

THE CROATIAN PARLIAMENT

1958

Pursuant to Article 88 of the Constitution of the Republic of Croatia, I hereby issue the

DECISION PROMULGATING THE ACT ON BIOCIDAL PRODUCTS

I hereby promulgate the Act on Biocidal Products, passed by the Croatian Parliament at its session on 1 June 2007.

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Zagreb, 6 June 2007

The President of the Republic of Croatia
Stjepan Mesić, m.p.

ACT ON BIOCIDAL PRODUCTS

I GENERAL PROVISIONS

Scope Article 1

For the purposes of protecting human life and health and the environment, this Act regulates the placing on the market and use of biocidal products in the Republic of Croatia, mutual recognition of authorisations for the placing on the market of biocidal products in the European Union, implementation of the procedure for the inclusion of active substances in the list of active substances which may be used in biocidal products, evaluation of biocidal products and assessment of their efficacy, and supervising the implementation of this Act.

Definitions Article 2

For the purposes of this Act the following definitions apply:

1. Biocidal products mean the 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 term biocidal product also includes low-risk biocidal products, unless otherwise prescribed by this Act.

2. List I, I A and I B are the lists of active substances established at the level of the European Union, whereas:

- List I – list of active substances permitted for inclusion in biocidal products,
- List I A – list of active substances permitted for inclusion in low-risk biocidal products,
- List I B – list of basic substances with requirements for inclusion in biocidal products.

3. Low-risk biocidal products mean biocidal products which contain only one or more of substances listed in the List I A or active substances which are in the procedure of admission to the list and for which the European Commission determined that the documentation for admission to the List I A is complete and which does not contain any substances of concern. Under the prescribed conditions of use, the biocidal product shall pose only a low risk to humans, animals or the environment.
4. Basic substance means a substance which is listed in the List I B, 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 dangerous. Basic substance is not to be directly marketed for biocidal use. The substances, which could potentially enter the List I B, are *inter alia* the following: carbon dioxide, nitrogen, ethanol, 2-propanol, acetic acid, kieselguhr.
5. Active substances in biocidal products mean substances or micro-organisms including viruses or fungi having general or specific action on harmful organisms.
6. Existing active substances mean active substances placed on the market in any Member State of the European Union as an ingredient of a biocidal product before 14 May 2000.
7. New active substances mean active substances placed on the market as an ingredient of a biocidal product in one of the Member States of the European Union after 14 May 2000, until they are listed on one of the substance Lists I, I A or I B.
8. Substance of concern means any substance, other than the active substance, which is present or is produced in a biocidal product in sufficient concentration to cause an adverse effect on humans, animals or the environment.
Such a substance should be classified as a dangerous chemical and should be present in the biocidal product at concentrations according to which this product should be classified in accordance with the regulations relating to the classification, packaging and labelling of dangerous chemicals.
9. Harmful organism means any organism which has an unwanted presence or a detrimental effect for humans, their activities or the products they use, or for animals or for the environment.
10. Residues mean one or more of the substances present in a biocidal product which remains after its use including the metabolites of such substances and products resulting from their degradation or reaction.
11. Placing on the market means any supply to a third person, whether in return for payment or free of charge, or subsequent storage (other than storage for the purpose of exportation outside the customs territory of the Republic of Croatia or waste disposal). Importation of a biocidal product into the customs territory of the Republic of Croatia shall be deemed to constitute placing on the market for the purposes of this Act.
12. Full procedure (authorisation) means the procedure of issuance of an authorisation by which the ministry competent for health (hereinafter: the Ministry) authorises, following an application submitted by an applicant, the placing on the market of a biocidal product in the territory of the Republic of Croatia.
13. Simplified procedure (registration) means the procedure by which the Ministry, following an application submitted by an applicant, after verification that the documentation meets all the requirements of this Act and subordinate regulations adopted on the basis thereof, issues an authorisation for the placing on the market of a low-risk biocidal product in the territory of the Republic of Croatia.
14. Special procedure means a procedure for the placing on the market and use of a biocidal product on the basis of the frame-formulation in the territory of the Republic of Croatia.
15. Frame-formulation means a specification 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 authorised biocidal product only to the extent in which they do not affect their efficacy and the level of risk associated with them. A permitted 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 some other substance presenting the same or a lower risk, and which do not decrease its efficacy.

16. Letter of access means a document, signed by the owner of relevant data protected under the provisions of this Act, which states that these data may be used by the competent authorities for the purpose of granting an authorisation in a full or simplified procedure, in a special procedure or for the entry of active substances in the substance Lists I, I A or I B.

17. Scientific research and development means scientific experimentation, analysis of chemical substances carried out under controlled conditions and the determination of intrinsic properties, performance and efficacy as well as scientific investigation related to development of a new biocidal product.

18. Process-orientated research and development means research for the purpose of further development of a biocidal product in the course of which trials on the experimental and production level are used to test the other potential fields of application of the biocidal product.

19. General use means any use of biocidal products which is not professional.

20. Professional use means any use of a biocidal product when performing a registered activity including any transaction (import, export, transit, retail and wholesale purchase and sale of a biocidal product and intermediation in the domestic and foreign markets).

21. Unforeseen hazard means a hazard of damage caused to humans, their property, animals or the environment by harmful organisms, the occurrence of which was impossible to predict, prevent or restrict or for which it was not possible to develop appropriate protection measures.

22. Applicant means a manufacturer or his authorised representative requesting the placing on the market of a biocidal product. An authorised representative may be a legal or natural person.

An applicant for granting of an authorisation in a full or simplified procedure or the entry of an active substance in the substance Lists I, I A or I B is a legal or natural person responsible for the first placing on the market of a biocidal product or the authorised representative of such a person.

An applicant must have his headquarters in the Republic of Croatia or in one of the Member States of the European Union.

23. Authorisation holder means a legal or natural person identified in the decision authorising the placing on the market of a biocidal product and its use and who has headquarters in the Republic of Croatia or in one of the Member States of the European Union.

Exemptions

Article 3

The provisions of this Act do not apply to:

- medicinal products and homeopathic medicinal products for human use, active implantable medical devices, medical aids and devices and other medical products, pursuant to special regulations,
- medicinal products, immunological medicinal products and homeopathic medicinal products for use in veterinary medicine, pursuant to special regulations,
- foodstuffs, food additives, flavourings for use in foodstuffs and source materials for their production, materials and articles intended to come into contact with foodstuffs, pursuant to

special regulations,

- feedingstuffs and additives in feedingstuffs, certain products used in animal nutrition, pursuant to special regulations,
- waste, pursuant to special regulations,
- detergents, pursuant to special regulations, provided that no biocidal effect is expected and that such an effect is not listed when placing them on the market,
- cosmetic products, pursuant to special regulations,
- plant protection products, pursuant to special regulations.

The provisions of this Act do not apply to biocidal products in transit through the territory of the Republic of Croatia, and to products which are under customs supervision, provided that they are not treated, processed or altered in any way.

The provisions of this Act apply without prejudice to special regulations relating to the following:

- production, marketing and use of dangerous chemicals,
- export and import of certain dangerous chemicals,
- prohibiting the placing on the market and use of plant protection products containing certain active substances,
- health protection at work,
- misleading advertising.

The provisions of this Act relating to the classification, packaging and labelling of biocidal products do not apply to the carriage of biocidal products by rail, road, sea, inland waterway and air.

Principles Article 4

A biocidal product may be placed on the market if, in the light of current scientific and technical knowledge, and having regard to all authorised conditions under which the biocidal product may be used and how the material treated with it may be used as well as the consequences from its use and disposal, it is determined that the biocidal product, when used as authorised, is:

- sufficiently effective,
- has no unacceptable effects on the target organisms, such as unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates,
- has no unacceptable effects itself, or as a result of its residues, on human or animal health, directly or indirectly (e.g. through drinking water, food or feed, indoor environment or in the place of work) or on surface water and groundwater,
- has no unacceptable effects itself, or as a result of its residues, on the environment having particular regard to its retention and behaviour in the environment, contamination of surface waters (including estuarine and seawater), groundwater and drinking water, as well as having no unacceptable impact on non-target organisms,
- the nature and quantity of its active substances and, where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants, and its residues of toxicological or environmental significance, which result from authorised uses, can be determined according to the special regulations referred to in Article 7, paragraph 3 of this Act,
- its physical and chemical properties have been determined and deemed acceptable for the purposes of appropriate use, storage and transport of the product.

The properties referred to in paragraph 1 of this Article must be presented in the evaluation of documentation referred to in Article 28 of this Act, which must be in accordance with the

special regulation laying down the common principles for evaluation of biocidal products. The data on impacts and effects of biocidal products referred to in paragraph 1 of this Article are to be obtained in such a way as to minimise the number of tests on vertebrate animals.

Application of regulations relating to dangerous chemicals and general usage items Article 5

Unless otherwise provided by this Act, the provisions of special regulations relating to dangerous chemicals and general usage items apply in an appropriate manner to the production and placing on the market of biocidal products and to consequences of their use.

Responsibility of users of biocidal products Article 6

The users of biocidal products shall be obliged to use them in such a way as not to endanger their own life, life of other persons and not to cause adverse effects on human and animal health or the environment.

The users referred to in paragraph 1 of this Article shall be obliged to apply a combination of physical, biological, chemical or other measures to control harmful organisms as appropriate, whereby this shall include compliance with measures to protect human and animal health as well as the environment established according to instructions for use listed on the label, also including the instruction for preparing the prescribed concentration of the biocidal product for use.

The use of biocidal products shall be limited to the minimum necessary.

Where biocidal products are used professionally, the users referred to in paragraph 1 of this Article shall comply with the regulations on protection of workers.

Special regulations Article 7

The list of active substances shall be established by the minister competent for health (hereinafter: the Minister).

The Minister shall establish a list of existing active substances permitted in biocidal products and the list of existing active substances prohibited in biocidal products by an ordinance.

The Minister shall establish documentation for evaluation of the active substance in biocidal products, documentation for evaluation of biocidal products, procedures for evaluation of biocidal products and their use as well as the biocidal product types with their description and common principles for evaluation of biocidal products by an ordinance.

II ACTIVE SUBSTANCES

Placing active and basic substances on the market Article 8

Unless otherwise provided by this Act, the active substance may be placed on the market and used in biocidal products in the Republic of Croatia if it fulfils the conditions set out in this Act and regulations adopted on the basis thereof and if it is entered or is in the procedure of entry in the substance Lists I or I A.

The provision of paragraph 1 of this Article does not apply to active substances used for the purposes of scientific research.

The active substance referred to in paragraph 1 of this Article shall be classified, packaged

and labelled in accordance with special regulations relating to dangerous chemicals. Basic substances may be placed on the market and used as biocidal products only if they are entered in the substance List I B and if they fulfil the conditions relating to classification, packaging and labelling pursuant to this Act and if a safety-data sheet has been drawn up in accordance with special regulations relating to dangerous chemicals.

Inclusion of active substances in the substance Lists I, I A or I B Article 9

In the light of current scientific and technical knowledge, an active substance shall be included in the List I, List I A or I B for an initial period not exceeding 10 years if it may be expected that the biocidal products containing the active substance, low-risk biocidal products or basic substances and their products will fulfil the conditions for the granting of an authorisation for the placing on the market pursuant to Article 28 of this Act, taking into account, where relevant, cumulation effects from the use of biocidal products containing the same active substances.

A low-risk active substance shall not be included in the List I A if it is classified, according to the special regulations relating to the classification, packaging and labelling of dangerous chemicals, as carcinogenic, mutagenic, toxic for reproduction, sensitising, or is bioaccumulative and does not readily degrade. Where appropriate, the entry of an active substance in the List I A shall refer to the concentration ranges between which the substance can be used in biocidal products.

Inclusion of an active substance in the List I, I A or I B shall, where appropriate, be subject to the following:

1. requirements on:

- a) the minimum degree of purity of the active substance,
- b) the nature and maximum content of certain impurities,
- c) biocidal product type in which it may be used,
- d) manner and area of use,
- e) designation of categories of users (e.g. industrial, professional or non-professional use),
- f) other particular conditions for the evaluation of the information which has been made available to the Ministry within the meaning of this Act,

2. the establishment of the following:

- a) acceptable operator exposure level (AOEL), if necessary,
- b) where relevant, an acceptable daily intake for man (ADI) and the permitted maximum residue limit (MRL),
- c) behaviour in the environment and impact on non-target organisms.

The inclusion in the List I, I A or I B of an active substance shall be restricted to those product types for which relevant data have been submitted in accordance with Articles 28 and 29 of this Act.

The inclusion of an active substance in the List I, I A or I B may be renewed on one or more occasions for periods not exceeding 10 years. The initial inclusion, as well as any renewed inclusion, may be reviewed at any time if there are indications that any of the requirements referred to in paragraphs 1 to 3 of this Article are not longer satisfied. Renewal may, where necessary, be granted only for the minimum period necessary to complete a review, where an application has been made for such renewal, and shall be granted for the period necessary to provide further information requested in accordance with Article 11 of this Act.

An entry of an active substance in the List I and, where relevant, in the List I A or I B may be refused or removed,

— if the evaluation of the active substance in accordance with Article 11 of this Act shows that, under authorised conditions of use, risks to human health or the environment still give rise to concern, and

— if there is another active substance on the List I for the same product type which, in the light of scientific or technical knowledge, presents significantly less risk to health of humans and animals or to the environment.

When such a refusal or removal is considered, an assessment of the documentation of an alternative active substance or substances shall take place to demonstrate that it can be used with similar effect on the target organism without significant economic and practical disadvantages for the user and without an increased risk for health of humans, animals or for the environment.

The refusal of entry of active substances in the List I and, where relevant, I A or I B, or their removal from the mentioned Lists, shall be carried out under the following conditions:

1. the chemical diversity of the active substances should be adequate to minimise occurrence of resistance in the target organism,
2. it should be applied only to active substances which, when used under normal conditions in authorised biocidal products, present a significantly different level of risk,
3. it should be applied only to active substances used in products of the same product type,
4. it should be applied only after allowing the possibility, where necessary, of acquiring experience from use in practice, if it is not already available;
5. the complete documentation of data for the evaluation serving or having served for entry in List I, I A or I B shall be submitted.

A decision to remove an active substance from the List shall not have immediate effect but shall be delayed for a period of up to a maximum of four years from the date of that decision.

Procedure of the competent authority for inclusion of active substances in the substance List I, I A or I B
Article 10

Inclusion of an active substance in one of the substance Lists I, I A or I B for use in a biocidal product or as a basic substance shall be carried out following an application submitted by an applicant.

The application referred to in paragraph 1 of this Article shall be submitted to the Ministry and shall contain the documentation referred to in paragraph 4 of this Article.

Along with an application for inclusion of an active substance in the substance List I or I A, the applicant may also request the granting of provisional authorisation in accordance with Article 34 of this Act.

Documentation for the evaluation of entry of active substances in one of the substance Lists I, I A or I B, in addition to the personal name or the company name of the applicant, address or headquarters of the applicant, personal name or company name of the authorisation holder with an address or headquarters of the authorisation holder, it shall also contain information on tests performed on the active substance and on at least one biocidal product containing the active substance on the basis of which, according to Article 11 of this Act, it is possible to draft the assessment of efficacy and of the unacceptable effects.

By way of derogation from paragraph 4 of this Article, the application need not supply information which is not necessary owing to the nature of the biocidal product or of its proposed uses as well as information where it is not scientifically necessary or technically possible to supply the information. The Ministry shall evaluate the completeness of an application on a case-by-case basis.

After receipt of an application and documentation prescribed for the inclusion of an active

substance in the substance List I, I A or I B, the Ministry shall examine their completeness. If the Ministry determines that the documentation is incomplete, it shall require the supplement of the application within a prescribed period of time. If the documentation is not supplemented within the prescribed time period, the Minister shall refuse the application and notify the European Commission about the refusal. The provisions of the special regulation referred to in Article 7, paragraph 3 of this Act applies to procedures and time periods. When the Ministry establishes that the documentation is complete, it shall provide a verification and agreement to the applicant to deliver the summary of the documentation to the European Commission and other Member States of the European Union. The Ministry shall carry out the procedure of evaluation within a period of 12 months from the date when it is established that the documentation is complete. If, when the documentation is evaluated, it appears that further information is necessary for full evaluation to be made, the Ministry shall ask that the applicant submit such information in a prescribed period of time. The period for evaluation shall be suspended for the period approved for the applicant to deliver requested information and it shall start on the date the information is received. The Ministry shall inform the European Commission and other Member States of the European Union of the requested additional information which was submitted.

Evaluation of active substances Article 11

The evaluation of active substances performed for the purpose of inclusion of active substances in one of the substance Lists I, I A or I B means the identification of their impact on human and animal health or the environment, identification of potential adverse effects on target organisms and identification of their efficacy and hazards in the prescribed manner of use.

The evaluation of active substances shall be carried out in line with the professional guidelines which are used in the European Union and according to the common principles for evaluation.

Evaluations shall be carried out by legal persons authorised by the Minister.

The legal persons referred to in paragraph 3 of this Article shall meet the requirements set out in the special regulation referred to in Article 7, paragraph 3 of this Act relating to the procedures for evaluation of biocidal products.

The list of legal persons referred to in paragraph 3 of this Article shall be published in the Official Gazette.

The costs of evaluation of active substances shall be covered by the applicant.

Substance Lists I, I A and I B Article 12

The substance Lists I, I A and I B and their amendments shall be published in the Official Gazette following the adoption of decisions on the European Union level and after the publication in the Official Journal of the European Communities.

III EVALUATION AND PLACING ON THE MARKET OF BIOCIDAL PRODUCTS AND THEIR USE Evaluation of biocidal products Article 13

The evaluation performed in the procedure of granting an authorisation to place on the market and use a biocidal product, in accordance with the provisions of this Act, means the identification of their impact on human and animal health or the environment, identification of potential adverse effects on target organisms and identification of their efficacy and hazards in the suggested manner of use.

Taking into consideration the intended use and manner of use of biocidal products, the evaluation shall, together with the common principles, take into account also the geographical, environmental and health characteristics of the territory of the Republic of Croatia.

The evaluation of biocidal products shall be carried out in line with the professional guidelines which are used in the European Union and according to the common principles for evaluation.

Evaluations shall be carried out by legal persons authorised by the Minister.

The legal persons referred to in paragraph 4 of this Article shall meet the requirements set out in the special regulation referred to in Article 7, paragraph 3 of this Act relating to the procedures for evaluation of biocidal products.

The list of legal persons referred to in paragraph 4 of this Article shall be published in the Official Gazette.

The costs of evaluation of biocidal products shall be covered by the applicant.

Documentation for the evaluation of biocidal products

Article 14

An application for the evaluation of a biocidal product, in addition to the personal name or the company of the applicant, address and headquarters of the applicant, personal name or company of the authorisation holder and address or headquarters of the authorisation holder, shall also contain information on tests on the basis of which, in accordance with Article 13 of this Act, it is possible to draft the assessment of efficacy and hazards of the biocidal product. By way of derogation from paragraph 1 of this Article, the information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied in the procedure of evaluating a biocidal product as well as information which cannot be supplied because it is not scientifically necessary or technically possible. In such cases a justification must be submitted to the Ministry. The Ministry shall evaluate the grounds for each application on a case-by-case basis.

Avoidance of unnecessary testing on vertebrate animals

Article 15

In the case of a biocidal product which has already been authorised in accordance with the provisions of this Act and the ordinances passed pursuant to this Act, and without prejudice to the provisions of this Act on information protection, the Ministry may agree that a second or subsequent applicant for placing the biocidal product on the market may refer to data provided by the first applicant in so far as the second or subsequent applicant can provide evidence that the biocidal product is similar and its active substances are the same as the one formerly authorised, including degree of purity and nature of impurities.

By way of derogation from the provisions of this Act regulating the contents of the documentation for the placing on the market of an active substance and of a biocidal product, an applicant for the placing on the market of a biocidal product shall, before carrying out experiments involving vertebrate animals, enquire of the Ministry the information on:

- whether the biocidal product for which an application is to be made is similar to a biocidal

product for which authorisation has been granted, and

- as to the name and address of the holder of the authorisation.

The enquiry shall be supported by evidence that the prospective applicant intends to apply for authorisation on his own behalf and that the other information referred to in Article 28 of this Act is available.

The Ministry, if satisfied that the applicant who intends to apply meets the requirements referred to in paragraph 3 of this Article, shall provide the name and addresses of the holders of former relevant authorisations for the placing on the market of the biocidal product and shall at the time inform the holder of the authorisations of the name and address of the applicant. The holder of former authorisations and the applicant shall take all reasonable steps to reach agreement on the sharing of information so as to avoid the duplication of testing on vertebrate animals.

The Ministry shall encourage reaching the agreement referred to in paragraph 5 of this Article.

If it is still not possible for the holders of former authorisations and the applicant for authorisation to reach agreement, the Ministry shall decide on the manner of use of data for the next applicant.

Placing a biocidal product on the market Article 16

A biocidal product can be placed on the market and used in the Republic of Croatia only if it has authorisation for the placing on the market and if it is classified, packaged and labelled and has instructions for use in accordance with this Act.

The authorisation referred to in paragraph 1 of this Article shall be granted or refused by an administrative decision against which no appeal is admitted but an administrative dispute may be instituted.

The placing on the market of a biocidal product on the grounds of a full or simplified procedure shall be authorised on the basis of the decision referred to in paragraph 2 of this Article. When reaching a decision, the opinion of the Committee referred to in Article 22 of this Act shall be taken into account.

By way of derogation from the provision of paragraph 1 of this Article, basic substances included in the List I B and biocidal products which contain only those basic substances as active substances can be placed on the market for intended uses as biocides without an authorisation, according to the regulations relating to dangerous chemicals.

The authorisation referred to in paragraph 1 of this Article shall be granted for a maximum period of 10 years and may be renewed under the conditions prescribed by this Act. In the case of inclusion of the active substance in one of the Lists I or I A, the authorisation shall be granted without exceeding the deadline specified for the active substance in one of those Lists.

When issuing the authorisation referred to in paragraph 1 of this Article, the evaluation of a biocidal product provided pursuant to this Act and the inclusion of an active substance in the List I or I A shall be taken into account.

Notwithstanding regular authorisations, the Minister may also grant a special authorisation for the placing on the market of a biocidal product in accordance with this Act, in which case the opinion of the Committee referred to in Article 22 of this Act shall be taken into account.

The costs of carrying out the procedure for granting an authorisation for the placing on the market of a biocidal product shall be covered by the applicant.

Conditions for authorisation issue

Article 17

The Minister shall issue an authorisation for the placing on the market of a biocidal product if the conditions referred to in Article 4 of this Act have been satisfied and if, according to the special regulations referred to in Article 7, paragraph 3 of this Act, it is possible to determine the type and quantity of its active substances and any toxicologically or ecotoxicologically significant impurities and co-formulants, and its residues of toxicological or environmental significance, which result from authorised uses, if its physical and chemical properties have been determined and deemed acceptable for purposes of the appropriate use, storage and transport of the product.

When issuing an authorisation, it is necessary to take into account the provisions of special regulations relating to the health and safety at work, consumer protection, animal health protection, environmental protection and, where necessary, to issue the authorisation subject to the requirements pursuant to those regulations.

Application for authorisation for placing a biocidal product on the market

Article 18

The application for authorisation for placing a biocidal product on the market in the territory of the Republic of Croatia shall be submitted to the Ministry.

The application referred to in paragraph 1 of this Article shall contain documentation in accordance with the regulation passed pursuant to Article 29, paragraph 4 of this Act.

The applicant shall be obliged to submit to the Ministry the information on the personal name or company name of the authorisation holder for biocidal products for which the placing on the market is requested.

At the request of the Ministry, the applicant shall provide samples of the biocidal product and its composition, proposals for labelling, packaging, instructions for use and advertising.

Frame-formulation for biocidal products

Article 19

A frame-formulation may be established at the request of the applicant, or may be established by the Ministry on its own initiative.

When the establishment of a frame-formulation is initiated upon the request, the applicant shall submit the application together with the request for a full or simplified procedure, within the meaning of this Act, and provide all necessary information and evidence that the variations which may be predicted within the frame-formulation do not increase the level of risk and decrease efficacy in comparison with the proposed biocidal product.

The Ministry shall establish a frame-formulation if the biocidal product satisfies the conditions prescribed by this Act relating to the necessary documentation, if the variations are within limits laid down in this Act and if those variations do not increase the level of risk and do not affect the decrease in efficacy of the biocidal product.

The Ministry shall communicate the establishment of a frame-formulation to the applicant when issuing an authorisation for a particular biocidal product. When the Ministry establishes a frame-formulation for biocidal products, it shall communicate it to the applicant within a period of 30 days from the date of the establishment of a frame-formulation.

Contents of authorisation

Article 20

The authorisation referred to in Article 16, paragraph 1 of this Act shall contain data on the applicant and the authorisation holder for the placing on the market, trade name of the biocidal product and the amount of active substances and other substances which have a sufficiently high concentration to effect the efficacy of the biocidal product or to its classification, intended use and conditions of use as well as any other relevant data or requirements relating to the biocidal product.

The authorisation may determine particular conditions for the placing on the market and use of the biocidal product, for example, the location of sale of the biocidal product.

Restrictions on placing biocidal products on the market Article 21

Biocidal products which are, due to their dangerous properties, classified as very toxic, toxic, or as a category 1 or 2 carcinogen, or as a category 1 or 2 mutagen or classified as toxic for reproduction category 1 or 2, shall not be authorised for marketing to, or use by the general public.

The biocidal products referred to in paragraph 1 of this Article may be placed on the market only for professional use.

Committee on Biocidal Products Article 22

The Committee on Biocidal Products (hereinafter: the Committee) shall be established and appointed by the Minister and composed of representatives of the Ministry as well as acknowledged experts in the fields of medicine, veterinary medicine, pharmacy, chemistry, ecology, biology, agronomy and public health.

The Committee shall have nine members.

The Committee referred to in paragraph 1 of this Article shall provide its expert opinion in the procedure of authorising the placing on the market and use of a biocidal product.

Inventory of biocidal products Article 23

The inventory of biocidal products authorised for the placing on the market shall be published in the Official Gazette once a year.

The inventory referred to in paragraph 1 of this Article shall be communicated to the other Member States of the European Union and the European Commission once a year.

The inventory referred to in paragraph 1 of this Article shall contain at least the following information:

1. the name of the manufacturer and the full name or company and headquarters of the authorisation holder,
2. the trade name of a biocidal product,
3. the name and amount of all active substances as well as the name and amount of other substances in a biocidal product, if classified and labelled as dangerous chemicals,
4. classification of all active and other substances, if classified as dangerous chemicals according to the special regulations relating to dangerous chemicals,
5. the product-type and the use for which it is authorised,
6. the type of formulation of a biocidal product (liquid, granules, powder, solids),
7. the class, register number and the date of issue of the authorisation,

8. the period for which the authorisation is issued,
9. any proposed limits on residues, if established,
10. conditions under which biocidal products may be placed on the market and used,
11. reasons for the modification or renewal of an authorisation;
12. the type of procedure used for granting the authorisation
13. and any other particular conditions or requirements in relation to the placing on the market and use of a biocidal product.

Renewal of authorisation Article 24

An authorisation for the placing on the market and use of a biocidal product may be renewed following an application by the applicant if the requirements of this Act have been satisfied. The application for renewal shall be submitted at least 60 days before the expiration of the period for which it was granted, if an authorisation has been issued in a simplified procedure or at least one year before the expiration of the period for which it was granted if an authorisation has been issued in a full procedure. Before reaching a decision on renewal of an authorisation, where necessary for the purpose of review of documentation, the authorisation may be granted only for the minimum period necessary to complete a review.

If it is established that the conditions for the safe placing on the market of a biocidal product are still satisfied, the Minister shall grant a renewal or, if those conditions are no longer satisfied, refuse a renewal by a decision.

If there is new information or concern that some of the conditions under which the authorisation was granted are no longer satisfied, the Ministry may request further information and renew the authorisation for the period which is, considering the existing practice in each particular case, necessary to provide further information requested.

Modification and cancellation of authorisation Article 25

The Minister may modify an authorisation for the placing on the market of a biocidal product in:

- the manner of use or the amounts used of a biocidal product on the basis of developments in scientific and technical knowledge and to protect health and the environment,
- if the applicant for authorisation so requests and states the reasons for the modification.

Where a proposed modification concerns an extension of uses, the Minister shall extend the authorisation subject to the particular conditions placed on the active substance included in the List I or I A.

Where a proposed modification of an authorisation involves changes to the particular conditions placed on the active substance included in the List I or I A, such changes can be made only after evaluation of the active substance, with regard to the proposed changes, in accordance with the procedures laid down in Article 10 of this Act.

An authorisation can be modified only if it is established that the conditions referred to in Article 17 of this Act remain satisfied.

The modification of an authorisation for placing a biocidal product on the market shall be granted or refused by the Minister within a period of 60 days from the date of receipt of the application.

The Minister shall cancel the authorisation for placing a biocidal product on the market before the expiry of the period for which the authorisation was granted if it is determined that:

- the active substance is no longer included in the list of active substances of the European Union or if its inclusion in the list is not authorised;
- the conditions for obtaining the authorisation for the placing on the market of a biocidal product have changed or are no longer satisfied;
- if the applicant for authorisation so requests and states the reasons for the cancellation;
- it is discovered that false or misleading information were supplied concerning the facts on the basis of which the authorisation for the placing on the market of a biocidal product was granted.

Procedure for the biocidal product after cancellation or modification of authorisation Article 26

In cases where the Minister modifies or cancels an authorisation for the placing on the market of a biocidal product, the decision shall establish a manner and conditions for the procedure for the biocidal product after the cancellation or modification of its authorisation.

After the expiry of an authorisation or in the case when a regular authorisation is not granted, the Ministry, on the basis of a written proposal from the authorisation holder, shall determine an appropriate period for the use of remaining stocks of biocidal products or it shall order their destruction, if it is in accordance with this Act.

Safeguard clause Article 27

If there are valid reasons to consider that a biocidal product which was authorised in a full or simplified procedure, or a biocidal product which is in the process of being placed on the market, constitutes an unacceptable risk to human or animal health or the environment, the Minister shall prohibit or restrict the placing on the market or use of that product on the territory of the Republic of Croatia.

The Minister shall immediately inform the European Commission and the other Member States of the European Union of such provisional decision on the prohibition or restriction of the placing on the market or use of that product on the territory of the Republic of Croatia and give reasons for such decision. A decision shall be taken on the matter within 90 days from the date of issuing the prohibition or restriction of the placing on the market.

Authorisation issued in a full procedure (authorisation) Article 28

Biocidal products may be placed on the market in a full procedure (authorisation), if they are containing the active substances included in the substance List I or I A. The application for authorisation for the placing on the market in a full procedure shall contain the prescribed documentation for each active substance in the biocidal product and for the biocidal product itself or the letter of access to that information.

The documentation referred to in paragraph 1 of this Article shall include a detailed and full description of the studies conducted and of the methods used or a bibliographical reference to those methods. The information in the documentation supplied in a full procedure shall be sufficient for an evaluation to be made of the effects and properties referred to in Article 4 of this Act.

The documentation referred to in paragraph 1 of this Article shall be submitted in the form of a technical dossier, containing the information and results of the studies pursuant to the special regulation relating to the content of primary documentation for active substances and

biocidal products and if it is necessary, depending on the biocidal product type, relevant parts of documentation pursuant to the special regulation relating to the content of additional documentation for active substances and biocidal products.

Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied in the documentation referred to in paragraph 1 of this Article. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases, a justification, acceptable to the Ministry must be submitted and it can include the information on a frame-formulation which the applicant has the right to access.

If the evaluation of the documentation shows that, to evaluate the risks of the biocidal product in accordance with a separate ordinance passed by the Minister, further information, including data and results from further testing, is necessary, the applicant shall be obliged to submit such information.

The time period for the evaluation of the documentation referred to in paragraph 5 of this Article shall start only after the documentation is complete.

The name of an active substance must be given in accordance with the special regulation relating to the classification, packaging and labelling of dangerous chemicals or, if the name is not included therein, as given in the European Inventory of Existing Chemical Substances (EINECS), or, if the name is not included therein, the active substance must be given its International Standards Organisation (ISO) common name. If the latter is not available, the substance must be designated by its chemical designation according to International Union of Pure and Applied Chemistry (IUPAC) rules.

Tests must be conducted according to the methods described in the special regulations relating to the classification, packaging and labelling of dangerous chemicals and in accordance with the provisions of special regulations concerning the principles of good laboratory practice and the protection of animals.

Where test data exist that have been generated before the entry into force of the special regulations referred to in paragraph 8 of this Article, the adequacy of such data and the need to conduct new tests must be decided, taking into account, among other factors, the need to minimise testing on vertebrate animals.

The Ministry may require from the applicant to provide a sample of the biocidal product and individual samples of its ingredients.

On request by the European Commission and the competent authorities of Member States of the European Union, the Ministry shall be obliged to provide:

1. a copy of the application,
2. a record of administrative decisions taken concerning the application and concerning the documentation submitted for the granting of the authorisation for the placing on the market, including the summary of the evaluation.

Additional to the information referred to in paragraph 11 of this Article, the Ministry shall supply, on request by the European Commission and the competent authorities of Member States, all information necessary for full comprehension of applications and shall, where requested, ensure that the applicant provides a copy of the documentation referred to in paragraph 1 of this Article.

Authorisation issued in a simplified procedure (registration)

Article 29

Low-risk biocidal products may be placed on the market in a simplified procedure (registration), if the active substance is included in the substance List I A.

The application for authorisation for the placing on the market of a low-risk biocidal product

in a simplified procedure shall contain information on the applicant, biocidal product, intended uses, efficacy, method of analysis, proposal for classification, packaging and labelling, safety-data sheet pursuant to the regulations relating to dangerous chemicals and, where applicable, the letter of access to information relating to the biocidal product and each active substance in the biocidal product as well as any other information on the basis of which it is possible to evaluate the impact of the biocidal product on human and animal health or the environment.

The provisions of Article 28, paragraphs 2 – 5 of this Act shall appropriately apply to the granting of an authorisation in a simplified procedure.

Detailed documentation for issuing an authorisation in a simplified procedure, documentation procedures and time periods for submitting documentation shall be prescribed by the Minister.

Processing of applications and time periods for full and simplified procedures Article 30

The Ministry, following the receipt of the application for granting an authorisation for the placing on the market of a biocidal product shall without delay examine the completeness of the application. When the application is incomplete, the Ministry shall require the applicant to supplement the application within a prescribed time period. If the application is not supplemented within the time period prescribed, the Ministry may, on the basis of justification by the applicant, set a new time period whereas the duration of a whole procedure must not exceed a period of 6 months from the initial request to supplement the application. If the application is not supplemented within the additional time period, the Ministry shall cancel the procedure and consider the application not submitted.

The time period for granting an authorisation for the placing on the market of a biocidal product shall start on the date of submitting a complete application.

If further procedure shows that further information is necessary to evaluate the biocidal product, the Ministry shall ask the applicant to submit such information and determine a deadline for their submission.

In the case referred to in paragraph 3 of this Article, the time period laid down in paragraph 5 of this Article shall be suspended until the required information is submitted.

A time period for granting an authorisation in a full procedure shall be one year from the date of receipt of a complete application, and in a simplified procedure shall be 60 days from the date of receipt of a complete application.

Authorisation issued in a special procedure Article 31

An authorisation in a special procedure shall be issued on the basis of an application submitted by an applicant in cases concerning biocidal products which are by their composition, purity of active substances and efficacy so similar to biocidal products which have already been authorised and a frame-formulation established that the same documentation may be used for them.

The authorisation referred to in paragraph 1 of this Article shall be granted or refused by an administrative decision of the Minister and no appeal is admissible against it but an administrative dispute may be instituted.

The authorisation referred to in paragraph 1 of this Article shall be issued within a period of 60 days from the date of receipt of the application, if it is determined:

- that the applicant is requesting it as the authorisation holder in an authorisation or registration procedure for a biocidal product for which the frame-formulation has already

been established according to this Act. In that case the applicant in the application for the granting of an authorisation in a special procedure must provide evidence the frame-formulation for the biocidal product has been established; or

- that the applicant has a right of access to the frame-formulation in the form of a letter of access.

The authorisation referred to in paragraph 1 of this Article shall be issued for the period identical to the period granted for the authorisation for the placing on the market of the biocidal product for which the frame-formulation has been established. The authorisation shall include the possibility of its modification in the case of the modification or cancellation of the authorisation, which was granted in an authorisation or registration procedure of the biocidal product, on which the frame-formulation is based.

IV AUTHORISATIONS BASED ON THE MUTUAL RECOGNITION OF AUTHORISATIONS IN THE EUROPEAN UNION

Mutual recognition of authorisations

Article 32

The Ministry shall, on the basis of an application submitted by an applicant, recognize the authorisation for the placing on the market of a biocidal product granted in a full or simplified procedure in other Member States of the European Union, if such applications have been issued in accordance with the provisions of this Act.

The application referred to in paragraph 1 of this Article must contain the following information:

- a summary of the documentation referred to in Article 28, paragraphs 2 and 3 of this Act, if the authorisation was granted in a full procedure, or the data referred to in Article 29, paragraphs 2 and 3 of this Act, if the authorisation was granted in a simplified procedure, except for the efficacy data for which a summary shall suffice,
- a certified copy of the first authorisation granted, unless the Ministry can obtain the copy of the first authorisation by itself,
- a certified translation in the Croatian language and Latin alphabet of the first authorisation granted.

In the procedure of mutual recognition of authorisations, the Minister shall, based on the opinion of the Committee, grant an approval within 60 days, when a full procedure is concerned, or in 30 days, when a simplified procedure is concerned, provided that the active substance is included in the substance List I or I A. The authorisation may be granted for the period identical to the authorisation in the Member State of the European Union where the first authorisation was granted.

The time period for the granting of the authorisation referred to in paragraph 3 of this Article shall start from the date the Ministry determines the application as complete.

Refusal or restriction of mutual recognition

Article 33

The Minister may, where justified, refuse recognition of an authorisation granted in a full or simplified procedure for product types avicides, piscicides and agents for control of other vertebrates, except rodents referred to in the special regulation on the types and description of biocidal products.

When the relevant circumstances of use of the biocidal product differ significantly from those in the Member State of the European Union where the biocidal product was first authorised, and an unchanged authorisation may therefore present unacceptable risks to human and

animal health or the environment, the Minister shall establish the adjustments of the authorisation relating to the time period and manner of use, and the time period in which the biocidal product realizes its effect, directions for first aid, disposal and information relating to the risks to human and animal health or the environment.

The Minister may provisionally refuse the mutual recognition of the authorisation granted in a simplified procedure by another Member State of the European Union, if that biocidal product is not a low-risk biocidal product within the meaning of Article 2, paragraph 1, item 3 of this Act. The Minister shall communicate the decision on provisional refusal referred to in this Article to the European Commission, Member States of the European Union and the applicant.

If the Minister believes a biocidal product authorised by another Member State of the European Union cannot meet the conditions set out in this Act, he or she shall notify the European Commission, other Member States of the European Union and the applicant and shall provide them with an explanatory document containing the name of the product and its specification and setting out the grounds on which he or she proposes to refuse or to restrict the authorisation.

V SPECIAL AUTHORISATIONS

Provisional authorisation for placing a biocidal product containing a new active substance on the market
Article 34

By way of derogation from Article 28 of this Act, the Ministry may, if the procedure for inclusion in one of the substance lists is not yet completed, provisionally authorise the placing on the market of a biocidal product which contains a new active substance for other uses except those for scientific research and development and process-orientated research and development, if the competent authority in one of the Member States of the European Union established the completeness of an application and no other Member State of the European Union, on the basis of the summary documentation, made a legitimate objection to the completeness of the application, and if the Ministry believes that:

- the new active substance satisfies the requirements laid down by this Act,
- the biocidal product may be expected to satisfy the conditions for the granting of an authorisation in accordance with this Act,
- the new active substance is classified, packaged, properly labelled and the safety-data sheet exists pursuant to the provisions of this Act and the regulations relating to dangerous chemicals,
- the biocidal product has no dangerous properties which would cause its classification in one of the groups referred to in Article 21, paragraph 1 of this Act.

The applicant shall be obliged to provide the following information with the application:

- evidence on the completeness of documentation,
- statement or evidence that the biocidal product for which the issuing of a provisional authorisation is requested contains the active substance which is in the process of inclusion to one of the substance lists,
- summary of the documentation on the active substance and
- summary of the documentation on the biocidal product.

The Minister shall grant a provisional authorisation for a period not exceeding 3 years.

In cases where, after the expiry of a provisional authorisation, an active substance is not included in the substance List I or I A because the process of inclusion is not yet completed and providing there are no changes to the good reasons to believe the active substance will satisfy the requirements for its inclusion in the substance List I or I A, the Minister may

prolong the provisional authorisation for a period not exceeding one year.

The provisional authorisation shall be cancelled if it is decided, on the level of European Union, that the active substance does not satisfy the requirements for its inclusion in the substance List I or I A.

Authorisation for placing a biocidal product on the market due to unforeseen danger Article 35

By way of derogation from Articles 28 to 32 of this Act, relating to granting an authorisation for the placing on the market of biocidal products, if in the Republic of Croatia there is no relevant biocidal product which was authorised for the placing on the market and there is a need to prevent the development of a particular harmful organism, the Minister may authorise temporarily for a period not exceeding 120 days, the placing on the market of a biocidal product under prescribed conditions and in a prescribed quantity for the biocidal product which is not authorised or may extend an authorisation for a biocidal product authorised for the placing on the market. Such an authorisation shall be issued by the Minister *ex officio* or on request of an interested party.

The authorisation must present information on the manufacturer, biocidal product, the quantity to be placed on the market, intended use, area and conditions of use, manner of safe use, information on the persons who will use it and the obligation of maintaining a register on the biocidal product.

The Minister shall modify or cancel that special authorisation if the biocidal product did not achieve the desired results or the adverse effects of its use are greater than the damage which may be caused by the harmful organism referred to in paragraph 1 of this Article.

The Ministry shall immediately inform the European Commission and other Member States of the European Union of the authorisation referred to in paragraph 1 of this Article and provide justification for it.

Research authorisation Article 36

When a biocidal product containing a new active substance, which is unauthorised for the placing on the market pursuant to the provisions of this Act, is used for the purposes of scientific research and development and for process-orientated research and development (hereinafter: the research), or in researches not involving a release into the environment and in researches which may result in a release into the environment, it shall be required to obtain an authorisation before the placing on the market for the purposes of research.

The authorisation referred to in paragraph 1 of this Article shall be granted or refused by a decision of the Minister against which no appeal is admitted but an administrative dispute may be instituted.

The research holder may use the biocidal product for purposes referred to in paragraph 1 of this Article only in the quantities and areas prescribed in the research authorisation and in accordance with other conditions for safe use of the biocidal product laid down in the research authorisation.

The application for the granting of a research authorisation shall include information on the purpose of research, method of intended application of research, professional qualification of personnel, description of area and conditions for application of research, method of maintaining records on research progress, manner of use of the biocidal product and the method of maintaining records on waste as well as the information on their safe disposal.

The research holder shall be obliged to maintain written records detailing the identity of the

biocidal product or active substance, labelling data, quantities supplied and the names and addresses of those persons receiving the biocidal product or active substance and compile documentation containing all available data on possible effects on human or animal health or impact on the environment. The research holder shall be obliged to submit to the Ministry the written records, documentation and a written statement on the progress and results of research.

In the case of process-oriented research and development, the information required in accordance with paragraph 5 of this Article shall be notified to the Ministry and to the competent authority of the Member State where the experiment or test is to be conducted before placing on the market occurs.

If the proposed experiments or tests referred to in this Article are liable to have harmful effects on human and animal health or the environment, the Minister may either prohibit them or only allow them subject to such conditions necessary to ensure safe application of research. In cases where research involving a research holder with the headquarters in the Republic of Croatia is not to be conducted in the Republic of Croatia, the research holder shall notify the competent authority of the Member State in the territory of which the research is to be conducted in a period of 8 days from the date of receiving the research authorisation. The research authorisation shall not apply if the Ministry has granted the research holder the right to undertake certain research and has determined the conditions under which the research has to be undertaken. The research holder shall notify the Ministry of the research and shall maintain written records in accordance with paragraph 5 of this Article.

VI CLASSIFICATION, PACKAGING AND LABELLING OF BIOCIDAL PRODUCTS

Classification, packaging, labelling and safety-data sheets

Article 37

Unless otherwise provided by this Act, the provisions of regulations relating to dangerous chemicals shall apply to the classification, packaging and labelling of biocidal products and the provision of a safety-data sheet.

In addition, the packaging of biocidal products shall also comply with the following requirements:

- (a) biocidal products which may be mistaken for food, drink or feedingstuff shall be packaged to minimize the likelihood of such a mistake being made,
- (b) biocidal products available to the general public which may be mistaken for food, drink or feedingstuff shall contain components to discourage their consumption.

Labels of biocidal products shall not be misleading or give an exaggerated impression of the product and, in any case, not mention the indications 'low-risk biocidal product', 'non-toxic', 'harmless' or similar indications.

In addition, the label must show clearly and indelibly the following:

- a) the identity of every active substance and its concentration in metric units,
- b) the class and the register number of an authorisation,
- c) the type and form of preparation (e.g. liquid concentrates, granules, powders, solids, etc.),
- d) the uses for which the biocidal product is authorised (e.g. disinfection, wood preservation, surface biocide, anti-fouling, etc.),
- e) instructions for use and the dose rate, expressed in metric units, for each use provided for under the terms of the authorisation,
- f) particulars of likely direct or indirect adverse side effects and any directions for first aid,
- g) if the packaging is accompanied by a leaflet, the sentence 'Read attached instructions before use',

- h) directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging,
- i) the formulation batch number or designation and the expiry date relevant to normal conditions of storage,
- j) the period of time needed for the biocidal effect, the interval to be observed between two applications of the biocidal product or between application and the next use of the product treated with the biocidal product, or the next access by man or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of areas treated with the biocidal product, particulars for adequate cleaning of equipment, directions concerning precautionary measures during use, storage and transport (e.g. personal protective clothing and equipment, covering of furniture, removal of food and feedingstuff, directions to prevent animals from being exposed, measures for protection against fire); and where applicable,
- k) the categories of users to which the biocidal product is restricted,
- l) information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water,
- m) for microbiological biocidal products, labelling requirements according to the special regulation on the protection of workers from risks related to exposure to biological agents at work.

The label on the packaging of a biocidal product must always contain the following:

- a) the identity of every active substance and its concentration in metric units,
- b) the class and the register number of an authorisation,
- c) the uses for which the biocidal product is authorised (e.g. disinfection, wood preservation, surface biocide, anti-fouling, etc.); and where applicable
- d) if the packaging is accompanied by a leaflet, the sentence 'Read attached instructions before use',
- e) the categories of users to which the biocidal product is restricted.

The information referred to in paragraph 3, items c), e), f), h), i), j) and l) shall be permitted to be carried elsewhere on the packaging of a biocidal product or on an accompanying leaflet integral to the packaging.

These items of information shall be regarded as label information for the purposes of this Act. Where biocidal products classified as insecticide, acaricide (agent against mites which cause a type of mange (acariasis) in domestic animals, wine grape disease (acarinosi)), rodenticide (agent against harmful rodents), avicide (agent against harmful birds) or molluscicide (agent against shells and molluscs) are authorised pursuant to this Act and are also subject to the special regulations relating to classification, packaging and labelling of dangerous chemicals, changes may be permitted to the packaging and labelling which may be required as a consequence of those regulations in so far as they do not conflict with the conditions of an authorisation issued under this Act.

The Ministry may require the provision of samples, models or drafts of the packaging, labelling and accompanying leaflets.

The placing of biocidal products on the market shall be permitted only for biocidal products labelled in the Croatian language and Latin alphabet.

Restrictions relating to packaging and labelling Article 38

Biocidal products classified as dangerous shall not be labelled as less dangerous or harmless to human and animal health or the environment or labelled with a description or indications which would be misleading.

Under no circumstances may the packaging of biocidal products referred to in paragraph 1 of this Article use descriptions as ‘low-risk biocidal product’, ‘non-toxic’, ‘harmless’ or any similar indications.

The packaging of biocidal products in any manner which would be misleading to a user shall not be permitted.

Obligations of authorisation holders, legal and natural persons Article 39

The authorisation holder who is placing a biocidal product on the market shall be obliged to ensure the proper classification, packaging and labelling of a product and ensure the safety-data sheet which is to be supplemented according to new knowledge pursuant to the regulations relating to dangerous chemicals.

Legal and natural persons placing a biocide on the market shall make the safety-data sheet available to any professional and industrial user and, as appropriate, other users on their request when purchasing biocidal products, with the purpose of enabling them to take the necessary measures for the protection of the environment and health as well as health and safety at the workplace concerning the performance of a registered activity.

Advertising Article 40

Advertising, providing recommendations and advice shall be allowed only for biocidal products placed on the market.

When advertising a biocidal product, every advertisement shall be accompanied by the sentence ‘Use biocidal products safely. Always read the label and product information before use’. The sentence shall be clearly distinguishable in relation to the whole advertisement or they shall be clearly separate from the rest of the textual part of an advertisement.

The words ‘Biocidal product’ referred to in paragraph 2 of this Article may be replaced with an accurate description of the product-type being advertised, for example wood preservatives, disinfectants, surface biocides, anti-fouling products, etc.

Advertisements for biocidal products shall not refer to the product in a manner which is misleading in respect of the manner of use, efficacy or risks from the product to man or the environment.

Under no circumstances may the advertising of a biocidal product contain text which would indicate a lower risk, non-toxicity or harmlessness of a biocidal product to humans, animals or the environment, for example ‘low-risk biocidal product’, ‘non-toxic’, ‘harmless’.

VII OBLIGATION OF MONITORING CHANGES AND NEW KNOWLEDGE ON BIOCIDAL PRODUCTS, NOTIFICATION AND KEEPING OF RECORDS

Monitoring the changes and new knowledge on biocidal products

Article 41

The authorisation holder for a biocidal product shall be obliged, following the granting of an authorisation for the placing on the market, to monitor any effects and knowledge on the biocidal product which may have an adverse impact on human and animal health or the environment and the results and knowledge on the efficacy of the biocidal product.

The authorisation holder shall immediately notify the Ministry of information of which he or she is aware or for which he or she can assume they may affect further validity or the granting of an authorisation.

In particular, the authorisation holder shall notify the Ministry of the following:

- new knowledge or information on the effects of the biocidal product or its active substances and the effects of other ingredients on human and animal health or the environment,
- changes in the source or composition of the active substance,
- changes in composition of a biocidal product,
- development of resistance,
- changes of an administrative nature (for example, change of the authorisation holder, change of the product trade name) or other aspects, such as the nature of the packaging.

The obligation of notifying information on the effects referred to in paragraph 3, subparagraph 1 and 4 of this Article shall also apply to those persons who are using biocidal products.

The Ministry shall immediately notify the European Commission and other Member States of any new information referred to in paragraph 1 of this Article concerning potentially harmful effects for humans, animals or the environment or the new composition of a biocidal product, its active substances, impurities, co-formulants or residues.

Register Article 42

Authorisation holders and legal and natural persons who use biocidal products professionally shall be obliged to maintain a register in accordance with the special regulations relating to dangerous chemicals.

The aggregate annual data from the register shall be submitted to the Croatian Institute for Toxicology (hereinafter: the CIT) not later than 31 January for the previous year.

Notification of information on poisoning Article 43

The activities of collecting and exchanging information on acute poisoning and other effects of biocidal products placed on the market, including safety-data sheets, information on the chemical composition of such products and their effects on human and animal health and the environment shall be performed by the CIT.

The information referred to in paragraph 1 of this Article shall be delivered or submitted for inspection by the CIT to the Poison Control Centre (hereinafter: the PCC). Such information may only be used to meet any medical demand by formulating preventive and curative measures for poisoning, in particular in emergencies, and it may not be used for other purposes.

The CIT and PCC shall be obliged to maintain the confidentiality of information referred to in paragraph 1 of this Article.

The manufacturers, authorisation holders or persons responsible for placing biocidal products on the market shall be obliged to ensure that the CIT has at its disposal all the information referred to in paragraph 1 of this Article.

For biocidal products already placed on the market on the date of entry into force of this Act, the manufacturers, authorisation holders or persons responsible for placing biocidal products on the market shall be obliged to submit the information referred to in paragraph 1 of this Article to the CIT not later than one year from the date of entry into force of this Act.

VIII TESTING LABORATORIES AND TESTING METHODS

Testing Article 44

For laboratories conducting tests, which represent the basis for evaluation of a biocidal product in relation to its effect on human and animal health or the environment, in the procedure of granting an authorisation for the placing on the market, including the methods used for that procedure and including the quality system, the regulations relating to dangerous chemicals shall apply.

By way of derogation from paragraph 1 of this Article, the Minister may, subject to the approval of the Minister competent for the economy, prescribe for technical and economic reasons other requirements which have to be satisfied by testing laboratories for the purposes of the application procedure referred to in Article 64 of this Act,.

IX EXCHANGE, CONFIDENTIALITY AND PROTECTION OF INFORMATION

International and internal information exchange

Article 45

The Ministry shall, on an international level, ensure the exchange of information on biocidal products and adopted measures as well as other required information pursuant to the provisions of this Act and the assumed international obligations.

Within a period of one month from the end of each quarter, the European Commission and Member States shall be informed of any biocidal products which have been authorised in a full or simplified procedure in the Republic of Croatia or for which an authorisation has been refused or modified or renewed or cancelled, in accordance with the information referred to in Articles 24 and 25 of this Act.

Where the Ministry receives the information referred to in paragraph 2 of this Article and has legitimate reason to believe the documentation is incomplete, it shall without undue delay inform the Committee and the European Commission and other Member States of the European Union of its concerns.

The Ministry, pursuant to the regulations relating to the right of access to information, shall make the information on biocidal products available to other authorities and legal persons which require the information for everyday work provided they are obliged to use such information in accordance with the regulations relating to the protection of information confidentiality.

Information confidentiality

Article 46

If an applicant provides a valid justification that the disclosure of the full composition of the biocidal product and required information, which constitutes an industrial or commercial secret, might harm him commercially, he shall have a right to specify them as confidential from all persons other than the European Commission and the competent authorities of Member States of the European Union.

The validity of an application referred to in paragraph 1 of this Article shall be determined by the Ministry.

If the application referred to in paragraph 1 of this Article is determined as valid and the disclosure of information would be harmful for the applicant, the Ministry shall confirm the confidentiality of such information. When determining the validity of an application for keeping information confidential, the Ministry shall take into account the conditions laid down in the regulations relating to the right of access to information.

The Ministry shall treat the information received by the other competent authority of a Member State of the European Union as being confidential if the other competent authority of

a Member State used that information in the same way.

After the authorisation for the placing on the market of a biocidal product has been granted, confidentiality shall not in any case apply to the following information:

- a) the name and address of the applicant,
- b) the name and address of the biocidal product producer,
- c) the name and address of the active substance producer,
- d) the names and content of the active substance or substances in the biocidal product and the name of the biocidal product,
- e) the names of other substances which are classified as dangerous pursuant to the regulations relating to dangerous chemicals and contribute to the classification of the product as dangerous,
- f) physical and chemical data concerning the active substance and biocidal product,
- g) any ways of rendering the active substance or biocidal product harmless,
- h) a summary of the results of the tests required pursuant to this Act and regulations adopted on the basis thereof to establish the substance's or product's efficacy and effects on humans, animals and the environment and, where applicable, its ability to promote resistance,
- i) recommended methods and precautionary measures to reduce dangers from handling, storage, transport and use as well as from fire or other hazards,
- j) safety data sheets,
- k) methods of analysis for determining the active substances and any toxicologically or ecotoxicologically significant impurities and other substances resulting from authorised uses,
- l) methods of disposal of the biocidal product residues and of its packaging,
- m) procedures to be followed and measures to be taken in the case of spillage or leakage,
- n) first aid and medical advice to be given in the case of injury to persons.

If the applicant or manufacturer or importer of the biocidal product or active substance should later disclose previously confidential information, he shall be obliged to inform the Ministry in writing within a period of 8 days.

Data protection Article 47

The information submitted by the first applicant for authorisation for placing active substances on the market may be used for the benefit of a second or subsequent applicant:

- a) if the second or subsequent applicant has the written agreement in the form of a letter of access of the first applicant that use may be made of such information and that evidence for it has been provided,
- b) in the case of a new active substance after the expiry of a period of 15 years from the date of first inclusion in the List I or I A, or
- c) in the case of an existing active substance after the expiry of a period of:
 - 10 years for any information submitted according to the provisions of this Act;
 - 10 years from the date of entry of an active substance in the List I or I A for information submitted for the first time in support of the first inclusion to the List I or I A of either the active substance or an additional product type for that active substance,
- d) in the case of any further information submitted for the first time for any of the following:
 - variation of the requirements of the entry on the List I or I A, or
 - extension of the entry in the List I or I A

for a period of 5 years from the date of decision, following receipt of further information unless the five-year period expires before the period provided for in paragraph 1, items b) and c), in which case the period of five years shall be extended so as to expire on the same date as those periods.

The information submitted by the first applicant for authorisation for placing on the market of a biocidal product may be used for the benefit of a second or subsequent applicant:

a) if the second or subsequent applicant has the written agreement in the form of a letter of access of the first applicant that use may be made of such information and that evidence for it has been provided,

b) in the case of a new active substance after the expiry of a period of 10 years from the date of first authorisation for the placing on the market in the Republic of Croatia or in any Member State of the European Union,

c) in the case of an existing active substance after the expiry of a period of:

- 10 years for any information submitted according to the provisions of this Act;

- 10 years from the date of entry of an active substance in the List I or I A for information submitted for the first time in support of the first inclusion to the List I or I A of either the active substance or an additional product type for that active substance,

d) in the case of any data submitted for the first time for either of the following:

- variation of the conditions of granting an authorisation for the placing on the market of a biocidal product or

- submission of documentation necessary to maintain entry of an active substance in the List I or I A for a period of 5 years from the date of decision, following receipt of further information, unless the five-year period expires before the period referred to in paragraph 2, items b) and c), in which case the period of five years shall be extended so as to expire on the same date as those periods.

Keeping of documentation

Article 48

An applicant for the placing on the market of a biocidal product shall be obliged to keep the documentation on the biocidal product, potential letter of access to information and other evidence in accordance with the regulations relating to dangerous chemicals.

X PROTECTION OF HUMAN AND ANIMAL HEALTH AND THE ENVIRONMENT

Prevention or reduction of risk to human and animal health and the environment

Article 49

Legal and natural persons who are placing biocidal products on the market shall ensure conditions for the prevention or reduction of risk to human and animal health and the environment and shall guarantee the replacement of dangerous biocidal products with less dangerous ones.

Restriction on sale

Article 50

Legal and natural persons who are placing biocidal products on the market for which an issued authorisation for the placing on the market imposes the restriction on sale only in designated locations shall satisfy the requirements laid down for marketing of dangerous chemicals in accordance with the regulations relating to dangerous chemicals.

Professional use of biocidal products

Article 51

The biocidal products referred to in Article 21 of this Act for professional use may be used only by legal and natural persons who fulfil the requirements of this Act concerning the proper use of biocidal products and who receive an authorisation for their use in accordance with the special regulations relating to dangerous chemicals from the competent authority. By way of derogating from paragraph 1 of this Article, in the case of an unforeseen danger the Minister may authorise exceptions and determine the conditions for use of a particular biocidal product.

Prohibitions and restrictions on the placing on the market or production of biocidal products Article 52

Prohibitions and restrictions of the placing on the market or production of biocidal products shall be determined in accordance with the regulations relating to dangerous chemicals.

Subject to the hazard presented by a biocide, a decision may include the following:

- prohibition or restriction of biocidal products which contain the identified substances or which are classified as the identified types of biocidal products,
- prohibition or restriction of biocidal products with identified dangerous properties,
- prohibition of substances which cannot be contained in biocidal products or may be contained in them under prescribed conditions.

The prohibitions and restrictions referred to in paragraph 1 of this Article can determine the date from which the substances and other ingredients of a biocidal product shall be prohibited from further production, placing on the market and use. The provisions of Article 26 of this Act shall apply to the remaining stocks of biocidal products.

Liability for damage Article 53

The authorisation holder, manufacturer or person using a biocidal product in the territory of the Republic of Croatia shall be liable for any damage caused relating to the handling of a biocidal product due to non-compliance with the requirements of this Act or due to the labelled properties of a biocidal product which may be affected by them.

XI COSTS Article 54

The costs associated with the procedure of issuing an authorisation for the placing on the market and the inclusion of active substances in one of the substance Lists I, I A or I B and the placing on the market of biocidal products shall be covered by the applicants.

The administrative decision on the amount of costs referred to in paragraph 1 of this Article shall be passed by the Minister.

XII IMPORTS Article 55

Biocidal products may be imported by the authorisation holders for the placing on the market of a biocidal product.

Biocidal products, classified as dangerous chemicals, for further sale may be imported by legal persons meeting the requirements laid down for wholesale marketing of dangerous chemicals, and biocidal products for personal use may be imported by legal persons meeting the requirements laid down for the production or use of dangerous chemicals. Low-risk

biocidal products may be imported by legal persons meeting the requirements laid down for the production and marketing of general usage items (hereinafter: the importer).

Before the customs clearance of a biocidal product, the importer shall be obliged to submit a request for the performance of sanitary inspection for a biocidal product being imported to a border sanitary inspector of the Ministry. The importer shall be obliged to submit the decision authorising the placing on the market of the biocidal product.

A customs office shall not perform the procedure of customs clearance if the procedure referred to in paragraph 3 of this Article has not been performed.

The provisions of paragraphs 1 to 3 of this Article shall apply also to biocidal products imported into the free zones or free warehouses in the Republic of Croatia.

XIII SUPERVISION Competent authorities Article 56

The administrative supervision of the implementation of this Act and subordinate regulations adopted on the basis thereof, notification of the European Commission and ensuring the international information exchange shall be performed by the Ministry.

The inspectional supervision of the implementation of this Act and subordinate regulations adopted on the basis thereof shall be performed by the sanitary inspectors of the Ministry and by the sanitary inspectors of the state administration offices in counties and in the City Office of the City of Zagreb.

Article 57

In the course of inspectional supervision, the sanitary inspector shall inspect business premises, facilities, devices, equipment and documentation.

Legal and natural persons placing on the market or using biocidal products shall be obliged to provide samples of biocidal products to competent sanitary inspectors (hereinafter: the sanitary inspector) on their request.

The analysis of samples shall be performed by authorised legal persons (laboratories) in accordance with the regulations relating to dangerous chemicals.

Article 58

In the course of inspectional supervision, the sanitary inspector shall have the following rights and obligations to:

1. prohibit a legal or natural person from placing on the market a biocidal product for which the authorisation has not been issued in accordance with this Act,
2. prohibit a legal or natural person from placing on the market a biocidal product classified and labelled as a dangerous chemical, if such person does not have a decision of the competent authority for the performance of activity or does not comply with the location of sale prescribed in the authorisation,
3. prohibit a legal or natural person from placing on the market a dangerous biocidal product for which the safety-data sheet has not been obtained,
4. prohibit a legal or natural person from placing on the market a biocidal product which is not properly classified, packaged or labelled,
5. prohibit a legal or natural person from placing on the market a biocidal product which does not meet the requirements prescribed by this Act,
6. prohibit a legal or natural person from performing activities if such person is placing

biocides on the market and does not have a decision for the performance of activity,
7. order the performance of other measures within his authority under this Act and other regulations.

Article 59

In the course of supervision of biocidal products being imported, the border sanitary inspector of the Ministry shall have the authority to:

1. prohibit the import of a biocidal product whose placing on the market is not authorised in the territory of the Republic of Croatia and to order that the biocidal product is returned to its sender,
2. prohibit the crossing of the state border and transit of a biocidal product whose packaging or labelling is not in accordance with the provisions of this Act and regulations adopted on the basis thereof and to order that the biocidal product is returned to its sender until the established deficiencies are eliminated,
3. order the performance of other measures prescribed when human or animal health and the environment are endangered.

XIV PENAL PROVISIONS

Article 60

A legal person shall be fined for a misdemeanour in the amount of HRK 50,000.00 to 100,000.00 if:

1. the user of biocidal products uses a biocidal product contrary to the provisions of Article 6 of this Act,
2. the legal person places on the market or uses active and basic substances contrary to the provisions of Article 8 of this Act,
3. the legal person places on the market or uses a biocidal product contrary to the provisions of Article 16 of this Act,
4. the legal person, on request of the Ministry, does not provide samples of the biocidal product and its composition, proposal for labelling, packaging, instructions for use and advertising (Article 18, paragraph 4),
5. the legal person places on the market or uses general usage items as biocidal products which are, due to their dangerous properties, classified as very toxic, toxic, or as a category 1 or 2 carcinogen, or as a category 1 or 2 mutagen or classified as toxic for reproduction category 1 or 2 (Article 21, paragraph 1),
6. the research holder uses the biocidal product in the quantities and areas different from those prescribed in the research authorisation and contrary to other conditions for safe use of the biocidal product laid down in the research authorisation (Article 36, paragraph 3) and if he or she does not maintain written records detailing the identity of the biocidal product or active substance, labelling data, quantities supplied and the names and addresses of those persons receiving the biocidal product or active substance or if he or she does not compile documentation containing all available data on possible effects on human or animal health or impact on the environment or if he or she does not submit to the Ministry the written records, documentation and a written statement on the progress and results of the research (Article 36, paragraph 5),
7. the legal person packages and labels a biocidal product contrary to the provisions of Article 37 of this Act,
8. the legal person labels a biocidal product classified as dangerous as less dangerous or harmless to human and animal health or the environment or labels it with a description or

indications which would be misleading or uses descriptions as 'low-risk biocidal product', 'non-toxic', 'harmless' or any similar indications (Article 38, paragraph 1 and 2), or he or she packages a biocidal product in any manner which would be misleading to a user (Article 38, paragraph 3),

9. the legal person does not make the safety-data sheet available to any professional and industrial user and, as appropriate, other users on their request when purchasing biocidal products (Article 39, paragraph 2),

10. the legal person advertises a biocidal product contrary to Article 40 of this Act,

11. the legal person does not monitor any effects and knowledge on the biocidal product which may have an adverse impact on human and animal health or the environment (Article 41, paragraph 1) or does not immediately notify the Ministry of information of which he or she is aware or for which he or she can assume they may affect the validity or the granting of an authorisation (Article 41, paragraph 2),

12. the legal person does not maintain a register in accordance with the special regulations relating to dangerous chemicals (Article 42, paragraph 1) or he or she does not submit the aggregate annual data from the register to the Croatian Institute for Toxicology not later than 31 January for the previous year (Article 42, paragraph 2),

13. the legal person acts contrary to Article 43, paragraphs 4 and 5 of this Act,

14. the legal person does not ensure conditions for the prevention or reduction of dangers to human and animal health and the environment (Article 49),

15. the legal person does not keep the documentation on the biocidal product, potential letter of access to information and other evidence in accordance with the regulations relating to dangerous chemicals (Article 48)

16. the legal person acts contrary to Article 51 of this Act,

17. the legal person acts contrary to the prohibition or restriction of the placing on the market or production (Article 52),

18. the legal person imports biocidal products contrary to Article 55 of this Act,

19. the legal person acts contrary to Article 57, paragraph 2 of this Act.

For the acts referred to in paragraph 1 of this Article, the responsible person within a legal person shall also be fined in the amount of HRK 10,000.00 to 15,000.00.

For the acts referred to in paragraph 1, items 1, 2, 3, 4, 5, 10, 11, 12, 13, 14, 15, 16, 17, and 19 of this Article a natural person shall also be fined in the amount of HRK 10,000.00 to 15,000.00.

For an attempt to commit acts referred to in paragraph 1, items 1, 2, 3, 5, 6, 7, 8, 10, 16, 17, and 18 of this Article the committer shall be fined.

XV TRANSITIONAL AND FINAL PROVISIONS

Article 61

Following the accession of the Republic of Croatia to the European Union, activities of supervising the import of biocidal products from Member States of the European Union shall be transferred to the internal market which is supervised by the sanitary inspection of the Ministry and the sanitary inspection in state administration offices in counties.

Article 62

Following the accession of the Republic of Croatia to the European Union, the application for the placing on the market of a biocidal product in the territory of the Republic of Croatia may also be submitted by a legal or natural person with a seat in any Member State of the

European Union.

Article 63

Following the accession of the Republic of Croatia to the European Union, biocidal products may be placed on the market and used in the territory of the Republic of Croatia by legal or natural persons with a seat in any Member State of the European Union if they satisfy the requirements laid down in this Act and the regulations adopted on the basis thereof.

Article 64

The Minister shall be obliged to adopt the ordinances for whose adoption he is authorised by virtue of this Act, within a period of one year from the date of entry into force of this Act.

Article 65

For biocidal products already on the market on the date of entry into force of this Act, the manufacturers, authorisation holders and persons responsible for the placing on the market shall be obliged to submit to the Ministry a safety-data sheet and information for the entry in the inventory of biocidal products pursuant to Article 23 of this Act not later than one year from the date of entry into force of this Act.

The Minister may, on the basis of the opinion of the Committee on the manner of safe use and potential adverse effects on human and animal health and the environment, include the biocidal product referred to in paragraph 1 of this Article in the inventory or require the supplement of the documentation in accordance with the special regulations referred to in Article 7, paragraph 3 of this Act. In the case of a negative opinion of the Committee or if the required supplement of the documentation is not submitted, the Minister shall refuse the entry of the biocidal product in the inventory and determine the conditions for withdrawal of the biocidal product from the market.

For biocidal products not on the market on the date of entry into force of this Act, and which contain existing active substances listed in the special regulation referred to in Article 7, paragraph 1 of this Act, the manufacturer or person responsible for the placing on the market may submit to the Ministry an application for the placing on the market and provide a safety-data sheet and information for the entry in the inventory of biocidal products pursuant to Article 23 of this Act.

The Minister may, on the basis of the opinion of the Committee on the manner of safe use and potential adverse effects on human and animal health and the environment, grant the authorisation for the placing on the market and include such a biocidal product in the inventory or require the supplement of the documentation in accordance with the special regulations referred to in Article 7, paragraph 3 of this Act. In the case of a negative opinion of the Committee or if the required supplement of the documentation is not submitted, the Minister shall refuse the placing on the market of a biocidal product or the entry of a biocidal product in the inventory.

After reaching a decision to include active substances contained in biocidal products referred to in paragraphs 1 and 2 of this Article in the List I, I A or I B, the manufacturer of a biocidal product or his authorised representative shall be obliged to submit an application for the granting of an authorisation for the placing of a biocidal product on the market for the purpose of aligning with the provisions of this Act.

After reaching a decision not to include active substances contained in biocidal products referred to in paragraphs 1 and 2 of this Article in the List I, I A or I B, the Ministry shall

require to align with the provisions of this Act from the authorisation holder for the placing on the market of a biocidal product.

Article 66

The Ministry shall, within 30 days from the date of accession of the Republic of Croatia to the European Union, inform the European Commission of the competent authorities referred to in Article 56, paragraph 2 of this Act.

Article 67

The Ministry shall be obliged to deliver a report on the implementation of this Act and subordinate regulations adopted on the basis thereof, including the information on any poisoning caused by biocidal products to the European Commission every three years until 30 October.

Article 68

The provisions of Article 1, paragraph 2; Article 2, items 10, 11, 24; Articles 14 – 24; Article 29, paragraph 2, item 3; Article 32 in the part relating to biocidal products; Article 35, paragraph 2; Article 62, paragraph 2; Article 66, paragraph 1, items 7 – 10 of the Chemicals Act (Official Gazette 150/05) shall cease to have effect on the date of entry into force of this Act.

Article 69

This Act shall enter into force on the eighth day after the day of its publication in the Official Gazette, with the exception of the provisions of Article 1 in the part relating to the mutual recognition of authorisations for the placing on the market of biocidal products in the European Union, Article 10, paragraphs 7, 8 and 10 in the part relating to the notification of the European Commission, Article 12, Article 23, paragraph 2; Article 27, paragraph 2; Article 28, paragraphs 11 and 12; Articles 32 and 33, Article 34, paragraph 1 in the part relating to the European Union and paragraph 4 of the same Article, Article 35, paragraph 4; Article 36, paragraphs 6 and 8 in the part relating to the notification of information to the Member States of the European Union, Article 45, paragraphs 2 and 3 in the part relating to the European Union and Article 46, paragraphs 1 and 4 in the part relating to the European Union, which shall enter into force on the date the Republic of Croatia accedes to the European Union.

Class: 541-01/07-01/02
Zagreb, 1 June 2007

THE CROATIAN PARLIAMENT
The President of the Croatian Parliament
Vladimir Šeks, m.p.