Protection Against the Harmful Impact of Chemical Substances and Preparations Act

(Title amended, SG No. 114/2003)

Promulgated, State Gazette No. 10/4.02.2000 (effective 5.02.2002), amended, SG No. 91/25.09.2002, No. 86/30.09.2003, amended and supplemented, SG No. 114/30.12.2003 (effective 31.01.2004)

Chapter One
GENERAL PROVISIONS

Article 1. (Amended, SG No. 114/2003) This Act shall regulate the conditions and the procedure for placing on market, trade, import, export, storage, and use of chemical substances and preparations, the state control over them, as well as the rights and duties of natural and legal persons who place them on the market, trade in them, store, use, import or export them, with a view to protecting the health and the life of man and the environment.

(2) This Act shall also apply to chemical substances and preparations located on the territory of the Republic of Bulgaria in free zones.

Article 2. (Amended, SG No. 114/2003) Dangerous chemical substances and preparations shall be chemical substances and preparations which are classified in one or more of the following categories:

1. explosive;
2. oxidising;
3. extremely flammable;
4. (Amended, SG No. 114/2003) highly flammable;
5. flammable;
6. very toxic;
7. toxic;
8. harmful;
9. (Amended, SG No. 114/2003) corrosive;
10. irritating;
11. sensitizing;
12. carcinogenic;
13. toxic for reproduction;
14. mutagenic;
15. dangerous for the environment.

Article 3. (Amended, SG No. l 14/2003) The provisions of this Act shall not apply to substances and preparations whose placing on the market, trade, import, export, storage and use are subject to regulation in accordance with specific laws, such as:

1. (Amended, SG No. 114/2003) medicinal products for human or veterinary use;
2. cosmetic products;
3. (Amended, SG No. 114/2003) foodstuffs and animal feedingstuffs;
4. radioactive substances and wastes and nuclear materials;
5. (Repealed, SG No. 114/2003);
6. (Amended, SG No. 114/2003) wastes;
7. (Amended, SG No. 114/2003) chemical substances and preparations transported across the territory of the Republic of Bulgaria as transit goods which are not treated or processed on the territory of the country.
8. (New, SG No. 114/2003) dangerous chemical substances and preparations transported by rail, sea, air, or other land or waterways;
9. (New, SG No. 114 /2003) invasive medicinal products or medicinal products intended for use in direct physical contact with the human body.

Article 4. (Amended, SG No. 114/2003) Advertising of dangerous chemical substances and preparations without explicit indication of their category of danger as referred to in Article 2 shall be prohibited.

Chapter Two
CLASSIFICATION, PACKAGING AND LABELLING OF DANGEROUS CHEMICAL SUBSTANCES AND PREPARATIONS

(Title amended, SG No. 114/2003)

Article 5. (Amended, SG No. 114/2003) (1) Any person placing a chemical substance or preparation on the market shall be required to classify it in one or more categories of danger as referred to in Article 2, as well to package and label it in accordance with the category or categories of danger specified in the classification.

(2) The procedure and method of classification, packaging and labelling of chemical substances and preparations shall be determined with a regulation issued by the Council of Ministers.

(3) The classification of chemical substances and preparations shall be made on the basis of their physico-chemical, toxicological and ecotoxicological properties.

(4) Laboratory tests for determination of the properties referred to in Paragraph 3 shall be carried out in compliance with the principles of good laboratory practice in accredited laboratories.

(5) The laboratories referred to in Paragraph 4 shall be accredited by the Executive Agency "Bulgarian Accreditation Service" in accordance with the regulation referred to in Article 6.

(6) The principles, the inspection and the certification of good laboratory practice shall be determined with a regulation issued by the Council of Ministers.

Article 5a. (New, SG No. 114/2003) The specific requirements for placing detergents on the market shall be determined with a regulation issued by the Council of Ministers.

Article 6. (1) (Redesignated from Article 6, amended, SG No. 114/2003) The packaging of dangerous chemical substances and preparations shall satisfy the following minimum requirements:

1. (Supplemented, SG No. 114/2003) the packaging must be designed in a way which does not allow its content to spill or leak, save in the cases where special safety devices are required, as provided for in the regulation referred to in Article 5, Paragraph 2;

2. the packaging and fastenings must be made of materials which do not interact with the packaged contents;

3. the packaging and fastenings must withstand the normal loading during transportation and handling;

4. containers fitted with replaceable fastening devices must have such devices that can be re-fastened without the contents spilling or leaking;

5. (Repealed, SG No. 114/2003)

6. (Repealed, SG No. 114/2003)

(2) (New, SG No. 114/2003) Chemical substances not classified as dangerous, which nevertheless may represent a specific danger, shall be packed in compliance with the requirements of Paragraph 1.

(3) (New, SG No. 114/2003) Additional requirements to the packaging of certain substances and preparations shall be determined with the regulation referred to in Article 5, Paragraph 2

Article 7. (Amended, SG No. 114/2003) (1) The labels of dangerous chemical substances and preparations shall include the following minimum information in the Bulgarian language:

1. name;

2. for preparations – chemical name of the dangerous substance or of the dangerous chemical substances contained in the preparation;

3. the name and complete address, including the telephone number, of the person placing the chemical substance or preparation on the market;

4. danger symbols and signs determined with the regulation referred to in Article 5, Paragraph 2;

5. R-phrases – standard texts warning about the risk related to the use of the dangerous chemical substance or preparation;

6. S-phrases – standard texts advising on the safe storage and use of the dangerous chemical substance or preparation;

(2) Indications denying one or more of the dangerous properties of the chemical substance or preparation or leading to underestimation of the dangers, must not appear on the label or the packaging.

(3) The regulation referred to in Article 5, Paragraph 2 shall lay down additional requirements to labelling of certain chemical substances and preparations.

(4) Chemical substances not classified as dangerous but which may nevertheless represent a specific danger, shall be labelled in compliance with Paragraph 1, items 1 and 3.

Article 7a. (New, SG No. 114/2003) For contracts negotiated at a distance, as referred to in Article 69 of the Consumer Protection and Rules of Trade Act, the proposal shall contain the category or categories of danger of the substance or preparation.

Article 7b. (New, SG No. 114/2003) (1) Dangerous chemical substances and preparations, as well as preparations not classified as dangerous, which however may represent a specific danger when placed on the market for professional use, shall be accompanied by a safety data sheet;

(2) The safety data sheet shall be provided by the person placing on the market the chemical substance or preparation prior to or during the first delivery.

(3) The safety data sheet shall indicate the storage conditions of the chemical substances and preparations.

(4) The requirements to the format and content of safety data sheets shall be determined with the regulation referred to in Article 5, Paragraph 2.

Article 7c. (New, SG No. 114/2003) (1) Where mentioning the chemical name of a substance contained in the preparation on the label or in the safety data sheet breaches the intellectual property rights of the persons placing the preparation on the market, they may mention such a name of the chemical substance that identifies the most important functional chemical groups, as well as include in the label an alternative name after receiving permission from the Minister of Health or an official authorised by him/her.

(2) Mentioning an alternative name on the label shall be permitted only in cases where the substance contained in the preparation is classified in one or more of the following categories:

1. irritant – excluding those indicated with the R-phrase "R41: Risk of serious damage to eyes ", or irritants in combination with one or more if the following properties: explosive, oxidising, extremely flammable, highly flammable, flammable, dangerous for the environment;

2. harmful with an acute lethal effect or harmful in combination with an irritant and/or one or more of the properties mentioned in item 1 with an acute lethal effect.

(3) The criteria for choice of an alternative name to be included in the label shall be determined with the regulation referred to in Article 5, Paragraph 2.

Article 7d. (New, SG No. 114/2003) (1) For obtaining the permission referred to in Article 7c, Paragraph 1, the person placing a dangerous chemical substance on the market shall submit to the Ministry of Health an application in standard format determined with the regulation referred to in Article 5, Paragraph 2.

(2) The Minister of Health may require additional information necessary to estimate how well-grounded the application is.

(3) The Minister of Health or an official authorised by him/her shall grant a permission or issue a motivated refusal within a period of 60 days from the date of application referred to in Paragraph 1, or from the date of receiving the additional information referred to in Paragraph 2.

(4) The refusal referred to in Article 3 shall be subject of appeal pursuant to the Supreme Administrative Court Act, respectively the Administrative Procedure Act.

Article 7e. (New, SG No. 114/2003) The provisions of Article 7c shall not apply to chemical substances for which exposure limits have been adopted.

Article 7f. (New, SG No. 114/2003) (1) The person placing on the market a chemical preparation classified as dangerous due to its physico-chemical, toxicological and ecotoxicological properties, shall submit to the Ministry of Health information regarding its chemical composition, physico-chemical, and toxicological properties.

(2) The information referred to in Paragraph 1 shall also be used by medical and health establishments with a view to protecting the health and life of man and planning preventive measures or treatment.

(3) The Ministry of Health shall keep confidential the production and trade secrecy of the information received.

(4) The provisions of Paragraphs 1, 2 and 3 shall also apply to biocides.

Chapter Three
NOTIFICATION OF NEW CHEMICAL SUBSTANCES

Article 8. (Amended, SG No. 114/2003) (1) All new chemical substances which will be placed on the market as such or in the form of a constituent part of a preparation shall be subject to notification.

(2) For new substances which are intermediate products and are produced or imported in quantities larger or equal to 1 ton per annum the notifier may request from the Minister of Environment and Water the application of a reduced test package.

(3) The Minister of Environment and Water shall grant permission to apply a reduced test package for an intermediate under the following conditions:

1. the use of the intermediate is limited to a maximum of two users;

2. the intermediate is solely manufactured for usage in a chemical process for producing a new chemical substance/substances, excluding monomers which are processed to chemical substances other than polymers;

3. the notifier delivers the intermediate to the user directly and not through an intermediary;

4. a closed system during the entire lifecycle of the intermediate is provided;

5. technologies for control and reduction of emissions in case of potential risk of exposure, failure, waste generation and prior to maintenance and cleaning works on the facility/system are introduced;

6. transport operations are carried out in compliance with the requirements of the Carriage by Road Act;

7. a management system must exist which identifies the duties and responsibilities of the individuals responsible for implementation of the activities referred to in items 4 and 5;

8. the packaging and labelling are carried out in compliance with the requirements of Chapter Three of this Act and the secondary legislation for its application, and the label will additionally carry the sentence: "Caution –substance not yet fully tested";

9. the notifier must monitor the users referred to in item 1 to ensure compliance with the conditions listed in items 2 through 8.

(4) The Minister of Environment and Water shall issue a motivated refusal for application of a reduced test package where the requirements referred to in Paragraph 3 are not satisfied.

(5) The refusal referred to in Paragraph 4 shall be subject of appeal pursuant to the Supreme Administrative Court Act.

(6) The procedure and method of notification of intermediates shall be determined with the regulation referred to in Article 11.

(7) The Minister of Environment and Water or an official authorised by him/her shall issue a certificate of registration of a notified chemical substance.

(8) Notification shall not be required for a new chemical substance which:

1. is intended for inclusion in medicines for human medicine, veterinary medicinal products, plant protection products, biocidal products and supplements for foodstuffs and animal feedingstuffs;

2. is in the form of polymer containing in bound form less than 2% of the new substance;

3. is intended to be placed on the market in quantities not exceeding 10 kg per manufacturer or importer per calendar year;

4. is intended solely for purposes of scientific research and development in quantities not exceeding 100 kg per manufacturer or importer per calendar year;

5. is intended solely for purposes of process-oriented research and development for one year by a limited number of users in limited quantities.

(9) In the cases referred to in Article 8, item 3, the manufacturer or importer shall submit to the Ministry of Environment and Water identity data and information on the new substance determined with the regulation referred to in Article 11.

(10) In the cases referred to in Article 8, item 4, the manufacturer or importer of a new chemical substance shall be obliged to keep and submit to the Ministry of Environment and Water upon request information on the identity of the new substance, the quantity, labelling data and user list.

(11) The notification waiver referred to in Paragraph 8, item 5 shall not be required provided that the manufacturer or the importer submits to the Ministry of Environment and Water information on the identity of the new substance, the quantity, labelling data, user list, justification for the quantity, research and development programme and a technical dossier as determined with the regulation referred to in Article 11.

(12) In the cases referred to in Paragraph 8, items 2, 3, 4 and 5 the manufacturer or the importer shall be obliged to package and provisionally label the new chemical substance in compliance with Articles 6 and 7.

Article 9. (Amended, SG No. 114/2003) (1) The Minister of Environment and Water may, as an exception, extend the term referred to in Article 8, Paragraph 8, item 5 by one calendar year on the basis of an application submitted by the person placing the new chemical substance on the market, provided that:

1. justified evidence is submitted that extending the term is necessary for the needs of research and development activities;

2. there are no doubts for possible harmful effects on life and health of man and the environment;

3. justified evidence is submitted that the substance is intended solely for professional use and will not be placed on the market for mass consumption.

(2) The application referred to in Paragraph 1 shall be submitted three months prior to the expiry of the one-year term.

Article 10. (Amended, SG No. 114/2003) The notifier of a new chemical substance being placed on the market as such or in the form of a constituent part of a preparation shall submit to the Minister of Environment and Water the following documents:

1. a technical dossier on a paper or electronic carrier, depending on the quantity of substance being placed on the market;

2. a statement on the possible harmful effects of the chemical substance, depending on its method of usage;

3. classification and labelling proposal;

4. information on the quantity of the substance which the notifier intends to place on the market annually;

5. proposal for the contents of the safety data sheet referred to in Article 7b;

6. a power of attorney by the notifier, in case the notification is carried out by a representative;

7. evidence of paid charge under Article 71 of the Environmental Protection Act.

Article 10a. (New, SG No. 114/2003) (1) The notifier of a new chemical substance shall submit to the Minister of Environment and Water a justified request for announcing data from its technical dossier confidential in order to protect its industrial or trade interests.

(2) The following shall not be considered industrial and commercial secret:

1. the trade name of the chemical substance;

2. the name of the manufacturer or the importer;

3. physico-chemical properties of the chemical substance;

4. the possible ways of rendering the substance harmless;

5. the summary results of the toxicological and ecotoxicological tests;

6. if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives classified as dangerous;

7. the recommended methods and precautions mentioned in the technical dossier;

8. the information contained in the safety data sheet;

9. the analytical methods for determining the dangerous substance;

(3) The information referred to in Paragraph 1 which is considered confidential shall be identified by the inscription "For official use".

(4) In case the notifier announces part or all of the information referred to in Paragraph 3 as non-confidential, he shall notify the Ministry of Environment and Water thereof in writing.

(5) The Minister of Environment and Water shall keep the industrial and trade secrecy of the information referred to in Paragraph l which is considered confidential.

Article 10b. (New, SG No. 114/2003) The Ministry of Environment and Water shall keep the notification documents for 10 years from the last registration of the notified chemical substance.

Article 10c. (New, SG No. 114/2003) The Minister of Environment and Water may require from the notifier:

1. additional information and tests for an already notified substance in case of receiving new data on the substance's properties;

2. a sample of the notified substance for conducting control tests;

3. additional control tests for checking and/or confirmation of the notified substances and/or transformation products thereof;

4. to take appropriate measures related to the safe use of the substance.

Article 10d. (New, SG No. 114/2003) The Minister of Environment and Water shall keep a public register of the notified chemical substances.

Article 11. (Amended, SG No. 114/2003) (1) The procedure and method of notification of new chemical substances shall be laid down by a regulation issued by the Council of Ministers.

(2) The regulation referred to in Paragraph 1 shall also specify the notifier's obligations after receiving the registration certificate of the notified chemical substance, as well as the content of the register referred to in Article 10d.

Article 12. (Amended, SG No. 114/2003) The Minister of Environment and Water shall issue to the notifier a certificate for the conducted assessment of risk to man and the environment of the notified chemical substance after the registration certificate of the notified chemical substance has been issued.

Article 12a. (New, SG No. 114/2003) (1) The certificate of assessment of the risk to man and the environment of the notified chemical substance shall be issued on the basis of an expert assessment of risk to man and an expert assessment of risk to the environment.

(2) The Ministry of Health shall carry out the expert assessment of risk to man.

(3) The Ministry of Environment and Water shall carry out the expert assessment of risk to the environment.

Article 12b. (New, SG No. 114/2003) Where the technical dossier data referred to in Article 10, Paragraph 1 is insufficient for assessing the risk, the Minister of Environment and Water shall require the submission of additional information from the person placing the new chemical substance on the market.

Article 12c. (New, SG No. 114/2003) The Minister of Environment and Water shall issue the certificate referred to in Article 12a, Paragraph 1 within 12 months from issuing the registration certificate of the notified chemical substance referred to in Article 8, Paragraph 7, or from receipt of the additional information referred to in Article 12b.

Article 13. (Amended, SG No. 114/2003) The procedure and method of carrying out an assessment of risk to man and the environment of notified chemical substances shall be laid down by a regulation issued by the Council of Ministers.

Chapter Four

(Repealed, SG No. 91/2002, new, SG No. 114/2003)

PLACING OF BIOCIDAL PRODUCTS ON THE MARKET

Section I

(Effective 1.01.2007)

Conditions and procedure for placing active substances and biocidal products on the market

Article 14. (1) An active substance and a biocidal product shall be placed on the market where a permit has been issued for them in compliance with this Act.

(2) Low-risk biocidal products shall be placed on the market in case a registration certificate has been issued for them.

(3) The permit referred to in Paragraph 1 and the certificate referred to in Paragraph 2 shall be issued by the Minister of Health or a person authorised by him/her.

(4) The Ministry of Health shall, on request or on their own initiative, establish a frame-formulation and communicate it to the applicant.

(5) Biocidal products shall be classified, packaged and labelled in accordance with the provisions of Chapter Two.

Article 14a. The permit referred to in Article 14, Paragraph 1 shall not be issued for:

1. active substances and basic substances referred to in Article 16;

2. biocides intended for scientific research;

3. biocides intended for development activities;

4. biocides intended for experiments under which a biocidal product or an active substance is released or may be released.

Article 14b. (1) The manufacturer or importer of a biocide intended for scientific research shall be obliged to keep and submit under request to the Minister of Health information about the identity of the biocide, labelling data, quantities supplied, a list of users and the technical dossier containing all available data for possible impacts on the health of man or animals and on the environment.

(2) The manufacturer or importer of a biocide intended for use in development activities must submit to the Ministry of Health the information referred to in Paragraph 1 before starting the process-orientated development.

Article 14c. Where scientific research and development may have a harmful impact on the health of man or animals or an unfavourable impact on the environment, the Minister of Health, in coordination with the Minister of Environment and Water, may prohibit or permit these activities under certain conditions with a view to preventing the harmful or unfavourable impacts.

Article 14d. (1) The experiments referred to in Article 14a, item 4 shall be permitted after the issuance of the permit by the Minister of Health or an official authorised by him/her.

(2) In order to have the permit referred to in Paragraph 1 granted, the manufacturer or importer shall submit to the Ministry of Health an application accompanied by:

1. certificate for current status of the court registration;

2. information on the identity of the biocide, labelling data, quantities supplied, list of places where experiments will be carried out, and a list of users;

3. data about the groups of population who may be exposed and the ways of exposure;

4. information about the environment components which may be exposed to impact and the ways of distribution;

5. preventive and control measures of the exposure of man and the environment.

(3) Where the submitted documents are found incomplete, within 14 days of the date of their receipt the Minister of Health shall require from the persons referred to in Paragraph 2 to submit the necessary information.

(4) Within a period of 5 days from the submission of the documents or from the elimination of the incompleteness, the Minister of Health shall send the documents referred to in Paragraph 2 to the Minister of Environment and Water for opinion.

(5) The Minister of Environment and Water shall return the opinion within 30 days of the receipt of the documents referred to in Paragraph 2.

(6) The Minister of Health may reasonably require from the persons referred to in Paragraph 2 additional information on the possible impacts on the health of man and animals, and on the environment.

(7) The Minister of Health or an official authorised by him/her shall grant the permit referred to in Paragraph 1 within 60 days from the date of filing the application or of eliminating the incompleteness in the documents referred to in Paragraph 2, and/or submission of the information referred to in Paragraph 6.

(8) The permit referred to in Paragraph 1 shall determine the quantities of biocide, the places where the experiments shall be held, and other conditions related to the prevention of harmful impacts on man, animals and/or the environment.

Article 14e. Where the experiments referred to in Article 14d may have a harmful impact on the health of man, animals or the environment, the Minister of Health, in coordination with the Minister of Environment and Water, may prohibit these experiments.

Article 15. (1) The Minister of Health shall keep public registers of:

1. permitted active substances;

2. permitted biocidal products;

3. registered low-risk biocidal products.

(2) The content of the registers referred to in Paragraph 1 shall be determined with the regulation referred to in Article 16.

Article 16. (1) The conditions and procedure for placing of biocides on the market shall be determined with a regulation issued by Council of Ministers.

(2) The regulation referred to in Paragraph 1 shall also determine:

1. the form and content of the technical dossier and the documents which the applicant should submit in order to have a permit granted or a registration;

2. the form and content of the permit and the certificate of registration referred to in Article 14, Paragraphs 1 and 2;

3. the additional requirements for packaging and labelling of biocides;

4. the conditions and procedure for use of the information by a consequent applicant.

Article 17. (1) Placing of biocidal products on the market shall be allowed provided that:

1. they contain an active substance or active substances determined with the regulation referred to in Article 16 or included in the register referred to in Article 15, Paragraph 1, item 1;

2. they are sufficiently effective;

3. they have no adverse effects on the target organisms and do not cause unnecessary suffering and pain in vertebrates;

4. they or their residues cause no direct or indirect adverse effects on human or animal health through drinking water, food or feed, indoor air or consequences in the place of work or on surface water and groundwater;

5. they have no unacceptable effect themselves, or as a result of their residues, on non-target organisms;

6. they have no unacceptable effect themselves, or as a result of their residues, on the components of the environment;

7. analytical methods are developed for determination of the type and the quantity of the active substance, the residues, the impurities and the additives of toxicological or ecotoxicological significance;

8. their physical and chemical properties have been determined and deemed acceptable for purposes of the appropriate use, storage, transport and range of use;

9. the modes of use and the fields of application are determined.

(2) Biocidal products classified as toxic, very toxic, carcinogenic (category 1 and 2), mutagenic (category 1 and 2) and classified as toxic for reproduction (category 1 and 2) shall be authorised solely for professional use.

Article 17a. An active substance intended for inclusion into a biocidal product or a low-risk biocidal product shall be authorised provided that:

1. the biocidal product or the low-risk biocidal product which will contain the active substance must meet the conditions referred to in Article 17, Paragraph 1, items 2 – 8;

2. it is not classified in one or more of the following danger categories referred to in Article 2:

a) carcinogenic;

b) mutagenic;

c) toxic for reproduction;

d) sensitizing;

3. does not bioaccumulate and is not difficult to decompose.

Article 18. (1) In order to have the permit referred to in Article 14, Paragraph 1 granted, the person placing a biocidal product or an active substance on the market, shall submit an application to the Ministry of Health, accompanied by:

1. for a biocidal product;

a) a certificate of current status of the court registration;

b) a technical dossier for the biocidal product, on a paper or electronic carrier, or a declaration for use of information;

c) a technical dossier for each of the authorized active substances contained in the biocidal product, on a paper or electronic carrier, or a declaration for use of information;

d) the safety data sheet referred to in Article 7b;

e) a document for paid charge as referred to in Article 19y;

2. for an active substance:

a) a certificate of current status of the court registration;

b) a technical dossier for the active substance, on a paper or electronic carrier, or a declaration for use of information;

c) the safety data sheet referred to in Article 7b;

d) a declaration that the active substance is intended for manufacturing a specific type of biocidal product;

e) the technical dossier of at least one biocidal product for whose manufacture the active substance is intended;

f) a document for paid official charge as referred to in Article 19y;

(2) The active substance shall be permitted after assessment of the following from the technical dossier:

1. minimum purity degree and content of impurities;
2. type of biocidal products which may contain the active substance;
3. modes of use and fields of application;
4. category of users;
5. limit values for the active substance in the working place air, where appropriate;
6. admissible daily dosage for man and maximum values of residues;
7. distribution and behaviour in the environment;
8. impact on the organisms which are not subject of the proposed use.

Article 18a. (1) Where the submitted documents are found incomplete, within 30 days of the date of their receipt the Minister of Health shall require from the persons placing a biocidal product or an active substance on the market information which they shall be obliged to provide.

(2) Within a period of 14 days from the submission of the documents or from the elimination of the incompleteness, the Minister of Health shall send the documents referred to in Article 18 to the Minister of Environment and Water.

(3) The Minister of Environment and Water shall send the expert assessment within 30 days of receipt of the documents referred to in Article 18, Paragraph 1, item 1 and within 90 days of receipt of the documents referred to in Article 18, Paragraph 1, item 2.

(4) The Minister of Health may require from the manufacturer or importer submission of additional information necessary for assessment of the technical dossiers.

Article 18b. The Minister of Health may require samples of a biocidal product for conformity check with:

1. the conditions referred to in Article 17;
2. the data referred to in Article 18.

Article 19. (1) The Minister of Health or an official authorised by him/her shall issue an permit for placing an active substance on the market within a period of 12 months from the date of submission of the application referred to in Article 18, Paragraph 1, item 2, or from the date of elimination of the incompleteness in the documents referred to in Article 18a, Paragraph 1 and/or from submission of the additional information referred to in Article 18a, Paragraph 4.

(2) The Minister of Health or an official authorised by him/her shall issue a permit for placing a biocidal product on the market within two months of the date of submission of the application referred to in Article 18, Paragraph 1, item 1, or of the date of elimination of the incompleteness in the documents referred to in Article 18a, Paragraph 1 and/or from submission of the additional information referred to in Article 18a, Paragraph 4.

Article 19a. (1) The Minister of Health or an official authorised by him/her shall issue a motivated refusal to grant a permit for placing an active substance on the market, when:

1. the assessment of the technical dossier indicates that under normal conditions of use it may present a risk to man’s health and/or the environment;
2. there is an alternative active substance referred to in Article 14a, item 1 and Article 15, Paragraph 1, item 1 which is intended for manufacture of the same type of biocidal product and creates a substantially lower risk to man’s health and/or the environment.

(2) In the cases referred to in Paragraph 1, item 2 an assessment of the technical dossiers of one or more alternative active substances shall be carried out in order to establish that:

1. they have the same effect on the organisms which are subject of the proposed use;
2. they do not lead to substantial harms to the user;
3. they do not lead to an increased risk to man’s health or the environment.

(3) The assessment referred to in Paragraph 2 shall be carried out by the Ministry of Health after receipt of an expert assessment from the Ministry of Environment and Water.

(4) The refusal referred to in Paragraph 1 shall be subject of appeal pursuant to the Supreme Administrative Court Act, respectively the Administrative Procedure Act.

Article 19b. (1) The permit for placing of a biocidal product and an active substance on the market referred to in Article 14, Paragraph 1 shall be issued for a period of 10 years.

(2) The holder of a permit for an active substance and/or a biocidal product may submit an application for its renewal for another 10 years, provided the conditions referred to in Article 17a – for an active substance, and Article 17 – for a biocidal product, are fulfilled.

Article 19c. (1) The Minister of Health may review and amend the permit for placing a biocidal product on the market, in case:

1. the information submitted under Article 19f contains data for alteration of the mode of use and field of application determined in Article 17, Paragraph 1, item 9;

2. new scientific and technical data has been found, which requires a change in the quantities used and in the mode of use, in order to protect man's health and the environment;

3. information referred to in Article 19 f has been received regarding a change of the packaging and/or a change of the court registration of the person placing the biocidal product on the market;

4. a motivated request has been received from the holder of the permit for placing the biocidal product on the market, regarding extension of the field of application.

(2) In the cases referred to in Paragraph 1 the Minister of Health may require submission of additional information.

(3) The amendment to the permit referred to in Paragraph 1 shall be made provided the conditions of Article 17 are fulfilled.

(4) In case of motivated request from the permit holder regarding a change in the conditions determined for the active substance in the permit referred to in Article 14, Paragraph 1, an assessment of the active substance pursuant to Article 18, Paragraph 2 shall be carried out.

(5) For carrying out the assessment referred to in Paragraph 4, the permit holder shall submit to the Ministry of Health information on the identity of the active substance.

(6) The Minister of Health may require additional information necessary for carrying out the assessment referred to in Paragraph 4.

(7) The term for preparing the assessment shall be 12 months of the date of submission of the information referred to in Paragraph 5, or of submission of the additional information referred to in Paragraph 6.

(8) Based on the assessment carried out, the Minister of Health may amend the permit where no risk to the health of man and/or environment has been found, or to refuse the requested amendment where such a risk has been found.

Article 19d. (1) The Minister of Health shall suspend the permit for placing a biocidal product on the market when:

1. the conditions referred to in Article 17, Paragraph 1, items 1 – 8 are breached;

2. the applicant has submitted incorrect and/or misleading information in order to obtain the permit.

(2) Before suspension of the permit, the Minister of Health shall notify the permit holder and shall give him the opportunity to submit additional information regarding the grounds for suspension.

(3) Along with the suspension of the permit, the Minister of Health shall determine a time limit for disposal or storage, use and distribution of the available quantities of the biocidal product.

Article 19e. The Minister of Health may discontinue the permit for placing a biocidal product on the market, in case a motivated request has been submitted from the holder thereof.

Article 19f. The holder of a permit for placing a biocidal product on the market shall immediately notify the Minister of Health about any new information he is aware of which may lead to an amendment in the permit referred to in Article 14, Paragraph 1, relating to:

1. new data about the effects of the active substance or the biocidal product on man and the environment;

2. change in the court registration of the person placing the biocidal product on the market;

3. changes in the composition of the active substance and/or the biocidal product;

4. development of resistance of the target toward the applied biocidal product;

5. change of packaging.

Article 19g. A low-risk biocidal product shall be registered in case it meets the conditions referred to in Article 17, Paragraph 1 and does not contain substances of concern.

Article 19h. (1) The person placing a low-risk biocidal product on the market shall submit to the Ministry of Health an application accompanied by:

1. certificate of current status of the court registration;

2. name and address of the manufacturer of the low-risk biocidal product if it is different from the person referred to in Paragraph 1;

3. name and address of the manufacturer of the low-risk biocidal product if it is different from the person referred to in Paragraph 1 or item 2;

4. trade name and composition of the low-risk biocidal product;

5. information on the physical and chemical properties, suitable for the mode of use, the field of application and the method of storage;

6. type of preparation, field of application and the mode of use;

7. category of users;

8. efficiency data;

9. analytical methods for determination of the type and the nature of the active substance in the low-risk biocidal product and its residues;

10. information on the classification, packaging and labelling, including a draft-design for the label;

11. the safety data sheet referred to in Article 7b;

12. declaration for use of information where appropriate;

13. document for paid official charge referred to in Article 19y.

(2) Where the submitted documents are found incomplete within 30 days of their receipt, the Minister of Health shall require from the persons referred to in Paragraph 1 information which they shall be obliged to provide.

(3) The Minister of Health may require additional information necessary for assessment of the data submitted.

(4) The Minister of Health shall issue a certificate of registration of a low-risk biocidal product within a period of 2 months of the date of submission of the application referred to in Paragraph 1, or of the date of elimination of the incompleteness in the documents referred to Paragraph 2, and/or submission of the additional information referred to in Paragraph 3.

Article 19i. (1) The certificate of registration of a low-risk biocidal product shall be issued for a period of 10 years.

(2) Within 6 months prior to the expiry of the term referred to in Paragraph 1, the holder of a certificate of registration of a low-risk biocidal product may apply for its renewal for another 10 years, provided the conditions referred to in Article 19g are fulfilled.

Article 19j. The Minister of Health shall issue a certificate of change of registration when:

1. the holder of certificate for registration requests an extension of the field of application and the modes of use.

2. new scientific and technical data have been found requiring a change in the quantities used and the modes of use of the biocidal product with a view to protecting man’s health and the environment

Article 19k. (1) The Minister of Health shall strike off the registration:

1. upon request of the holder of certificate for registration;

2. when the conditions referred to in Article 19g are breached;

3. when the applicant has submitted incorrect and/or misleading information under Article 19h, Paragraph 1.

(2) Before striking off the registration, the Minister of Health shall notify the holder of the certificate and shall give him an opportunity to submit additional information regarding the grounds for striking off the registration.

(3) In the cases referred to in Paragraph 2, the Minister of Health shall settle a time limit for disposal or storage, use and distribution of the available quantities of low-risk biocidal product

Article 19l. (1) The person placing a biocidal product on the market shall submit to the Minister of Health a motivated request for announcing certain information from the technical dossier confidential in order to protect his industrial or trade interests.

(2) Industrial and commercial secrecy shall not apply to:

1. name and address of the person placing a biocidal product on the market;

2. name and address of the manufacturer of a biocidal product and the active substance, if different form the person referred to in item 1;

3. the composition of the active substance or substances in the biocidal product and the name of the biocidal product;

4. the names of dangerous substances in the biocidal product which contribute to the classification of the preparation;

6. physical and chemical properties of the active substance and the biocidal product;

7. methods of disposal of the active substance or biocidal product;

8. a summary of the results of the tests for assessing the efficiency of the substance or preparations, the effects on humans, plants, animals and the environment and, where applicable, its ability to promote resistance;

9. recommended methods and precautions to reduce dangers from handling, storage, transport and use, as well as from fire or other hazards;

10. information contained in the safety data sheets referred to in Article 7b;

11. methods of analysis of the active substance;

12. methods of disposal;

13. first aid and medical advice to be given in the case of accidents.

(3) The information referred to in Paragraph 1 which is considered confidential shall be identified by the inscription "For official use".

(4) In case the person placing the biocidal product on the market announces part or all of the information referred to in Paragraph 1 as non-confidential, he shall notify the Minister of Health in writing

Article 19m. (1) The advertisement for the biocidal product shall include the following sentences, which shall be clearly distinguishable in relation to the whole advertisement:

1. "Use biocides safely";

2. "Always read carefully the label and product information before use".

(2) The person placing the biocidal product on the market may replace the words "biocidal product" in the advertisement with an accurate description of the type of biocidal product being advertised.

(3) The advertisement shall not refer to the product in a manner which is misleading in respect of the risks to man and the environment.

(4) Under no circumstances may the advertising of a biocidal product mention "low-risk biocidal product", "non-toxic", "harmless" or any similar indications.

Section II

(Effective 1.01.2007)

Conditions and procedure for placing biocidal products on the market

Article 19n. A biocidal product shall be placed on the market where a permit has been issued for it in compliance with the provisions of this section.

Article 19o. (1) The conditions and procedure for placing biocidal products on the market shall be laid down by a regulation of the Minister of Health.

(2) The regulation referred to in Paragraph 1 shall also determine:

1. the form and content of the documents which the applicant should submit in order to have a permit granted;

2. the form and content of the permit for placing on the market;

3. additional requirements to the packaging and labelling of biocidal products.

Article 19p. (1) The biocidal product shall be permitted in case the active substance intended for inclusion in its composition has been specified by the regulation referred to in Article 19o, Paragraph 1.

(2) The permits referred to in Paragraph 1 shall be issued by the Minister of Health or an official authorised by him/her.

(3) Biocidal products shall be classified, packaged and labelled in compliance with the provisions of Chapter Two.

Article 19q. In order to have the permit referred to in Article 19n granted, the person placing the biocidal product on the market shall submit to the Ministry of Health an application accompanied by:

1. certificate of current status of the court registration;

2. a technical dossier on a paper or electronic carrier containing the following data:

a) trade name of the biocidal product;

b) chemical name of the active substance and classification data thereof;

c) composition of the biocidal product;

d) physical and chemical properties of the biocidal product;

e) analytical method for determining the concentration of the active substance in the biocidal product;

f) type of the biocidal product and fields of use;

g) efficiency and resistance data;

h) modes of use;

i) category of users;

j) summary of the toxicological and ecotoxicological properties of the active substance;

k) toxicological data for the biocidal product;

1) data for the package;

m) label draft-design;

3. safety data sheet referred to in Article 7b;

4. document for paid official charge referred to in Article 19y.

Article 19r. (1) Where the submitted documents are found incomplete, the Minister of Health shall within 7 days notify the person referred to in Article 19q about the information that should be provided.

(2) The Minister of Health shall send the documents referred to Article 19q to the Minister of Environment and Water for opinion.

(3) The Minister of Environment and Water shall return the opinion within 30 days of receipt of the documents referred to in Paragraph 2.

(4) The Minister of Health or an official authorised by him/her shall issue the permit for placing the biocidal product on the market within 60 days of the date of submission of the documents referred to in Article 19q, or from the date of submission of the information referred to in Paragraph 1.

Article 19s. (1) The Minister of Health may review the issued permit in case of:

1. new data about the effects of the active substance or the biocidal product on man and environment has been found;

2. change of the court registration of the person placing the biocidal product on the market;

3. change of packaging.

(2) In the cases referred to in Paragraph 1 the Minister of Health or an official authorised by him/her may require additional information and amend the conditions of the permit issued.

Article 19t. The Minister of Health shall issue a new permit pursuant to Article 19q in cases of:

1. change of the biocidal product composition;

2. development of resistance.

Article 19u. The Minister of Health shall suspend the permit for placing a biocidal product on the market in case the applicant has submitted incorrect and/or misleading data in order to obtain the permit referred to in Article 19n:

Article 19v. (1) The Minister of Health shall keep a public register of the permitted biocidal products.

(2) The register referred to in Paragraph 1 shall contain:

1. number and date of the permit for placing a biocidal product on the market;

2. name and address of the person placing the biocidal product on the market;

3. name of the active substances contained in the product;

4. type of the biocidal product;

5. field of application;

6. category of users.

Article 19w. (1) The person placing a biocidal product on the market shall submit to the Minister of Health a motivated request for announcing the confidentiality of data from his technical dossier with a view to protecting his industrial or trade interests.

(2) Industrial and commercial secrecy shall not apply to:

1. name and address of the person placing the biocidal product on the market;

2. name and address of the manufacturer of the biocidal product and the active substance, if different form the person referred to in item 1;

3. the relative share of the active substance or substances in the biocidal product and the name of the biocidal product;

4. the names of dangerous chemical substances in the biocidal product which contribute to the classification of the preparation;

5. physical and chemical properties of the active substance and the biocidal product;

6. summary of the toxicological and ecotoxicological properties of the active substance or preparation;

7. the information included in the safety data sheet referred to in Article 7b;

8. methods of analysis of the active substance;

9. first aid measures and medical advice to be given in case of accidents.

(3) The information referred to in Paragraph 1 which is considered confidential shall be identified by the inscription "For official use".

(4) In case the person placing the biocidal product on the market announces part or all of the information referred to in Paragraph 1 as non-confidential, he shall notify the Minister of Health in writing.

Article 19x. (1) The advertisement for the biocidal product shall include the following sentences,

1. "Use biocides safely.";

2. "Always read carefully the label and product information before use".

(2) The person placing the biocidal product on the market may replace the words "biocidal product" in the advertisement with an accurate description of the type of biocidal product being advertised.

(3) The advertisement shall not refer to the product in a manner which is misleading in respect of the risks to man and the environment.

(4) Under no circumstances may the advertising of a biocidal product mention "low-risk biocidal product", "non-toxic", "harmless" or any similar indications, which is misleading in respect of the risks related to the use of the biocidal product.

Article 19y. Charges determined in a tariff issued by the Council of Ministers shall be collected for issuance of:

1. permit for placing on the market biocidal products and active substances referred to in Article 14, Paragraph 1;

2. certificate of registration of a low-risk biocidal product referred to in Article 14, Paragraph 2;

3. permit for placing on the market of a biocidal product referred to in Article 19n.

Chapter Five

(Amended, SG No. 86/2003, repealed, SG No. 114/2003)

SAFE PRODUCTION AND USE OF CHEMICAL SUBSTANCES, PREPARATIONS AND PRODUCTS

Articles 20 – 21. (Repealed, SG No. 114/2003)

Chapter Six

IMPORT, EXPORT AND TRADE IN CHEMICAL SUBSTANCES AND PREPARATIONS

(Title amended, SG No. 114/2003)

Article 22. (1) (Repealed, SG No. 114/2003).

(2) (Amended, SG No. 114/2003) The procedure and method of import and export of dangerous chemical substances and preparations on the territory of the Republic of Bulgaria shall be determined with a regulation issued by the Council of Ministers.

(3) (New, SG No. 114/2003) The regulation referred to in 2 shall also determine:

1. the dangerous chemical substances and preparations which are subject to an import and export ban or subject to an import license.

2. the conditions for export registration and notification of the countries of export;

3. the content and the format of the documents for registration of export and for licensing the import

(4) (New, SG No. 114/2003) The Minister of Environment and Water or an official authorised by him/her shall issue a certificate of import registration and shall authorise the import of dangerous chemical substances and preparations determined with the regulation referred to in Paragraph 2.

Arti**cle 22a.** (New, SG No. 114/2003) (1) The importer of dangerous chemical substances and preparations which are subject of an import license shall submit to the Minister of Environment and Water an import license form.

(2) The form referred to in Paragraph 1 shall be accompanied by:

1. certificate of current status of the court registration of the importer, and for foreign persons – document certifying the legal status of the importer issued in compliance with the national legislation thereof;

2. safety data sheet referred to in Article 7b;

3. document of paid charge referred to in Article 71 of the Environmental Protection Act.

(3) In case of mistakes and incompleteness in the documents referred to in Paragraphs 1 and 2, the Minister of Environment and Water shall, within 5 days, notify the importer thereof.

Article 22b. (New, SG No. 114/2003) (1) The Minister of Environment and Water shall, within 3 days, send for opinion the documents referred to Article 22a to the Regional Inspectorate of Environment and Water (RIEW) on whose territory the enterprise or the warehouse of the importer is located.

(2) The Regional Inspectorate of Environment and Water shall send the opinion to the Minister of Environment and Water within a period of 5 days.

Article 22c. (New, SG No. 114/2003) (1) The Minister of Environment and Water or an official authorised by him/her shall issue an import license within 20 days of the date of submission of the documents referred to in Article 22a.

(2) In the cases referred to in Article 22a, Paragraph 3, the 20-day period shall start from the date of submission of the revised and supplemented documents.

(3) The import license referred to in Paragraph 1 shall be valid until the end of the calendar year in which it has been issued.

Article 22d. (New, SG No. 114/2003) Any person exporting independently or through a person authorised by him/her a dangerous chemical substance or preparation determined with the regulation referred to in Article 22, Paragraph 2, shall enclose to the customs declaration a certificate for registration of this substance or preparation referred to in Article 22f, Paragraph 2.

Article 22e. (New, SG No. 114/2003) (1) In order to register the export of a dangerous chemical substance and preparation which do not have a certificate of export registration, the exporter shall submit to the Minister of Environment and Water the following documents:

1. application for export registration;

2. certificate of current status of the court registration of the exporter and for foreign persons – document certifying the legal status of the exporter issued in compliance with the national legislation thereof;

3. safety data sheet referred to in Article 22, Paragraph 2;

4. document of paid charge referred to in Article 71 of the Environmental Protection Act,

(2) The documents referred to in Paragraph 1 shall be submitted 30 days prior to export.

(3) In case of mistakes and incompleteness in the documents referred to in Paragraph 1, the Minister of Environment and Water shall notify thereof the exporter within a period of 5 days.

Article 22f. (New, SG No. 114/2003) (1) The Minister of Environment and Water or an official authorised by him/her shall notify the competent authority in the country, to which the dangerous chemical substance or preparation shall be exported within 15 days of the date of submission of the documents referred to in Article 22e.

(2) In case the import consent is granted, the Minister of Environment and Water shall issue a certificate of export registration, which shall be promulgated in the State Gazette and shall not be amended for each subsequent export to the same country.

(3) In case of denial from the country accepting the export, the Minister of Environment and Water shall not issue a certificate of export registration.

(4) Each calendar year the exporter of a dangerous chemical substance or preparation for which a certificate of registration has already been issued shall notify the Minister of Environment and Water about the first export of this substance or preparation 15 days prior to export.

(5) The Minister of Environment and Water shall notify the competent authority in the country to which the dangerous chemical substance or preparation is exported, after receipt of the notification referred to in Paragraph 4.

Article 22g. (New, SG No. 114/2003) New export registration shall be made where:

1. after the first export amendments in the legislation of the Republic of Bulgaria have occurred regarding the subject of export, placing on the market, use or labelling of dangerous chemical substances and preparations;

2. the composition of the preparation has been changed to such an extent that its labelling needs to be revised.

Article 22h. (New, SG No. 114/2003) The provisions Article 22e, Paragraph 2and Article 22f shall not apply in cases where a delay of the export may endanger the health and life of man and the environment, and there is consent from the country to which the export shall be made.

Article 22i. (New, SG No. 114/2003) (1) The Minister of Environment and Water shall be obliged to keep the industrial and commercial secrecy during fulfilment of his duties.

(2) The information from the safety data sheet referred to in Article 22e, Paragraph 1, item 3 shall not be considered industrial and commercial secret.

Article 22j. (New, SG No. 114/2003) (1) By the end of the first quarter of each calendar year the importer/exporter of a dangerous chemical substance or preparation shall submit to the Ministry of Environment and Water information on the exported/imported quantities of the substance or preparation in question and the countries of export/import.

(2) The Minister of Environment and Water shall keep a public register of exported/imported dangerous chemical substances and preparations.

(3) The content of the register referred to in Paragraph 2 shall be determined with the regulation referred to in Article 22, Paragraph 2.

Article 23. (Amended, SG No. 114/2003) Dangerous chemical substances and preparations which are subject to banned or restricted marketing and use shall be determined with a regulation issued by the Council of Ministers.

Article 24. (Amended, SG No. 114/2003) When exporting chemical substances and preparations, the natural and legal persons shall also observe the requirements of the importing country where this does not contradict the international treaties to which the Republic of Bulgaria is a party.

Article 24a. (New, SG No. 114/2003) Persons who place on the market, trade in and export chemical substances and preparations shall be obliged to store them under the conditions specified by the manufacturer in the safety data sheet referred to in Article 7b.

Chapter Seven
CONTROL OVER CHEMICAL SUBSTANCES AND PREPARATIONS

(Title amended, SG No. 114/2003)

Article 25. (Amended, SG No. 114/2003) Subject to control shall be:

1. the classification, packaging and labelling of chemical substances and preparations;

2. the notified chemical substances;

3. the intermediates for which a reduced test package has been permitted;

4. dangerous chemical substances and preparations subject to banned or restricted marketing and use;

5. manufacture of goods which may contain dangerous chemical substances and preparations subject to banned or restricted use;

6. dangerous chemical substances and preparations for which export/import requirements have been determined;

7. the storage conditions specified by the manufacturer in the safety data sheet.

Article 26. (1) Control shall be exercised:

1. in case of suspicion;

2. continuously;

3. without prior notification;

4. (Repealed, SG No. 114/2003).

(2) The control shall comprise of checks on the implementation of the provisions of this Act.

Article 27. (Amended, SG No. 114/2003) (1) The Minister of Environment and Water or officials authorised by him/her shall exercise control in the cases referred to in Article 25, items 3, 6 and 7 with a view to protecting the environment.

(2) The Minister of Health or officials authorised by him/her shall exercise control in the cases referred to in Article 25, items 1, 2, 4 and 5 with a view to protecting man's health.

(3) The state control authorities under the Plant Protection Act shall exercise control over the plant protection products placed on the market.

Article 28. (Amended, SG No. 114/2003) (1) The authorities referred to in Article 27 shall be entitled to:

1. unimpeded access to enterprises and sites which manufacture, import, use, store and trade in dangerous chemical substances and preparations;

2. require information and documents and take samples for laboratory analyses related to the manufacture, import, use, storage and trade in dangerous chemical substances and preparations;

3. where breaches are established, make obligatory prescriptions for eliminating them.

(2) The authorities referred to in Article 27 shall be obliged not to make public the information considered as industrial or trade secrecy.

Article 29. (Previous Article 30, amended, SG No. 114/2003) A state authority may not ban, limit or impede the placing on the market of dangerous chemical substances and preparations which meet the requirements of this Act.

Article 30. (Renumbered from Article 29, amended, SG No. 114/2003) (1) The authorities referred to in Article 27 may temporarily prohibit the placing on the market of chemical substances and preparations which comply with the provisions of this Act, where new information emerges that these substances are of immediate and great danger to man's health and/or the environment.

(2) In the emergence of an immediate danger to man and/or the environment which cannot be eliminated otherwise, the use of a biocidal product not meeting the requirements of Chapter Four shall be permitted. The biocidal product shall be permitted temporarily for a term of 120 days under conditions of controlled and restricted use.

Article 31. (Repealed, SG No. 91/2002).

Chapter Eight
ADMINISTRATIVE AND PENAL PROVISIONS
Section I
Compulsory administrative measures

Article 32. With a view to preventing and stopping the administrative violations under this Act, as well as with a view to preventing and stopping their adverse effects, the competent authorities or persons authorised by them shall apply compulsory administrative measures pursuant to Article 33.

Article 33. (1) (Amended, SG No. 114/2003) The Minister of Health and the Minister of Environment and Water or officials authorised by them, in accordance with their authorities, shall suspend the use, placing on the market and import of chemical substances and preparations.

(2) (Amended, SG No. 114/2003) The suspension of activities referred to in Paragraph 1 may be for a period sufficient to eliminate the reason which led to imposing the compulsory administrative measure.

Article 34. Compulsory administrative measures may be appealed pursuant to the Administrative Procedure Act.

Section II
ADMINISTRATIVE VIOLATIONS AND PENALTIES

Article 35. (1) (Amended, SG No. 114/2003) Subject to penalties shall be persons who:

1. do not classify, package and label the chemical substance or preparation in accordance with the requirements of this Act;

2. violate the requirements for placing on the market of a chemical substance or preparation;

3. advertise a chemical substance or preparation in violation of Articles 4, 19nand19x;

4. do not fulfil their obligation to notify new chemical substances in accordance with the requirements of this Act;

5. do not fulfil their obligations referred to in Articles 7b, 7f, 14b and 14d;

6. breach the bans and restrictions for trade and use referred to in Article 23;

7. import a chemical substance or preparation in violation of Article 22;

8. do not fulfil their obligations with respect to the state control authorities in accordance with requirements of Article 28, Paragraph 1;

9. do not observe the storage conditions specified by the manufacturer in the safety data sheet

(2) (Amended, SG No. 114/2003) For violations referred to in Paragraph 1 the fine, respectively the property sanction, shall be as follows:

1. under items 1, 2, 4 and 6 – between BGN 10,000 and BGN 100,000;

2. under items 5 and 7 – between BGN 5,000 and BGN 50,000;

3. under items 3, 8 and 9 – between BGN 4,000 and BGN 40,000.

(3) In the case of repeated violation the fine, respectively the property sanction referred to in Paragraph 2 shall be doubled.

Article 36. (1) (Amended, SG No. 114/2003) The violations referred to in Article 35 shall be ascertained with a statement issued by an official determined by the Minister of Health or the Minister of Environment and Water, in accordance with their authorities.

(2) (Amended, SG No. 114/2003) The penal decrees shall be issued by the Minister of Health or the Minister of Environment and Water in accordance with their authorities, or by officials authorised by them.

Article 37. Violations shall be established, statements shall be drawn up, penal decrees shall be issued, appealed and executed pursuant to the Administrative Violations and Sanctions Act.

ADDITIONAL PROVISIONS

§ 1. (Amended, SG No. 114/2003) For the purpose of this Act:

1. "Chemical substances" shall mean chemical elements and their compounds as they occur in the natural state or as produced by an industrial process which includes additives necessary for stabilization of the products and impurities occurring in the production process used but excludes any solvent which might be separated without affecting the stability of the substance or changing its composition.

2. "Preparations" shall mean mixtures or solutions composed of two or more substances.

3. "Polymer" shall mean a substance whose molecules consist of a sequence of at least three covalently bound monomer units of the same type or of different types. In the context of this definition a "monomer unit" shall mean the reacted form of a monomer in a polymer.

4. "Existing chemical substances" shall mean chemical substances listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) until 18 September 1981.

5. "New chemical substances" shall mean those substances which are not included in the inventory referred to in Paragraph 4.

6. "Dangerous chemical substances and preparations" shall mean the chemical substances and preparations which are:

a) Explosive – solid, liquid, pasty or gelatinous chemical substances and preparations which may also react exothermically without atmospheric oxygen thereby quickly evolving gases, and which under defined test conditions detonate, quickly deflagrate or upon heating explode when partially confined;

b) Oxidising – chemical substances and preparations which give rise to highly exothermic reaction when in contact with other substances, particularly flammable substances.

c) Extremely flammable – Liquid chemical substances having an extremely low flash point and a low boiling point and gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure;

d) Highly flammable;

- chemical substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy;

- chemical substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities;

- solid chemical substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition;

- liquid chemical substances and preparations having a very low flash point;

e) Flammable – liquid chemical substances and preparations having a low flash point;

f) Very toxic – chemical substances and preparations which in very low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

g) Toxic – chemical substances and preparations which in low quantities may cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

h) Harmful – substances and preparations which may cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

i) Corrosive – substances and preparations which may, on contact with living tissues, destroy them;

j) Irritant – non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, may cause inflammation;

k) Sensitizing – chemical substances and preparations which, if they are inhaled or if they penetrate the skin, are capable of eliciting a reaction of hypersensitiveness such that on further exposure to the substance, characteristic effects are produced;

l) Carcinogenic – chemical substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence;

m) Toxic for reproduction – chemical substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may produce or increase the incidence of, non-heritable adverse effects in the progeny or the impairment of male or female reproductive functions or capacity;

n) Mutagenic – chemical substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce heritable genetic defects or increase their incidence;

o) Dangerous for the environment – chemical substances and preparations which, were they to enter into the environment would present or may present an immediate or delayed danger for one or more compartments of the environment.

7. "Classification" shall mean the procedure of assessing whether the chemical substance or preparation possesses one or more hazardous properties, depending on which it is referred to a specific category.

8. "Labelling" shall mean all texts, symbols, images and signs placed on the packaging of a chemical substance or preparation indicating the presence of a potential danger with a view to classification.

9. "Notification" shall mean the submission to the competent authorities of documents containing the necessary information on new chemical substances.

10. "Manufacturer" shall mean any natural or legal person extracting or producing chemical substances and/or preparations.

11. "Importer" shall mean any natural or legal person importing a chemical substance or preparation on the territory of the Republic of Bulgaria. A natural or legal person carrying out transit transportation through the territory of the Republic of Bulgaria of a chemical substance or preparation shall not be considered an importer, provided that during transportation the chemical substance or preparation is not treated or processed.

12. "Tactile sign" shall mean a tangible sign intended for use by visually impaired persons.

13. "Storage" shall mean any method of storing chemical substances or preparations prior to their use, processing or transportation.

14. "Repeated violation" shall mean a violation committed within one year of the coming into force of a penal decree for a violation of the same type.

15. "Notifier" shall mean a person who:

a) for substances manufactured on the territory of the Republic of Bulgaria, is a manufacturer placing on the market a new chemical substance either on its own or in a preparation;

b) for substances manufactured outside the territory of Republic of Bulgaria, is:

aa) registered under the Commerce Act and responsible for placing on the market of the new chemical substance either on its own or in a preparation;

bb) authorised by the importer for the purposes of notification as a sole representative for placing on the market of the new chemical substance either on its own or in a preparation;

16. "Placing on the market" shall mean making the chemical substance or preparation available to third parties against payment or free of charge for distribution and/or use.

17. "Professional user" shall mean any Bulgarian or foreign natural or legal person which is registered under the Commerce Act or its national legislation or which is a free lancer within the meaning of the Personal Income Tax Act, which uses or places dangerous chemical substances and preparations on the market.

18. "Professional use" shall mean the activities performed by the persons referred to in item 17.

19. "Biocidal product" shall mean an active substance or biocide preparation containing one or more active substances in a ready-to-use, 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.

20. "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.

21. "Active substance" shall mean a chemical substance or micro- organism, including viruses or fungi, having general or specific action on or against harmful organisms.

22. "Scientific research" shall mean scientific experiments, analyses or chemical tests carried out under controlled conditions related to product development;

23. " Development" shall mean the further research on a substance under production trials to test different fields of application.

24. "Detergent" shall mean any preparation specially designed to provide washing and cleaning properties, having as a main component surface active agents (anionic, non-ionogenic, cationic and amphoteric) and subsidiary constituents such as boosters, builders and fillers.

25. "Low-risk biocidal product" shall mean a biocidal product which contains one or more authorised active substance(s) and which does not contain any substance(s) of concern. Under proper use, the biocidal product poses only a low risk to humans, animals and the environment.

26. "Basic substance" shall mean a substance determined in the regulation referred to in Article 16, 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 biocide use.

27. "Substance of concern" shall mean a substance, other than the active substance, which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present or is produced in a biocidal product in a sufficient concentration to create such an effect. Such a substance would be normally classified in one or more of the categories of danger referred to in Article 2, and present in the biocidal product at a concentration leading the product to be regarded as dangerous.

28. "Residues" shall mean quantities of one or more of the substances present in a biocidal product which remain as a result of its use, including the metabolites of such substances and products resulting from their degradation or reaction.

29. "Frame-formulation" shall mean a specification for a group of biocidal products of the same type and having the same use and user type. This group of products must contain the same active substances with the same specifications. Their chemical composition must present only variations of the composition of a previously permitted biocidal product. The variations from the original composition should not affect the efficacy and the level of risk associated with the use. In this context, a variation may constitute: a reduction in the percentage of the active substance and/or an alteration in percentile 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 efficiency.

30. "Declaration for use of information" shall mean a document signed by the owner or the owners of information which is protected as confidential by the provisions of this Act, certifying that the Ministry of Health may use this information for authorisation or registration of another biocidal product.

31. "Admissible daily dose" shall mean the quantity of substance which can be consumed daily with the food during the life cycle without any risk to human health.

32. "Limit value" shall mean the average measured value of a certain chemical agent or dust in the air in the breathing field of the worker at his working place for a specified period of time.

33. "Intermediate" shall mean a chemical substance produced solely for use in a chemical process for obtaining another chemical substance.

34. "Reduced test package" shall mean the required minimum of data for notification of a new chemical substance determined as an intermediate.

35. "Provision of a closed system during the lifecycle of the intermediate" shall mean use of technical means (closed type construction which is air-tight or with an integrated suction ventilation) intended to insulate the substance during its lifecycle. This includes production, transportation, purification, cleaning and maintenance, sampling, analyses, loading/unloading of equipment/vessels; disposal, rendering harmless and storage of waste.

36. "Exposure" shall mean exposing the human organism and the components of the environment to the effects of chemical substances, preparations and biocides.

TRANSITIONAL AND FINAL PROVISIONS

§ 2. The persons performing activities referred to in Article 1 for which registration pursuant to Chapter Four is required, shall submit an application for registration within six months after the coming into force of this Act.

§ 3. (Amended, SG No. 114/2003) The Minister of Health and the Minister of Environment and Water may consign their functions, rights and obligations under this Act to their deputies and to other officials within the structure of the respective ministries.

§ 4. The Act shall become effective two years after its promulgation in the State Gazette.

§ 5. (Amended – SG No. 114/2003) The enforcement of this Act shall be assigned to the Minister of Agriculture and Forestry, the Minister of Health and the Minister of Environment and Water.

TRANSITIONAL AND FINAL PROVISIONS
to the Act amending and supplementing the Protection Against the Harmful Impact of Chemical Substances and Preparations Act

(SG No. 114/2003, effective 31.01.2004)

§ 40. The Council of Ministers shall adopt the regulations referred to in Articles 11, 13 and Article 16, Paragraph 1 within one year from the date of promulgation of this Act in the State Gazette

. . . . . .

§ 42. (1) This Act shall enter into force one month after its promulgation in the State Gazette, save for the provisions of Chapter Four, Section I "Conditions and procedure for placing active substances and biocidal products on the market", which shall become effective as of 1 January 2007.

(2) The provisions of Chapter Four, Section II "Conditions and procedure for placing of biocidal products on the market", shall apply until 1 January 2007.