Republic of Latvia

Cabinet
Regulation No 184
Adopted 15 April 2003

Requirements for Activities with Biocidal Products

Issued pursuant to
Section 9, Paragraph seven of
the Law On Chemical Substances and Chemical Products

I. General Provisions

1. These Regulations prescribe the requirements to be complied with in performing activities with biocidal products, except for such activities with chemical substances and chemical products or other products and materials the composition of which is the same as or similar to biocidal products, but which are:

1.1. medicinal products, pharmaceutical and other medical products;

1.2. veterinary pharmaceutical products including homeopathic and immunological products;

1.3. food additives;

1.4. animal feed and animal feed additives; and

1.5. plant protection materials.

2. An active substance is a chemical substance or a virus, a fungus or another micro-organism, which is utilised for the production of a biocidal product and has an effect on harmful organisms.

3. Residues are substances included in the composition of a biocidal product, remaining after the utilisation of the biocidal product, including the products of degradation and metabolism (metabolites) of such substances and products resulting from the reaction thereof.

4. A harmful organism is an organism, the presence of which is undesirable or which has a detrimental effect on humans, animals and the environment, on products produced or utilised, or on an economic activity.

5. A target organism is a harmful organism, which it is intended to destroy or otherwise affect by subjecting it to the relevant biocidal product. A target species is a species of

harmful organism, which it is intended to destroy or otherwise affect, by subjecting it to the relevant biocidal product.

6. Frame-formulation is the common characterisation of several biocidal products if the relevant biocidal products have the same type of utilisation, identical effect on target organisms, active substances with identical properties and other components, impurities or additives, which do not reduce the effect of biocidal products and do not increase the risk caused by biocidal products to humans or environment (including the percentage reduction of the active substance in biocidal products, variations of percentage composition of one or several inactive substances in biocidal products, as well as replacement of pigments, dyes and perfumes by other similar substances performing the same functions), and such products are used by the same groups of users.

7. A basic substance is a chemical substance which in most cases is used otherwise than for the destruction or affection of harmful organisms, and is not marketed as a biocidal product, but which is mentioned in the list of basic substances and which can be utilised as a biocidal product (without ancillary substances) or as an active substance in the composition of a biocidal product if the ancillary substances are not potentially dangerous.

8. A potentially dangerous substance is a substance which is not an active substance, but a dangerous chemical substance, dangerous chemical product or a product having such properties which may cause an adverse effect on humans, animals or the environment and which is present or is produced by the composition of a biocidal product in such concentration as to cause such an effect.

9. Low-risk biocidal products are biocidal products which do not contain potentially dangerous substances and do not cause risk or cause minimum risk to humans, animals and the environment under the intended conditions of use, and the active substance of which is mentioned in the European Community list of active substances included in the low-risk biocidal products (hereinafter – list of low-risk biocidal products), if the conditions referred to in this list are complied with.

10. Importation of biocidal products or active substances, including importation into the customs territory, sale or other type of supply for payment or free of charge and storage after sale or supply, except for disposal, or transit operations under customs supervision (hereinafter – trade) and manufacturing is permitted only if:

10.1. recording, inventory and registration of existing active substances (placed on the market prior to 14 May 2000) or biocidal products (containing one or several existing active substances) have been performed or an authorisation has been received for the use of the biocidal product or the active substance (hereinafter – authorisation for use) in conformity with the requirements referred to in Chapters II, III and IV of these Regulations – within the time periods co-ordinated with the Latvian Environment Agency. The registration or an authorisation for use is not necessary if the active

substance is a basic substance and potentially dangerous substances are not included in the composition of the biocidal product;

10.2. the effects of a new active substance (placed on the market after 14 May 2000) or biocidal product (containing one or several new active substances) on the environment and the health of animals and humans has been investigated, as well as temporary registration, registration has been performed or an authorisation for use has been received in conformity with the requirements referred to in Chapters II, III and IV of these Regulations. The temporary registration, registration or an authorisation for use is not necessary if the active substance is a basic substance and potentially dangerous substances are not included in the composition of the biocidal product; and

10.3. scientific experiments or studies are carried out with a new active substance (placed on the market after 14 May 2000) or biocidal product containing the new active substance, or experimental manufacturing of a new active substance or biocidal product is also carried out – the relevant scientific experiments, experimental manufacturing or studies shall comply with the requirements referred to in Paragraphs 5 and 6 of these Regulations.

11. The Latvian Environment Agency (hereinafter – Agency) shall:

11.1. register biocidal products if the biocidal products are low-risk biocidal products;

11.2. issue authorisations for use if the active substance is included in the European Community list of active substances (hereinafter – list of active substances) to be utilised for the production of biocidal products taking into account the conditions referred to in the relevant list for the particular biocidal product or the active substance;

11.3. perform temporary registration of biocidal products, if:

11.3.1. the biocidal product and the active substance are not listed in the list of active substances, the list of basic substances or the list of low-risk biocidal products; and

11.3.2. the active substance is listed in the list of basic substances, but the biocidal product includes one or several potentially dangerous substances; and

11.4. upon request provide the necessary information regarding the lists of low-risk biocidal products, active substances and basic substances, as well as the conditions referred to in such lists.

12. In performing scientific studies, experiments or experimental production, the performer of such activities shall:

12.1. draw up and keep protocols, which specify:

12.1.1. the identity, classification and labelling of a biocidal product or an active substance;

12.1.2. the quantity of a biocidal product or an active substance manufactured, imported, purchased and utilised;

12.1.3. the information regarding persons who will receive the biocidal product or active substance (given name, surname, address and telephone number);

12.1.4. the group and type of the biocidal product in conformity with Annex 1 of these Regulations;

12.1.5. the field or sector intended for use of the biocidal product or active substance, or the planned manufacturing of the biocidal product in which the active substance will be utilised; and

12.1.6. additional conditions to be complied with in performing activities with active substances or biocidal products;

12.2. document and keep the results of the studies regarding the potential effects of biocidal products or active substances on human health, animals and the environment;

12.3. if an investigation of the technological process has been provided for, submit the information referred to in Sub-paragraphs 12.1 and 12.2 of these Regulations to the Agency before commencing the investigation;

12.4. upon the request of the Agency, State Environment Inspection or State Sanitary Inspection, specify the information referred to in Sub-paragraphs 12.1 and 12.2 of these Regulations; and

12.5. comply with the precautionary principles and other environment protection conditions in determining the permissible concentration or quantity of biocidal products or active substances for the emission in the environment, working environment or waste depending on the degree of danger of the biocidal products or active substances.

13. If such scientific experiments or studies with a new biocidal product or an active substance or such experimental manufacturing of the referred to biocidal products or active substances which causes or may cause the spread of the relevant biocidal products or active substances into the environment are intended to be performed, the performer of activities shall submit an application to the Agency which characterises the intended studies, experiments or manufacturing and comply with the conditions for experimental production referred to in an authorisation for use, a registration certificate or a temporary registration certificate issued by the Agency.

14. The Agency shall provide the Poisons Information Centre of the Toxicology Centre with all the information at the disposal thereof regarding the registered, temporary registered or authorised biocidal products and active substances. The Poisons Information Centre of the Toxicology Centre shall utilise such information for providing information regarding symptoms of poisoning, prevention, first aid, emergency and medical treatment measures in cases of poisoning, other accidents and emergency or extreme situations.

15. Marketing of biocidal products or active substances classified as very toxic, toxic, carcinogens of category 1 or 2, mutagens of category 1 or 2 or category 1 or 2 substances toxic to the reproductive system, is permitted for professional use only.

16. During the transportation of biocidal products or active substances, they shall be packaged and labelled in conformity with the regulatory enactments regulating the transportation, classification, packaging and marking of dangerous freight.

17. A performer of activities shall maintain records of biocidal products or active substances specifying the following information:

17.1. the trade name of a biocidal product with which it will be marketed in Latvia;

17.2. the names of active substances:

17.2.1. the name specified in the list of dangerous chemical substances approved by the Minister for Environment (hereinafter – list of dangerous chemical substances) or, if such substance is not listed in the list of dangerous chemical substances, in the International Union of Pure and Applied Chemistry (hereinafter – IUPAC) nomenclature, designation and a registration number of the chemical substance in the Chemical Abstracts Service (CAS number), if the active substance is a chemical substance;

17.2.2. the scientific and common name, as well as the taxonomic relationship if the active substance is not a chemical substance; and

17.3. the type and quantity of activities performed, specifying the quantity of biocidal products manufactured, imported, marketed, stored, utilised or buried in each equipment, object or territory; and

17.4. the safety data sheet.

18. Fulfilment of the requirements of these Regulations shall be controlled by:

18.1. the State Sanitary Inspection – for the marketing and professional use in disinfection, disinsectisation and deratisation;

18.2. the State Labour Inspection – in relation to the compliance with labour protection requirements in performing activities with biocidal products or active substances; and

18.3. the State Environment Inspection – for other cases.

II. Submission of Applications

19. A manufacturer or an importer of biocidal products or active substances:

19.1. shall, in order to register temporary a biocidal product or an active substance, classify the relevant biocidal product or active substance and submit to the Agency:

19.1.1. the records or inventory data;

19.1.2. information certifying that the activities with biocidal products or active substances have been performed prior 14 May 2000; and

19.1.3. an application in accordance with Annex 2 of these Regulations (in writing and electronically); and

19.2. in order to register a biocidal product or an active substance or to receive an authorisation for use, determine the properties of the biocidal product or active substance and evaluate the effects thereof on human health and the environment under the intended conditions of use, as well as classify the relevant biocidal product or active substance and submit an application to the Agency in accordance with Annex 2 of these Regulations (in writing and electronically).

20. An application regarding a biocidal product or an active substance shall be submitted by:

20.1. the manufacturer of a biocidal product or an active substance if the biocidal product or active substance is manufactured in the territory of the State; and

20.2. the importer or another performer of activities authorised by the manufacturer to apply the biocidal products or active substances for trade (hereinafter – authorised representative of the manufacturer) if the biocidal products or active substances are manufactured outside the territory of the State.

21. The application shall be accompanied by the following information:

21.1. whether the active substance is listed in the list of active substances or the list of low-risk biocidal products:

21.1.1. a technical report (in conformity with Annex 3 of these Regulations) regarding active substances if the active substances are not chemical substances;

21.1.2. a technical report (in conformity with Annex 4 of these Regulations) regarding biocidal products if the active substances included in the composition of the biocidal products are chemical substances;

21.1.3. a technical report (in conformity with Annex 5 of these Regulations) regarding active substances if the active substances are chemical substances, but the applicant must perform additional studies in accordance with Sub-paragraph 29.2 of these Regulations;

21.1.4. a technical report (in conformity with Annex 6 of these Regulations) regarding biocidal products if the active substances included in the composition of the biocidal products are chemical substances, but the applicant must perform additional studies in accordance with Sub-paragraph 29.3 of these Regulations;

21.1.5. a technical report (in conformity with Annex 7 of these Regulations) regarding active substances if the active substances are fungi, micro-organisms or viruses; and

21.1.6. a technical report (in conformity with Annex 8 of these Regulations) regarding biocidal products if the active substances included in the composition of the biocidal products are fungi, micro-organisms or viruses;

21.2. information necessary to identify a biocidal product or an active substance, and a technical report (in conformity with Annex 9 of these Regulations) if the biocidal product or active substance is not listed in the list of active substances, the list of low-risk biocidal products or the list of basic substances;

21.3. substantiation of the study methods utilised, a description of the analysis, examinations, experiments and studies performed (hereinafter – studies), a description of the study methods utilised or a bibliographical reference to the study methods utilised;

21.4. proposals and the justification thereof regarding:

21.4.1. classification of biocidal products, necessary packaging and labelling; and

21.4.2. the safety data sheet;

21.5. samples, models or drafts of packaging, labels or instructions (upon the request of the Agency);

21.6. information necessary to assess the risk to the environment and human health or life, or prior risk assessment in conformity with Annex 10 of these Regulations; and

21.7. if a biocidal product or an active substance is manufactured outside the territory of the State – a statement by the manufacturer regarding the applicant being an authorised representative of the manufacturer.

22. An applicant shall submit a justified explanation to the Agency if it is not possible to obtain technically the information referred to in Paragraph 21 of these Regulations or the information is not necessary because it does not characterise the properties of the biocidal products, activities with such biocidal products or the effects thereof on the environment or human health.

23. If the biocidal product or active substance is listed in the list of low-risk biocidal products, additional information or studies regarding biocidal products (Annex 6) are not necessary.

24. Pursuant to co-ordination with the Agency, the application shall not include information, which is not necessary taking into account the information known regarding the biocidal product (including the formula of frame-formulation of the biocidal product, the properties of the biocidal product and intended type of use).

25. An applicant shall prepare a technical report taking into account the scientific and technical information available, and supplement the technical report if there is new scientific or technical information or new data regarding the properties or effects of the biocidal product or active substance on the environment or human health.

26. In order to prevent duplication of information, an applicant may submit to the Agency a copy of the opinion of the competent authority of the European Union Member State (hereinafter – Member State) and a copy of the application submitted to such authority, an officially approved copy of the first authorisation for use issued, as well as translations of the referred to documents in the official language if the biocidal product or active substance is manufactured or applied in any of the Member States.

27. An applicant shall justify and in the application or additional information specify such information, which he or she considers to be restricted access information:

27.1. up to temporary registration, registration or receipt of an authorisation for use of biocidal products or active substances; or

27.2. permanently.

28. If the manufacturer has not entrusted the restricted access information to an authorised representative, the authorised representative of the manufacturer shall submit together with the application a written confirmation of the manufacturer that upon the

request of the Agency the manufacturer will immediately provide the Agency with the necessary restricted access information.

29. An applicant shall submit additional information to the Agency if:

29.1. the information provided in the application or the previous risk assessment does not comply with the requirements of these Regulations;

29.2. the information provided does not ensure the performance of risk assessment or the taking of a decision regarding issuing of an authorisation for use, a registration certificate or a temporary registration certificate for activities with biocidal products or active substances;

29.3. an applicant has performed additional studies in accordance with a justified request of the Agency, in order to determine the effects of the biocidal products, active substances or potentially dangerous substances on the environment or human health, or studies which are necessary for additional risk assessment;

29.4. it is necessary to change the conditions referred to in an authorisation for use, a registration certificate or a temporary registration certificate;

29.5. the changes referred to in Paragraph 45 of these Regulations are implemented (before the implementation of changes); and

29.6. an applicant has evidence that the planned studies will not provide the necessary results or that alternative studies are more appropriate.

30. The Agency has the right not to request the applicant to perform individual studies or to permit the replacement of the planned studies with another study if the applicant submits substantiated information that the planned studies will not provide the necessary results or that alternative studies are more appropriate for the determination of properties or effects of biocidal products or active substances on humans or the environment.

III. Evaluation of Applications

31. The Agency (if necessary, by inviting experts) shall:

31.1. evaluate whether an application has been drawn up in conformity with the requirements of these Regulations, verify the completeness and scientific justification of the data submitted and evaluate whether the information submitted allows the evaluation of the effects of biocidal products or active substances on human health and the environment taking into account the contents and criteria of risk assessment specified in Annex 10 of these Regulations, as well as the effect on target organisms;

31.2. examine whether a biocidal product or an active substance is listed in the list of active substances, the list of low-risk biocidal products or the list of basic substances;

31.3. examine whether the laboratory methods approved by the Minister for Environment or other standardised methods for the determination of physical, chemical, toxicological or ecotoxicological properties of chemical substances and chemical products (hereinafter – approved or standardised methods) are utilised and evaluate whether the most appropriate methods of analysis, experiments and studies are utilised. If biocidal products or active substances has been placed on the market prior to 14 May 2000, the results of studies performed by other methods shall also be taken into account;

31.4. assess whether the classification of biocidal products or active substances conforms to the dangerous properties determined;

31.5. if it is necessary and possible, the formula of frame-formulation shall be determined and notified to the applicant.

31.6. evaluate whether the applicant has proposed all the necessary measures in order to reduce the undesirable consequences or adverse effects of biocidal products or active substances on the environment and human health (including restrictions for use);

31.7. examine whether the label of the biocidal product or instructions attached provide the information necessary to reduce to a minimum the risk and effects on human health, animals and the environment, when using biocidal products, except for effects on target organisms;

31.8. in conformity with Paragraph 34 and Annex 10 of these Regulations evaluate the risk to the environment and animal and human health or life, as well as the previous risk assessment submitted by the applicant;

31.9. examine whether the applicant has provided the packaging appropriate to the dangerous properties of the biocidal product or active substance in order to prevent a possibility of biocidal products or active substances escaping from the packaging thus endangering human life or health, or the environment;

31.10. examine whether the applicant has provided for the recovery, processing or burial of waste containing the biocidal products or active substances or packaging waste that is safe for the environment and humans;

31.11. for preparation of an opinion utilise an opinion of the competent authority of a Member State or an authorisation for use and the summary of applications or technical reports submitted to such authority, if such documents are attached to the application;

31.12. if necessary, request additional information from the applicant that is necessary for the evaluation of the application and the risk to human health or environment;

31.13. prepare proposals regarding additional evaluation of biocidal products or active substances or potentially dangerous substances;

31.14. determine the requirements, conditions or restrictions for the utilisation of biocidal products or active substances;

31.15. prepare proposals regarding additional measures necessary for the reduction of undesirable consequences or adverse effects caused by biocidal products or active substances on human health and life, animals or the environment; and

31.16. prepare recommendations to State administrative institutions regarding the control of biocidal products and reduction of the risk, including restrictions of marketing and utilisation of biocidal substances or active substances, precautionary, emergency and emergency readiness measures, as well as means and methods for rendering biocidal products or active substances harmless.

32. The Agency shall forward to the State agency *Sabiedrības veselības aģentūra* [Public Health Agency] (hereinafter – Public Health Agency), a copy of the application, additional information or information provided in order to prolong the authorisation for use, the registration certificate or temporary registration certificate, or to examine, re-

examine and change the conditions referred to in the authorisation for use or relevant certificate. The Public Health Agency shall assess the risk caused by biocidal products or active substances to human health and provide an opinion. The opinion shall be provided within the following period of time:

32.1. within 30 days – if an application for the registration of biocidal products or active substances has been submitted;

32.2. within 30 days – if an application for receipt of an authorisation for use has been submitted and the composition of the biocidal products (regarding which the application has been submitted) is formed on the basis of the previously specified frame-formulation and if the properties and effects of biocidal products on human health and the environment are known and previously evaluated by approved or standardised methods; or

32.3. within 60 days – if an application for receipt of an authorisation for use or temporary registration of biocidal products or active substances has been submitted.

33. In the opinion, the Public Health Agency shall specify the criteria (in conformity with Annex 10 of these Regulations) and methods utilised for risk assessment of biocidal products, the results of assessment of the risk to human health, justified conclusions, as well as recommendations regarding necessary additional measures and recommendations to the Agency regarding the taking of a decision.

34. In assessing the risk, the Agency and the Public Health Agency in conformity with the competence and time periods specified in these Regulations shall take into account the information specified in the application or submitted additionally and all the measures necessary to protect humans, animals and the environment during the intended period of use of biocidal products and in cases of foreseeable undesirable events, poisoning and accidents, as well as:

34.1. in evaluating conformity, usefulness and efficiency of the study methods used for the determination of dangerous properties of biocidal products, active substances or potentially dangerous substances, determine the adverse effects thereof or the consequences of such effects on human health and the environment which are caused or may be caused by active substances or potentially dangerous substances present in the composition of biocidal products due to the dangerous properties characteristic thereto (hereinafter – danger identification);

34.2. determine the effects of active substances or potentially dangerous substances on human health and the environment and the consequences thereof depending on a dose or concentration of a biocidal product, an active substance or a potentially dangerous substance, if possible, determining the severity and frequency of consequences and the maximum dose or concentration of active substances or potentially dangerous substances present in the composition of biocidal products which does not cause undesirable consequences or adverse effects (hereinafter – no observed adverse effect level), or the concentration below which no effects and consequences are caused (hereinafter – no-effect concentration);

34.3. determine the potential emission of biocidal products or active substances, and movement, speed of movement, transformation or degradation in the environment of

biocidal products or active substances, and assess the concentration or dose or way in which the biocidal products, active substances or potentially dangerous substances affect or may affect groups of persons – manufacturers, professional users, non-professional users and inhabitants (persons who are not users of biocidal products, but who may be subject indirectly through the environment to the biocidal products or active substances), as well as the environment (hereinafter – exposure assessment).

34.4. determine the prevalence, frequency and severity of the potential adverse effect or undesirable consequences caused during the process of actual or foreseen exposure of biocidal products or active substances (hereinafter – risk characterisation). If necessary, in determining the risk characterisation, the calculation shall be made assessing numerically the possibility of the risk. The risk caused by biocidal products shall be determined by assessment of risks caused by all active substances or potentially dangerous substances included in the biocidal product – individually for each substance and total risk. The risk assessment shall be performed and the risk characterisation shall be prepared for the intended type of utilisation of the biocidal product and active substance and for the actual variant of development of the undesirable events, which may cause the most serious consequences to the environment and humans when performing the manufacturing, storage, transportation, use, processing, destruction or burial of biocidal products or active substances or materials treated therewith;

34.5. determine whether the risk reduction measures recommended by the applicant are appropriate and efficient for the danger and intended type of use of biocidal products or active substances, whether they eliminate or reduce the risk to humans and the environment effectively;

34.6. develop recommendations for the reduction of risk to the applicant, other performers of activities or users of biocidal products or active substances; and

34.7. prepare recommendations regarding amendments to the classification, labelling of biocidal products or active substances or the safety data sheet in conformity with the requirements specified in these Regulations and regulatory enactments – particularly in cases when amendments to the classification, labelling of biocidal products or active substances or the safety data sheet are necessary for the protection of employees and other users.

IV. Registration of Biocidal Products or Active Substances or Issuance of Authorisation for Use and Extension or Cancellation of Registration Certificate or Authorisation for Use

35. In taking a decision regarding the temporary registration, registration of the biocidal product or active substance or the issuance of an authorisation for use or regarding the refusal to register the biocidal product or active substance or to issue an authorisation for use, the Agency shall take into account:

35.1. the results of the risk assessment, particularly the connection between the exposure to biocidal products or active substance and the effect or consequences of the effect caused thereby;

35.2. the type, severity, prevalence and frequency of undesirable consequences and effects on the environment;

35.3. whether the biocidal product is a low-risk biocidal product;

35.4. the risk control and management applicable;

35.5. the field of use of the biocidal product;

35.6. the effect of the biocidal product on the target organism;

35.7. the physical properties of the biocidal product;

35.8. the necessity to utilise the biocidal product and returns provided by the utilisation of the biocidal products;

35.9. the accuracy of results, presumptions, uncertainties and interpretation of studies performed by the applicant;

35.10. the possible effects on groups of inhabitants and users (including professional users, non-professional users and inhabitants) which are or may be subject to the direct or indirect effects of the biocidal product or active substance;

35.11. the safety coefficient determined in accordance with Annex 10 of these Regulations;

35.12. the environment which is or may be subject to the effects of the biocidal product or active substance or the consequences thereof;

35.13. if the biocidal product has a fixed formula of frame-formulation, the results of assessment of the frame-formulation properties, the risk and effects of the biocidal product; and

35.14. the results of the risk assessment of other biocidal products or active substances having the same or similar effect.

36. Taking into account the conditions referred to in this Chapter, the Agency shall take one of the following decisions (justifying the decision taken regarding each biocidal product or active substance, and each field of use of the biocidal product regarding which the application has been submitted):

36.1. to issue an authorisation for use (Annex 11), a registration certificate of the biocidal product or active substance (Annex 12) or a temporary registration certificate of the biocidal product or active substance (Annex 13), if necessary, specifying special conditions, requirements or restrictions; or

36.2. to issue a written refusal to register the biocidal product or active substance or to issue an authorisation for use specifying one of the following justifications:

36.2.1. the use of the biocidal product or active substance may cause severe consequences or negative effects on human health or the environment (hereinafter – unacceptable risk); or

36.2.2. additional information is necessary for taking a decision regarding the biocidal product or active substance or regarding the intended application or activities with biocidal products or active substances.

37. A registration certificate or a temporary registration certificate of biocidal products or active substances, or an authorisation for use shall be issued only if:

37.1. the physical and chemical properties of biocidal products or active substances have been determined using approved or standardised methods and they conform to the requirements specified for the intended use, as well as for storage and transportation;

37.2. it is possible to determine the properties, movement, movement speed, transformation or degradation in the environment of the biocidal products, active substances, all toxicologically or ecotoxicologically dangerous impurities, co-formulants and residues and, taking into account the exposure assessment, quantity and the effect thereof in accordance with the requirements specified in these Regulations;

37.3. an assessment has been made and a technical report has been prepared taking into account the scientific and technical information available and the consequences of the correct use and burial of biocidal products and active substances under the intended circumstances; and

37.4. the risk assessment performed in accordance with Paragraph 34 and Annex 10 of these Regulations indicates that the biocidal product:

37.4.1. has sufficient effect on target organisms;

37.4.2. does not cause undesirable effects on target organisms (including undesirable resistance or cross-resistance) or unnecessary suffering and pain to animals, in particular, vertebrates;

37.4.3. an active substance, a biocidal product or the residues thereof do not cause unacceptable risk or direct or indirect (with potable water, air pollution at the workplace, food or animal feed) undesirable effects on human health, animals or surface water, or groundwater; or

37.4.4. an active substance, a biocidal product or the residues thereof do not cause unacceptable risk or undesirable effects on the environment (also on non-target organisms). The assessment shall consider the persistency or transformation and movement of biocidal products in the environment, in particular, surface water or groundwater pollution caused thereby.

38. The Agency shall not issue an authorisation for use or shall refuse registration or temporary registration (except for cases referred to in Paragraph 40 of these Regulations) if:

38.1. the application and additional information fails to conform to the requirements of these Regulations;

38.2. taking into account the intended use and actual variant for the development of undesirable events which may cause the most severe consequences to humans and the environment, the risk assessment (in conformity with criteria and principles referred to in Paragraph 10 of these Regulations) confirms that the active substance, biocidal product or degradation products, or residues thereof cause unacceptable risk, direct or indirect undesirable effects on human health, animals or environment (also on surface waters and groundwater, sediments, soil, air or non-target organisms);

38.3. in providing for the measures for risk reduction, it is not possible to reduce the effects or consequences caused by exposure to the biocidal products or active substances so as such biocidal products or active substances do not cause substantial effects on human health or the environment;

38.4. biocidal products which are intended as products against vertebrates do not cause death simultaneously with the extinction of consciousness, or the death of animals does not occur immediately, or vital functions are not reduced gradually without sign of

obvious sufferings and do not cause the effect intended for repellent products without unnecessary suffering and pain for target organisms (vertebrates);

38.5. utilising the biocidal product in accordance with the conditions specified on the label and in accordance with the conditions referred to in an authorisation for use or a registration certificate, the target organisms are not affected; and

38.6. biocidal products classified as very toxic, toxic, category 1 and 2 carcinogens, category 1 and 2 mutagens or toxic to the category 1 and 2 reproductive system, are intended for use by non-professional users and the only possible method for the reduction of harmful effects of the biocidal product and risk to users is the use of personal protective equipment.

39. The Agency has the right not to issue an authorisation for use or to refuse registration or temporary registration, or not to extend a temporary registration certificate, registration certificate or the authorisation for use if:

39.1. a biocidal product registered in another state as a low risk biocidal product causes risk in conformity with scientific information or in connection with local circumstances. In such cases the Agency shall notify the competent institution of such state which has registered the biocidal product as a low-risk biocidal product regarding the refusal and justify why the biocidal product causes risk; and

39.2. information has become known that the target organisms have undesirable tolerance or resistance against the biocidal product.

40. If the use of biocidal products is necessary for the suspension of an emergency situation, epidemic or other undesirable events and limitation or elimination of consequences, but the effect of the relevant biocidal product on the environment, animal and human health has not been assessed or does not conform to the requirements of these Regulations, the Agency may permit the use of the biocidal product or trade of the biocidal products for a time period not exceeding 120 days restricting the field of use thereof and determining the control measures necessary.

41. In preparing conditions which are intended for specification in the temporary registration certificate, registration certificate or authorisation for use of biocidal products or active substances, the Agency shall assess the measures necessary for the reduction of adverse effects of the biocidal products and active substances and undesirable consequences in relation to each group of persons or ecosystem taking into account that some measures which restrict the adverse effects on one group of persons or ecosystem may increase the risk to another group of persons or ecosystem. On the basis of the assessment the Agency shall indicate in the temporary registration certificate, registration certificate or the authorisation for use of a biocidal product or an active substance:

41.1. such measures for risk reduction so as the risk to all groups of persons (manufacturers, professional users, non-professional users and inhabitants), the environment and all its ecosystems is minimal; and

41.2. what additional studies, information or measures for risk reduction are necessary in relation to each undesirable effect or consequences on any ecosystem or

group of persons, as well as the reasons for the necessity of such studies, information or measures.

42. If the Agency takes a decision to register a biocidal product or an active substance, or to authorise the use thereof, it shall issue:

42.1. a temporary registration certificate – for a time period not exceeding three years which may be extended for a time period not exceeding a year if the manufacture and trade of the relevant biocidal product in any of the Member States of the European Union has been commenced after 14 May 2000 – not later than 120 days after the day when all the information necessary for the evaluation of the application and the assessment of risk to human health and the environment has been submitted by the applicant;

42.2. a registration certificate – for a time period not exceeding 10 years – not later than 60 days after the day when all the information necessary for the evaluation of the application and the assessment of risk to human health and the environment has been submitted by the applicant;

42.3. an authorisation for use for a time period not exceeding 10 years – not later than 120 days after the day when all the information necessary for the evaluation of the application and the assessment of risk to human health and the environment has been submitted by the applicant; or

42.4. a registration certificate or an authorisation for use for a time period not exceeding 10 years – not later than 60 days after the day when all the information necessary for the evaluation of the application has been submitted by the applicant, if the composition of a biocidal product (regarding which the application has been submitted) has been formed on the basis of a previously specified frame-formulation and if the properties and effects of the biocidal product on human health and the environment are known and previously evaluated by approved and standardised methods.

43. In accordance with Annexes 11, 12 and 13 of these Regulations, the Agency shall specify the characterisation of the risk caused by a biocidal product or an active substance (including an evaluation regarding the severity, prevalence and frequency of potential adverse effect or undesirable consequences) and the measures for risk reduction proposed by the applicant in the temporary registration certificate, registration certificate or authorisation for use.

44. Expenditure related to the services of experts in the evaluation of applications and assessment of risk to human health or environment shall be covered by the applicant.

45. Each applicant of an authorised or temporary registered biocidal product or active substance shall notify the Agency in writing:

45.1. regarding such newly acquired information regarding the effects of the biocidal product or the active substance on humans or the environment which were not known when submitting the application, and regarding the precautionary measures to be taken for the reduction of newly discovered adverse effects;

45.2. if such types of use of the biocidal product or the active substance have been indicated on the label, instructions attached to the biocidal product or active substance or in the advertisement of the biocidal product or active substance which are not referred to in a temporary registration certificate, a registration certificate or an authorisation for use;

45.3. regarding changes in the raw materials, manufacturing or composition of the active substance;

45.4. if such an active substance is intended for the utilisation in the manufacture of a biocidal product which has not been indicated in an application or technical report by the manufacturer;

45.5. regarding changes in the composition of the biocidal product;

45.6. regarding the development of resistance;

45.7. regarding changes in packaging; and

45.8. regarding other changes which may affect the environment and human health or safety adversely, or may affect the extension of a temporary registration certificate, a registration certificate or an authorisation for use or the changes in conditions referred to in the relevant certificate or authorisation for use.

46. The Agency shall revise an authorisation for use, registration or temporary registration if:

46.1. the applicant of a biocidal product or an active substance shall submit the relevant information in accordance with Paragraph 45 of these Regulations;

46.2. the term of validity of a temporary registration certificate, a registration certificate or an authorisation for use of a biocidal product or an active substance has expired;

46.3. on the basis of scientific or technical information, as well as in order to protect human health and the environment, it is necessary to change the conditions referred to in an authorisation for use, a registration certificate or a temporary registration certificate (also in relation to the type of use and dose of the biocidal product or active substance);

46.4. if such types of utilisation of a biocidal product or an active substance have been indicated on the label, instructions attached to the biocidal product or active substance or in the advertisement of the biocidal product or active substance which are not referred to in a temporary registration certificate, a registration certificate or an authorisation for use;

46.5. an applicant has submitted a written request to change the conditions referred to in an authorisation for use, a registration certificate or a temporary registration certificate specifying:

46.5.1. justified reasons indicating the necessity to change the referred to conditions;

46.5.2. evaluation of the planned changes specifying that the risk to human health or environment does not increase; and

46.5.3. whether amendments to the list of active substances, the list of basic substances or the list of low-risk biocidal products are necessary. If such amendments are necessary, an applicant shall perform additional evaluation of an

active substance and prepare the documentation in accordance with Chapter VII of these Regulations;

46.6. after making amendments to the list of active substances, the list of basic substances or the list of low-risk biocidal products it is necessary to change the conditions referred to in an authorisation for use, a registration certificate or a temporary registration certificate; or

46.7. it is necessary to change the conditions referred to in an authorisation for use, a registration certificate or a temporary registration certificate due to other reasons (for example, if the term of validity of the authorisation for use, the registration certificate or the temporary registration certificate has not expired, but there is some information that the requirements of these Regulations or conditions referred to in the authorisation for use, the registration certificate or the temporary registration certificate have not been complied with).

47. The Agency and the Public Health Agency shall evaluate the information that has been submitted in order to revise and extend or change the conditions referred to in an authorisation for use, a registration certificate or a temporary registration certificate in accordance with the procedures specified in Chapter III of these Regulations.

48. On the basis of the information submitted by the applicant and the evaluation performed, the Agency shall:

48.1. extend the term of validity of an authorisation for use, a registration certificate or a temporary registration certificate or change the conditions referred to in the authorisation for use, the registration certificate or the temporary registration certificate if the conditions referred to in Paragraph 37 of these Regulations have been complied with;

48.2. change the conditions referred to in the authorisation for use, the registration certificate or the temporary registration certificate and authorise the types of utilisation of a biocidal product or an active substance that have not been referred to in the temporary registration certificate, the registration certificate or the authorisation for use, but are referred to in the list of active substances;

48.3. if the conditions referred to in Paragraph 38 of these Regulations have been complied with:

48.3.1. not extend the term of validity of an authorisation for use, a registration certificate or a temporary registration certificate;

48.3.2. suspend the registration, temporary registration or an authorisation for use of a biocidal product or an active substance if the term of validity of the authorisation for use, the registration certificate or the temporary registration certificate has not expired; and

48.3.3. cancel a temporary registration certificate, a registration certificate or an authorisation for use of a biocidal product or an active substance if the conditions referred to in Clauses 48.3.1, 50.1.1, 50.1.2 or 50.1.3 of these Regulations have been complied with;

48.4. if the conditions referred to in Sub-paragraph 39.1 of these Regulations have been complied with:

48.4.1. in extending the term of validity of the authorisation for use, registration certificate or the temporary registration certificate of a biocidal product or an active substance, additional conditions shall be set regarding the measures for risk reduction, as well as the restrictions for specific type of use (particularly in connection with use under local circumstances); and

48.4.2. not extend the term of validity of the authorisation for use, registration certificate or the temporary registration certificate of a biocidal product if the biocidal product or active substance causes unacceptable risk to human or animal health or the environment; and

48.5. not extend the term of validity of a temporary authorisation for use, a registration certificate or a temporary registration certificate of a biocidal product if undesirable tolerance or resistance against the biocidal product has appeared in target organisms.

49. If necessary, the Agency shall extend the term of validity of an authorisation for use, a registration certificate or a temporary registration certificate for the minimum possible time period which is necessary for:

49.1. an applicant to complete the preparation of a new application or additional information;

49.2. the Agency to evaluate an application or additional information and to prepare amendments to the conditions referred to in the authorisation for use, the registration certificate or the temporary registration certificate, an extension of the term of validity of the authorisation for use, the registration certificate or the temporary registration certificate or a refusal to extend the term of validity of the authorisation for use, the registration certificate or the temporary registration certificate; and

49.3. an applicant to develop and implement a plan regarding the use, burial, destruction or otherwise disposing of existing supplies of a biocidal product or an active substance (for which it is intended to cancel the temporary registration certificate, registration certificate or the authorisation for use). In developing and implementing the relevant plan, an applicant shall comply with the conditions referred to in the authorisation for use, registration certificate or temporary registration certificate and the reason for cancellation, these Regulations and regulatory enactments regulating waste management, as well as the restrictions and prohibitions regarding the use and trade of dangerous chemical substances and dangerous chemical products.

50. The Agency shall cancel:

50.1. an authorisation for use, a registration certificate or a temporary registration certificate if:

50.1.1. it has been disclosed that the authorisation for use, the registration certificate or the temporary registration certificate has been granted on the basis of false or misleading information referred to in the application or additional information;

50.1.2. the conditions referred to in Paragraphs 37 and 42 of these Regulations or the conditions referred to in the authorisation for use, the

registration certificate or the temporary registration certificate have not been complied with;

50.1.3. a biocidal product or an active substance causes unacceptable risk to human health, animals or environment; and

50.1.4. an applicant has submitted a written request to cancel the authorisation for use or the temporary registration certificate specifying the reasons;

50.2. an authorisation for use if an active substance is deleted from the list of active substances;

50.3. a registration certificate if an active substance is deleted from the list of low-risk biocidal products; and

50.4. a temporary registration certificate, a registration certificate or an authorisation for general use of biocidal products by non-professional users if the conditions referred to in Sub-paragraph 38.6 of these Regulations are fulfilled and the biocidal product causes unacceptable risk to human health.

51. If the Agency has information that a biocidal product or an active substance may cause an unacceptable risk or negative effects on human health or the environment, the Agency shall take a decision that additional information is necessary or that the risk assessment shall be continued. The Agency has the right to suspend an authorisation for use, registration or temporary registration, or to restrict the utilisation or trade of a biocidal product or an active substance for the time period necessary for the acquisition of additional information.

52. The Agency shall give an applicant an opportunity to submit explanations or additional information within a time period of two weeks before taking a decision regarding the refusal to register a biocidal product or an active substance or regarding the issuance of a temporary registration certificate, a registration certificate or an authorisation for use or extension of the term of validity thereof, as well as prior to the suspension of operations or cancellation of the temporary registration certificate, the registration certificate or the authorisation for use;

53. The Agency, by specifying the reasons, shall notify the applicant in writing regarding the fact that an authorisation for use, a registration certificate or a temporary registration certificate will not be issued or the term of validity thereof will not be extended, or that the operation of the temporary registration certificate, the registration certificate or the authorisation for use will be suspended or the relevant certificate or authorisation will be cancelled.

54. The Agency shall establish and maintain a database regarding biocidal products and active substances applied for. The database shall include the following information:

54.1. information regarding the applicant;

54.2. date of submission of the application;

54.3. names of the biocidal products and active substances;

54.4. information regarding the conformity of the application or additional information to the requirements of these Regulations and the decision of the Agency in accordance with Paragraph 35 of these Regulations;

54.5. number, date of issue, term of validity of a temporary registration certificate, registration certificate or an authorisation for use of a biocidal product or an active substance;

54.6. number, date of issue and term of validity of a temporary registration certificate of experimental manufacturing, a registration certificate or an authorisation for use of a biocidal product or active substance if the conditions referred to in Paragraph 13 of these Regulations have been complied with; and

54.7. classification and labelling of the biocidal products and active substances;

55. Applications, temporary registration certificates, registration certificates and authorisations for use of biocidal products or active substances shall be kept for 10 years.

56. On the basis of the conditions referred to in a temporary registration certificate, a registration certificate or an authorisation for use, the Agency shall prepare and submit information and recommendations regarding the control and reduction of risk, including recommendations regarding restrictions in trade or utilisation of a biocidal product or an active substance, precautionary, immediate and emergency measures, as well as regarding ways and methods for rendering the biocidal product and active substance harmless to the State Sanitary Inspection, Environment State Inspectorate, State Labour Inspection, State Fire-Fighting and Rescue Service, regional environment boards and State Environmental Impact Assessment Bureau (hereinafter – Bureau), if necessary, also to other State administrative institutions.

57. Information regarding the dangerous properties of a biocidal product or active substance, effects on human health or the environment, safety, precautionary and protection measures and immediate measures to be performed in case of poisoning, as well as regarding ways and methods to render the biocidal product or active substance harmless is not restricted access information.

58. The following information shall not be considered as restricted access information (in addition to conditions referred to in Paragraph 57 of these Regulations) after the issue of a temporary registration certificate, a registration certificate or an authorisation for use of a biocidal product or active substance:

58.1. the name and address of the applicant;

58.2. the name and address of the producer of the biocidal product;

58.3. the name and address of the manufacturer of the active substance;

58.4. the names of the biocidal product and active substances, contents of active substances in the biocidal product;

58.5. the names of chemical substances referred to in the list of dangerous chemical substances and included in the composition of a biocidal product (in particular – if the presence of the relevant substance in a biocidal product may affect the classification of the biocidal product);

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

58.7. the ways and methods for rendering the biocidal product and active substance harmless;

58.8. a summary (including conclusions) of such tests and studies which have been performed in order to determine the effect of a biocidal product or active substance on a target organism, ability to cause resistance and effects on humans, animals and the environment;

58.9. fire safety, anti-explosive protection, work safety and other safety and precautionary measures, technologies or recommended methods to be complied with in order to reduce the risk when performing activities with a biocidal product;

58.10. safety data sheets;

58.11. methods for the determination of dangerous properties and effects of a biocidal product or active substance on human health or the environment and the methods by which the quantity of a biocidal product or active substance in an organism and the environment (including the quantity of a biocidal product or active substance in emission or accidental leakage) may be determined;

58.12. the conditions for the management or processing of biocidal waste and packaging waste; and

58.13. immediate measures to be performed if poisoning with a biocidal product or active substance has occurred, fire has started, unexpected leakage of a biocidal product or active substance, or another undesirable event or accident has occurred.

59. Employees of the Agency and the Public Health Agency have the right to acquire restricted access information regarding studies conducted by the applicant or to receive information regarding a biocidal product or active substance and to refer to such in an opinion or a temporary registration certificate, a registration certificate or an authorisation for use of a biocidal product or an active substance.

60. The State administrative authorities shall ensure that restricted access information regarding a biocidal product or an active substance is not accessible and is not disclosed (except for cases specified in these Regulations and regulatory enactments regulating confidentiality of information).

61. In its Internet home page the Agency shall include the list of such biocidal products and active substances regarding which temporary registration certificates, registration certificates and authorisations for use have been issued, as well as ensure the provision of necessary information to the public.

62. If an applicant considers that the information indicated as restricted access information in an application or information additionally provided is no longer restricted access information, he or she shall notify in writing the Agency thereof.

63. The Agency has the right to utilise restricted access information provided by the applicant when examining the applications of applicants and preparing temporary registration certificates, registration certificates or authorisations for use only if:

63.1. there is a written authorisation from the previous applicant that the information specified in an application or additionally provided regarding a biocidal product or an active substance may be utilised;

63.2. a biocidal product or active substance has been placed on the market prior to 14 May 2000 – information may be utilised after 14 May 2010;

63.3. an active substance, which has not been placed on the market prior to 14 May 2000, is included in the list of active substances or the list of low-risk biocidal products for at least 15 years;

63.4. a biocidal product containing an active substance has not been placed on the market prior to 14 May 2000 or on 14 May 2000, but is registered for at least 10 years and authorised in any Member State – only information regarding a biocidal product may be utilised; and

63.5. the time periods referred to in Sub-paragraphs 63.2 and 63.3 of these Regulations and at least five years have elapsed after submission of the first additional information regarding a biocidal product or an active substance – such additional information may be utilised.

64. In order to avoid duplication of the testing of physical and chemical properties or toxicological or ecotoxicological studies, the next applicant of the biocidal product or active substance may refer to the results of testing or studies submitted to the Agency by the first applicant if:

64.1. the next applicant can prove that:

64.1.1. the active substance applied is identical to an active substance already applied for (evaluating the degree of purity and types of impurities) or a biocidal product is similar (the biocidal product contains the same active and potentially dangerous substances) to a biocidal product registered or authorised; and

64.1.2. it is not necessary to perform analogue studies or tests; and

64.2. the first applicant has given his or her consent in writing that results of the studies submitted by him or her are utilised.

65. In order to prevent analogous experiments with animals (in particular with vertebrates):

65.1. an applicant shall submit a submission to the Agency at least two months before the application of a biocidal product or an active substance in order to ascertain whether an identical active substance or similar biocidal product has been registered or permitted. the submission shall include the information referred to in Clause 65.1.1 or 65.1.2 and information referred to in Clause 65.1.3:

65.1.1. the name, molecular formula, structural formula of an active substance to be applied for and information regarding the amount of the active substance to be manufactured and imported, and in what types of biocidal products the relevant active substance may be utilised;

65.1.2. the name of a biocidal product to be applied for, composition of the biocidal product specifying an active substance included in the composition of the biocidal product and the names, molecular formulae, structural formulae of potentially dangerous substances, and information regarding amount of the biocidal product to be manufactured or imported; and

65.1.3. certification that an applicant is planning to submit an application and he or she has already prepared the other information necessary for the application;

65.2. within a time period of a week the Agency shall notify an applicant in writing regarding the previous applicant specifying his or her name and address, as well as notify the previous applicant in writing regarding the applicant specifying his or her name and address; and

65.3. if possible, an applicant and the previous applicant shall co-operate and provide each other with information in order to avoid the performance of analogous experiments with animals (in particular with vertebrates).

66. If an applicant and the previous applicant have not agreed regarding co-operation in order to prevent analogous experiments with animals, the Agency has the right to request the performance of the exchange of information specifying the conditions and procedures to be complied with when performing the exchange of information.

V. Requirements for Labelling, Packaging, Safety Data Sheet, Trade and Advertising of Biocidal Products

67. Trade in such biocidal products or active substances is permitted which are packaged and comply with the following conditions:

67.1. the packaging is of sufficient strength under the conditions of use and storage provided for by the manufacturer;

67.2. the material of the packaging does not form chemical compounds with the packaged biocidal product or active substance and does not react with it;

67.3. the construction and material of packaging is such as not to cause losses of the contents during the period of transportation and storage;

67.4. the packaging bears a label in accordance with Chapter V of these Regulations;

67.5. biocidal products or active substances which may be mistaken for food, drink or feedingstuffs shall be packaged to prevent or minimise a possibility to mistake such biocidal products or active substances for food, as well as such components shall be added which would prevent the utilisation thereof for unintended purposes if the biocidal product is intended for general (non-professional) use; and

67.6. it is prohibited to store a biocidal product or active substance together with food or animal feed. At retail selling points biocidal products or active substances shall be placed at the height of at least 1.5 m (except for packaging, which cannot be opened by children).

68. Trade in a biocidal product or active substance is prohibited if:

68.1. the biocidal product or active substance is not labelled and the packaging of the relevant biocidal product or active substance does not have instructions attached or the label or packaging has no instructions regarding safe management or processing of waste containing the biocidal product or active substance and packaging waste in conformity with the requirements of these Regulations and the regulatory enactments regulating waste management; and

68.2. labelling or packaging of the biocidal product or active substance does not conform to the labelling or packaging specified in the authorisation for use, registration certificate or temporary registration certificate.

69. An active substance which is a chemical substance and a biocidal product which is a chemical substance or a chemical product or which contains a chemical substance or a chemical product shall be classified, labelled and packaged in accordance with the regulatory enactments regulating the classification, labelling and packaging of chemical substances and chemical products.

70. A biocidal product or an active substance shall be:

70.1. utilised in conformity with the instructions provided in the label thereof and the instructions attached in compliance with all precautionary measures necessary to ensure human safety and health and environmental protection;

70.2. used in the minimum necessary amount with the most appropriate technologies and in combination with other methods which are provided for in order to destroy, repel and render harmful organisms harmless, and to inhibit the effects thereof or otherwise affect them;

70.3. when utilised in a work place, the regulatory enactments regulating labour protection shall be complied with; and

70.4. it is prohibited to be utilised by professional users if the safety data sheet of such biocidal product or active substance is not available in accordance with Chapter V of these Regulations.

71. A label of a biocidal product or an active substance shall specify:

71.1. the trade name of the biocidal product or active substance and the identity of each active substance included in the biocidal product and the concentration in the biocidal product which is expressed in units of measurements of the international system of measurements;

71.2. the number of the authorisation for use, the registration certificate or the temporary registration certificate. Until an authorisation for use, a registration certificate or a temporary registration certificate is issued, an inventory number in conformity with the information submitted to the Agency shall be specified for the existing active substance (placed on the market prior to 14 May 2000) or the biocidal product containing one or several existing active substances;

71.3. authorised types of utilisation of the biocidal product in conformity with Annex 1 of these Regulations;

71.4. the preparatory form and physical state of the biocidal product or active substance (solution, granules, powder, solid);

71.5. conditions for use and doses to be used for each type of utilisation in accordance with the conditions referred to in the authorisation for use, registration certificate or temporary registration certificate;

71.6. detailed information regarding possible direct or indirect side effects and instructions regarding first aid in case of poisoning with the biocidal product or active substance;

71.7. instructions for the safe management, processing of waste containing the biocidal product or active substance or packaging waste or a prohibition for re-use of the packaging;

71.8. the date by which the biocidal product or active substance is fit for the intended application if the conditions for storage of the relevant biocidal product or active substance are complied with;

71.9. number or designation of series or batch of biocidal products (concurrently produced biocidal products with the same composition and the same type of use and preparatory form);

71.10. the time period and interval for the effect of the biocidal product on target organisms which shall be observed between:

71.10.1. uses of the biocidal product;

71.10.2. the treatment of a product or an object with the biocidal product and the use of the product or object treated; and

71.10.3. the utilisation of the biocidal product and the presence of humans or animals in the territory, premises or other places in which the biocidal product has been used;

71.11. detailed information regarding purification products and measures after the use of the biocidal product, as well as the necessary period for the ventilation of equipment, premises or structures treated with the biocidal product;

71.12. information regarding necessary cleaning and cleaning products;

71.13. information regarding security and precautionary measures during utilisation, storage and transport (including regarding necessary personal protective clothing and equipment, fire safety measures, coverage of machines or tools, removal of food and animal feed materials) and instructions regarding how to protect animals against the effects of the biocidal product;

71.14. information regarding the fact that the utilisation of the biocidal product is restricted or prohibited for a specified group of users (for example, non-professional users);

71.15. information regarding the danger of the biocidal product to the environment and the measures necessary for the reduction of the relevant danger (in particular – for the protection of organisms for the destruction of which the biocidal product is not intended, and for the prevention of water contamination);

71.16. for biocidal products the active substances of which are fungi, micro-organisms or viruses – classification and instructions for the protection of employees in accordance with the regulatory enactments regulating labour protection requirements when coming into contact with biological substances; and

71.17. the name, address and telephone number of the manufacturer, importer or supplier.

72. If the place provided for on a label or packaging is too small for the placement of information, the information referred to in Sub-paragraphs 71.3, 71.4, 71.5, 71.6, 71.7, 71.8, 71.9, 71.10, 71.11, 71.12, 71.13, 71.14. and 71.15 of these Regulations may be specified in the instructions. The instructions are an integral part of the labelling. If the instructions have been attached, the label shall have an indication "Pirms lietošanas izlasiet pievienoto instrukciju!" [Read the attached instructions before use!].

73. The labelling of a biocidal product or an active substance may not be misleading. The label of a biocidal product or an active substance may not bear indications that the biocidal product or active substance does not cause a danger to humans, animals or the environment (for example "zema riska biocīds produkts" [low-risk biocidal product], "nav toksisks" [non-toxic], "nav bīstams" [non-dangerous], "nekaitīgs" [harmless]).

74. In examining applications, the Agency has the right to request that before the commencement of trade the applicant of the biocidal product or active substance prepares and submits samples, models or drafts of packaging, labels or instructions, if necessary, in order to prevent threats to humans, animals or the environment.

75. The applicant, in accordance with the regulatory enactments prescribing the requirements for safety data sheets of chemical substances and chemical products, shall prepare and forward safety data sheets if a biocidal product or an active substance or a potentially dangerous substance included in the composition of the biocidal product has been classified as a dangerous chemical substance or a dangerous chemical product or the maximum permissible concentrations or concentration limits of contamination in work places have been determined for the biocidal product, active substance or potentially dangerous substance which is a chemical substance or a chemical product.

76. If the active substance in the composition of a biocidal product has not been classified in conformity with the classification of chemical substances and chemical products and it is utilised only in biocidal products, the applicant shall prepare the safety data sheet in accordance with Annex 14 of these Regulations.

77. In classifying and labelling a pesticide (insecticide, acaricide, rodenticide, avicide or molluscicide) which has been registered, classified and labelled as a plant protection product and permitted or registered as a biocidal product, it is permitted to use identical classification and labelling to a plant protection product if such classification or labelling is not contrary to the conditions referred to in an authorisation for use, a registration certificate or a temporary registration certificate of a biocidal product. The classification and labelling of insecticides, acaricides, rodenticides, avicides or molluscicides shall be changed in conformity with the conditions referred to in an authorisation for use, a registration certificate or a temporary registration certificate of a biocidal product if the classification or labelling of the relevant pesticide as a plant protection product does not conform to the requirements of these Regulations or the conditions referred to in an

authorisation for use, a registration certificate or a temporary registration certificate of the biocidal product.

78. An advertisement of biocidal products shall include the instructions “Lietojiet biocīdus uzmanīgi! [Use biocidal products safely!] Vienmēr pirms lietošanas izlasiet etiķeti un informāciju par produktu!" [Always read the label and product information before use!]. The referred to instructions must be clearly visible and distinguishable.

79. In the advertising of a biocidal product, the word “biocīds” [biocidal product] may be replaced by the description of the type of the biocidal product advertised (for example, “koksnes konservants” [wood preservative], “dezinfekcijas līdzekļi” [disinfectant]).

80. In the advertisements of a biocidal product or an active substance it is prohibited to characterise the relevant biocidal product in a way which may mislead a consumer and to specify that the biocidal product does not cause any risk to humans or the environment, that the biocidal product is a low-risk biocidal product or that the biocidal product or the active substance is not toxic.

VI. Inclusion of Active Substances in the List of Active Substances, the List of Low-risk Biocidal Products or the List of Basic Substances and Deletion from the Referred to Lists

81. In order to include an active substance or additional information regarding the active substance in the list of active substances, the list of low-risk biocidal products or the list of basic substances:

81.1. the applicant shall prepare and submit to the Agency, an application regarding an active substance or at least one biocidal product containing the relevant active substance (in accordance with the available scientific or technical information and in conformity with Annex 2 of these Regulations) as well as:

81.1.1. a technical report regarding the active substance (in conformity with Annex 3 if the active substance is a chemical substance or Annex 7 if the active substance is not a chemical substance) and upon request of the Agency – additional information in conformity with Annex 5 of these Regulations; or

81.1.2. a technical report regarding a biocidal product (in conformity with Annex 4 if the active substance contained in the biocidal product is a chemical substance or Annex 8 if the active substance contained in the biocidal product is not a chemical substance, conforms to the conditions referred to in Paragraph 37 of these Regulations, but is not a the low-risk biocidal product);

81.2. the Agency and the Public Health Agency, taking into account the conditions referred to in Paragraph 86 of these Regulations, shall evaluate the application in accordance with the procedures specified in Chapter III of these Regulations;

81.3. if necessary, the Agency shall request additional information from the applicant and notify the European Commission and competent authorities of all Member States regarding such a request, as well as notify the European Commission and competent authorities of all Member States regarding:

81.3.1. additional information submitted by the applicant; and

81.3.2. the fact that the applicant has not submitted additional information within a time period of 12 months from the day of sending the request; and

81.4. if necessary, upon the request of a competent authority of any Member State, the Agency shall submit a technical report submitted by the applicant for evaluation thereto.

82. The Agency, taking into account the evaluation referred to in Sub-paragraph 81.2 of these Regulations and the conditions referred to in Paragraphs 85, 86, 87 and 88, shall perform one of the following activities:

82.1. if the application has been drawn up in conformity with the requirements of these Regulations and the active substance does not cause unacceptable risk to human health or environment, it accepts technical reports regarding a biocidal product and an active substance and, in co-ordination with the applicant, submits the summary of such reports, as well as the recommendations and conditions regarding the inclusion of the active substance in the list of active substances, the list of low-risk biocidal products or the list of basic substances to the European Commission and competent authorities of all Member States; and

82.2. submit to the European Commission and competent authorities of all Member States the summary of technical reports and justification why the relevant active substance may not be included in the list of active substances, the list of low-risk biocidal products or the list of basic substances or why it shall be deleted from the referred to list, as well as proposals for a time period for the implementation of such decision.

83. If it is necessary to evaluate the risk caused by a biocidal product or an active substance under Latvian circumstances, the Agency shall request the competent authority of a Member State to submit a technical report regarding the inclusion of an active substance or new information regarding the relevant active substance in the list of active substances, the list of low-risk biocidal products or the list of basic substances.

84. The Agency shall evaluate the technical reports received in accordance with Paragraph 83 of these Regulations and not later than 12 months after the receipt of a technical report send the evaluation and a recommendation regarding the inclusion of an active substance in the list of active substances, the list of low-risk biocidal products or the list of basic substances, or a justification why such active substances may not be included in the list of active substances, the list of low-risk biocidal products or the list of basic substances to the applicants, the European Commission and competent authorities of all Member States.

85. In evaluating an application regarding the inclusion of an active substance in the list of active substances, the list of low-risk biocidal products or the list of basic substances the following shall be determined:

85.1. if necessary, the permissible occupational exposure level;

85.2. if necessary, the permissible daily dose which does not cause adverse effects on human health;

85.3. the maximum permissible amount, volume or other limit value of residues

85.4. the movement, transformation and circulation of a biocidal product or an active substance in the environment, as well as effects on non-target organisms;

85.5. the requirements for the purity of an active substance specifying the degree of purity;

85.6. the requirements for the properties of impurities and maximum contents thereof in an active substance or a biocidal product;

85.7. the types of biocidal products for the production of which it is permitted to utilise the relevant active substance taking into account that the active substance may be utilised only for the production of the types of biocidal products specified in Annex 1 of these Regulations regarding which an application and, if necessary, additional information in conformity with the conditions referred to in Chapter II of these Regulations has been submitted;

85.8. the field of utilisation, circumstances intended for use and conditions for the utilisation of a biocidal product for particular groups of users (manufacturers, professional users or non-professional users);

85.9. special conditions arising from the technical report, application or other information submitted in conformity with the requirements of these Regulations and from results of the evaluation;

85.10. the maximum and minimum concentration at which the active substance may be present in the composition of the biocidal product if it is necessary to specify such concentration of the active substance in the list of biocidal products; and

85.11. the time period (not exceeding 10 years) for which it is recommended to include the active substance in the list of active substances, the list of low-risk biocidal products or the list of basic substances.

86. The Agency, in accordance with Sub-paragraph 81.1 of these Regulations, shall recommend the inclusion of an active substance in the list of active substances, the list of low-risk biocidal products or the list of basic substances if biocidal products containing the active substance conform to the conditions referred to in Paragraph 37 of these Regulations taking into account the cumulative effects of biocidal products containing one active substance, including a recommendation to include the active substance in:

86.1. the list of low-risk biocidal products if the active substance causes minimum risk to humans and the environment; and

86.2. the list of basic substances if the active substance is a basic substance.

87. The Agency, in accordance with Sub-paragraph 81.2 of these Regulations, shall recommend not to include an active substance in the list of low-risk biocidal products if in accordance with the regulatory enactments regulating the classification, labelling and packaging of chemical substances and chemical products the relevant substance has been classified as carcinogenic, mutagenic, toxic to the reproductive system, sensitising or bio-accumulative and does not readily degrade.

88. The Agency, in accordance with Sub-paragraph 81.2 of these Regulations, shall recommend not to include an active substance in the list of low-risk biocidal products or the list of basic substances or to delete from the referred to list if:

88.1. the evaluation of the application regarding the inclusion of an active substance in the list and the risk assessment performed in accordance with the requirements of these Regulations show that by utilising the biocidal product under intended conditions of use thereof the risk to human health or environment increases and the relevant biocidal product causes substantially greater risk to human health or environment that the active substances referred to in Sub-paragraph 88.2 of these Regulations; and

88.2. the list of active substances, the list of low-risk biocidal products or the list of basic substances includes other active substances:

88.2.1. which are used in the same types of biocidal products;

88.2.2. which in accordance with study results and conclusions cause a substantially lower risk to human health or environment; and

88.2.3. which are in sufficient number to select several active substances with different chemical properties and structures having effects on the relevant target organisms.

89. Before the submission of an application regarding the inclusion of an active substance in the list of active substances, the list of low-risk biocidal products or the list of basic substances or deletion from the referred to lists, the Agency shall:

89.1. provide an opportunity to the applicant to carry out tests of the active substance for use under intended conditions if such tests have not been carried out previously – depending on the time necessary for the relevant test, but not longer than two months;

89.2. evaluate the properties, effects and risk to humans and the environment of other active substances referred to in Sub-paragraph 88.2 of these Regulations in order to prove that:

89.2.1. the effects thereof on target organisms is similar;

89.2.2. the use thereof does not increase the risk to human health and the environment; and

89.2.3. irrecoverable losses of an economic and practical nature are not caused to the users of the active substance; and

89.3. submit the evaluation referred to in Sub-paragraph 88.2 of these Regulations to the European Commission and send it for revision to the competent authorities of all Member States.

90. If necessary the Agency shall submit a recommendation to the European Commission:

90.1. to review the time period for which a biocidal product or an active substance is included in the list of active substances, the list of low-risk biocidal products or the list of basic substances;

90.2. to reduce the time period for which the active substance is included in the list of active substances, the list of low-risk biocidal products or the list of basic

substances if it has been discovered that the active substance causes an unacceptable risk to humans and the environment or if the conditions referred to in the list of active substances, the list of low-risk biocidal products or the list of basic substances do not come into effect or are not complied with; and

90.3. to renew or extend the time period for which an active substance is included in the list of active substances, the list of low-risk biocidal products or the list of basic substances:

90.3.1. for a time period not exceeding 10 years; or

90.3.2. for a time period necessary for the applicant to prepare additional information and for the Agency to evaluate the application or additional information.

VII. Provision of Information to the European Commission and Recognition of Authorisations for Use or Registrations issued by Member States

91. On the basis of the copy of a registration or an authorisation for use and an application officially approved by the competent authority (which was the first to issue an authorisation for use or to register the relevant biocidal product or active substance) of a Member State, the Agency shall perform the relevant evaluation in accordance with the requirements of these Regulations and ensure the recognition of the authorisation for use or registration. The application must include a summary of the technical report (for a low-risk biocidal product) or the technical report (for an active substance and a biocidal product other than a low-risk biocidal product).

92. The Agency shall evaluate the authorisation for use or registration of a biocidal product or an active substance referred to in Paragraph 91 of these Regulations if:

92.1. the active substance is listed in the list of active substances or the list of low-risk biocidal products;

92.2. the conditions for the relevant active substance or biocidal product which are referred to in the list of active substances, the list of low-risk biocidal products or the list of basic substances are complied with; and

92.3. the biocidal product or active substance does not cause an unacceptable risk to human health and the environment.

93. The Agency shall evaluate the authorisation for use or the registration of a biocidal product or an active substance and take a decision regarding the recognition thereof or regarding the refusal to ensure recognition thereof:

93.1. not later than 60 days after receipt of the summary of the technical report – for a low- risk biocidal product; and

93.2. not later than 120 days after receipt of the technical report and the copy of the first issued authorisation for use officially approved – for an active substance or a biocidal product other than a low-risk biocidal product.

94. The Agency in recognising an authorisation for use or a registration shall indicate additional provisions if:

94.1. it has been determined in the evaluation that the target species are not in such quantity as being able to cause harmful effects to human health, animals, the environment, products produced or utilised, or economic activities;

94.2. it has been determined in the evaluation that the biocidal product causes undesirable tolerance or resistance in a target organism;

94.3. the conditions for the utilisation of a biocidal product in Latvia (climate or reproduction period of target species) differ considerably from the conditions in a Member State in which the first authorisation for use has been issued and therefore the biocidal product may cause an undesirable risk to humans or the environment; and

94.4. measures are necessary which arise from the requirements of other regulatory enactments (including regulatory enactments regarding environmental protection in relation to the manufacture, trade or utilisation of a biocidal product or active substance in order to protect the health of distributors, users or employees of the relevant biocidal product or active substance and the environment.

95. The Agency, justifying the decision, has the right to refuse the recognition of an authorisation for use or registration for the following types of biocidal products:

95.1. avicides (15th type of products in accordance with Annex 1 of these Regulations);

95.2. piscicides (17th type of products in accordance with Annex 1 of these Regulations); and

95.3. products for the destruction of vertebrates (23rd type of products in accordance with Annex 1 of these Regulations).

96. If the Agency considers that an active substance or a biocidal product which has been authorised or registered in a Member State does not conform to the requirements (in particular to Paragraph 37) of these Regulations it shall:

96.1. submit justified objections to the European Commission and the competent authority of such Member State in which the relevant biocidal product or active substance has been registered or authorised; or

96.2. recommend to refuse an authorisation for the use or registration or to determine additional requirements or restrictions when performing activities with a biocidal product or an active substance specifying a justification, as well as the name, composition, characterisation of components and properties of the active substance or biocidal product dangerous to environment or human health.

97. If a biocidal product which has been registered in a Member State as a low-risk biocidal product causes risk, the Agency shall notify regarding the refusal to the competent authority of such Member State which has registered the relevant biocidal product as a low-risk biocidal product justifying why the biocidal product causes risk and, if an agreement with the relevant competent authority has not been reached, notify the European Commission thereof. The Agency shall register the relevant biocidal product as a low-risk biocidal product if the European Commission approves the initial registration.

98. If the Agency has registered a biocidal product as a low-risk biocidal product and received a refusal from the Member State to register the relevant biocidal product as a low-risk biocidal product, it shall revise the registration taking into account such refusal and, if necessary, request additional information from the applicant. The Agency shall notify the Member State, which has submitted the refusal and the European Commission regarding the decision, which has been taken in revising the registration.

99. The Agency shall notify the European Commission and Member States:

99.1. within the time period of one month after the end of each quarter – regarding all authorisations for use issued or the registrations performed and refusals to register active substances or biocidal products, or to issue an authorisation for use specifying at least:

99.1.1. the name and address of an undertaking of the applicant;

99.1.2. the trade name of the biocidal product or active substance;

99.1.3. the name and quantity of the biocidal product or active substance and of each active substance included in the composition of the biocidal product, as well as the classification thereof if the active substance is a dangerous chemical substance;

99.1.4. the type of a biocidal product or authorised type of utilisation of the biocidal product or active substance;

99.1.5. the type of manufacturing of the biocidal product;

99.1.6. the restrictions or other conditions regarding quantity or the concentration of residues of the biocidal product;

99.1.7. the conditions of an authorisation for use or registration to be complied with when performing activities with a biocidal product or an active substance and, if necessary, the reasons for changing or cancellation of the conditions of the authorisation for use or registration; and

99.1.8. an indication that a biocidal product is a low-risk biocidal product or that the biocidal product has a specific formulae of frame formulation;

99.2. before the issue of an authorisation for use – an approval that:

99.2.1. the requirements in relation to the intended or prohibited type or field of utilisation have been specified in an authorisation for use or a registration certificate; and

99.2.2. the classification, labelling and safety data sheet of a biocidal product or an active substance have been prepared in conformity with the requirements of these Regulations;

99.3. regarding other decisions in relation to authorisations for use issued or registration performed and refusals to register active substances or biocidal products or to issue an authorisation for use;

99.4. regarding new information regarding possible harmful effects of an active substance or a biocidal product on human health or environment, as well as regarding biocidal products with similar composition (including an active substance, impurities, ancillary substances or residues thereof);

99.5. if a technical report or the summary thereof is considered incorrect or incomplete, notifying immediately its considerations thereof why the technical report or

the summary thereof should be considered incorrect or incomplete to the competent authority of the relevant Member State which first issued an authorisation for use or registered the relevant biocidal product or active substance;

99.6. regarding active substances or biocidal products authorised or registered within a calendar year submitting annually the list of biocidal products authorised or registered in the State territory;

99.7. regarding biocidal products which do not conform to the requirements of these Regulations, but which are authorised in accordance with Paragraph 40 of these Regulations;

99.8. if the Agency has determined additional requirements or restrictions, suspended the operation of a registration certificate or an authorisation for use, or cancelled the referred to certificate or authorisation because information has become known that the relevant biocidal product or active substance causes an unacceptable risk to human or animal health or the environment;

99.9. if an authorisation for use or a registration certificate has been issued or extended for an active substance not referred to in the list of active substances, the list of low-risk biocidal products or the list of basic substances because the assessment of technical reports is not completed; and

99.10. regarding activities thereof within a time period of three years (including information regarding cases of poisoning with biocidal products) – by 30 November of the last accounting year.

VIII. Procedures for Dispute and Appeal of Decisions of the Agency

100. An applicant, as well as any natural or legal person whose health, safety or property may be affected by a decision taken by the Agency regarding the temporary registration, registration or issuance of an authorisation for use of a biocidal product or an active substance, within a time period of one month from the day when the relevant person became aware thereof, but not later than within a year from the day of coming into effect of the relevant decision, may dispute in the Bureau the refusal to issue an authorisation for use, the recognition of the authorisation for use or registration or the refusal to recognise the authorisation for use or registration.

101. If the Bureau requires additional information for taking a decision it shall assign the Agency or the applicant to prepare the necessary information. In such cases the decision shall be taken not later than within a time period of three months from the day of submission of the complaint.

102. The applicant has the right not to perform individual studies or to replace the studies requested by other studies if he or she proves to the Agency that the studies requested will not provide the necessary results or that alternative studies are more appropriate for the determination of the properties or effects of a biocidal product or an active substance on humans or the environment.

103. If in evaluating the information submitted, the Bureau concludes that in accordance with an authorisation for use issued, registration or temporary registration performed, the safety of human life, health or the environment is not guaranteed or the requirements specified in regulatory enactments have not been taken into account, it shall take a decision to revoke the decision of the Agency and assign the Agency to review the matter.

104. If in evaluating the information submitted, the Bureau concludes that in accordance with an authorisation for use issued, registration or temporary registration performed, the requirements specified in regulatory enactments have been complied with, it shall take a decision to reject the complaint.

105. The decision of the Bureau may be appealed in court in accordance with the procedures specified in regulatory enactments.

IX. Closing Provisions

106. The manufacturer or importer of a biocidal product or an active substance (trade of which has been commenced by 1 July 2003) shall submit the following information to the Agency by 1 January 2004:

106.1. the name, legal address and location of the manufacturer or importer;

106.2. the name and registration number of the manufacturer or importer in the commercial register, as well as the code of the value added tax payer;

106.3. the natural person responsible for the submission of information regarding a biocidal product or an active substance (position, given name, surname, telephone and fax number, e-mail address);

106.4. the location of the manufacturing plant and the name of the manufacturer if the biocidal product or an active substance is imported;

106.5. the name of the biocidal product or the active substance in accordance with the requirements of these Regulations;

106.6. the intended or existing type of utilisation of the biocidal product or the active substance;

106.7. the total quantity of the biocidal product or active substance imported or manufactured per year;

106.8. evidence (if possible) that the biocidal product or active substance has been placed on the market prior to 14 May 2000;

106.9. a timetable for the performance of studies, as well as for the development and submission of an application to the Agency if the biocidal product or the active substance has not been identified in any of Member States or has been applied to the European Commission for inclusion in the list of active substances, the list of basic substances or the list of low-risk biocidal products; and

106.10. an agreement with the applicant who has applied with the biocidal product or active substance to the European Commission for inclusion in the list of active substances, the list of basic substances or the list of low-risk biocidal products if the active substance has been identified in any Member State.

107. Registration or an authorisation for use by 14 May 2010 is not required for active substances with which trade has been commenced by 14 May 2000 or for biocidal products which contain such active substances and regarding which information has been submitted to the Agency in conformity with Paragraph 106 of these Regulations.

108. Chapters II, III, IV, VI, VII and VIII; Paragraphs 10 and 11, as well as Sub-paragraphs 71.2 and 106.10 shall come into force by special Cabinet regulations.

109. These Regulations shall come into force on 1 July 2003.

Informative Reference to European Union Directives

These Regulations contain legal norms arising from Directive 98/8/EC.

Prime Minister E. Repše

Minister for the Environment R. Vējonis

Annex 1
Cabinet Regulation No. 184
15 April 2003

Types of Biocidal Products and Descriptions Thereof

No.	Type of products	Description of biocidal products
1	2	3
Main group 1. Disinfectants and general biocidal products This group of products does not include cleaning agents for which a biocidal effect is not provided for, including detergents and powders		
1.	Human hygiene biocidal products	Products of this type are biocidal products used for human hygiene.
2.	Disinfectants of residential, public and private buildings and territories	Products of this type are biocidal products utilised for the disinfection of air, surfaces, materials, equipment and furniture which are not intended for direct contact with food products or animal feed in the private, public and industrial sector, including hospitals, as well as products used as algaecides. They are used for the disinfection of swimming-pools, aquariums, bathing and other waters provided for hygienic procedures, in air-conditioning systems, for the disinfection of walls and floors in health care and other institutions, as well as for the disinfection of toilets, waste waters, hospital waste, soil, ground or substrates thereof (for example in playgrounds). Disinfectants of residential, public and private buildings and territories are divided into the following sub-groups: biocidal products utilised for the disinfection of water in swimming pools and elsewhere (2.02), biocidal products utilised in air-conditioning equipment (2.03), biocidal products for toilets, treatment of waste waters and hospital waste (2.04) and other biocidal products of this type (2.05)
3.	Veterinary hygiene biocidal products	Products of this type are biocidal products utilised for veterinary hygiene including products utilised in areas where animals are housed, kept or transported
4.	Disinfectants used in the production and circulation of food products and animal feed	Products of this type are biocidal products utilised for the disinfection of consumption utensils or accessories, equipment, containers or other packaging, pipe-work and surfaces related to the production, acquisition, processing, treatment, transportation, storage and consumption of food products, animal feed or drinks (including drinking water

5.	Disinfectants of drinking water	Products or this type are biocidal products utilised for the disinfection of drinking water, including such disinfection for needs of water animals
Main group 2. Preservatives		
6.	In-can preservatives	Products or this type are biocidal products utilised for the preservation of such products in jars, barrels or other packaging which are not food products or animal feed in order to ensure the shelf life thereof protecting from microbial deterioration. In-can preservatives shall be divided into the following sub-groups: detergent preservatives (6.01.) and other in-can preservatives (6.02)
7.	Film preservatives	Products of this type are biocidal products utilised for the preservation of films or coatings protecting from microbial deterioration in order to protect the initial properties of the surface of paints, plastic, sealing tapes, adhesives, binders, wallpapers, art works or other similar materials, surfaces or objects.
8.	Wood preservatives	Products of this type are biocidal products utilised for the preservation of wood or wood products (also in saw mills, protecting against wood-destroying or wood-disfiguring organisms). Wood preservatives shall be used for the prevention and purification and curing of wood. Wood preservatives shall be divided into the following sub-groups: wood preservatives used for pre-treatment in industry (in pressure or vacuum impregnation equipment) (8.01.) and other wood preservatives (8.02).
9.	Fibre, leather, rubber and polymerised material preservatives	Products of this type are biocidal products utilised for the preservation of fibrous or polymerised materials, leather products, rubber, paper or textile products protecting from microbial deterioration. Fibre, leather, rubber and polymerised materials preservatives shall be divided into the following sub-groups: textile product and leather product preservatives (9.01), paper preservatives (9.02), rubber and polymerised material preservatives, as well as other biocidal products of product type 9 (9.03).
10.	Masonry preservatives	Products of this type are biocidal products utilised for the preservation and treatment of masonry constructions, masonry and other construction materials other than wood for cleaning thereof from microbes and algae or to protect against growing of microbes and algae.
11.	Preservatives for cooling and technological equipment or	Products of this type are biocidal products utilised for the protection of water or other liquids used in cooling and

	system liquids	technological equipment or systems against microbes, algae, molluscs and other harmful organisms living in water. This product type shall not include drinking water disinfectants. Preservatives for cooling and technological equipment or system liquids shall be divided in the following sub-groups: preservatives used in flow systems (11.01) and preservatives utilised in circulatory systems (11.02)
12.	Slimicides	Products of this type are biocidal products utilised for the prevention of slime growth on structures, equipment and materials utilised in industry (for example, on wood and paper mass or pulp, on porous sand strata in oil extraction) or for the protection of the referred to structures, equipment and materials from slime growth. Slimicides shall be divided into the following sub-groups: anti-slime products for pulp (12.01.), anti-slime products for oil extraction (12.02.) and other anti-slime products (12.03.)
13.	Metalworking fluid preservatives	Products of this type are biocidal products utilised for the protection of metalworking fluids, including solutions, against microbial deterioration.
Main group 3. Pest control products		
14.	Rodenticides	Products of this type are biocidal products utilised for the protection against mice, rats or other rodents.
15.	Avicides	Products of this type are biocidal products utilised for the protection against birds.
16.	Molluscicides	Products of this type are biocidal products used for the protection against molluscs.
17.	Piscicides	Products of this type are biocidal products utilised for the protection against fish, except for medicinal products for the treatment of fish diseases.
18.	Insecticides, acaricides and products to control other arthropods	Products of this type are biocidal products utilised for the protection against arthropods (for example, insects, arachnids and crustaceans). Insecticides, acaricides and products to control other arthropods shall be divided in the following subgroups depending from users utilising thereof: for professional use (18.01.), for utilisation by non-professional users (18.02.)
19.	Repellents and attractants	Products of this type are biocidal products utilised for the protection against harmful organisms, including invertebrates (for example, fleas) and vertebrates (for examples, birds) by repelling or attracting thereof. This

		product type shall also include biocidal products directly or indirectly utilised for human or veterinary hygiene. Repellents and attractants shall be divided into the following subgroups: repellents used directly on human or animal skin (19.01.), attractants and repellents not used directly on human or animal skin (19.02.)
Main group 4. Other biocidal products		
20.	Preservatives for food products or animal feed	Products of this type are biocidal products utilised for the protection of food products or animal feed, including the feed in warehouses, against harmful organisms
21.	Antifouling products	Products of this type are biocidal products utilised for the prevention of growth and colony-forming of fouling organisms (microbes and plant or animal species) in vessels, aquaculture equipment or other structures used in water.
22.	Embalming and taxidermist fluids	Products of this type are biocidal products utilised for the disinfection and preservation of human or animal corpses or parts thereof.
23.	Products for destruction of vertebrates	Products of this type are biocidal products utilised for protection against insects, rats and other vertebrates which are harmful organisms

Minister for Environment R. Vējonis

Annex 2
Cabinet Regulation No. 184
15 April 2003

Application for Registration, Temporary Registration of Biocidal Products or Active Substances or Receipt of Authorisation

<table>
<tr><td colspan="3">1. Information regarding the applicant</td></tr>
<tr><td rowspan="2">Name</td><td colspan="2">Registration No.</td></tr>
<tr><td colspan="2">Date of registration in the commercial register</td></tr>
<tr><td colspan="3">Legal address</td></tr>
<tr><td>Person responsible for the submission of the application and additional information regarding the biocidal product or active substance

_____
(given name, surname)</td><td colspan="2">Telephone _____
Fax _____
E-mail _____</td></tr>
<tr><td>Person responsible for the performance of activities with the biocidal product or active substance[1]

_____
(given name, surname)</td><td colspan="2">Telephone _____
Fax _____
E-mail _____</td></tr>
<tr><td colspan="3">A statement regarding the fact that the applicant is an authorised representative of the manufacturer if the biocidal product or active substance is manufactured outside the territory of Latvia (in Annex)[2]</td></tr>
</table>

<table>
<tr><td>2. General information regarding the biocidal product or active substance

_____
(the trade name and manufacturer’s code of the biocidal product or active substance)

_____
(the group and type of the biocidal product in accordance with Annex 1 of these Regulations)

_____
(the (preparatory) way of manufacturing of the biocidal product)

_____
(the packaging of the biocidal product or active substance)</td></tr>
</table>

3. Information regarding classification and marking of the biocidal product or active substance	
Classification of the biocidal product or active substance:	
Class of danger	
Designation of danger by letters	
Characterisation of exposure effects	
Designations of safety requirements	
The risk group if the active substance is a fungus, a micro-organism or a virus	
Marking of the biocidal product or active substance (Symbol of danger) (Explanation of danger)	(Symbol of danger) (Explanation of danger)

4. Composition of a biocidal product						
No.	Name of components[3]	CAS, EINECS, or ELINCS number[4]	Class of danger and designation of danger by letters	Letters and numbers of effect characterisation of exposure and safety requirements	Risk group if the active substance is a fungus, a micro-organism or a virus	Component concentration or quantity in a biocidal product (in metrical units of measurements or of international system of measurements or percentage by weight or volume)
4.1.	Active substances					
4.2.	Potentially dangerous substances					
4.3.	Other					

	components, impurities					

5. Special indications regarding the type of manufacture or composition of a biocidal product or active substance	
The active substance is a basic substance	
The biocidal product has a specific formula of frame-formulation	
The biocidal product is a low-risk biocidal product	
The biocidal product belongs to another group of biocidal products in relation to which special conditions exist.	

6. General information regarding efficiency of effects of the biocidal products on target organisms

7. Information regarding intended types of use of biocidal products	
Intended field or sector for use of the biocidal product	
Other types of biocidal product utilisation	
Groups or categories of users of the biocidal products, including professional users or non-professional users	
Properties of the biocidal product or active substance which may have a negative effect on intended use, storage and transport of the biocidal product, and potential undesirable consequences or adverse effects under the intended conditions for use.	

8. Conditions for use of the biocidal product or active substance	
Methods, conditions for use and doses to be used	
The time period and interval necessary for effect of the biocidal product on target organisms to be observed between uses of the biocidal product, between the treatment of a product with the biocidal product and the	

use of the treated product, as well as between the utilisation of the biocidal product and entering or presence of a person or animals in the territory, room or other place where the biocidal product has been utilised	
The date by which a biocidal product or active substance is valid for the intended application if the conditions for the storage of the relevant biocidal product or active substance are complied with	
Information regarding security and precautionary measures during utilisation, storage and transport (including information regarding necessary personal protective clothing and equipment, fire safety measures, coverage of machines or tools, removal of food and animal feed materials) and instructions for protecting animals against the effects of the biocidal products	
Instructions for the protection of employees in accordance with regulatory enactments regulating labour protection requirements (including in relation to microbiological biocidal products or active substances – in accordance with regulatory enactments regulating labour protection requirements when in contact with biological substances)	
Information regarding adequate and appropriate methods and products for the cleaning of equipment and detailed information regarding purification products and measures after the use of biocidal products, as well as information regarding the period of ventilation necessary if the equipment, premises or structures are treated with biocidal products	
Information regarding potential direct or indirect harmful side effects	
Information regarding the danger to the environment (in particular, if it is necessary to protect organisms for the destruction of which the biocidal product is not intended, and not to allow water contamination)	
Instructions for first aid if poisoning with the biocidal product or active substance has occurred	
Groups of users for whom the use of the biocidal product is not recommended and utilisation thereof is restricted	
Instructions for the safe management or processing of biocidal waste and packaging waste and, if necessary, prohibition to reuse the packaging	
Safety data sheet (in Annex)	
Samples of packaging, labels or instructions, models	

(simplified reproductions of samples) or outline drawings, if necessary (in Annex)[5]	

9. Information regarding studies	
Name of the person performing the tests or studies	
Evidence that the laboratory which has performed the studies conforms with the requirements[6]	
The date of issue, term of validity of the authorisation for experiments with animals and essential conditions referred to in the authorisation and a copy of the relevant authorisation (in Annex)	
Measures to prevent the performance of analogous experiments with animals by several applicants of identical biocidal products or active substances	
Justification of the study methods utilised and a description of studies performed and methods used or a bibliographical reference to such methods (in Annex)[7]	
Justification if it is not possible technically or it is scientifically necessary to obtain information (because such information would not characterise the properties of the biocidal product, activities with such biocidal product or the effect thereof on the environment or human health)[8]	
Justification of proposals regarding the classification, labelling of the biocidal product or active substance and safety data sheets (in Annex)[9]	

10. Technical report (in Annex)[10]	
A technical report regarding the active substance if the active substance is a chemical substance	
A technical report regarding the biocidal product if the active substance in the composition of the biocidal product is a chemical substance	
A technical report which includes additional information regarding the active substance if the active substance is a chemical substance	
A technical report which includes additional information regarding the biocidal product if the active substance in the composition of the biocidal product is a chemical substance	
A technical report regarding an active substance if the	

active substance is fungi, micro-organisms or viruses	
A technical report regarding the biocidal product if the active substance in the composition of the biocidal product is fungi, micro-organisms or viruses	
A technical report for the temporary registration of the biocidal product or active substance if the active substance is not included in the list of active substances, the list of low-risk biocidal products or the list of basic substances	

11. Information necessary to assess the risk to the environment and human health or life, or prior risk assessment (in Annex)[11]

12. Information regarding the manufacturer or importer of the biocidal product or active substance	
12.1. Information regarding the manufacturer, importer or supplier of the biocidal product or active substance registered in Latvia[12]	
Name	Registration No. Date of registration in the commercial register
Legal address	
Person responsible for the performance of activities with the biocidal product or active substance _____ (given name, surname)	Telephone _____ Fax _____ E-mail _____

12.2. Information regarding the manufacturer of the biocidal product or active substance if the biocidal product or active substance is manufactured outside the territory of Latvia
Name of the manufacturer
Legal address
Location of the manufacturing establishment

I certify that information provided in the application is true and accurate.

Given name, surname _____ Date _____

_____ Place for a seal
(signature)

Telephone _____

Note regarding receipt in the Latvian Environment Agency _____
(date of receipt and registration number)

Notes.

1. To be completed if the applicant manufactures, imports or supplies the biocidal product or the active substance.

2. The application form shall specify whether the statement has been attached.

3. The name of dangerous chemical substances in the composition of the biocidal product in accordance with the list of dangerous chemical substances approved by the Minister for Environment. The generally accepted name of chemical substances (other than dangerous chemical substances) in the composition of the biocidal product or the name in conformity with the nomenclature of the International Union of Pure and Applied Chemistry (IUPAC).

4. The registration number of the chemical substance in the Chemical Abstracts Service (CAS number). The number of the chemical substance in the European Inventory of Existing Commercial Chemical Substances (EINECS number) or the European List of Notified Chemical Substances (ELINCS number), if known.

5. The application form shall specify whether the samples or models of packaging, label or instructions have been attached.

6. The laboratory conforms to the requirements of good laboratory practice, if the laboratory is inspected and operates in accordance with regulatory enactments, which regulate requirements for the quality of laboratory operation and inspection of laboratories.

7. The application form shall specify in which Annex and the number of pages of the justification and other information regarding study methods utilised are provided.

8. Such justification may include information regarding frame-formulation.

9. The application form shall specify in which Annex and the number of pages of the justification for proposals regarding the classification, labelling of the biocidal products or active substances and safety data sheets.

10. The application form shall specify the technical reports attached.

11. The application form shall specify the contents of the Annex:

11.1. information necessary for evaluation of the risk to the environment and human health or life;

11.2. prior risk assessment.

12. To be completed in the following cases:

12.1. the applicant is not the manufacturer, importer or supplier of the biocidal product or the active substance who is registered in Latvia;

12.2. there are other manufacturers or importers of the biocidal product or active substance registered in Latvia who on the basis of the authorisation issued to the applicant, will also manufacture or import the relevant biocidal product or active substance.

Minister for Environment R. Vējonis

Annex 3
Cabinet Regulation No. 184
15 April 2003

Contents of the Technical Report regarding Active Substances if the Active Substances are Chemical Substances

1. Information regarding the manufacturer of the active substance:
    1.1. the name, legal address and location of the manufacturer;
    1.2. the name of the person performing tests or studies; and
    1.3. the location of the manufacturing plant,

2. The name and legal address of the importer.

3. Identity of the active substance:
    3.1. the name in accordance with IUPAC nomenclature;
    3.2. the name approved by the International Organisation for Standardisation (hereinafter – ISO) or the name recommended for ISO approval and synonyms thereof;
    3.3. the development code number of manufacturer (number or another designation assigned to the active substance by the manufacturer);
    3.4. CAS number, the number of the chemical substance in the European Inventory of Existing Commercial Chemical Substances (EINECS number) or the European List of Notified Chemical Substances (ELINCS number) (hereinafter – EC number) if the active substance is mentioned in the relevant list;
    3.5. molecular and structural formula, including information regarding the types and molar mass of isomers;
    3.6. the method of manufacture of the active substance (short outline of the manufacturing process);
    3.7. the degree of purity of the active substance (g/kg or g/l);
    3.8. the identity of impurities or additives (for example, stabilisers), the structural formula thereof and possible quantity of impurities or additives (g/kg or g/l) specifying the minimum or maximum quantity or range thereof;
    3.9. the natural origin of the active substance or the initial origin of the active substance (materials, plants or organisms from which the active substance is obtained, for example, an extract of a flower);
    3.10. information regarding exposure, including information regarding the effect of the active substance:
        3.10.1. on human (including employees) health; and
        3.10.2. in the environment, including the information regarding the substance being recognised in regulatory enactments as particularly dangerous or dangerous to the aquatic environment, or a priority substance.

4. Physico-chemical properties of active substances:
    4.1. melting temperature, boiling temperature, relative density;

4.2. vapour pressure for the purified active substance (Pa);

4.3. physical state and colour;

4.4. spectral analysis data (ultraviolet (UV), infra-red (IR), nuclear magnetic resonance (NMR) or visible radiation spectrum or mass spectrum and extinction coefficient characterising molar extinction (molar absorption) a relevant wavelength);

4.5. solubility in water, including observed effects, if pH is from 5 to 9, and temperature effect on solubility;

4.6. partition coefficient – solubility of the relevant substance in n-octanole against solubility in water, including the observed effects if pH is from 5 to 9 depending on the temperature;

4.7. thermal stability, identity of the relevant breakdown products;

4.8. flammability including self-ignition temperature and identity of the combustion products;

4.9. flash point;

4.10. surface tension;

4.11. explosive properties (capability of explosion);

4.12. oxidising properties; and

4.13. reactivity with packaging material.

5. Analytical methods for detection and identification of active substances:

5.1. analytical methods for the determination of pure active substance and, if necessary, the determination of relevant degradation products, isomers and impurities of the active substance and additives (for example, stabilisers); and

5.2. analytical methods for the determination of active substance and residues thereof in environment or organisms specifying the applicability or determination limit characteristic to each environment or organism and method, and the frequency or time period for recovery of the environment to be tested, including analytical methods for the determination of active substance and residues thereof in:

5.2.1. soil;

5.2.2. air;

5.2.3. water, justifying the selection of a method and specifying the sensitivity of the method that ensures that using such method the active substance and all degradation products thereof are determined with such reliability and accuracy which is necessary in determining or examining the conformity with the requirements of the quality or harmlessness of water intended for human consumption (for example, maximum permissible norm in relation to quantity of active substance in water); and

5.2.4. in animal and human body fluids and tissues.

6. Efficacy on harmful target organisms and intended uses:

6.1. name or characterisation of the type or group of biocidal products (in compositions of which the relevant active substance is used) in conformity with the intended use or effect (for example, fungicide, rodenticide, insecticide, bactericide);

6.2. harmful target organisms necessary to be destroyed, repelled, rendered harmless or otherwise affected, and products, organisms, subjects or other objects which must be protected;

6.3. effect on target organisms and potential concentration or dose for use;

6.4. types of effects, including effects, which may appear after some time;

6.5. field or sector of utilisation – existing or planned;

6.6. users – in manufacture, professional or non-professional users;

6.7. information regarding the possibility of the occurrence and development of resistance, and measures necessary that are to be taken if the resistance has occurred; and

6.8. planned trade volume – tonnes per year.

7. Toxicological studies regarding acute toxicity, which may be caused by the active substance if it is administered orally or inhaled, or if it comes into contact with skin, shall determine skin irritation, eye irritation (except for cases when corrosivity has been determined) and skin sensitisation. The acute toxicity of active substances shall be evaluated as follows:

7.1. acute toxicity of active substances other than gases shall be evaluated at least by two methods (one of which – administering orally). The second evaluation method shall be selected depending on properties of the active substance and potential effect on humans; and

7.2. acute toxicity of active substances, which are gases or volatile liquids, shall be evaluated by inhaling.

8. Other toxicological studies:

8.1. metabolism studies for mammals, including a toxicokinetic and dermal absorption study;

8.2. short-term repeated dose toxicity studies (28 days) – are not necessary if sub-chronic studies for rodents are available;

8.3. sub-chronic toxicity studies – 90-day studies for two species one of which is rodent, but the other is non-rodent;

8.4. chronic toxicity studies for two species one of which is rodent, the other – other mammal species;

8.5. mutagenicity studies:

8.5.1. gene mutation study in bacteria in laboratory conditions (*in vitro*), utilising a bacteriological (reverse mutation) method;

8.5.2. cytogenicity studies in mammalian cells in laboratory conditions (*in vitro*);

8.5.3. gene mutation assay studies in mammalian cells in laboratory conditions (*in vitro*);

8.5.4. additional gene mutation studies *in vivo* – bone marrow assay (for chromosomal damage) or micronucleus studies, if the results are positive in any of the assays referred to in Sub-paragraphs 8.5.1., 8.5.2 or 8.5.3. of this Annex. By micronucleus test the substances causing cytogenetic damage are determined due to which micronuclei are formed in which the fragments of chromosomes or whole chromosomes are detained;

8.5.5. additional studies *in vivo* in order to examine whether mutagenicity or deoxyribonucleic acid (DNS) damages are present in other tissues (other than bone marrow) if the results of studies referred to in Clause 8.5.4 of this Annex are negative, but the results are positive in any of the studies referred to in Clauses 8.5.1, 8.5.2 or 8.5.3 of this Annex; and

8.5.6. studies regarding the effect on germ cells (mammalian spermatogonial chromosome aberration test) or embryonic cells (rodent dominant lethal test) if the results of studies referred to in Clause 8.5.4 of this Annex are positive and if necessary;

8.6. carcinogenicity studies for two species one of which is rodent, the other – another mammalian species; These studies may be combined with the studies referred to in Sub-paragraph 8.5 of this Annex;

8.7. studies regarding the toxicity of active substance to reproductive system:

8.7.1. teratogenicity studies- to rabbits and one rodent species; and

8.7.2. reproductive toxicity studies of two generations in order to ascertain the effect of active substance on fertility of males and females of one species;

8.8. studies which are necessary in accordance with Sub-paragraphs 8.2, 8.3, 8.4, 8.5, 8.6 and 8.7 of this Annex. Studies are performed by the oral administration of the active substance, except for cases when another way of performing of the study is more appropriate; and

8.9. long-term toxicological and carcinogenicity studies may not be performed if the results of all toxicological studies indicate that the active substance has not mutagenic, carcinogenic or toxic effects.

9. Medical information in compliance with personal data protection requirements if the relevant information is available:

9.1. information regarding medical surveillance of employees in the manufacturing plant of the active substance also specifying the medical examination data;

9.2. information regarding direct observations also specifying clinical and poisoning cases;

9.3. medical examination protocols or opinions regarding the state of health of employees in the manufacturing plant of the active substance or the public;

9.4. information regarding observations related to the exposure of the public to the effects of the active substance and data of epidemiological studies;

9.5. information regarding cases of poisoning and the diagnosis thereof specifying specific signs of poisoning and results of clinical tests;

9.6. prognosis of expected effects of poisoning; and

9.7. information regarding observations related to sensitivity and allergy.

10. Information regarding action and emergency assistance if the poisoning of a person with the active substance occurs, including first aid, products to be utilised for the reduction of the harmful effect of the active substance, and treatment methods (if known).

11. Summary regarding toxicological studies specifying also no-observed adverse effect level, any no-observed effect level, general description of studies and evaluation of

results taking into account all the toxicological data and other characteristic information relating to active substances, as well as the recommendations regarding the measures necessary for the protection of employees and other users of the active substance.

12. Ecotoxicological studies regarding :

12.1. acute toxicity to fish;

12.2. acute toxicity to daphnia (*Daphnia magna*);

12.3. algae growth inhibition;

12.4. inhibition to microbiological activity;

12.5. bio-accumulation;

12.6. circulation of the active substance in the environment, providing a general description and specifying mobility, spreading, persistence (stability), degradation or other modification of the active substance in environment;

12.7. degradation of the active substance:

12.7.1. biological degradation, including complete biological degradation and, if possible, characteristic biodegradability; and

12.7.2. abiotic degradation – the hydrolysis speed shall be determined depending on pH and photo-transformation in water, including the identity of the products of the transformation; and

12.8. adsorption and desorption, and additional studies in accordance with Annex 5 of these Regulations if the results of such a test indicates the necessity of such studies; and

12.9. summary specifying the conclusions regarding ecotoxicological effects of the active substance, circulation and the behaviour thereof in the environment.

13. Measures necessary for the protection of humans, animals and the environment:

13.1. recommended methods, technologies, precautionary and security measures in manufacturing, storing, managing, transporting or performing other activities with the active substance, as well as in case of fire;

13.2. special protection measures in cases of fire – depending on the possible chemical reactions and mutual effects of substances, as well as the properties of reaction products or combustion gases or other negative effects;

13.3. measures in case of accident, emergency or extreme situations;

13.4. measures for the prevention, collection and decontamination of accident release into the environment (air, water (including potable water) or soil); and

13.5. management of the active substance and the waste thereof for industry or professional users:

13.5.1. possibility to use the active substance as recycled raw material or to reuse it;

13.5.2. possibility to prevent or reduce undesirable consequences or harmful effects;

13.5.3. conditions for the burial, disposal and monitoring of wastewater, including emission monitoring and permissible pollution; and

13.5.4. conditions for waste incineration and monitoring thereof; and

13.6. observations regarding undesirable or unintended side-effects on other organisms other than the harmful target organisms.

14. Proposals and justification thereof regarding the classification and labelling of the active substance in conformity with the regulatory enactments regulating the classification, labelling and packaging of chemical substances and chemical products, and the date of labelling, specifying:

14.1. danger symbols;

14.2. explanation of danger;

14.3. characterisation of effects of the substance; and

14.4. designations of safety requirements;

15. Evaluation and summary of such information which has been acquired in performing studies regarding the active substance which is a chemical substance.

Minister for Environment R. Vējonis

Annex 4
Cabinet Regulation No. 184
15 April 2003

Contents of Technical Report regarding Biocidal Products if the Active Substance in the Composition of the Biocidal Products is a Chemical Substance

1. Information regarding the manufacturing of the biocidal product and the active substance:

1.1. the name, legal address and location of the manufacturer of the biocidal product and active substance;

1.2. the name of the person performing the tests or studies; and

1.3. locations of manufacturing establishments.

2. The name and legal address of the importer.

3. Identity of the biocidal product:

3.1. the trade name or proposed trade name and development code number of manufacturer (a number or another designation assigned by the manufacturer to the relevant biocidal product);

3.2. detailed information regarding the quantitative and qualitative composition of the biocidal product, including active substances, impurities, additives, inert and other components and information regarding whether the substance has been recognised as a particularly dangerous or dangerous to the aquatic environment, or as a priority substance in regulatory enactments; and

3.3. type of preparations of the biocidal product (type in which the biocidal product has been prepared for delivery or sale to a consumer (for example, solutions, moistened powder, emulsifiable concentrate)) and properties characteristic or directly related to the type of preparations of the biocidal product.

4. Physico-chemical and mechanical properties of biocidal products:

4.1. the physical state and colour;

4.2. the explosive properties;

4.3. the oxidising properties;

4.4. flash-point and other information regarding flammability or spontaneous ignition;

4.5. acidity or alkalinity and, if necessary, pH value (1% in water);

4.6. relative density;

4.7. storage stability and shelf life. Effects of light, temperature and humidity on properties of a biocidal product (in particular to mechanical properties), reactivity to packaging material;

4.8. characterisation of mechanical and other properties of a biocidal product (for example, wettability, characterisation of foaming (persistent foaming), flowability, pourability and foaming); and

4.9. physical and chemical compatibility with other products including other biocidal products with which the relevant biocidal product must be used.

5. Methods of biocidal product identification and analysis not specified in accordance with the requirements set out in Annex 3 of these Regulations:

5.1. analytical methods for determining the concentration of the active substance in the biocidal product; and

5.2. analytical methods for the determination of such components of the biocidal product in the environment and organisms which have ecotoxicological, irritating, corrosive, sensitising, mutagenic, carcinogenic, harmful, toxic or very toxic effects specifying the applicability or determination limit characteristic to each environment or organism and method, and the frequency or time period for recovery of the environment to be tested, including analytical methods for the determination of components of the biocidal product:

5.2.1. in the soil;

5.2.2. in the air;

5.2.3. in water (including potable water);

5.2.4. in animal and human body fluids and tissues; and

5.2.5. treated food products or animal feed.

6. Effectiveness of the biocidal products on harmful target organisms and intended uses:

6.1. type of the biocidal product and intended field of use;

6.2. methods and technologies for use, including a description of activities to be performed;

6.3. dose of the biocidal product to be used for treatment at one time and duration of the treatment, if necessary, including the concentration of the biocidal product and active substance or residues thereof in the product, system or territory in which the product will be used (for example, in cooling water, surface waters, water for heating system);

6.4. the number of times necessary to perform treatment with the biocidal product, duration of one treatment with the biocidal product and other conditions in relation to the duration or time of the treatment with the biocidal product. If necessary, detailed information regarding the diversity of geographical and climatic conditions, as well as whether a waiting period is necessary in order to protect humans and animals (for example, between the treatment of the product with the biocidal product and the use of the product, subject, equipment, surface, structure or place treated);

6.5. the name or characterisation of the type or group of biocidal products in conformity with the intended use or effect (for example, fungicide, rodenticide, insecticide, bactericide);

6.6. harmful target organisms necessary to be destroyed, repelled, rendered harmless or otherwise affected, and products, organisms, materials, subjects or other objects which must be protected against the effects of the target organisms;

6.7. effect on target organisms;

6.8. the types of effects, including effectiveness which may appear after some time;

6.9. users – in manufacture, professional or non-professional users;

6.10. proposals and a justification regarding the contents of the label depending on the results of studies also taking into account the results of studies regarding efficacy of the biocidal product and available protocols and surveys regarding the laboratory and field trial; and

6.11. information regarding the effects of other factors including the possibility of occurrence and development of resistance.

7. Toxicological studies* regarding acute toxicity, which may be caused by the biocidal product if it is administered orally or inhaled or if it comes in contact with skin, shall determine the skin irritation, eye irritation (except for cases if corrosion has been determined or the biocidal product indicates potentially corrosive properties). If it is necessary to utilise two or more biocidal products, studies regarding acute dermal toxicity and skin and eye irritation, if possible, shall be performed to the relevant biocidal mixture. The acute toxicity to biocidal products shall be evaluated as follows:

7.1. acute toxicity of biocidal products other than gases shall be evaluated at least by two methods (one of which – administering orally). The second evaluation method shall be selected depending on properties of the active substance and potential effect on humans; and

7.2. acute toxicity of biocidal products which are gases or volatile liquids shall be evaluated by inhaling.

8. Other toxicological studies or information* regarding:

8.1. dermal absorption of the biocidal product;

8.2. effects of the biocidal products on humans who may come into contact with the biocidal product or who may be subject indirectly to the exposure of the biocidal product through environment, including the effects of the biocidal products on employees; and

8.3. other substances which are included in the compositions of the biocidal product and which are not active substances, in particular regarding the toxicological effects of potentially dangerous substances. Toxicological studies regarding potentially dangerous substances which are in the compositions of the biocidal product and which are not active substances shall be performed in accordance with Paragraphs 9, 10, 11, 12 and 13 of this Annex of properties, structure or other signs certifies that it may be very toxic, toxic, carcinogen, toxic or mutagen to reproductive system.

9. Toxicological studies* on acute toxicity, which may be caused by the biocidal product if it is administered orally or inhaled, as well as if it comes in contact with skin, shall determine the skin irritation, eye irritation (except for cases if corrosion has been determined) and skin sensitivity. The acute toxicity of potentially dangerous substances shall be evaluated as follows:

9.1. acute toxicity of potentially dangerous substances other than gases shall be evaluated at least by two methods (one of which – administering orally). The second evaluation method shall be selected depending on properties of the potentially dangerous substance and potential effects on humans; and

9.2. acute toxicity of potentially dangerous substances which are gases or volatile liquids shall be evaluated by inhaling.

10. Other toxicological studies:

10.1. metabolism studies for mammals, including a toxicokinetic and dermal absorption study;

10.2. short-term repeated dose toxicity studies (28 days) – are not necessary if sub-chronic studies for rodents are available;

10.3. sub-chronic toxicity studies – 90-day studies for two species one of which is rodent, but the other is non-rodent;

10.4. chronic toxicity studies for two species one of which is rodent, the other – other mammal species;

10.5. mutagenicity studies:

10.5.1. gene mutation study in bacteria in laboratory conditions (*in vitro*), utilising a bacteriological (reverse mutation) method;

10.5.2. cytogenicity studies in mammalian cells in laboratory conditions (*in vitro*);

10.5.3. gene mutation assay studies in mammalian cells in laboratory conditions (*in vitro*);

10.5.4. additional gene mutation studies *in vivo* – bone marrow assay (for chromosomal damage) or micronucleus studies, if the results are positive in any of the assays referred to in Clauses 10.5.1., 10.5.2 or 10.5.3. of this Annex By micronucleus test the substances causing cytogenetic damage are determined due to which micronuclei are formed in which fragments of chromosomes or whole chromosomes are detained;

10.5.5. additional studies *in vivo* in order to examine whether mutagenicity or deoxyribonucleic acid (DNS) damages are present in other tissues (other than bone marrow) if the results of the studies referred to in Clause 10.5.4 of this Annex are negative, but results are positive in any of the studies referred to in Clauses 10.5.1, 10.5.2 or 10.5.3 of this Annex; and

10.5.6. studies regarding the effect on germ cells (mammalian spermatogonial chromosome aberration test) or embryonic cells (rodent dominant lethal test) if the results of studies referred to in Clause 10.5.4 of this Annex are positive and if necessary;

10.6. carcinogenicity studies for two species one of which is rodent, the second – other mammal species; These studies may be combined with studies referred to in Sub-paragraph 10.5 of this Annex;

10.7. studies regarding the toxicity of potentially dangerous substance to reproductive system:

10.7.1. teratogenicity studies- to rabbits and one rodent species; and

10.7.2. reproductive toxicity studies of two generations in order to ascertain the effect of the potentially dangerous substance on fertility and reproduction of males and females representatives of one species;

10.8. studies which are necessary in accordance with Sub-paragraphs 10.2, 10.3, 10.4, 105., 10.6 and 10.7 shall be performed by oral administration of the potentially

dangerous substance, except for cases when another type of performing the study is more appropriate; and

10.9. long-term toxicological and carcinogenicity studies may not be performed if the results of all toxicological studies indicate that the potentially dangerous substance does not have mutagenic, carcinogenic or toxic effects.

11. Medical information* in compliance with personal data protection requirements (if the relevant information is available):

11.1. information regarding medical surveillance of employees in the manufacturing plant of potentially dangerous substances specifying the medical examination data;

11.2. information regarding direct observations specifying also clinical and poisoning cases;

11.3. medical examination protocols or opinions regarding the state of health of employees in the manufacturing plant of potentially dangerous substances or people;

11.4. information regarding observations related to exposure of people to the effects of the potentially substance and the data of epidemiological studies;

11.5. information regarding cases of poisoning and diagnosis thereof specifying specific signs of poisoning and results of clinical tests;

11.6. prognosis of foreseeable consequences of poisoning with a potentially dangerous substance; and

11.7. information regarding observations related to sensitivity and allergy.

12. Information* regarding action and emergency assistance if the poisoning of a person with an active substance occurs, including first aid, products to be utilised for reduction of harmful effects of the active substance, and treatment methods (if known).

13. Summary of toxicological studies* also specifying the no-observed adverse effect level, any observed effect level, a general description of the studies and evaluation of results taking into account all the toxicological data and other characteristic information relating to potentially dangerous substances, as well as recommendations regarding measures necessary for the protection of humans (employed in manufacturing of the biocidal product, professional users, non-professional users and humans) against the possible harmful effect of the biocidal product, in particular, a particularly dangerous substance.

14. Ecotoxicological studies or information* regarding:

14.1. the way in which the biocidal product enters into the environment (for example, by emission in water, by rainwater, air, soil, residues). The evaluation shall be performed on the basis of intended use;

14.2. the ecotoxicological effect caused by an active substance in the composition of the biocidal product if such effect cannot be determined on the basis of the results of the studies performed regarding the properties and effects of the relevant active substance; and

14.3. the ecotoxicological effect of other substances (other than active substances) in the composition of the biocidal product, in particular, on the ecotoxicological effect of potentially dangerous substances. Information regarding the ecotoxicological effects of a potentially dangerous substance shall be indicated on the basis of information included in the safety data sheets.

15. Measures* necessary for the protection of humans, animals and environment:

15.1. recommended methods, technologies, precautionary and security measures in manufacturing, storing, managing, transporting or performing other activities with a biocidal product, as well as in case of fire; and

15.2. specific protection measures in case of an accident and first aid if poisoning with a biocidal product of a person occurs including the means to be used for the reduction of harmful effects of the biocidal product and treatment methods if such measures are not referred to in Annex 3, Paragraphs 10 and 13 of these Regulations (for example, if the poisoning has been caused by a potentially dangerous substance included in the compositions of the biocidal product);

15.3. conditions for cleaning containers and the equipment used if the biocidal product is used for the treatment of equipment or substances, products, materials or subjects in the equipment or container, or special equipment or containers are necessary for activities with the biocidal product;

15.4. special protection measures in case of fire – depending on the properties of the most important combustion products and the effects on human health and the environment;

15.5. conditions for management, processing or reuse of biocidal waste and packaging waste and conditions for drainage of waste waters, waste burial and monitoring:

15.5.1. in manufacturing;

15.5.2. for professional users; and

15.5.3. for non-professional users;

15.6. measures for prevention, collection and decontamination of accident emissions and releases in the environment (air, water (including potable water) or soil);

15.7. observations regarding undesirable or unintended side-effects on other organisms other than harmful target organisms; and

15.8. specific measures in relation to the properties and composition of the biocidal product – components of the biocidal product shall be specified which prevent or reduce the ability of repellents to repel or poisonous (toxic) or harmful effects of other biocidal products on organisms other than harmful target organisms.

16. The classification, packaging and labelling or the biocidal product in accordance with Chapter V of these Regulations:

16.1. proposals for packaging and labelling;

16.2. justification of classification and labelling:

16.2.1. danger symbols;

16.2.2. explanation of danger;

16.2.3. characterisations of effects of the substance; and
16.2.4. designations of safety requirements;
16.3. proposals for the safety data sheet, if necessary; and
16.4. packaging (form, materials, size), compatibility of the biocidal product with possible packaging material.

17. Evaluation and summary of such information* which has been acquired performing studies with the biocidal product.

Note.
*Information or studies are not necessary if the active substance has been mentioned in the list of low-risk biocidal products.

Minister for Environment R. Vējonis

Annex 5
Cabinet Regulation No. 184
15 April 2003

Additional Information or Studies regarding the Active Substance if the Active Substance is a Chemical Substance

1. Physical and chemical properties of active substances:

1.1. solubility in organic solvents including effect of temperature on solubility. The examination shall be performed for a pure active substance with a degree of purity (%), properties and conditions determined; and

1.2. identity and stability of the most important breakdown products in organic solvents utilised in biocidal products. The examination shall be performed for a non-purified active substance which has specific impurities or degree of purity (%) and properties;

2. Analytical methods for the determination of an active substance and residues thereof in food products or animal feed, and other products (including on the surface thereof) specifying the applicability or determination limit characteristic to each method, and the frequency or time period for recovery of the environment to be tested, if necessary.

3. Toxicological and metabolic studies:

3.1. neurotoxicity studies shall be performed for active substances which are organophosphorus compounds or other chemical substances or chemical products regarding which there are indications that they may have neurotoxic properties. The test species is the adult hen (except for cases when another test species is more appropriate for research into the neurotoxic effects of the active substance). If necessary, delayed neurotoxicity shall be determined which is a long-term neurotoxic effect caused by the active substance the symptoms of which may appear after some time. If it has been determined that the active substance has anticholine esterase effects that block enzymes – cholinesterasis (including acetyl cholinesterasis), an examination shall be performed ascertaining the response caused by reactivating agents (substances recovering the blocked activity of acetyl cholinesterasis);

3.2. toxic effects on livestock and domestic animals;

3.3. studies regarding active substances which may be utilised in the preparation, utilisation or storage of food products and animal feed shall be performed in accordance with Paragraph 6 of this Annex;

3.4. exposure assessment of the active substance and studies regarding the effects of the active substance on human health, if the results of the studies previously performed or special features (properties or structure of the substance) indicate regarding the necessity of such studies and the potential effects of the substance;

3.5. studies regarding the toxic effects of plant metabolism products (metabolites) which effects are different from the toxic effects determined to animals if the biocidal product containing the active substance is intended for the treatment of plants; and

3.6. other studies necessary for the specification of results of the previous toxicity studies and the characterisation of effects determined therein.

4. Ecotoxicological studies:

4.1. acute toxicity study on organisms other than target organisms and aquatic organisms;

4.2. studies in accordance with Sub-paragraph 8.4. of this Annex shall be performed if the result of the characteristic biodegradability test (performed in accordance with Annex 3, Sub-paragraph 12.6 of these Regulations) is negative, but the purification and drainage of waste waters of the active substance is necessary;

4.3. other biodegradability studies. The studies shall be performed if the evaluation of results of the previous biodegradability tests of the active substance (performed in accordance with Annex 3, Sub-paragraph 12.6 of these Regulations) indicates the necessity of the relevant studies;

4.4. additional biodegradability studies in accordance with Clauses 7.1.1 and 7.2.1, and Sub-paragraph 7.3 of this Annex. Studies shall be performed if:

4.4.1. the evaluation of results of the previous biodegradability studies of the active substance (performed in accordance with Annex 3, Sub-paragraph 12.6 of these Regulations or Sub-paragraph 4.3 of this Annex) indicates the necessity of the relevant studies; and

4.4.2. the active substance has no abiotic degradation or low degradation;

4.5. phototransformation in air (assessment method) including the identification of breakdown products; and

4.6. other studies in accordance with Paragraphs 7 and 8 of this Annex shall be performed if the previous results of ecotoxicological effect studies and the intended use of the active substance indicate the dangerousness of the relevant active substance to the environment.

5. Measures which are necessary for the protection of humans, animals and the environment specifying particularly whether in accordance with regulatory enactments regarding the emission of polluting substances, the quality of surface and underground waters and water management, the active substance (or residues thereof) has been recognised as particularly dangerous or dangerous to the aquatic environment or as a priority substance.

6. Additional studies regarding the effects of such food products and animal feed on human health which has been treated or contaminated with the active substance:

6.1. determination of degradation and reaction products and of metabolites of the active substance in food products or animal feed treated or contaminated with the active substance;

6.2. a study regarding the absorption, distribution, release (excretion) of degradation products of the active substance, residues and metabolites thereof (if necessary) or any other transformation in food products or animal feed which have been treated or contaminated with the active substance. A study regarding the absorption, distribution, excretion of degradation products, residues and metabolites of the active

substance from the food product or animal feed to be studied shall also include the characterisation of the kinetics of the relevant excretion;

6.3. a study regarding the effects of the active substance on human or animal health depending on the contents of residues of the relevant active substance in food products or animal feed specifying:

6.3.1. the overall balance of use of the active substance, including the quantity or concentration of residues of the active substance in food products or animal feed depending on the properties, doses, types of use and other conditions;

6.3.2. the experimental data regarding the effects of the active substance on human or animal health depending on the contents of residues of the relevant active substance in food products or animal feed; and

6.3.3. justification (taking into account the information referred to in Clauses 6.3.1 and 6.3.2 of this Annex) that the active substance would not have adverse effects on human or animal health;

6.4. actual or potential exposure assessment of the active substance through food or any other contact with food products or animal feed which have been treated or contaminated with the active substance;

6.5. feeding and metabolism studies for domestic animals if residues of the active substance remain or accumulate permanently in animal feed – residues of the relevant active substance and the maximum possible quantity thereof in food products of animal origin shall be evaluated;

6.6. a study regarding the properties and amount of residues of the active substance depending on the type of preparation of food products or animal feed, also depending on whether the food products or animal feed are produced under industrial conditions or prepared at home;

6.7. justification and proposals regarding the type and maximum permissible amount of contamination or residues of the active substance that may be present in food products or animal feed;

6.8. other available and important information or studies regarding the effects of the active substance on human and animal health depending on the contents of residues thereof in food products or animal feed; and

6.9. information summary and evaluation regarding the effects of the active substance on human and animal health depending on the contents of residues thereof in food products or animal feed.

7. Additional studies regarding the circulation of the active substance in the environment:

7.1. studies regarding the movement, transformation and degradation of the active substance in soil:

7.1.1. a study regarding the rate and way of degradation of the active substance shall determine all degradation processes and products (including metabolites) in at least three soil types in conditions which are identical to the conditions of use of the active substance;

7.1.2. a study regarding the absorption and desorption of the active substance in at least three soil types. If necessary, absorption and desorption of metabolites and degradation products shall also be determined;

7.1.3. a study regarding the mobility of the active substance in at least three soil types. If necessary, mobility of metabolites and degradation products shall also be determined; and

7.1.4. determination of the extent and properties of bound residues;

7.2. studies regarding the movement, transformation and degradation of the active substance in water shall determine:

7.2.1. the rate and type of degradation of the active substance in water, including all degradation products and metabolites if they have not been determined in accordance with the requirements referred to in Annex 3, Sub-paragraph 12.6 of these Regulations; and

7.2.2. absorption and desorption of the active substance in sediments, precipitate or other soil or ground layer on the bed of a water body or other water. If necessary, absorption and desorption of metabolites and degradation products shall be determined;

7.3. studies regarding the movement, transformation and degradation of the active substance in air. The rate and type of degradation shall be determined if they have not been determined in accordance with the requirements referred to in Sub-paragraph 4.5 of this Annex and if:

7.3.1. the active substance is intended for use in disinfectants;

7.3.2. it is intended to use a spray method;

7.3.3. the active substance is volatile; and

7.3.4. other information or results of the previous studies indicate regarding the necessity to determine the rate and type of degradation in air; and

7.4. summary and evaluation of additional studies regarding circulation of the active substance in the air.

8. Additional ecotoxicological studies:

8.1. effects on birds:

8.1.1. acute oral toxicity – it shall be performed if studies with any avian species have not been performed in accordance with the requirements referred to in Sub-paragraph 4.1 of this Annex;

8.1.2. short-term toxicity – it shall be determined performing an eight-day study in at least one avian species (except for chickens) if the active substance is ingested through food (orally); and

8.1.3. studies regarding the effects on reproduction;

8.2. effects on aquatic organisms:

8.2.1. prolonged toxicity studies to appropriate species of fish;

8.2.2. studies regarding the effects on reproduction and growth rate of appropriate species of fish;

8.2.3. bio-accumulation test in appropriate species of fish;

8.2.4. studies regarding the reproduction and growth rate of daphnia (*Daphnia magna*);

8.3. effects on other organisms other than target organisms:

8.3.1. studies regarding acute toxicity to honeybees and other beneficial arthropods (for example, natural enemies of harmful organisms (predatory

insects)). Such organisms shall be selected for studies regarding which studies have not been performed in accordance with the requirements referred to in Sub-paragraph 4.1 of this Annex;

8.3.2. studies regarding toxicity to earthworms and soil macro-organisms other than target organisms;

8.3.3. studies regarding the effects on other soil organisms other than target organisms; and

8.3.4. studies regarding the effects on other organisms other than target organisms (flora and fauna) if the active substance may cause the risk of adverse effect on such organisms;

8.4. other effects – activated sludge respiration inhibition test; and

8.5. summary and evaluation of additional ecotoxicological studies.

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Annex 6
Cabinet Regulation No. 184
15 April 2003

Additional Information or Studies regarding a Biocidal Product if the Active Substance in the Composition of the Biocidal Product is a Chemical Substance

1. Additional studies regarding the effects of the biocidal product on human health:

1.1. studies regarding the effects of food products and animal feed on human health if the referred to products and feed have been treated or contaminated with an active substance:

1.1.1. feeding and metabolism studies for domestic animals if the residues of the biocidal product remain or accumulate permanently in animal feed – residues of the relevant biocidal product and maximum possible and permitted quantity thereof in food products of animal origin shall be evaluated; and

1.1.2. a study regarding the properties and amount of residues of the biocidal product depending on whether the food products or animal feed are produced under industrial conditions or prepared at home; and

1.2. exposure assessment of the biocidal product and studies regarding the effects of the biocidal product on human health if the results of studies previously performed (regarding the relevant biocidal product or an active substance in the composition of the biocidal product) or special features (for example, properties and structure of the substance) indicate on the necessity for such studies and potential effects of the biocidal product.

2. Additional studies regarding the circulation of the biocidal product in the environment. In performing the studies referred to in Annex 5, Paragraph 7 of these Regulations the movement, transformation and degradation in soil, water and air of such components of the biocidal products which have ecotoxicological effects.

3. Additional ecotoxicological studies:

3.1. studies regarding the effects of the biocidal product on birds – acute oral toxicity shall be determined if studies have not been performed in accordance with the requirements referred to in Annex 4, Paragraph 14 of these Regulations;

3.2. studies regarding the effects on water organisms if the biocidal product is used in water, on water or near the water surface:

3.2.1. detailed studies regarding the effects on fish and other aquatic organisms;

3.2.2. studies regarding such residues of the active substance and metabolites thereof in fish which are or may be toxic or dangerous to the environment or may form, cause or promote development of toxic compounds or compounds dangerous to the environment; and

3.2.3. studies regarding potentially dangerous substances or other main components of the biocidal product other than active substances – studies referred

to in Sub-paragraph 3.6 of this Annex shall be performed if the Latvian Environment Agency in accordance with Sub-paragraph 25.3 of these Regulations have indicated that the relevant studies must be performed;

3.3. a field trial (a study outdoors under natural conditions or conditions similar to natural conditions in compliance with conditions and terms for use of the biocidal product) regarding the effects of the biocidal product and risk to aquatic organisms if the biocidal product must be sprayed near the water surface and if the Latvian Environment Agency in accordance with Sub-paragraph 25.3 of these Regulations have indicated that the relevant study must be performed;

3.4. studies regarding the effects on other organisms other than target organisms:

3.4.1. studies regarding toxic effects on terrestrial vertebrates other than birds;

3.4.2. studies regarding acute toxicity to honeybees;

3.4.3. studies regarding the effects on other beneficial arthropods, other than bees;

3.4.4. studies regarding toxic effects on earthworms and soil macro-organisms other than target organisms, if the biocidal product may cause the risk of adverse effects on such organisms;

3.4.5. studies regarding the effects on other soil organisms other than target organisms; and

3.4.6. studies regarding the effects on other organisms (flora and fauna) other than target organisms, if the biocidal product may cause the risk of adverse effects on such organisms;

3.5. if the biocidal product is in the form of granules or bait, the following shall be performed:

3.5.1. trials under field conditions and observations in order to assess the risk to organisms other than target organisms in life environment thereof; and

3.5.2. a study regarding the effects of the biocidal product on feeding of organisms if there is a risk that the relevant biocidal product causes adverse effects on the feeding of the organisms other than target organisms. The study shall determine the effects of the biocidal product on the feeding of the relevant organisms and whether the use of the biocidal product is permissible; and

3.6. studies regarding the effects on aquatic organisms:

3.6.1. prolonged toxicity studies to appropriate species of fish;

3.6.2. studies regarding the effects on reproduction and growth rate of appropriate species of fish;

3.6.3. a bio-accumulation test in appropriate species of fish; and

3.6.4. studies regarding the reproduction and growth rate of daphnia (*Daphnia magna*);

4. Summary and evaluation of such information which has been acquired in performing the ecotoxicological studies and studies regarding the effects of the biocidal product on human health and circulation of the biocidal product in the environment.

Minister for Environment R. Vējonis

Annex 7
Cabinet Regulation No.184
15 April 2003

Contents of Technical Reports regarding Active Substance if the Active Substance is a Fungus, Micro-organism or Virus

1. Information regarding the production of an active substance – a fungus, a micro-organism or a virus (hereinafter – active organism);

1.1. the name, legal address and location of the manufacturer;

1.2. the name of the person performing tests or studies; and

1.3. location of the manufacturing establishment,

2. The name and legal address of the importer.

3. Identity of the active organism:

3.1. common name and other names;

3.2. taxonomic name of species and strain specifying whether it is a stock variant or a mutant strain (hereinafter – mutant strain), for viruses – taxonomic name of the agent, serotype or mutant strain;

3.3. collection and culture reference number if the culture is deposited; and

3.4. morphology, biochemistry, serology and other methods, procedures and criteria for the determination of the presence and identity of the active organism.

4. Origin and acquisition of the active organism:

4.1. present in nature or artificially created;

4.2. isolation methods for the active organism or active strain;

4.3. culture methods;

4.4. production technology and methods, including detailed information regarding the procedures and measures for the provision of the quality and acquisition of uniform source material of active organisms. If the active organism is a mutant strain, detailed information shall be provided regarding the acquisition, isolation and separation process specifying all known differences between mutant strains and the parent strain, and wild strains;

4.5. composition, properties, purity, identity and specific nature of the final active organism material, content of impurities and extraneous organisms in the active organism;

4.6. methods to prevent the infection or contamination of source material or stock culture and loss of virulence; and

4.7. waste management.

5. Analysis methods:

5.1. methods for the determination of the presence and identity of the active organism;

5.2. methods for the determination of the identity and purity of the source material (from which active organisms are produced), including test results and variability of test conditions and results;

5.3. methods for the determination and control of microbiological purity of final active organisms which ensure that impurities to the active organisms and extraneous organisms in the active organisms culture do not exceed the permissible level of contamination of active organisms, including test results and variability of test conditions and results;

5.4. methods for the determination of contamination of human and other mammalian pathogens in active organisms, also for the determination of fungi and protozoa at various temperatures (35 ºC and other temperatures characteristic to the formation and development process of pathogen contamination); and

5.5. if necessary, methods for the determination of viable and non-viable residues (for example, toxins) in products treated with active organisms, food products, animal feed, animal and human body fluids and tissues, soil, water and air (including on the surface of soil, water, structures, subjects, products or organisms).

6. The biological properties and characterisation of active organisms:

6.1. origin and current and previous use thereof (including natural origin and incidence and, if necessary, geographical distribution);

6.2. the relationship and relation to pathogens of vertebrates, invertebrates, plants and other organisms;

6.3. effects on target organisms; Information regarding antagonism to the host organism or information regarding the fact that the active organism is a pathogen host organism. Detailed information regarding host organisms and the specific nature thereof;

6.4. infective dose, type of effects and spreading ability or transmissibility to other organisms (transmissibility). It shall be specified if there are or are not toxins in the composition of the active organism, also in case it may create toxins. The identity, chemical structure (composition and structure formula), physico-chemical properties, stability, toxicity of toxins and possibility of intoxication shall be characterised in particular under intended conditions of use of the active organisms, if necessary;

6.5. possible effects on organisms which are not target organisms, but which have similar properties, susceptibility to infectious diseases, transmissibility and pathogenicity of infectious diseases or they are related to target organisms;

6.6. transmissibility to other organisms other than target organisms;

6.7. other adverse biological modifications in organisms other than target organisms, if the active organism is utilised correctly under intended conditions for use;

6.8. infectivity and physical stability under intended conditions for use;

6.9. genetic stability (for example, mutation speed) under the intended conditions for use taking into account the effects of climate and other environmental conditions and factors;

6.10. pathogenic effects or capacity to infect humans and animals under conditions of suppressed immunity; and

6.11. pathogenic effects or capacity to infect target organisms of specified parasite or predator species.

7. Effectiveness on harmful target organisms and intended uses:

7.1. harmful target organisms necessary to be destroyed, repelled, rendered harmless or otherwise affected, and products, substances, organisms, subjects or other objects which must be protected and treated with the active organism;

7.2. intended type of uses (for example, fungicide, rodenticide, insecticide, bactericide);

7.3. observations and information regarding the undesirable or unintended side effects on other organisms, other than harmful target organisms, caused by the active organisms concurrently with the effects on target organisms;

7.4. information regarding the possibility of occurrence and development of resistance and measures if the resistance has occurred;

7.5. effects on target organisms; and

7.6. users – in manufacture, professional or non-professional users.

8. Toxicological studies regarding acute toxicity which may be caused by the active organisms if:

8.1. the active organism is administered orally;

8.2. the active organism is inhaled, if necessary, respiratory sensitisation shall be determined;

8.3. the active organisms comes in contact with skin – skin irritation and sensitivity shall be determined;

8.4. the active organisms may enter the eyes – eye irritation shall be determined; and

8.5. the active organism is a virus or viroid – in addition to studies referred to in Sub-paragraphs 8.1, 8.2, 8.3 and 8.4 of this Annex cell culture studies shall be performed utilising purified infective viruses and primary cell cultures of mammalian, avian and fish cells.

9. If in performing studies regarding acute toxicity in accordance with Paragraph 8 of this Annex, one dose or one test is insufficient to determine infectivity, toxins or other very toxic substances in the composition of the active organism or its residues, and effects thereof, additional tests or examinations shall be performed.

10. 40-day studies for two species (one rodent, one non-rodent) regarding sub-chronic toxicity which may be caused by the active organisms, if:

10.1. the active organism is administered orally;

10.2. the active organisms is inhaled (if necessary);

10.3. the active organisms come in the contact with skin (if necessary); and

10.4. the active organism is a virus or viroid – in addition to the studies referred to in Sub-paragraphs 10.1, 10.2 and 10.3 of this Annex infectivity shall be determined using a bio assay or the most appropriate cell culture at least seven days after administration to test animals.

11. Other toxicological studies:

11.1. a study for two species (one rodent, one – other mammal species) regarding chronic toxicity which may be caused by the active organism if it is administered orally (except for cases when another type of study is more appropriate regarding chronic toxicity);

11.2. carcinogenicity studies for two species (one rodent, the other – other mammal species. These studies may be combined with the studies referred to in Sub-paragraph 7.3 of this Annex;

11.3. mutagenicity studies in accordance with Annex 3, Sub-paragraph 8.5 of these Regulations;

11.4. studies regarding the toxicity of active organisms to reproductive system:

11.4.1. teratogenicity studies- to rabbits and one rodent species; and

11.4.2. reproductive toxicity studies of two generations in order to ascertain the effect of the active substance on fertility and reproduction of representatives of one species;

11.5. metabolism studies for mammals including toxicokinetic assessment, studies regarding absorption (including dermal absorption), distribution and excretion from mammal organism indicating the organs in which the main metabolic processes and concentration of toxic metabolites take place;

11.6. neurotoxicity studies – they shall be performed if the construction , properties or other special features of the active organisms indicate that the active organism may have anticholinesterase effects or other neurotoxic effects. If necessary, delayed neurotoxicity shall be determined to adult hens; and

11.7. immunotoxicity studies (for example, allergies).

12. Assessment of accidental leakage or incidental exposure and the possible adverse effects thereof if the active organism is intended for use in biocidal products used in places where food products or animal feed are produced, prepared, consumed or stored, and humans, livestock or domestic animals may come into contact with places, structures, equipment or materials treated with the relevant biocidal product.

13. The following medical information without specifying information regarding persons (if such available):

13.1. medical surveillance of manufacturing plant employees including the medical examination data;

13.2. direct observations (for example, clinic cases, poisoning cases);

13.3. information regarding professional users and other persons who are or have been in other contact with active organisms (for example, carriers);

13.4. medical examination protocols or opinions regarding the state of health of employees in the manufacturing plant (producing the active organism), professional users or people;

13.5. observations regarding the exposure of people to effects of the active organisms and data of epidemiological studies;

13.6. poisoning incidents and diagnosis thereof including special poisoning signs and results of clinical tests; and

13.7. prognosis of the expected effects of poisoning. 14. Summary and conclusions regarding the toxicological effects on mammals specifying also the no-observed adverse effect level, any no-observed effect level, acceptable daily dose (for a human), assessment of information and results regarding all types of toxicological effects, pathogenicity and infectivity, as well as other information regarding the active organisms and recommendations on measures necessary for the protection of employees and other users.

15. Ecotoxicological studies:

15.1. acute toxicity to fish;

15.2. acute toxicity to daphnia (*Daphnia magna*);

15.3. algae growth inhibition test;

15.4. acute toxicity to one organism species non-aquatic, non-target organisms;

15.5. pathogenicity and infectiousness for honeybees and earthworms;

15.6. acute toxicity or pathogenicity and infectivity in relation to organisms other than target organisms if the active organism may cause the adverse effect risk to such organisms;

15.7. other studies regarding the effects on flora and fauna;

15.8. studies referred to in Annex 3, Sub-paragraphs 12.1, 12.2, 12.3, 12.4 and 12.5 of these Regulations regarding toxins if the active organism may produce toxins;

15.9. spread, mobility, multiplication and stability of the active organism in air, soil and water; and

15.10. studies and summary referred to in Annex 3, Sub-paragraphs 12.6, 12.7, 12.8 and 12.9 of these Regulations regarding toxins if the active organism may produce toxins;

16. Measures necessary for the protection of humans, non-target organisms and environment:

16.1. recommended methods, technologies, precautionary and security measures in manufacturing, storing, transporting or performing other activities with the active organism, as well as in case of an accident or fire;

16.2. environments or other conditions in which it is prohibited to use the active organism or to perform other activities therewith;

16.3. possibility and measures or methods for the reduction or prevention of infectivity of the active organism;

16.4. consequences of the contamination of air, soil and water (particularly potable water);

16.5. measures in case of an accident, emergency or extreme situations;

16.6. waste management of the active organism (including measures regarding the surface runoff and infiltration from waste disposal and the control of water contamination); and

16.7. measures in cases of accidental release into the environment (air, water (including potable water) or soil) – collection and purification, disposal or decontamination.

17. Proposals and justification thereof regarding the classification of active organisms in the risk group, taking into account the ability thereof to cause health problems, in accordance with regulatory enactments regulating the labour protection requirements when coming into contact with biological substances.

18. Evaluation and summary of such information which has been acquired performing studies regarding the active organism.

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Annex 8
Cabinet Regulation No. 184
15 April 2003

Content of Technical Reports regarding Biocidal Products if the Active Substances in the Composition of the Biocidal Products are Active Organisms (Fungi, Micro-organisms or Viruses)

1. Information regarding the manufacture of a biocidal product or an active organism:

1.1. the name, legal address and location of the manufacturer of the biocidal product and active organism;

1.2. the name of the person performing the tests or studies; and

1.3. the locations of manufacturing plants.

2. The name and legal address of the importer.

3. Identity of a biocidal product:

3.1. the trade name or proposed trade name and manufacturer's development code number (a number or another designation assigned by the manufacturer to the relevant biocidal product);

3.2. detailed quantitative and qualitative information regarding the compositions of the biocidal product including regarding active organisms, extraneous organisms, inert and other components;

3.3. preparatory form and physical state or other physical properties of the biocidal product which are related to the preparatory form (for example, moistened powder, emulsifiable concentrate); and

3.4. the concentration of active organisms in the source material.

4. Physico-chemical, mechanical and biological properties of the biocidal product:

4.1. appearance, colour and odour;

4.2. storage stability and shelf life. The effects of temperature, packaging, storage conditions and methods and other factors on the biological activity of the biocidal products and retention of such biological activity;

4.3. the mechanical and other similar properties of the biocidal product:

4.3.1. the ability to moisten (susceptibility to moisture);

4.3.2. characterisation of foaming (persistent foaming);

4.3.3. suspensibility and suspension stability;

4.3.4. wet sieve test and dry sieve test;

4.3.5. particle size and characterisation of the composition of the biocidal product depending on the particle size (including the contents of dust and fine particles in the biocidal product), attrition between particles and friability;

4.3.6. granule sieve test and characterisation of the composition of the biocidal product depending on the granule mass specifying the contents of

particles in the biocidal product. The contents of such particles in the biocidal product shall be definitely be specified the size of which exceeds a millimetre;

4.3.7. content of active organisms in the biocidal product, in the product or material treated with the biocidal product or on the surface of the treated product or material (it shall be specified to biocidal products produced as granules or baits);

4.3.8. emulsifiability, re-emulsifiability, emulsion stability; and

4.3.9. flowability, pourability and dustability;

4.4. physical and chemical compatibility with other products (including other biocidal products with which the relevant biocidal product must be used);

4.5. wetting and adherence, as well as the movement of the biocidal product in the environment, product or elsewhere after the use thereof; and

4.6. changes to the biological properties of the active organism after the inclusion of the active organism in the composition of the biocidal product (particularly – changes in pathogenicity or infectivity).

5. Methods for the identification and analysis of biocidal products:

5.1. analytical methods for the determination of the composition of the biocidal product;

5.2. methods for determining residues (for example, bioassay);

5.3. methods for the determination and control of microbiological purity of the biocidal product;

5.4. methods for the determination of human and mammalian pathogens in the biocidal product and control of the relevant pathogens;

5.5. methods for the determination of other pathogens in the biocidal product and control, if necessary; Pathogens harmful to the environment and pathogens harmful to non-target organisms shall be determined and controlled; and

5.6. techniques to ensure the homogeneity of the biocidal product and the uniformity of the relevant biocidal products, methods for the standardisation and quality control thereof.

6. Effect of the biocidal product on harmful target organisms and intended uses, as well as:

6.1. the type of a biocidal product in conformity with Annex 1 of these Regulations and the intended sector for use;

6.2. detailed information regarding intended use (for example, harmful organisms to be controlled, materials, products, equipment or places to be treated);

6.3. the characterisation of one type of use (for example, doses of the biocidal product to be used for treatment);

6.4. conditions for use of the biocidal product (considering the results and conclusions of studies), also in relation to climatic or other environmental conditions;

6.5. environmental or other specific conditions (factors) under which biocidal products may not be used taking into account the results and conclusions of studies;

6.6. methods and techniques of utilisation;

6.7. the number of times necessary to perform treatment with a biocidal product, the duration of a single treatment with a biocidal product and other conditions in relation to the duration or time of the treatment with the biocidal product;

6.8. proposals for instructions for use;

6.9. studies regarding the intervals between treatments with a biocidal product or uses of a biocidal product;

6.10. field experiments or trials;

6.11. information regarding the possible occurrence and development of resistance; and

6.12. effects on the quality of products, materials, equipment, subjects or surfaces to be treated.

7. Toxicological studies to be performed in addition to studies regarding the toxicity of the active organism which have been performed in accordance with Annex 7 of these Regulations, if:

7.1. one dose is administered orally;

7.2. one dose is administered subcutaneously;

7.3. the biocidal product is inhaled;

7.4. the biocidal product comes into contact with the skin – skin irritation and sensitivity shall be determined; or

7.5. the biocidal product may enter the eyes – eye irritation shall be determined.

8. Toxicological studies or information regarding the toxic effects of other substances (other than active organisms) in the composition of the biocidal product, particularly – regarding the toxic effects of potentially dangerous substances.

9. Exposure and effects of the biocidal product on human health shall be evaluated:

9.1. depending on the type of production or preparation, methods and techniques of use of the biocidal product:

9.1.1. subcutaneous absorption; or

9.1.2. if the biocidal product is inhaled; and

9.2. performing a field trial and determining effects on employees under intended conditions of use. If necessary, the exposure shall be evaluated in numbers and permissible occupational exposure level shall be determined.

10. Information or ecotoxicological studies to be performed in addition to the studies which have been performed in accordance with Annex 7 of these Regulations:

10.1. observations regarding undesirable or unintended side-effects (for example, to non-target organisms); and

10.2. stability in the environment.

11. Measures necessary for the protection of humans, animals and the environment:

11.1. recommended methods, techniques, precautionary and security measures in manufacturing, storing, managing, transporting or performing other activities with biocidal products;

11.2. precautionary and safety measures for the protection of humans and animals, including a time period which must be observed between the treatment of a product with the biocidal product and the use of the product treated or between the utilisation of the biocidal product and entering or presence of a person or animals in the territory, room or another place in which the biocidal product has been used;

11.3. risk reduction measures in cases of an accident and measures for elimination of the accident;

11.4. waste management of the biocidal product; and

11.5. management of biocidal product packaging (including cleaning, processing or burial of the packaging).

12. The classification, packaging and labelling or the biocidal product in accordance with Chapter VI of these Regulations:

12.1. justification of classification and marking depending on the properties of such chemical substances which are included in the compositions of the biocidal product specifying:

12.1.1. danger symbols;

12.1.2. explanation of danger;

12.1.3. characterisation of effects of the substance; and

12.1.4. designations of safety requirements;

12.2. the biological danger symbol and risk group of the active organism in accordance with the regulatory enactments regulating the labour protection requirements when coming into contact with biological substances;

12.3. proposals for packaging and labelling;

12.4. proposals for the safety data sheet, if necessary; and

12.5. packaging (form, materials, size), packaging samples and compatibility of the biocidal product with possible packaging material.

13. Evaluation and summary of information regarding the biocidal product.

Minister for Environment R. Vējonis

Annex 9
Cabinet Regulation No. 184
15 April 2003

Contents of Technical Reports if an Application regarding Temporary Registration has been submitted

I. General Provisions

1. Assurance of the applicant that:

1.1. the information submitted is correct and true;

1.2. the information submitted is based on the results of studies; and

1.3. he or she undertakes to submit complete information and documentation (also regarding studies which have been started or ordered).

2. Evidence that the biocidal product or active substance has been placed on the market prior 14 May 2000 (in accordance with Sub-paragraphs 2.1 or 2.2 of this Annex):

2.1. In Latvia. Confirmation of the fact that the substance has been utilised as an active substance in the composition of the biocidal product shall be the recipe or label of the relevant biocidal product (which has been placed on the market prior 14 May 2000) on which the name of such active substance is indicated; and

2.2. in a Member State if the active substance has been identified or the European Union Commission has been notified regarding the active substance and biocidal product providing a reference to the relevant identification or notification.

3. Accounting or inventory data regarding the biocidal product or active substance if:

3.1. the applicant is a manufacturer – information regarding the volume of trade each year within a time period from 1998 to 2002 shall be submitted; The information shall include data on the biocidal product and active substance specifying the quantity of the active substance in each type of biocidal product which is referred to in Annex 1 of these Regulations and which include the relevant active substance;

3.2. the applicant who imports or performs other activities (except for manufacturing) with the active substance shall specify information regarding the volume of trade of the active substance each year within a time period from 1998 to 2002;

3.3. the applicant who imports or performs other activities (except for manufacturing) with the biocidal product shall specify information regarding the volume of trade of the biocidal product each year within a time period from 1998 to 2002.

4. Information regarding performance deadlines of studies which have been commenced or ordered (which are necessary to evaluate the utilisation and effects of the biocidal product or active substance on human health and the environment). The applicant shall also indicate if he or she considers that any study or information is not necessary for the evaluation of the effects on human health and the environment and performance of risk assessment.

5. If the active substance is an active organism, the information requested in this Annex regarding the active substance shall be provided taking into account the specific properties specified in Annex 7 of these Regulations. Information not referred to in Annex 7 of these Regulations need not be specified.

6. The final target indicator of the studies need not be indicated if the information thereof is not necessary for the characterisation of the type and field of use of the biocidal product to be applied or the effects of the biocidal product or active substance on human health or the environment justifying why the information regarding the target indicator of the studies is not provided (for example, that it is not possible or necessary to determine this point).

II. Information regarding the Manufacturing or Importation of Biocidal Products and Active Substances

7. Information regarding the manufacture of an active substance if the active substance is applied for:

name, legal address and location of the manufacturer;

7.2. the name of the person performing tests or studies; and

7.3. location of the manufacturing plant.

8. Information regarding the manufacturing of the biocidal product or the active substance, if the biocidal product is applied for:

8.1. names, legal addresses and location of the manufacturer of the biocidal product and active substance;

8.2. the name of the person performing tests or studies; and

8.3. locations of manufacturing plants.

9. The name and legal address of the importer.

III. Information regarding Active Substances

10. Identity of the active substance:

10.1. name in accordance with IUPAC nomenclature;

10.2. the name approved by the International Organisation for Standardisation (hereinafter – ISO) or the name recommended for ISO approval and synonyms thereof;

10.3. manufacturer's development code number (number or another designation assigned to the active substance by the manufacturer);

10.4. CAS number, the number of a chemical substance in the European Inventory of Existing Commercial Chemical Substances (EINECS number) or the European List of Notified Chemical Substances (ELINCS number) (hereinafter – EC number) if the active substance is mentioned in the relevant list;

10.5. molecular and structural formula;

10.6. method of manufacture of the active substance (short outline of the active substance synthesis process);

10.7. degree of purity of the active substance (g/kg or g/l);

10.8. identity of impurities or additives (for example, stabilisers), structural formula thereof and possible quantity of impurities or additives (g/kg or g/l) specifying their minimum or maximum quantity or range; and

10.9. the natural origin of the active substance or the initial origin of the active substance (product materials, plants or organisms from which the active substance is obtained).

11. Physico-chemical properties of active substances:

11.1. melting temperature, boiling temperature, relative density;

11.2. vapour pressure for the purified active substance (Pa);

11.3. solubility in water, including observed effects, if pH is from 5 to 9, and temperature effect on solubility; and

11.4. partition coefficient – solubility of the relevant substance in n-octanol in relation to solubility in water.

12. Toxicological studies regarding acute toxicity which may be caused by the active substance if:

12.1. the active substance is administered orally;

12.2. the active substance is inhaled;

12.3. the active substance comes into contact with skin – skin irritation and sensitivity shall be determined; and

12.4. active substances may contact with eyes – eye irritation shall be determined.

13. Other toxicological studies:

13.1. metabolism studies in mammals if such are necessary and available;

13.2. 90-day studies of sub-chronic toxicity. If the 90-day studies of sub-chronic toxicity are not available, studies of short-term repeated dose toxicity (28 days) may be submitted instead of them. If the short-term repeated dose toxicity studies (28 days) are not available they shall not be performed;

13.3. chronic toxicity studies, if such are necessary and available;

13.4. mutagenicity studies:

13.4.1. gene mutation study in bacteria in laboratory conditions (*in vitro*), utilising a reverse mutation method;

13.4.2. cytogenicity studies in mammalian cells in laboratory conditions (*in vitro*);

13.4.3. gene mutation assay studies in mammalian cells in laboratory conditions (*in vitro*);

13.4.4. additional gene mutation studies *in vivo* if any of the examinations referred to in Clauses 13.4.1, 13.4.2 or 13.4.3 of this Annex is positive;

13.4.5. repeat gene mutation studies *in vivo* if results of the studies referred to in Clause 13.4.4 of this Annex are negative, but results of the studies performed in laboratory conditions (*in vitro*) are positive; and

13.4.6. studies regarding the effects on germ cells (mammalian spermatogonial chromosome aberration test) or embryonic cells (rodent dominant lethal mutation test) if results of the studies referred to in Clause 13.4.4 of this Annex are positive and if it is necessary;

13.5. carcinogenicity studies, if such are necessary and available;

13.6. studies on toxicity of active substance to reproductive system:

13.6.1. teratogenicity studies, if such are necessary and available; and

13.6.2. fertility studies, if such are necessary and available; and

13.7. observations regarding exposure of people to the effects of the active substance, and data of epidemiological studies, if such are necessary and available.

14. Ecotoxicological studies:

14.1. acute toxicity to fish;

14.2. acute toxicity to daphnia (*Daphnia magna*);

14.3. algae growth inhibition test;

14.4. microbiological activity inhibition test;

14.5. bio-concentration (bio-accumulation) studies if such are necessary and available;

14.6. degradation of the active substance:

14.6.1. ready biodegradability;

14.6.2. inherent biodegradability (if such studies are necessary and available);

14.6.3. abiotic degradation determining the hydrolysis speed depending on pH and the identity of transformation products; and

14.6.4. abiotic degradation determining phototransformation in water and identity of transformation products (if such studies are necessary and available); and

14.7. adsorption and desorption test.

15. Proposals and justification thereof regarding the classification and labelling of the active substance in conformity with regulatory enactments regulating the classification, labelling and packaging of chemical substances and chemical products, and the date of labelling, specifying:

15.1. danger symbols;

15.2. explanation of danger;

15.3. characterisation of effects of the substance; and

15.4. designations of safety requirements;

16. If the results of studies previously performed or special features (for example, properties or structure of the substance) indicate to the necessity of studies referred to in Sub-paragraphs 13.1, 13.2, 13.3, 13.4 and 13.5; Clauses 13.4.6, 13.6.1, 13.6.2, 13.7, 14.5, 14.6.2 and 14.6.4 of this Annex and possible effects of the substance, but such studies have not been performed or are not available, the application shall specify when such studies will be performed.

17. Evaluation and summary of information regarding the active substance.

IV. Information regarding Biocidal Products

18. Information in accordance with Annex 4 of these Regulations if the active substance included in the composition of the biocidal product is a chemical substance, or Annex 8 of these Regulations if the active substance included in the composition of the biocidal product is an active organism.

19. If the results of studies previously performed or special features indicate the necessity of the studies referred to in Annex 4 or Annex 8 of these Regulations, but such studies have not been performed or are not available, the application shall specify when such studies will be performed.

20. Evaluation and summary of information regarding the biocidal product:

Minister for Environment R. Vējonis

Annex 10
Cabinet Regulation No. 184
15 April 2003

Criteria, Principles and Contents of Risk Assessment of Biocidal Products

Contents, General Principles and Criteria for Risk Assessment of Biocidal Products

1. The risk assessment shall include risk assessment to human health, risk assessment to animals and risk assessment to the environment. Each risk (risk to human health, risk to animals and risk to the environment) assessment shall contain:

1.1. danger identification and, if possible, determination of the no-observed adverse effect level;

1.2. evaluation regarding the adverse effects or the dependence of severity and frequency of undesirable consequences on the volume of concentration or dose;

1.3. exposure assessment; and

1.4. risk characterisation.

2. In performing a risk assessment of a biocidal product or an active substance the following general principles shall be observed:

2.1. possible effects on human health, animals and the environment which may occur utilising the biocidal products and the risk caused by such effects shall be evaluated in the risk assessment. Other undesirable effects and consequences which the utilisation of the biocidal products may cause to property or economic activities shall also be evaluated in the risk assessment;

2.2. danger identification shall be performed for all biocidal products and active substances;

2.3. the risk assessment shall evaluate what possible effects utilising a biocidal product may cause the most severe consequences to human health, animals and the environment and determine the prevalence, danger and possibility of occurrence of such consequences;

2.4. in order to characterise the risk:

2.4.1. it shall be evaluated in numbers, but if it is not possible, the risk shall be evaluated qualitatively; and

2.4.2. the acceptable risk shall be determined;

2.5. the time necessary for the killing of a vertebrate and conditions under which death occurs shall be evaluated if the intended effect of a biocidal product is the death of a vertebrate (which is a target organism);

2.6. in order to determine the risk caused by a biocidal product, the risk caused by components (in particular – each active substance and potentially dangerous substances) to human health, animals and the environment shall be evaluated;

2.7. in risk assessment, synergistic effects of components (in particular – the active substance and potentially dangerous substance) of a biocidal product shall be taken into account as the mutual effect of substances if one substance intensifies the effects of other substance;

2.8. risk assessment results shall be summarised and efficacy assessment shall be performed to the following effects:

2.8.1. the effects of the biocidal product on humans;

2.8.2. the effects of the biocidal product on animals;

2.8.3. the effects of the biocidal product on the environment; and

2.8.4. undesirable effects;

2.9. overall effect of the biocidal product and the risk thereof to human health, animals and the environment shall be assessed taking into account the results of risk assessment and conclusions regarding active substances and potentially dangerous substances included in the compositions of the biocidal product;

2.10. use of the biocidal product shall not be permitted if in compliance with the conditions referred to in an authorisation for use, a registration certificate or a temporary registration certificate it does not have such effects on target organisms as indicated on the label or in the instructions for use. The efficacy of the biocidal product on target organisms must be identical and similar to the standard efficacy of the relevant biocidal product (if a standard sample of the biocidal product is used for assessment) or it must be verifiable through other means. Conclusions regarding the efficacy of the biocidal product shall be indicated for all intended fields of use of the biocidal product, except for cases when the label of a biocidal product specifies that the biocidal product is intended for use under special conditions. In determining the efficacy of the biocidal product it shall be evaluated whether the intended dose is the lowest dose causing the necessary effects on target organisms in evaluating the study data regarding responses depending on the dose of the biocidal product;

2.11. it is not permitted to use the biocidal product if there is a possibility that such resistance against the active substance of the biocidal product may to develop which may not be reduced providing special measures;

2.12. if it is not possible to perform risk assessment utilising the technical report submitted by an applicant, the applicant shall submit the minimum additional information necessary for the risk assessment; and

2.13. in applying the criteria and principles referred to in this Annex all the undesirable consequences, effects of the biocidal product, necessity for utilisation of the biocidal product shall be assessed and it shall be determined whether the utilisation of the biocidal product or the active substance may be permitted or it is necessary to specify restrictions for use and other conditions.

3. General criteria for risk assessment of biocidal products or active substances shall be as follows:

3.1. veracity, completeness of information submitted by the applicant and conformity to the need to perform the risk assessment;

3.2. adverse effects and undesirable consequences caused by the biocidal product or the active substance, severity, prevalence thereof, as well as the degree of risk caused by the biocidal product or the active substance. In evaluating biocidal products and active substances it shall be taken into account whether the biocidal product or the active substance causes serious risk to human health, animals or the environment;

3.3. dependence of the severity or prevalence of adverse effects and undesirable consequences on exposure to the biocidal product or the active substance;

3.4. maximum possible level of protection of humans, animals and the environment against the risk caused by the biocidal product or the active substance;

3.5. efficacy of the biocidal product on target organisms justified by the data of studies regarding the processing and manufacture of the biocidal product. The biocidal product shall have sufficient effect in order to destroy, repel or render chemically or biologically the target organisms harmless, to prevent effects thereof or affect otherwise;

3.6. advantages, type and amount thereof provided by the utilisation of the biocidal product, and intended field or sector of use of the biocidal product;

3.7. inability of the target organisms to develop a resistance to the active substance of the biocidal product. It shall be taken into account that a target organism may not develop a resistance to the active substance of the biocidal product; and

3.8. without causing unnecessary pain and suffering to animals (in particular – vertebrates). It is not permitted to use biocidal products for the control of vertebrates if:

3.8.1. death is not synchronous with the extinction of consciousness;

3.8.2. death does not occur immediately; and

3.8.3. vital functions are not reduced without signs of obvious suffering.

II. Content and Principles for Risk Assessment to Human Health caused by Biocidal Products

4. Risk assessment to human health caused by biocidal products, active substances or potentially dangerous substances shall include:

4.1. evaluation of the following activities:

4.1.1. acute and chronic toxicity;

4.1.2. irritating effects;

4.1.3. corrosivity;

4.1.4. sensitising effects;

4.1.5. repeated dose toxicity;

4.1.6. mutagenic effects;

4.1.7. carcinogenic effects;

4.1.8. toxicity to reproductive system;

4.1.9. toxic effects on nervous system (neurotoxicity);

4.1.10. adverse effects and consequences caused by physico-chemical properties; and

4.1.11. specific adverse effects of an active substance or potentially dangerous substance; and

4.2. health risk assessment to the following groups of people who are or may be subject to effects of a biocidal product or active substance:

4.2.1. employees or professional users;

4.2.2. consumers or non-professional users; and

4.2.3. people subject indirectly through the environment to the effects of the biocidal product or the active substance.

5. In assessing risk caused by biocidal products, active substances or potentially dangerous substances to human health the following principles shall be complied with:

5.1. dependence of the severity and frequency of adverse effects or undesirable consequences on the concentration or dose shall be determined, exposure assessment shall be performed and risk characterisation shall be specified if the biocidal product contains a group 2, 3 or 4 biological agent or if the active substance or potentially dangerous substance has properties due to which the biocidal product should be classified as a dangerous chemical product;

5.2. risk characterisation shall be specified without indication of the dependence on adverse effects or undesirable consequences of the concentration or dose if a biocidal product and the residues thereof may cause undesirable effects on human health or the environment, but it is not possible to determine the dependence of the relevant effects or consequences on the concentration or dose;

5.3. risk characterisation shall not be specified if, on the basis of results of the studies which have been performed by the most appropriate approved study method or another standardised method, it is not possible to identify the danger of the biocidal product and the biocidal product should not be classified as a dangerous chemical product, the active substance in the composition of the biocidal product is not a group 2, 3 or 4 biological agent and the biocidal product and residues thereof may not cause undesirable effects on human health or the environment;

5.4. repeated dose toxicity and toxic effects on the reproductive system shall be determined of any active substance and potentially dangerous substance in the composition of the biocidal product; In order to determine the repeated dose toxicity and toxic effects on the reproductive system, the level of no-observed adverse effects or the lowest dose or concentration causing undesirable consequences or adverse effects shall be determined (lowest observed adverse effect level);

5.5. in order to evaluate the dependence of adverse effects or undesirable consequences of toxicity, corrosivity or irritation on the volume of concentration or dose, the following shall be determined:

5.5.1. no-observed adverse effect level or lowest observed adverse effect level if it is possible to determine such utilising approved methods;

5.5.2. for acute toxicity – lethal dose (LD_{50}, mg/kg), lethal concentration (LC_{50}, mg/l) or if the fixed dose method is utilised for determination of acute toxicity, - the characteristic discriminating dose; and

5.5.3. for corrosivity or irritation – whether an active substance or a potentially dangerous substance has properties which cause or may cause the referred to effects;

5.6. in order to evaluate the dependence of adverse effects or undesirable consequences of mutagenicity and carcinogenicity on the volume of concentration or dose, the following shall be determined:

5.6.1. no-observed adverse effect level or lowest observed adverse effect level if the active substance or potentially dangerous substance is carcinogenic, but not genotoxic; and

5.6.2. whether the active substance or the potentially dangerous substance has properties which cause or may cause such effects;

5.7. it shall be determined whether the active substance or potentially dangerous substance which is in the compositions of the biocidal product during utilisation has properties which may cause skin and respiratory sensitisation if it is not possible to determine a dose or concentration below which harmful effects will not be caused when the sensitisation has occurred;

5.8. in evaluating the biocidal product or the active substance the available medical data and information regarding the toxic effects of the biocidal product on humans, including observations regarding the exposure of the public or employees to the effects of the active substance and data of epidemiological studies shall be taken into account;

5.9. exposure assessment of the biocidal product or the active substance shall be performed for each group of people (professional users, non-professional users and people who are subject indirectly through environment to the effects of the biocidal product or active substance) which may come into contact with the relevant biocidal product or active substance in the intended conditions of use thereof;

5.10. in performing exposure assessment a dose or concentration and type shall be characterised or determined quantitatively by which the active substance or potentially dangerous substance in the composition of the biocidal product has effects or may have effects during the utilisation of the biocidal product;

5.11. in performing exposure assessment the following shall be taken into account:

5.11.1. adequate data of observations and measurements regarding biocidal products and active substances having identical or similar type of use, properties and exposure or effects;

5.11.2. type of the biocidal product;

5.11.3. preparatory form of the biocidal product;

5.11.4. methods, conditions for use (for example, duration and intervals of use between uses of the biocidal product) and doses to be used;

5.11.5. physico-chemical properties of the biocidal product;

5.11.6. type of exposure or the way how the biocidal product or active substance affects or may affect (for example, by inhalation, oral administration, contact with skin), and transportation routes, transformation or degradation in the environment, potential for absorption of the biocidal product or active substance;

5.11.7. various duration, frequency, amount and prevalence of exposure or effects;

5.11.8. information characterising groups of people which are exposed or may be exposed to effects of a biocidal product or an active substance specifying the number, age, sex of the people and composition of the group (employees, consumers, people exposed to the biocidal product or active substance indirectly through the environment); and

5.11.9. other information provided for in the application (in particular – in the technical report) and another available and relevant information;

5.12. if in performing exposure assessment of the biocidal product or the active substance it is necessary to utilise assessment or calculation methods of technical modelling, such methods shall be used:

5.12.1. which taking into account the actual parameters and assumptions provide the most correct and accurate assessment of all possible conditions, activities with the biocidal product or active substance, conditions and processes (also in relation to movement, transformation or degradation in the environment of the biocidal product or active substance);

5.12.2. which may be evaluated taking into account possible uncertainty;

5.12.3. results of which have been confirmed performing measurements (measurements and comparison of results have been performed in relation to the main field of use); and

5.12.4. which are suitable for the evaluation of the circumstances and conditions for utilisation of the biocidal product or active substance;

5.13. comparison of a dose or concentration of the biocidal product or the active substance (by which the relevant active substance or biocidal product has effects thereof) with the relevant no-observed adverse effect level or lowest observed adverse effect level for types of the effects referred to in Sub-paragraph 4.1 of this Annex shall be indicated to each group of people which is or may be subject to the effects of the biocidal product or active substance. If possible, the comparison shall be indicated in numbers;

5.14. results of risk assessment obtained shall be compared to the results of the previous risk assessment (where the risk of identical or similar harmful effects has been assessed) and relevant safety coefficient shall be determined; Numerical value of the safety coefficient shall be adopted depending on dangerous properties and effects of the biocidal product or active substance (in particular – taking into account the critical toxicological effects). Safety coefficient 100 shall be used normally;

5.15. if it is not possible to determine the no-observed adverse effect level, lowest observed adverse effect level or another numerical exposure characterisation for the types of effects referred to in Sub-paragraph 4.1 of this Annex, the relative severity, prevalence and possibility of adverse effects or undesirable consequences shall be indicated to each group of people; and

5.16. biocidal products shall not be registered and the use thereof shall not be permitted if the results of the risk assessment (where the actually possible variant for the development of undesirable events with most severe consequences is evaluated) show that the intended use causes an unacceptable risk to human health.

III. Principle for the Assessment of Risk caused by Biocidal Products to Animals

6. The risk to animal health caused by biocidal products shall be evaluated in similar way to the risk to human health taking into account the information referred to in Paragraphs 4 and 5 of this Annex.

IV. Principles for the Assessment of Risk to the Environment caused by Biocidal Products

7. In assessing the risk to the environment, the following principles shall be taken into account:

7.1. any adverse effect or undesirable consequences to flora and fauna which may be caused by utilising a biocidal product shall be evaluated;

7.2. in identifying the danger of a biocidal product, the properties of active substances and potentially dangerous substances included in the composition of the biocidal product and any adverse effect or undesirable effect which may be caused by the relevant active substance or potentially dangerous substance shall be evaluated;

7.3. if the active substance in the composition of the biocidal product is a group 2, 3 or 4 biological agent or if the active substance or potentially dangerous substance has properties due to which the biocidal product should be classified as a dangerous chemical product, the dependence of severity and frequency of adverse effects or undesirable consequences on the concentration or dose shall be determined, exposure assessment shall be performed and risk characterisation shall be prepared;

7.4. risk characterisation shall not be prepared if, on the basis of results of such studies which have been performed by the most appropriate study method, it is not possible to identify the danger of the biocidal product and the biocidal product should not be classified as a dangerous chemical product, the active substance in the composition of the biocidal product is not a group 2, 3 or 4 biological agent and the biocidal product and the residues thereof may not cause undesirable effects on human health or the environment;

7.5. risk characterisation shall be prepared if in identifying the danger of a biocidal product there are:

7.5.1. features which indicate to possible potential for bio-accumulation of the biocidal product (including active substance or potentially dangerous substance);

7.5.2. features which indicate the possible stability of the biocidal product (including active substance or potentially dangerous substance) in the environment;

7.5.3. results of studies of the ecotoxic effects – relation between toxic effect determined and time (the shape of toxicity/time curve);

7.5.4. based on the studies of toxic effects, the biocidal product (including the active substance or potentially dangerous substance) has been classified as a very toxic, toxic or mutagen, as well as dangerous with a characterisation of effects of the substance “Iespējams nopietns kaitējums veselībai pēc ilgstošas saskares” [Danger of serious damage to health by prolonged exposure] or “Iespējams neatgriezeniskas iedarbības risks” [Possible risk of irreversible effects];

7.5.5. information regarding a biocidal product having similar composition and regarding active substances and potentially dangerous substance having a similar structure indicating the possible danger of the biocidal product; and

7.5.6. information regarding the effects of the biocidal product on the endocrine system;

7.6. in evaluating the dependence of the severity and frequency of adverse effects or undesirable consequences on the concentration or dose, the concentration shall be determined below which no adverse consequences or no effect on water, air, terrestrial

ecosystem or another part of the environment are caused (hereinafter – predicted no-effect concentration);

7.7. predicted no-effect concentration shall be determined for the active substance or the potentially dangerous substance on the basis of the application or additional information regarding the results of ecotoxicological studies and studies performed regarding the effects on harmful target organisms;

7.8. if it is not possible to determine in numbers the predicted no-effect concentration for the active substance, the relative evaluation of the dependence of severity and frequency of adverse effects or undesirable consequences on the concentration or dose shall be performed;

7.9. in calculating the predicted no-effect concentration, the following doses or concentrations obtained in ecotoxicological studies shall be used:

7.9.1. level or concentration of any no-observed effect;

7.9.2. lowest observed effect level or concentration;

7.9.3. lethal dose (usually determined as LD_{50}, mg/kg);

7.9.4. lethal concentration (usually determined as LC_{50}, mg/l);

7.9.5. efficient (effective) concentration (EC_{50}); and

7.9.6. concentration causing the inhibition of development of specific functions, parameters or properties (usually the inhibiting (retaining) concentration (IC_{50}) is determined) in organisms to be studied;

7.10. in calculating the predicted no-effect concentration an uncertainty assessment coefficient shall be taken into account. An uncertainty assessment coefficient shall be used in order to extrapolate the results of studies which have been performed on one or several species and to predict the effects of the biocidal product on the environment;

7.11. the numerical value of an uncertainty assessment coefficient shall be determined taking into account the parameters characteristic to the relevant part of the environment, the number of species studied, the duration, reliability, possible inaccuracy and uncertainty of studies performed, as well as other available information (the more complete the information and the longer the studies, the lower is the uncertainty assessment coefficient). An uncertainty assessment coefficient shall be determined in the same way as such coefficient is determined for new chemical substances in accordance with the regulatory enactments regulating the risk assessment of new chemical substances;

7.12. the environment in which the emission of the biocidal product has been provided or the distribution, transformation or degradation thereof has been predicted, as well as the environment with which the biocidal product may come into direct contact in producing, storing, utilising, disposing or performing other activities with the biocidal product or in case of undesirable events shall be determined, as well as the exposure in air, soil, water, including the bed of water bodies, flora and fauna shall be evaluated;

7.13. in the exposure assessment, the principle referred to in Clauses 7.13.1 or 7.13.2 of this Annex shall be complied with:

7.13.1. if possible, the concentration of the active substance or the potentially dangerous substance shall be determined which is or may be present in

air, soil, water, including the beds of water bodies, flora and fauna (hereinafter – predicted environmental concentration); or

7.13.2. the relative exposure characterisation shall be determined to each part of the environment for which it is not possible to determine the predicted environmental concentration;

7.14. in determining predicted environmental concentration or the relative exposure, the following shall be taken into account:

7.14.1. the data of observations and measurements regarding biocidal products and active substances having identical or similar way of use, properties and exposure or effects;

7.14.2. the type of the biocidal product;

7.14.3. the preparatory form of the biocidal product;

7.14.4. the methods, conditions for use (for example, duration and intervals of use between uses of the biocidal product) and doses to be used;

7.14.5. the physico-chemical properties of the biocidal product;

7.14.6. the degradation and transformation of the biocidal product in the environment, including the degradation and transformation products;

7.14.7. the type of exposure or the type by which the biocidal product or the active substance has or may have an effect on the environment (flora and fauna), and movement routes, transformation or degradation of the biocidal product or active substance in the environment, as well as potential for absorption or desorption; and

7.14.8. various duration or frequency of exposure or efficacy;

7.15. if in performing exposure assessment of the biocidal product or the active substance it is necessary to utilise the assessment or calculation methods of technical modelling, such methods shall be used:

7.15.1. which, taking into account the actual parameters and assumptions, provide the most correct and accurate assessment of all possible conditions, activities with the biocidal product or the active substance, conditions and processes (in particular in relation to movement, transformation or degradation in the environment of the biocidal product or active substance) and effects on flora and fauna;

7.15.2. which may be evaluated taking into account the possible uncertainty;

7.15.3. results of which have been confirmed performing measurements (measurements and comparison of results have been performed in relation to the main fields of use); and

7.15.4. which are suitable for the evaluation of the circumstances and conditions for the utilisation of the biocidal product or active substance;

7.16. the risk characterisation shall specify the comparison of the predicted environmental concentration with the predicted no-effect concentration (including the calculated ratio of the predicted environmental concentration and the predicted no-effect concentration);

7.17. if it is not possible to calculate the ratio of the predicted environmental concentration and the predicted no-effect concentration, a possibility shall be evaluated

that the adverse effects on the environment or undesirable consequences may occur under predicted exposure or predicted exposure conditions; and

7.18. the possibility of accidents or undesirable events (as the result of which the environment is polluted) must be minimal. Instructions for use of the biocidal product or the active substance shall provide measures for the reduction of accidents or undesirable events and consequences.

Special Criteria for Risk Assessment of Biocidal Products

8. In assessing risk to human health, the criteria shall be severity, prevalence and frequency of effects of the types referred to in Sub-paragraph 4.1 of this Annex, as well as the dependence of the relevant adverse effects on the exposure concentration or the amount of doses of the biocidal product or the active substance. The risk to human health shall not permitted if:

8.1. the dose or concentration is higher that the no-observed adverse effect level or lower observed adverse effect level of the relevant biocidal product or active substance; and

8.2. on the basis of the relative evaluation of adverse effects or undesirable consequences it may be concluded that the biocidal product or the active substance will cause adverse effects with unacceptably severe consequences.

9. The criteria for risk assessment of animal health shall be severity, prevalence and frequency of adverse effects (including toxicity, neurotoxicity, corrosivity, irritation, sensitising, mutagen, carcinogenic or other type of effects), as well as the dependence of the relevant adverse effects on the exposure concentration or amount of a dose of the biocidal product or active substance. It is prohibited to utilise the biocidal product if the risk assessment confirms that the biocidal product causes an undesirable risk to animals other than target organisms.

10. The criteria for environmental risk assessment shall be adverse effects, undesirable consequences or risk to the environment caused by the active substance or potentially dangerous substance in the composition of the biocidal product, residues of the biocidal product or degradation or the reaction products thereof. The utilisation of the biocidal product is prohibited if the risk assessment confirms that the biocidal product causes an unacceptable risk to non-target organisms living in the air, water (including beds of water bodies), soil and land.

11. The main criteria of the environmental risk shall be the ratio of the predicted environmental concentration to the predicted no-effect concentration if:

11.1. the ratio of the predicted environmental concentration and predicted no-effect concentration is one or less than one – additional risk reduction measures and additional information is not necessary while the volume of trade of the biocidal product or active substance is not increased or other changes are not performed;

11.2. the ratio of the predicted environmental concentration and predicted no-effect concentration is greater than one – the environmental risk is unacceptable. On the

basis of the size of the ratio of predicted environmental concentration and predicted no-effect concentration and the features referred to in Sub-paragraph 7.5 of this Annex it shall be determined whether:

11.2.1. additional information is necessary;

11.2.2. additional risk reduction measures are necessary; and

11.2.3. utilisation of the biocidal product or the active substance is prohibited; and

11.3. numerical evaluation of the ratio of the predicted environmental concentration and predicted no-effect concentration is not available – the relative evaluation of the predicted effects of the biocidal product or the active substance shall be provided. The environmental risk is unacceptable if the relative evaluation of the predicted effects of the biocidal product or active substance shows that the biocidal product or active substance may cause adverse effects with very severe consequences.

12. The risk to the aquatic environment is unacceptable and the utilisation of the biocidal product shall be prohibited if:

12.1. utilising the biocidal product in accordance with the intended conditions for use, the predicted concentration of the active substance or potentially dangerous substance, metabolites, degradation or reaction products of the biocidal product in water or beds of water bodies may cause adverse effects on aquatic organism species other than target organisms (including marine, coastal or transitional water environments), except for cases when it has been determined in trials under field conditions that there are no relevant adverse effects;

12.2. in utilising the biocidal product in accordance with the intended conditions for use, the concentration of the active substance or potentially dangerous substance, metabolites, degradation or reaction products of the biocidal product in groundwater exceeds:

12.2.1. the quality norms for groundwater which are utilised for the acquisition of potable water and which have been specified in accordance with regulatory enactments regarding the quality of groundwater, except for cases when it has been determined in trials under field conditions that the relevant quality norms are not exceeded; and

12.2.2. the maximum concentration which based on toxicological information has been specified in the list of active substances, the list of basic substances or the list of low-risk biocidal products, except for cases when it has been determined in trials under field conditions that the relevant lowest concentration is not exceeded; and

12.3. in utilising the biocidal product in accordance with the intended conditions for use, the concentration of the active substance or potentially dangerous substance, metabolites, degradation or reaction products of the biocidal product in water or sediments (in beds of water bodies) exceeds:

12.3.1. the concentration determined in relation to the quality of potable water in accordance with regulatory enactments regarding the quality of surface water and groundwater if it is possible to utilise the biocidal product in places in where potable water may be acquired, except for cases when it has been

determined in trials under field conditions that the relevant concentration is not exceeded; and

12.3.2. the concentration causing adverse effects or undesirable consequences to non-target organisms, except for cases when it has been determined in trials under field conditions that the relevant concentration is not exceeded.

13. The risk to soil is unacceptable and the utilisation of the biocidal product is prohibited if undesirable contamination of soil with the biocidal product is possible and after the utilisation of the biocidal product the active substance or potentially dangerous substance thereof:

13.1. has no degradation for more than one year (determined by tests under field conditions);

13.2. forms non-extractable residues after 100 days (exceeding 70% of the initial dose) with a mineralization rate of less than 5% (determined by tests in a laboratory);

13.3. causes undesirable consequences or effects on non-target organisms; and

13.4. the information referred to in Sub-paragraphs 13.1, 13.2 and 13.3 of this Annex shall not be taken into account if trials under field conditions show that the undesirable accumulation of the biocidal product will not occur;

14. The risk to air environment is unacceptable and the utilisation of the biocidal product is prohibited if there is a predicted possible undesirable effect, except for cases when it has been determined in trials under field conditions that the undesirable effects of the biocidal product are not likely to occur.

15. The risk to non-target organisms is unacceptable and the utilisation of the biocidal product is prohibited if:

15.1. the exposure of organisms (other than target organisms) to the biocidal product is foreseen and for the active substance or potentially dangerous substance thereof :

15.1.1. the ratio of predicted environmental concentration and predicted no-effect concentration is more than one, except for cases when the risk assessment confirms that, utilising the biocidal product in accordance with the provided conditions for use, there are no adverse effects or undesirable consequences after the use of the biocidal product in real conditions; and

15.1.2. the bio-concentration factor related to fat tissues of vertebrates (other than target organisms) is more than one, except for cases when the risk assessment confirms that, utilising the biocidal product in accordance with the provided conditions for use, there are neither direct nor indirect adverse effects or undesirable consequences after the use of the biocidal product in real conditions;

15.2. the exposure of aquatic organisms (including marine organisms and organisms living in coastal and transitional waters) to the biocidal product is foreseen and for the active substance or potentially dangerous substance thereof:

15.2.1. the ratio of predicted environmental concentration and predicted no-effect concentration is more than one, except for cases when the risk

assessment confirms that, utilising the biocidal product in accordance with the provided conditions for use, the biocidal product does not threaten the viability of aquatic organisms (including marine and estuarine organisms) in real conditions; and

15.2.2. the bio-concentration factor for biodegradable substances is more than 1000 or the bio-concentration factor for partly biodegradable is more than 100, except for cases when the risk assessment confirms that, utilising the biocidal product in accordance with the provided conditions for use, the biocidal product does not threaten the viability of aquatic organisms (including marine and estuarine organisms) in real conditions; and

15.3. it is possible that the biocidal product has an effect on micro-organisms (activated sludge) in sewage treatment plants if the ratio of the predicted environmental concentration and the predicted no-effect concentration of the active substance, potentially dangerous substance, metabolites, degradation or reaction products of the biocidal product is more than one, except for cases when the risk assessment confirms that there are neither direct nor indirect adverse effects on the viability of micro-organisms in the sewage treatment plants in real conditions.

16. The advantages for utilisation of the biocidal product shall be regarded as more significant than the risk to the organisms referred to in Sub-paragraph 15.2 of this Annex if the biocidal product is intended to be utilised as an anti-fouling product on commercial, public institution and seagoing vessels and the use of anti-fouling products is permitted up to 2008, taking into account the resolutions and recommendations of the International Maritime Organisation and if similar fouling control cannot be achieved by other practicable means.

Minister for Environment R. Vējonis

Annex 11
Cabinet Regulation No. 184
15 April 2003

Authorisation for Use of Biocidal Product or Active Substance

Ministry of Environment
Latvian Environment Agency

Authorisation No._____

_____
(trade name of biocidal product or active substance)

_____
(group and type of biocidal product in accordance with Annex 1 of these Regulations)

_____
(preparatory form of biocidal product)

Valid until_____

Validity period extended until_____

1. Authorisation issued to the applicant	
Name	Registration No. Date of registration in the commercial register
Legal address	
Person responsible for submission of the application and additional information regarding the biocidal product or active substance _____ (given name, surname)	Telephone _____ Fax _____ E-mail_____
Person responsible for performing activities with the biocidal product or active substance _____ (given name, surname)	Telephone _____ Fax _____ E-mail _____

2. Authorisation valid to the person performing activities (other than applicant)[1]	
Name	Registration No. Date of registration in the commercial register

Legal address	
Person responsible for performing activities with the biocidal product or active substance _____ (given name, surname)	Telephone _____ Fax _____ E-mail _____
2.1. Authorisation is valid for the following activities: manufacturing (placing on the market) import	

3. Location of the manufacturing plant of the biocidal product or active substance

4. Authorised ways of utilisation of the biocidal product or active substance	
Field or sector for the utilisation of biocidal product	
Other ways for the utilisation of such biocidal product	

5. Packaging of the biocidal product or active substance

6. Information regarding the classification and labelling of the biocidal product or active substance	
Classification of the biocidal product or active substance:	
Class of danger	
Designation of danger by letters	
Characterisation of effects of the substance	
Designations of safety requirements	
Risk group if the active substance is a fungus, a micro-organism or a virus	
Labelling of the biocidal product or active substance (Symbol of danger) (Explanation of danger)	(Symbol of danger) (Explanation of danger)

7. Composition of the biocidal product						
No.	Name of components[2]	CAS, EINECS, or ELINCS number[3]	Class of danger and designation of danger by letters	Letters and numbers of effect characterisation of the substance and safety requirements	Risk group if the active substance is a fungus, a micro-organism or a virus	Concentration or amount of components in the biocidal product
7.1.	Active substances					
7.2.	Potentially dangerous substances					
7.3.	Other components, impurities					

8. Special indication regarding type of production or composition of the biocidal product	
Biocidal product has specific formula of frame formulation	
Biocidal product belongs to another group of biocidal products in relation to which special conditions exist	

9. Summary of risk assessment (in annex, if necessary)	
Risk characterisation – evaluation regarding volume (severity, prevalence or frequency) of potential adverse effects or undesirable consequences caused by the biocidal product or active substance depending on the amount of	

the predicted exposure specifying uncertainty assessment coefficients	
Risk reduction measures provided by the applicant	
Conclusions regarding all types of adverse effects or undesirable consequences of the biocidal product or active substance to each group of people and the ecosystem.	

10. Conditions referred to in the authorisation (in annex, if necessary)	
10.1. Restrictions for activities with the biocidal product or active substance or other restrictions or prohibitions	
Properties of the biocidal product or the active substance which may have a negative effect on intended use, storage and transport of the biocidal product, and potential undesirable consequences or adverse effects under the intended conditions of use.	
Restrictions for utilisation of the biocidal product: If necessary, groups of users for whom the use of the biocidal product is not recommended and the utilisation thereof is restricted.	
Restrictions or other conditions regarding the quantity or limit values of residues.	
Other restrictions or prohibitions	
10.2. Conditions or requirements for manufacture of the biocidal product or active substance	
10.3. Conditions or requirements for placing on the market of the biocidal product or active substance	
10.4. Conditions for use of the biocidal product or active substance	
Methods, conditions for use and doses to be used	
Time period and interval necessary for the effect of the biocidal product on target organisms to be observed between uses of the biocidal product, between the treatment of a product with the biocidal product and the use of the treated product, as well as between the utilisation of the biocidal product and entering or presence of humans or animals in the territory, room or other place where the biocidal product has been used.	
Time period during which (or date by which) the biocidal product or active substance is fit for the intended	

application if conditions for storage of the relevant biocidal product or active substance are complied with (term of validity)	
Information regarding the security and precautionary measures during utilisation, storage and transport (including information on necessary personal protective clothing and equipment, fire safety measures, coverage of machines or tools, removal of food and animal feed materials) and instructions on how to protect animals against the effects of the biocidal products	
For microbiological biocidal products or active substances – instructions for the protection of employees in accordance with regulatory enactments regulating labour protection requirements when coming into contact with biological substances	
Information regarding adequate and appropriate methods and products for the cleaning of equipment and information regarding purification products and measures after the use of the biocidal products, as well as information regarding the necessary period of ventilation if equipment, premises or structures are treated with biocidal products	
Information regarding the potential direct or indirect harmful undesirable side effects	
Information regarding danger to the environment (in particular if it is necessary to protect organisms for destruction of which the biocidal product is not intended, and to avoid water pollution)	
Conditions for the utilisation of the biocidal product in relation with climatic conditions, reproduction period of target species or other conditions	
10.5. Conditions for immediate and emergency readiness measures for the protection of humans, animals and the environment	
Instructions regarding first aid in cases if poisoning with the biocidal product or active substance has occurred	
Conditions or measures in case of an accident, emergency or extreme situations	
Special protection measures in case of fire – depending on the possible chemical reactions and mutual effects of substances, as well as the properties of reaction products or combustion gases or other negative effects	
Types and methods for rendering the biocidal product or active substance harmless (neutralisation)	

Measures for the prevention, collection and decontamination of accident emissions and releases into the environment (air, water (including potable water) or soil)	
10.6. Conditions or requirements for the disposal or destruction of the biocidal product or active substance	
Possibilities to utilise the biocidal product or active substance as secondary raw material or to reuse it – for professional users	
Possibility to prevent or reduce undesirable consequences or harmful effects – for professional users	
Conditions for the drainage of waste waters, waste disposal and the monitoring thereof, including for the monitoring of releases and contamination permissible in releases – professional users	
Conditions for waste incineration and the monitoring thereof – professional users	
Instructions for safe management of the packaging of the biocidal product or biocidal waste or, if necessary, a prohibition to reuse the packaging – for professional and non-professional users	
10.7. Other conditions which may be reasons for the cancellation of the authorisation	
Additional measures for risk reduction which ensure that the risk to all groups of people and the environment is minimum, as well as, if necessary, time periods in which the relevant additional measures must be performed	
Additional studies or information, and time periods in which such information must be provided	
10.8. Safety data sheet (in annex)	

Date of submission of the application or additional information	
For the issuance of the authorisation	
For changes of conditions referred to in the authorisation	
For extension of the term of validity of the authorisation	

The authorisation or conditions referred to in the authorisation may be disputed in accordance with the procedures specified in Chapter IX of these Regulations.

Date of authorisation issue _____

Director of the Latvian Environment Agency
Given name, surname: _____ Date _____

_____Place for a seal
(signature)
Telephone_____

Date of changes of conditions referred to in the authorisation _____

Director of the Latvian Environment Agency
Given name, surname _____ Date _____

_____Place for a seal
(signature)

Telephone _____

Date of current authorisation term of validity extension_____
Director of the Latvian Environment Agency
Given name, surname _____ Date _____

_____Place for a seal
(signature)

Telephone _____

Notes.

1. This shall be indicated if:

1.1. the applicant is a legal person other than the manufacturer, importer or supplier of the biocidal product or active substance registered in Latvia;

1.2. there are other manufacturers or importers of the biocidal product or active substance registered in Latvia who on the basis of the authorisation issued to the applicant, will also manufacture or import the relevant biocidal product or active substance.

2. The name of dangerous chemical substances in the composition of the biocidal product in accordance with the list of dangerous chemical substances approved by the Minister for Environment. The generally accepted name of chemical substances (other than dangerous chemical substances) in the composition of the biocidal product or the name in

conformity with the nomenclature of the International Union of Pure and Applied Chemistry (IUPAC).

3. The registration number of a chemical substance in the Chemical Abstracts Service (CAS number). The number of the chemical substance in the European Inventory of Existing Commercial Chemical Substances (EINECS number) or the European List of Notified Chemical Substances (ELINCS number), if known.

Minister for Environment R. Vējonis

Annex 12
Cabinet Regulation No. 184
15 April 2003

Registration Certificate of a Biocidal Product or Active Substance

Ministry of Environment **Latvian Environment Agency** **Registration Certificate No._____**
_____ (trade name of the low-risk biocidal product or active substance)
_____ (group and type of the low-risk biocidal product in accordance with Annex 1 of these Regulations)
_____ (preparatory form of low-risk biocidal product)
Valid until_____
Validity period extended until

1. Registration certificate issued to the applicant	
Name	Registration No.
	Date of registration in the commercial register
Legal address	
Person responsible for submission of the application and additional information regarding the low-risk biocidal product or active substance _____ (given name, surname)	Telephone _____ Fax _____ E-mail_____
Person responsible for performing activities with the low-risk biocidal product or active substance _____ (given name, surname)	Telephone _____ Fax _____ E-mail_____

2. Registration certificate valid to the person performing activities (other than applicant)[1]	
Name	Registration No.
	Date of registration in the commercial register

Legal address Person responsible for performing activities with the low-risk biocidal product or active substance Telephone Fax E-mail _____ (given name, surname)
2.1. Registration certificate is valid for the following activities: manufacturing (placing on the market) import

3. Location of manufacturing plant of the low-risk biocidal product or active substance

4. Authorised ways of utilisation of the low-risk biocidal product or active substance	
Field or sector for the utilisation of the biocidal product	
Other ways for the utilisation of such biocidal product	

5. Packaging of the low-risk biocidal product or active substance

6. Information regarding the classification and labelling of the low-risk biocidal product or active substance	
Classification of the biocidal product or active substance:	
Class of danger	
Designation of danger by letters	
Characterisation of effects of the substance	
Designations of safety requirements	
Risk group if the active substance is a fungus, a micro-organism or a virus	
Labelling of the biocidal product or active substance (Symbol of danger) (Explanation of danger)	(Symbol of danger) (Explanation of danger)

7. Composition of low-risk biocidal product						
No.	Name of components[2]	CAS, EINECS, or ELINCS number[3]	Class of danger and designation of danger by letters	Letters and numbers of effect characterisation of the substance and safety requirements	Risk group if the active substance is a fungus, a micro-organism or a virus	Concentration or amount of components in biocidal product
7.1.	Active substances					
7.2.	Other components, impurities					

8. Summary of risk assessment (in annex, if necessary)	
Risk characterisation	
Risk reduction measures provided by the applicant	
Conclusions	

9. Justification that the biocidal product is a low-risk biocidal product

10. Conditions referred to in the registration application (in annex, if necessary)
10.1. Conditions or requirements for the manufacture of the low-risk biocidal product or active substance
10.2. Conditions or requirements for the placing on the market of the low-risk biocidal product or active substance

10.3. Conditions for the use of the low-risk biocidal product or active substance	
Methods, conditions for use and doses to be used	
Time period and interval necessary for the effect of the biocidal product on target organisms to be observed between uses of the biocidal product, between the treatment of a product with the biocidal product and the use of the treated product, as well as between the utilisation of the biocidal product and entering or presence of humans or animals in the territory, room or other place where the biocidal product has been used.	
Time period during which (or date by which) the biocidal product or active substance is fit for the intended application if conditions for storage of the relevant biocidal product or active substance are complied with (term of validity)	
Information regarding security and precautionary measures during utilisation, storage and transport (including information regarding necessary personal protective clothing and equipment, fire safety measures, coverage of machines or tools, removal of food and animal feed materials) and instructions on how to protect animals against the effects of the biocidal products	
For microbiological biocidal products or active substances – instructions for the protection of employees in accordance with regulatory enactments regulating labour protection requirements when coming into contact with biological substances	
Information regarding adequate and appropriate methods and products for the cleaning of equipment and information regarding purification products and measures after the use of the biocidal products, as well as information regarding the necessary period of ventilation if equipment, premises or structures are treated with the biocidal products	
Conditions for utilisation of the biocidal product in relation to climatic conditions, reproduction periods of the target species or other conditions	
10.4. Conditions regarding immediate and emergency readiness measures for the protection of humans, animals and the environment (if necessary)	
Instructions regarding first aid in cases if poisoning with the biocidal product or active substance has occurred	
Other conditions or measures in case of an accident,	

emergency or extreme situations	

10.5. Conditions or requirements for disposal or destruction of the biocidal product or active substance	
Possibilities to utilise the biocidal product or active substance as secondary raw material or to reuse it – for professional users	
Possibility to prevent or reduce undesirable consequences or harmful effects – for professional users	
Conditions for drainage of waste waters, waste disposal and the monitoring thereof, including the monitoring of releases and contamination permissible in releases – professional users	
Conditions for waste incineration and the monitoring thereof – professional users	
Instructions for safe management of the packaging of the biocidal product or biocidal waste or, if necessary, a prohibition to reuse the packaging – for professional and non-professional users	
10.6. Other conditions	
Additional studies regarding the active substance or information and time periods in which such information must be provided	
10.7. Safety data sheet (in annex)	

Date of submission of the application or additional information	
For submission of the registration application	
For changes in conditions referred to in the registration certificate	
For extension of the term of validity of the registration certificate	

The registration certificate or conditions referred to in the registration certificate may be disputed in accordance with the procedures specified in Chapter IX of these Regulations.

Date of the registration certificate issue _____

Director of the Latvian Environment Agency
Given name,_____ Date_____

surname: _____ _____

_____Place for a seal
(signature)

Telephone _____

Date of changes in conditions referred to in the registration certificate _____

Director of the Latvian Environment Agency
Given name, Date
surname: _____ _____

_____Place for a seal
(signature)

Telephone _____

Date of registration certificate term of validity extension _____

Director of the Latvian Environment Agency
Given name, Date
surname: _____ _____

_____Place for a seal
(signature)

Telephone _____

Notes.

1. This shall be specified if:

1.1. the applicant is not the manufacturer, importer or supplier of the low-risk biocidal product or active substance registered in Latvia;

1.2. there are other manufacturers or importers of the low-risk biocidal product or active substance registered in Latvia who on the basis of the registration certificate issued to the applicant, will also manufacture or import the relevant biocidal product or active substance.

2. The name of the dangerous chemical substances in the composition of the low-risk biocidal product in accordance with the list of dangerous chemical substances approved by the Minister for Environment. The generally accepted name of the chemical substances (other than dangerous chemical substances) in the composition of the biocidal product or the name in conformity with the nomenclature of the International Union of Pure and Applied Chemistry (IUPAC).

3. The registration number of a chemical substance in the Chemical Abstracts Service (CAS number). The number of the chemical substance in the European Inventory of Existing Commercial Chemical Substances (EINECS number) or the European List of Notified Chemical Substances (ELINCS number), if known.

Minister for Environment R. Vējonis

Annex 13
Cabinet Regulation No. 184
15 April 2003

Temporary Registration Certificate of a Biocidal Product or Active Substance

Ministry of Environment **Latvian Environment Agency** **Temporary Registration Certificate No._____**
_____ (trade name of the biocidal product or active substance)
_____ (group and type of the biocidal product in accordance with Annex 1 of these Regulations)
_____ (preparatory form of biocidal product)
Valid until_____
Validity period extended until_____

1. Temporary registration certificate issued to the applicant		
Name	Registration No. Date of registration in the commercial register	
Legal address		
Person responsible for submission of the application and additional information regarding the biocidal product or active substance _____ (given name, surname)	Telephone Fax E-mail	
Person responsible for performing activities with the biocidal product or active substance _____ (given name, surname)	Telephone Fax E-mail	

2. Temporary registration certificate valid to the person performing activities (other than applicant)[1]	
Name	Registration No. Date of registration in the commercial register
Legal address	

Person responsible for performing activities with the biocidal product or active substance _____ (given name, surname)	Telephone Fax E-mail
2.1. Temporary registration certificate is valid for the following activities: manufacturing (placing on the market) import	

3. Biocidal product or active substance manufacturing plant location

4. Authorised ways of utilisation of the biocidal product or active substance	
Field or sector for the utilisation of the biocidal product	
Other ways of utilisation of such biocidal product	

5. Packaging of the biocidal product or active substance

6. Information regarding the classification and labelling of the biocidal product or active substance	
Classification of the biocidal product or active substance:	
Category of dangerousness	
Designation of danger by letters	
Characterisation of effects of the substance	
Designations of safety requirements	
Risk group if the active substance is a fungus, a micro-organism or a virus	
Labelling of the biocidal product or active substance (Symbol of danger) (Explanation of danger)	(Symbol of danger) (Explanation of danger)

7. Composition of biocidal product						
No.	Name of components[2]	CAS, EINECS, or ELINCS number[3]	Class of danger and designation of danger by letters	Letters and numbers of effect characterisation of the substance and safety requirements	Risk group if the active substance is a fungus, a micro-organism or a virus	Concentration or amount of components in biocidal product
7.1.	Active substances					
7.2.	Potentially dangerous substances					
7.3.	Other components, impurities					

8. Special indications regarding the type of production or the composition of the biocidal product	
Biocidal product has a specific formula of frame formulation	
The biocidal product is a low-risk biocidal product	
The biocidal product belongs to another group of biocidal products in relation to which special conditions exist.	

9. Summary of risk assessment (in annex, if necessary)	
Risk characterisation – evaluation regarding	

volume (severity, prevalence or frequency) of the possible adverse effects or undesirable consequences caused by biocidal product or active substance depending on the amount of the predicted exposure specifying uncertainty assessment coefficients	
Risk reduction measures provided by the applicant	
Conclusions regarding all types of adverse effects or undesirable consequences of biocidal product or active substance to each group of humans and the ecosystem.	

10. Conditions referred to in the temporary registration application (in annex, if necessary)	
10.1. Restrictions for activities with the biocidal product or active substance or other restrictions or prohibitions	
Properties of the biocidal product or the active substance which may have a negative effect on intended use, storage and transport of the biocidal product, and potential undesirable consequences or adverse effects under the intended conditions of use.	
Restrictions for utilisation of the biocidal product. If necessary, groups of users for whom the use of the biocidal product is not recommended and the utilisation thereof is restricted.	
Restrictions or other conditions regarding the quantity or limit values of residues.	
Other restrictions or prohibitions	
10.2. Conditions or requirements for the manufacture of the biocidal product or active substance	
10.3. Conditions or requirements for the placing on the market of the biocidal product or active substance	
10.4. Conditions for use of the biocidal product or active substance	
Methods, conditions for use and doses to be used	
Time period and interval necessary for the effect of the biocidal product on target organisms to be observed between uses of the biocidal product, between the treatment of a product with the biocidal product and the use of the treated product, as well as between the utilisation of the biocidal product and entering or presence	

of a human or animals in the territory, room or other place where the biocidal product has been used.	
Time period during which (or date by which) the biocidal product or active substance is fit for the intended application if conditions for storage of the relevant biocidal product or active substance are complied with (term of validity)	
Information regarding security and precautionary measures during utilisation, storage and transport (including on necessary personal protective clothing and equipment, fire safety measures, coverage of machines or tools, removal of food and animal feed materials) and instructions regarding the protection of animals against the effects of the biocidal products	
For microbiological biocidal products or active substances – instructions for the protection of employees in accordance with regulatory enactments regulating labour protection requirements when coming into contact with biological substances	
Information regarding adequate and appropriate methods and products for the cleaning of equipment and information regarding purification products and measures after the use of the biocidal products, as well as information regarding the necessary period of ventilation if equipment, premises or structures are treated with biocidal products	
Information regarding potential direct or indirect harmful undesirable side effects	
Information regarding danger to the environment (in particular if it is necessary to protect organisms for destruction of which the biocidal product is not intended, and to avoid water pollution)	
Conditions for utilisation of the biocidal product in relation with climatic conditions, reproduction period of the target species or other conditions	
10.5. Conditions regarding immediate and emergency readiness measures for the protection of humans, animals and the environment	
Instructions regarding first aid in cases if poisoning with the biocidal product or active substance has occurred	
Conditions or measures in case of an accident, emergency or extreme situations	
Special protection measures in case of fire – depending on possible chemical reactions and mutual effects of	

substances, as well as the properties of reaction products or combustion gases or other negative effects	
Types and methods for rendering the biocidal product or active substance harmless (neutralisation)	
Measures for the prevention, collection and decontamination of accident emissions and releases into the environment (air, water (including potable water) or soil)	
10.6. Conditions or requirements for disposal or destruction of the biocidal product or active substance	
Possibilities to utilise the biocidal product or active substance as secondary raw material or to reuse it – for professional users	
Possibility to prevent or reduce undesirable consequences or harmful effects – for professional users	
Conditions for drainage of waste waters, waste disposal and the monitoring thereof, including the monitoring of releases and contamination permissible in releases – professional users	
Conditions for waste incineration and the monitoring thereof – professional users	

Instructions for safe management of packaging of the biocidal product or biocidal waste or, if necessary, a prohibition to reuse the packaging – for professional and non-professional users	
10.7. Other conditions which may be reasons for the cancellation of the temporary registration certificate	
Additional measures for risk reduction which ensure that the risk to all groups of people and environment is minimal, as well as, if necessary, time periods for the performance of the relevant additional measures	
Additional studies or information, and time periods in which such information must be provided	
10.8. Safety data sheet (in annex)	

Date of submission of the application or additional information	
For temporary registration certificate issue	
For changes in conditions referred to in the temporary	

registration certificate	
For extension of the term of validity of the temporary registration certificate	

The temporary registration certificate or conditions referred to in the temporary registration certificate may be disputed in accordance with the procedures specified in Chapter IX of these Regulations.

Date of issue of the temporary registration certificate _____

Director of the Latvian Environment Agency
Given name, surname: _____ Date _____

_____ Place for a seal
(signature)

Telephone _____

Date of changes in conditions referred to in the temporary registration certificate __

Director of the Latvian Environment Agency
Given name, surname: _____ Date _____

_____ Place for a seal
(signature)

Telephone _____

Date of term of validity extension of the temporary registration certificate _____

Director of the Latvian Environment Agency
Given name, surname: _____ Date _____

_____ Place for a seal
(signature)

Telephone _____

Notes.

1. This shall be specified if:

1.1. the applicant is not the manufacturer, importer or supplier of the biocidal product or active substance registered in Latvia;

1.2. there are other manufacturers or importers of the biocidal product or active substance registered in Latvia who on the basis of the temporary registration certificate issued to the applicant, will also manufacture or import the relevant biocidal product or active substance.

2. The name of the dangerous chemical substances in the composition of the biocidal product in accordance with the list of dangerous chemical substances approved by the Minister for Environment. The generally accepted name of the chemical substances (other than dangerous chemical substances) in the composition of the biocidal product or the name in conformity with the nomenclature of the International Union of Pure and Applied Chemistry (IUPAC).

3. The registration number of the chemical substance in the Chemical Abstracts Service (CAS number). The number of the chemical substance in the European Inventory of Existing Commercial Chemical Substances (EINECS number) or the European List of Notified Chemical Substances (ELINCS number), if known.

Minister for Environment R. Vējonis

Annex 14
Cabinet Regulation No. 184
15 April 2003

Contents of the Safety Data Sheet for Biocidal Products the Active Substance in the Composition of which is not classified in conformity with the Classification of Chemical Substances and Chemical Products and is utilised only in Biocidal Products

1. Identification of the biocidal product and the active substance and information regarding the manufacturer, importer or supplier of the active substance or biocidal product:
    1.1. name and code number;
    1.2. information regarding the undertaking;
        1.2.1. manufacturer;
        1.2.2. importer;
        1.2.3. supplier;
        1.2.4. person performing other activities with biocidal products;
        1.2.5. registration number of the undertaking; and
        1.2.6. address, telephone number, fax number, e-mail address; and
    1.3. emergency telephone number:
        1.3.1. medical assistance; and
        1.3.2. manufacturer.

2. Composition of the biocidal product and information regarding the components thereof;
    2.1. description (intended use); and
    2.2. information regarding harmful components:
        2.2.1. identification code;
        2.2.2. name of component;
        2.2.3. concentration; and
        2.2.4. danger symbols, risk factors and other information.

3. Characteristics of the danger.
    4. First aid measures:
    4.1. general information and special instructions;
    4.2. if the biocidal product is inhaled;
    4.3. if the biocidal product comes into contact with skin;
    4.4. if the biocidal product comes into contact with eyes; and
    4.5. if the biocidal product is swallowed;

5. Fire safety and explosion safety measures:
    5.1. recommended fire-fighting devices;
    5.2. fire-fighting devices which are prohibited to be used; and

5.3. additional information.

6. Measures to be taken in case of an accident:
    6.1. staff protection;
    6.2. environmental protection;
    6.3. collection methods; and
    6.4. special instructions.

7. Provisions for storage and use:
    7.1. use; and
    7.2. storage.

8. Provisions for work safety:
    8.1. technical equipment;
    8.2. permissible concentration at work places; and
    8.3. staff protection:
        8.3.1. general requirements;
        8.3.2. protection of respiratory tract;
        8.3.3. protection of hands;
        8.3.4. protection of eyes; and
        8.3.5. other instructions.

9. Physical, chemical, mechanical and biological properties.

10. Stability and reactivity:
    10.1. compatibility including organisms, materials, substances and products which shall be avoided to come into contact with; and
    10.2. dangerous breakdown products.

11. Toxicological information:
    11.1. acute toxicity;
    11.2. irritation and corrosivity;
    11.3. sensibility; and
    11.4. empirical information regarding effects on humans:
        11.4.1. inhalation;
        11.4.2. contact with skin;
        11.4.3. contact with eyes; and
        11.4.4. other effects.

12. Ecological information including information regarding toxic effects on organisms and plants.

13. Possible types of waste processing or recovery:
    13.1. waste containing biocidal products; and
    13.2. packaging waste.

14. Information regarding transportation.

15. Information regarding regulatory enactments regulating:
    15.1. labelling; and
    15.2. activities with biocidal products.

16. Other information:
    16.1. intended use;
    16.2.instructions and restrictions for use; and
    16.3. other information.

Minister for Environment R. Vējonis