

Republic of Latvia  
Cabinet  
Regulation No. 341  
Adopted 5 October 1999

**Registration Procedures for Plant Protection Products**

Issued pursuant to Section 5, Clause 2 of the  
Law on the Protection of Plant Varieties

1. These Regulations determine the registration procedures for plant protection products.
2. A chemical plant protection product, as well as a plant protection product containing micro-organisms or viruses, shall be registered only if:
  - 2.1. it contains active substances that are included in the list of active substances registered in the Community or for which the applicant for registration has submitted an assessment made by a European Union Member State regarding their conformity for inclusion in the said list, or the active substance is a component of such plant protection product as has been registered in seven European Union Member States after 1 January 1995;
  - 2.2. the applicant for registration has carried out trials and studies and has submitted a relevant dossier containing information in accordance with Annexes 1 and 2 of these Regulations;
  - 2.3. when analysing the effects of correct application of the plant protection product under the conditions of intended use in accordance with the information referred to in Annexes 1 and 2 of these Regulations, it has been established that:
    - 2.3.1. it has no harmful effect, directly or indirectly (through drinking water, food or animal feed) on human or animal health or ground-water;
    - 2.3.2. it has no unacceptably negative impact on the environment (on water, air, ground, soil, wild species of fauna and flora and any interaction between such, as well as any interconnection between the aforementioned and live organisms) – its behaviour in the environment, the analysis of the risk of water contamination, including drinking water and groundwater, and its impact on non-target species conform to the specified requirements;
    - 2.3.3. its active substance, the amount of such substance, toxicologically or ecotoxicologically significant chemical elements and compounds thereof derived as a result of synthesising the active substances, including any substance unavoidably formed in the process of synthesising and any substance included in the composition of the plant protection product (hereinafter – formulants), can be determined by standardised methods in general use;
    - 2.3.4. it has sufficient efficacy, certified by two years of results of trials to establish efficacy carried out in Latvia by the person referred to in Paragraph 5 of these Regulations (if the active substance is included in the register of plant protection products (hereinafter – register), one-year trials to establish efficacy);
    - 2.3.5. it has no unacceptably negative impact on plants or plant products;
    - 2.3.6. its physical and chemical properties have been determined by standardised methods in general use and conform to the requirements specified for the intended use and storage; and
    - 2.3.7. the toxicologically or ecotoxicologically significant pesticide residues under conditions of intended use can be determined by standardised methods in general use;
  - 2.4. its packaging meets the following criteria:
    - 2.4.1. is of sufficient strength under normal conditions of use and storage;
    - 2.4.2. the material of the packaging does not form chemical compounds with the packaged plant protection product and does not react with it;
    - 2.4.3. the design and material of the packaging is such as not to cause losses of the contents during the period of storage of the plant protection product;
    - 2.4.4. the design of the packaging is such as not to cause losses of the contents after repeated closing; and
    - 2.4.5. the packaging is sealed so that the seal will be damaged when opening it for the first time;

2.5. the packaging bears a label containing relevant information (Annex 3) in the Latvian language and meets the following criteria:

2.5.1. the label is placed horizontally on one or more surfaces of the packaging;

2.5.2. the size of the label is determined by taking into account the size of the packaging: if the capacity of the package does not exceed three litres, the minimum dimensions of the label shall be 52 x 74 mm; if the capacity of the package is from three to 50 litres, the minimum dimensions of the label shall be 74 x 105 mm; if the capacity of the package is from 51 to 500 litres, the minimum dimensions of the label shall be 105 x 148 mm; if the capacity of the package exceeds 500 litres, the minimum dimensions of the label shall be 148 x 210 mm;

2.5.3. hazard symbols according to the classification are indicated on the label of the package of plant protection products of any capacity and weight. Each hazard symbol covers not less than one-tenth of the surface of the label or not less than one square centimetre;

2.5.4. the label is fully glued to the package;

2.5.5. the background colour of the label is such as to ensure that the hazard symbols are clearly distinguishable; and

2.5.6. the label does not bear an indication that the relevant plant protection product creates no threats, for example, “nav bīstams” [not dangerous], “nav kaitīgs” [harmless].

3. Plant protection products containing parasites and predators shall be registered if the applicant for registration has submitted information conforming to generally recognised level of science and technology (Annex 4), the labelling of these products conforms to the requirements of these Regulations (Annex 3), and the applicant for registration has carried out efficacy assessment trials.

4. Conformity with the conditions referred to in Sub-paragraph 2.3 of these Regulations and with the requirements of Paragraph 3 of these Regulations shall be proved by official (or officially recognised) trials and analyses that have been carried out under conditions relevant to the spread of harmful organisms and under environmental (also climatic) conditions appropriate to Latvia.

5. Trials to establish efficacy shall be conducted by qualified persons who, on the basis of principles of good research practice, have been recognised by the State Plant Protection Service as conforming to the specified requirements. The said persons shall be appointed by the Director of the State Plant Protection Service.

6. Plant protection products shall be registered for ten years and may be re-registered.

7. After the expiry of the term of validity of registration, distribution of the relevant plant protection product shall be prohibited, but the users of such plant protection product shall be allowed to use the existing supplies for two years after expiry of the term of validity of registration, except in the case referred to in Paragraph 30 of these Regulations.

8. In order to register a plant protection product, a person (hereinafter – applicant for registration) shall submit to the State Plant Protection Service:

8.1. an application for registration of the plant protection product;

8.2. the documentation necessary for registration containing information conforming to generally recognised level of science and technology on the plant protection product and its active substance in accordance with the requirements of these Regulations (Annexes 1, 2 and 4) and the results of efficacy trials carried out in Latvia; and

8.3. samples of the label with text in the Latvian language that includes the relevant information in accordance with Annex 3 of these Regulations.

9. The State Plant Protection Service is entitled to request in addition that a sample of the plant protection product or its components and packaging be submitted.

10. The State Plant Protection Service shall:

10.1. verify that the information, documents and submitted samples of the label and packaging conform to the requirements specified in Annexes 1, 2, 3 and 4 of these Regulations, and assess whether the data submitted ensure that an expert-examination has been conducted. If necessary, the State Plant Protection

Service shall request additional information, request analysis of relevant data, and involve appropriately qualified experts; and

10.2. on the basis of an analysis of the usefulness and the risk of use of the plant protection product, prepare an evaluation of the plant protection product.

11. Evaluation of a plant protection product shall be prepared by observing the following principles:

11.1. its efficacy and phytotoxicity shall be assessed for each intended use of the plant protection product, identifying and evaluating possible risks and its effect on humans, animals and the environment;

11.2. effect of application of the plant protection product under conditions of its proposed use shall be evaluated, and the evaluation shall be made on the basis of the recommended application rate, method of application, goal, timing and number of applications, taking into account the composition, properties of the plant protection product and principles of integrated plant protection methods;

11.3. agricultural conditions, spread of the harmful organisms and environmental (also climatic) conditions in the territories intended for use of the plant protection product shall be evaluated;

11.4. the evaluation shall be carried out in two stages, the first stage on the basis of information reflecting the actual application conditions of the plant protection product, the second stage on the basis of possible critical data and taking into account the worst possible conditions of application that may cause adverse effects;

11.5. such calculation models shall be used as allow analysis of the characteristics essential for its evaluation, data regarding application of the plant protection product in the territories intended for use, as well as critical data regarding application under the worst possible conditions of use; and

11.6. only such metabolites, breakdown or reaction products shall be considered essential for the relevant criteria which may substantially affect evaluation of the relevant plant protection product.

12. The State Plant Protection Service shall take a decision to register a plant protection product or to refuse registration on the basis of an evaluation and recommendations of the plant protection product registration commission (hereinafter – registration commission) within a period of one year from the submission of the documents and information referred to in Paragraph 8 of these Regulations to the State Plant Protection Service by the applicant for registration.

13. The registration commission shall consist of seven members: two representatives from the State Plant Protection Service, one representative from the Ministry of Welfare, one representative from the Ministry of Environmental Protection and Regional Development, and three representatives of agricultural and other sciences. The chairperson of the registration commission shall be a representative of the State Plant Protection Service.

14. The registration commission personnel shall be approved by the Minister for Agriculture.

15. Meetings of the registration commission shall be convened by the chairperson of the registration commission.

16. The registration commission shall have a quorum if not less than five members of the registration commission participate in the meeting.

17. If necessary, the chairperson of the registration commission may request additional information for analysis of the evaluation of a plant protection product or analysis of relevant data, and may invite appropriately qualified experts.

18. When taking a decision to register a plant protection product, the State Plant Protection Service shall determine the use of the relevant plant protection product (cultivated species, harmful organisms, also application methods, restrictions, dosage, waiting periods, maximum permitted number of applications per season), the class of registration of the plant protection product and the volume or weight of packages for distribution in Latvia.

19. Having taken a decision, the State Plant Protection Service shall:

19.1. inform in writing the applicant for registration regarding the relevant decision (registration or refusal of registration). If a decision has been taken to refuse registration, the reasons for such decision shall be provided;

19.2. approve the text of the label;

19.3. enter in the register the name and form of preparation of the plant protection product; the name, quantity, degree of purity of the active substance; the name and address of the holder of the registration certificate; information regarding the manufacturer of the plant protection product and the active substance; the information referred to in Paragraph 18 of these Regulations, the date of registration and the shelf life;

19.4. issue to the applicant for registration a certificate of plant protection product registration (hereinafter – registration certificate) which confirms inclusion of the plant protection product in the register; and

19.5. the registration certificate shall include the following information: name, form of preparation, the number and date of registration of the plant protection product; the person who has registered the plant protection product; the content of the active substance and its degree of purity; the information referred to in Paragraph 18 of these Regulations and the term of validity of the registration certificate.

20. If the holder of a registration certificate intends to distribute the registered plant protection product in another form of preparation or with another active substance, the State Plant Protection Service shall register the relevant plant protection product if the requirements set out in Sub-paragraph 2.2 of these Regulations have been complied with and conformity with the conditions referred to in Sub-paragraph 2.3 of these Regulations has been proven.

21. The holder of a registration certificate shall notify the State Plant Protection Service of amendments to documents submitted for registration, substantiating the necessity for and conformity of such amendments to registration in accordance with the requirements set out in Paragraphs 2 and 3 of these Regulations.

22. The holder of a registration certificate has a duty to inform without delay the State Plant Protection Service of the harmful effects of the registered plant protection product and its residues on human or animal health and the environment.

23. After the expiry of the term of validity of the registration, a plant protection product may be re-registered one or more times for ten years if its conformity with the requirements set out in Paragraphs 2 or 3 of these Regulations has been proven.

24. The holder of a registration certificate shall submit an application for re-registration to the State Plant Protection Service not later than one year before the expiry of the term of validity of registration, together with updated information necessary for re-registration in accordance with Paragraphs 2 or 3 of these Regulations.

25. If there is cause for suspicion that a plant protection product does not conform to the requirements specified in Paragraph 4 and Paragraph 2 or 3 of these Regulations, the conformity of registration of the plant protection product may be re-evaluated. In such cases the State Plant Protection Service shall request that additional information or evaluation of individual studies be submitted by the holder of the registration certificate within the term specified by the State Plant Protection Service.

26. Necessary amendments to the register may be made pursuant to a decision of the State Plant Protection Service or upon request from the holder of the registration certificate, stating the reasons and observing the requirements set out in Paragraph 2 or 3 of these Regulations.

27. An entry in the register shall be cancelled in the following cases:

27.1. the plant protection product no longer conforms to the conditions of these Regulations;

27.2. the information referred to in Sub-paragraph 8.2 of these Regulations is false or intentionally distorted;

27.3. the requested information has not been submitted within the specified term; or

27.4. cancellation is requested by the holder of the registration certificate.

28. If it is necessary to re-register a plant protection product, to make amendments or to cancel an entry, the relevant decision shall be taken in conformity with the registration procedure in accordance with the requirements set out in Paragraphs 10, 11, 12, 17, 18 and 19 of these Regulations.

29. The State Plant Protection Service shall without delay inform the holder of a registration certificate of the cancellation of the entry of a plant protection product, as well as ensure the publication of such information in the newspaper *Latvijas Vēstnesis* [the official Gazette of the Government of Latvia].

30. Depending on the reasons for the cancellation of the registration entry of a plant protection product, the State Plant Protection Service may set a time period for the storage, use or exportation from the State of such plant protection product.

31. Pursuant to the recommendations of scientific research institutions or persons involved in agricultural production, the State Plant Protection Service may permit extension of the scope of use of a registered plant protection product if:

31.1. there is an objective justification for extending the scope of use of the plant protection product;

31.2. the planned scope of use of the plant protection product is small;

31.3. the plant protection product is permitted for the intended use in a European Union member state in which agricultural conditions, conditions for the spread of harmful organisms and environmental (also climatic) conditions that are significant for the use of this plant protection product are comparable to those existing in Latvia;

31.4. the initiator of the extension of the scope of use of the plant protection product has submitted the necessary information regarding the intended use with respect to the conditions referred to in Sub-paragraphs 2.3.1 and 2.3.2 of these Regulations (if such information is not at the disposal of the State Plant Protection Service);

31.5. the initiator of the extension of the scope of use of the plant protection product has submitted information providing substantiation that the plant protection product is effective and has no unacceptable influence on plants or plant products if utilised for the intended purpose;

31.6. it is established that the conditions referred to in Sub-paragraphs 2.3.1 and 2.3.2 of these Regulations have been complied with; and

31.7. the initiator of the extension of the scope of use of the plant protection product has in addition submitted, to the State Plant Protection Service for approval, instructions for use relevant to the extended scope of use of the relevant plant protection product.

32. The State Plant Protection Service shall, pursuant to an agreement with the holder of the registration certificate, permit extension of the scope of use of a registered plant protection product. If no agreement is reached, the State Plant Protection Service may allow extension of the scope of use of the registered plant protection product only if it has available information that the objections of the holder of the registration certificate pertaining to the efficacy of the plant protection product and its harmful effects on plants and plant products are not substantiated.

33. The publication of instructions for use with respect to extension of the scope of use of a relevant plant protection product in the newspaper *Latvijas Vēstnesis* shall be ensured by the State Plant Protection Service.

34. When extending the scope of use of a relevant plant protection product, the holder of the registration certificate shall be liable for possible harmful effects of the plant protection product or its active substances on human or animal health and the environment.

35. A person using the plant protection product in conformity with the extension of its scope of use shall be liable for the possible harmful effects thereof on plants or plant product and harvest losses.

36. The State Plant Protection Service and the registration commission shall not utilise the information referred to in Annexes 1, 2 and 4 of these Regulations for the benefit of another applicant for registration if there is no mutual agreement in writing between the submitter of the information and the relevant applicant.

37. The State Plant Protection Service and the registration commission shall ensure restricted access to information at its disposal if such is requested by the applicant for registration.

On behalf of the Prime Minister –  
Minister for Justice

V.Birkavs

Minister for Agriculture

A. Kalvītis

## Information on Plant Protection Products

### I. Chemical Plant Protection Products

#### 1. Identity:

- 1.1. applicant (name, address, etc.);
- 1.2. manufacturer of the plant protection product and the active agent (name, address, including address of the place of manufacture);
- 1.3. trade name or proposed trade name of the plant protection product, as well as the code of the manufacturer;
- 1.4. detailed quantitative and qualitative information on the composition of the plant protection product (active substances, impurities and formulants);
- 1.5. the physical state and form of preparation of the plant protection product (emulsifiable concentrate, wettable powder, solution, etc.); and
- 1.6. use category (herbicide, insecticide, etc.).

#### 2. Physical, chemical and technical properties:

- 2.1. appearance, colour, odour and physical state;
- 2.2. explosive and oxidising properties;
- 2.3. flash point and other indications of flammability or auto-flammability;
- 2.4. acidity/alkalinity and, if necessary, pH value;
- 2.5. viscosity and surface tension;
- 2.6. relative density and volume per weight;
- 2.7. storage – stability and shelf-life (effect of light, temperature and humidity on the technical characteristics of the plant protection product);
- 2.8. technical characteristics of the plant protection product:
  - 2.8.1. wettability rate;
  - 2.8.2. foaming characteristics;
  - 2.8.3. suspensibility and suspension stability;
  - 2.8.4. dilution stability;
  - 2.8.5. wet sieve test and dry sieve test (wetable powder and granules);
  - 2.8.6. particle size, specification of dust and fines content (for granules), friability and attrition (for granules);
  - 2.8.7. emulsifiability, re-emulsifiability and emulsion stability;
  - 2.8.8. flowability, pourability and dustability;
- 2.9. physical and chemical compatibility with other products, including plant protection products with which its use is to be authorised;
- 2.10. adherence to and coating on seeds (mordants); and
- 2.11. summary and evaluation of the necessary information provided in this Paragraph.

#### 3. Information on application:

- 3.1. intended use, for example, for field crops, covered crops, in the storage of plant products, etc.;
- 3.2. effect on harmful organisms (for example, contact poison, inhalation poison or stomach poison, fungitoxic, fungistatic, as well as systemic or not in plants);
- 3.3. details of intended use, for example, harmful organisms to be controlled and/or plants or plant products to be protected;
- 3.4. application rate;
- 3.5. concentration of the active substance in the material used (for example, concentration of the application liquid);
- 3.6. method of application;
- 3.7. number and timing of applications, duration of effect of the plant protection product;
- 3.8. necessary waiting period and precautions in order to avoid phytotoxic effects on succeeding crops; and

3.9. draft instructions for use.

4. Further information:

- 4.1. packaging (type, material, size, etc.) and compatibility of the plant protection product with the packaging material;
- 4.2. methods for cleaning plant treatment equipment and protective clothing;
- 4.3. period of danger, necessary waiting period and other precautions to protect humans, animals and the environment;
- 4.4. precautions during handling, storage and transport of the plant protection product, or in case of fire;
- 4.5. emergency measures in case of accident; and
- 4.6. technological processes of destruction or neutralisation of the plant protection product and its packaging – possibility of neutralisation, controlled incineration and other methods.

5. Analytical methods:

- 5.1. methods for determining the composition of the plant protection product;
- 5.2. methods for determining the residues of the active substance (hereinafter – residues):
  - 5.2.1. in treated plants, plant products, animal feed and food, or on treated plants, plant products, animal feed and food;
  - 5.2.2. in soil;
  - 5.2.3. in water (including drinking water);
  - 5.2.4. in air; and
  - 5.2.5. in animal and human body fluids and tissues.

6. Evaluation of efficacy:

- 6.1. range-finding trials;
- 6.2. efficacy trials;
- 6.3. information on the development of resistance or its possible development;
- 6.4. effect on the quantity and/or quality of the yield of treated plants or plant products:
  - 6.4.1. effect on the quality of plants or plant products;
  - 6.4.2. effect on plant or plant product processing processes and quality of the resulting products; and
  - 6.4.3. effect on the yield of treated plants or plant products during storage;
- 6.5. phytotoxicity to treated plants (different cultivars) or plant products;
- 6.6. observations on undesirable or unintended side-effects:
  - 6.6.1. effect on succeeding crops;
  - 6.6.2. effect on other plants, including non-target crops and interplants (clover, etc.);
  - 6.6.3. effect on treated plants or parts of plants used for propagation (for example, seeds, cuttings, sprouts); and
  - 6.6.4. effect on beneficial and other live organisms; and
- 6.7. summary and evaluation of the information provided in this Paragraph.

7. Toxicological studies:

- 7.1. acute toxicity:
  - 7.1.1. oral (effect through the mouth);
  - 7.1.2. percutaneous effect;
  - 7.1.3. inhalation;
  - 7.1.4. skin irritation;
  - 7.1.5. eye irritation;
  - 7.1.6. skin sensitisation; and
  - 7.1.7. studies of the toxicity of the plant protection product in a mixture of the working liquid and the relevant plant protection product;
- 7.2. information on the effect of the plant protection product on the operator during application:
  - 7.2.1. exposure of the operator to the effects of the plant protection product – evaluation and measuring thereof;
  - 7.2.2. exposure of unauthorised persons to the effects of the plant protection product – evaluation and measuring thereof; and

7.2.3. exposure of persons involved in agricultural production to the effects of the plant protection product – evaluation and measuring thereof;

7.3. dermal absorption of the plant protection product (if necessary) – evaluation and measuring of absorption; and

7.4. information on the toxicity of impurities and formulants.

8. Residues in or on treated products, food and animal feed:

8.1. metabolism, localisation, identity and quantity of residues in plants, animal body tissues and fluids;

8.2. studies on the maximum possible level of residues in plants or plant products after treatment in conformity with principles of good agricultural practice;

8.3. studies on residues in animal tissues and fluids;

8.4. studies on residues in animal or plant products after industrial processing or culinary preparation;

8.5. studies on residues in succeeding crops;

8.6. maximum permissible residue limits;

8.7. interval between application of the plant protection product and harvesting, or the waiting or storage period if treatment is intended after harvesting;

8.8. estimation of the potential and actual effect of residues ingested with food and by other means; and

8.9. summary and evaluation of the information provided in this Paragraph.

9. Fate and behaviour in the environment:

9.1. fate and behaviour in soil:

9.1.1. rate of degradation in soil – laboratory studies and field trials;

9.1.2. studies on mobility in soil; and

9.1.3. information on expected concentration in soil, and evaluation;

9.2. fate and behaviour in water:

9.2.1. information on expected concentration in groundwater, and evaluation;

9.2.2. effect on water purification processes; and

9.2.3. information on expected concentration in surface waters, and evaluation thereof; and

9.3. fate and behaviour in air.

10. Ecotoxicological studies:

10.1. effect on birds:

10.1.1. acute oral toxicity;

10.1.2. supervised studies to assess risk under conditions of intended use of the plant protection product;

10.1.3. studies to assess whether birds can ingest the relevant plant protection product with granules, treated seeds or in some other way; and

10.1.4. evaluation of the secondary risk of poisoning;

10.2. effect on aquatic organisms:

10.2.1. acute toxicity to fish and aquatic invertebrates, or effect on growth of algae;

10.2.2. microcosm or mesocosm studies;

10.2.3. information on residues in fish;

10.2.4. chronic toxicity to fish;

10.2.5. studies on the effect on fish propagation and development;

10.2.6. bioaccumulation in fish; and

10.2.7. information on toxicity to daphnia;

10.3. effect on terrestrial vertebrates other than birds;

10.4. effect on bees;

10.5. effect on arthropods other than bees;

10.6. effect on earthworms and other soil macro-organisms:

10.6.1. acute toxicity; and

10.6.2. effect of a sub-lethal dose;

10.7. effect on soil micro-organisms; and

10.8. studies on the possible effect of the plant protection product on beneficial and other species of fauna and flora, and evaluation thereof.

11. Summary and evaluation of the information provided in Paragraphs 9 and 10 of these Regulations.

12. Further information:

12.1. information on registration of the plant protection product in other states;

12.2. information on the established maximum residue limits in other states;

12.3. proposals regarding classification and labelling, and justification thereof:

12.3.1. hazard symbols;

12.3.2. indications of danger;

12.3.3. risk phrases;

12.3.4. safety requirements; and

12.4. sample of the proposed packaging and draft instructions.

## II. Plant Protection Products Containing Micro-organisms or Viruses

13. Identity:

13.1. applicant (name, address, etc.);

13.2. manufacturer of the plant protection product and the active organism (name and address, including address of the place of manufacture);

13.3. trade name or proposed trade name of the plant protection product and, if necessary, the code of the manufacturer of the plant protection product;

13.4. detailed quantitative and qualitative information on the composition of the plant protection product (active organisms, inert components, extraneous organisms, etc.);

13.5. physical state and form of the preparation of the plant protection product (emulsifiable concentrate, wettable powder, solution, etc.); and

13.6. use category (insecticide, fungicide, etc.).

14. Physical properties:

14.1. appearance, colour and odour; and

14.2. storage stability – depending on the shelf-life, effect of temperature, method of packaging, method of storage and other factors on the retention of biological activity;

14.3. methods for establishing storage stability and shelf-life;

14.4. technical characteristics of the plant protection product:

14.4.1. wettability;

14.4.2. foaming;

14.4.3. suspensibility and suspension stability;

14.4.4. wet sieve test and dry sieve test;

14.4.5. particle size, specification of the content of dust and fines (for granules), friability and attrition (for granules);

14.4.6. granule sieve test and indications of mass of granules (at least in cases where the particle size exceeds 1 mm);

14.4.7. content of active substances in granules or on treated seeds;

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

14.4.9. flowability, pourability and dustability;

14.5. physical and chemical compatibility with other products, including plant protection products the use of which is allowed in working liquids; and

14.6. wetting, adherence and movement in treated plants.

15. Information on application:

15.1. intended use: for field crops, for cover crops, in storage facilities for food or animal feed;

15.2. details of intended use, for example, harmful organisms to be controlled and/or plants or plant products to be protected;

15.3. application rate;

15.4. if necessary, information on specific agricultural conditions, spread of harmful organisms and/or environmental conditions under which the use of the plant protection product is/is not possible;

- 15.5. concentration of the active substance recommended for use (for example, concentration of the working liquid);
  - 15.6. method of application;
  - 15.7. timing and number of applications;
  - 15.8. phytopathogenicity; and
  - 15.9. draft instructions for use.
16. Further information:
- 16.1. packaging (type, material, size, etc.) and compatibility of the plant protection product with the proposed packaging materials;
  - 16.2. methods for cleaning application equipment and protective clothing;
  - 16.3. necessary waiting period and information on other precautions to protect humans and animals;
  - 16.4. methods and precautions during handling, storage and transport of the plant protection product;
  - 16.5. instructions in case of accident; and
  - 16.6. methods for destruction of the plant protection product and its packaging.
17. Analytical methods:
- 17.1. methods for determining the composition of the plant protection product;
  - 17.2. methods for determining residues in treated plants or plant products, or upon them (for example, a biological test);
  - 17.3. methods for determining the microbiological purity of the plant protection product;
  - 17.4. methods for identifying human or mammalian pathogens (if necessary, also bee pathogens) in the plant protection product; and
  - 17.5. techniques used to ensure a standardised plant protection product and methods for assessment of the quality of such product.
18. Evaluation of efficacy:
- 18.1. preliminary range-finding tests;
  - 18.2. efficacy tests;
  - 18.3. information on the development of resistance or its possible development;
  - 18.4. studies on the effect on quantity or quality of the yield of treated plants and/or plant products:
    - 18.4.1. effect on the quality of plants or plant products;
    - 18.4.2. effect on the processes of plants or plant product processing; and
    - 18.4.3. effect on the yield of treated plants or on plant products;
  - 18.5. phytotoxicity of treated plants or plant products, including effect on various cultivars;
  - 18.6. observations on undesirable or unintended side-effects:
    - 18.6.1. effect on succeeding crops;
    - 18.6.2. effect on other plants, including non-target crops;
    - 18.6.3. effect on treated plants or parts of plants used for propagating purposes (for example, seeds, cuttings, sprouts); and
    - 18.6.4. effect on beneficial and other live organisms;
  - 18.7. summary and evaluation of the information provided in this Paragraph.
19. Studies of toxicity and/or pathogenicity and the risk of infection:
- 19.1. oral (single dose);
  - 19.2. percutaneous (single dose);
  - 19.3. inhalation;
  - 19.4. skin and eye irritation;
  - 19.5. skin sensitisation;
  - 19.6. information on toxicity of non-active components;
  - 19.7. information on the effect of the plant protection product on the operator during use:
    - 19.7.1. exposure of operator to the effects of the plant protection product – evaluation and measuring thereof;
    - 19.7.2. exposure of unauthorised persons to the effects of the plant protection product – evaluation and measuring thereof;
    - 19.7.3. exposure of persons working in agricultural production to the effects of the plant protection product – evaluation and measuring thereof; and

19.7.4. if dermal absorption of the plant protection products possible – evaluation and measuring of the effects.

20. Residues in or on the treated products, in food and in animal feed:

20.1. information on viable and non-viable residues, including information on tests on plants, animal feed or food in various climatic and agricultural conditions of intended use;

20.2. studies on the quantity and characteristics of residues in products after industrial processing or culinary preparation;

20.3. effect of residues on taint, odour, taste and other quality aspects (if necessary) on fresh or processed products;

20.4. studies on residues in products of animal origin;

20.5. studies on residues in succeeding crops;

20.6. necessary interval between application of the plant protection product and crop harvesting, or the waiting or storage period if treatment is intended after harvesting;

20.7. maximum permissible residue limit (for toxins); and

20.8. summary and evaluation of the information provided in this Paragraph (based on the data submitted in conformity with the requirements referred to in this Paragraph).

21. Fate and behaviour in the environment:

21.1. fate and behaviour in soil:

21.1.1. rate of degradation – laboratory studies and field trials;

21.1.2. mobility; and

21.1.3. information on expected concentration and evaluation;

21.2. fate and behaviour in water:

21.2.1. information on expected concentration in groundwater and evaluation;

21.2.2. effect on water purification processes; and

21.2.3. information on expected concentration in surface waters and evaluation;

21.3. fate and behaviour in air.

22. Ecotoxicological studies:

22.1. effect on aquatic organisms:

22.1.1. effect on fish;

22.1.2. effect on *Daphnia magna* and species related to the harmful organisms to be controlled;

22.1.3. effect on aquatic micro-organisms;

22.2. effect on beneficial and other live organisms:

22.2.1. effect on bees;

22.2.2. effect on other beneficial organisms;

22.2.3. effect on earthworms;

22.2.4. effect on other soil fauna;

22.2.5. effect on other live organisms that may be exposed to risk; and

22.2.6. effect on soil microflora.

23. Summary and evaluation of the information provided in Paragraphs 21 and 22 of this Annex.

24. Further information:

24.1. information on registration of the plant protection product in other states;

24.2. information on the established maximum permissible residue limits in other states;

24.3. proposals for classification and labelling and the justification of such:

24.3.1. hazard symbols;

24.3.2. indications of danger;

24.3.3. risk phrases; and

24.3.4. safety requirements;

24.4. a sample of the proposed packaging and draft instructions.

Note. The studies and analyses referred to in this Annex shall be certified by the signature of an appropriately qualified person.

Minister for Agriculture

A. Kalvītis

## Information on Active Substances of Plant Protection Products

### I. Active Substances of Chemical Plant Protection Products

1. Identity of the active substance of a chemical plant protection product (hereinafter – active substance):
  - 1.1. applicant (name, address, etc.);
  - 1.2. manufacturer (the name and address, including the address of the place of manufacture);
  - 1.3. proposed name or ISO-approved name and synonyms;
  - 1.4. chemical name (according to IUPAC and CA nomenclature);
  - 1.5. identification (code) of the manufacturer;
  - 1.6. CAS, EEC and CIPAC numbers (if available);
  - 1.7. molecular formula, structural formula and molecular mass;
  - 1.8. method of manufacture (synthesis pathway) of the active substance;
  - 1.9. degree of purity of the active substance (except non-active isomers);
  - 1.10. identity of impurities, isomers and formulants, the specification of structural formula and quantity in g/kg for each; and
  - 1.11. data of the chemical composition analysis of the active substance sample and specification of the quantity up to 98 per cent.
2. Physical and chemical properties:
  - 2.1. melting and boiling point;
  - 2.2. relative density;
  - 2.3. vapour pressure (Pa) and volatility (for example, Henry's constant);
  - 2.4. appearance, colour, odour and physical state;
  - 2.5. spectrum – UV/VIS, IR, NMR, MS and molecular extinction at relevant wavelengths;
  - 2.6. solubility in water, taking into account the effect of pH (including pH 4-10);
  - 2.7. solubility in organic solvents;
  - 2.8. partition coefficient in N-octanol/water, taking into account the effect of various pH values (including pH 4-10);
  - 2.9. stability in water, hydrolysis rate, photochemical degradation, quantum yield, identity of breakdown products, and dissociation constant, taking into account various pH values (including pH 4-9);
  - 2.10. stability in air, photochemical degradation, identity of breakdown products;
  - 2.11. flammability, including auto-flammability;
  - 2.12. flash point;
  - 2.13. explosive properties;
  - 2.14. surface tension; and
  - 2.15. oxidising properties.
3. Further information on the active substance:
  - 3.1. use category: fungicide, herbicide, insecticide, repellent or plant growth regulator, indicating the appropriate:
    - 3.1.1. acaricide;
    - 3.1.2. bactericide;
    - 3.1.3. fungicide;
    - 3.1.4. herbicide;
    - 3.1.5. insecticide;
    - 3.1.6. molluscicide;
    - 3.1.7. nematocide;
    - 3.1.8. plant growth regulator;
    - 3.1.9. repellent;
    - 3.1.10. rodenticide;
    - 3.1.11. semi-chemicals;
    - 3.1.12. talpicide;

- 3.1.13. viricide; and
- 3.1.14. other (must be indicated);
- 3.2. effect on harmful organisms: contact poison, inhalation poison or stomach poison, fungitoxic as well as systemic or not in plants;
- 3.3. intended use, for example, for field crops, cover crops, in storage of plant products;
- 3.4. plants to be protected, harmful organisms to be controlled, and products to be protected or treated;
- 3.5. the mechanism of biochemical and physiological effects and involvement in metabolic processes;
- 3.6. information on the development of resistance or possible occurrence thereof, as well as appropriate response strategies;
- 3.7. recommended precautions during handling, storage or transport, and in case of fire;
- 3.8. procedures for destruction or neutralisation; and
- 3.9. emergency measures in case of accident, including procedures for purification of polluted water.

#### 4. Analytical methods:

- 4.1. methods for identification of the active substance and additives produced by the relevant manufacturer and determination of the degree of purity of the active substance;
- 4.2. multi-methods (or alternative methods) for determination of the active substance and significant metabolic residues:
  - 4.2.1. in plants, plant products, food (of plant and animal origin) and animal feed;
  - 4.2.2. in soil;
  - 4.2.3. in water (including drinking water, groundwater and surface waters);
  - 4.2.4. in air; and
  - 4.2.5. in animal and human body fluids and tissues.

#### 5. Toxicology and metabolism studies:

- 5.1. absorption, spreading, excretion and metabolism studies in mammalian organisms;
- 5.2. acute toxicity:
  - 5.2.1. oral (effect through the mouth);
  - 5.2.2. percutaneous (effect through the skin);
  - 5.2.3. inhalation (breathing in);
  - 5.2.4. skin irritation;
  - 5.2.5. eye irritation; and
  - 5.2.6. skin sensitisation;
- 5.3. short-term toxicity:
  - 5.3.1. oral toxicity studies (28-day study);
  - 5.3.2. oral toxicity studies (90-day study); and
  - 5.3.3. other types of studies;
- 5.4. genotoxicity:
  - 5.4.1. studies in vitro;
  - 5.4.2. studies in vivo in somatic cells; and
  - 5.4.3. studies in vivo in embryonic cells;
- 5.5. long-term toxicity and carcinogenicity;
- 5.6. reproductive toxicity:
  - 5.6.1. generation studies; and
  - 5.6.2. toxicity studies in the embryo development process;
- 5.7. neurotoxicity studies (after-effects);
- 5.8. medical information on registered cases of poisoning; and
- 5.9. summary and evaluation of the information provided in this Paragraph.

#### 6. Residues in treated plants, plant products, food and animal feed, or on the surface of treated plants, plant products, food and animal feed:

- 6.1. residue metabolism, localisation, identity and quantity in plants;
- 6.2. residue metabolism, localisation, identity and quantity in animal tissues and fluids;
- 6.3. studies on the rate of residue degradation and maximum possible level of residues in plants and plant products after treatment in conformity with the principles of good agricultural practice;

- 6.4. studies on residues in animal tissues and fluids;
  - 6.5. studies on residues in animal or plant products after industrial processing or culinary preparation;
  - 6.6. studies on residues in succeeding crops;
  - 6.7. maximum permissible residue limits;
  - 6.8. interval between application of the plant protection product and crop harvesting, or the waiting or storage period if treatment takes place after harvesting of the crop;
  - 6.9. estimation of the potential and actual effect of residues (ingested with food or by other means);
- and
- 6.10. summary and evaluation of the information provided in this Paragraph.

7. Fate and behaviour in the environment:

- 7.1. fate and behaviour in soil:
  - 7.1.1. type and rate of degradation – laboratory studies and field trials: aerobic, anaerobic, and photolytic degradation, biodegradation, studies on the accumulation in soil of the active substance and significant metabolite breakdown and reaction products, studies on the level of active substance residues in soil during the period of crop harvesting and sowing of succeeding crops;
  - 7.1.2. adsorption and desorption;
  - 7.1.3. mobility — laboratory studies, lysimetric studies or soil erosion studies;
- 7.2. fate and behaviour in water and air:
  - 7.2.1. types and rate of degradation in water systems in so far as such do not apply to Sub-paragraph 2.9 of these Regulations; and
  - 7.2.2. types and rate of degradation in air in so far as such do not apply to Sub-paragraph 2.10 of these Regulations;
- 7.3. proposals regarding permissible levels of residues in soil, water and air; and
- 7.4. monitoring data on the fate and behaviour of the active substance and its most important metabolites, breakdown products and reaction products.

8. Ecotoxicological studies:

- 8.1. effect on birds:
    - 8.1.1. acute oral toxicity;
    - 8.1.2. short-term toxicity – if the active substances have been ingested with food;
    - 8.1.3. sub-chronic and reproductive toxicity;
  - 8.2. effect on aquatic organisms:
    - 8.2.1. acute toxicity to fish;
    - 8.2.2. chronic toxicity to fish;
    - 8.2.3. bioaccumulation in fish;
    - 8.2.4. acute toxicity to aquatic invertebrates;
    - 8.2.5. chronic toxicity to aquatic invertebrates;
    - 8.2.6. effect on the growth of algae;
    - 8.2.7. effect on organisms living in sediments; and
    - 8.2.8. effect on aquatic plants;
  - 8.3. effect on arthropods:
    - 8.3.1. effect on bees – acute toxicity, studies of the effect on the development of bee larvae;
- and
- 8.3.2. effect on other arthropods;
- 8.4. effect on earthworms:
    - 8.4.1. acute toxicity; and
    - 8.4.2. effect of sub-lethal dose;
  - 8.5. effect on soil micro-organisms;
  - 8.6. effect on live organisms (species of fauna and flora); and
  - 8.7. effect on biological waste water treatment procedures.

9. Summary and evaluation of the information provided in Paragraphs 7 and 8 of this Annex.

10. Proposals regarding classification and labelling, and justification thereof:

- 10.1. hazard symbols;

- 10.2. indications of danger;
- 10.3. risk phrases; and
- 10.4. safety requirements.

11. The information referred to in Annex 1, Chapter I of these Regulations regarding the plant protection product containing the relevant active substance.

## II. Micro-organisms and Viruses

### 12. Identity:

- 12.1. applicant (name, address, etc.);
- 12.2. manufacturer (name and address, including address of the place of manufacture);
- 12.3. common name or alternative and superseded names;
- 12.4. taxonomic name and strain for bacteria, protozoa and fungi, indicating whether it is a stock variant or a mutant strain; for viruses – taxonomic designation of the agent, serotype, and strain or mutant;
- 12.5. sample and culture identification number in the collection;
- 12.6. identification methods, procedures and criteria (i.e., morphology, biochemistry, serology); and
- 12.7. detailed quantitative and qualitative information on the active organism – microbiological purity, characteristics, identity, properties, impurity content and quantity of extraneous organisms.

### 13. Biological properties:

- 13.1. organisms to be treated, pathogenicity or the type of antagonism to host, infective dose, transmissibility and information on mode of action;
- 13.2. history of the organism and its uses; natural occurrence and geographical distribution;
- 13.3. information on infectivity, pathogenicity and transmissibility: host specificity range and effect on species other than the harmful target organisms, including species closely related to the target species;
- 13.4. infectivity and physical stability under conditions of intended use, effect of temperature and exposure to air radiation, stability when used in suitable environmental conditions;
- 13.5. interaction of the organism with plant pathogens or also with pathogens of vertebrate species or non-target invertebrate species;
- 13.6. information on genetic stability (i.e. mutation rate) under conditions of intended use of the plant protection product; and
- 13.7. toxins, their presence, characteristics, identity and stability, as well as the chemical structure (if necessary).

### 14. Information on use:

- 14.1. use category: fungicide, herbicide, repellent or growth regulator;
  - 14.2. effect on the harmful organism: contact poison, inhalation poison or stomach poison, fungitoxic or fungistatic as well as systemic or not in plants;
  - 14.3. intended use of the plant protection product, for example, for field crops, cover crops, in storage facilities for food or animal feed;
  - 14.4. studies of specific agricultural conditions, plant health or environmental conditions under which active organisms may (may not) be used;
  - 14.5. harmful organisms to be controlled and plants or plant products to be protected;
  - 14.6. techniques used to ensure a standardised material and methods for the assessment of the quality thereof. If the active organism is a mutant strain – detailed information regarding its acquisition, including information on the differences between the mutant strain and the parent strain;
  - 14.7. methods to maintain virulence;
  - 14.8. methods and precautions during handling, storage and transport of the plant protection product;
- and
- 14.9. possibility of rendering the organism non-infective.

### 15. Analytical methods:

- 15.1. methods for establishing the identity and purity of seed stock (parent culture), including information on mutations;
- 15.2. methods for establishing the microbiological purity and toxins of the active organism, including information on mutations;

- 15.3. methods for identification of human or mammalian pathogens in the active organism, including fungi and protozoa in a range of temperatures (35 °C and other relevant temperatures); and
- 15.4. methods for the determination of viable and non-viable (for example, toxins) residues on treated products or in treated products, food, animal feed, animal and human body tissues and fluids, soil, water and air (according to circumstances).
16. Toxicological, pathogenicity and infectivity studies:
- 16.1. bacteria, fungi, protozoa and mycoplasma:
- 16.1.1. toxicity and/or pathogenicity and infectivity – oral single dose, percutaneous single dose, inhalation single dose, intraperitoneal single dose, if necessary – skin and eye irritation, skin sensitisation studies and supplementary studies;
- 16.1.2. short-term toxicity (effects within a 90-day period); and
- 16.1.3. supplementary toxicological and/or pathogenicity and infectivity studies – oral chronic toxicity and carcinogenicity, mutagenicity, teratogenicity, multigeneration studies in mammals (at least two generations), metabolic studies (absorption, distribution and excretion in mammals, including information on metabolic pathways), neurotoxicity studies, immunotoxicity, i.e., allergenicity, pathogenicity and infectivity under immunosuppression;
- 16.2. viruses and viroids:
- 16.2.1. acute toxicity and/or pathogenicity and infectivity, the information set out in Sub-paragraph 16.1.1 of this Annex, and cell culture studies utilising purified infective viruses and primary cell cultures of mammalian, avian and fish cells;
- 16.2.2. short-term toxicity; and
- 16.2.3. supplementary toxicological and pathogenicity or infectivity studies referred to in Sub-paragraph 16.1.3 of this Annex;
- 16.3. toxic effects on livestock and pets;
- 16.4. medical data:
- 16.4.1. medical surveillance of crop farming personnel;
- 16.4.2. health records of industrial and agricultural personnel;
- 16.4.3. observations on exposure of people to the effects of the plant protection product, and epidemiological data;
- 16.4.4. diagnosis of poisoning, signs of specific poisoning and clinical tests;
- 16.4.5. observations on sensitisation or allergenicity;
- 16.4.6. instructions on emergency measures in case of accident: first aid measures, antidotes and medication (according to circumstances); and
- 16.4.7. prognosis of expected effects of poisoning;
- 16.5. summary of mammalian toxicology and conclusions (including NOAEL, NOEL and ADI (according to circumstances)) and overall evaluation of toxicological pathogenicity and infectivity.
17. Residues in plants treated products, food and animal feed:
- 17.1. identification of viable or non-viable (i.e., toxins) residues in treated plants or products thereof;
- 17.2. studies on the ability of the active organism to multiply in plants or food which studies include information on any effects on food quality;
- 17.3. if residues of toxins remain on edible plant products, the information referred to in Sub-paragraph 4.2 and Paragraph 6 of this Annex is required; and
- 17.4. summary and evaluation of residue behaviour resulting from the data referred to in this Paragraph.
18. Fate and behaviour in the environment:
- 18.1. spread, mobility, multiplication and persistence in air, water and soil;
- 18.2. information relating to possible fate of residues in food chains; and
- 18.3. if toxins are produced, the data referred to in Paragraph 7 of this Annex are required.
19. Ecotoxicological studies:
- 19.1. effect on birds – acute oral toxicity and/or pathogenicity and infectivity;
- 19.2. effect on fish – acute oral toxicity and/or pathogenicity and infectivity;
- 19.3. toxicity to *Daphnia magna*;
- 19.4. effect on the growth of algae;

- 19.5. effects of target species on important parasites and predators – acute toxicity and/or pathogenicity and infectivity;
- 19.6. effect on bees – acute toxicity and/or pathogenicity and infectivity;
- 19.7. effect on earthworms – acute toxicity and/or pathogenicity and infectivity;
- 19.8. effect on other live organisms (that are exposed to risk) – acute toxicity and/or pathogenicity and infectivity;
- 19.9. extent of indirect contamination on adjacent agricultural cultures, wild plants and water;
- 19.10. effect on other species of fauna and flora; and
- 19.11. if toxins are produced, depending on the circumstances the data specified in Sub-paragraphs 8.1.2, 8.1.3, 8.2.2, 8.2.4, 8.2.5, 8.2.6, 8.2.7 and 8.3.3 are required.

20. Summary and evaluation of the information referred to in Paragraphs 18 and 19 of this Annex.

21. Proposals regarding classification and labelling of the active organism and the justification for such:

- 21.1. hazard symbols;
- 21.2. indications of danger;
- 21.3. risk phrases; and
- 21.4. safety requirements.

22. Information referred to in Annex 1, Chapter I of these Regulations regarding the plant protection product which contains the relevant active organism.

Note. The studies and analyses referred to in this Annex shall be certified by the signature of an appropriately qualified person.

Minister for Agriculture

A. Kalvītis

## Information to be Included on Labels of Plant Protection Products

### I. Labels of Protective Packaging

1. Trade name of the plant protection product.
2. Form of preparation (for example, wettable powder, emulsifiable concentrate).
3. Use category of the plant protection product (for example, insecticide, plant growth regulator).
4. Characteristics of the danger.
5. Name and address of the holder of the registration certificate.
6. Name and address of the manufacturer, distributor or representative.
7. Registration number.
8. Batch number (lot number).
9. Date of manufacture.
10. Net weight.
11. Conditions for storage.
12. Warning of danger.
13. Safety requirements.

Note. Protective packaging is, for example, a box or a cardboard container which ensures protection of one or more packages (pre-packages), and it must be strong enough to prevent the contents from being crushed or from other types of damage. It is used to package one or more pre-packages together and usually ensures their special protection against adjacent packages, for example, protects against damage during loading.

### II. Labels of Packaging

14. Trade name of the plant protection product.
15. Name of the active substance and its concentration in the preparation.
16. Form of preparation (for example, wettable powder, emulsifiable concentrate).
17. Use category of the plant protection product (for example, insecticide, plant growth regulator).
18. Characteristics of the danger.
19. Name and address of the holder of the registration certificate.
20. Name and address of the manufacturer, distributor or representative.
21. Registration number.
22. Class of registration.

23. Batch number.
24. Date of manufacture.
25. Net weight.
26. Conditions for storage.
27. Expiry date.
28. Warning of danger.
29. Instructions to be observed when rendering first aid.
30. Summary of the use of the plant protection product.
31. Instructions for destruction of the plant protection product and its packaging.
32. Instructions for use:
  - 32.1. protected cultivated species;
  - 32.2. harmful organisms to be controlled;
  - 32.3. timing, dosage and number of applications;
  - 32.4. interval between application and the presence of humans or animals on the field;
  - 32.5. methods of application;
  - 32.6. conditions for use;
  - 32.7. restrictions on use;
  - 32.8. waiting periods until harvesting of crops;
  - 32.9. compatibility with other preparations;
  - 32.10. if necessary, the safety interval between each application and:
    - 32.10.1. the sowing or planting of cultivated protected species;
    - 32.10.2. the sowing or planting of succeeding crops;
    - 32.10.3. the presence of humans or animals on the field;
    - 32.10.4. harvesting of crops; and
    - 32.10.5. consumption of plants or plant products;
  - 32.11. possible phytotoxicity, sensitivity of various species and different reactions, as well as possible side-effects on plants and plant products, which effects are to be considered for the period between application of the preparation and sowing or planting:
    - 32.11.1. cultivated species to be treated; and
    - 32.11.2. individual crops.
33. Legal liability.
34. If the space available on the package is too small for presenting the information, the information referred to in Paragraphs 32 and 33 of this Annex shall be presented in a separate instruction. The instruction shall include the information specified in Paragraphs 1, 2, 3, 4, 26, 28, 29, 30 and 31. The instruction shall be considered as part of the label and the label shall bear an indication “Pirms augu aizardzības līdzekļa lietošanas izlasīt pievienoto instrukciju” [Read accompanying instructions before using the plant protection product].

Note. Packaging: bags, bottles (glass, polyethylene or plastic bottles for which the size of stopper shall not exceed 63 mm), metal cans and barrels.

Information on Plant Protection Products Containing Parasitic and Predatory Live Organisms

1. Identity of the plant protection product:
  - 1.1. applicant (name and address);
  - 1.2. manufacturer (name and address);
  - 1.3. trade name or proposed trade name;
  - 1.4. information on the quality, quantity and composition of the plant protection product (live organism, extraneous organisms, inert components);
  - 1.5. use category; and
  - 1.6. samples of proposed packaging and label.
  
2. Identity of the live organism:
  - 2.1. Latin name and Latvian name (synonyms);
  - 2.2. taxonomic category;
  - 2.3. ontogenesis;
  - 2.4. description;
  - 2.5. natural occurrence and geographical distribution; and
  - 2.6. indication of the manner of acquisition of the live organism (natural population or artificially created population, information on all known differences from natural population, etc.).
  
3. Biological properties of the live organism:
  - 3.1. harmful organisms to be controlled and type of effect;
  - 3.2. effect on useful insects;
  - 3.3. storage stability, shelf-life, conditions for transporting and storage (temperature, packaging, effect on biological activity); and
  - 3.4. possibilities of use utilising the integrated plant protection method.
  
4. Information regarding application:
  - 4.1. field of use envisaged (in greenhouse, on open field crops, orchards, etc.);
  - 4.2. cultivated species to be protected and harmful organisms to be controlled;
  - 4.3. method of application, dosage, number and timing of applications (plant vegetation period, pest development stage, etc.); and
  - 4.4. if necessary, all environmental agricultural conditions, and conditions for the spread of harmful organisms which determine or restrict the use of the plant protection product.
  
5. Efficacy:
  - 5.1. biological efficacy:
    - 5.1.1. time to produce an effect and period of activity retention in biocenosis;
    - 5.1.2. pest mortality rate per time unit;
  - 5.2. if necessary, an evaluation of efficacy utilising the integrated plant protection method.

Note. The studies and analyses referred to in this Annex shall be certified by the signature of an appropriately qualified person.

Minister for Agriculture

A. Kalvītis