# Republika e Kosovës
**Republika Kosovo-Republic of Kosovo**
*Kuvendi - Skupština - Assembly*

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**Law No. 03/L-119**

**ON BIOCIDE PRODUCTS**

**Assembly of Republic of Kosovo,**

Based on Article 65 point (1) of the Constitution of the Republic of Kosovo,

Adopts

## LAW ON BIOCIDE PRODUCTS

## CHAPTER I
## GENERAL PROVISIONS

### Article 1
### Scope

Main goal of this draft law is to determine and regulate conditions for placing in the market and utilization of active substance(s) used for production of biocide products in the territory of Republic of Kosovo and with this to protect human animal health and environment.

### Article 2
### Definitions

Terms and expressions, used in this Law, have the following meaning:

"**Biocide products"** means chemical preparations containing one or more active substances intended to destroy, deter or prevent harmful organism, without causing harmful effect on other organisms or in the environment.

"**List I, I.A and I.B**" means a list harmonized in EU level for active substances, and these substances are listed in Annex I.; IA.; IB.; of the Directive 98/8/EC:

1. List I. – The list of active substances, use of which is permitted in biocide products,

2. List I.A – List of the substances, use of which is permitted in biocide products of low risk,

3. List I.B – list of the basic substances and conditions for use in biocide products Annexes of this Law IIA; IIB; IIIA; IIIB; IVA; IVB and V, are also Annexes of the Directive 8/8/EC, and mean:

4. Annex IIA, documentation compilation of active substances –chemicals substances ,

5. Annex IIB, documentation compilation of BP –chemical products,

6. Annex IIIA, Additional documentation compilation of active substances –chemical substances,

7. Annex IIIB, Additional documentation compilation of BP-chemical products,

8. Annex IVA, documentation compilation of the active substances –fungus, micro-organisms and viruses,

9. Annex IVB, documentation compilation of BP-fungus, micro-organisms and viruses,

10. Annex V, Types of BP and their description.

11. Annex VI, Common Principles for the evaluation of dossiers for biocidal products.

"**Biocide low-risk products"** means a biocide product which contains only one or more active substance(s) which under the conditions of use shall pose only a low risk to humans, animals and the environment and are presented in Annex I.

"**Basic substance"** A substance which is listed in Annex I B, whose primary use is non-pesticidal but which has some minor use as a biocide either directly or in a product consisting of the substance and a simple diluent which itself is not a substance of concern and which is not directly marketed for this biocidal use. The substances, which could potentially enter Annex IB in compliance with Article 10 and 11, of this Law, among others are: Carbon, Dioxide Nitrogen, ethanol, 2 –propanol, acetic acid and silica gel.

"**Active substances in biocide products"** A substance or micro-organism including a virus or a fungus having general or specific action on harmful organisms.
"**Existing active substances"** shall mean substances which are in a composition of biocide products, and placed in to a market in every EU Member State, before 14$^{th}$ of May 2000.

"**New active substances**" shall mean substances, which are in composition of biocide products, placed on the market in another EU member state, after May 14$^{th}$ of 2000, and until it has not been introduced in one of the lists of the substances I, IA, or I B.

"**Suspected substances"** Any substance, other than the active substance, which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present or is produced in a biocide product in sufficient concentration to create harmful effect. Such a substance, unless there are other grounds for concern, would be normally a substance classified as dangerous according to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (1), and present in the biocide product at a concentration leading the product to be regarded as dangerous within the meaning of Article 3 of Council Directive88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations .

"**Harmful organism"** shall mean all live organisms' presence of which is unwanted and having a harmful effect in human health, animal health and environment.

"**Residues"** shall mean one or more active substances in composition of biocide products, remained after their use indissoluble, including metabolic substances and their products after the reaction or their dispersion.

"**Placement on the market"** shall mean each supply or offer for sale in market of biocide products by authorized subjects with this law in the territory of the Republic of Kosovo.

**"Authorization"** shall mean an administrative act by which the MESP shall authorize the person that after submission of the request, to place on the market biocide products within the territory of the Republic of Kosovo.

"**Registration"** shall mean an administrative act, by which the Ministry ,and in accordance with application submitted by a person and after the verification that the record (file) is in compliance with relevant requirements according to this Law ,issues the authorization for placement on the market the low –risk biocide products ,within the territory of the Republic of Kosovo.

"**Notification"** shall mean a defined procedure about the information given to MESP, regarding to appropriate records for BP, which notifier intends to place on the market BP, respectively notification is an information or presence of the active substance, or BP, through the documentation of the required information.

"**Notifier"** shall mean, a manufacturer, importer, distributor, or their authorized representative, or a person who issues the information through certain documentation, required by the Law for notification of the active substances and BP.
"**Specific procedure**" shall mean a procedure for placement on the market, or use of BP, based in a formulated structure of BP, in Republic of Kosovo.

"**Formulated structure of BP"** Specifications for a group of biocide 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 previously authorised biocide products which do not affect the level of risk associated with them and their efficacy. In this context, a variation is the allowance of a reduction in the percentage of the active substance and/or an alteration in percentage composition of one or more non-active substances and/or the replacement of one or more pigments, dyes, perfumes by others presenting the same or a lower risk, and which do not decrease its efficacy.

"**Document of approach (declaration)"** shall mean a document, signed by owner, or owners of relevant information and protected information in accordance to the provisions of this Law, which means that these data can be used by the Minister to grant authorization or registration of BP, in accordance with this Law**.**

"**Scientific research and development"** shall mean researches, by experiments, chemical analyses, screening tests of substances under monitoring conditions and setting of the important attributes and effects, in that manner that scientific researches should be the development of new biocide products.

"**General consumption"** shall mean every usage of biocide product, which has not been made professionally.

"**Professional usage** "shall mean usage of every biocide product, carried out by authorized person.

"**Presenter of the request"** shall mean manufacturer, importer, distributor, or their authorized representative, who submits a written request for placement of the biocide product on the market.

"**Bearer of license"** shall mean an appointed person by the competent authority and by a decision has been issued an authorization for usage and placement on the market BP.

**"Ministry"** shall mean, The Ministry of Environment and Spatial Planning.

"**The competent authority"** shall mean organizational unit, within the Ministry which will carry out tasks, in accordance with the Law, regarding to chemicals and biocide products.

"**Competent body"** shall mean the Department of Environment protection, respectively MESP;

"**Commission"** shall mean an expert group who in cooperation with competent authority are authorized to give professional evaluation for permission of license for placement and usage of the biocide product on the market.

"**Respective Ministries"** shall mean Ministry of Environment and Spatial Planning, Ministry of Health, Ministry of Agriculture, Forestry and Rural Development, and other relevant Ministries, related to biocide products.

**"BP register"** shall mean the List of BP, authorized (licensed) for usage and marketing, within the Republic of Kosovo and in other EU Member States.

**"Inventory of BP"** shall mean the List of BP which can be found in use and marketing, within the territory of the Republic of Kosovo.

"**Accompanying document shall"** mean declaration of BP, in which are given instructions, explanations, or other information, to be considered important for the user of BP.

"**Assays"** shall mean researches where active substances have been included in composition of BP which can be used with an authorization issued by the Ministry for scientific and research purposes.

"**Person"** shall mean every natural or legal entity that is possessor, importer, distributor and salesman of BP.

"**Legal persons**" shall mean persons officially registered to carry out any activity according to the official list of the economic activities within the Republic of Kosovo according to the laws in force.

**"EINECS''** means the European Inventory of Existing Commercial Substances. This inventory contains the definitive list of all substances deemed to be on the Community market on 18 September 1981.

**"MoH"** shall mean Ministry of Health.

"**MAFRD"** shall mean Ministry of Agriculture, Forestry and Rural Development.

## Article 3
## Main (Key) principles

1. BP can be placed on the market if scientific, technical and existing knowledge and having in regard application of all permitted conditions for their use in products and materials, effects and after-effects during their use and storage shall be verified that, BP are : licensed for the use:

1.1. shall be well effective,

1.2. shall not cause undesirable effects in organisms ,as it is undesirable produce of immunity cause ,contradictory effects or causing unnecessary pain or suffer for vertebrates,

1.3. BP and their residues shall not have direct or indirect effects in human health and animal health (for example through food, water or introduction in internal areas and working places etc), and through superficial and underground waters,

1.4. for their BP and their residues shall not have harmful impact in environment ,especially having in regard their composition and effects in environment , ,effects in superficial and ground waters ,harmful effects in live organisms ,not included in a group which should be fighted from effect of biocide products,

1.5. to be able to define the nature and quantity of the active substances contained ,and if appropriate every ecotoxicological or toxicological effect of impurities contaminants, additives or residues ,having importance to environment ,and created after permitted usage ,in accordance with Article 6. paragraph 3.of this Law.

1.6. where what are determined physical and chemical attributes, and have been verified and accepted for conditions of usage, storage and transport of biocide products.

2. Attributes from paragraph 1, of this Article, are presented in a dossier for assessment of BP, according to the Article 25 of this Law.

3. Data regarding to impacts and effects of BP, and in accordance of the paragraph 1 of this Article shall be acceptable if the tests are reduced as much as possible.

### Article 4
### Responsibilities of the users of BP

1**.** Persons who are using BP must be very careful, in a manner that they should not put in risk their life and lives of others and they must not cause harmful effects in human health, animal health and environment.

2. Persons from paragraph 1. of this Article must implement methods or combined biological, physical and chemical measures and other adequate measures to unstop harmful organisms, and implement legal measures for protection of human health, animal health and environment, in compliance with instructions for usage of BP.

3. Consumption of the biocide product is allowed up to limitation values according to this law and other laws in force.

4. Consumption of BP in a professional manner shall be implemented by the persons from paragraph 1 of this Article, and in compliance with Provisions of the Law for safety at work, health protection of the employees and working environment Law No. 2003/19.

## CHAPTER II
## ACTIVE SUBSTANCES

### Article 5

**Registering and Evaluation of Active substances**

1. The register of active substances by sub-legal act shall be issued by the Government with proposal of the and in consultation with MoH and MAFRD.

2**.** The register of active substances, authorized to be used in BP and register of active substances that are not allowed to be used in BP, by sub legal act shall be issued by the Government with proposal of the Minister, in consultation with Ministries with MoH and MAFRD.

3. The method of assessment and preparation of documentation for assessment of active substances in BP and documentation dossier for assessment of active substances and BP ,their use ,categories ,groups and types of BP and their description and unique principles for assessment of BP ,shall be issued by the Government with proposal of the Minister and in cooperation with MoH and MAFRD.

**Article 6**
**Placement of active and basic substances on the market**

1 **.**Active substances shall be authorized to be placed on the market and to be processed in BP ,if they do comply with conditions and in accordance with provisions of this Law and sub-laws laid down in this law ,and if they are registered ,or they are in process of registration in the Lists of substances I ,or IA.

2. Paragraph 1, of this Article shall not be applied for active substances used for purposes of scientific researches.

3. Active substances from paragraph 1, of this Article, absolutely must be classified packed and labeled, in compliance with specific provisions, by which are regulated harmful chemicals in the Law on chemicals.

4. Basic substances may be placed on the market and may be used as biocide products ,only if they are registered in the List of substances I B. and if they do comply with conditions for classification ,packaging ,and labeling ,in compliance with provisions of this Law ,and if there is a List of technical safety in accordance with Law on chemicals.

**Article 7**
**Registration of active substances in the Lists I.I A. or I B**

1**.** Active substance is registered in the Lists I., I.A, or I B, for a period of time, not exceeding ten (10) years and according to the current technical and scientific knowledge may be expected that: containing active substance, BP with low risk, respectively basic substances and their products, certain substances ,in accordance with definition in Article 3 ,paragraph 1 ,point 5 of this Law fulfills conditions for taking of license concerning to placement on the market ,according to Article 25 of this Law.

2. Active substances of low risk shall not be registered in the List I.A, if provisions for harmful chemicals, regarding to classification, packaging and labeling are classified as: Cancerous,

Mutagen, Toxic for reproduction, Substances, causing high sensitivity, and Substances, hard to be resolved.

3. However, if appropriate, active substance shall be registered in the List I.A, and then it should be defined range of its concentration, the substance may be used in BP.

4**.** Registration of active substances in the List I, I.A or I.B, depends from:

4.1. requirements based in:

4.1.1**.** determination of minimum level of purities in the active substance;

4.1.2. characteristics of the active substance where the value of impurity content is the highest;

4.1.3. type of the biocide product which can be used;

4.1.4. method of use and the field where could be used;

4.1.5. users' categories, industrial, professional , or nonprofessional;

4.1.6. All other specific conditions for assessment of the submitted information (documents) to the Ministry;

4.2. **c**onfirmation:

4.2.1. if appropriate, permitted values for exposure of the user to BP (AOEL Acceptable Operator Exposure Level),

4.2.2. where is important, permitted value of the daily intake of the BP for human (ADI - acceptable daily intake) and highest values of permitted concentration of the residues (MRL-Maximum Residue Limits),

4.2.3. effects in the environment and effects in organisms which do not belong to the group of organisms intended to be fighted.

5. Registration of active substances in the Lists I, I A or I B, is limited for those types of products that are regulated by specific acts for the type and description of BP, according to Article 6, paragraph 3, and for which have been accepted required information, according to Article 25 and Article 26 of this Law.

6. Registration of the active substances in the Lists I,I A ,or I B ,may be repeated one ,or more times ,for a period of time, not exceeding ten (10) years .First registration and all other repeated registrations may be reviewed at any time ,if there are facts that any of conditions from paragraphs 1.2, and 4 of this Article have not been fulfilled.

7. If the presenter of the request has not fulfilled the conditions, then it may be given an additional time to carry out analyses and to offer additional information, in accordance to Article 9 of this Law.

8. Registration of active substances in the List I, or where important in the List I A or I B, may be refused or cleared, if:

8.1. in the assessment of the active substance, according to Article 9. of this Law, has been verified that under the permitted conditions, present a risk to human health and environment;

8.2. in the List I is registered another active substance for the similar type of BP and based in technical and scientific knowledge, evidently presents less risk to human health and environment than such substance.

9. Decision for refusal of registration or clear –of ,of the certain active substance from the Lists I, I A ,or I B ,shall be taken based on assessment of the documentation for active substances, substitutive active substances, in a manner to verify effects of their use in organisms to be fighted and they will not cause a risk to human health and environment than previous active substances.

**Article 8**
**Conditions for registration of active substance in the Lists I. IA or IB**

1 **.**For the registration of the active substance, used in BP or as a basic active substance in one of the Lists I, I A, or I B, or any other change of these lists shall be made by submission of the request by the applicant.

2. A request from paragraph 1 of this Article, with completed documentation, according to paragraph 4. of this Article shall be submitted to the Ministry.

3. A presenter of the request in his request for registration of the active substance in the Lists I, IA may require issuance of temporary authorization, in compliance with Article 29. of this Law.
4. Documentation for evaluation of active substance and registration in one of the lists I,I A or I B, contains:

4.1. name of the person ,or name of the plant ,name of the trade association;

4.2. address of the person;

4.3. records for examination of active substance, and if there is known at least one BP, containing respective active substance and on the base of Article 9 of this Law shall be carried out evaluation of the effects.

5. To the request for evaluation of active substance shall be attached the documentation as follows:

5.1. identity of active substance;

5.2. physical and chemical characteristics;

5.3. additional information for active substances as are: usage, method of action, storage, protection measures and similar;

5.4. analytical methods;

5.5. metabolic and toxicological studies;

5.6. riskiness data ( information ) and the mean of impact of active substance in the environment during their usage ,ecotoxicologtical studies;

5.7. interpretation of classification as well as wrapping and labeling of harmful substances in accordance with Law on chemicals;

5.8. if the substance contains viruses or micro-organisms ,shall be given information about micro-organisms or viruses;

5.9. documentation for assessment of preparations ,based on active substances;

5.10. safety records during the work

5.11. other necessary records according to the laws in force.

6. Excluding from provisions of paragraph 4 of this Article, there is no need for evaluation records of certain BP, expected to be used, and records which for the known reason is not able to be provided.

7. The attached documentation shall be verified by the Ministry, with the request for registration of active substance in the Lists I, I A, or I B, regarding to its completion. If the documentation is not completed by the presenter of the request, then it will be required that within certain period of time to complete the documentation.

8. If, during the evaluation procedure is verified that there is a need for additional information, then for the presenter of the request the Ministry shall determine a deadline to provide those information. During this time, the deadline shall be lifted, until the required information to be provided.

9. Where it is verified that documentation of the dossier is completed, then for the presenter of the request, the Ministry shall issue license.

10. The Ministry shall carry out evaluation procedures, within twelve (12) months from the day when it has been verified and confirmed that documentation is completed.

11. If the request is not complete in certain dead line, the Minister shall refuse the Request.

### Article 9
### Assessment of active substances

1. Evaluation of active substance, done with purpose of rank in one of the Lists I, I A ,or I B, and with objective to verify effects in a human health, animal health and environment.

2. Evaluation of active substances shall be done in compliance with methods and standards, used in EU, and in accordance with provisions of Article 3 of this Law and Main principles for evaluation of documentation Dossier for BP, which by the sub-law issues the Minister and in cooperation with Minister of MoH and Minister of MAFRD.

3**.** The evaluation of the active substances shall be carried out, by competent body.

4. The register of the active substances from paragraph 3. of this Article, shall be kept in the Ministry, and shall be made public by publication in the official gazette.

## CHAPTER III
## EVALUATION, PLACEMENT ON THE MARKET AND USAGE OF BIOCIDE PRODUCTS

### Article 10

## A) EVALUATION OF BIOCIDE PRODUCTS

1. The evaluation of biocide products shall be carried out before the licensing of the product which is going to be placed on the market and their usage, with scope to verify the effects in human health, animal health and environment.

2. Evaluation of the BP is carried out in compliance with integrated methods and standards, used in EU, in compliance with assessments according to basic principles, defined in accordance with Article 3 of this Law, and in accordance with regulations defined by provisions of the Law on chemicals.

3. Evaluation of BP shall be made by competent body.

4**.** The register of BP from paragraph 3 shall be kept by the Ministry and it shall make public, publishing in the Official Gazette.

### Article 11
### Documentation for assessment of BP

1. An evaluation request of BP shall contain personal data of the presenter of the request, respectively establishment, address, documentation about testing results, and on the base of which, and in accordance with Article 10 of this Law shall be made evaluation of the effects from the aspect of risk of BP.

2. According to paragraph 1 of this Article, the request should fulfill defined conditions, according to provisions of Article 5 paragraph 3, of this Law.

3. Excluding from the paragraph 1. of this Article ,there is no need to be presented ,information for assessment ,if it is required so ,having in regard the usage of the type of BP ,and information for the known reason or technical reasons shall not be able to be provided .In such cases shall be offered a justification to the Ministry .The Ministry shall make the evaluation of the reasons, presented in the request.

### Article 12
### Common conditions for placement of BP in the market

1. In cases where a BP is authorized, according to provisions of this Law, The Ministry may permit to next the presenter of the request, placement on the market of BP even that the same person has used information of the first presenter of the request, and by a condition to verify that there is a same BP, containing the same active substance.

2. Without prejudice to provisions of this Law, by which is regulated content of appropriate request for placement on the market of active substance and BP, before carrying out an examination in vertebrates, the presenter of the request shall require from the Ministry additional information:

2.1. if there was any similar authorization previously by any other presenter of the request, regarding to BP for which is asked the authorization,

2.2. name and address of the previous bearer of the authorization,

3. To the request from paragraph 2 of this Article shall be attached a documentation that the next presenter of the request shall submit the request on his name and has the documentation in accordance with Article 25 of this Law.

4. In the case when it has been assessed that next presenter of the request fulfills conditions from paragraph 3, of this Article, The Minister shall give the name and address of the previous bearer of the authorization, and shall inform him regarding to granting of authorization to the next presenter of the request.

5. Between the previous bearers of the authorization and the next presenter of the request shall be made an agreement for use of the information, with the purpose to avoid repeating of the experiments in vertebrates.

6. The agreement between the parties shall be made by the Ministry, in accordance with provisions laid down in the Law on chemicals.

7. If the previous authorization holder and the current applicant can not agree between themselves. The Ministry shall decide about services and information for the other applicant.

8. During reviewing of request for evaluation of BP, shall be accepted only examinations, carried out in animals from EU Member States, by a condition that such analyses have been carried out in accordance with best laboratory practices.

**Article 13**
**B) PERMITS**

1. A person, may place on the market and use a BP within the territory of the Republic of Kosovo, only if it has been granted an authorization, in compliance with provisions of this Law.

2. The Permits from paragraph 1 of this Article shall be granted-discontinued, by a special decision issued by Minister, against whom is not allowed the plaint. The person has a right to plaint to the Competent Court.

3. Decision from paragraph 2 of this Article shall be taken after the review and recommendation of the opinion from the Commission for evaluation of BP, in accordance with Article 19 of this Law.

4. By way of derogation from provisions of paragraph 1, of this Article, active substances registered in the List I B and BP, and composed by the same active substance may be placed on the market, to be used as biocide product, without authorization but only if it is in compliance with provisions of the Law on chemicals.

5. According to the paragraph 1 of this Article, the authorization shall be granted for a period of time, for at least ten (10) years and may be renewed under conditions defined by this Law. If the active substance is registered in the List I or I A, authorization shall be granted for the period of time, registered in these Lists.

6. During granting the permits from paragraph 1 of this Article, shall be taken in to a consideration, made evaluation for BP, according to provisions of this Law, and the facts that substances are registered in the Lists I, or I A.

**Article 14**
**Conditions for granting permits**

1 .The Minister shall grant an authorization to place the BP on the market, if:

1.1. are completed the conditions according to Article 3 of this Law,

1.2 . are completed conditions according to the provisions of Article 5 paragraph 3 of this Law,

1.3. can be verified the quantity and type of active substance, and all impurities and toxicological and eco-toxicological additives, even, authorized may cause consequences during the use,

1.4. are known physical and chemical qualities, and

1.5. if the storage conditions for BP are not fulfilled.

2. Pursuant to provisions of this Law and by the evaluation of the Commission from Article 19 of this Law, except the formal authorization, The Minister may grant special authorization for placement on the market of the BP.

3. During ,granting the authorization shall be taken in to a consideration ,provisions of certain acts ,by which is regulated protection and safety at work ,consumers protection ,protection of animal health and environment and if appropriate other conditions in compliance with those acts.

**Article 15**
**Request for granting Permits**

1. A request for granting an authorization shall be made by producers, traders or those persons who are using BP, as well as their representatives.

2. A request from paragraph 1 of this Article shall be accompanied by appropriate, legal acts and issued in accordance with Article 27 paragraph 4, of this Law.

3. According to paragraph 1 of this Article, presenter of the request shall attach the following information:

3.1. name and their address of the presenter of the request ;

3.2. name and number of authorization ,granted for BP in one of EU Member States;

3.3. name and address of authorization holder, name of the EU Member State which has granted authorization;

3.4. name of the active substance ,wrapping ,labeling of BP;

3.5. proposed name for placement on the market within the territory of the Republic of Kosovo;

3.6. label proposed by authorized holder, producer or user.

4. By the moment of submission of the authorization in the Ministry, the person is obliged to bring samples and composition of BP, declaration proposed or label, packaging or instruction for use.

**Article 16**
**Determination and permission of formulated structure of BP**

1. Formulated structure of BP shall be defined by the Ministry, by a request of a person or without his request.

2. If the request for determination of the formulated structure of BP is made by the person then to the application for an authorization (registration) of BP, shall be submitted all relevant information, facts and changes that may happen within the formulated structure of BP, or do not produce any risk or reduce the effectiveness, comparing to proposed BP.

3. The Ministry shall approve the formulated structure of BP, if have been complied conditions regarding to the completion of documentation, and in accordance with this Law within sixty (60) days from the date of the submission of request.

4. Regarding to formulate structure of BP, The Ministry shall inform the person for authorization, within thirty (30) days from submission of the request.

**Article 17**
**The content of Authorization**

1. An authorization from paragraph 1, Article 13, of this Law shall contain the following information:

1.1. name of biocide product;

1.2. name and address or residence of the person;

1.3. list of active substances ,their chemical names ,or other names which allow to identify substance ,as well as name and address of their producer;

1.4. type of biocide product ,its characteristics and dedication;

1.5. scope ,marketing conditions and use of biocide product;

1.6. packaging ( wrapping ) type;

1.7. content of the label and accompanying document ,or instruction for use;

1.8. expiry date of biocide product;

1.9. the expiry date of authorization;

1.10. number and date of granted authorization, registration or, special or temporary authorization.

2. In the authorization may be defined specific conditions regarding to placement on the market of the BP: place of sale, storage area, or for any other purpose, if there is a reason.

**Article 18**
**Restriction for placement on the market of BP**

1. BP having harmful characteristics and registered as toxic, very toxic ,carcinogenic in the Group I or II, are mutagenic in the group I or II ,or as toxic substances for reproduction in a group I or II, the same can not be placed on the market and used for consumption.

2. BP from paragraph 1, of this Article may be placed on the market for purposes of professional use.

3. For BP which has not been granted an authorization, in compliance with this Law shall be not placed on the market within the territory of the Republic of Kosovo.

4. If, by the aspect of technical or scientific knowledge there is a reason for suspicion that a BP presents harm to human health and environment, the Minister, by a decision may ban or restrict placement on the market of that BP.

5. All bans defined by the Directive of European Commission for BP, must needs to be implemented by the Ministry, which by a decision bans placement on the market and use of such products.

**Article 19**
**Evaluation commission for BP**

1. Evaluation commission for BP shall be appointed by the Ministry and shall be constituted by professional experts in the field of: toxicology, medicine, pharmacology, pharmacy, chemistry, biology ecology, veterinary, agronomy, chemical engineering and other relevant fields.

2. The Commission shall be appointed by the Minister in cooperation with MoH and MAFRD.

3. The Commission shall be comprised by at least eleven (11) members.

4**.** Commission from paragraph 1 of this Article, after reviewing of presented documentation by the presenter of the request, shall give a professional recommendation for granting an authorization for placement on the market and use of BP.

5. The commission shall carry out the following tasks:

5.1. gives recommendation to grant or refuse an authorization;

5.2. gives recommendation to ban and restrict use of BP;

5.3. gives recommendation of determination of the formulated structure of BP .

6. Regarding to the functioning of the commission, the method of numeration of representation in commission, obligations of the commission's members, method of drafting report ,and carrying out other tasks by the commission .The Minister in consultation with Minister of the MoH and Minister of MAFRD shall issue a sub -law act.

7. Members of the commission should not have conflict of interest with presenter of the request, who produce or place on the market BP.

**Article 20**
**Register of BP**

1. The Ministry shall keep the register of the authorizations granted for BP and all changes of the authorizations.

2. The register of BP, for which has been granted authorization for placement of the BP on the market shall be published annually in official gazette of the Republic of Kosovo.

3. If appropriate and in different period of time the Ministry may publish amendments of the register, according to paragraph 1 and 2 of this Article.

4. According to paragraph 1 of this Article, the register shall contain the following information:

4.1. name of the producer and the full denomination of the subject;

4.2. address of the presenter of the request;

4.3. the trade name of BP;

4.4. name and composition of every active substance ,name and composition of other substances in BP, if they are registered and labeled as harmful chemical substances;

4.5. register of all active substances and other substances, if they are registered as harmful chemicals, in compliance with provisions of the Law on chemicals;

4.6. type of the substance and authorization for use;

4.7. type and aggregate condition of BP;

4.8. class according to the risk and number of the order;

4.9. number and date of granted authorization ,its expiry date;

4.10. any proposed limits ,residues which have been established;

4.11. conditions under which the BP may be placed on the market and may be used;

4.12. reasons for modification of the authorization;

4.13. procedures related to granting the authorization;

4.14. all requirements for characteristics ,regarding to placement on the market and use of BP.

**Article 21**
**Renewal of Permit**

1. Authorization for placement of the BP on the, market shall be renewed, if have been fulfilled conditions by this Law.

2. The request for renewal of the authorization shall be submitted ,within period of time of sixty (60) days ,before the expiry date of the previous authorization ,if this authorization has been granted with short procedure ,whereas within one year if the authorization has been granted by full procedure.

3. If it is verified that conditions for placement of the BP on the market have not been changed,

respectively if those conditions have not been completed, then the Minister shall decide whether to renew the approval or reject renewal of permit.

4**.** If there are new information or suspicions that there is not completed any of these conditions, on the bases of which has been granted authorization, the Minister shall require additional information within certain period of time.

**Article 22**
**Modifications and revocation of authorization**

1. Minister can modify authorization for placement on the market and use of BP, if:

1.1. from aspect of the method of use and quantity of BP, on the base of technical and scientific knowledge is on the interest of protection of human health and environment .

1.2. it is required by the holder of authorization.

2. If it has been required the modification of authorization, because of the expansion of the field of use, the Minister shall issue a decision to complete authorization, respecting specific conditions for active substance, registered in List I or I A.

3. Authorization can be modified, only if have been verified conditions from Article 14 of this Law.

4. If we take in to account specific conditions for the proposed modifications in authorization of the active substance registered in list I or IA, modifications may be authorized only after the evaluation of the active substance, and taking in to account defined conditions, according to the provisions of Article 8 of this Law.

5. Authorization for placement on the market of BP shall be approved by Minister within sixty (60) days, from the date of presenting the request.

6. Minister shall cancel the authorization for placement on the market of BP, before the expiry date, if it has been verified that:

6.1. active substance is not in the EU register of active substances, because it is not authorized registering in such lists;

6.2. the conditions have been modified for granting the authorization;

6.3. has been required by the presenter of the request a comprehensive justification and verification for BP;

6.4. the authorization has been granted, based on incorrect information, or suspicious information.

**Article 23**
**Actions with BP after cancellation of the authorization**

1. In cases where happen modification or suspensions of authorizations for placement on the market of BP. The Minister shall decide regarding to conditions, how to deal with BP, after the modification or suspension of authorization.

2. After the suspension of authorization, in cases where a specific authorization has been granted, the Minister, based on written request of the authorization holder shall approve usage of remained quantity of BP, or shall order destruction disposal, in compliance with provisions of this Law.

**Article 24**
**Protection measures**

1. If there is a based suspicion that biocide products have been authorized, or they are in process of the placement on the market and usage, and such product presents a risk to human health, animal health and environment, the Minister immediately shall revoke or restrict placement on the market and use of such product, within the territory of the Republic of Kosovo.

2. For prohibition or restriction of the placement on the market and usage of BP, within the territory of the Republic of Kosovo, the Minister shall inform Government. In this case, describes reasons of decision for limiting or halting.

3. The decision shall be taken within thirty (30) days from the day of prohibition or restriction.

## C) NORMAL PERMITS FOR PLACEMENT ON THE MARKET OF BP

**Article 25**
**Permits with completed procedure -Authorization**

1. Placement on the market of BP, with authorization of completed procedure - authorization shall be made if the active substances are registered in the List I or I A.

2. To the application for granting such authorization, according to completed procedure shall be submitted an appropriate documentation for every active substance in a composition of BP and for every BP, and declaration for access in presented information and documentation.

3. The documentation from paragraph 2 of this Article shall contain completed information, details about tests carried out, methods applied and bibliographic citations of those methods .The documentation dossier with presented information for granting of authorization should be sufficient for evaluation of the quality and effects of BP, according Article 3 of this Law.
4. The documentation from paragraph 2 of this Article shall be prepared and submitted in a form of technical dossier in which are given information according to specific acts of Article 5 paragraph 3. of this Law, for active substances in composition of BP and for BP.

5. Based on qualities and proposals for usage of BP, information not necessarily shall not be included in documentation, in accordance with paragraph 2 of this Article .in this documentation shall not be included information of not such importance or from technical aspect is hard to be provided .In these cases, to the Ministry shall be offered, based reasons for not providing such information.

6. If in compliance with sub-law act for evaluation of the risk from BP ,approved by the Minister and it has been verified that for such evaluation are needful additional information ,including here information for additional tests carried out ,the presenter of the request for such authorization keeps the obligation to provide such information.

7. The date for assay of the documentation, according to paragraph 6 of this Article shall start to be valid after the completion of the documentation.

8. The name of active substance shall be indicated in a compliance with specific act by which is regulated classification ,packaging, labeling of harmful chemicals ,or if the substance is not included in specific act ,the labeling of the substance shall be made according to European of Existing Chemicals (EINECS), or ,if the substance is not included in this register then the labeling shall be made according to International Standardization organization ( ISO ). If these are not available, the labeling shall be made according to chemical name, in accordance with the rules of International Union for Pure Applicative Chemistry (IUPAC).

9. The Ministry may require from the applicant to offer samples of BP and samples of every component of BP.

10. The Ministry based on the request of European Union is obliged for providing request records.

11. Necessary Documentation for Bp authorization , authorization procedures ,limits for submission of the documentation ,and license issuance , ,The Government with proposal of the Minister shall issue certain sub-legal acts in cooperation with Minister of the MoH and Minister of MAFRD.

**Article 26**
**Authorization of short procedure - Registration**

1. Low-risk biocide products shall be placed on the market with authorization granted in a short procedure –Registration if their active substance is not listed in the List IA.

2. Application for granting an authorization with short procedure for placement on the market of BP of the List I A shall contain the following information: information about the presenter of the request, information about BP ,purpose of use ,impacts and effects of BP ,assay methods, proposal for their classification ,packaging ( wrapping ) and labeling ,List of technical safety according to provisions of the Law on chemicals provisions for harmful chemicals ,if appropriate declaration for access in information related to BP ,all active substances in composition of BP, and other information of importance for protection of human health ,animal health and environment.

3. In a more detailed way regarding to appropriate documentation for registration of biocide product, registration procedures, deadlines for submission of the documentation, issuance of the license, the Government by the proposal of the Minister shall issue specific sub law acts in cooperation with Minister of MoH and Minister of MAFRD.

**Article 27**
**Assay of the request and deadlines for procedure of Permits**

1 .After receiving of the request for granting an authorization for placement on the market of BP, the Ministry shall verify the documentation, and if such documentation is not completed, the Ministry shall award a deadline for its completion.

2. If the documents are not completed pursuant to paragraph 1, of this article in certain dead line then, the Ministry based in justification of the presenter of the request shall appoint additional deadline which can not be exceeded the overall limit of legal procedure over six (6) months. If the presenter of the request again does not fulfill required conditions, then the Ministry has an obligation to suspend the procedure of granting authorization.

3. The time limit for assay of the regular procedure for assay of application starts from the day of the completion of documentation.

4. If ,during the procedure of assay of the application has been verified that for evaluation of the BP is required additional information ,the ministry shall require them from the presenter of the request ad shall define a time limit for offering such information.

5. In the case ,as in paragraph 3 of this Article ,the time limit from paragraph 6 of this Article, shall discontinue ,and shall began to be valid the time limit for offering information.

6. The time limit for granting an authorization, according to full procedure Authorization is one year from the date of receiving of completed documentation, whereas according to a short procedure–Registration is sixty (60) days from the date of the receiving completed documentation.

## D) AUTHORIZATION, BASED ON MUTUAL RECOGNITION IN EUROPEAN COMMUNITY

### Article 28
### Mutual recognition of authorization

1. The Ministry shall verify, whether the procedures are in compliance with provisions of this Law, procedures for granting an authorization for placement on the market of BP from another EU Member State.

2. The application for verification according to paragraph 1, of this Article should contain:

2.1. a summary of documentation from paragraph 2 and 3, in accordance with Article 25 of this Law If authorization has been granted on the bases of full procedure –Authorization;

2.2. documentation with information ,according to Article 26 .paragraph 2 and 3, of this Law, except information about the effects ,which is sufficient documentation dossier ,if the authorization has been granted in a short procedure –Registration;

2.3. a certified copy of the former authorization ,except in the cases where the Ministry can provide from its archive.

3. If the procedure of mutual recognition among countries and based on evaluation of the office/competent authority /sector for biocide products, the Minister may grant an authorization for a period of time of one hundred twenty (120) days, related to authorization of BP, respectively sixty (60) days if we have to do with registration, under the conditions that active substance is registered in one of the lists I, or I.A. .Authorization can be granted for the same period of time for which has been granted by EU Member State.

4. The time limit for granting an authorization, in accordance to paragraph 3, of this Article shall begin to be valid, when the Competent Authority verifies that the documentation is completed.

5. Content and conditions of the application for mutual recognition of the authorizations, by sub law act, in a detail shall be issued by the Minister.

## E) SPECIAL AUTHORIZATION

### Article 29
### Provisional authorization for placement on the market of BP

1. Exclusively from Article 25 this Law, the Minister may provisionally authorize placement on the market a BP, containing a new active substance, produced for known usage, except for scientific researches, if the documentation is completed and the Ministry evaluates that:

1.1. new substance meets conditions ,defined by this Law;

1.2. is expected that BP meets conditions for granting of authorization in accordance to this Law;

1.3. new substance is registered ,labeled and packed properly and for such substance there is a technical safety List ,completed in compliance with provisions of the Law on chemicals;

1.4. BP does not present any harm which will determine in a group from paragraph 1, Article 19 of this Law.

2. Applicant is obliged that to the request must attach:

2.1. declaration or certificate that BP contains active substance which is in process of registration in one of the Lists for registration;

2.2. dossier of the documentation for active substance;

2.3. dossier of documentation for BP.

3. The Minister shall grant provisional authorization for a period of time, not more than three (3) years.

4. If after the expiry date of provisional authorization ,the active substance still is not registered in one of the lists of substances I ,or I A ,because that the procedure of registration is not completed and from the aspect of former evaluations have not been changed ,and also there is no suspicion that the substance shall not be registered in the List I ,or I A ,then the Minister may extend date of provisional authorization ,not more than one year.

5. Provisional authorization shall be discontinued if in the level of EU is decided that active substance does not meet conditions to be registered in the List I or I A.

**Article 30**
**Authorization of BP for unusual situations**

1 .Exclusively from Articles 25, 26, 27, and 28 of this Law, and if in the Republic of Kosovo does not exist an adequate BP, but there is a need to fight, eliminate or destroy certain harmful organisms, The Minister shall grant authorization for a period of time, not more than one hundred twenty (120) days, for certain conditions and quantities.

2. In the authorization shall be information about the producer of the BP, quantity which shall be placed on the market, the method of use, area where shall be used, conditions under which the BP shall be used, information about the user and method of keeping evidence for BP.

3. The Minister suspends or modifies an authorization for unusual situations ,if the BP does not meet requirements and effects .If the BP is not needed or consequences of its use are greater than its useful effects.

**Article 31**
**Authorization for scientific research and development**

1. For any scientific research or testing ,having an objective of scientific development ,and there is a need to be used any active substance or BP that person is not authorized for placement on the market ,preliminarily should be authorized ,taking in to account provisions of this Law.

2. Authorization from paragraph 1, of this Article shall be granted or derogate, by decision of the Minister, and against this decision shall not be a plaint. The unsatisfied person may exercise the plaint to the competent court.

3. Holder of the authorization from paragraph 1 of this Article is obliged to use the BP in a designed quantities and places, according to conditions designated in authorization for scientific researches.

4. Application for granting an authorization for scientific researches ,shall contain information for the purposes of scientific researches ,definite method for development of the research, professional preparation of the staff that shall perform the research, method for description of the premises, spaces and conditions in which the researches shall be carried out ,method of the researches and ,method of data record ,method of the use of BP during the research, residues, their treatment and information about them.

5. The holder of the authorization for scientific research has an obligation to offer details about BP or active substance, as are: labeling details (information), quantity supplied, name and address of the manufacturer, file of documentation, on the bases of which shall be given all information about the impact and effects to human health, animal health and environment.

6. The holder of the authorization for scientific research is obliged to submit in a written form to the Ministry all relevant documentation and notification, regarding to developments and results of scientific research.

7. The information required from paragraph 5 and 6 of this Article, shall be given in the Ministry.

8. If the proposed scientific research may cause negative effects to human health, animal health and environment, then the Minister can stop or determine other specific conditions which enable a safe scientific research.

# CHAPTER IV
## NOTIFICATION AND INVENTARIZATION OF ACTIVE SUBSTANCE AND BP

### Article 32
### Inventory of biocide product and biocide active substance

1**.** Inventory for BP and active substances shall be prepared by the Ministry, in compliance with provisions of this chapter, and continuously shall be updated with new information. This inventory shall contain:

1.1. the list of biocide products notified, according to Article 33 and the products in the list shall be on the market until the expiry of authorization or unless the placement on the market of such product shall be prohibited or restricted by decision of the Ministry;

1.2. the list from paragraph 1 point 1 shall be updated continuously including accepted notifications and additional information;

1.3. the list of active substances which shall be authorized to be used in biocide products, thirty (30) months after the coming in to the force of this Law ,hereinafter (active substance in the List I,I A ,I B), containing existing active substance as defined in Article 2, paragraph 1, point 6 of this Law. This List shall be updated continuously in compliance with developments in the List I, I A and I B, of the Annex in Directive 98/8/EC for Biocide Products and Annex II of Regulation No. 1451/2007/EC.

2. The inventory of Biocide products and active biocide substances shall be public and shall be published in the Web Site of the Ministry.

### Article 33
### Notification and Inventory

1. Producers, importers or distributors of BP, being placed on the market before the date of coming in to a force of this Law, and these products placed in the market shall be notified in the Ministry, within one year (1) after coming in to a force of this Law.

2. The Ministry, within two (2) years after coming in to a force of this Law shall evaluate received notifications and shall establish the inventory of the biocide products, authorized to be placed on the market, before coming in to a force of this Law.

3. Producers ,importers ,or distributors of BP ,which are going to placed on the market for the first time, from the date of coming in to a force of this Law new biocide products, their notification shall be made in the Ministry, before BP their placement on the market and as follows :

3.1. placement on the market shall be authorized only, when the Ministry receives a notification or shall grant a provisional authorization, or registration as it has been required by provisions of this Law.

3.2. received notifications for new biocide products shall be evaluated by the Ministry and the Ministry within thirty (30) days after the receiving of the notification shall confirm acceptance or not acceptance for inclusion in the inventory.

4. The inventory shall be made, by completing of notification form from presenter of the request and, if appropriate by submission of other information, especially for every product, according to Annex VII, of this Law.

5. Producers, importers or distributors that are included on of BP inventory with all relevant information, and records if appropriate for improvement or updating with new information, shall submit the required changes for a specific biocide product, using the notification form in accordance with Annex VII, of this Law.

6. The Ministry shall decide about proceedings of such information in the Inventory of biocides if the changes are acceptable, or if the changes are of importance, then the information shall be included in Inventory.

**Article 34**
**Criterions of non acceptance of BP in Inventory**

1. Notification of BP shall not be accepted, if:

1.1. active substance composing biocide product is not registered in one of the lists I, I A, or I B, of this Law;

1.2. biocide product contains prohibited or restricted chemical substances, set out in Law on chemicals;

1.3. biocide products already placed on the market for general consumption and contain:

1.3.1. carcinogenic substances from category 1 or 2 ,with an equal percentage or higher than 0,1 % (gassy biocide products or ,or non gassy );

1.3.2. mutagenic substances from category 1 or 2 ,with an equal percentage ,or higher than 0,1 % (gassy or not gassy biocide products ),or

1.3.3. or toxic substances for reproduction of category 1 or 2 ,with an equal percentage or higher than 0,2 % (gassy biocide products ) ,or with an equal percentage ,or higher than 0,5 % (non gassy biocide products ).

2. In case when have been established specific limits of the concentration for substances with one of these harmful chemicals, according to provisions for chemicals Law, regarding to classification, wrapping and labeling of harmful substances, then these limits of concentration shall have priority.

**Article 35**
**Revocation of biocide product from inventory**

1. If the producer, importer or distributor of biocide product, included in inventory of biocides, decides to revoke them from the market, they shall inform the Ministry and they shall specify a final date, until when the product shall be on the market.

2. The Ministry shall indicate in the inventory that biocide product has been revoked from the market, within twelve (12) months, after the taking of such decision, and shall grant a period of time for marketing and use of the existing quantity of BP, up to twelve (12) months.

# CHAPTER V
## CLASSIFICATION, PACKAGING AND LABELLING OF BP

### Article 36
### Classification, packaging and labeling of BP

1. For classification, packaging and labeling of BP, shall be implemented provisions for harmful chemicals set out in the Law on chemicals if by this Law is not regulated differently.

2. According to Article 6 of the Directive 88/379/EEC, for packaging of BP shall be completed the following conditions:

2.1. BP which can be mistaken for food, drink or feeding stuff, shall be packed to minimize the likelihood of such a mistake being made,

2.2. BP available to a general public which may be mistaken for food, drink or feeding stuff, shall contain components to discourage their consumption.

3. Declaration of the BP ,in the Label shall not be misleading or give an exaggerated impression of the product ,and may not , in any case mention the indications as, “low-risk biocide product” ”non – toxic” ,”harmless” , or similar indications.

4. The label must show clearly:

4.1. the identity of every active substance, and its concentration in metric units,

4.2. the class and authorization number allocated to the biocide product by the competent authority,

4.3. the type and form of BP as: liquid, concentrates, granules, powders, solids etc,

4.4. the use and dedication for which biocide product is authorized disinfection, wood preservation , surface use, anti-fouling.

4.5. directions for use and the dose rate ,expressed in metric units ,for each use provided for under the terms of authorization,

4.6. particulars of likely direct or indirect adverse side effects and any directions for first aid,

4.7. the packaging of BP should contain the accompanied leaflet with instructions;

4.8. directions for safe disposal of the BP should contain the sentence “Read attached instructions before use of BP” including its packaging and where necessary mentioning any prohibition on their reuse of packaging,

4.9. the formulation batch number or designation and the expiry date to normal conditions of storage,

4.10. the period of time needed for the biocide effect ,the interval to be observed between the application of biocide product ,or between application and next the next use of the product treated ,or next access by man ,or animals to the area where the biocide product has been used,

4.11.including specifics concerning to needed means for decontamination ,measures for adequate cleaning ,measures for caution, storage, transport and where the biocide product can be used;

4.12. the group of users to which the biocide product is restricted.

4.13. information on any specific danger to the environment, particularly concerning protection of non-target organisms and avoidance of contamination of water .

5. Information from paragraph 4, points 1, 2, 4, 7 and 11 of this Article always is carried out in the label of the BP.

6. Information from paragraph 4, points 3, 5, 6, 8, 9, 10 and 12, of this Article shall be permitted to be carried out elsewhere on the packaging or an accompanying leaflet integral to the packaging – instruction for use.

7. Where a biocide product identified as insecticide, acaricide, rodenticide, avicide or molluscicide is authorised pursuant to this Directive and according to of the laws of the Chemicals classification, packaging and labelling of dangerous preparations (pesticides) by virtue of other Community provisions, shall permit changes to the packaging and labelling of that product which may be required as a consequence of those provisions in so far as they do not conflict with the conditions of an authorisation issued under this Directive. 78/631/EEC of 26 June 1978. The Ministry may require the provision of the samples, models or drafts of packaging, labeling and leaflets regarding to use of BP.

8. On the market can be placed only those BP, having a declaration in the official languages in the Republic of Kosovo.

**Article 37**
**Prohibitions for packaging and labeling**

1. BP which has been classified as risk shall not be authorized to be labeled by words as: dangerous, not dangerous to human health, animal health or environment, or to be labeled by words creating confusion.

2. The labeling of BP by the word ,pursuant to paragraph 1 ,of this Article ,and ,in any case not mention the indications, low-risk biocide product," on –toxic", harmless", or different .

3. It is prohibited that PB to be packaged in order for creating confusion, uncertainty or dilemma for their users.

**Article 38**
**Safety data sheets**

1. The authorization holder for placement on the market of BP has an obligation to provide safety technical list, which enables the information of users for professional use of the BP.

2. The safety technical list for BP shall be completed, based on the Law on chemicals as follows:

2.1. for BP which have been classified as dangerous and in accordance to Article 10 of the Directive 88/379/EEC, and

2.2. for active substances, used exclusively in BP in accordance with provisions of Article 26 of the Directive 67/548/EEC.

**Article 39**
**Advertising of BP**

1. Publications, instructions and advices are authorized only for BP having an authorization to be placed on the market.

2. Every publication for BP is accompanied by a sentence "Use biocides safely, always read the label and product information before use ".the sentence shall be placed in visible place, clearly distinguishable in relation to whole publications.

3. Words "Biocide products, in accordance to paragraph 2 .of this Article can be replaced with detailed description of the product type, being advertised, for example, wood preservatives, disinfectants, etc.

4. Advertisements, labels, instructions and advices for BP shall be made in compliance with provisions of Article 33 of this Law.

# CHAPTER VI
## OBLIGATIONS FOR CONDUCTING OF THE EFFECTS, CHANGES AND NEW KNOWLEDGES FOR BP, KEEPING OF RECORD AND INFORMATION

**Article 40**
**Conducting and identification of innovations, regarding to BP**

1. A holder of authorization for placement on the market of BP has an obligation to conduct all harmful effects and impacts in human health, animal health, or environment and new knowledge for BP.

2**.** A person from paragraph 1, of this Article has an obligation to inform the Ministry with all details which may effect in the further validity of the authorization particularly for:

2.1. knowledge and details about the effects of BP ,active substance ,or effects ,caused by other components of BP in human health ,animal health ,and environment,

2.2. modifications in the composition of active substance,

2.3. modifications in composition of BP,

2.4. withstanding development of the micro-organisms in BP,

2.5. changing of license holder , name of BP trade ,and changing of packaging type.

3. Obligations to inform the Ministry about the effects of BP about the effects of the BP, according to paragraph 2, point 4 of this Article, is related to persons who are using BP as well.

**Article 41**
**Keeping of the records for PB**

1. An authorization holder and professional user of BP have an obligation to keep the evidence, in compliance with provisions of according to the Law on chemicals.

2. Information kept in the evidence during the previous calendar year shall be reported to the Ministry, not later than 31 march of the following calendar year.

**Article 42**
**Information about harmful effects and poisons caused by BP**

1. Recipiency and information exchange, regarding to acute poisons and other effects of BP, which are placed on the market, including technical safety list, information about chemical composition and their effect in environment and in human health shall be made by Ministry MoH and MAFRD.

2. Records, according to paragraph 1, of this Article shall be available to National Institute of Public health and these records can be used for medicinal purposes, to protect human health, animal health and environment.

3. The competent authority of the public health is National institute of public health has an obligation to no make public the received information by the Ministry.

4. The holder of the authorization and user of BP ,which have been placed on the market already have an obligation to inform and report to the Ministry the records information, from paragraph 1, of this Article, within one year after the coming in to the force of this Law.

**Article 43**
**Screenings –testing**

1. The screening of BP shall be carried out according to provisions of Chemical Law, no.2007/02-L116, under the certain methods and conditions in laboratories in which are carried out examinations of BP, presenting a key element for evaluation of effects and impacts in human health, animal health and environment.
2. Exclusively from paragraph 1, of this Article, by a sub law act the Minister shall determine specific conditions which shall be completed by laboratory for screening of BP.

## CHAPTER VII
## PROTECTION OF INFORMATIONS AND EXCHANGE

**Article 44**
**Information exchange within the country and abroad**

1. Based on the level of international obligations, the information exchange for BP shall be carried out by the Ministry.

2. The Ministry shall offer all information in accordance with provisions amending free access to information and in accordance with provisions amending the confidentiality of the information.

3. Every year the Ministry shall publish, the List of authorized BP in the official gazette of the Republic of Kosovo, and in different period of time, if appropriate, can publish amendments of the registers and information.

**Article 45**
**Confidentiality of records**

1. If the presenter of the request may indicate to the competent authority the information which he considers to be commercially sensitive and disclosure of which might harm him industrially or commercially and which he therefore to be kept confidential besides for Ministry.

2. If the request in accord to paragraph 1. of this article is based in evidences that free information harm license holder The Minister shall order keeping on secret of this records having on mind conditions pursue to legal provisions regulates right on approach to official documents.

3. Information accepted by the competent authority of another country, shall be considered as being confidential by the Ministry.

4. After the authorization has been granted for placement on the market of BP, confidentiality, shall not in any case apply to:

4.1. name and address of the applicant,

4.2. the name and address of BP manufacturer,

4.3. the name and address of the active substance manufacturer,

4.4. the names and content of the active substance or substances in BP,

4.5. the name of other substances ,taking in to account of legal provisions for harmful chemicals,

4.6. physical and chemical data , concerning the active substance and BP,

4.7. any ways of rendering the active substance or biocide product harmless,

4.8. a summary of the results of the tests required ,pursuant to this Law ,and other sub-law acts,

4.9. adequate methods and precautions to reduce dangerous from handling, storage, transport and use ,as well as from fire or other hazards,

4.10. safety data sheets,

4.11. analytical methods of toxicological ,or ecotoxicological testing of the active substance, impurities and other substances,

4.12. methods of disposal of the product and of its packaging,

4.13. measures and actions to be taken in case of leakage of BP,

4.14. first aid and treatment to be given in case of injury to persons.

5. If the holder of authorization should later disclose previously confidential information, the Ministry shall be informed accordingly in a written form within eight (8) days.

### Article 46
### Restriction in using information about active substances or BP

Restriction, use or notification about the information included in the dossier of documentation, for any active substance or any BP, previously authorized which information under possession of the Ministry, shall be used for service and on interest of another presenter of the request, if are respected rules and requirements set out by sub law act, issued by the Government with proposal of the Ministry in cooperation with MoH and MAFRD.

### Article 47
### Keeping of the documentation

An authorization holder for placement on the market of BP has an obligation to keep the documentation of BP, declaration for access in the documents and other facts, pursuant to provisions of the Law on chemicals.

## CHAPTER VIII
## MEASURES TO PROTECT HUMAN HEALTH, ANIMAL HEALTH AND ENVIRONMENT

### Article 48
### Prohibition and reduction of the risk for human health animal health and environment

Persons who are placing on the market BP shall ensure conditions to prohibit or reduce risk from BP, and if possible the harmful BP to be replaced with a harmless BP.

### Article 49
### Professional usage of BP

1. According to Article 18 of this Law the BP for professional usage shall be used only by professionals, pursuant to provisions of the Law on chemicals.

2**.** Where we have to deal with unpredictable risk, by way of derogation from Article 1 the Minister can define, authorize and certify conditions for use of certain BP.

### Article 50
### Prohibitions and restrictions for manufacturing or placement on the market of BP

1. Prohibitions and restrictions for manufacturing and placement on the market of BP shall be made pursuant to provisions of the sub-law for harmful chemicals from Law on chemicals. Dependently from the risk that may present BP, shall be decided to:

1.1. prohibition or restriction BP, containing different substances ,or they are grouped in a certain type of BP,

1.2. prohibition or restriction of BP, qualified as harmful,

1.3. prohibition and restriction of substances ,authorized and are in composition of BP or they are under specific conditions.

2. Prohibition or restriction from paragraph 1, of this Article can happen from the moment when the substance or other components of BP shall not be authorized for production, placement on the market and use. For the remained quantities of BP, shall be applied provisions of Article 23, of this Law

**Article 51**
**Liabilities for detriments**

A holder of authorization for placement on the market and user of BP, within the territory of the Republic of Kosovo shall be responsible for detriments, caused from non implementation of the conditions according to this Law, or because of incorrect declarations for BP contain.

**Article 52**
**Holder of the charges**

1. Charges for evaluation procedure, granting authorization for placement on the market of BP, and registration of active substances in one of the Lists I, I A, or I B shall be carried by presenter of the request.

2. The sub-legal act about fees of charges, in accordance to paragraph 1 of this Article shall be issued by Minister.

**Article 53**
**Imports of BP**

1. The import of BP within the territory of the Republic of Kosovo shall be made only by authorized persons for placement on the market and use of BP, and persons fulfilling the conditions for placement on the market and use of harmful chemicals.

2. The importer has an obligation to submit an application to a sanitary and phytosanitary inspector in the border crossing point for inspection of BP.

3. Customs shall not do the customs of BP, if has not been implemented provisions of paragraph 2. of this Article.

4. Importer has an obligation to produce (present) to a sanitary and phytosanitary inspector in the border, a decision regarding to placement on the market of BP.

5. Provisions of the paragraph 1, 2 and 3, of this Article shall be applied for BP kept in areas, stores in a free customs zones in the Republic of Kosovo.

# CHAPTER IX
## INSPECTION

### Article 54
### The competent authority for Inspection of BP

1. Supervision in implementation of provisions of this Law and other sub-laws coming out from this Law, information and exchange of information shall be carried out by the Ministry.

2. Inspection for implementation of this Law and other sub-laws shall be carried out by sanitary, phytosanitary and environmental inspectors.

### Article 55
### Duties of the Inspector

1. Environmental /sanitary and phytosanitary Inspector during the surveillance shall inspect areas, premises, equipments and application.

2. Persons who are using and placing on the market BP, by request of the Inspector have an obligation to show a sample of BP.

3. Analyses of the samples shall be carried out in certified laboratories, according to provisions of this Law and Law on chemicals.

### Article 56

1. During inspection has an obligation to:

1.1. prohibit placement on the market of BP, for which has not been granted an authorization, in accordance with this Law,

1.2. be prohibited to placement on the market of BP ,if which is classified and labeled as harmful chemicals and does not have a decision by the competent authority for develop of activity or disrespects place of sale, it is fixed by authorization,

1.3. BP shall be prohibited to be placed on the market, if it is not provided technical safety list,

1.4. BP shall be prohibited to be placed on the market it is not divided, and labeled in accordance with this Law,

1.5. BP shall not be placed on the market if they do not comply with other conditions, in accordance with this Law,

1.6. BP shall be prohibited to be placed on the market, if there is no authorization for carrying out such activity,

1.7. shall order to take other measures, which i s authorized by provisions of this Law and other Laws in force.

**Article 57**

1. During inspection of the import of BP, phytosanitary inspector in custom is authorized:

1.1. to prohibit import of BP ,for which has not been granted an authorization ,to be placed on the market within the territory of the Republic of Kosovo and returns the BP to their sender or producer,

1.2. to prohibit crossing the border or transporting if the BP have not been packed or labeled properly ,in accordance with this Law ,and shall order elimination of all irregularities or shall return the BP,

1.3. shall give other orders in accordance with this law , if the human health, animal health and environment is endangered.

## CHAPTER X
## PENALTY PROVISIONS

**Article 58**
**Penalties**

1 . Shall be condemned for violation from five thousand (5000) to fifty thousand (50000) Euro, a legal person, if:

1.1. the user of the BP ,uses in challenge with provisions of Article 4 of this Law,

1.2. shall place on the market or use active substances or basic substances in a challenge with provisions of Article 6 of this Law,

1.3. BP is placed on the market or it is used in a challenge with provisions of Article 14 of this Law.

1.4. by the request of the Ministry does not present samples of BP and their composition, according to Article 15, paragraph 4 of this law;

1.5. BP are placed on the market and used as good for general consumption, Article 18, paragraph 1 of this law;

1.6. a holder of authorization for scientific researches and development ,use BP in a different surfaces and quantities ,other than those authorized ,carries out researches under other conditions from those authorized ,according to Article 31, paragraph 3 of this law and if does not keep a written evidence ,and does not keep evidence about the labeling and quantity supplied ,names and addresses of the persons receiving BP ,about chances of the effect in human health and

environment ,respectively these information does not present in written form to the Ministry, documentation and notification /reporting regarding to the research development and the results of such research Article 31, paragraph 5 of this Law.

1.7. BP, placed on the market and used in challenge of provisions of Article 32, 33, 34 and 35 of this Law.

1.8. BP is packed and declared in challenge with provisions of Article 36 of this Law.

1.9. BP ,classified as harmful ,is labeled as less harmful .or harmless to human health ,animal health and environment or it is labeled by words which make hesitation ,uncertainty ,and confusion to a user, Article 37 paragraph 1 and 2 respectively ,if packs BP so ,to make a dilemma to a user ,Article 37, paragraph 3 of this Law.

1.10. shall not make available the technical safety list ,to all professional users of BP and if appropriate to all other users of BP ,on their request Article 38 paragraph 2 of this Law.

1.11. the BP has been declared in challenge with provisions of the Article 39 of this Law.

1.12. does not conduct and survey all effects and new knowledge of BP which may have harmful effects to human health, animal health and environment, Article 36 paragraph 1 of this law, if does not notify the Ministry in time for all information available to him and which may have effect on the validity of the authorization granted, or granting an authorization Article 40 paragraph 2 of this Law.

1.13. does not keep evidence in compliance with specific legal acts ,in which are set down rules for harmful chemicals Article 41 paragraph 1 of this law ,or does not notify the Ministry ,until March 31$^{st}$ of the following year for the previous calendar year Article 37 paragraph 2 of this Law;

1.14. acts in challenge with Article 42 paragraph 3 and 4 of this Law;

1.15. does not provide conditions which prohibit or reduce harm to human health, animal health and environment, Article 48 of this Law;

1.16. does not keep the documentation of BP as set down in Article 47 of this Law;

1.17. acts in contrary with Article 49 of this Law;
1.18. acts in challenge with prohibition, respectively restrictions for manufacturing or placement on the market of BP, Article 50 of this Law.

1.19. imports BP in challenge with Article 53 of this Law.

1.20. acts in challenge with Article 55 paragraph 2 of this Law.

2. Shall be condemned for violation with fine from one thousand (1000) to ten thousand (10000) Euro from paragraph 1. of this Article a person in charge of legal person.

3. A person shall be condemned for violation with a fine from one thousand (1000) to five thousand (5.000) Euro for violation from paragraph 1. points 1. 2. 3. 4. 5. 10. 11, 12. 13. 14. 15. 16. 17. and 19. of this Article.

4. For attempt of breaking from Paragraph 1, points 1. 2. 3. 5. 6. 7. 8. 10. 16. 17.and 18. of this Article shall be fined with one thousand (1000) Euro.

## CHAPTER XI
## TRANSITIONAL AND FINAL PROVISIONS

### Article 59

1. If by provisions of this Law are not include rules for matters of manufacturing and placement on the market of BP ,as well as consequences of their use ,shall be implemented ,provisions of the Law on chemicals .

2. Sub legal acts issued by this Law must to be approved in terms of thirty six (36) months by the day of approval of this Law.

### Article 60
### Abrogation Provisions

Each Administrative Instruction or other sub-legal act that is contradiction to this Law is not valid.

### Article 61

Part of this law are Annexes from one (1) to seven (7).

### Article 62
### Entry into force

This Law enters in to a force fifteenth (15) days after being published in the Official Gazette of the Republic of Kosovo.

**Law No. 03/L-119**
**27 May 2008**

**President of the Assembly of the Republic of Kosovo**

**_____**

**Jakup KRASNIQI**

**Republika e Kosovës**
**Republika Kosovo-Republic of Kosovo**
*Kuvendi - Skupština - Assembly*

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**Law No. 03/L-119**

**ON BIOCIDE PRODUCTS**

# ANEXES OF LAW ON BIOCIDAL PRODUCTS

***ANEX- I***

***ANEX- IA***

***ANEX- IIA***

***ANEX- IIB***

***ANEX- IIIA***

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***ANEX- IVA***

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ANEXES OF DIRECTIVE 98/8/ EC

***ANEX- I***

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***ANEX- IIA***

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***ANEX- V***

***ANEX-V I***

## ANNEX I.

**LIST OF ACTIVE SUBSTANCES WITH REQUIREMENTS AGREED AT COMMUNITY LEVEL FOR INCLUSION IN BIOCIDAL PRODUCTS**

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## ANNEX I.A

**LIST OF ACTIVE SUBSTANCES WITH REQUIREMENTS AGREED AT COMMUNITY LEVEL FORINCLUSION IN LOW-RISK BIOCIDAL PRODUCTS**

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# ANNEX I.B

**LIST OF BASIC SUBSTANCES WITH REQUIREMENTS AGREED AT COMMUNITY LEVEL**

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# ANNEX II.A

**COMMON CORE DATA SET FOR ACTIVE SUBSTANCES**

**CHEMICAL SUBSTANCES**

1. Dossiers on active substances are required to address at least all the points listed under 'Dossier requirements'. Responses are required to be supported by data. The dossier requirements must be in line with technical development.

2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

**Dossier requirements**

I. Applicant

II. Identity of the active substance

III. Physical and chemical properties of the active substance

IV. Methods of detection and identification

V. Effectiveness against target organisms and intended uses

VI. Toxicological profile for man and animals including metabolism

VII. Ecotoxicological profile including environmental fate and behaviour

VIII. Measures necessary to protect man, animals and the environment

IX. Classification and labeling

X. Summary and evaluation of Sections II to IX

The following data will be required to support submission on the above points.

**I. APPLICANT (PRESENTER OF THE REQUEST)**

Name and address, etc.

Active substance manufacturer (name, address, location of plant).

**II. IDENTITY**

2.1. Common name proposed or accepted by ISO and synonyms;

2.2. Chemical name (IUPAC nomenclature);

2.3. Manufacturer's development code number(s);

2.4. CAS and EC numbers (if available);

2.5. Molecular and structural formula (including full details of any isomeric composition), molecular mass;

2.6. Method of manufacture (syntheses pathway in brief terms) of active substance;

2.7. Specification of purity of the active substance in g/kg or g/l, as appropriate
EN 24.4.98 Official Journal of the European Communities L 123/25;

2.8. Identity of impurities and additives (e.g. stabilisers), together with the structural formula and the possible range expressed as g/kg or g/l, as appropriate;

2.9. The origin of the natural active substance or the precursor(s) of the active substance, e.g. an extract of a flower;

2.10. Exposure data in conformity with Annex VIIA to Directive 92/32/EEC (*).

**III. PHYSICAL AND CHEMICAL PROPERTIES**

3.1. Melting point, boiling point, relative density (1);

3.2. Vapor pressure (in Pa) (1);

3.3. Appearance (physical state, colour) (2);

3.4. Absorption spectra (UV/VIS, IR, NMR), and a mass spectrum, molar extinction at relevant wavelengths, where relevant (1);

3.5. Solubility in water including effect of pH (5 to 9) and temperature on solubility, where relevant (1);

3.6. Partition coefficient n-octanol/water including effect of pH (5 to 9) and temperature (1);

3.7. Thermal stability, identity of relevant breakdown products;

3.8. Flammability including auto-flammability and identity of combustion products;

3.9. Flash-point;

3.10. Surface tension;

3.11. Explosive properties;

3.12. Oxidising properties;

3.13. Reactivity towards container material

## IV. ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of the active substance and additives (e.g. stabilisers);

Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following:

(a) soil;

(b) air;

(c) water: the applicant should confirm that the substance itself and any of its degradation products which fall within the definition of pesticides given for parameter 55 in Annex I to Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption(**) can be estimated with adequate reliability at the MAC specified in that Directive for individual pesticides;

(d) animal and human body fluids and tissues.

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(*) OJ L 154, 5.6.1992, p. 1.

(**) OJ L 229, 30.8.1980, p. 11. Directive as last amended by Directive 91/692/EEC (OJ L 377, 31.12.1991, p. 48).L 123/26 EN Official Journal of the European Communities 24.4.98

## V. EFFECTIVENESS AGAINST TARGET ORGANISMS AND INTENDED USES

5.1. Function, e.g. fungicide, rodenticide, insecticide, bactericide;

5.2. Organism(s) to be controlled and products, organisms or objects to be protected;

5.3. Effects on target organisms, and likely concentration at which the active substance will be used;

5.4. Mode of action (including time delay);

5.5. Field of use envisaged;

5.6. User: industrial, professional, general public (non-professional);

5.7. Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies;

5.8. Likely tonnage to be placed on the market per year.

## VI. TOXICOLOGICAL AND METABOLIC STUDIES

6.1. Acute toxicity

For studies 6.1.1 to 6.1.3, substances other than gases shall be administered via at least two routes, one of which should be the oral route. The choice of the second route will depend on the nature of the substance and the likely route of human exposure. Gases and volatile liquids should be administered by the inhalation route.

6.1.1. Oral;

6.1.2. Dermal;

6.1.3. Inhalation;

6.1.4. Skin and eye irritation (3);

6.1.5. Skin sensitization;

6.2. Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study
For the following studies, 6.3 (where necessary), 6.4, 6.5, 6.7 and 6.8, the required route of administration is the oral route unless it can be justified that an alternative route is more appropriate;

6.3. Short-term repeated dose toxicity (28 days)
This study is not required when a sub-chronic toxicity study is available in a rodent

6.4. Subchronic toxicity 90-day study, two species, one rodent and one non-rodent;

6.5. Chronic toxicity (4)
One rodent and one other mammalian species

6.6. Mutagenicity studies;

6.6.1. *In-vitro* gene mutation study in bacteria;

6.6.2. *In-vitro* cytogenicity study in mammalian cells;

6.6.3. *In-vitro* gene mutation assay in mammalian cells;

6.6.4. If positive in 6.6.1, 6.6.2 or 6.6.3, then an *in-vivo* mutagenicity study will be required (bone marrow assay for chromosomal damage or a micronucleus test);

6.6.5. If negative in 6.6.4 but positive *in-vitro* tests then undertake a second *in-vivo* study to examine whether mutagenicity or evidence of DNA damage can be demonstrated in tissue other than bone marrow EN 24.4.98 Official Journal of the European Communities L 123/27;

6.6.6. If positive in 6.6.4 then a test to assess possible germ cell effects may be required;

6.7. Carcinogenicity study (4)One rodent and one other mammalian species. These studies may be combined with those in 6.5;

6.8. Reproductive toxicity (5);

6.8.1. Teratogenicity test — rabbit and one rodent species;

6.8.2. Fertility study — at least two generations, one species, male and female;

6.9. Medical data in anonymous form;

6.9.1. Medical surveillance data on manufacturing plant personnel if available;

6.9.2. Direct observation, e.g. clinical cases, poisoning incidents if available;

6.9.3. Health records, both from industry and any other available sources;

6.9.4. Epidemiological studies on the general population, if available;

6.9.5. Diagnosis of poisoning including specific signs of poisoning and clinical tests, if available;

6.9.6. Sensitisation/allergenicity observations, if available;

6.9.7. Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment, if known;

6.9.8. Prognosis following poisoning;

6.10. Summary of mammalian toxicology and conclusions, including no observed adverse effect level (NOAEL), no observed effect level (NOEL), overall evaluation with regard to all toxicological data and any other information concerning the active substances. Where possible any suggested worker protection measures should be included in summary form

## VII. ECOTOXICOLOGICAL STUDIES

7.1. Acute toxicity to fish;

7.2. Acute toxicity to *Daphnia magna;*

7.3. Growth inhibition test on algae;

7.4. Inhibition to microbiological activity;

7.5. Bioconcentration;
Fate and behaviour in the environment

7.6. Degradation;

7.6.1. Biotic;

7.6.1.1. Ready biodegradability;

7.6.1.2. Inherent biodegradability, where appropriate;

7.6.2. Abiotic;

7.6.2.1. Hydrolysis as a function of pH and identification of breakdown products;

7.6.2.2. Phototransformation in water including identity of the products of transformation (1);

7.7. Adsorption/desorption screening test;
Where the results of this test indicate the need to do so, the test described in Annex IIIA Part XII.1 paragraph 1.2 shall be required, and/or the test described in Annex IIIA Part XII.2 paragraph 2.2;

7.8. Summary of ecotoxicological effects and fate and behaviour in the environment.

## VIII. MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

8.1. Recommended methods and precautions concerning handling, use, storage, transport or fire;

8.2. In case of fire, nature of reaction products, combustion gases, etc.;

8.3. Emergency measures in case of an accident;

8.4. Possibility of destruction or decontamination following release in or on the following:
(a) air;(b) water, including drinking water ;(c) soil.

8.5. Procedures for waste management of the active substance for industry or professional users;

8.5.1. Possibility of reuse or recycling;

8.5.2. Possibility of neutralization of effects;

8.5.3. Conditions for controlled discharge including leachate qualities on disposal;

8.5.4. Conditions for controlled incineration;

8.6. Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms

## IX. CLASSIFICATION AND LABELLING

Proposals including justification for the proposals for the classification and labelling of the active substance according to Directive 67/548/EEC;

Hazard symbol(s);

Indications of danger;

Risk phrases;

Safety phrases

## X. SUMMARY AND EVALUATION OF SECTIONS II TO IX

Notes

(1) These data must be submitted for the purified active substance of stated specification.

(2) These data must be submitted for the active substance of stated specification.

(3) Eye irritation test shall not be necessary where the active substance has been shown to have potential corrosive properties.

(4) The long-term toxicity and carcinogenicity of an active substance may not be required where a full justification demonstrates that these tests are not necessary.

(5) If, in exceptional circumstances, it is claimed that such testing is unnecessary, that claim must be fully justified.

# ANNEX II.B

## COMMON CORE DATA SET FOR BIOCIDAL PRODUCTS
## CHEMICAL PRODUCTS

1. Dossiers on biocidal products are required to address at least all the points listed under 'Dossier requirements'. Responses are required to be supported by data. The dossier requirements must be in line with technical development.

2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Directive 88/379/EEC should be used wherever possible to minimise animal testing.

**Dossier requirements**

I. Applicant (presenter of the request)

II. Identity of the biocidal product

III. Physical and chemical properties of the biocidal product

IV. Methods for identification and analysis of the biocidal product

V. Intended uses of the biocidal product and efficacy for these uses

VI. Toxicology data for the biocidal product (additional to that for the active substance)

VII. Ecotoxicology data for the biocidal product (additional to that for the active substance)

VIII. Measures necessary to protect man, animals and the environment

IX. Classification, packaging and labeling

X. Summary and evaluation of Sections II to IX

The following data will be required to support submission on the above points.

**I. APPLICANT (PRESENTER OF THE REQUEST)**

Name and address, etc.;

Formulator of the biocidal product and the active substance(s) (names, addresses, including location of plant(s))

**II. IDENTITY**

2.1. Trade name or proposed trade name, and manufacturer's development code number of the preparation, if appropriate;

2.2. Detailed quantitative and qualitative information on the composition of the biocidal product, e.g. active substance(s), impurities, adjutants, inert components;

2.3. Physical state and nature of the biocidal product, e.g. emulsifiable concentrate, wettable powder, solution

**III. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES**

3.1. Appearance (physical state, colour);

3.2. Explosive properties;

3.3. Oxidising properties;

3.4. Flash-point and other indications of flammability or spontaneous ignition;

3.5. Acidity/alkalinity and if necessary pH value (1% in water);

3.6. Relative density;

3.7. Storage stability — stability and shelf-life. Effects of light, temperature and humidity on technical characteristics of the biocidal product; reactivity towards container material;

3.8. Technical characteristics of the biocidal product, e.g. wettability, persistent foaming, flowability, pourability and dustability;

3.9. Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorized

## IV. METHODS OF IDENTIFICATION AND ANALYSIS

4.1. Analytical method for determining the concentration of the active substance(s) in the biocidal product;

4.2. In so far as not covered by Annex IIA, paragraph 4.2, analytical methods including recovery rates and the limits of determination for toxicologically and ecotoxicologically relevant components of the biocidal product and/or residues thereof, where relevant in or on the following:

a) soil;

b) air;

c) water (including drinking water);

d) animal and human body fluids and tissues;

e) treated food or feedingstuffs

## V. INTENDED USES AND EFFICACY

5.1. Product type and field of use envisaged;

5.2. Method of application including description of system used;

5.3. Application rate and if appropriate, the final concentration of the biocidal product and active substance in the system in which the preparation is to be used, e.g. cooling water, surface water, water used for heating purposes;

5.4. Number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and Animals;

5.5. Function, e.g. fungicide, rodenticide, insecticide, bactericide;

5.6. Pest organism(s) to be controlled and products, organisms or objects to be protected;

5.7. Effects on target organisms;

5.8. Mode of action (including time delay) in so far as not covered by Annex IIA, paragraph 5.4;

5.9. User: industrial, professsional, general public (non-professional);
Efficacy data;

5.10. The proposed label claims for the product and efficacy data to support these claims, including any available standard protocols used, laboratory tests, or field trials, where appropriate;

5.11. Any other known limitations on efficacy including resistance

## VI. TOXICOLOGICAL STUDIES

6.1. Acute toxicity
For studies 6.1.1 to 6.1.3, biocidal products other than gases shall be administered via at least two routes, one of which should be the oral route. The choice of the second route will depend on the nature of the product and the likely route of human exposure. Gases and volatile liquids should be administered by the inhalation route

6.1.1. Oral;

6.1.2. Dermal;

6.1.3. Inhalation;

6.1.4. For biocidal products that are intended to be authorised for use with other biocidal products, the mixture of products, where possible, shall be tested for acute dermal toxicity and skin and eye irritation, as appropriate;

6.2. Skin and eye irritation (1);

6.3. Skin sensitization;

6.4. Information on dermal absorption;

6.5. Available toxicological data relating to toxicologically relevant non-active substances (i.e. substances of concern);

6.6. Information related to the exposure of the biocidal product to man and the operator
Where necessary, the test(s) described in Annex IIA, shall be required for the toxicologically relevant non-active substances of the preparation

## VII. ECOTOXICOLOGICAL STUDIES

7.1. Foreseeable routes of entry into the environment on the basis of the use envisaged;

7.2. Information on the ecotoxicology of the active substance in the product, where this cannot be extrapolated from the information on the active substance itself;

7.3. Available ecotoxicological information relating to exotoxicological relevant non-active substances (i.e. substances of concern), such as information from safety data sheets

## VIII. MEASURES TO BE ADOPTED TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

8.1. Recommended methods and precautions concerning handling, use, storage, transport or fire;

8.2. Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available; emergency measures to protect the environment; in so far as not covered by Annex IIA, paragraph 8.3;

8.3. Procedures, if any, for cleaning application equipment;

8.4. Identity of relevant combustion products in cases of fire;

8.5. Procedures for waste management of the biocidal product and its packaging for industry, professional users and the general public (non-professional users), e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration;

8.6. Possibility of destruction or decontamination following release in or on the following:

(a) air;

(b) water, including drinking water;

(c) soil;

8.7. Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms;

8.8. Specify any repellents or poison control measures included in the preparation that are present to prevent action against non-target organisms.

## IX. CLASSIFICATION, PACKAGING AND LABELLING

- Proposals for packaging and labelling;

- Proposals for safety-data sheets, where appropriate;

- Justification for the classification and labelling according to the principles of Article 20 of this Directive;

- Hazard symbol(s);

- Indications of danger;

- Risk phrases;

- Safety phrases;

- Packaging (type, materials, size, etc.), compatibility of the preparation with proposed packaging materials to be included.

## X. SUMMARY AND EVALUATION OF SECTIONS II TO IX

Notes

(1) Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

# ANNEX III.A

## ADDITIONAL DATA SET FOR ACTIVE SUBSTANCES CHEMICAL SUBSTANCES

1. Dossiers on active substances are required to address at least all the points listed under ‘Dossier requirements’. Responses are required to be supported by data. The dossier requirements must be in line with technical development.

2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

### III. PHYSICAL AND CHEMICAL PROPERTIES

1. Solubility in organic solvents, including effect of temperature on solubility (1);

2. Stability in organic solvents used in biocidal products and identity of relevant breakdown products(2)

### IV. ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

1. Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, in/on food or feedstuffs and other products where relevant

## VI. TOXICOLOGICAL AND METABOLIC STUDIES

1. Neurotoxicity study
If the active substance is an organophosphorus compound or if there are any other indications that the active substance may have neurotoxic properties then neurotoxicity studies will be required. The test species is the adult hen unless another test species is justified to be more appropriate. If appropriate, delayed neurotoxicity tests will be required. If anticholine esterase activity is detected a test for response to reactivating agents should be considered;

2. Toxic effects on livestock and pets;

3. Studies related to the exposure of the active substance to humans;

4. Food and feedingstuffs;
If the active substance is to be used in preparations for use where food for human consumption is prepared, consumed or stored, or where feedingstuff for livestock is prepared, consumed or stored the tests referred to in Section XI, part 1, shall be required;

5. If any other tests related to the exposure of the active substance to humans, in its proposed biocidal products, are considered necessary, then the test(s) referred to in Section XI, part 2 shall be required;

6. If the active substance is to be used in products for action against plants then tests to assess toxic effects of metabolites from treated plants, if any, where different from those identified in animals shall be required;

7. Mechanistic study — any studies necessary to clarify effects reported in toxicity studies.

## VII. ECOTOXICOLOGICAL STUDIES

1. Acute toxicity test on one other, non-aquatic, non-target organism;

2. If the results of the ecotoxicological studies and the intended use(s) of the active substance indicate a danger for the environment then the tests described in Sections XII and XIII shall be required;

3. If the result of the test in paragraph 7.6.1.2 of Annex IIA is negative and if the likely route of disposal of the active substance is by sewage treatment then the test described in Section XIII, part 4.1 shall be required;

4. Any other biodegradability tests that are relevant from the results in paragraphs 7.6.1.1 and 7.6.1.2 of Annex IIA;

5. Phototransformation in air (estimation method), including identification of breakdown products (1);

6. If the results from paragraphs 7.6.1.2 in Annex IIA or from paragraph 4, above, indicate the need to do so, or the active substance has an overall low or absent abiotic degradation, then the tests described in Section XII, part 1.1, part 2.1 and, where appropriate, part 3 shall be required

## VIII. MEASURES NECESSARY TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT

1. Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances (*)

*Notes*
(1) These data must be submitted for the purified active substance of stated specification.
(2) These data must be submitted for the active substance of stated specification.

## XI. FURTHER HUMAN HEALTH-RELATED STUDIES

1. Food and feedingstuffs studies;

1.1. Identification of degradation and reaction products and of metabolites of the active substance in treated or contaminated foods or feedstuffs;

1.2. Behaviour of the residue of the active substance, its degradation products and, where relevant, its metabolites on the treated or contaminated food or feedstuffs including the kinetics of disappearance;

1.3. Overall material balance for the active substance. Sufficient residue data from supervised trials to demonstrate that residues likely to arise from the proposed use would not be of concern for human or animal health;

1.4. Estimation of potential or actual exposure of the active substance to humans through diet and other means;

1.5. If residues of the active substance remain on feedingstuffs for a significant period of time then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin;

1.6. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the active substance;

1.7. Proposed acceptable residues and the justification of their acceptability;

1.8. Any other available information that is relevant

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(*) OJ L 20, 26.1.1980, p. 43.

1.9. Summary and evaluation of data submitted under 1.1 to 1.8
2. Other test(s) related to the exposure to humans
Suitable test(s) and a reasoned case will be required

## XII. FURTHER STUDIES ON FATE AND BEHAVIOUR IN THE ENVIRONMENT

1. Fate and behaviour in soil;

1.1. Rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions;

1.2. Absorption and desorption in at least three soil types and, where relevant, absorption and desorption of metabolites and degradation products;

1.3. Mobility in at least three soil types and where relevant mobility of metabolites and degradation products;

1.4. Extent and nature of bound residues;

2. Fate and behaviour in water;

2.1. Rate and route of degradation in aquatic systems (as far as is not covered by Annex IIA, paragraph 7.6) including identification of metabolites and degradation products;

2.2. Absorption and desorption in water (soil sediment systems) and, where relevant, absorption and desorption of metabolites and degradation products;

3. Fate and behaviour in air
If the active substance is to be used in preparations for fumigants, if it is to be applied by a spray method, if it is volatile, or if any other information indicates that this is relevant, then the rate and route of degradation in air shall be determined as far as is not covered by Section VII, part 5;

4. Summary and evaluation of parts 1, 2 and 3.

## XIII. FURTHER ECOTOXICOLOGICAL STUDIES

1. Effects on birds;

1.1. Acute oral toxicity — this need not be done if an avian species was selected for study in Section VII, part 1;

1.2. Short-term toxicity — eight-day dietary study in at least one species (other than chickens);

1.3. Effects on reproduction;

2. Effects on aquatic organisms;

2.1. Prolonged toxicity to an appropriate species of fish;

2.2. Effects on reproduction and growth rate on an appropriate species of fish;

2.3. Bioaccumulation in an appropriate species of fish;

2.4. *Daphnia magna* reproduction and growth rate;

3. Effects on other non-target organisms;

3.1. Acute toxicity to honeybees and other beneficial arthropods, e.g. predators. A different test organism shall be chosen from that used in Section VII, part 1;

3.2. Toxicity to earthworms and to other soil non-target macro-organisms;

3.3. Effects on soil non-target micro-organisms;

3.4. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk;

4. Other effects;

4.1. Activated sludge respiration inhibition test;

5. Summary and evaluation of parts 1, 2, 3 and 4

# ANNEX III.B

## ADDITIONAL DATA SET FOR BIOCIDAL PRODUCTS CHEMICAL PRODUCTS

1. Dossiers on biocidal products are required to address at least all the points listed under ‘Dossier requirements’. Responses are required to be supported by data. The dossier requirements must be in line with technical development.

2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Directive 88/379/EEC should be used wherever possible to minimise animal testing.

### XI. FURTHER HUMAN HEALTH-RELATED STUDIES

1. Food and feedingstuffs studies;

1.1. If residues of the biocidal product remain on feedingstuffs for a significant period of time, then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin;

1.2. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product;

2. Other test(s) related to the exposure to humans
Suitable test(s) and a reasoned case will be required for the biocidal product

## XII. FURTHER STUDIES ON FATE AND BEHAVIOUR IN THE ENVIRONMENT

1. Where relevant all the information required in Annex IIIA, Section XII;

2. Testing for distribution and dissipation in the following:

a) soil;

b) water;

c) air

Test requirements 1 and 2 above are applicable only to ecotoxicologically relevant components of the biocidal product

## XIII. FURTHER ECOTOXICOLOGICAL STUDIES

1. Effects on birds;

1.1. Acute oral toxicity, if not already done in accordance with Annex IIB, Section VII;

2. Effects on aquatic organisms;

2.1. In case of application on, in, or near to surface waters;

2.1.1. Particular studies with fish and other aquatic organisms;

2.1.2. Residue data in fish concerning the active substance and including toxicologically relevant metabolites;

2.1.3. The studies referred to in Annex IIIA, Section XIII, parts 2.1, 2.2, 2.3 and 2.4 may be required for relevant components of the biocidal product;

2.2. If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms under field conditions;

3. Effects on other non-target organisms;

3.1. Toxicity to terrestrial vertebrates other than birds;

3.2. Acute toxicity to honeybees;

3.3. Effects on beneficial arthropods other than bees;

3.4. Effects on earthworms and other soil non-target macro-organisms, believed to be at risk;

3.5. Effects on soil non-target micro-organisms;

3.6. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk;

3.7. If the biocidal product is in the form of bait or granules;

3.7.1. Supervised trials to assess risks to non-target organisms under field conditions;

3.7.2. Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk;

4. Summary and evaluation of parts 1, 2, and 3

# ANNEX IV.A

## DATA SET FOR ACTIVE SUBSTANCES FUNGI, MICRO-ORGANISMS AND VIRUSES

1. Dossiers on active organisms are required to address at least all the points listed under 'Dossier requirements' below. Responses are required to be supported by data. The dossier requirements must be in line with technical development.

2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases, a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

**Dossier requirements**

I. Applicant details

II. Identity of the active organism

III. Source of active organism

IV. Methods of detection and identification

V. Biological properties of active organism including pathogenicity and infectivity for target and non-target organisms including man

VI. Effectiveness and intended uses

VII. Toxicological profile for man and animals including metabolism of toxins

VIII. Ecotoxicological profile including environmental fate and behaviour of the organisms and of toxins it produces.

IX. Measures necessary to protect man, non-target organisms and the environment

X. Classification and labeling

XI. Summary and evaluation of Sections II to X

The following data will be required to support submissions on the above points.

**I. APPLICANT (PRESENTER OF THE REQUEST)**

Applicant (name, address, etc.);

Manufacturer (name, address, plant location).

**II. IDENTITY OF THE ORGANISM**

2.1. Common name of organism (including alternative and superseded names);

2.2. Taxonomic name and strain indicating whether it is a stock variant or a mutant strain; for viruses, taxonomic designation of the agent, serotype, strain or mutant;

2.3. Collection and culture reference number where the culture is deposited;

2.4. Methods, procedures and criteria used to establish the presence and identity of the organism (e.g. morphology, biochemistry, serology, etc.)

**III. SOURCE OF THE ORGANISM**

3.1. Occurrence in nature or otherwise;

3.2. Isolation methods for organism or active strain;

3.3. Culture methods;

3.4. Production methods including details of containment and procedure to maintain quality and ensure a uniform source of active organism. For mutant strains detailed information should be provided on production and isolation, together with all known differences between the mutant strains and parent and naturally occurring strains;

3.5. Composition of the final active organism material i.e. nature, purity, identity, properties, content of any impurities and extraneous organisms;

3.6. Methods to prevent contamination of seed stock and loss of virulence of seed stock;

3.7. Procedures for waste management.

## IV. METHODS OF DETECTION AND IDENTIFICATION

4.1. Methods for establishing the presence and identity of the organism;

4.2. Methods for establishing the identity and purity of seed stock from which batches are produced and results obtained, including information on variability;

4.3. Methods to show the microbiological purity of the final product and showing that contaminants have been controlled to an acceptable level, the results obtained and information on variability;

4.4. Methods used to show that there are no human or other mammalian pathogens as contaminants in the active agent, including in the case of protozoa and fungi, the effects of temperature (35°C and other relevant temperatures);

4.5. Methods to determine viable and non-viable (e.g. toxins) residues in or on treated products, foodstuffs, feedingstuffs, animal and human body fluids and tissues, soil, water and air, where relevant.

## V. BIOLOGICAL PROPERTIES OF THE ORGANISM

5.1. History of the organism and its uses including as far as is known its general natural history and, if relevant, its geographical distribution;

5.2. Relationship to existing pathogens of vertebrates, invertebrates, plants or other organisms;

5.3. Effects on target organism. Pathogenicity or kind of antagonism to the host. Details of host specificity range should be included;

5.4. Transmissibility, infective dose and mode of action including information on presence, absence or production of toxins with, if appropriate, information on their nature, identity, chemical structure and stability and potency;

5.5. Possible effects on non-target organisms closely related to the target organism including infectivity, pathogenicity, and transmissibility;

5.6. Transmissibility to other non-target organisms;

5.7. Any other biological effects on non-target organisms when properly used;

5.8. Infectivity and physical stability when properly used;

5.9. Genetic stability under environmental conditions of proposed use;

5.10. Any pathogenicity and infectivity to man and animals under conditions of immunosuppression;

5.11. Pathogenicity and infectivity for known parasites/predators of the target species

## VI. EFFECTIVENESS AND INTENDED USES

6.1. Harmful organisms controlled and materials, substances, organisms or products to be treated or protected;

6.2. Uses envisaged (e.g. insecticide, disinfectant, anti-fouling product, etc.);

6.3. Information or observations on undesirable or unintended side effects;

6.4. Information on the occurrence or possible occurrence of the development of resistance and possible management strategies to deal with this;

6.5. Effects on target organisms;

6.6. Category of user

## VII. TOXICOLOGICAL AND METABOLIC STUDIES

7.1. Acute toxicity
In cases where a single dose is not appropriate, a set of range finding tests must be carried out to reveal highly toxic agents and infectivity

1. oral;

2. dermal;

3. inhalation;

4. skin and where necessary eye irritation;

5. skin sensitisation and, where necessary, respiratory sensitisation and

6. for viruses and viroids, cell culture studies using purified infective virus and primary cell cultures of mammalian, avian and fish cells;

7.2. Sub-chronic toxicity 40-day study, two species, one rodent, one non-rodent;

1. oral administration;

2. other routes (inhalation, dermal) as appropriate and

3. for viruses and viroids test for infectivity carried out by bio assay or on a suitable cell culture at least seven days after administration to test animals;

7.3. Chronic toxicity
Two species, rodent and one other mammal, oral administration unless another route is more Appropriate

7.4. Carcinogenicity study
May be combined with studies in 6.3. One rodent and one other mammal

7.5. Mutagenicity studies
As specified in Annex IIA, Section VI, part 6.6

7.6. Reproductive toxicity

Teratogenicity test — rabbit and one rodent species. Fertility study — one species, minimum of two generations, male and female

7.7. Metabolism studies
Basic toxicokinetics, absorption (including dermal absorption) distribution and excretion in mammals including elucidation of metabolic pathways

7.8. Neurotoxicity studies: required where there is any indication of anticholinerterase activity or other neurotoxic effects. Delayed neurotoxicity tests using adult hens should be performed where appropriate

7.9. Immunotoxicity studies (e.g. allergenicity);

7.10. Incidental exposure studies: required where the active substance will be in products for use where human food or animal feedingstuffs are prepared, consumed or stored and where humans, livestock or pets are likely to be exposed to treated areas or materials;

7.11. Human exposure data including:

1. Medical data in anonymous form (if available);

2. Health records, medical surveillance data on manufacturing plants personnel (if available);

3. Epidemiological data (if available);

4. Poisoning incidents data;

5. Poisoning diagnosis (signs, symptoms) including details of any analytical tests;

6. Proposed treatment of poisoning and prognoses;

7.12. Summary of mammalian toxicology — conclusions (including NOAEL, NOEL and if appropriate ADI), overall evaluation with regard to all toxicological, pathogenicity and infectivity data and any other information concerning the active organism. Where possible suggested user protection measures should be included in summary form

**VIII. ECOTOXICOLOGICAL STUDIES**

8.1. Acute toxicity to fish;

8.2. Acute toxicity to *Daphnia magna;*

8.3. Effects on algae growth (inhibition test);

8.4. Acute toxicity on one other, non-aquatic, non-target organism;

8.5. Pathogenicity and infectivity for honeybees and earthworms;

8.6. Acute toxicity and/or pathogenicity and infectivity for other non-target organisms believed to be at risk;

8.7. Effects (if any) on other flora and fauna;

8.8. In cases where toxins are produced, data as outlined in Annex IIA, Section VII, parts 7.1 to 7.5 should be produced Fate and behaviour in the environment;

8.9. Spread, mobility, multiplication and persistence in air, soil and water;

8.10. In cases where toxins are produced, data as outlined in Annex IIA, Section VII, parts 7.6 to 7.8.

## IX. MEASURES NECESSARY TO PROTECT HUMANS, NON-TARGET ORGANISMS AND THE ENVIRONMENT

9.1. Methods and precautions to be taken for storage, handling, transport and use; or in the event of fire or other likely incident;

9.2. Any circumstances or environmental conditions under which the active organism should not be used;

9.3. The possibility of rendering the active organism non-infective and any method for doing this;

9.4. Consequences of the contamination of air, soil and water, particularly drinking water;

9.5. Emergency measures in case of accident;

9.6. Procedures for waste management of the active organism including leachate qualities on disposal;

9.7. Possibility of destruction or decontamination following release in or into the following: air, water, soil, others if appropriate.

## X. CLASSIFICATION AND LABELLING

Proposals for allocation to one of the risk groups outlined in Article 2(d) of Directive 90/679/EEC with justifications for the proposal together with indications on the need for products to carry the biohazard sign specified in Annex II to Directive 90/679/EEC

## XI. SUMMARY AND EVALUATION OF SECTIONS II TO X

# ANNEX IV.B

## DATA SET FOR BIOCIDAL PRODUCTS
## FUNGI, MICRO-ORGANISMS AND VIRUSES

1. Dossiers on biocidal products are required to address at least all the points listed under ‘Dossier requirements’. Responses are required to be supported by data. The dossier requirements must be in line with technical development.

2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases, a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Directive 88/379/EEC should be used wherever possible to minimise animal testing.

**Dossier requirements**

I. Applicant (presenter of the request)

II. Identity and composition of the biocidal product

III. Technical properties of the biocidal product and any biocidal properties additional to those of the active organism

IV. Methods for identification and analysis of the biocidal product

V. Intended uses and efficacy for those uses

VI. Toxicological information (additional to that for the active organism)

VII. Ecotoxicological information (additional to that for the active organism)

VIII. Measures to be adopted to protect humans, non-target organisms and the environment

IX. Classification, packaging and labelling of the biocidal product

X. Summary of Sections II to IX

The following data will be required to support submission on the above points.

**I. APPLICANT/PRESENTER OF THE REQUEST**

1.1. Name and address, etc.;

1.2. Manufacturers of biocidal products and active organisms including location of plants.

**II. IDENTITY OF BIOCIDAL PRODUCT**

2.1. Trade name or proposed trade name and manufacturer's development code number for biocidal product, if appropriate;

2.2. Detailed quantitative and qualitative information on the composition of the biocidal product (active organisms, inert components, extraneous organisms, etc.);

2.3. Physical state and nature of the biocidal product (emulsifiable concentrate, wettable powder, etc.);

2.4. Concentration of active organism in material used

**III. TECHNICAL AND BIOLOGICAL PROPERTIES**

3.1. Appearance (colour and odour);

3.2. Storage — stability and shelf-life. Effects of temperature, method of packaging and storage, etc. on retention of biological activity;

3.3. Methods for establishing storage and shelf-life stability;

3.4. Technical characteristics of the biocidal product;

3.4.1. Wettability;

3.4.2. Persistent foaming;

3.4.3. Suspensibility and suspension stability;

3.4.4. Wet sieve test and dry sieve test;

3.4.5. Particle size distribution, content of dust/fines, attrition and friability;

3.4.6. In the case of granules, sieve test and indications of weight distribution of the granules, at least of the fraction with particle sizes bigger than 1 mm;

3.4.7. Content of active substance in or on bait particles, granules or treated material;

3.4.8. Emulsifiability, re-emulsifiability, emulsion stability;

3.4.9. Flowability, pourability and dustability;

3.5. Physical and chemical compatibility with other products including biocidal products with which its use is to be authorized;

3.6. Wetting, adherence and distribution following application;

3.7. Any changes to biological properties of the organism is a result of formulation. In particular changes in pathogenicity on infectivity.

## IV. METHOD FOR IDENTIFICATION AND ANALYSIS

4.1. Analytical methods for determining the composition of the biocidal product;

4.2. Methods for determining residues (e.g. biotest);

4.3. Methods used to show microbiological purity of the biocidal product;

4.4. Methods used to show the biocidal product to be free from any human and other mammalian pathogens or, if need be, from pathogens harmful to non-target organisms and the environment;

4.5. Techniques used to ensure a uniform product and assay methods for its standardization.

## V. INTENDED USES AND EFFICACY FOR THESE USES

5.1. Use
Product-type (e.g. wood preservative, insecticide, etc.)

5.2. Details of intended use, (e.g. types of harmful organism controlled, materials to be treated, etc.);

5.3. Application rate;

5.4. Where necessary, in the light of the test results, any specific circumstances or environmental conditions under which the product may or may not be used;

5.5. Method of application;

5.6. Number and timing of applications;

5.7. Proposed instructions for use;

Efficacy data

5.8. Preliminary range-finding tests;

5.9. Field experimentation;

5.10. Information on the possible occurrence of the development of resistance;

5.11. Effects on the quality of materials or products treated

## VI. TOXICITY INFORMATION ADDITIONAL TO THAT REQUIRED FOR THE ACTIVE ORGANISM

6.1. Oral single dose;

6.2. Percutaneous single dose;

6.3. Inhalation;

6.4. Skin and where relevant eye irritation;

6.5. Skin sensitization;

6.6. Available toxicological data relating to non-active substances;

6.7. Operator exposure;

6.7.1. Percutaneous absorption/inhalation depending on formulation and method of application;

6.7.2. Likely operator exposure under field conditions, including where relevant quantitative analysis of operator exposure.

## VII. ECOTOXICITY INFORMATION ADDITIONAL TO THAT REQUIRED FOR THE ACTIVE ORGANISM

7.1. Observations concerning undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms or persistence in the environment

## VIII. MEASURES TO BE ADOPTED TO PROTECT MAN, NON-TARGET ORGANISMS AND THE ENVIRONMENT

8.1. Recommended methods and precautions concerning handling, storage, transport and use;

8.2. Re-entry periods, necessary waiting periods or other precautions to protect humans and animals;

8.3. Emergency measures in case of an accident;

8.4. Procedures for destruction or decontamination of the biocidal product and its packaging

## IX. CLASSIFICATION, PACKAGING AND LABELLING

9.1. Proposals including justification for the classification, packaging and labeling;

I. With regard to non-biological components of the product in accordance with Directive 88/379/EEC

- Hazard symbol(s);
- Indications of danger;
- Risk phrases;
- Safety phrases

II. With regard to the active organisms labelling with the appropriate risk group as outlined in Article 2(d) of Directive 90/679/EEC together with the biohazard sign specified in that Directive if appropriate;

9.2. Packaging (type, materials, size, etc.), compatibility of the biocidal product with proposed packaging materials;

9.3. Specimens of proposed packaging.

## X. SUMMARY OF SECTIONS II. to IX.

# ANNEX V.

## BIOCIDAL PRODUCT-TYPES AND THEIR DESCRIPTIONS AS REFERRED TO IN ARTICLE 2(1) (a) OF THIS DIRECTIVE
## (Referred in Article 2, of this Law on biocidal products)

These product-types exclude products where they are covered by the Directives mentioned in Article 1(2) of this Directive for the purposes of these Directives and their subsequent modifications.

**Main Group 1**: Disinfectants and general biocidal products
These product types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.

***Product-type 1:*** Human hygiene biocidal products
Products in this group are biocidal products used for human hygiene purposes.

***Product-type 2****:* Private area and public health area disinfectants and other biocidal products
Products used for the disinfection of air, surfaces, materials, equipment and furniture which are not used for direct food or feed contact in private, public and industrial areas, including hospitals, as well as products used as algaecides.
Usage areas include, *inter alia,* swimming pools, aquariums, bathing and other waters; air-conditioning systems; walls and floors in health and other institutions; chemical toilets, waste water, hospital waste, soil or other substrates (in playgrounds).

***Product-type 3****:* Veterinary hygiene biocidal products
Products in this group are biocidal products used for veterinary hygiene purposes including products used in areas in which animals are housed, kept or transported.

***Product-type 4****:* Food and feed area disinfectants
Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food, feed or drink (including drinking water) for humans and animals.

***Product-type 5:*** Drinking water disinfectants
Products used for the disinfection of drinking water (for both humans and animals).

**Main Group 2:** Preservatives
***Product-type 6****:* In-can preservatives
Products used for the preservation of manufactured products, other than foodstuffs or feedingstuffs, in containers by the control of microbial deterioration to ensure their shelf life.

***Product-type 7****:* Film preservatives
Products used for the preservation of films or coatings by the control of microbial deterioration in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.

***Product-type 8:*** Wood preservatives
Products used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms.
This product type includes both preventive and curative products.

***Product-type 9:*** Fibre, leather, rubber and polymerised materials preservatives
Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products and rubber by the control of microbiological deterioration.

***Product-type 10:*** Masonry preservatives
Products used for preservation and remedial treatment of masonry or other construction materials other than wood by the control of microbiological and algal attack.

***Product-type 11:*** Preservatives for liquid-cooling and processing systems
Products used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels.
Products used for the preservation of drinking water are not included in this product type.

***Product-type 12****: Slimicides*
Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.

***Product-type 13****: Metalworking-fluid preservatives*
Products used for the preservation of metalworking fluids by the control of microbial deterioration.

**Main Group 3:** Pest control
***Product-type 14****:* Rodenticides
Products used for the control of mice, rats or other rodents.

***Product-type 15****:* Avicides
Products used for the control of birds.

***Product-type 16:*** Molluscicides
Products used for the control of molluscs.

***Product-type 17****:* Piscicides
Products used for the control of fish; these products exclude products for the treatment of fish diseases.

***Product-type 18:*** Insecticides, acaricides and products to control other arthropods
Products used for the control of arthropods (e.g. insects, arachnids and crustaceans).

***Product-type 19:*** Repellents and attractants
Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds), by repelling or attracting, including those that are used for human or veterinary hygiene either directly or indirectly.

**Main Group 4**: Other biocidal products
***Product-type 20:*** Preservatives for food or feedstocks
Products used for the preservation of food or feedstocks by the control of harmful organisms.

***Product-type 21****:* Antifouling products
Products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.

***Product-type 22:*** Embalming and taxidermist fluids
Products used for the disinfection and preservation of human or animal corpses, or parts thereof.
***Product-type 23****:* Control of other vertebrates
Products used for the control of vermin.

# ANNEX VI.

## COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS FOR BIOCIDAL PRODUCTS

CONTENTS



**DEFINITIONS**
(a) *Hazard identification*

This is the identification of the adverse effects which a biocidal product has an inherent capacity to cause.

(b) *Dose (concentration) — response (effect) assessment*
This is the estimate of the relationship between the dose, or level of exposure, of an active substance or substance of concern in a biocidal product and the incidence and severity of an effect.

(c) *Exposure assessment*
This is the determination of the emissions, pathways and rates of movement of an active substance or a substance of concern in a biocidal product and its transformation or degradation in order to estimate the concentration/doses to which human populations, animals or environmental compartments are or may be exposed.

(d) *Risk characterisation*
This is the estimation of the incidence and severity of the adverse effects likely to occur in a human population, animals or environmental compartments due to actual or predicted exposure to any active substance or substance of concern in a biocidal product. This may include 'risk estimation' i.e. the quantification of that likelihood.

(e) *Environment*
Water, including sediment, air, land, wild species of fauna and flora, and any interrelationship between them, as well as any relationship with living organisms.

**INTRODUCTION**

1. This Annex lays down principles to ensure that evaluations made and decisions taken by a Member State concerning the authorisation of a biocidal product providing it is a chemical preparation results in a harmonised high level of protection for humans, animals and the environment in accordance with Article 5(1)(b) of this Directive.

2. In order to ensure a high and harmonised level of protection of human and animal health and of the environment, any risks arising from the use of a biocidal product shall be identified. To achieve this risk assessment shall be carried out to determine the acceptability or otherwise of any risks identified during the proposed normal use of the biocidal product. This is done by carrying out an assessment of the risks associated with the relevant individual components of the biocidal product.

3. A risk assessment on the active substance or substances present in the biocidal product is always required. This will already have been carried out for the purpose of Annexes I, IA or IB. This risk assessment shall entail hazard identification, and, as appropriate, dose (concentration) — response (effect) assessment, exposure assessment and risk characterisation. Where a quantitative risk assessment cannot be made a qualitative assessment shall be produced.

4. Additional risk assessments shall be carried out, in the same manner as described above, on any other substance of concern present in the biocidal product where relevant for the use of the biocidal product.

5. In order to carry out a risk assessment data are required. These data are detailed in Annexes II, III and IV and, recognizing that there are a wide variety of product types, are flexible according to the product type and associated risks. The data required shall be the minimum necessary to carry out an appropriate risk assessment. Member States should take due consideration of the requirements of

Articles 12 and 13 of this Directive in order to avoid duplication of data submissions. The minimum set of data required for an active substance in any biocidal product type, however, shall be that detailed in Annex VIIA to Directive 67/548/EEC; these data will already have been submitted and assessed as part of the risk assessment required for entry of the active substance into Annex I, IA or IB to this Directive. Data may also be required on a substance of concern present in a biocidal product.

6. The results of the risk assessments carried out on an active substance and on a substance of concern present in the biocidal product shall be integrated to produce an overall assessment for the biocidal product itself.

7. When making evaluations and taking decisions concerning the authorisation of a biocidal product the Member State shall:

a) take into consideration other relevant technical or scientific information which is reasonably available to them with regard to the properties of the biocidal product, its components, metabolites, or residues;

b) evaluate, where relevant, justifications submitted by the applicant for not supplying certain data.

8. The Member State shall comply with the requirements of mutual recognition as stated in Articles 4(1), (2) and (6) of this Directive.

9. It is known that many biocidal products present only minor differences in composition and this should be taken into account when evaluating dossiers. The concept of ‘frame-formulations’ is relevant here.

10. It is known that certain biocidal products are considered as posing only a low risk, these biocidal products, while complying with the requirements of this Annex, are subject to a simplified procedure as detailed in Article 3 of this Directive.

11. The application of these common principles shall lead to the Member State deciding whether or not a biocidal product can be authorised, such authorisation may include restrictions on use or other conditions. In certain cases the Member State may conclude that more data are required before an authorisation decision can be made.

12. During the process of evaluation and decision-making, Member States and applicants shall cooperate in order to resolve any questions on the data requirements quickly or to identify at an early stage any additional studies required, or to amend any proposed conditions for the use of the biocidal product or to modify its nature or its composition in order to ensure full compliance with the requirements of this Annex or of this Directive. The administrative burden, especially for small and medium-sized enterprises (SMEs), shall be kept to the minimum necessary without prejudicing the level of protection afforded to humans, animals and the environment.

13. The judgments made by the Member State during the evaluation and decision-making process must be based on scientific principles, preferably recognised at international level, and be made with the benefitof expert advice.

**EVALUATION**

General principles

14. The data submitted in support of an application for authorisation of a biocidal product shall be examined for completeness and overall scientific value by the receiving Member State. After

acceptance of these data the Member State shall utilise them by carrying out a risk assessment based on the proposed use of the biocidal product.

15. A risk assessment on the active substance present in the biocidal product shall always be carried out. If there are, in addition, any substances of concern present in the biocidal product then a risk assessment shall be carried out for each of these. The risk assessment shall cover the proposed normal use of the biocidal product together with a realistic worst-case scenario including any relevant production anddisposal issue either of the biocidal product itself or any material treated with it.

16. For each active substance and each substance of concern present in the biocidal product, the risk assessment shall entail a hazard identification and the establishment of appropriate no-observed-adverse-effect levels (NOAEL), where possible. It shall also include, as appropriate, a dose (concentration) — response (effect) assessment, together with an exposure assessment and a risk characterisation.

17. The results arrived at from a comparison of the exposure to the no-effect level concentrations for each of the active substances and any substances of concern shall be integrated to produce an overall risk assessment for the biocidal product. Where quantitative results are not available the results of the qualitative assessments shall be integrated in a similar manner.

18. The risk assessment shall determine:

a) the risk to humans and animals,

b) the risk to the environment,

c) the measures necessary to protect humans, animals and the general environment during both the proposed normal use of the biocidal product and in a realistic worst-case situation.

19. In certain cases it may be concluded that further data are required before a risk assessment can be finalised. Any such additional data requested shall be the minimum necessary to complete such a risk assessment.

Effects on humans

20. The risk assessment shall take account of the following potential effects arising from the use of the biocidal product and the populations liable to exposure.

21. The effects previously mentioned result from the properties of the active substance and any substance of concern present. They are:

- acute and chronic toxicity,

- irritation,

- corrosivity,

- sensitisation,

- repeated dose toxicity,

- mutagenicity,

- carcinogenicity,

- reproduction toxicity,

- neurotoxicity,

- any other special properties of the active substance or substance of concern,

- other effects due to physico-chemical properties.

22. The populations previously mentioned are:

- professional users,

- non-professional users,

- humans exposed indirectly via the environment.

23. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. If this results in the biocidal product being classified according to the requirements of Article 20 of this Directive then dose (concentration) — response (effect) assessment, exposure assessment and risk characterisation shall be required.

24. In those cases where the test appropriate to hazard identification in relation to a particular potential effect of an active substance or a substance of concern present in a biocidal product has been conducted but the results have not lead to classification of the biocidal product then risk characterisation in relation to that effect shall not be necessary unless there are other reasonable grounds for concern, e.g. adverse environmental effects or unacceptable residues.

25. The Member State shall apply paragraphs 26 to 29 when carrying out a dose (concentration) — response (effect) assessment on an active substance or a substance of concern present in a biocidal product.

26. For repeated dose toxicity and reproductive toxicity the dose response relationship shall be assessed for each active substance or substance of concern and, where possible, the no-observed-adverse-effect level (NOAEL) identified. If it is not possible to identify a NOAEL, the lowest-observed-adverse-effect level (LOAEL) shall be identified.

27. For acute toxicity, corrosivity and irritation, it is not usually possible to derive a NOAEL or LOAEL on the basis of tests conducted in accordance with the requirements of this Directive. For acute toxicity, the LD50 (median lethal dose) or LC50 (median lethal concentration) value or, where the fixed dose procedure has been used, the discriminating dose shall be derived. For the other effects it shall be sufficient to determine whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the product.

28. For mutagenicity and carcinogenicity it shall be sufficient to determine whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the biocidal product.
However, if it can be demonstrated that an active substance or a substance of concern identified as a carcinogen is non-genotoxic, it will be appropriate to identify a N(L)OAEL as described in paragraph 26.

29. With respect to skin sensitisation and respiratory sensitisation, in so far as there is no consensus on the possibility of identifying a dose/concentration below which adverse effects are unlikely to occur in a subject already sensitised to a given substance, it shall be sufficient to evaluate whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the biocidal product.

30. Where toxicity data derived from observations of human exposure, e.g. information gained from manufacture, from poison centres or epidemiology surveys, are available special consideration shall be given to those data when carrying out the risk assessment.

31. An exposure assessment shall be carried out for each of the human populations (professional users, non-professional users and humans exposed indirectly via the environment) for which exposure to a biocidal product occurs or can reasonably be foreseen. The objective of the assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of each active substance or substance of concern to which a population is, or may be exposed during use of the biocidal product.

32. The exposure assessment shall be based on the information in the technical dossier provided in conformity with Article 8 of this Directive and on any other available and relevant information.

Particular account shall be taken, as appropriate, of:

- adequately measured exposure data,

- the form in which the product is marketed,

-the type of biocidal product,

- the application method and application rate,

- the physico-chemical properties of the product,

- the likely routes of exposure and potential for absorption,

- the frequency and duration of exposure,

- the type and size of specific exposed populations where such information is available.

33. Where adequately measured, representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied.

These models shall:

- make a best possible estimation of all relevant processes taking into account realistic parameters and assumptions,

- be subjected to an analysis taking into account possible elements of uncertainty,

- be reliably validated with measurements carried out under circumstances relevant for the use of the model,

- be relevant to the conditions in the area of use.

Relevant monitoring data from substances with analogous use and exposure patterns or analogous properties shall also be considered.

34. Where, for any of the effects set out in paragraph 21 a NOAEL or LOAEL had been identified, the risk characterisation shall entail comparison of the NOAEL or LOAEL with the evaluation of the dose/concentration to which the population will be exposed. Where a NOAEL or LOAEL cannot be established a qualitative comparison shall be made.

Effects on animals

35. Using the same relevant principles as described in the section dealing with effects on humans, the Member State shall consider the risks posed to animals from the biocidal product.

Effects on the environment

36. The risk assessment shall take account of any adverse effects arising in any of the three environmental compartments — air, soil and water (including sediment) — and of the biota following the use of the biocidal product.

37. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. If this results in the biocidal product being classified according to the requirements of this Directive then dose (concentration) — response (effect) assessment, exposure assessment and risk characterisation shall be required.

38. In those cases where the test appropriate to hazard identification in relation to a particular potential effect of an active substance or a substance of concern present in a biocidal product has been conducted but the results have not led to classification of the biocidal product then risk characterisation in relation to that effect shall not be necessary unless there are other reasonable grounds for concern. Such grounds may derive from the properties and effects of any active substance or substance of concern in the biocidal product, in particular:

- any indications of bioaccumulation potential,

- the persistence characteristics,

- the shape of the toxicity/time curve in ecotoxicity testing,

- indications of other adverse effects on the basis of toxicity studies (e.g. classification as a mutagen),

- data on structurally analogous substances,

- endocrine effects.

39. A dose (concentration) — response (effect) assessment shall be carried out in order to predict the concentration below which adverse effects in the environmental compartment of concern are not expected to occur. This shall be carried out for the active substance and for any substance of concern present in the biocidal product. This concentration is known as the predicted no-effect concentration (PNEC). However, in some cases, it may not be possible to establish a PNEC and a qualitative estimation of the dose (concentration) — response (effect) then has to be made.

40. The PNEC shall be determined from the data on effects on organisms and ecotoxicity studies submitted in accordance with requirements of Article 8 of this Directive. It shall be calculated by applying an assessment factor to the values resulting from tests on organisms, e.g. LD50 (median lethal dose), LC50 (median lethal concentration), EC50 (median effective concentration), IC50 (concentration causing 50% inhibition of a given parameter, e.g. growth), NOEL(C) (no-observed-effect level (concentration)), or LOEL(C) (lowest-observed-effect level (concentration)).

41. An assessment factor is an expression of the degree of uncertainty in extrapolation from test data on a limited number of species to the real environment. Therefore, in general, the more extensive the data and the longer the duration of the tests, the smaller is the degree of uncertainty and the size of the assessment factor.
The specifications for the assessment factors shall be elaborated in the notes for technical guidance which, to this end, shall be based particularly on the indications given in Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and environment from substances notified in accordance with Council Directive 67/548/EEC(*).

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(*) OJ L 227, 8.9.1993, p. 9.

42. For each environmental compartment an exposure assessment shall be carried out in order to predict the concentration likely to be found of each active substance or substance of concern present in the biocidal product. This concentration is known as the predicted environmental concentration (PEC). However in some cases it may not be possible to establish a PEC and a qualitative estimate of exposure then has to be made.

43. A PEC, or where necessary a qualitative estimate of exposure, need only be determined for the environmental compartments to which emissions, discharges, disposal or distributions including any relevant contribution from material treated with biocidal products are known or are reasonably foreseeable.

44. The PEC, or qualitative estimation of exposure, shall be determined taking account of, in particular, and if appropriate:

- adequately measured exposure data,

- the form in which the product is marketed,

- the type of biocidal product,

- the application method and application rate,

- the physico-chemical properties,

- breakdown/transformation products,

- likely pathways to environmental compartments and potential for adsorption/desorption and degradation,

- the frequency and duration of exposure.

45. Where adequately measured, representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied. The characteristics of these models shall be as listed in paragraph 33. Where appropriate, on a case-by-case basis, relevant

monitoring data from substances with analogous use and exposure patterns or analogous properties should also be considered.

46. For any given environmental compartment, the risk characterisation shall, as far as possible, entail comparison of the PEC with the PNEC so that a PEC/PNEC ratio may be derived.

47. If it has not been possible to derive a PEC/PNEC ratio, the risk characterisation shall entail a qualitative evaluation of the likelihood that an effect is occurring under the current conditions of exposure or will occur under the expected conditions of exposure.

**UNACCEPTABLE EFFECTS**

48. Data shall be submitted to and evaluated by the Member State to assess whether the biocidal product does not cause unnecessary suffering in its effect on target vertebrates. This shall include an evaluation of the mechanism by which the effect is obtained and the observed effects on the behaviour and health of the target vertebrates; where the intended effect is to kill the target vertebrate the time necessary to obtain the death of the target vertebrate and the conditions under which death occurs shall be evaluated.

49. The Member State shall, where relevant, evaluate the possibility of the development of resistance to an active substance in the biocidal product by the target organism.

50. If there are indications that any other unacceptable effects may occur the Member State shall evaluate the possibility of such effects occurring. An example of such an unacceptable effect would be an adverse reaction to fastenings and fittings used in wood following the application of a wood preservative.

**EFFICACY**

51. Data shall be submitted and evaluated to ascertain if the efficacy claims of the biocidal product can be substantiated. Data submitted by the applicant or held by the Member State must be able to demonstrate the efficacy of the biocidal product against the target organism when used normally in accordance with the conditions of authorisation.

52. Testing should be carried out according to Community guidelines if these are available and applicable. Where appropriate, other methods can be used as shown in the list below. If relevant acceptable field data exist, these can be used.

- ISO, CEN or other international standard method

- national standard method

- industry standard method (accepted by Member State)

- individual producer standard method (accepted by Member State)

- data from the actual development of the biocidal product (accepted by Member State).

Summary

53. In each of the areas where risk assessments have been carried out, i.e. effects on man, animals, and the environment, the Member State shall combine the results for the active substance together

with the results for any substance of concern to produce an overall assessment for the biocidal product itself. This should take account of any likely synergistic effects of the active substance(s) and substances of concern in the biocidal product.

54. For biocidal products containing more than one active substance any adverse effects shall also be combined to produce an overall effect for the biocidal product itself.

## DECISION MAKING

### General principles

55. Subject to paragraph 96, the Member State shall come to a decision regarding the authorisation for use of a biocidal product as a result of the integration of the risks arising from each active substance together with the risks from each substance of concern present in the biocidal product. The risk assessments shall cover normal use of the biocidal product together with a realistic worst-case scenario including any relevant disposal issue either of the biocidal product itself or any material treated with it.

56. In making a decision concerning authorisation, the Member State shall arrive at one of the following conclusions for each product type and for each area of use of the biocidal product for which application has been made:

1. the biocidal product cannot be authorised;

2. the biocidal product can be authorised subject to specific conditions/restrictions;

3. more data is required before a decision on authorisation can be made.

57. If the conclusion arrived at by the Member State is that additional information or data are required before an authorisation decision can be made, then the need for any such information or data shall be justified. This additional information or data shall be the minimum necessary to carry out a further appropriate risk assessment.

58. The Member State shall comply with the principles of mutual recognition as detailed in Article 4 of this Directive.

59. The Member State shall apply the rules concerning the concept of ‘frame formulations’ when making an authorisation decision on a biocidal product.

60. The Member State shall apply the rules concerning the concept of ‘low risk’ products when making an authorisation decision on such a biocidal product.

61. The Member State shall only grant authorisation to those biocidal products which, when used according to their conditions of authorisation, do not present an unacceptable risk to humans, animals or the environment, are efficacious and which contain active substances permitted at Community level to be used in such biocidal products.

62. The Member State shall impose, where appropriate, conditions or restrictions when giving authorisations. The nature and severity of these shall be selected on the basis of, and be appropriate to, the nature and extent of the expected advantages and the risks likely to arise from the use of the biocidal product.

63. In the decision-making process the Member State shall take into consideration the following:

- the results of the risk assessment, in particular the relationship between exposure and effect,

- the nature and severity of the effect,

- the risk management which can be applied,

- the field of use of the biocidal product,

- the efficacy of the biocidal product,

- the physical properties of the biocidal product,

- the benefits of using the biocidal product.

64. The Member State shall, when taking a decision concerning the authorisation of a biocidal product, take into account the uncertainty arising from the variability in the data used in the evaluation and decision-making process.

65. The Member State shall prescribe that biocidal products shall be used properly. Proper use shall include application at an efficacious dose and minimisation of use of biocidal products where possible.

66. The Member State shall take the necessary measures to ensure that the applicant proposes a label, and, where relevant, the safety-data sheet, for the biocidal product which:

- fulfils the requirements of Articles 20 and 21 of this Directive,

- contains the information on the protection of users required by Community legislation on worker protection,

- specifies in particular the conditions or restrictions under which the biocidal product may or may not be used.

Before issuing an authorisation the Member State shall confirm that these requirements must be satisfied.

67. The Member State shall take the necessary measures to ensure that the applicant proposes packaging and, where appropriate, the procedures for destruction or decontamination of the biocidal product and its packaging or any other relevant material associated with the biocidal product, which conforms to the relevant regulatory provisions.

Effects on humans

68. The Member State shall not authorise a biocidal product if the risk assessment confirms that, in foreseeable application including a realistic worst possible scenario, the product presents an unacceptable risk to humans.

69. The Member State shall consider possible effects on all human populations, namely professional users, non-professional users and humans exposed directly or indirectly through the environment when making a decision on the authorisation of a biocidal product.

70. The Member State shall examine the relationship between the exposure and the effect, and use this in the decision-making process. A number of factors need to be considered when examining

this relationship and one of the most important is the nature of the adverse effect of the substance. These effects include acute toxicity, irritancy, corrosivity, sensitisation, repeated dose toxicity, mutagenicity, carcinogenicity, neurotoxicity, reproduction toxicity together with physico-chemical properties, and any other adverse properties of the active substance or substance of concern.

71. The Member State shall, where possible, compare the results obtained with those obtained from previous risk assessments for an identical or similar adverse effect and decide on an appropriate margin of safety (MOS) when making an authorisation decision.
An appropriate MOS is typically 100 but an MOS higher or lower than this may be appropriate depending on, among other things, the nature of the critical toxicological effect.

72. The Member State shall, if appropriate, impose, as a condition of authorisation, the wearing of personal protective equipment such as respirators, breathing-masks, overalls, gloves and goggles in order to reduce exposure for professional operators. Such equipment must be readily available to them.

73. If for non-professional users the wearing of personal protective equipment would be the only possible method for reducing exposure, the product shall not normally be authorised.

74. If the relationship between the exposure and the effect cannot be reduced to an acceptable level then no authorisation can be given by the Member State for the biocidal product.

75. No biocidal product classified according to Article 20(1) of this Directive as toxic, very 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 be authorised for use by the general public.

Effects on animals

76. The Member State shall not authorise a biocidal product if the risk assessment confirms that, in normal use, the biocidal product presents an unacceptable risk to non-target animals.

77. Using the same relevant criteria as described in the section dealing with effects on humans, the Member State shall consider the risks posed to animals from the biocidal product when making an authorization decision.

Effects on the environment

78. The Member State shall not authorise a biocidal product if the risk assessment confirms that the active substance, or any substance of concern, or any degradation, or reaction product presents an unacceptable risk in any of the environmental compartments, water (including sediment), soil and air.
This shall include the assessment of risks to non-target organisms in these compartments.
In considering whether there is an unacceptable risk Member States shall, when coming to a final decision in accordance with paragraph 96, take into account the criteria in paragraphs 81 to 91.

79. The basic tool used in the decision making is the PEC/PNEC ratio or, if this is not available, a qualitative estimation. Due consideration shall be given to the accuracy of this ratio due to variability in the data used both in measurements of concentration and of estimation.
In the determination of the PEC the most appropriate model should be used taking into account the environmental fate and behaviour of the biocidal product.

80. For any given environmental compartment if the PEC/PNEC ratio is equal to or less than 1 the risk characterisation shall be that no further information and/or testing are necessary.
If the PEC/PNEC ratio is greater than 1 the Member State shall judge, on the basis of the size of that ratio and on other relevant factors, if further information and/or testing are required to clarify the concern or if risk reduction measures are necessary or if the product cannot be given an authorization at all. Relevant factors to be considered are those previously mentioned in paragraph 38.*Water*

81. The Member State shall not authorise a biocidal product, if under the proposed conditions of use, the foreseeable concentration of the active substance or of any other substance of concern or of relevant metabolites or breakdown or reaction products in water (or its sediments) has an unacceptable impact on non-target species in the aquatic, marine or estuarine environment unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

82. The Member State shall not authorise a biocidal product if, under the proposed conditions of use, the foreseeable concentration of the active substance or of any other substance of concern or of relevant metabolites or breakdown or reaction products in groundwater exceeds the lower of the following concentrations:

a) the maximum permissible concentration laid down by Directive 80/778/EEC, or

b) the maximum concentration as laid down following the procedure for including the active substance in Annex I, IA or IB to this Directive, on the basis of appropriate data, in particular toxicological data unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.

83. The Member State shall not authorise a biocidal product if the foreseeable concentration of the active substance or a substance of concern or of relevant metabolites, breakdown or reaction products to be expected in surface water or its sediments after use of the biocidal product under the proposed conditions of use:

- exceeds, where the surface water in or from the area of envisaged use is intended for the abstraction of drinking water, the values fixed by

- Council Directive 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States (1),

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(1) OJ L 194, 25.7.1975, p. 26. Directive as last amended by Directive 91/692/EEC (OJ L 377, 31.12.1991, p. 48).

- Directive 80/778/EEC or

- has an impact deemed unacceptable on non-target species unless it is scientifically demonstrated that under relevant field conditions this concentration is not exceeded.

84. The proposed instructions for use of the biocidal product, including procedures for cleaning application equipment, must be such that the likelihood of accidental contamination of water or its sediments is minimised.

**Soil**

85. Where unacceptable contamination of soil is likely to occur, the Member State shall not authorise a biocidal product if the active substance or substance of concern contained in it, after use of the biocidal product:

- during tests in the field, persists in soil for more than one year, or

- during laboratory tests, forms non-extractable residues in amounts exceeding 70 % of the initial dose after 100 days with a mineralisation rate of less than 5% in 100 days,

- has unacceptable consequences or effects on non-target organisms, unless it is scientifically demonstrated that under field conditions there is no unacceptable accumulation in soil.

**Air**

86. The Member State shall not authorise a biocidal product where there is a foreseeable possibility of unacceptable effects on the air compartment unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.
*Effects on non-target organisms*

87. The Member State shall not authorise a biocidal product where there is a reasonably foreseeable possibility of non-target organisms being exposed to the biocidal product if for any active substance or substance of concern:

- the PEC/PNEC is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable effects occur after use of the biocidal product according to the proposed conditions of use, or

- the bioconcentration factor (BCF) related to fat tissues in non-target vertebrates is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable effects occur, either directly or indirectly, after use of the product according to the proposed conditions of use.

88. The Member State shall not authorise a biocidal product where there is a reasonably foreseeable possibility of aquatic organisms including marine and estuarine organisms being exposed to the biocidal product if for any active substance or substance of concern in it:

- the PEC/PNEC is above 1 unless it is clearly established in the risk assessment that under field conditions the viability of aquatic organisms including marine and estuarine organisms is not threatened by the biocidal product according to the proposed conditions of use, or

- the bioconcentration factor (BCF) is greater than 1 000 for substances which are readily biodegradable or greater than 100 for those which are not readily biodegradable unless it is clearly established in the risk assessment that under field conditions no unacceptable impact, either directly or indirectly, occurs on the viability of exposed organisms including marine and estuarine organisms after use of the biocidal product according to the proposed conditions of use.
By way of derogation from this paragraph, Member States may, however, authorise an anti-fouling product used on commercial, public service and naval seagoing vessels for a period of up to 10 years from the date on which this Directive enters into force if similar fouling control cannot be achieved by other practicable means. When implementing this provision, Member States shall, if appropriate, take into account relevant International Maritime Organisation (IMO) resolutions and recommendations.

89. The Member State shall not authorise a biocidal product where there is a reasonably foreseeable possibility of micro-organisms in sewage treatment plants being exposed to the biocidal product if for any active substance, substance of concern, relevant metabolite, breakdown or reaction product the PEC/PNEC ratio is above 1 unless it is clearly established in the risk assessment that under field

conditions no unacceptable impact, either directly or indirectly, occurs on the viability of such micro-organisms.

Unacceptable effects

90. If the development of resistance to the active substance in the biocidal product is likely the Member State shall take steps to minimise the consequences of this resistance. This may involve modification of the conditions of authorisation or even refusal of any authorisation.

91. An authorisation for a biocidal product intended to control vertebrates shall not be given unless:

- death is synchronous with the extinction of consciousness, or,

- death occurs immediately, or,

- vital functions are reduced gradually without signs of obvious suffering.
For repellent products, the intended effect shall be obtained without unnecessary suffering and pain for the target vertebrate.

**Efficacy**

92. Member States shall not authorise a biocidal product which does not possess acceptable efficacy when used in accordance with the conditions specified on the proposed label or with other conditions of authorisation.

93. The level, consistency and duration of protection, control or other intended effects must, as a minimum, be similar to those resulting from suitable reference products, where such products exist, or to other means of control. Where no reference products exist, the biocidal product must give a defined level of protection or control in the areas of proposed use. Conclusions as to the performance of the biocidal product must be valid for all areas of proposed use and for all areas in the Member State except where the proposed label prescribes that the biocidal product is intended for use in specific circumstances. Member States shall evaluate dose response data generated in trials (which must include an untreated control) involving dose rates lower than the recommended rate, in order to assess if the recommended dose is the minimum necessary to achieve the desired effect.

**Summary**

94. In each of the areas where risk assessments have been carried out, i.e. effects on humans, animals, and the environment, the Member State shall combine the conclusions arrived at for the active substance and the substances of concern to produce an overall conclusion for the biocidal product itself. A summary should also be made of the efficacy assessment and of the unacceptable effects.
The result shall be:

- a summary of the effects of the biocidal product on humans,

- a summary of the effects of the biocidal product on animals,

- a summary of the effects of the biocidal product on the environment,

- a summary of the efficacy assessment,

- a summary of the unacceptable effects.

**OVERALL INTEGRATION OF CONCLUSIONS**

95. The Member State shall combine the individual conclusions arrived at with regard to effects of the biocidal product on the three sectors namely, humans, animals and the environment to arrive at an overall conclusion for the global effect of the biocidal product.

96. The Member State shall then take due consideration of any relevant unacceptable effects, the efficacy of the biocidal product and the benefits of using the biocidal product before taking an authorization decision on the biocidal product.

97. The Member State shall ultimately decide whether or not the biocidal product can be authorised and whether this authorisation shall be subject to any restrictions or conditions in conformity with this Annex and this Directive.

## ANEX VII.

**Republic of Kosovo**

*Ministry of Environment And Spatial Plannin*

**NOTIFICATION OF A BIOCIDAL PRODUCT**
**(please read attached instructions)**

| | | | | | |
|---|---|---|---|---|---|
| **1. Name of the product** | | | | | |
| 2. Date of submission of the notification | Notification number (to be filled in by the Competent Authority for Biocides) | | | | |
| 3. Name of the Applicant/ Applying Company | | | | | |
| 4. Qualification of the Appli-cant/Applying Company (tick appropriate box) | Manufacture r | *Processor* | Importer | Distributor | Formulator |
| | | | | | |
| 5. Contact details | | | Telephone. | | |
| Address of the Appli-cant/Applying Company | | | Fax. | | |
| Business number | | | E-mail: | | |
| Name of contact person | | | | | |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 6. Intended use of the product (description) | | | | | | | | | | | | |
| 7. Product type (fill in every appropriate PT number ) | | | | | | | | | | | | |
| 8. Marketed / Not marketed within EU | | | | Yes. | | | | No. | | | | |
| 9. If marketed in EU, give: | Product name | | | | | | | | | | | |
| | EU country | | | | | | | | | | | |
| | Authorization / registration number | | | | | | | | | | | |
| 10. User category | industrial | | | professional | | | | non-professional | | | | |
| 11. Type of use | INDOOR | | | OUTDOOR | | | | CLOSED SYSTEM | | | | |
| 12. Physical state of biocidal product | Solid | | Liquid | | Gas | | Aerosol | | Other (specify) | | | |
| 13. Safety data sheet | Attached | | | | | Not attached | | | | | | |
| Classification and libeling of the product | Risk phrase(R) | | | | | Safety (instruction) phrase(S) | | | | | | |
| 14. Bazard symbole if applicable | | | | | | | | | | | | |

## 15. Active Substances

| IUPAC Name | Common name | EC Number | CAS Number | Included in Annex A to the Law (yes/no) | Included in Annex I or IA to the Law (yes/no) | Concentration in metric units $g.l^{-1}$ ☐ $g.kg^{-1}$ ☐ |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

## 16. Other Substances

| IUPAC -Name | Common name | EC- Number | CAS Number | Concentration in metric units $g.l^{-1}$ ☐ $g.kg^{-1}$ ☐ |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

[*] **Annex A – List of existing active substance**

**17. FURTHER INFORMATION TO BE REQUIRED:**

**i)** PRODUCT LABEL

ii) OTHER DATA (if available)

iii) IUCLID file (information can be checked on the website http://ecb.jrc.it/esis/index.php?PGM=dat)

iv) a) Classification of the active and other substances according to the classification and labelling system existing in Kosovo at the time of submitting the notification form; information to be attached

b) Please add classification and labelling according to the Kosovo Law on Classification and Labelling (i. e. classification according to Annex I, of Directive 67/548/EC which can be checked on http://ecb.jrc.it, or provisional self-classification), information to be attached.

| | |
|---|---|
| **1** | Fill in the commercial name of the biocidal product placed on the Kosovo market, i.e. the trade name as on the package label |
| **2** | Fill in the date of postage of the notification or actual submission to the Kosovo Competent Authority for Biocides |
| **3** | Official name of the Kosovo applicant (company or any other legal person) |
| **4** | Mark with a cross in the appropriate box and/or boxes |
| **5** | Fill in the official place of business or official mailing address of the company, the business number, telephone number, fax number, e-mail address and the full name of the contact person for further communication |
| **6** | Fill in the intended use or uses of the product for each product type in accordance with the label claim; the information should include the target organisms, type of application etc. and should be sufficient to unequivocally allocate the biocidal product to the product type(s) as listed under pt. 7. |
| **7** | Fill in every product type (PT) number, to which the biocidal product has to be allocated, according to the following classification :<br><br>**Main Group 1: Disinfectants & General Biocidal Products**<br>Product type: |

| | | |
|---|---|---|
| o 1 | o Human hygiene biocidal products | Used for human hygiene purposes. |
| o 2 | o Private and public health area disinfectants and other biocidal products | Used for the disinfection of air, surfaces, materials, equipment and furniture which are not used for direct food or feed contact in private, public or industrial areas, including hospitals, as well as products used as algaecides. Usage areas include swimming pools, aquariums, bathing and other waters; air-conditioning units; walls and floors in health and other institutions; chemical toilets, waste water, hospital waste, soil and other substrates (in playgrounds). |
| o 3 | o Veterinary hygiene biocidal products | Includes products used in areas in which animals are housed, kept or transported. |
| o 4 | o Food and feed area disinfectants | Used for the disinfection of equipment, containers, consumption utensils, surfaces or paperwork associated with the production, transport, storage, or consumption of food, feed or drink (including drink water) for humans and animals. |
| o 5 | o Drinking water disinfectants | For both humans and animals. |

Main Group 2: Preservatives

| | | |
|---|---|---|
| o 6 | o In-can preservatives | Used for the preservation of manufactured products, other than foodstuffs or feeding stuffs, in containers by the control of microbial deterioration to ensure their shelf life. |

| | | |
|---|---|---|
| o 7 | o Film preservatives | Used for the preservation of films or coatings by the control of microbial deterioration in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works etc. |
| o 8 | o Wood preservatives | For wood from and including saw-mill stage, and wood products (including preventative and curative products). |
| o 9 | o Fibre, leather, rubber and polymerised materials preservatives | Includes the preservation of fibrous materials, such as paper or textile products. |
| o 10 | o Masonry preservatives | Used for the preservation and remedial treatment of masonry or other construction materials other than wood by the control of microbiological algal attack. |
| o 11 | o Preservatives for liquid-cooling and processing systems | Use for the preservation of water and other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels (not drinking water preservation products). |
| o 12 | o Slimicides | Used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, and porous sand strata in oil extraction. |
| o 13 | o Metalworking-fluids preservatives | Products used for the preservation of metalworking fluids by the control of microbial deterioration. |
| Main Group 3: Pest Control | | |
| o 14 | o Rodenticides | Control of mice, rats or other rodents. |
| o 15 | o Avicides | Control of birds. |
| o 1 | o Molluscicides | Control of molluscs, e.g. snails that may clog pipes. |

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|---|---|---|---|
| | 6 | | |
| | o 17 | o Piscicides | Control of fish; excludes products for the treatment of fish diseases. |
| | o 18 | o Insecticides, acaricides and to control other arthropods | e.g. insects arachnids and crustaceans |
| | o 19 | o Repellents or attractants | Used to control, harmful organisms (invertebrates such as fleas, vertebrates such as birds), by repelling or attracting, including those that are used for human or veterinary hygiene either directly or indirectly. |
| | Main Group 4: Other Biocidal Products | | |
| | o 20 | o Preservatives for food and feedstocks | Used for the preservation of food or feedstuffs by the control of harmful organisms. |
| | o 21 | o Antifouling products | Used to control growth and settlement of fouling organisms (microbes and higher forms of plant and animal species) on vessels, aquaculture equipment or other structures used in water. |
| | o 22 | o Embalming or taxidermist fluids | Used for the disinfection and preservation of human or animal corpses, or parts thereof. |
| | o 23 | o Control of vertebrates | i.e. vermin |

| | |
|---|---|
| **8** | Indicate whether the biocidal product is already marketed within the EU. Mark the appropriate box. |
| **9** | Fill in the appropriate boxes |
| **10** | Mark the appropriate box or boxes. |
| **11** | Mark the appropriate box or boxes. |
| **12** | Mark the appropriate box or boxes. |
| **13** | Mark the appropriate box. |

| | |
|---|---|
| | If a Safety data sheet (SDS) is not attached, fill in the risk phrase(s) and safety (instruction) phrase(s) according to the classification and labelling system existing in Kosovo for biocidal products at the time of submitting the notification form. Add the classification and labelling according to the Law on Classification and Labelling if already published and as far as relevant (i. e. classification according to transposed Annex I, of Directive 67/548/EC (can be checked on http://ecb.jrc.it ) or provisional self-classification. |
| **14** | Provide the respective hazard symbol according to the same regulations and principles as mentioned under point 13. |
| **15** | Use separate line for each active substance. The common name of an active substance must be given (in the listed priority sequence)<br>a) as registered in the list contained in Annex I, to Directive 67/548/EEC (Link http://ecb.jrc.it/classification-labelling/ Search CLASS LAB/ Search Annex I) or, if the name is not included therein,<br>b) as given in the European Inventory of Existing Chemical Substances (EINECS, Link: http://ecb.jrc.it/esis/), or, if the name is not included therein,<br>c) the active substance must be given its International Standards Organisation (ISO) common name (Link: http://www.alanwood.net/pesticides/). If the latter is not available,<br>d) the substance must be designated by its chemical designation according to International Union of Pure and Applied Chemistry (IUPAC) rules (Link: http://www.chem.qmul.ac.uk/iupac/).<br>The EC- number and the CAS number can be checked in EINECS, available through the European Chemical Substances Information System (Link: http://ecb.jrc.it/esis/),<br>Active substances included in Annex A, to the Law on Biocidal Products are allowed on the EU market because they are under evaluation in the EU Review Programme, i.e. they have been notified as existing active substances under the Biocidal Products Directive 98/8/EC: Please indicate (fill in Yes or No) whether the active substance is included in the specified Annex to the Law on Biocidal Products.<br>Information on the existing active substances in the EU Review Programme and the underlying legislation is available on: http://ec.europa.eu/environment/biocides/index.htm.<br>Concentration: please mark the appropriate metric unit and fill in the respective concentration. In total, the concentrations given for the active substance(s) and all other substances should yield 1000 g/l or 1000 g/kg. |
| **16** | Use separate line for each other substance. For the common name of the other substances the same principles as under point 15 apply, in the listed priority sequence.<br>The EC -number and the CAS- number can be checked in EINECS, available through the European Chemical Substances Information System (Link: http://ecb.jrc.it/esis/).<br>Concentration: please mark the appropriate metric unit and fill in the respective concentration. In total, the concentrations given for the active substance(s) and all other substances should yield 1000 g/l or 1000 g/kg. |
| **17** | The information and or /documents under i) to iv) a) are obligatory. The information under iv) b) is required according to the legal status of the Law on Classification and Labelling.<br>Information on classification and labelling of substances according to Annex I, of 67/548/EC can be checked through http://ecb.jrc.it/classification-labelling/ Search CLASSLAB/Search Annex I. |