when they are a threat to the protection of human health and of the environment.
Data relevant for protection of human health and environment and which are not going to be assumed as secret are:

1. trade name of substance or product,
2. name and address of the manufacturer of the chemical, biocide product i.e. active substance for biocide product,
3. name and address of the notifier i.e. the applicant,
4. name and contents of the active substance in the biocide product and the name of the biocide product,
5. physical and chemical properties of the chemical, biocide product i.e. active substance for biocide product,

6. description of the methods and measures for protection against the harmful effects of the substance or for recording of the substance as harmless,
7. summary results of the investigations and tests of the biocide product implemented according to article 31 of this Law,
8. summary results of the toxicological and eco-toxicological investigations,
9. degree of purity of the substance and identification of dangerous additional substances and compounds if they are dangerous and if it is necessary for classification and labeling of the substance,
10. recommendations about the preventive measures during handling, storage, transportation, use and urgent measures in case of fire and other hazards,
11. data from the instructions about the safety measures,
12. methods for removal of waste and its packaging,
13. procedures which have to be followed and urgent measures which need to be undertaken in case of leakage,
14. analytical methods for assessment of the exposition of humans and environment,
15. first aid measures and medical advice in case of personal injury.

If the manufacturer, the applicant or the importer of the biocide product or active substance for biocide product decides to make available the previously classified data, it is obligated to inform the Bureau for medicinal products for that decision.

IX. MANUFACTURING OF CHEMICALS

Article 76

The legal entity which manufacture dangerous chemicals are obligated to provide conditions which will reduce or prevent the danger for human health and to the environment and to provide substitution of the dangerous chemicals with less dangerous.

Article 77

The legal entity which manufacture dangerous chemicals have to fulfill the conditions prescribed in this Law and in the regulations enacted based on this Law and to have a license for performing activity – manufacturing of dangerous chemicals.

The Minister of Health shall issue the license stipulated in paragraph 1 of this article, upon prior consent by the Minister of Agriculture, Forestry and Water Economy, the Minister of Labor and Social Policy, the Minister of Environment and Physical Planning and the Minister of Economy.

The Bureau for Medicinal Products shall keep records about the legal entities which have been licensed for manufacturing of dangerous chemicals.

Article 78

The legal entities which manufacture dangerous chemical must have appropriate premises, equipment and staff.

The Minister of Health with consent by the Minister of Environment and Physical Planning shall prescribe the detailed conditions regarding the premises, equipment and staff stipulated in paragraph 1 of this article.

Article 79

The legal entity which performs manufacturing of dangerous chemicals has to familiarize all staff with the dangers for the health and environment posed by the dangerous chemicals and with the protection measures.

The staff that handle and work with dangerous chemicals must be professionally trained for safety in work with chemicals.

The legal entities stipulated in paragraph 1 of this article are obligated to take care about the continuous training of the staff that handle and work with dangerous chemicals.

The training of the staff that handle and work with dangerous chemicals shall be performed by legal entities which fulfill the conditions with respect to space, equipment and staff on the basis of an authorization from the Minister of Health

The Minister of Health upon consent by the Minister of Labor and Social Policy, the Minister of Environment and Physical Planning and the Minister of Agriculture, Forestry and Water Economy shall prescribe the contents of the training program, the manner of training, the knowledge of the employee depending on the work he/she performs, as well as the space, equipment and staff which have to be fulfilled by the legal entities which implement the training.

Article 80

The legal entities which manufacture dangerous chemicals are obligated to keep records which shall be include the following: data about the name of the chemical, produced quantities, expiration date, date of production, and the purpose.

Article 81

The legal entities which manufacture dangerous chemicals are obligated to take care about the collection, proper storage and safe disposal of the waste in accordance with the waste regulations.

Article 82

The manufacturer of dangerous chemicals is obligated to inform the Bureau for Medicinal Products about any change which could affect the meeting of the conditions prescribed in this Law.

If the manufacturing conditions are not fulfilled, the Bureau for Medicinal Products shall revoke the license for work and shall remove the legal entity from the records of legal entities which perform manufacturing of chemicals.

X. TRADE OF CHEMICALS

Article 83

Trade of chemicals may be performed by legal entities which fulfill the conditions regarding premises, equipment and staff prescribed in this Law and in the regulations enacted based on this Law and possess a license to performs activity issued by the Bureau for Medicinal Products.

The License for trade of dangerous chemical shall be grated for the period of 5 years.

The Bureau for Medicinal Products shall maintain records about the legal entities who have been licensed for performing trade of dangerous chemicals.

Article 84

Except the general conditions, the legal entities are obligated to fulfill the following minimum standards for performing trade of dangerous chemicals:

1. To have staff with university degree in the field of chemistry, technology, pharmacy, medicine, biology, agriculture or veterinary medicine depending on the purpose of the chemicals and to be professionally trained for handling chemicals.

2. To have appropriate premises for housing, storage and issuing of the dangerous chemicals, which regarding the location, the construction, ventilation, temperature and humidity, fulfill the technical and sanitary and hygiene conditions and other conditions prescribed by a Law.

3. To have visible instructions about the measures and means for prevention of poisoning, the first aid in case of poisoning, the way of removal of the chemical that is placed on the market (neutralization, washing agents).

4. To have available various first aid kits (antidotes, washing agents etc.).

The Minister of Health upon consent by the Minister of Environment shall prescribe the detailed conditions regarding the premises and equipment.

The provision of paragraph 1 of this article shall not apply to the scientific and research, the education and healthcare institutions which use the chemical only for their basic activity.

Article 85

The legal entity which performs trade of dangerous chemicals is obligated to provide professional training of the persons who work with the chemicals and to take care about their continuous training.

The Minister of Health upon consent by the Minister of Labor and Social Policy, the Minister of Environment and Physical Planning and the Minister of Agriculture, Forestry and Water Economy shall prescribe the contents of the training program, the manner of training, the knowledge of the employee depending on the work he/she performs, as well as the conditions which have to be fulfilled by the legal entities which implement the training.

Article 86

The legal entities which perform trade of dangerous chemicals are obligated to maintain record which shall include the following:

- data about the chemical (name of the chemical, quantities handed, expiration date, purpose),
- data bout the user (name, surname, unique record number, address, signature of the person who has handed and the one who has received the dangerous chemical and date).

The data stipulated in paragraph 1 of this article shall be archived for at least 5 years.

It is forbidden to hand dangerous chemicals to persons younger than 18 years of age.

Article 87

The legal entity which performs trade of chemicals may import dangerous chemicals stipulated in article 2 item 2 sub-items f) through i) of this Law, based on import license issued by the Bureau for Medicinal Products.

The Bureau for Medicinal Products shall maintain records about the issued licenses for import and export of chemicals stipulated in paragraph 1 of this article.

Article 88

The legal entities which perform trade of dangerous chemicals are obligated to take care about collecting, proper storage and safe disposal of the waste according to the dangerous waste regulations.

XI. PROTECTION OF THE GENERAL HEALTH AND ENVIRONMENT

Article 89

The Minister of Health and the Minister of Environment and Physical Planning may temporary ban or limit the production, distribution or use of dangerous chemicals if there is suspicion that they are harmful for the human health and for the environment.

The Minister of Health and the Minister of Environment and Physical Planning may ban or limit the production, distribution or use of dangerous chemicals which are on the list of ratified international conventions.

The Minister of Health and the Minister of Environment and Physical Planning may approve placing on the market or use under special circumstances of certain dangerous chemicals which contain or may discharge substances harmful for the humans or environment.

XII. PROCEDURE FOR MUTUAL RECOGNITION OF THE TRAILS CERTIFICATES

Article 90

The non-clinical trials of certain chemical, which results enable the assessment of their potential danger for the humans and environment, and which are performed in the procedures for placing of the chemical on the market and the use, registration, reporting or informing shall be performed according to the Good Laboratory Practice principles.

The Minister of Health shall prescribe the Good Laboratory Practice principles.

Article 91

The responsible persons who submit results from the trials are obligated to confirm that the trails on which the results are based are in accordance with the requirements of the Good Laboratory Practice principles. The confirmation has to include the following:

1. Good Laboratory Practice certificate,

2. Statement issued by the laboratory which has performed the test and confirmation that the test has been performed in accordance with the Good Laboratory Practice principles (GLP).

The certificate issued by a foreign country with which the Republic of Macedonia has signed an agreement for mutual recognition of the data shall be equally valid as the certificate stipulated in paragraph 1 of this article.

XIII. INSPECTION SUPERVISION

Article 92

The inspection supervision on the implementation of this Law and the regulations enacted based on this Law shall be performed by the State Sanitary and Health Inspectorate through the inspectors for chemicals.

The inspection supervisions on the chemicals for protection of the plants shall be performed by the competent authority in the Ministry of Agriculture, Forestry and Water Economy.

The inspection supervision on the fulfillment of the conditions for manufacturing and trade of chemicals regarding the environmental protection against undesired reactions of chemicals shall be performed by the competent authority in the State Inspectorate for Environmental Protection.

The supervision on the fulfillment of the conditions for work protection shall be performed by the competent authority in the State Inspectorate for Labor.

Article 93

Inspectors for chemicals may be persons which is addition to the general conditions from the Law on Civil Servants have high education in the field of pharmacy, chemistry, technology with passed exam for familiarity with chemicals, and at least five years working experience.

The Minister of Health upon consent by the Minister of Environment and Physical Planning shall prescribe the method for implementation of the training and the exam for familiarity with chemicals.

Article 94

The inspectors for chemicals may take samples of chemicals, without compensation in order to check their quality.

The analyses of the samples taken by the inspectors shall be performed in accredited laboratories.

The accreditation of the laboratories shall be performed according to the accreditation regulations.

Until the accreditation of the laboratories, the analysis of the samples stipulated in paragraph 2 of this article shall be performed in the existing laboratories.

Article 95

During the inspection, the inspector, within his/her competences, has the right and obligation to:

1. ban manufacturing and trade of chemicals if the conditions prescribed by this Law and by the regulations enacted based on this Law are not fulfilled;
2. ban manufacturing and trade of chemicals if there is direct danger for the human health and for the environment;
3. ban manufacturing or trade of chemicals if the substance is not reported according to this Law and is not registered in the list of chemicals which is maintained in the Bureau for Medicinal Products;
4. ban manufacturing and trade of dangerous chemical which is not classified, labeled and packed according to this Law and by the regulations enacted based on this Law;
5. ban trade of dangerous chemical which does not have instructions for the safety measures;
6. order other measures and determine deadlines for their execution for harmonization of the activity of the legal entities with this Law and by the regulations enacted based on this Law.

Article 96

The inspector, with resolution, determines the measures for which is authorized according to the regulations for general administrative procedure and this Law.

The appeal upon the resolution does not postpone its enforcement.

The Minister of Health decides in second instance upon appeal against the inspector's resolution.

XIV. MISDEMEANOR PROVISIONS

Article 97

A fine in the amount of the denar equivalent of 3000 to 6000 EUR shall be imposed against legal entities if:

1) they fail for submit the data upon a request from the center (article 7);
2) they do not use the existing classification data to avoid unnecessary tests on experimental animals (article 11 paragraph 9);
3) they do not submit a notification with documentation stipulated in article 14 paragraph 1 of this law to the competent authority in the country where the substance is produced or in the country where the notifier has a headquarters;
4) does not submit a notification according to article 15 of this law;
5) does not submit a request for renewal of the decision for placement of new substance in the market 120 days before the expiration of the validity of the decision (article 20,

paragraph 3);
6) fails to provide written agreement from the first notifier for the utilization of the results from the listed tests for notified substances (article 21 paragraph 2);
7) they fail to prove that the substance they want to notify is identical to the already registered substance, if they do not ask for information whether the substance had already been registered and who is the first applicant, if they do not submit a proof that they intend to place the substance on the market and if they do not stipulate the quantities (article 21, paragraphs 4, 5 and 6);
8) as a holder of the marketing authorization, they do not provide data at the request from the Bureau for medicinal products which are required for the change (article 27 paragraph 2);
9) if they do not act in accordance with article 32 paragraph 1 of this law before commencing procedures involving experiments of vertebrates;
10) if they do not submit the relevant information from article 34 paragraph 1 of this law to the Bureau for medicinal products;
11) if it fails to secure a license from the Bureau for medicinal products to implement of an experiment or test a biocide which will not be placed on the market on the Territory of the Republic of Macedonia (article 48 paragraph 1);
12) places on the market detergents which do not fulfill the conditions related to biodegradability and labeling determined with this law and detergents and/or surfactants for detergents which are not harmonizes with the provisions of this law (article 51 paragraphs 1 and 3);
13) does not act in accordance with article 54 of this law;
14) does not pack and label chemicals according to the provision of this law (article 55);
15) places on the market dangerous chemicals in packets that do not fulfill the conditions from article 56 of this law;
16) places on the market packets which contain dangerous materials contrary to the articles 57 and 58 paragraph 2, 3, and 4 of this law;
17) places on the market chemicals which do not fulfill the conditions with respect to the labeling of the packet (article 59) or contrary to the article 62 of this law;
18) does not include the information from article 63 of this law in the instructions for use of the general use preparations which contain substances from article 2, item 2 of this law;
19) does not provide for a safety sheet according to article 65, paragraphs 1 and 2 of this law;
20) does not act according to article 66 of this law;
21) advertises dangerous chemicals without stipulating the category of danger according to article 2, item 2 of this law (article 67);
22) advertises biocides contrary to article 68 of this law;
23) places on the market detergents in a manned contrary to article 69 of this law;
24) does not ensure chemical safety and does not submit the instructions for proper use to the users (article 70, paragraphs 1 and 2 and 71);
25) does not submit regularly the data from article 72, paragraph 1 of this law to the Bureau for medicinal products;
26) does not submit the data from articles 72, paragraph 2 of this law in the predicted deadline;
27) does not provide for conditions which will reduce or prevent the threat to human health and environment and does not provide for a replacement of the dangerous

chemicals with less dangerous (article 76);
28) manufactures dangerous chemicals contrary to the articles 77 and 78 of this law;
29) does not familiarize the staff with the threat to human health and environment from the dangerous chemicals and the method for protection and does not provide continuous training of the staff (articles 79 paragraphs 1, 2 and 3 and 85);
30) does not keep the records stipulated in articles 80 and 86 paragraph 1 of this article;
31) does not inform about any change that may influence the fulfillment of the conditions prescribed with this law (article 82 paragraph 1);
32) markets dangerous chemicals contrary to the articles 83 and 84 of this law;
33) does not keep the data in the deadline determined in article 86 paragraph 2 of this law;
34) issues dangerous chemicals to persons younger than 18 years (article 86, paragraph 3);
35) imports chemicals from article 2 item 2, sub items f to h of this law, without a license issued by the Bureau for medicinal products (article 87 paragraph 1) and
36) does not implement the principles of Good Laboratory Practice when performing non clinical trials on chemicals (article 90).
For the misdemeanor stipulated in paragraph 1 of this article, a fine in the amount of the denar equivalent to 1000 to 2000 EUR shall be imposed against the responsible person in the legal entity.
For the misdemeanor stipulated in paragraph 1 items 28 and 31 of this article, in addition to the fine stipulated in paragraph 1 of this article, the legal entity shall be subject to a misdemeanor sanction prohibition to perform a core business activity for a period of six months to two years.

XV. TRANSITIONAL AND FINAL PROVISIONS

Article 98

The bylaws envisaged with this Law shall be enacted within 18 months of the day when this law becomes effective.

The existing regulations shall apply until the enactment of the regulations stipulated in paragraph 1 of this article.

Article 99

The legal entities which market chemicals shall harmonize their work with the provisions of this law within one year from the day when the law enters into force

Article 100

The submitted requests for manufacturing, marketing and distribution of preparations by toxicity group shall be resolved, until the time of legal effectiveness of this law, in accordance with the procedures that applies until the day of effectiveness of this Law.

Article 101

The Minister of Health shall authorize a public healthcare institution which will perform the activities of Information Center for Poisoning of Chemicals within three months of the day of effectiveness of this Law and will begin to work from 1 January 2008.

Article 102

The Government of the Republic of Macedonia shall for the inter-sector body from article 8 of this law within three months from the legal effectiveness of this law and this body shall start to work from 1 January 2008.

Article 103

The Law on Trade of Poisons (Official Gazette of SFRY no. 13/91) and the Law on Production of Poisons (Official Gazette of SRM no 18/76) shall cease to apply on the day of effectuation of this Law.

Article 104

This Law shall become effective on the eighth day after its publication in the “Official Gazette of the Republic of Macedonia”.