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If a whole or part of a paragraph has been amended, the date of the amending regulation appears in square brackets at the end of the paragraph. If a whole paragraph or sub-paragraph has been deleted, the date of the deletion appears in square brackets beside the deleted paragraph or sub-paragraph.

Republic of Latvia

Cabinet
Regulation No 156
Adopted 23 March 2004

Registration Procedures for Plant Protection Products

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

I. General Provisions

1. These Regulations prescribe registration procedures for plant protection products, as well as for plant protection products containing micro-organisms and viruses (hereinafter – plant protection products):

1.1. for the inclusion or the repeated inclusion in the register of plant protection products (hereinafter – register);

1.2. for the granting of an authorisation for an extension of the scope of use of the plant protection product included in the register;

1.3. for the granting of an authorisation for the distribution and use in studies and experiments of plant protection products not included in the register;

1.4. for the granting of an authorisation for the distribution and use of a plant protection product that does not conform to the requirements of registration; and

1.5. for the granting of an authorisation for the parallel importation of plant protection products.
[6 March 2007]

1.[1] The parallel importation of plant protection products is the importation for distribution of plant protection products identical to the plant protection products included in the register from Member States of the European Union or states of the European Free Trade Association, which have signed the European Economic Area agreement.
[6 March 2007]

2. The State Plant Protection Service shall control compliance with these Regulations.

II. Inclusion of a Plant Protection Product in the Register

3. The State Plant Protection Service (hereinafter – Service) shall include the plant protection product in the register for a period of 10 years or, in accordance with Chapter V of these Regulations – for a time period of three years. After the term of validity of the registration certificate has expired, the plant protection product may be re-registered if so requested by the holder of the registration certificate.

4. The Service shall include a plant protection product in the register if:

4.1. the active substance in the composition thereof is included in the list of active substances registered in the European Community or in the list which has been distributed in the Member States of the European Union by 25 July 1993 and, in accordance with regulatory enactments of the European Community regarding the gradual assessment of active substances, shall be evaluated for inclusion in such list;

4.2. the results acquired in trials, studies and analyses, which are carried out in accordance with Annexes II and III to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (Official Journal of the European Union, 01.05.2004, Chapter 3 Volume 11, p. 330) (hereinafter – Directive 91/414/EEC), Annexes I, II and III to Commission Directive 93/71/EEC of 27 July 1993 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Official Journal of the European Union, 01.05.2004, Chapter 3 Volume 15, p. 50) (hereinafter – Directive 93/71/EEC), Annexes I and II to Commission Directive 94/37/EC of 22 July 1994 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Official Journal of the European Union, 01.05.2004, Chapter 3 Volume 16, p. 312) (hereinafter – Directive 94/37/EC), Annexes I and II to Commission Directive 94/79/EC of 21 December 1994 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Official Journal of the European Union, 01.05.2004, Chapter 3 Volume 17, p. 73) (hereinafter – Directive 94/79/EC), Annex to Commission Directive 95/35/EC of 14 July 1995 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Official Journal of the European Union, 01.05.2004, Chapter 3 Volume 18, p. 48) (hereinafter – Directive 95/35/EC), Annexes I and II to Commission Directive 95/36/EC of 14 July 1995 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Official Journal of the European Union, 01.05.2004, Chapter 3 Volume 18, p. 50) (hereinafter – Directive 96/36/EC), Annexes I and II to Commission Directive 96/46/EC of 16 July 1996 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Official Journal of the European Union, 01.05.2004, Chapter 3 Volume 19, p. 371) (hereinafter – Directive 96/46/EC), Annexes I and II to Commission Directive 96/68/EC of 21 October 1996 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Official Journal of the European Union, 01.05.2004, Chapter 3 Volume 19, p. 483) (hereinafter – Directive 96/68/EC) and Annexes I and II to Commission Directive 2001/36/EC of 16 May 2001 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Official Journal of the European Union, 01.05.2004, Chapter 3 Volume 11, p. 330) (hereinafter – Directive 2001/36/EC) after the evaluation thereof following the requirements specified in the Annex to Council Directive 97/57/EC of 22 September 1997 establishing Annex VI to Directive 91/414/EEC concerning the placing of

plant protection products on the market (Official Journal of the European Union, 01.05.2004, Chapter 3 Volume 21, p. 450) (hereinafter – Directive 97/57/EC) and the Annex to Council Directive 2005/25/EC of 14 March 2005 amending Annex VI to Directive 91/414/EEC as regards plant protection products containing micro-organisms (Official Journal of the European Union, 08.04.2005, L 90/1) (hereinafter – Directive 2005/25/EC) regarding requirements for the evaluation of the risk of plant protection products and regarding criteria for taking of a decision concerning all circumstances and consequences characteristic of the intended use, certify that, in using the plant protection product in accordance with the instructions on the label, the principles of good plant protection practice and the principles of integrated plant protection:

4.2.1. the relevant plant protection product is sufficiently effective;

4.2.2. the relevant plant protection product has no unacceptably negative impact upon plants or plant products;

4.2.3. the relevant plant protection product does not cause additional pain and suffering to the vertebrates for the restriction of the spread of which it is intended to be used;

4.2.4. the relevant plant protection product and the residues thereof have no harmful effect, directly or indirectly (through drinking water, food or animal feed) on human or animal health or groundwaters; and

4.2.5. the relevant plant protection product and the residues thereof have no unacceptably negative impact upon the environment, taking into account in particular any possible changes thereto and the capability thereof to spread into the environment (to come into reservoirs, especially into groundwater and drinking water reservoirs, as well as to impact on non-target species);

4.3. in accordance with the requirements for evaluation and criteria for the taking of a decision specified in the Annex to Directive 97/57/EC and Directive 2005/25/EC it is proved that:

4.3.1. the active substance of the plant protection product, the amount thereof, toxicologically or ecotoxicologically significant chemical admixtures derived or included in the process of synthethising the active substance, formulants and co-formulants included in the composition of the plant protection product, can be determined by suitable and standardised methods in the European Community;

4.3.2. it is possible by suitable methods to determine toxicologically significant or environmentally significant residues of the plant protection product which have arisen through the application of the plant protection product in accordance with the intended use thereof; and

4.3.3. physical and chemical properties of the plant protection product conform to the requirements specified for the intended use and storage;

4.4. the applicant for registration carrying out trials in Latvia has proven the effectiveness of the plant protection product under the circumstances in Latvia. The effectiveness of a plant protection product is proven by positive results from two years of trials (if the plant protection product contains an active substance which is in the composition of a plant protection product included in the register, - by positive results from one year of trials); and

4.5. in the regulatory enactments regarding the control of pesticide residues in products of plant or animal origin, the maximum residue level is approved for residues from a plant protection product in products of plant and animal origin targeted by the use thereof which are used in food or animal feed, or, for a time period pending the approval of the maximum residue level, the Service has specified a provisional maximum residue level.

[4 July 2006]

5. In order to register a plant protection product, an applicant for registration shall submit:

5.1. a application for registration of the plant protection product;

5.2. the dossiers of trials, studies and analyses referred to in Annex II to Directive 91/414/EEC, Annex I to Directive 93/71/EEC, Annex I to Directive 94/37/EC, Annex I to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex I to Directive 95/36/EC, Annex I to Directive 96/12/EC, Annex I to Directive 96/46/EC, Annex I to Directive 96/68/EC, Annex I to Directive 2001/36/EC and Annex III to Directive 91/414, Annex II and III to Directive 93/71/EC, Annex II to Directive 94/37/EC, Annex II to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex II to Directive 95/36/EC, Annex II to Directive 96/12/EC, Annex II to Directive 96/46/EC, Annex II to Directive 96/68/EC and Annex II to Directive 2001/36/EC, together with data regarding the identity of the active substance or plant protection product and specifications in accordance with Paragraph 1 of Annex II to Directive 91/414/EEC, Annex I to Directive 94/37/EEC and Annex I or Paragraph 1 of Annex III to Directive 94/79/EC, Annex II to Directive 94/37/EC and Annex II to Directive 94/79/EC if:

5.2.1. the plant protection product contains an active substance that is included in the list of active substances registered in the European Community;

5.2.2. the applicant for registration in accordance with Chapter XIV of these Regulations uses studies made by another applicant for registration; and

5.2.3. the applicant for registration has already submitted to the Service information regarding the active substance in relation to the inclusion in the register of another plant protection product;

5.3. the results of efficiency examination trials carried out in Latvia

5.4. a draft of the label text in Latvian where the information referred to in the Annex to these Regulations shall be indicated;

5.5. the list of trials and studies and the following information shall be set out therein:

5.5.1. name and reference number of the document;

5.5.2. the author and the year of completion of the document;

5.5.3. information regarding the compliance of trials and studies with regulatory enactments regarding the quality of work at laboratories and the principles of good laboratory practice prescribed for the inspection of laboratory work or with the principles of good experimental practice prescribed in Paragraph 21 of these Regulations;

5.5.4. an indication regarding publication; and

5.5.5. the holder of the trial and studies and the requirement regarding the protection of information, if the source of information is not published;

5.6. the list of those documents for which the applicant for registration requires to grant the status of restricted access information, indicating reference to the source of information and a substantiation for the determination of secrecy for the commercial activities; and

5.7. a document (copy) which certifies that the evaluation of the possible risk of the plant protection product 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 plant protection product contains genetically modified micro-organisms.

[4 July 2006]

6. The Service is entitled to require the applicant for registration to submit to the Service samples of the plant protection product and the formulants thereof, samples of technical active substances, pure active substances, impurities and any substances referred to in the definition

of residues, as well as a sample of the packaging for the plant protection product if it is required for the preparation of the evaluation referred to in Sub-paragraphs 30.2 and 30.3 of these Regulations.

7. If the holder of a registration certificate intends to distribute a registered plant protection product, the preparative form or content of the active substance of which differs from the registered preparative form or content of the active substance of the plant protection product, he or she shall submit to the Service the documents referred to in Paragraph 5 of these Regulations. The Service, in accordance with Chapter IV of these Regulations, shall take a decision regarding the inclusion of the plant protection product in the register.

III. Trials, Studies and Analyses

8. The trials and studies referred to in Sub-paragraph 5.2 of these Regulations shall be carried out under circumstances that, according to the prevalence of agricultural, environmental, harmful organisms and other characteristic indications are appropriate to the territory where the relevant plant protection product is intended to be used. The results obtained in trials and studies, pursuant to the level of modern science and technology, shall demonstrate the effects, which arise in the use of the plant protection product in accordance with the intended use thereof and the principles referred to in Sub-paragraph 4.2 of these Regulations.

9. Trials, studies and analyses shall be performed in accordance with the methods and standards referred to in Annex II to Directive 91/414, Annex I to Directive 93/71/EEC, Annex I to Directive 94/37/EC, Annex I to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex I to Directive 95/36/EC, Annex I to Directive 96/12/EC, Annex I to Directive 96/46/EC, Annex I to Directive 96/68/EC, Annex I to Directive 2001/36/EC and Annex III to Directive 91/414, Annex II and III to Directive 93/71/EC, Annex II to Directive 94/37/EC, Annex II to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex II to Directive 95/36/EC, Annex II to Directive 96/12/EC, Annex II to Directive 96/46/EC, Annex II to Directive 96/68/EC and Annex II to Directive 2001/36/EC.
[4 July 2006]

10. If trials, studies and analyses are performed utilising methods, which are not referred to in and standards referred to in Annex II to Directive 91/414, Annex I to Directive 93/71/EEC, Annex I to Directive 94/37/EC, Annex I to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex I to Directive 95/36/EC, Annex I to Directive 96/12/EC, Annex I to Directive 96/46/EC, Annex I to Directive 96/68/EC, Annex I to Directive 2001/36/EC and Annex III to Directive 91/414, Annex II and III to Directive 93/71/EC, Annex II to Directive 94/37/EC, Annex II to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex II to Directive 95/36/EC, Annex II to Directive 96/12/EC, Annex II to Directive 96/46/EC, Annex II to Directive 96/68/EC and Annex II to Directive 2001/36/EC, or there are deviations from the referred to methods, the applicant for registration shall submit to the Service a justification and, upon the request of the Service – a description of the method utilised, as well as a document which certifies that the method utilised is recognised internationally or standardised in the relevant country.
[4 July 2006]

11. If, taking into account the properties of the plant protection product or the intended use, the submitted information in accordance with Annex II to Directive 91/414, Annex I to

Directive 93/71/EEC, Annex I to Directive 94/37/EC, Annex I to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex I to Directive 95/36/EC, Annex I to Directive 96/12/EC, Annex I to Directive 96/46/EC, Annex I to Directive 96/68/EC, Annex I to Directive 2001/36/EC, Annex III to Directive 91/414, Annex II and III to Directive 93/71/EC, Annex II to Directive 94/37/EC, Annex II to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex II to Directive 95/36/EC, Annex II to Directive 96/12/EC, Annex II to Directive 96/46/EC, Annex II to Directive 96/68/EC and Annex II to Directive 2001/36/EC is not complete or, pursuant to scientific opinion it is not essential to be provided, or it is not technically possible to obtain such information, the applicant for registration shall submit a justification.
[4 July 2006]

12. If the trials, studies and analyses require a continuous dose of the plant protection product or active substance, one batch of the active substance or plant protection product shall be used (if stability permits that). If various batches are used, the comparability of the batches shall be proven.

13. If different doses of plant protection products are used in trials and studies, the information regarding the mutual relationship between the negative effects of the plant protection product and dose shall be submitted to the Service.

14. The Service shall require trials, studies and analyses to be conducted with significant metabolites and substances arising as a result of the decomposition and reactions of the active substance in the plant protection product only if it is not possible to evaluate the effects thereof on the basis of studies regarding the active substance.

15. The applicant for registration shall provide detailed information regarding the specification of residues from the plant protection product, toxicity and ecotoxicity, as well as the spread into the environment and the impact upon the environment of the plant protection product and active substance used in the trials, studies and analyses. Trials, studies and analyses shall be carried out with the active substance, the specification of which complies with the specification of the technical active substance included in the composition of the plant protection product the registration of which has been applied for, or the applicant for registration shall submit a substantiation that the results of studies carried out with the pure active substance do not significantly vary.

16. If the plant protection function is provided by residues from the toxin of the micro-organism or metabolite or if they do not provide the function of plant protection, but with respect to the evaluation of the risk they are of a significant quantity, then the dossiers of the studies referred to in Annex II to Directive 91/414, Annex I to Directive 93/71/EEC, Annex I to Directive 94/37/EC, Annex I to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex I to Directive 95/36/EC, Annex I to Directive 96/12/EC, Annex I to Directive 96/46/EC, Annex I to Directive 96/68/EC, Annex I to Directive 2001/36/EC regarding the relevant metabolite or toxin shall be submitted.
[4 July 2006]

17. Before starting any trials and studies with warm-blooded animals, a person who has decided to submit an application for the registration of such a plant protection product which contains an active substance included on the list of active substances registered in the European Community, shall request from the Service:

17.1. information regarding whether a plant protection product with the same composition is not included in the register; and

17.2. information regarding any current or former holder of the registration certificate (name and address).

18. The Service:

18.1. shall provide the information referred to in Sub-paragraphs 17.1 and 17.2 of these Regulations if the person submits to the Service written certification that:

18.1.1. he or she will be the applicant for registration of a plant protection product;

18.1.2. he or she has all the other information referred to in Annex II to Directive 91/414, Annex I to Directive 93/71/EEC, Annex I to Directive 94/37/EC, Annex I to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex I to Directive 95/36/EC, Annex I to Directive 96/12/EC, Annex I to Directive 96/46/EC, Annex I to Directive 96/68/EC, Annex I to Directive 2001/36/EC, Annex III to Directive 91/414, Annex II and III to Directive 93/71/EC, Annex II to Directive 94/37/EC, Annex II to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex II to Directive 95/36/EC, Annex II to Directive 96/12/EC, Annex II to Directive 96/46/EC, Annex II to Directive 96/68/EC and Annex II to Directive 2001/36/EC; and

18.2. shall inform the holders of the relevant registration certificates regarding the person referred to in Paragraph 17 of these Regulations (given name, surname, designation and address).

[4 July 2006]

19. The Service is entitled to require that the person referred to in Paragraph 17 of these Regulations agree with the current or former holder of the registration certificate regarding the provision of information in order to avoid any repeated experimentation with warm-blooded animals.

20. If a person requests from the Service the information referred to in Sub-paragraphs 17.1 and 17.2 of these Regulations in order to ensure the inclusion on the list of active substances registered in the European Community of such an active substance that has been distributed in the Member States of the European Union until 25 July 1993, the Service shall facilitate the co-operation of holders of the registration certificates in the provision of information in order to avoid any repeated experimentation with warm-blooded animals.

21. The person who carries out the trials referred to in Sub-paragraph 4.4 of these Regulations (hereinafter – performer of trials), shall comply with the following work quality requirements (hereinafter – principles of good experimental practice):

21.1. The education, skills, technical knowledge and experience of the scientific and technical staff of the performer of trials shall be sufficient for the conduct of the relevant study;

21.2. suitable technical equipment for the proper performance of trials and measurements shall be at the disposal thereof. This equipment shall be appropriately maintained and calibrated before any commencement of studies, as well as subsequently according to a specified plan;

21.3. fields (experimental) and, where appropriate, greenhouses or warehouses intended for trials shall be at the disposal thereof. The trial environment shall not influence the results or precision of measurement thereof;

21.4. he or she shall provide the staff involved in the trials with descriptions of the procedures and records regarding the conduct of the trials;

21.5. he or she shall guarantee appropriate quality of the trials; and

21.6. he or she shall guarantee the keeping of the records of calibration, as well as the final dossiers of trials until the inclusion of the relevant plant protection product in the register.

22. The analyses and studies referred to in Annex II to Directive 91/414, Annex I to Directive 93/71/EEC, Annex I to Directive 94/37/EC, Annex I to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex I to Directive 95/36/EC, Annex I to Directive 96/12/EC, Annex I to Directive 96/46/EC, Annex I to Directive 96/68/EC, Annex I to Directive 2001/36/EC, Annex III to Directive 91/414, Annex II and III to Directive 93/71/EC, Annex II to Directive 94/37/EC, Annex II to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex II to Directive 95/36/EC, Annex II to Directive 96/12/EC, Annex II to Directive 96/46/EC, Annex II to Directive 96/68/EC and Annex II to Directive 2001/36/EC initiated after 25 July 1993 and from which experimental data are obtained on the properties of the plant protection product and the active substance, or on the possible risk to human or animal health or the environment, except for the trials referred to in Paragraph 6 of Annex II to Directive 91/414/EEC and Sub-paragraph 4.4 of these Regulations, shall be performed in accordance with the principles of good laboratory practice.
[4 July 2006]

23. Studies and analyses initiated before 31 December 1999 in order to obtain data regarding the properties and safety of a plant protection product with respect to honey-bees or other useful arthropods, may be performed in accordance with the requirements of good experimental practice.

24. Trials on plant protection product residues referred to in Paragraph 8 of Annex III to Directive 91/414/EEC initiated before 31 December 1997 may be performed in accordance with the requirements of good experimental practice if a plant protection product contains an active substance, which has been distributed in the Member States of European Union by 25 July 1993.

25. If the active substances of a plant protection product are micro-organisms or viruses, studies and analyses for obtaining experimental data regarding the properties and safety thereof, except for the effects thereof upon human health, may be performed in accordance with the requirements of good experimental practice.

26. The applicant for registration shall submit a certificate (copy) attesting that studies have been performed and supervised in accordance with the principles of good laboratory practice set forth in regulatory enactments regarding the quality of work of laboratories or with the principles of good experimental practice referred to in Paragraph 21 of these Regulations. Certificates that, in accordance with the rules laid down in Latvia or the European Community have been issued in Member States of the European Union, in member states of the European Free Trade Association and the Organisation for European Economic Co-operation and Development, shall be recognised in Latvia.

27. Toxicity studies shall be performed:

27.1. in order to evaluate the conformity of a plant protection product with the conditions referred to in Clause 4.2.4 of these Regulations;

27.2. to ensure the classification of hazards for a plant protection product and the active substance, as well as the taking of a decision regarding the labelling in respect of hazard symbols, indications of danger, as well as indications of possible risk and recommendations to ensure the safety of people and warm-blooded animals in accordance with regulatory enactments regarding the classification of hazards and procedures for the labelling of plant protection products.

27.3. to determine the maximum acceptable daily intake of the active substance for a person;

27.4. to determine the acceptable operator exposure level with the plant protection product during its use; and

27.5. to prescribe measures of first aid, as well as appropriate diagnostic and therapeutic methods, if poisoning with the relevant plant protection product has occurred.

28. Trials and studies regarding residues of a plant protection product shall be performed in order to evaluate the conformity of the plant protection product with the conditions referred to in Clause 4.2.4 of these Regulations, as well as to prescribe the use restrictions upon the plant protection product. Trials shall be performed in the following cases:

28.1. if the plant protection product is intended to be used for plants or plant products used in food or feedingstuff, or it is foreseeable that plants or plant products used in food or feedingstuff may take up the residues of the plant protection product from the soil or other substrate;

28.2. for the modelling of the circumstances under which, using the relevant plant protection product in accordance with the intended conditions of use, the largest quantity of residues from the plant protection product is possible in plants or plant products (maximum number of treatments, maximum dose, the shortest waiting period until harvesting or until use of the treated plants in food or feedingstuff); and

28.3. at least two growing seasons, if the aggregate of circumstances for variable growing is comparable.

29. Studies of ecotoxicity and studies regarding the spread and behaviour in the environment of an active substance shall be performed:

29.1. in order to evaluate the conformity of a plant protection product with the conditions referred to in Clause 4.2.5 of these Regulations;

29.2. to identify and evaluate any potentially possible negative environmental impact;

29.3. to identify plant and animal species for which the plant protection product shall not be intended to be used, but which may be subject to contact with the plant protection product;

29.4. to prescribe measures for the reduction of environmental pollution and the reduction of impact upon the species of plants and animals for which the plant protection product is not intended to be used;

29.5. to prescribe safety measures and use restrictions; and

29.6. to ensure the classification of hazard for the plant protection product and the taking of a decision regarding labelling with respect to hazard symbols, indications of danger, as well as indications of any possible risk and recommendations for the protection of plant and animal species and the environment unrelated to use in accordance with regulatory enactments regarding the classification of hazards and procedures for the labelling of plant protection products.

IV. Decision-Taking Regarding the Inclusion of a Plant Protection Product in the Register

30. The Service:

30.1. within a time period of three months shall examine:

30.1.1. the conformity of a plant protection product with the conditions referred to in Sub-paragraph 4.1. of these Regulations

30.1.2. the conformity of the documents and samples referred to in Paragraphs 5 and 6 of these Regulations (if such are required) to the requirements of these Regulations;

30.1.3. whether, based on the information regarding plant protection products containing an active substance included on the list of active substances registered in the European Community, it is possible to prepare an evaluation in compliance with the requirements specified in the Annex to Directive 97/57/EC and the Annex to 2005/25/EC regarding the conformity of a plant protection product with the conditions referred to in Paragraph 4 of these Regulations;

30.1.4. the submitted information and require the submission of additional information within a time period specified by the Service which shall not exceed 30 days if, based on the relevant information, it is not possible to prepare an evaluation in accordance with the requirements specified in the Annex to Directive 97/57/EC and the Annex to 2005/25/EC; and

30.1.5. the submitted information and take a decision not to include in the register of plant protection products, if a person has handed in an incorrect or intentionally distorted submission or information not in accordance with the requirements of these Regulations, or has not submitted the additional information referred to in Clause 30.1.4 of these Regulations within the time period specified by the Service;

30.2. shall prepare an evaluation regarding the conformity of a plant protection product with the conditions referred to in Sub-paragraphs 4.2, 4.3 and 4.4 of these Regulations. If necessary, the Service shall require the applicant for registration to provide an analysis of the relevant data or shall involve experts in the relevant field;

30.3. in accordance with regulatory enactments regarding the classification of the hazards and procedures for the labelling of plant protection products, shall evaluate the conformity of a plant protection product with the relevant hazard category:

30.3.1. explosive;
30.3.2. extremely flammable;
30.3.3. highly flammable;
30.3.4. flammable;
30.3.5. oxidiser;
30.3.6. very toxic;
30.3.7. toxic;
30.3.8. harmful;
30.3.9. corrosive;
30.3.10. irritant;
30.3.11. sensitising;
30.3.12. carcinogenic;
30.3.13. mutagenic;
30.3.14. toxic to the reproductive system; and
30.3.15. dangerous to the environment;

30.4. shall prepare an evaluation regarding the conformity of the packaging and the closing design thereof of a plant protection product with the following requirements:

30.4.1. the packaging and the closing design thereof shall ensure reliability under intended conditions of use and storage;

30.4.2. the plant protection product shall not damage the packaging or the material of the closing design thereof, and shall not form hazardous compounds therewith;

30.4.3. the packaging and the closing design thereof shall ensure leak-tightness;

30.4.4. the closing design of the packaging shall ensure leak-tightness after repeated closures;

30.4.5. the packaging is sealed shut;

30.4.6. upon the opening of the packaging for the first time, the seal referred to in Clause 30.4.5 of these Regulations shall be spoiled completely;

30.4.7. the shape or visual presentation of the packaging shall not attract the attention of children and shall not mislead the consumer about the content of the packaging;

30.4.8. there shall not be symbols or ornamental elements used in the visual presentation of the packaging which are being used in the design of packaging for any food, feedingstuff, medical or cosmetic products; and

30.4.9. the trade name of the plant protection product shall not be used for the labelling of any food, feeding-stuff, medical or cosmetic products, and no other plant protection product with the same name shall be included in the register;

30.5. at the request of the applicant for registration, shall determine the third class of registration for a plant protection product in such packaging according to the content of which no more than a 5000 m^2 area can be treated, calculated on the basis of the minimum registered dose of the plant protection product, if:

30.5.1. the plant protection product is not classified as very toxic, corrosive or toxic (if the hazard category "toxic" has been assigned due to carcinogenic or mutagenic reaction or reproductive toxicity);

30.5.2. for a plant protection product which is classified as toxic, harmful, extremely flammable or highly flammable, the packaging is labelled with a tactile warning symbol of hazard; and

30.5.3. for a plant protection product, which is classified as toxic, the packaging is provided with a child-proof opening design;

30.6. shall determine the first class of registration for a plant protection product if it:

30.6.1. could create an elevated hazard due to certain properties or in cases when it has been handled incorrectly or used inappropriately; and

30.6.2. is classified as very toxic in accordance with Sub-paragraph 31.3 of these Regulations;

30.7. shall submit the following to the plant protection product registration commission (hereinafter – registration commission) in order to prepare a recommendatory decision on the inclusion of a plant protection product in the register, as well as recommendations regarding the provisional maximum residue level in products of plant and animal origin that are targeted by the use of the plant protection products:

30.7.1. the evaluation specified in Sub-paragraphs 30.2, 30.3 and 30.4 of these Regulations;

30.7.2. information regarding the specified class of registration; and

30.7.3. the draft of the label text referred to in Sub-paragraph 5.4. of these Regulations; and

30.8. shall inform the European Commission regarding the decision and shall submit thereto all of the data regarding the identity and specification of the active substance, if a decision has been taken, in accordance with Clause 30.1.1. of these Regulations, that the active substance produced by another manufacturer or produced according to a production method other than that specified in the documents submitted to the European Commission for the primary inclusion of the active substance on the list of active substances registered in the European Community is the same as that included on the list of active substances registered in the European Community.
[4 July 2006]

31. The conformity of genetically modified plant protection products or plant protection products containing genetically modified organisms to the conditions referred to in Clause 4.2.5 of these Regulations shall be evaluated in accordance with the regulatory enactments regarding procedures for the use and distribution of genetically modified organisms.

32. The Minister for Agriculture shall approve the composition of the registration commission.

33. The registration commission shall consist of seven members: two representatives from the Service, one representative of the environmental sciences, one representative of the medical sciences, one representative of the biological sciences, and two representatives of the agricultural sciences. A representative from the Service shall be the chairperson of the registration commission.

34. The chairperson of the registration commission shall convene meetings of the registration commission.

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

36. The registration commission:
36.1. shall evaluate the documents referred to in Sub-paragraph 30.7 of these Regulations;
36.2. shall prepare a recommendation for a decision regarding the inclusion of a plant protection product in the register; and
36.3. shall prepare a recommendation regarding the provisional maximum residue level in products of plant and animal origin that are targeted by the use of the plant protection product.

37. The registration commission may require from the Service:
37.1. any essential additional information;
37.2. a separate analysis of data; and
37.3. the consultation of an appropriately qualified expert.

38. The Service shall take a decision regarding the inclusion of a plant protection product in the register on the basis of the evaluation referred to in Sub-paragraphs 30.2, 30.3 and 30.4 of these Regulations and the recommendation of the registration commission referred to in Sub-paragraph 36.2 of these Regulations, as well as in accordance with the criteria for decision-taking specified in the Annex to Directive 97/57/EC and the Annex to 2005/25/EC within a period of one year after having received all of the documents and samples necessary for the

taking of a decision. The applicant for registration shall submit the documents and samples to the Service in accordance with the requirements specified in these Regulations.
[4 July 2006]

39. The Service shall specify the following in the decision regarding the inclusion of a plant protection product in the register:

39.1. instructions for the use of the plant protection product:

39.1.1. the combinations "kultūraugs/kaitīgais organisms" [crop/harmful organism] or "lietošanas mērķis/vieta" [target/place of use] pursuant to the intended use;

39.1.2. dose;

39.1.3. the time interval from the treatment of plants until harvesting, the waiting period until the utilisation of the treated plants (plant products) for food or feedingstuff, admittance of domestic animals into treated areas, resumption of crop farming work, sowing or planting of successive crops (if necessary);

39.1.4. the method of application;

39.1.5. restrictions upon use, also protection measures for bodies of water and groundwater, if necessary;

39.1.6. maximum permissible number of treatments during a season;

39.1.7. useful life, taking into account the stage of development of the crop or harmful organism;

39.2. the trade name or names for distribution in Latvia;

39.3. the class of registration of the plant protection product;

39.4. the capacity or weight of the packaging, and type of packaging for the distribution of the plant protection product in Latvia;

39.5. labelling requirements in accordance with Sub-paragraph 30.3 of these Regulations:

39.5.1. a description of the hazard, hazard symbols and indications of danger;

39.5.2. indications of possible risk in accordance with regulatory enactments regarding the classification of hazards and procedures for the labelling of plant protection products; and

39.5.3. recommendations to ensure safety for users of the plant protection product in accordance with regulatory enactments regarding the classification of hazards and procedures for the labelling of plant protection products;

39.6. the registration number of the plant protection product; and

39.7. the provisional maximum residue level of the plant protection product in products of plant and animal origin targeted by the use of the plant protection product.

40. The following documents shall be attached to the decision:

40.1. information regarding the approved or specified provisional maximum residue level of the plant protection product in products of plant and animal origin targeted by the use of the plant protection product which are used in food or feedingstuff;

40.2. the labelling text approved by the Service;

40.3. the list of the documents for which the status of restricted access information has been assigned; and

40.4. the list of the documents on the basis of which a decision has been taken regarding the inclusion of a plant protection product in the register and for which the applicant for registration has requested protection of information.

41. In specifying the instructions for use referred to in Sub-paragraph 39.1 of these Regulations, the Service shall ensure that the maximum residue level or the provisional maximum residue level of the plant protection product in products of plant and animal origin targeted by the use of the plant protection product which are used in food or feedingstuff is not exceeded.

42. The inclusion of a plant protection product in the register is attested by the registration certificate for the plant protection product issued by the Service (hereinafter – certificate) .

43. The Service shall issue a certificate and make the entry into the register only after:

43.1. the applicant for registration has submitted to the Service a document regarding the payment of the State fee; and

43.2. the conformity of the text of the label to the specified requirements has been approved and on the label:

43.2.1. is all the information referred to in the Annex to these Regulations in the Latvian language;

43.2.2. the information on the label conforms to the conditions of the decision referred to in Paragraph 39 of these Regulations;

43.2.3. is the text "Lai nepakļautu riskam cilvēkus un vidi, izlasīt un izpildīt lietošanas instrukcijas prasības" [In order not to expose people and the environment to risk, read and fulfil the requirements of the instructions for use]; and

43.2.4 does not bear any indication characterising the safety of the plant protection product, for example "Nav bīstams" [Harmless], "Nav toksisks" (Non-toxic]. If the relevant plant protection product is to be used during the activity period of honey-bees or other specific organisms not targeted by the use of the plant protection product, the hazard of which due to the use of the plant protection product is not significant, the label of this plant protection product shall indicate that the use thereof is permitted during activity periods of honey-bees and other useful organisms, during the time of flowering of crops or weeds, or similar information.

[6 March 2007]

44. In order to approve the labelling text, the applicant for registration, in accordance with Paragraph 43 of these Regulations, shall submit to the Service a prepared sample of the text for the label.

45. Within ten days after the approval of a label text, the Service shall send to the applicant for registration a decision regarding the inclusion of the plant protection product in the register, the information referred to in Paragraph 40 of these Regulations, as well as the registration certificate and shall make the entry into the register. The Service shall substantiate any decision not to include a plant protection product from the register.

46. The registration certificate shall include the following information:

46.1. the name of the applicant for registration;

46.2. the name of the plant protection product;

46.3. the registration number,

46.4. the preparatory form;

46.5. the class of registration;

46.6. the volume or weight of the packaging for distribution in Latvia;

46.7. the name, content, degree of purity of the active substance contained in the plant protection product;

46.8. the number of the decision;
46.9. the date of registration; and
46.10. the term of validity of the registration certificate;

47. The following information regarding a plant protection product shall be indicated in the register:
47.1. name;
47.2. registration number;
47.3. preparatory form;
47.4. the name, quantity, degree of purity of the active substance contained in it;
47.5. name and address of the holder of the registration certificate;
47.6. name and address of the manufacturer of the active substance;
47.7. the class of registration;
47.8. the capacity or weight of the packaging for distribution of the plant protection product in Latvia;
47.9. the date of registration and number of the decision;
47.10. the term of validity of the registration; and
47.11. the information referred to in Sub-paragraph 39.1 of these Regulations.

48. If the Service, in accordance with Sub-paragraph 4.5 of these Regulations, has specified a provisional maximum residue level, it shall inform the European Commission in accordance with Chapter XVI of these Regulations.

49. The Service shall establish a file for each application for registration. The file shall include the following documents:
49.1. a copy of the application for registration of the plant protection product;
49.2. the decision regarding the inclusion of the plant protection product in the register;
49.3. other administrative provisions issued by the Service connected with the taking of a decision on the inclusion of a plant protection product in the register; and
49.4. a summary of the trials, studies and analyses referred to in Annex II to Directive 91/414, Annex I to Directive 93/71/EEC, Annex I to Directive 94/37/EC, Annex I to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex I to Directive 95/36/EC, Annex I to Directive 96/12/EC, Annex I to Directive 96/46/EC, Annex I to Directive 96/68/EC, Annex I to Directive 2001/36/EC, Annex III to Directive 91/414, Annex II and III to Directive 93/71/EC, Annex II to Directive 94/37/EC, Annex II to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex II to Directive 95/36/EC, Annex II to Directive 96/12/EC, Annex II to Directive 96/46/EC, Annex II to Directive 96/68/EC and Annex II to Directive 2001/36/EC.
[4 July 2006]

50. The Service shall submit the following documents at the request of the responsible authorities of a Member State of the European Union or the European Commission:
50.1. copies of the documents referred to in Paragraph 49 of these Regulations; and
50.2. any other information related to the application for registration.

51. An applicant for registration has a duty to submit the information referred to in Annex II to Directive 91/414, Annex I to Directive 93/71/EEC, Annex I to Directive 94/37/EC, Annex I to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex I to Directive 95/36/EC, Annex I to Directive 96/12/EC, Annex I to Directive 96/46/EC, Annex I to Directive 96/68/EC,

Annex I to Directive 2001/36/EC, Annex III to Directive 91/414, Annex II and III to Directive 93/71/EC, Annex II to Directive 94/37/EC, Annex II to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex II to Directive 95/36/EC, Annex II to Directive 96/12/EC, Annex II to Directive 96/46/EC, Annex II to Directive 96/68/EC and Annex II to Directive 2001/36/EC to the responsible authorities of the Member States of the European Union or to the European Commission at the request of the Service.
[4 July 2006]

52. The holder of the registration certificate or the person referred to in Paragraph 69 of these Regulations has a duty to inform the Service, all the Member States of the European Union and the European Commission without delay regarding any newly obtained information which evidences possible harmful effects of the plant protection product or its residues upon human or animal health, groundwaters or the environment.

53. The holder of the registration certificate or the person referred to in Paragraph 69 of these Regulations has a duty to inform the Service without delay regarding any amendments made to the documents submitted for registration, substantiating the necessity for such amendments.

V. Provisional Inclusion of a Plant Protection Product in the Register

54. The Service shall include a plant protection product in the register for three years after the coming into effect of the European Commission Decision referred to in Sub-paragraph 54.2 of these Regulations if:

54.1. the relevant plant protection product contains an active substance that is included in the list of active substances registered in the European Community and which has not been distributed in the Member States of the European Union by 25 July 1993; and

54.2. with regard to the active substance contained in the plant protection product, the European Commission Decision is in effect regarding the conformity of the information of a plant protection product with the requirements prescribed in the European Community regarding the information to be submitted for the inclusion of an active substance on the list of active substances registered in the European Community.

55. In order to include a plant protection product in the register, the applicant for registration shall submit to the Service the information and documents referred to in Paragraph 5 of these Regulations.

56. The Service:

56.1. shall prepare an evaluation regarding the conformity of a plant protection product with the conditions referred to in Paragraph 103 of these Regulations, as well as the conformity of the plant protection product with the conditions referred to in Sub-paragraphs 4.2, 4.3 and 4.4 of these Regulations;

56.2. shall take a decision regarding the inclusion of the plant protection product in the register in accordance with Chapter IV of these Regulations ; and.

56.3. shall inform all the Member States of the European Union and the European Commission without delay regarding the evaluation referred to in Sub-paragraph 56.1 of these Regulations and the conditions of the decision referred to in Sub-paragraph 56.2, and shall provide the information referred to in Chapter XVI of these Regulations.

57. If the decision referred to in Sub-paragraph 54.2 of these Regulations regarding the active substance contained in a plant protection product is not taken, the Service shall recommend the taking of this decision to the European Commission in accordance with Paragraph 106 of these Regulations.

58. After the end of the term of validity of a temporary registration the Service may:

58.1. include the plant protection product in the register for 10 years, if the active substance is included on the list of active substances registered in the European Community;

58.2. extend the term of validity for temporary inclusion in the register in accordance with a decision regarding the extension of the term of validity of the temporary registration for the relevant active substance; or

58.3. recommend to the European Commission to extend temporarily the term of validity of the previously determined temporary registration necessary for completing the evaluation report and for the evaluation of additional information submitted by the applicant for registration.

VI. Recognition of the Registration of Another State

59. If the applicant for registration submits an application for the inclusion in the register of such a plant protection product which has been registered in a Member State of the European Union and requests from the Service permission not to repeat the trials, studies and analyses on the basis of the results of which the plant protection product has been registered in the relevant Member State, the Service shall recognise the registration of the relevant Member State and shall include the plant protection product in the register if:

59.1. the plant protection product contains only the active substances included on the list of active substances registered in the European Community

59.2. the decision regarding the registration of the plant protection product in the relevant Member State of the European Union has been taken in accordance with the criteria for the taking of decisions specified in the Annex to Directive 97/57/EC and the Annex to 2005/25/EC; and

59.3. agricultural conditions, conditions for the spread of harmful organisms, as well as environmental (including climatic) conditions that are significant for the use of this plant protection product in the Member State of the European Union where the plant protection product is registered are comparable to those existing in Latvia;
[4 July 2006]

60. The applicant for registration shall attach the following documents to the application:

60.1. the documentary evidence regarding the conformity of the application with the conditions referred to in Paragraph 59 of these Regulations; and

60.2. the documents referred to in Paragraph 5 of these Regulations, except for the results of trials referred to in Paragraph 5.3 of these Regulations.

61. The Service:

61.1. shall examine the application and within three months after the receipt thereof shall take a decision regarding the inclusion of the plant protection product in the register. The term of validity of registration shall comply with the term of validity specified in the relevant Member State.

61.2. shall prescribe the conditions for the distribution and use of the plant protection product with respect to the protection of the health of distributors, users and workers in agriculture;

61.3. if necessary, shall prescribe restrictions upon use in order to avoid, due to differences in dietary patterns, the exposure of consumers of treated products to the risks of dietary contamination in excess of the maximum acceptable daily intake of the active substance of the relevant plant protection product;

61.4. shall agree with the applicant for registration regarding any amendments to the conditions of use in order to render insignificant any agricultural, harmful organism spreading and environmental (including climatic) conditions, that are non-comparable to those existing in Latvia, and to ensure the taking of a decision regarding the comparability of circumstances for the use of the plant protection product in the regions concerned; and

61.5. shall submit to the European Commission the information with a justification regarding any case:

61.5.1. where the applicant for registration has submitted the documentary evidence regarding the conformity of the application with the conditions of Paragraph 59 of these Regulations and the Service has required the applicant for registration to repeat already conducted studies on the grounds of which the plant protection product has been registered in the appropriate Member State of the European Union; or

61.5.2. where it has taken a decision not to recognise the registration of the relevant Member State.

62. If, based on the information submitted by the Service to the European Commission, the decision of the European Commission regarding the conformity of the studies with the requirements of comparability of circumstances or the decision regarding the conformity of the application with the requirements of mutual recognition of registration enters into effect, the Service shall recognise the trials, studies and analyses or the registration of the relevant Member State without delay and shall include the plant protection product in the register in accordance with the decision of the European Commission referred to in this paragraph.

VII. Change of Holders of a Registration Certificate

63. If the holder of a registration certificate changes, the term of validity of the registration certificate remains unchanged.

64. In order to transfer the registration certificate to another holder, the present holder of the registration certificate shall submit an application to the Service and attach the documents certified with the signatures of the holder of the registration certificate, as well as the next holder of the certificate. The documents shall indicate:

64.1. the trade name or names of the plant protection product included in the register, the number of the registration certificate and the date of registration of the plant protection product;

64.2. the name and address of the present holder of the registration certificate and the name and address of the next holder of the registration certificate;

64.3. the document that certifies the transference of the registration documentation of the plant protection product and the accessibility thereof for the next holder of the certificate; and

64.4. the date when the present holder of the registration certificate transfers all of the duties of the holder of the plant protection product to the next holder of the certificate.

65. The Service:

65.1. shall examine the request referred to in Paragraph 64 of these Regulations within a period of 30 days after the receipt thereof; and

65.2. within 10 days:

65.2.1. shall notify in writing the present and next holder of the registration certificate regarding the decision taken;

65.2.2. shall issue a new registration certificate; and

65.2.3. shall make amendments in the register.

VIII. Re-registration of a Plant Protection Product in the Register

66. The applicant for registration shall submit a application for re-registration of a plant protection product to the Service not later than one year before the expiry of the term of validity of the registration, together with any updated information conforming with the requirements of Annex III to Directive 91/414, Annex II and III to Directive 93/71/EC, Annex II to Directive 94/37/EC, Annex II to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex II to Directive 95/36/EC, Annex II to Directive 96/12/EC, Annex II to Directive 96/46/EC, Annex II to Directive 96/68/EC, Annex II to Directive 2001/36/EC and of the Annex to these Regulations.
[4 July 2006]

67. The Service shall take a decision regarding the re-registration of a plant protection product in the register in accordance with Chapter IV of these Regulations.

68. After the expiry of the term of validity of registration, distribution of the relevant plant protection product shall be prohibited, whereas users of the plant protection product shall be allowed to use the existing supplies for one year after the expiry of the term of validity of the registration.

IX. Granting of Authorisation

69. The Service shall grant an authorisation to extend the scope of use of a registered plant protection product (combination "lietošanas mērķis/vieta" [crop/harmful organism] or "lietošanas mērķis/vieta" [target/place of use]) for the holder of the registration certificate of the plant protection product, a scientific research institution or person involved in agricultural production, if:

69.1. there is an objective justification for extension of the scope of use of the plant protection product;

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

69.3. the plant protection product complies with the conditions referred to in Clauses 4.2.3, 4.2.4 and 4.2.5 of these Regulations after the extension of the scope of use; and

69.4. the maximum residue level is approved in Latvia or the provisional maximum residue level of the plant protection product has been prescribed for products of plant and animal origin used in food or feedingstuff related to the extension of the scope of use of the plant protection product.

70. If the applicant for authorisation to extend the scope of use is not the holder of the registration certificate, the Service shall agree with the holder of the registration certificate of the plant protection product on the granting of the authorisation. If no agreement is reached, the Service may issue an authorisation to extend the scope of use of the plant protection product if the objections of the holder of the registration certificate pertain only to the efficacy of the plant protection product and its harmful effects upon plants and plant products and if the Service has at the disposal thereof information that these objections are not substantiated.

71. The Service shall take a decision on the granting of an authorisation to extend the scope of use of a plant protection product based on an evaluation regarding the conformity of the plant protection product with the conditions referred to in Paragraph 69 of these Regulations or by recognising the registration of a Member State of the European Union for the relevant use of the plant protection product and based on an evaluation regarding the conformity of the intended use with the conditions referred to in Sub-paragraphs 69.1 and 69.2 of these Regulations.

72. The Service shall take a decision on the conformity of a plant protection product with the conditions referred to in Sub-paragraphs 4.2.3, 4.2.4 and 4.2.5 of these Regulations after the extension of the scope of use, based on the results of corresponding trials and studies or scientifically substantiated evidence.

73. In order to receive an authorisation to extend the scope of use of a plant protection product, based on an evaluation regarding the conformity of the plant protection product with the conditions referred to in Paragraph 69 of these Regulations, the applicant for authorisation shall submit to the Service:

73.1. a application for the obtaining of an authorisation to extend the scope of use;

73.2. an accompanying letter in which the necessity for the authorisation is substantiated and a detailed description of the problem is given, information on the culturing amount, the significance in the crop production sector, the urgency of the resolution and possible alternatives;

73.3. draft instructions for use for the extension of the scope of use of the plant protection product; and

73.4. the results of trials and studies for the preparation of the evaluation regarding the conformity of the plant protection product with the conditions referred to in Clauses 4.2.3, 4.2.4 and 4.2.5 of these Regulations in accordance with Annex III to Directive 91/414, Annex II and III to Directive 93/71/EC, Annex II to Directive 94/37/EC, Annex II to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex II to Directive 95/36/EC, Annex II to Directive 96/12/EC, Annex II to Directive 96/46/EC, Annex II to Directive 96/68/EC and Annex II to Directive 2001/36/EC, indicating the information on the person who holds the rights of ownership to the trials and studies, or scientifically substantiated evidence that has been obtained by means of extrapolation from a certain use approved for the registered plant protection product.
[4 July 2006]

74. In order to receive an authorisation for an extension of the scope of use of a plant protection product, based on the recognition of the registration of a Member State of the European Union, the applicant for authorisation shall submit to the Service:

74.1. the information and documents specified in Sub-paragraphs 73.1, 73.2 and 73.3 of these Regulations;

74.2. the following information which ensures the recognition of the registration of a Member State of the European Union for the relevant use:

74.2.1. the identity of the plant protection product;

74.2.2. the use of the plant protection product specified in the relevant Member State of the European Union;

74.2.3. a copy of the registration certificate issued in the relevant Member State of the European Union, and of the label together with a translation in English and Latvian; and

74.3. data regarding the maximum residue level of the plant protection product specified in the relevant Member State of the European Union or European Community if the plant protection product is intended to be used on plants which are used in food and feedingstuff.

75. The Service shall recognise the registration or provisional registration of the use of a relevant plant protection product of a Member State of the European Union if:

75.1. an identical plant protection product has been registered for the intended use (it contains the appropriate active substance and it has the identical preparatory form):

75.1.1. in a Member State of the European Union in which agricultural conditions, conditions for the spread of harmful organisms and environmental (also climatic) conditions that are significant for the intended use of the plant protection product are comparable to those existing in Latvia and the plant protection product is intended for use upon open field crops;

75.1.2. in any Member State of the European Union if the plant protection product is intended to be used upon covered crops;

75.2. the appropriate use is included in the label of the plant protection product registered in a Member State of the European Union;

75.3. the dose of the plant protection product, time of treatment and number of treatments permitted during a season for the intended use of the plant protection product is not larger than specified in the relevant Member State of the European Union or it is similar to that specified in the relevant Member State of the European Union, as well as if the plant protection product is intended to be used with plants which are not used in food;

75.4. the method of application of the plant protection product and intended conditions (in open field or covered area) are the same as in the relevant Member State of the European Union or similar thereto if the plant protection product is intended to be used on plants which are not used in food;

75.5. the intended waiting time until harvesting for plants used in food is not less than that specified in the relevant Member State of the European Union; and

75.6. the criteria and conditions referred to in Sub-paragraphs 75.3, 75.4, 75.5 of these Regulations are not larger or the same as those specified in Latvia for use of the relevant plant protection product upon plants, which are not used in food.

76. The Service:

76.1. shall take a decision regarding the granting of an authorisation within six months of the receipt of all of the necessary information for the taking of a decision;

76.2. shall issue the authorisation for a term not exceeding the term of validity of the registration certificate of the plant protection product; and

76.3. shall approve the instructions for use for the extension of the scope of use of the plant protection product.

77. The Service shall specify the instructions for use for the extension of the scope of use of a plant protection product in the decision regarding the granting of the authorisation to extend the scope of use of the plant protection product:

77.1. the combinations "kultūraugs/kaitīgais organisms" [crop/harmful organism] or "lietošanas mērķis/vieta" [target/place of use] pursuant to the intended use;

77.2. dose;

77.3. the interval from treatment of the plants until harvesting, waiting time until use of the treated plants (plant products) for food or feedingstuff, admittance of domestic animals into treated areas, resumption of crop farming work, sowing or planting of succeeding crops (if necessary);

77.4. method of application;

77.5. restrictions upon use, also protection measures of bodies of water and groundwater if necessary;

77.6. maximum acceptable number of treatments during a season; and

77.7. useful life, indicating the stage of development of the crop or harmful organism;

78. The following documents shall be attached to the decision:

78.1. information regarding the maximum residue level of the plant protection product in products of plant or animal origin used in food or feedingstuff, upon which the relevant plant protection product is intended to be applied; and

78.2. the instructions for use for extension of the scope of use of the plant protection product approved by the Service.

79. The holder of the registration certificate of a plant protection product is responsible for any possible negative impact of the plant protection product upon human or animal health or the environment that has arisen from the use of the plant protection product in accordance with the instructions for use for extension of the scope of use.

80. The person using the plant protection product in accordance with the instructions for use for extension of the scope of use shall be liable for any possible negative impact of the plant protection product upon plants or plant products and harvest losses.

81. In order to receive an authorisation for distribution and use in studies and experiments of a plant protection product not included in the register, the applicant for registration or any other interested person, one month before commencement of the experiment or study, shall submit to the Service:

81.1. a application for the receipt of the authorisation;

81.2. all available information for preparation of the evaluation regarding the possible impact of the plant protection product upon human and animal health or the environment, as well as the following information:

81.2.1. the category of use of the plant protection product, the preparatory form, name and content of the active substance, acute toxicity of the active substance;

81.2.2. the pathogenicity of the active substance upon humans and warm-blooded animals if the plant protection product contains micro-organisms and viruses;

81.2.3. the natural incidence and prevalence in Latvia of micro-organisms and viruses contained in the active substance of the plant protection product (if such data is known);

81.2.4. use, indicating dose, plants to be treated, harmful organisms, waiting time from treatment until harvesting;

81.2.5. planned conditions for the study, also precautionary measures to prevent possible risks to the environment and health; and

81.2.6. the results of trials for residues of plants used in food and feedingstuff;

81.3. information (not to be provided by the person who carries out the trials referred to in Sub-paragraph 4.4 of these Regulations) regarding:

81.3.1. the site of the trial, indicating the given name, surname and address of the owner of the crops or domestic animals involved in the trial; and81.3.2. the person who is responsible for the experiment or study, indicating given name, surname and address; and

81.4. certification (not to be provided by the person carrying out the trials referred to in Sub-paragraph 4.4 of these Regulations) of the entitlement to use plant protection products.

82. The Service:

82.1. based on the submitted information, shall within a month evaluate the possible risk of a plant protection product upon health and the environment under the conditions of the experiment or study, and shall take a decision regarding permitting the experiment or study;

82.2. if, in accordance with the evaluation, the planned experiments or studies may have a harmful effect upon human or animal health or an unacceptably adverse impact upon the environment, shall prohibit the experiment or study from being carried out or permit the conducting thereof, specifying restrictions upon use in order to prevent any possible harmful consequences; and

82.3. shall require the elimination of plants utilised in an experiment or study which are used in food if:

82.3.1. trial data on residues are not available; and

82.3.2. for a plant protection product, which contains an active substance not included on the list of active substances registered in the European Community, which has not been distributed in the Member States of the European Union by 25 July 1993, the level of residues during harvesting exceeds the limit value for sensitivity (detection) of the residue analysis method.

83. In the decision regarding the granting of an authorisation the Service shall specify the following:

83.1. the term of validity of the authorisation;

83.2. the quantity permitted for distribution and use of the plant protection product;

83.3. the size of the area permitted for use;

83.4. the conditions for use with regard to the user and the plant protection product; and

83.5. the requirement for the elimination of plants used in the experiment or study, which are used in food in accordance with Sub-paragraph 81.3 of these Regulations.

84. The Service shall determine the size of the area permitted for use based on the request of the performer of the experiment or studies and the results of an evaluation, but it shall not exceed 20 ha per year for trials in an open field or 2 ha per year for trials in covered areas.

85. The Service shall determine the term of validity of the authorisation based on the request of the performer of the experiment or study and the results of the evaluation, but not to exceed two years.

86. In order to extend the term of validity of an authorisation, the holder of the authorisation shall submit a request to the Service for an extension of the term of validity thereof not later

than two months before the end of the term of validity. The Service shall extend the term of validity of the plant protection product in accordance with the request of the performer of the experiment or study, if the necessity to continue the trial or experiment is substantiated.

87. In order to receive an authorisation for distribution and use of a plant protection product not conforming with the conditions of registration for the implementation of emergency measures in accordance with regulatory enactments regarding prohibited plant protection products, the interested person shall submit to the Service:

87.1. an application for an authorisation;

87.2. a description of the situation, indicating the following information:

87.2.1. the identity of the harmful organism;

87.2.2. the extent, significance of the threat to crops and the economic threat;

87.2.3. a substantiation of the need for the authorisation (the sensitivity of specific varieties to the registered plant protection product or reduced immunity to a harmful organism, the beginning of favourable climatic conditions for the development of harmful organisms of local origin which are of low prevalence under normal circumstances, the beginning of favourable climatic conditions for the entry and development of harmful organisms from other countries, the beginning of favourable climatic conditions for the development of imported, peregrine origin harmful organisms);

87.3. all available information for the preparation of an evaluation of the possible impact of the plant protection product upon human and animal health and environment, as well as the following information:

87.3.1. the category of use of the plant protection product, the preparatory form, name and content of the active substance, the acute toxicity of the active substance;

87.3.2. the pathogenicity of the active substance in humans and warm-blooded animals, if the plant protection product contains micro-organisms and viruses, as well as the natural incidence thereof;

87.3.3. the natural incidence and prevalence in Latvia of micro-organisms and viruses contained in the active substance of the plant protection product (if such data are known);

87.3.4. the intended use, indicating dose, time of treatment, method, plants to be treated, harmful organisms, waiting time from treatment until harvesting;

87.3.5. precautionary measures to prevent any possible risk to the environment and health;

87.3.6. the site of the trial and name of the owner or user thereof (given name, surname and address);

87.3.7. the person responsible for use of the plant protection product (given name, surname and address); and

87.3.8. the results of trials for residues upon plants used in food and feedingstuff.

88. The Service:

88.1. based on the submitted, as well as other information at the disposal of the Service, shall, within two weeks, prepare an evaluation regarding the possible risk of the plant protection product to the environment and to human and animal health;

88.2. shall carry out an analysis of usefulness and risk, and shall take a decision on the granting of an authorisation if the positive effect which it is possible to achieve using plant the

protection product is greater than the possible risk to the environment or to human and animal health; and

88.3. shall inform all of the Member States of European Union and European Commission without delay regarding the granting of authorisation and the conditions of a decision.

89. The Service shall specify the following in a decision on the granting of an authorisation:

89.1. the term of validity of the authorisation;

89.2. the quantity permitted for distribution and use of the plant protection product;

89.3. the size of the area permitted for use;

89.4. the conditions for use with regard to the user and the plant protection product; and

89.5. the requirement for the elimination of plants or plant products used in food in accordance with Sub-paragraph 82.3 of these Regulations.

90. The Service, in accordance with the European Commission decision, shall amend the term of validity of an authorisation, decide regarding the repeated issuance of an authorisation or the withdrawal of an issued authorisation.

91. Before the entry into effect of the decision of the European Commission, the Service shall amend the term of validity of an authorisation if:

91.1. use of the plant protection product does not give the expected positive effect;

91.2. use of the plant protection product is no longer necessary; or

91.3. in accordance with newly obtained information, there is cause for suspicion regarding the possible harmful effects of the plant protection product or its residues upon human or animal health, groundwaters or the environment and, by performing repeated analyses of risk and usefulness, it is determined that the positive effect after use of the plant protection product does not justify the possible risk to the environment or to human and animal health.

91.[1] A person who is not the owner of the authorisation for a plant protection product or the authorised representative thereof and who has obtained an authorisation from the Service for the parallel importation of the plant protection product may parallel import such plant protection product.
[6 March 2007]

91.[2] In order to obtain an authorisation for the parallel importation of a plant protection product, the applicant for the authorisation shall submit to the Service:

91.[2].1. an application for the receipt of an authorisation for the parallel importation of a plant protection product, indicating in it the following information:

91.[2].1.1. the name or given name, surname, address, and telephone number of the applicant for the authorisation;

91.[2].1.2. the state from which the parallel importation of the plant protection product shall be performed;

91.[2].1.3. the name of the plant protection product to be parallel imported with which it is registered in the state from which it shall be imported into Latvia, and the name of the plant protection product included in the register;

91.[2].1.4. the name, address and telephone number of the owner of the authorisation for the plant protection product in the state from which it shall be imported, and

the name, address and telephone number of the owner of the plant protection product included in the register;

91.[2].1.5. the registration number of the plant protection product in the state from which it shall be imported, and number of the plant protection product included in the register;

91.[2].1.6. the name of the active substances and content of the plant protection product to be parallel imported; and

91.[2].1.7. the preparative form of the plant protection product to be parallel imported (for example, powder for suspension, emulsion concentrate);

91.[2].2. a copy of the original label of the plant protection product to be parallel imported with a translation in English or Latvian;

91.[2].3. a draft text of specified use of the plant protection product to be parallel imported in Latvian for the register, which conforms to Paragraph 43 of these Regulations and regulatory enactments regarding the requirements specified regarding the classification, labelling and packaging of plant protection products; and

91.[2].4. a copy of the document, which certifies payment for the preparation of an evaluation in order to obtain an authorisation for the parallel importation of the plant protection product in accordance with regulatory enactments regarding the price list for paid services of the Service.

[6 March 2007]

91.[3] The Service shall within a period of 30 days examine the submitted documents and, if the applicant for the authorisation has not submitted the information referred to in Paragraph 91.[2] of these Regulations or the information submitted is imprecise, shall request its adjustment and submission within a period of 30 days.

[6 March 2007]

91.[4] In respect of the identity of a plant protection product, the Service is entitled to request additional information from:

91.[4].1. the responsible institutions of the Member States of the European Union or a state of the European Free Trade Association (which has signed the European Economic Area agreement), which register plant protection products; and

91.[4].2. the owner of the authorisation for a plant protection product included in the register.

[6 March 2007]

91.[5] In order to protect the user rights of a plant protection product, the Service is entitled to request that the applicant for the parallel importation of the plant protection product within a period of 30 days submit information regarding the packaging material of the plant protection product to be parallel imported and a sample thereof, as well as a sample of the plant protection product to be parallel imported.

[6 March 2007]

91.[6] The Service shall take a decision regarding the issuing of an authorisation for the parallel importation of a plant protection product if:

91.[6].1. plant protection product to be parallel imported is identical to the plant protection product included in the register; and

91.[6].2. the text of the label conforms to the specified use of the plant protection product included in the register and the requirements specified in these Regulations and

regulatory enactments regarding the classification, labelling and packaging of plant protection products.
[6 March 2007]

91.[7] The plant protection product to be parallel imported is identical to the plant protection product included in the register if:

91.[7].1. the composition of the plant protection product to be parallel imported is identical to the plant protection product included in the register;

91.[7].2. the plant protection product to be parallel imported contains the same active substances as in plant protection product included in the register;

91.[7].3. the content of the active substances of the plant protection product to be parallel imported is identical to the content of the active substances of plant protection product included in the register; and

91.[7].4. the preparative form of the plant protection product to be parallel imported and the preparative form of the plant protection product included in the register is identical.
[6 March 2007]

91.[8] The plant protection product to be parallel imported and the plant protection product included in the register are identical if determined negligible differences in the composition of these plant protection products is determined in relation to admixtures, formulants and co-formulants and such differences:

91.[8].1. do not exceed 10% of the whole composition of the admixtures, formulants and co-formulants;

91.[8].2. do not give rise to a negative impact upon the health of humans and animals and the environment; and

91.[8].3. do not negatively influence the use of the plant protection product in the intended agricultural and climatic conditions.
[6 March 2007]

91.[9] The Service within a period of 45 days after having received the documents referred to in Paragraph 91.[2] of these Regulations, shall prepare an evaluation regarding:

91.[9].1. the identicalness of the plant protection product to be parallel imported with the plant protection product included in the register; and

91.[9].2. that the text of the label conforms to the specified use of the plant protection product included in the register and the requirements specified in these Regulations and regulatory enactments regarding the classification, labelling and packaging of plant protection products.
[6 March 2007]

91.[10] If the label of the plant protection product to be parallel imported does not conform to the requirements referred to in Sub-paragraph 91.[8].2., the Service shall send to the applicant for the authorisation information regarding necessary corrections to the text of the label, requesting that the adjusted label text be submitted within a period of 20 working days.
[6 March 2007]

91.[11] An authorisation for the parallel importation of a plant protection product shall be issued for a period up to the end of the term of validity of the plant protection product included in the register. The authorisation shall remain in effect if the registered owner of the plant protection product included in the register due to economic reasons requests the cancellation of the registration certificate prior to the end of the term of validity of the certificate.
[6 March 2007]

X. Re-assessment of a Registered Plant Protection Product

92. The Service shall re-assess the compliance of a plant protection product with the conditions set in order to register it in accordance with Chapters IV, V or VI of these Regulations or with the conditions for issuance of an authorisation to extend the scope of use if:

92.1. the holder of the registration certificate informs the Service regarding amendments to the documents submitted for registration, justifying the need for these amendments;

92.2. the holder of the registration certificate informs the Service regarding harmful effects of the registered plant protection product or its residues upon human or animal health, the groundwater or the environment;

92.3. there is a cause for suspicion that the plant protection product does not conform with any of the conditions referred to in Paragraph 4 of these Regulations; and

92.4. the active substance contained in the plant protection product included in the register is included on the list of active substances registered in the European Community during the term of validity of the registration certificate.

93. The holder of a registration certificate or the person who has received the authorisation referred to in Sub-paragraph 1.2 of these Regulations shall submit the required additional information for the preparation of a re-assessment within the time period specified by the Service in accordance with Annex III to Directive 91/414, Annex II and III to Directive 93/71/EC, Annex II to Directive 94/37/EC, Annex II to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex II to Directive 95/36/EC, Annex II to Directive 96/12/EC, Annex II to Directive 96/46/EC, Annex II to Directive 96/68/EC and Annex II to Directive 2001/36/EC.
[4 July 2006]

94. Based on the additional information, the Service shall prepare the evaluation referred to in Sub-paragraphs 30.2, 30.3 or 30.4 of these Regulations and within three months of receipt of the additional information shall take a decision regarding the conformity of the plant protection product with the conditions of registration. If a re-assessment is carried out based on Sub-paragraph 92.4 of these Regulations, the Service shall take a decision regarding the conformity of the plant protection product with the conditions of registration in accordance with the terms and conditions specified in regulatory enactments of the European Community regarding the inclusion of an active substance on the list of active substances registered in the European Community.

95. If the reason for a re-assessment is a suspicion regarding the non-conformity of a non-registered plant protection product with the conditions referred to in Clauses 4.2.4 or 4.2.5 of these Regulations, the Service may set restrictions or a prohibition upon the use and distribution of the relevant plant protection product for a time until the taking of a decision.

96. The Service shall inform without delay, indicating the reasons for the determination of restrictions or a prohibition:

96.1. the holder of the registration certificate;

96.2. responsible authorities of the Member States of the European Union; and

96.3. the European Commission.

XI. Amendments to a Decision on the Registration of a Plant Protection Product

97. The Service shall make amendments to a decision regarding the inclusion of a plant protection product in the register or to a decision regarding the granting of authorisation referred to in Sub-paragraph 1.2 of these Regulations, if:

97.1. taking into account scientific achievements and technological developments, it is possible to change the method of use or dose of the registered plant protection product; or

97.2. it is necessary in accordance with the results of a re-assessment of the plant protection product.

98. The Service may make amendments to a decision regarding the inclusion of a plant protection product in the register or to a decision regarding the granting of authorisation referred to in Sub-paragraph 1.2 of these Regulations, if such is requested by the holder of the registration certificate or the holder of the authorisation for the extension of the scope of use, justifying the need for the amendments.

99. In order to make amendments to a decision on the registration of a plant protection product, based on Sub-paragraph 97.1 and Paragraph 98 of these Regulations, the Service shall:

99.1. require the holder of the registration certificate or the person who has received the authorisation to extend the scope of use to submit within the time period specified by the Service the required additional information in accordance with Annex III to Directive 91/414, Annex II and III to Directive 93/71/EC, Annex II to Directive 94/37/EC, Annex II to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex II to Directive 95/36/EC, Annex II to Directive 96/12/EC, Annex II to Directive 96/46/EC, Annex II to Directive 96/68/EC and Annex II to Directive 2001/36/EC or with a separate evaluation of the studies;

99.2. within three months prepare the evaluation referred to in Sub-paragraphs 30.2, 30.3 and 30.4 of these Regulations; and

99.3. take a decision regarding the necessary amendments and enter the relevant amendments into the register, based on the evaluation referred to in Paragraph 94 or Sub-paragraph 99.2 of these Regulations and the recommendation of the registration commission. *[4 July 2006]*

XII. Withdrawal of a Registration Certificate and Authorisation of the Extension of the Scope of Use

100. The Service shall withdraw the registration certificate of a plant protection product and an entry in the register, as well as an authorisation for an extension of the scope of use if:

100.1. the plant protection product no longer conforms to the conditions referred to in Paragraph 4 of these Regulations;

100.2. the holder of the registration certificate or person to whom an authorisation of the extension of the scope of use has been issued, has submitted incorrect or intentionally distorted the information referred to in Paragraph 5 of these Regulations;

100.3. the required additional information for re-assessment of the plant protection product is not submitted within the time period specified by the Service;

100.4. the withdrawal of the registration is requested by the holder of the registration certificate or person to whom the authorisation of the extension of the scope of use has been issued, indicating the reasons; or

100.5. a decision of the European Commission enters into force regarding the exclusion of an active substance contained in the register or provisional register of plant protection products from the list of active substances registered in the European Community.

101. The Service shall inform the holder of a registration certificate and the holder of an authorisation for the extension of the scope of use regarding the withdrawal of the registration certificate of a plant protection product or authorisation within 10 days after the taking of the decision. The holder of the registration certificate or the authorisation for the extension of the scope of use shall transfer the registration certificate or authorisation to the Service within 30 days after the taking of the decision.

102. Depending upon the reasons for the withdrawal of the registration of a plant protection product, the Service may set a time period for the storage, distribution, use or exportation from the State of such plant protection product. If the registration certificate of the plant protection product is withdrawn, based on Sub-paragraph 100.5 of these Regulations, the Service shall set the time period for the storage, distribution or use in accordance with the decision of the European Commission regarding the exclusion of the relevant active substance from the list of active substances registered in the European Community.

XIII. Evaluation of the Active Substance for Inclusion on the List of Active Substances Registered in the European Community

103. The active substance shall be included on the list of active substances registered in the European Community if the plant protection product, which contains the relevant active substance, conforms to the following conditions:

103.1. its residues, which arise after the use of the plant protection product in accordance with the principles of good plant protection practice, do not cause a harmful impact upon human or animal health, ground-waters or the environment, and toxicologically significant or environmentally significant residues can be determined by suitable methods; and

103.2. in using the relevant plant protection product in accordance with the principles of good plant protection practice, it conforms to the conditions referred to in Clauses 4.2.4 and 4.2.5 of these Regulations.

104. In adding an active substance onto the list of active substances registered in the European Community the following shall be taken into account:

104.1. the maximum acceptable daily intake (*ADI*) for a person (if necessary);

104.2. the acceptable level of contact for an operator handling the active substance (if necessary); and

104.3. an estimate of the spread of the active substance into the environment, as well as its impact upon species not targeted by the intended use.

105. The following conditions for inclusion may be specified in a decision regarding the inclusion of an active substance on the list of active substances registered in the European Community:

105.1. the minimum degree of purity;

105.2. the nature and maximum content of certain impurities;

105.3. restrictions arising from the evaluation of the information referred to in Annex III to Directive 91/414, Annex II and III to Directive 93/71/EC, Annex II to Directive 94/37/EC, Annex II to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex II to Directive 95/36/EC, Annex II to Directive 96/12/EC, Annex II to Directive 96/46/EC, Annex II to Directive 96/68/EC and Annex II to Directive 2001/36/EC for the intended use of the plant protection product under corresponding agricultural conditions, conditions for the spread of harmful organisms and environmental (including climatic) conditions;

105.4. the preparatory form; and

105.5. the method of application of the plant protection product.

[4 July 2006]

106. Having received the application from the applicant for registration regarding inclusion of an active substance on the list of active substances registered in the European Community, the Service shall:

106.1. ensure immediately that the applicant for registration submits the information referred to in Annex II to Directive 91/414, Annex I to Directive 93/71/EEC, Annex I to Directive 94/37/EC, Annex I to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex I to Directive 95/36/EC, Annex I to Directive 96/12/EC, Annex I to Directive 96/46/EC, Annex I to Directive 96/68/EC, Annex I to Directive 2001/36/EC, Annex III to Directive 91/414, Annex II and III to Directive 93/71/EC, Annex II to Directive 94/37/EC, Annex II to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex II to Directive 95/36/EC, Annex II to Directive 96/12/EC, Annex II to Directive 96/46/EC, Annex II to Directive 96/68/EC and Annex II to Directive 2001/36/EC regarding at least one plant protection product which contains the relevant active substance to the responsible authorities of all Member States of the European Union and to the European Commission;

106.2. request the evaluation of the European Commission regarding the conformity of the information with the requirements specified in the European Community. If, in accordance with the European Commission decision, additional information or an evaluation of particular studies is required, the applicant for registration has a duty to submit such to the European Commission or to the Service;

106.3. prepare an evaluation report regarding the conformity of the active substance with the conditions referred to in Paragraph 103 of these Regulations in accordance with the requirements specified by the European Commission; and

106.4. submit the evaluation report to the European Commission for the taking of a decision regarding inclusion of the active substance on the list of active substances registered in the European Commission.

[4 July 2006]

107. In order to include for the first time an active substance which has not been distributed in the Member States of the European Union by 25 July 1993 on the list of active substances registered in the European Commission, the applicant for registration shall prove the conformity of at least one plant protection product which contains the relevant active substance with the conditions referred to in Paragraph 103 of these Regulations.

XIV. Protection of Information

108. The Service and registration commission may utilise the information referred to in Annex III to Directive 91/414, Annex II and III to Directive 93/71/EC, Annex II to Directive 94/37/EC, Annex II to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex II to Directive 95/36/EC, Annex II to Directive 96/12/EC, Annex II to Directive 96/46/EC, Annex II to Directive 96/68/EC and Annex II to Directive 2001/36/EC and in Sub-paragraph 5.3 of these Regulations for the benefit of another applicant for registration only if there is a mutual agreement in writing between the submitter of the information and the relevant applicant, or after 10 years since:

108.1. the taking of a decision regarding the registration of the plant protection product for the first time in a Member State of the European Union if any of the active substances contained in the plant protection product are included on the list of active substances registered in the European Community; and

108.2. the Service has taken a decision regarding the inclusion of a plant protection product for the first time in the register of plant protection products if none of the active substances contained in the plant protection product are included on the list of registered active substances in the European Community.

[4 July 2006]

109. The Service and registration commission may utilise the information referred to in Annex II to Directive 91/414, Annex I to Directive 93/71/EEC, Annex I to Directive 94/37/EC, Annex I to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex I to Directive 95/36/EC, Annex I to Directive 96/12/EC, Annex I to Directive 96/46/EC, Annex I to Directive 96/68/EC and Annex I to Directive 2001/36/EC for the benefit of another applicant for registration only if there is a mutual agreement in writing between the submitter of the information and the relevant applicant, or:

109.1. after 10 years since:

109.1.1. the active substance contained in the plant protection product has been included on the list of active substances registered in the European Commission for the first time if it has not been distributed in any of the Member States of the European Union by 25 July 1993;

109.1.2. the Service has taken a decision regarding the inclusion of the plant protection product in the register for the first time if the active substance contained in the plant protection product has been distributed in the Member States of the European Union by 25 July 1993; or

109.2. after five years since, based on the additional information submitted by the applicant for registration, the active substance has been included on the list of active substances registered in the European Union for the first time, the conditions for inclusion have been amended or it has been kept on the list of active substances registered in the European Community. If the period of five years ends before the time period referred to in Sub-paragraph 109.1 of these Regulations, it shall be extended until the end of the time period referred to in Sub-paragraph 109.1 of these Regulations.

[4 July 2006]

XV. Restricted Access Information

110. The Service and registration commission shall ensure the status of restricted access information for the information referred to in Annex II to Directive 91/414, Annex I to

Directive 93/71/EEC, Annex I to Directive 94/37/EC, Annex I to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex I to Directive 95/36/EC, Annex I to Directive 96/12/EC, Annex I to Directive 96/46/EC, Annex I to Directive 96/68/EC, Annex I to Directive 2001/36/EC, Annex III to Directive 91/414, Annex II and III to Directive 93/71/EC, Annex II to Directive 94/37/EC, Annex II to Directive 94/79/EC, Annex to Directive 95/35/EC, Annex II to Directive 95/36/EC, Annex II to Directive 96/12/EC, Annex II to Directive 96/46/EC, Annex II to Directive 96/68/EC and Annex II to Directive 2001/36/EC submitted to the Service, which encompasses the secrecy of commercial activities if the applicant for registration has declared such in writing as restricted access information and the Service recognises that the declared information encompasses the secrecy of commercial activities.
[4 July 2006]

111. Paragraph 110 shall not apply to:

111.1. the trade name of the plant protection product and the name and address of the owner of the registration certificate;

111.2. the name and content of the active substance;

111.3. the names of other substances contained in the plant protection product which, in accordance with regulatory enactments, are classified as hazardous;

111.4. the physical and chemical properties of the plant protection product and the active substance thereof;

111.5. the methods and techniques for elimination of the harmful impact of the plant protection product and active substance;

111.6. the summary of results of trials and studies that proves the efficacy and harmlessness of the plant protection product and active substance to plants, human and animal health and the environment;

111.7. the methods and measures for the reduction of hazards during use, storage, transportation, fire, as well as during other accidents;

111.8. the analytical methods referred to in Clauses 4.3.1 and 4.3.2 and Sub-paragraph 103.1 of these Regulations for the detection of the composition of the active substance and for the detection of the residues of the plant protection product;

111.9. the methods of neutralisation and disposal of the plant protection product and packaging thereof;

111.10. the procedure for neutralisation after any accidental spillage or leakage; and

111.11. emergency assistance and medical services after poisoning.

112. The applicant for registration has a duty to inform the Service without delay regarding a decision to make restricted access information publicly available.
[6 March 2007]

XVI. Exchange of Information and Publication

113. Within one month after the end of each quarter, the Service shall submit in writing information regarding any inclusion in the register or any withdrawal of a registration certificate for each chemical or micro-organism or virus-comprised plant protection product, as well as the following data or documents to the responsible authorities of the Member States of the European Union and to the European Commission:

113.1. the name of the holder of the registration certificate;

113.2. the trade name of the plant protection product;

113.3. the preparatory form of the plant protection product;

113.4. the name and contents of each active substance contained in the plant protection product;

113.5. approved use;

113.6. the specified provisional maximum residue level if the maximum residue level has not been approved in the European Community;

113.7. information that is necessary for determining the provisional maximum residue level; and

113.8. information regarding the reason for the withdrawal of the registration certificate if it is being withdrawn.

114. The Service shall submit the annual list of registered plant protection products to the European Commission and to the responsible authorities of the Member States of the European Commission.

115. The Service shall ensure the publication of the following information in the newspaper *Latvijas Vēstnesis* [the official Gazette of the Government of Latvia]:

115.1. the inclusion of a plant protection product in the register, the withdrawal of a registration certificate, the granting of an authorisation for the extension of the scope of use and any withdrawal thereof;

115.2. the text of instructions for use for an extension of the scope of use;

115.3. numerical indicators of provisional maximum residue level; and

115.4. the issuing of an authorisation for the parallel importation of plant protection products.

[6 March 2007]

XVII. Closing Provisions

116. These Regulations shall come into force on 1 May 2004.

117. For plant protection products which contain active substance not included on the list of active substances registered in the European Community, but have been distributed in Member States of the European Union by 25 July 1993 and the conformity thereof for inclusion on the said list has been evaluated in accordance with regulatory enactments of the European Community regarding the gradual evaluation of an active substance, shall apply the requirements specified in Cabinet Regulation No. 341 of 5 October 1999, Regulations regarding Registration Procedures for Plant Protection Products (*Latvijas Vēstnesis*, 1999, No. 331/332) regarding trials and studies until 31 December 2008.

118. Cabinet Regulation No. 341 of 5 October 1999, Regulations regarding Registration Procedures for Plant Protection Products (*Latvijas Vēstnesis*, 1999, No. 331/332), is repealed.

Informative Reference to European Union Directives

Legal norms have been included in these Regulations arising from:

1) Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances;

2) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC;

3) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market;

4) Commission Directive 93/71/EEC of 27 July 1993 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market;

5) Commission Directive 94/37/EC of 22 July 1994 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market;

6) Commission Directive 94/79/EC of 21 December 1994 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market;

7) Commission Directive 95/35/EC of 14 July 1995 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market;

8) Commission Directive 95/36/EC of 14 July 1995 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market;

9) Commission Directive 96/12/EC of 8 March 1996 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market;

10) Commission Directive 96/46/EC of 16 July 1996 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market;

11) Commission Directive 96/68/EC of 21 October 1996 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market;

12) Council Directive 97/57/EC of 22 September 1997 establishing Annex VI to Directive 91/414/EEC concerning the placing of plant protection products on the market;

13) Commission Directive 2001/36/EC of 16 May 2001 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market; and

14) Council Directive 2005/25/EC of 14 March 2005 amending Annex VI to Directive 91/414/EEC as regards plant protection products containing micro-organisms.

[4 July 2006]

Prime Minister I. Emsis

Minister for Agriculture M. Roze

Annex
Cabinet Regulation No. 451
23 March 2004

Information to be Included on the Label of a Plant Protection Product

I. Labels of Protective Packaging

1. Trade name or designation of the plant protection product.

2. Name and content of the active substance:

2.1. in percentage of weight – for sprays, volatile liquids (boiling point does not exceed 50 °C), viscous liquids (the lowest limit – 1 Pa s, at a temperature of 20 °C) or for plant protection products of solid physical state;

2.2. in percentage of weight and g/l, at a temperature of 20 °C (for other plant protection products of liquid physical state);

2.3. in percentage of volume (for plant protection products of gaseous physical state);

2.4. grams per unit (for impregnated objects); and

2.5. the number of active units per gram (number per litre) – for plant protection products containing micro-organisms.

3. The names of all substances contained in the plant protection product shall be indicated on the label:

3.1. if the plant protection product is classified as very toxic, toxic or harmful. Only the names of such very toxic, toxic or harmful substances the chemical concentration of which in the product is the equal to the lowest borderline concentration, which is indicated for each of them in the chemical substance list, or is greater than the lowest borderline concentration; and

3.2. if the plant protection product is classified as corrosive. Only the names of such corrosive substances the chemical concentration of which in the product is the equal to the lowest borderline concentration, which is indicated for each of them in the chemical substance list, or is greater than the lowest borderline concentration.

4. Preparatory form (for example, powder in suspension, emulsion concentrate).

5. Use category of the plant protection product (for example, insecticide, plant growth regulator).

6. Class of registration.

7. Registration number.

8. Description of hazards and hazard symbols.

9. The holder of the registration certificate (name and address).

10. The manufacturer and the person responsible for the packaging and labelling, if it is not the manufacturer (the name and address).

11. The person responsible for the initiating of distribution of the plant protection product – the representative, importer (the name, address, phone number).

12. The batch number or designation of the plant protection product for the identification thereof.

13. Date of manufacture.

14. Net weight.

15. Conditions for storage.

16. The warning regarding hazard to humans, animals or the environment, utilising adopted designations and standard phrases.

17. Safety requirements utilising adopted designations and standard phrases.

18. Expiry date.

II. Labels of Packaging

19. Trade name or designation of the plant protection product.

20. Name and content of the active substance:

20.1. in percentage of weight – for sprays, volatile liquids (boiling point does not exceed 50 °C), viscous liquids (the lowest limit – 1 Pa s, at a temperature of 20 °C) or for plant protection products of solid physical state;

20.2. in percentage of weight and g/l, at a temperature of 20 °C (for other plant protection products of liquid physical state);

20.3. in percentage of volume (for plant protection products of gaseous physical state);

20.4. grams per unit (for impregnated objects); and

20.5. the number of active units per gram (number per litre) – for plant protection products containing micro-organisms.

21. The names of all substances contained in the plant protection product shall be indicated on the label:

21.1. if the plant protection product is classified as very toxic, toxic or harmful. Only the names of such very toxic, toxic or harmful substances the chemical concentration of which in the product is the equal to the lowest borderline concentration, which is indicated for each of them in the chemical substance list, or is greater than the lowest borderline concentration; and

21.2. if the plant protection product is classified as corrosive. Only the names of such corrosive substances the chemical concentration of which in the product is the equal to the lowest borderline concentration, which is indicated for each of them in the chemical substance list, or is greater than the lowest borderline concentration.

22. Preparatory form (for example, powder in suspension, emulsion concentrate).

23. Use category of the plant protection product (for example, insecticide, plant growth regulator).

24. Class of registration.

25. Registration number.

26. The list of protected crops or target/place of use.

27. The indication "Lai nepakļautu riskam cilvēkus un vidi, izlasīt un izpildīt lietošanas instrukcijas prasības" [In order not to expose people and the environment to risk, read and fulfil the requirements of the instructions of use].

28. Description of hazards and hazard symbols.

29. The holder of the registration certificate (name and address).

30. The manufacturer and the person responsible for the packaging and labelling if it is not the manufacturer (name and address).

31. The person responsible for initiating distribution of the plant protection product – the representative, importer (name, address and phone number).

32. The batch number or designation of the plant protection product for the identification thereof.

33. Date of manufacture.

34. Net weight.

35. Conditions for storage.

36. Expiry date.

37. The warning regarding hazard to humans, animals and the environment, utilising adopted designations and standard phrases.

38. Safety requirements utilising adopted designations and standard phrases.

39. Instructions to be observed when rendering first aid and the phone number of the information centre for poisoning.

40. Instructions for elimination of the plant protection product and its packaging.

41. Environmental protection requirements.

42. Instructions for use:
    42.1. crops to be protected;
    42.2. harmful organisms to be controlled;
    42.3. useful life, dose, method and number of treatments;

42.4. methods of treatment;

42.5. conditions for use;

42.6. restrictions upon use (specific environmental conditions and conditions for the spread of harmful organisms under which the plant protection product may or may not be used);

42.7. compatibility (interoperability) with other preparations;

42.8. if required, the specified safety interval between each use for the protection of human and animal health and:

42.8.1. the sowing or planting of the crops to be protected;

42.8.2. the sowing or planting of succeeding crops;

42.8.3. the presence of humans or animals on the field;

42.8.4. harvesting;

42.8.5. consumption of plants or plant products;

42.9. possible phytotoxicity, sensitivity of various species and different reactions, as well as possible undesirable side-effects upon plants and plant products, indicating the interval to be considered for the period between use of the preparation and:

42.9.1. the sowing or planting of the crops to be protected;

42.9.2. the sowing or planting of succeeding crops;

43. Legal liability.

44. If the space available on the package is too small for presenting the information, the information referred to in Paragraphs 41 and 42 of this Annex shall be presented in a separate instruction. The instruction shall be deemed as a part of the label, and on the label shall be the indication "Lai nepakļautu riskam cilvēkus un vidi, izlasīt un izpildīt lietošanas instrukcijas prasības" [In order not to expose people and environment to risk, read and fulfil the requirements of the instructions of use]. The instruction shall include the information referred to in Paragraphs 19, 20, 22, 23, 24, 25, 26, 35, 36, 39 and 40 of this Annex.

Notes.

1. 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.

2. Information in English conforming to international requirements regarding the transportation of dangerous chemical products may be indicated on the label of the protective packaging.

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

[4 July 2006]

Minister for Agriculture M. Roze

