Republic of Latvia

Cabinet
Regulation No 568
Adopted 29 June 2004

Registration Procedures for Live Organisms

Issued pursuant to
Section 5, Clause 11
of the Plant Protection Law

I. General Provisions

1. These Regulations prescribe the procedures for the registration of live organisms and the inclusion of invertebrates, for example, insects, ticks, nematodes (hereinafter – live organism) in the Register of Plant Protection Products (hereinafter – Register).

2. The Plant Protection Service (hereinafter – the Service) shall include the live organism in the Register if, in accordance with the data and information referred to in Annexes 1 and 2 of these Regulations:

2.1. the identification and unambiguous recognition of the live organism is ensured;

2.2. it is verified that the live organism is sufficiently effective (the number of harmful organisms due to the impact thereof, the damages to plants caused by a direct or indirect impact of such organisms or harvest losses decrease by at least 10 per cent);

2.3. the following has been verified:

2.3.1. the environmental safety, especially taking into account the selectivity of the live organism in respect to the plant and animal species to restrict the spread of which it is intended to be used (hereinafter – host organism), and the possible effect on other plant and animal species;

2.3.2. the safety to human health, especially in relation to the persons involved in the multiplication and introduction of the live organism;

2.3.3. the purity of the batch, especially in relation to quarantine organisms and harmful organisms, which are utilised during the multiplication of the live organism for the feeding thereof or for the ensuring of the lifecycle thereof; and

2.3.4. the possibilities for the restriction of the spreading, if an undesirable impact of the live organism on the environment or human health is observed; and

2.4. the conformity of the packaging of the live organism to the following requirements has been verified:

2.4.1. the packaging has been manufactured from inert material, which does not affect the life processes of the live organism;

2.4.2. the packaging and the closing design thereof are durable in the intended transportation and storage conditions;

2.4.3. the packaging and the closing design thereof do not allow the escape of the live organisms from packaging during transportation and storage; and

2.4.4. the packaging ensures the possibility for control institutions to check the contents thereof without opening the packaging.

3. In including the live organism in the Register, the Service shall determine the third registration class to the live organism.

II. Inclusion of the Live Organism in the Register

4. In order to include the live organism in the Register, a submitter shall submit to the Service:

4.1. a submission regarding the registration of the live organism;

4.2. the documents containing the information referred to in Annexes 1 and 2 of these Regulations;

4.3. a written identity certification of the live organism issued by a scientific institution of a European Union Member State, a member state of the European Free Trade Association or the Organisation for European Economic Co-operation and Development, unless reduced requirements are specified for the information to be submitted regarding the live organism in accordance with Paragraph 7 of these Regulations;

4.4. a draft text of the label in Latvian language. The information referred to in Annex 3 of these Regulations shall be indicated in the draft text of the label;

4.5. an indication whether the live organism has been or has not been genetically modified;

4.6. a list of such documents for which the submitter requests to assign the status of restricted access information. The source of information and the justification for the designation of a commercial secret shall be indicated; and

4.7. a document (copy) which certifies that an evaluation of the possible risk posed by the live organism to the environment has been carried out in accordance with the requirements specified in regulatory enactments regarding the procedures for the utilisation and distribution of genetically modified organisms, if the live organism is a genetically modified organism.

5. The Service shall request from a submitter a sample of the live organism, a sample of the live organism batch ready for distribution and a sample of the packaging of the live organism if such are necessary in order to prepare the evaluation referred to in Sub-paragraph 10.2 of these Regulations.

6. A submitter shall notify the Service regarding any new information which indicates the negative impact of the live organism included in the Register to plant and animal species to restrict the spread of which it is not intended to be used, or to human health.

III. Information regarding the Live Organism

7. The Service shall determine reduced requirements in respect to the information to be submitted regarding the live organism and shall perform only a general assessment of the negative impact on the environment on the basis of the information referred to in Annex 2 of these Regulations in one of the following cases:

7.1. the species of the live organism is of local (Latvian) origin;

7.2. the live organism is included in the list of live organisms widely used in the states of the European and Mediterranean Plant Protection Organisation (hereinafter – *EPPO*) region and is in circulation in such states;

7.3. the live organism is mentioned in the list of those organisms which are intended to be included in the *EPPO* list of live organisms in circulation; or

7.4. the live organism has been included in the *EPPO* list of classic biological agents to be utilised t restrict the spread of harmful organisms.

8. If, taking into account the characteristics of the live organism or the intended use thereof, a submitter does not submit all the information referred to in Annexes 1 and 2 of these Regulations (for example, it is not required to submit such information or it is not possible technically to obtain it), the submitter shall submit a justification to the Service as to why the information has not been submitted.

9. The duty of a submitter is to immediately notify the Service regarding changes made in the documents submitted for the registration by justifying the necessity of the changes.

IV. Taking of a Decision regarding the Inclusion of the Live Organism in the Register

10. The Service shall:

10.1. examine whether the information submitted ensures the preparation of an assessment regarding the conformity of the live organism and the packaging thereof to the conditions referred to in Paragraph 2 of these Regulations and, if necessary, shall request the submission of additional information;

10.2. prepare the assessment regarding the conformity of the live organism and the packaging thereof to the conditions referred to in Paragraph 2 of these Regulations within the time period specified in Section 64 of the Administrative Procedure Law. If necessary, the Service shall request from a submitter an analysis of the relevant data or involve experts in the preparation of the assessment.;

10.3. evaluate whether those species of the live organism, which are not of local origin or have not been introduced in Latvia may not become a harmful organism in certain circumstances (for example, an insufficient amount of host organisms for the development or survival of the population, a selection of an alternative host organism, which is not a harmful organism). If the live organism may become a harmful organism in certain circumstances, a risk analysis of the referred-to harmful organism shall be carried out; and

10.4. submit the following documents to the Plant Protection Product Registration Commission (hereinafter – the Registration Commission) established in accordance with regulatory enactments regarding the procedures for the registration of plant protection products:

10.4.1. the assessment referred to in Sub-paragraph 10.2 of these Regulations; and

10.4.2. the draft text of the label referred to in Sub-paragraph 4.4. of these Regulations.

11. The Registration Commission shall:

11.1. evaluate the documents referred to in Sub-paragraph 10.4 of these Regulations; and

11.2. prepare a proposal regarding the inclusion of the live organism in the Register.

12. The Registration Commission may request from the Service:

12.1. additional information necessary for the preparation of the proposal referred to in Sub-paragraph 11.2 of these Regulations;

12.2. a separate analysis of data; and

12.3. a consultation of an adequately qualified expert.

13. The Service shall take a decision regarding the inclusion of the live organism in the Register on the basis of the assessment referred to in Sub-paragraph 10.2 of these Regulations and the proposal of the Registration Commission referred to in Sub-paragraph 11.2 of these Regulations.

14. The Service shall take a decision not to include the live organism in the Register in the following cases:

14.1. the live organism or the packaging thereof does not conform to one of the conditions referred to in Paragraph 2 of these Regulations;

14.2. a risk analysis of the harmful organism referred to in Sub-paragraph 10.3 of these Regulations proves that the introduction of the live organism in Latvia is not allowable;

14.3. a submitter has submitted incorrect or intentionally distorted data or information referred to in Annexes 1 and 2 of these Regulations; or

14.4. the submitter has not provided the additional information referred to in Sub-paragraph 10.1 of these Regulations within the term specified by the Service.

15. If a decision is taken not to include the live organism in the Register, the Service shall issue or send by post the decision and the justification thereof to a submitter within a period of 10 days after the taking of the decision.

16. If a decision is taken to include the live organism in the Register, the Service shall determine:

16.1. the conditions for the utilisation of the live organism:

16.1.1. the combination "crop/harmful organism" or "purpose of use/location";

16.1.2. dose;

16.1.3. method of application;

16.1.4. the period of application (the stage of development of the crop or harmful organism); and

16.1.5. the conditions necessary to ensure the spreading of the live organism population, for example, air temperature, humidity, daylight time, and lighting intensity;

16.2. the labelling requirements in respect to the indications regarding the safety to human health and the environment, if it is necessary in accordance with the assessment referred to in Sub-paragraph 10.2 of these Regulations;

16.3. the trade name (names) for distribution in Latvia;

16.4. the packaging material and type for the distribution of the live organism in Latvia, as well as the number of live organisms per packaging unit; and

16.5. a registration certificate number.

17. The following documents shall be attached to a decision regarding the inclusion of the live organism in the Register:

17.1. the labelling text approved by the Service; and

17.2. a list of such documents, which have been assigned the status of restricted access information.

18. Within a period of 10 days after the making of the decision referred to in Paragraph 16 of these Regulations, the Service shall request a submitter to submit a labelling text containing the information specified in Annex 3 of these Regulations, which corresponds to the information specified in the decision.

19. The Service shall approve a labelling text, make an entry in the register, issue or send by post to the submitter the decision regarding the inclusion of the live organism in the register, the documents attached thereto and a registration certificate within ten days after the receipt of a labelling text submitted for approval.

20. The following information shall be indicated in a registration certificate: given name, surname or name and address of a certificate owner, the trade name of the live organism, the genus and species name in Latvian (if available) and in Latin, the registration certificate number, the registration class, the number of live organisms in a packaging unit, registration date, the decision number and the term of validity of the certificate.

21. The following shall be indicated in the Register:

21.1. the trade name of the live organism;

21.2. the registration certificate number;

21.3. the genus and species name of the live organism in Latvian (if available) and in Latin;

21.4. given name, surname or name and address of the registration certificate holder;

21.5. given name, surname or name and address of the producer of the live organism;

21.6. the registration class ;

21.7. the type and material of packaging for the distribution of the live organism in Latvia, as well as the number of live organisms in one packaging unit;

21.8. the date of registration and the number of the decision;

21.9. the term of validity of the registration certificate; and

21.10. the information referred to in Sub-paragraph 16.1 of these Regulations.

V. Change in Ownership of a Registration Certificate

22. If the ownership of a registration certificate changes, the term of validity of the registration certificate shall remain unchanged.

23. In order to transfer a registration certificate to another owner, the current registration certificate holder shall submit a relevant submission to the Service. A confirmation signed by the current certificate holder and the next certificate holder regarding the transfer and acceptance of the registration certificate shall be appended to the submission. The following shall be indicated in the confirmation:

23.1. the trade name (names) of the live organism included in the Register, the registration certificate number and the date of registration of the live organism;

23.2. given name, surname or name and address of the current registration certificate holder and the given name, surname or name and address of the next registration certificate holder;

23.3. information regarding the transfer of the registration documentation of the live organism and the availability thereof to the next registration certificate holder; and

23.4. the date from which the current registration certificate holder shall transfer all rights and duties of a registration certificate holder to the next registration certificate holder, and the date from which the next registration certificate holder shall take over all rights and duties of the registration certificate holder.

24. The Service shall:

24.1. review the documents referred to in Paragraph 23 of these Regulations and shall take a decision within a period of one month after the receipt thereof; and

24.2. within a period of seven days after the taking of the decision referred to in Sub-paragraph 24.1 of these Regulations:

24.2.1. shall notify the current and the next registration certificate holder in writing regarding the making of the decision and shall issue the registration certificate; and

24.2.2. make the relevant amendments to the Register.

VI. Repeated Inclusion of the Live Organism in the Register

25. After the term of validity of a registration certificate has expired, the Service shall re-enter the live organism into the Register if the relevant submission is received from the registration certificate holder.

26. In order to re-enter the live organism into the Register, the registration certificate holder shall submit the relevant submission to the Service not later than one year before the expiration of the term of validity of the certificate together with the updated information referred to in Annexes 1 and 2 of these Regulations.

27. The Service shall take a decision regarding the re-entry of the live organism in the Register in accordance with the procedures specified in Chapter IV of these Regulations.

VII. Re-evaluation of the Live Organism Included in the Register

28. The Service shall re-evaluate the compliance of the live organism with the conditions of Paragraph 2 of these Regulations if:

28.1. the registration certificate holder has informed the Service regarding changes in the documents submitted for registration, justifying the necessity for such changes;

28.2. the registration certificate holder informs the Service regarding the possible harmful effects of the registered live organism on human health and the environment; or

28.3. there are reasonable suspicions that the live organism does not comply with any of the registration conditions referred to in Paragraph 2 of these Regulations.

29. The registration certificate holder shall submit the requested additional information, which is necessary for the preparation of a re-evaluation within the time period specified by the Service.

30. On the basis of the submitted additional information, the Service shall prepare an evaluation regarding the conformity of the live organism and the packaging thereof to the conditions referred to in Paragraph 2 of these Regulations and shall take a decision regarding

the conformity of the live organism to the conditions of registration within a period of three months after the receipt of the additional information .

31. If the reason for a re-evaluation is a suspicion regarding the non-conformity of a registered live organism to the conditions referred to in Sub-paragraphs 2.3.1 or 2.3.2 of these Regulations, the Service may impose restrictions or a ban on the use and distribution of the relevant live organism for a period up to the taking of a decision. The Service shall inform the registration certificate holder without delay regarding the restrictions or the ban, as well as shall indicate the reasons for the restrictions or the ban.

VIII. The Making of Amendments to the Register

32. The Service shall make amendments to the Register if:

32.1. taking into account the scientific achievements and technological developments, it is possible to change the method of use or the dose of a registered live organism; or

32.2. amendments are necessary in accordance with the results of a re-evaluation of the live organism.

33. The Service may make amendments to the Register, if a registration certificate holder requests such amendments and the necessity of the amendments is justified.

34. In order to make amendments to the Register, the Service shall:

34.1. request that the registration certificate holder submits the necessary additional information within the time period specified by the Service in accordance with Annexes 2 and 3 of these Regulations or with an evaluation of separate studies;

34.2. on the basis of the submitted additional information, prepare an evaluation regarding the conformity of the live organism and the packaging thereof to the conditions referred to in Paragraph 2 of these Regulations within a period of one month after the receipt of the additional information; and

34.3. within the time period specified in Section 64 of the Administrative Procedure Law, take a decision regarding the necessary amendments to the Register and make the relevant amendments on the basis of the evaluation referred to in Paragraph 30 and Sub-paragraph 34.2 of these Regulations and the recommendation of the Registration Commission.

IX. Revocation of a Registration Certificate

35. The Service shall revoke a registration certificate and an entry in the Register in the following cases:

35.1. the live organism does not comply with any of the conditions referred to in Paragraph 2 of these Regulations;

35.2. the registration certificate holder has submitted incorrect or intentionally distorted information referred to in Paragraph 4 of these Regulations;

35.3. the requested additional information for the re-evaluation of the live organism is not submitted within the time period specified by the Service; or

35.4. a relevant submission of the registration certificate holder has been received, in which the reasons for revocation are indicated.

36. The Service shall inform a registration certificate holder regarding the revocation of the registration certificate within a period of 10 days after the taking of the decision. The registration certificate holder shall surrender the registration certificate to the Service within a period of 30 days after the taking of the decision regarding the revocation of the registration certificate.

X. Protection and Publication of Information

37. The Service and the Registration Commission shall ensure the status of restricted access information in accordance with Annexes 1 and 2 of these Regulations for the information submitted to the Service, which contains secrets of commercial activities, if a submitter has requested such in writing and the Service acknowledges that the relevant information contains secrets of commercial activities.

38. The status of restricted accessibility shall not be assigned to:

38.1. the trade name of the live organism and the given name, surname or the name and address of the registration certificate holder;

38.2. the genus and species name of the live organism;

38.3. the methods and techniques for restricting the spread of the live organism and the elimination of the harmful effects thereof; and

38.4. a summary of the results of trials and studies that prove the efficacy and harmlessness of the live organism to plants, human health and the environment.

39. The Service shall ensure the publication of the following information in the newspaper *Latvijas Vēstnesis* [the official Gazette of the Government of Latvia] within a period of 10 working days after the taking of the relevant decision:

39.1. regarding the inclusion of the live organism in the Register (indicate the trade name of the live organism, the registration certificate holder, the number and the term of validity of the registration certificate);

39.2. regarding the revocation of a registration certificate (indicate the trade name of the live organism, the registration certificate holder and the registration certificate number; and

39.3. regarding the amendments to the published information referred to in Sub-paragraph 39.1 of these Regulations.

Prime Minister I. Emsis

Minister for Agriculture M. Roze

Annex 1
Cabinet Regulation No. 568
29 June 2004

Information to be Submitted regarding the Species of the Live Organism, which are not of Local Origin and are not Introduced in Latvia

Identity and Description of the Live Organism

(Provide precise information and a detailed description permitting unerring recognition of the live organism)

1. Identity of the live organism:

1.1. full scientific name, the given name of the person who identified the corresponding species of the live organism, the publication in which the official description of the live organism has been provided;1.2. the taxonomic classification (type, class, order, family, genus, sub-genus, species, sub-species), also information regarding the name of the corresponding taxonomic unit that is usually used, synonyms and a historical change of taxonomic names;

1.3. the means for precise identification, indicating the differences of the live organism species from the species closely related thereto, or, if such information does not exist, describing the features, which indicate the presence of the live organism (for example, any visible features that indicate the infection of a harmful organism with the live organism);

1.4. a general description of the development stages, also information regarding any difficulties in classification (for example, the complexity of the species, uncertain or poorly investigated species);

1.5. the known molecular information for identifying especially complicated and hard-to-identify species; and

1.6. an accurate morphological description of the live organism and information regarding the existence of a sample thereof in the collections of scientific institutions or cultures, indicating the name and address of the institution and the identification number of the live organism in the culture collection.

2. A description of the live organism:

2.1. the characteristic features of family and genus:

2.1.1. biology (morphology, gender dimorphism, dimensions, mass, winged or without wings, description of behaviour);

2.1.2. lifecycle description;

2.1.3. the mode of reproduction;

2.1.4. the nature of the reproduction season;

2.1.5. reproduction potential (for example, the number of eggs, juvenile specimens);

2.1.6. the number of generations a year;

2.1.7. lifespan; and

2.1.8. specific characteristics and features (for example, toxicity, the type of harmful impact, the ability to cause allergic reaction, a description of feeding, aggressive and defensive behaviour, unpleasant odour, characteristic plant damages, resistance to pesticides, frost resistance, aggressiveness in the search for food);

2.2. the factors, which may have an effect on the development and activity (effectiveness) of the population of the live organism after the spreading in the environment (for example, temperature, humidity, wind, rainfall, soil type, quality of water, elevation above the sea level of the corresponding zone of spreading, provision with species that the live organism uses for food or for ensuring the lifecycle (hereinafter – host organism);

2.3. the mechanism of spreading;

2.4. geographical and ecological spreading;

2.4.1. a zone of natural spreading (for example, tropical or subtropical) and the spreading in the world, also information regarding any known occurrence outside of the zone, where the live organism has been deliberately introduced or was introduced accidentally;

2.4.2. the special requirements in respect to the biotope (for example, dry land, water, meadow, forest, mountains, arable land, fallow land); and

2.4.3. the possibilities for spreading (for example, ability to fly, species which may be used as alternative host organisms, migration behaviour); and

2.5. a description of the live organism, which is as complete as possible, based on theoretical research, field observations and observations in the zone of natural spreading. The following information regarding the live organism shall be provided:

2.5.1. the requirements for ensuring the survival and reproduction, the optimal and the extreme climatic conditions in which the survival and reproduction of the live organism is possible, as well as the advantages of population development in the zone of natural spreading;

2.5.2. the relationship with the rest of the biotope – the ability to interact and unite with species existing in the new environment and the ability to form hybrids;

2.5.3. the host organism species (also the species to restrict the spread of which the live organisms are not intended to be used) in the zone of natural spreading and a description thereof;

2.5.4. the range of host organisms (indicate the primary host organism);

2.5.5. the biology of such predators, parasites or parasitoids, pathogens or commensal species present in the biotope, which may be transmitted to the place of introduction with the live organism or the host organisms to be used for breeding thereof;

2.5.6. the naturally occurring species, which use the same host organism for food or for ensuring the lifecycle as the relevant live organism;

2.5.7. the possibilities for adaptation to survive unfavourable conditions (for example, migrations, diapause, rest period);

2.5.8. the competitors and enemies within a zone of natural spreading and outside it, where the live organism is used for plant protection;

2.5.9. the species that have been examined as host organisms (a list) and official information regarding the range of host organisms;

2.5.10. the method, which is used to determine the range of host organisms (the planning and circumstances of an experiment, stages of development of the host organisms);

2.5.11. the methods of host organism cultivation and a description thereof (also the cultivation methods of those species to restrict the spread of which the live organism is not intended to be used); and

2.5.12. the statistical methods used and a description thereof.

II. Impact of the Live Organism on Human Health

3. Information regarding significant danger to human health or animals and any negative impact observed on users of the live organism and the persons involved in the multiplication thereof (for example, cases of contracting asthma or rhinitis, the ability of live organisms to cause skin irritation and allergic skin reactions to humans after continuous contact with large amounts of the live organisms, the transmission of diseases).

4. The measures for preventing the negative impact of the live organism on human health.

III. Impact of the Live Organism on the Environment

5. The impact observed in the conditions characteristic to the climatic zone of Latvia on the species to restrict the spread of which the live organism is not intended to be used.

6. Information regarding the role of the live organism in the natural ecosystem:

6.1. the range of host organisms (monophagous or oligophagous);

6.2. a competing, inhibiting or other kind of impact on the species present in nature, which use the same host organism for food or for ensuring the lifecycle as the live organism;

6.3. species which endanger the live organism (parasitoids, predators, pathogens);

6.4. the consequences of the impact of the live organism on a harmful organism, as well as on other species phylogenetically or ecologically related or unrelated to the live organism, which the live organism may use as a host organism;

6.5. the competition in the selection of a host organism between a harmful organism, to restrict of the spread of which the live organism is intended to be used, and the species which the live organism may use as a host organism, but to restrict the spread of which it is not intended to be used, an assessment of mutual replacement possibilities thereof;

6.6. the ability of the live organism to interbreed with local strains or with the same local or very closely related species, which use the same host organism for food or for ensuring the lifecycle as the live organism;

6.7. the impact on plants, if the organism is a herbivore and if phytotoxicity is possible, also the potential negative impact on crops to be protected or plant species for the protection of which it is not intended to be used;

6.8. the ability of the population of the live organism to pervade in the ecozone and to spread by moving from one ecozone to another. The following shall be evaluated:

6.8.1. the abiotic factors – the similarity of climatic conditions at the place of origin and at the place in which the live organism is intended to be used;

6.8.2. the biotic factors – an interaction opportunity with the species to restrict the spread of which the live organism is not intended to be used, but which the live organism may use as a host organism;

6.8.3. the combination possibilities of the biotic and abiotic factors and the availability of other resources in order for the live organism to survive and reproduce; and

6.8.4. diapause and hibernation;

6.9. the potential indirect impact on certain species and the ecosystem;

6.9.1. the data acquired during field observations and in farms of the live organisms regarding the ability of the live organism to transmit viruses and micro-organisms, which may negatively impact the species to restrict the spread of which the live organism is not intended to be used; and

6.9.2. the positive impact caused by the live organism on the environment in comparison to the existing or alternative methods for restricting the spread of the harmful organism (for example, the degree of restriction of the spread of the harmful organism, the development of resistance);

6.10. a summary of information regarding the impact of the live organism upon the ecosystem; and

6.11. a summary of information regarding the possible risk to the environment.

IV. An Assessment of the Effectiveness of the Use of the Live Organism

7. Information and data, which prove the effectiveness of the use of the live organism for the restriction of the spread of harmful organisms on crops, for which it is intended to be used. The conditions in which the use of the live organism is effective.

8. Any positive impact caused by the use of the live organism.

9. A summary of information regarding the effectiveness of the use of the live organism.

10. The significance of the live organism within the integrated plant protection system.

V. Manufacturing of the Live Organism and the Intended Use Thereof

11. A detailed description of the multiplication methods of the live organism.

12. The origin of the live organism (at the species level or at the lowest taxonomic level):

12.1. if the live organism has been acquired in field conditions:

12.1.1. the latitude and longitude, where it was acquired;

12.1.2. the zone of natural spreading, where it was acquired; and

12.1.3. the season when the initial population was created; and

12.2. if the live organism has been acquired in a laboratory culture;

12.2.1. the number of specimens in the initial population and the number of generations in the population; and

12.2.2. the person maintaining the population of the live organism: given name, surname or name and address thereof.

13. Impurities resulting in the manufacturing process of the live organism (also host organisms and substrates) and the procedures for the separation thereof, if it is necessary.

14. Host organisms used for the multiplication of the live organism. Information regarding any species not separated from the live organism, but which will be distributed together with it, and a description of such species.

15. The procedures which ensure the purity of the manufactured batch of the live organism before commencing distribution (for example, the washing of the surfaces of cocoons and mummies with a fungicide, the removal of specimens of an inadequate stage of development).

16. Evaluation (test) methods of the quality and purity of the live organism.

17. The type of genetic modification, if the live organism has been genetically modified.

18. The harmful organism to restrict the spread of which the live organism is intended to be used and the crops to be protected.

19. The possibilities for reducing the negative impact caused by the live organism, if it causes a negative impact.

20. The address of the production unit of the live organism.

21. Countries in which the live organism is used as a plant protection product.

Minister for Agriculture M. Roze

Annex 2
Cabinet Regulation No. 568
29 June 2004

Information to be Submitted regarding the Live Organism Species to Which Reduced Requirements Apply

Identity and Description of the Live Organism

1. Identity of the live organism:

1.1. full scientific name, the given name of the person who identified the corresponding species of the live organism, the publication in which the official description of the live organism has been provided;

1.2. the taxonomic classification (type, class, order, family, genus, sub-genus, species, sub-species), also information regarding the name of the corresponding taxonomic unit that is usually used, synonyms and a historical change of the taxonomic names; and

1.3. the means for precise identification, indicating the differences of the live organism species from the species closely related thereto, or, if such information does not exist, describing the features, which indicate the presence of the live organism (for example, any visible features that indicate the infection of a harmful organism with the live organism);

2. A description of the live organism:

2.1. the characteristic features of family and genus:

2.1.1. biology (morphology, gender dimorphism, dimensions, mass, winged or without wings, description of behaviour);

2.1.2. lifecycle description;

2.1.3. the mode of reproduction;

2.1.4. the nature of the reproduction season;

2.1.5. reproduction potential (for example, the number of eggs, juvenile specimens);

2.1.6. number of generations a year;

2.1.7. lifespan; and

2.1.8. specific characteristics and features (for example, toxicity, the type of harmful impact, the ability to cause allergic reaction, a description of feeding, aggressive and defensive behaviour, unpleasant odour, characteristic plant damages, resistance to pesticides, frost resistance, aggressiveness in the search for food);

2.2. the factors, which may have an effect on the development and activity (effectiveness) of the population of the live organism after the spreading in the environment (for example, temperature, humidity, wind, rainfall, soil type, quality of water, elevation above the sea level, provision with species that the live organism uses for food or for ensuring the lifecycle (hereinafter – host organism);

2.3. the mechanism of spreading;

2.4. geographical and ecological spreading;

2.4.1. the zone of natural spreading (for example, tropical or subtropical) and spreading in the world, also information regarding any known occurrence outside of the zone, where the live organism has been deliberately introduced or was introduced accidentally;

2.4.2. the special requirements with regard to a biotope (for example, dry land, water, meadow, forest, mountains, arable land, fallow land); and

2.4.3. the possibilities for spreading (for example, ability to fly, species which may be used as alternative host organisms, migration behaviour); and

2.5. the ecology of the live organism:

2.5.1. the requirements for ensuring the survival and reproduction, the optimal and the extreme climatic conditions in which the survival and reproduction of the live organism is possible;

2.5.2. the ability to interact and unite with the species existing in the environment and the ability to form hybrids;

2.5.3. the range of host organisms (indicate the possible host organisms and the primary host organism);

2.5.4. the naturally occurring species, which use the same host organism for food or for ensuring the lifecycle as the relevant live organism;

2.5.5. the possibilities for adaptation to survive unfavourable conditions (for example, migration, diapause, rest period); and

2.5.6. the methods of host organism cultivation.

II. Impact of the Live Organism on Human Health

3. Information regarding an observed unfavourable impact of the live organism on the health of the user and the persons employed in the multiplication thereof (for example, the observed cases of contracting asthma or rhinitis, the ability of the live organism to cause skin irritation and allergic skin reactions to humans after continuous contact with large amounts of the live organisms, the transmission of diseases).

4. The measures to prevent the negative impact of the live organism on human health.

III. Impact of the Live Organism on the Environment

5. Information regarding the impact of the live organism on the environment:

5.1. the range of host organisms;

5.2. the ability of the population of the live organism to pervade within an ecozone and to spread by moving from one ecozone to another;

5.3. indirect impact of the live organism on the ecosystem; and

5.4. the positive impact caused by the live organism on the environment in comparison to the existing or alternative methods of restricting the spread of a harmful organism (for example, the degree of restriction of the spread of the harmful organism, the development of resistance).

IV. Evaluation of Efficacy of the Live Organism

6. Information and data that prove the effectiveness of the live organism for the intended use thereof.

7. Information regarding any positive impact of the use of the live organism.

Manufacture of the Live Organism and the Intended Use Thereof

8. A detailed description of the multiplication methods of the live organism.

9. Impurities, which result in the manufacturing process of the live organism (also host organisms and substrates), and the procedures for the separation thereof, if it is necessary.

10. The host organisms used for the multiplication of the live organism. Information regarding any species that will not be separated from the live organism, but which will be distributed together with it, and a description of such species.

11. The procedures that ensure the purity of the manufactured batch of the live organism before the commencement of distribution (for example, the washing of the surfaces of cocoons and mummies with a fungicide, the removal of specimens of inadequate development stage).

12. Evaluation (test) methods of the quality and purity of the live organism.

13. The type of genetic modification, if the live organism has been genetically modified.

14. The harmful organism to restrict the spread of which the live organism is intended to be used and the crops to be protected.

15. The possibilities for reducing the negative impact caused by the live organism, if it causes a negative impact.

16. The address of the production unit of the live organism.

17. Countries in which the live organism is used as a plant protection product.

Minister for Agriculture M. Roze

Annex 3
Cabinet Regulation No. 568
29 June 2004

Information to be Included on the Label of the Live Organism

I. Protective Packaging Labels

1. An indication in the form of pictograms or a notice that the packaging contains the live organism.

2. An indication regarding the desirable conditions for transportation and storage of the live organism, for example, temperature and humidity conditions.

3. An indication in the form of pictograms or a notice regarding the correct position of a packaging (horizontal or vertical) when handling the packaging.

4. Information regarding the purpose of use of the live organism, for example, the live organism for combating plant pests.

5. The given name, surname or the name and address of the manufacturer and the person responsible for packaging and labelling (if the person is not the manufacturer).

6. The given name, surname or name, address and telephone number of the person (representative, importer) responsible for commencing the distribution of a plant protection product.

7. Date of packaging.

8. Expiration date.

9. Information in English complying with the international requirements regarding the transportation of live organisms may be indicated on the label of the protective packaging.

II. Packaging Labels

10. An indication in the form of pictograms or a notice that the packaging contains the live organism.

11. An indication regarding the desirable conditions for transportation and storage of the live organism, for example, temperature and humidity conditions.

12. An indication in the form of pictograms or a notice regarding the correct position of a packaging (horizontal or vertical) when handling the packaging.

13. The trade name of the live organism.

14. The registration certificate number.

15. The registration class.

16. The number of specimens of the live organism in a packaging unit.

17. Information regarding the live organism:

17.1. the genus and species name in Latin and Latvian (if available);

17.2. an indication regarding the development stage at which the live organism is distributed; and

17.3. the name of the genus and species of any organism distributed together with the live organism.

18. A summary of the lifecycle of the live organism, including information regarding the lifespan and the number of generations a year.

19. Instructions for use:

19.1. the harmful organism to be controlled;

19.2. the crop to be protected;

19.3. dose;

19.4. a description of the method of use;

19.5. the number and interval of uses;

19.6. the conditions for the use of the live organism, also the optimal and the critical conditions of light, temperature, humidity and the optimal and the critical conditions for the spread of a harmful organism, which are essential in order to ensure the effectiveness of the live organism; and

19.7. the vulnerability of the live organism to chemical plant protection products.

20. The optimal and the critical storage conditions of the live organism.

21. The given name, surname or the name and address of the manufacturer of the live organism and the person responsible for packaging and labelling (if the person is not the manufacturer).

22. The given name, surname or name, address and telephone number of the person (representative, importer) responsible for the distribution of the live organism.

23. Date of packaging.

24. Expiration date.

25. Restrictions for use (specific conditions in which the live organism may not be used).

26. Indications regarding the possible risk to the environment or human health (if necessary).

27. If the area intended on a packaging is too small, the information referred to in Paragraphs 18 and 19 of these Regulations shall be indicated separately, including also the information referred to in Paragraphs 13, 14, 15, 17, 20, 25 and 26 of this Annex.

Minister for Agriculture M. Roze