



REPUBLIC OF LITHUANIA

LAW ON THE AMENDMENT OF THE LAW ON PLANT PROTECTION

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Vilnius

(Žin., 1995, No 90-2013; 1998, No 56-1545; 2001, No 48-1655, No 110-3986)

Article 1. The new edition of the Republic of Lithuania law on plant protection

The Republic of Lithuania Law on Plant Protection shall be replaced as follows:

„REPUBLIC OF LITHUANIA LAW ON PLANT PROTECTION

SECTION ONE GENERAL PROVISIONS

Article 1. Objective of the Law

1. This Law shall establish activity of all natural and legal persons with respect to registration, import, storage, trade in, use and control of plant protection products.

2. This Law shall apply without prejudice to the legislation establishing:

- 1) the classification, labelling and packaging of chemical substances and preparations;
- 2) banned and restricted preparations;
- 3) conditions of land and forest usage, safety strips and zones for the protection of the shores of surface water bodies;
- 4) working conditions for children and young persons;
- 5) preventive health checks for persons working with plant protection products.

3. This Law, with the exception of Article 18, shall also apply to plant protection products which contain genetically modified organisms.

4. This Law shall not apply to the production of plant protection products, as well as to the storage, export, re-export and transit of plant protection products not intended to be used in Lithuania.

5. The objective of this Law shall be to ensure the application of the legislation of the European Union referred to in the Annex to this Law.

Article 2. Main definitions of this Law

1. **Environment** shall mean water, air, land, wild species of fauna and flora, and any interrelationship between them.

2. **Plants** shall mean live plants and live parts of plants, including fresh fruits and seeds.

3. **Plant products** shall mean products in the unprocessed state or having undergone only simple preparation such as milling, drying, pressing, etc., derived from plants, but excluding plants themselves.

4. **Plant protection products** shall mean active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to:

1) protect plants and plant products against all harmful organisms or prevent the action of such organisms, in so far as such substances or preparations are not otherwise defined below;

2) influence the life processes of plants, other than as a nutrient (e.g. growth regulators, etc.);

3) preserve plant products in so far as such substances or products are not subject to special provisions on preservatives;

4) destroy undesired plants;

5) destroy parts of plants or prevent undesired growth of plants.

5. **Residues of plant protection products** shall mean one or more substances (including their metabolites and products resulting from their degradation or interaction with other substances) present in or on plants or plant products, in or on animal products, in soil, water, as well as elsewhere after the use of plant protection products.

6. **Regulation on the use of plant protection products** shall mean an established purpose of the use, rate, number of pulverizations, conditions, time and restrictions on the use.

7. **Holder of registration of plant protection products** shall mean a Lithuanian or foreign natural or legal person in whose name a plant protection product is registered and to whom a registration certificate is issued.

8. **Registration of plant protection products** shall mean an administrative act by which the State Plant Protection Service authorizes, following an application submitted by an applicant, the placing on the market of a plant protection product.

9. **Placing on the market of plant protection products** shall mean any supply by natural and/or legal persons whether in return for payment or free of charge other than for storage followed by consignment from the territory of the European Union or disposal. Importation of plant protection products into the Republic of Lithuania shall be deemed to constitute placing on the market for the purposes of this Law.

10. **Existing active substances** – substances already on the market of the Member States of the European Union before 15 July 1993.

11. **Animals** shall mean animals kept or consumed by man.

12. **Individual users** shall mean natural persons who do not possess a diploma in agronomics or a certificate of completion of a plant protection course and be entitled to purchase and use only the plant protection products for individual use.

13. **Integrated control** shall mean the rational application of a combination biological, biotechnological, chemical, agricultural and plant-breeding measures whereby the use of chemical plant protection products is limited to the strict minimum necessary to maintain the pest population at levels below those causing economically unacceptable damage or loss.

14. **Harmful organisms** shall mean pests of plants and plant products belonging to the animal or plant kingdom, as well as viruses, bacteria, mycoplasmas, fungi and other pathogens.

15. **Consultative committee** shall mean a group of representatives of scientific and other institutions providing scientifically founded proposals and recommendations in the matter of registration of plant protection products.

16. **Substances** shall mean chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity resulting from the manufacturing process.

17. **New active substances** shall mean substances placed on the market of the Member States of the European Union after 15 July 1993.

18. **Operator** shall mean a worker who comes into contact with plant protection products while working.

19. **Applicant** shall mean a producer of plant protection products or a legal person authorized by him who submits the application for the registration of plant protection products.

20. **Trade in analogous plant protection products** shall mean trade in plant protection products which by their nature are identical to the plant protection products registered in the Republic of Lithuania, are of the same preparation form, manufactured using the same active substance, and have the same effect.

21. **Preparations** shall mean mixtures or solutions composed of two or more substances, of which at least one is an active substance, intended for use as a plant protection product.

22. **Professional users** shall mean persons having a diploma in agronomics or a certificate of completion of a plant protection course and entitled to purchase and use plant protection products for professional use.

23. **Risk phrase** shall mean a standard phrase indicating a specific risk arising from the use of a plant protection product.

24. **Safety phrase** shall mean a standard phrase advising on the safe use of a plant protection product.

25. **State Plant Protection Service** shall mean the state plant protection institution attached to the Ministry of Agriculture and authorized for the registration of plant protection products, for the control of their import, storage, sale and use.

26. **Active substances** shall mean substances or micro-organisms including viruses, having general or specific action against harmful organisms, live plants, live parts of plants or plant products.

Article 3. General requirements

1. Only the plant protection products registered in accordance with this Law may be imported, stored, sold and used in Lithuania, except in cases referred to in paragraph 3 of Article 1, Articles 18 and 31 of this Law.

2. Plant protection products must be used in compliance with the requirements laid down in paragraph 1 (7) of Article 6 and Article 17, as well as with the principles of good plant protection practice, and, whenever possible, with recommendations of integrated

control. Plant protection products for professional use must be applied by certified equipment.

3. Plant protection products must be placed on the market packaged, classified and labelled in accordance with the provisions of the Law on chemical substances and preparations and Article 17 of this Law. Specific risk and safety phrases for plant protection products shall be approved by the Minister of Agriculture after consulting the Minister of the Environment and the Minister of Health.

4. Plant protection products for professional use may not be used in garden plots of gardeners' associations.

SECTION TWO

REGISTRATION OF PLANT PROTECTION PRODUCTS

Article 4. Submission of applications for the registration of plant protection products

1. Applicants shall submit applications for the registration of plant protection products to the State Plant Protection Service, hereinafter referred to as 'the Service'. Applicants must be permanently established in one of the Member States of the European Union.

2. Applications for the registration of plant protection products shall be submitted in Lithuanian, and the information in accordance with the requirements referred to in paragraphs 3 and 4 below may be submitted in Lithuanian or English.

3. Requirements for the information to be provided on the active substances contained in the plant protection products shall be approved by the Minister of Agriculture after consulting the Minister of the Environment and the Minister of Health.

4. Requirements for the information to be provided on the plant protection products shall be approved by the Minister of Agriculture after consulting the Minister of the Environment and the Minister of Health.

Article 5. Submission of information for the registration of plant protection products

1. Applicants who apply for the registration of plant protection products shall submit together with their applications:

1) information on the plant protection products in accordance with the requirements of paragraph 4 of Article 4 of this Law;

2) information on the active substances contained in the plant protection products in accordance with the requirements of paragraph 3 of Article 4 of this Law.

2. Where the information on the active substances has been submitted in accordance with the requirements of paragraph 3 of Article 4 of this Law before they were included in the list of active substances referred to in paragraph 3 below, applicants are not required to submit the information referred to in paragraph 1 (2) above other than the information on the identity of the active substances, provided that such substances do not differ significantly from the active substances included in the list of active substances referred to in paragraph 3 below as regards their purity and nature of impurities.

3. The list of active substances, which may be contained in plant protection products, shall be approved by the Minister of Agriculture subject to the European Commission programme on the review of active substances and the relevant Commission decisions.

Article 6. Registration of plant protection products

1. Plant protection products shall be registered in the Republic of Lithuania, if:

1) their active substances are included in the list of active substances referred to in paragraph 3 of Article 5 of this Law and any conditions laid down therein are fulfilled, the plant protection products in question are evaluated according to the evaluation and decision-taking procedure with regard to plant protection products referred to in paragraph 13 below and the requirements of paragraph 1 (2), (3), (4), (5) and (6) are complied with;

2) on the evaluation of the information concerning the plant protection product in question provided in accordance with the requirements of paragraph 4 of Article 4 of this Law, as well as all the conditions under which it may be used and the possible consequences of its use, it is established that the plant protection product is effective on the target harmful organisms, has no unacceptable effect on plants or plant products, does not cause unnecessary suffering of pain to vertebrates, has no direct or indirect harmful effect on human or animal health and no unacceptable influence on the environment. Special attention should be given to the fate and distribution of plant protection products in the environment, its ability to contaminate drinking water and groundwater, its impact on beneficial plant and animal species;

3) their active substances and their quantities and, where appropriate, any toxicologically and ecotoxicologically significant impurities can be determined by appropriate methods;

4) residues resulting from proper use of plant protection products can be determined by appropriate methods;

5) their physical and chemical properties have been determined and it has been decided upon their evaluation that plant protection products are acceptable for use and storage;

6) maximum authorized residue levels of plant protection products in plants and plant products are provisionally established;

7) When registering plant protection products, the Service shall establish such regulations on their use as to ensure that the maximum residue levels provisionally authorized in plant protection products are not exceeded.

2. Tests and analyses performed to satisfy the requirements referred to in paragraph 1 (2), (3), (4), (5) and (6) above must be carried out at institutions which have certificates of good experimental practice and good laboratory practice and under agricultural, plant health and environmental conditions, under which these plant protection products will be used in the Republic of Lithuania. The Minister of Agriculture shall approve good experimental practice regulations. The Minister of Health, the Minister of the Environment, and the Minister of Agriculture shall approve good laboratory practice principles.

3. Plant protection products shall be registered for a period of up to 10 years. If another applicant submits a written statement from the holder of registration of a plant protection product giving his consent to the use of the information provided by him, plant protection products shall be registered for a period that may not exceed the period of registration of the initial products.

4. Documents concerning the registered plant protection products must be reviewed if the requirements referred to in paragraph 1 above are not satisfied. The Service must require the applicant to submit additional information necessary for the evaluation of plant protection products. The registration may be extended for the period necessary to submit the information and to carry out a new evaluation.

5. Where the new active substances of plant protection products are not included in the list of active substances referred to in paragraph 3 of Article 5 of this Law, such plant protection products may be registered provisionally, for a period not exceeding 3 years,

provided that the European Commission certifies that the information on the evaluation of the intended use of the active substances is complete.

6. Where the Service is satisfied that the active substances can meet the requirements of paragraph 3 of Article 4 of this Law and that the plant protection products can meet the requirements of paragraph 4 of Article 4 of this Law, as well as of paragraph 1 (2), (3), (4), (5) and (6) above, it shall immediately notify to the authorities authorized by the other Member States of the European Union and the European Commission the results of the evaluation and of the conditions for the registration of the plant protection products giving the information referred to in paragraph 1 of Article 20 of this Law.

7. If residues of plant protection products, hereinafter referred to as 'residues', appearing as a result of the use of a plant protection product are considered, according to the good plant protection practice, as harmful to human and animal health and groundwater or the environment, the Service, on the basis of the result of the evaluation carried out by the European Commission, shall withdraw the provisional registration of plant protection products.

8. By way of derogation, if, on expiry of the three-year period, a decision has not been taken by the Commission concerning the inclusion of active substances to the list, the Service may request an extension of provisional registration to enable a full examination of the documents or additional information.

9. In the case of provisional registration of plant protection products paragraphs 2 and 4 above shall be applied.

10. A separate file shall be constituted for each application. Each file shall contain the application, a decision concerning the registration of plant protection products, their toxicological and ecotoxicological evaluation, evaluation of their fate and distribution in the environment, physical and chemical properties, and biological efficacy, validation of analytical methods, recommendations on the maximum residue levels submitted by the institution authorized by the Ministry of Health, a label in Lithuanian approved by the Service in accordance with the requirements of Article 17 of this Law and a copy of the registration certificate for the plant protection product. This information shall be made available to the institutions authorized by the Member States of the European Union and to the European Commission upon request.

11. The Service shall register plant protection products, issue registration certificates, withdraw registration or amend the regulations on the use of plant protection products in accordance with the procedure established by the Minister of Agriculture and

on the basis of results of the European Union review programme of the existing and new active substances.

12. The physical and chemical properties, analytical methods, risk to human health and the environment, and the biological efficacy of plant protection products shall be evaluated in accordance with the guidelines established by the European Commission in the relevant area, as well as other internationally recognized evaluation criteria.

13. The evaluation and decision-taking procedure with regard to plant protection products shall be approved by the Minister of Agriculture after consultation with the Minister of the Environment and the Minister of Health.

14. Registration, re-registration, amendments to the regulations on use, extension of use, withdrawal of registration, its restriction or prohibition shall be published in the supplement of „Valstybės žinios“ (*Official gazette*), „Informaciniai pranešimai“ (*Information notices*).

Article 7. Re-registration of plant protection products

1. At the end of the registration period, plant protection products may be re-registered, provided that the applicant submits an application and it is established, following a verification, that the requirements laid down in paragraph 1 of Article 6 of this Law are complied with.

2. In order to re-register a plant protection product already registered in accordance with the requirements of this Law, the applicant shall submit an application and any additional information on the use of the plant protection product, its effects for man, animals and the environment.

3. Where a plant protection product has been registered before the entry into force of this Law, the applicant shall submit information in accordance with the requirements set out in paragraphs 3 and 4 of Article 4 of this Law.

Article 8. Amendment of regulations on the use of plant protection products

1. Regulations on the use of plant protection products may be amended:

- 1) based on new scientific data;
- 2) upon request of holders of registration of plant protection products.

2. The regulations on use of plant protection products may be amended upon request of the applicant, after submission of documents on the efficiency of a product and its residues.

3. Amendments to the regulations on use of plant protection products shall be made in accordance with the requirements set out in paragraph 1, Article 6 of this Law and in other relevant Lithuanian legislation.

Article 9. Extension of use of plant protection products for minor crops

1. Applications for the extension of use of registered plant protection products for minor crops may be submitted by scientific bodies involved in agricultural activities, growers' associations or professional users.

2. The Service shall extend the use of registered plant protection products for minor crops if:

1) the scientific bodies involved in agricultural activities, growers' associations or professional users have submitted documents concerning the effectiveness of these products and their residues justifying the extension of use;

2) the requirements laid down in paragraph 1 (3), (4) and (5) of Article 6 have been complied with and the plant protection product is effective for the control of target harmful organisms, has no unacceptable effect on plants or plant products, does not cause unnecessary suffering or pain to vertebrates, has no harmful effect on human or animal health, directly or indirectly (e.g. through drinking water, food, feed, etc.), has no unacceptable influence on the environment. Special attention should be given to the fate of these products and their distribution in the environment, their ability to contaminate drinking water and groundwater, and its impact on beneficial plant and animal species;

3) the extension of use concerns minor crops on the list approved by the Minister of Agriculture.

3. The Service, upon the extension of the use of plant protection products for minor crops, shall publish an official notification or shall establish an obligation, in writing, for the holders of registration of plant protection products to add relevant inscriptions on the label.

Article 10. Withdrawal of registration of plant protection products

1. The registration of plant protection products shall be withdrawn if:

1) the applicants have provided false documents or misleading information on the basis of which the product was registered;

2) an active substance of a plant protection product no longer satisfies the requirements indicated at the time of registration;

3) at the request of the holder of registration of plant protection products to withdraw registration.

2. The Service shall inform in writing the holders of registration of plant protection products of the withdrawal of registration of plant protection products and may grant a period for the disposal of plant protection products or for the use of the existing stocks. The length of this period shall depend on the reasons for the withdrawal of registration.

Article 11. Evaluation of information on active substances, drawing up of a report and its submission to the European Commission

1. The Service, authorized by the European Commission to draw up a report on the evaluation of information on active substances and to submit it to the European Commission, shall, upon receipt of an application and verification that the information is complete, establish an obligation for the applicants to communicate the information, in accordance with the requirements of paragraphs 3 and 4 of Article 4 of this Law, to the other institutions authorized by the Member States of the European Union and to the European Commission.

2. The procedure for the evaluation of information on active substances, the drawing up of a report and its submission to the European Commission shall be approved by the Minister of Agriculture.

Article 12. Submission of information on potentially harmful effects

1. Applicants or holders of registration of plant protection products shall notify to the Service all the latest information on potentially harmful effects of any plant protection product, registered or under the process of registration, of its active substances or residues on human or animal health, the environment, and groundwater.

2. The Service shall establish an obligation for the applicants or holders of registration of plant protection products to communicate the information referred to in paragraph 1 above to the other institutions authorized by the Member States of the European Union and to the European Commission.

Article 13. Recognition of registration of plant protection products in other Member States of the European Union

1. The Service, upon receipt of an application to register plant protection products already registered in another Member State of the European Union, and of documentary evidence substantiating the claim to comparability of conditions, must:

1) refrain from requiring the repetition of tests and analyses already carried out in connection with the registration in other Member States of the European Union, to the extent that agricultural, plant health and environmental conditions are comparable to those in the Republic of Lithuania;

2) register plant protection products, provided that their active substances, included in the list of active substances referred to in paragraph 3 of Article 5 of this Law, have been evaluated in accordance with the evaluation and decision-taking procedure with regard to plant protection products laid down in paragraph 13 of Article 6 of this Law, to the extent that the agricultural, plant health and environmental conditions are comparable to those in the Republic of Lithuania.

2. The Service, in recognizing the registration in other Member States of the European Union, may establish restrictions on the use of plant protection products arising from differences in dietary patterns in order to avoid the risks of contamination of foodstuffs with residues in excess of the acceptable daily intake.

3. At the time of registration of plant protection products already registered in other Member States of the European Union, the regulations on their use may, with the consent of the applicants, be modified in order to take into account agricultural, plant health or environmental conditions which are important in the Republic of Lithuania.

4. The Service shall inform the European Commission of repetitions of tests or of refusal to register plant protection products already registered in other Member States of the European Union, as well as of the applicants' claims that the agricultural, plant health and environmental conditions relevant to the use of the product in the regions of a Member State of the European Union where the tests were carried out or where the products were registered were comparable to those in the Republic of Lithuania. The Service shall indicate the reasons for repetitions of test or refusal to register.

5. In cases where the Service refuses to recognize and accept tests carried out in Member States of the European Union or authorize the placing on the market of the Republic of Lithuania of plant protection products, the final decision as to the comparability of agricultural, plant health or environmental conditions shall be taken by the European Commission.

Article 14. Restriction or prohibition of registration of plant protection products registered in accordance with Article 13 of this Law

Where there is reason to consider that plant protection products which are or have to be registered in accordance with Article 13 of this Law constitute a risk to human or animal health or the environment, the Service may provisionally restrict or prohibit the use and sale of plant protection products in the territory of the Republic of Lithuania and shall immediately inform the European Commission and the authorized institutions of the Member States of the European Union thereof and give reasons for restrictions or prohibitions.

Article 15. Protection and confidentiality of data provided for the registration of plant protection products

1. The Service, in registering plant protection products, shall not make use of the information provided in accordance with the requirements of paragraph 3 of Article 4 of this Law for the benefit of other applicants:

1) unless the applicants submit a written confirmation of the holders of registration of plant protection products that use may be made of such information;

2) for a period of 10 years from first inclusion of new active substances for the market of the Member States of the European Union in the list of active substances approved by the European Commission;

3) for a period of 10 years from the registration of existing active substances in the Republic of Lithuania;

4) for a period of five years from the submission of additional information on the modification or maintaining of conditions for the active substances included in the list of active substances referred to in paragraph 3 of Article 5 of this Law. Should the five-year period expire before the period provided for in paragraph 1 (2) and (3) above, the period of data protection shall be extended so as to expire on the date referred to in paragraph 1 (2) and (3) above.

2. In registering plant protection products, the Service shall not make use of the information provided pursuant to the requirements of paragraph 4 of Article 4 of this Law, for the benefit of other applicants:

1) unless the applicants submit a written confirmation of the holders of registration of plant protection products that use may be made of such information;

2) for a period of 10 years from the registration of plant protection products, provided that the active substances are first included, in any Member State of the European Union, in the list of active substances approved by the European Commission;

3) for a period of 10 years from the registration of the first plant protection products in Lithuania, where the registration of plant protection products precedes the inclusion of their active substances in the list referred to in paragraph 3 of Article 5 of this Law.

3. If the Service, on examination of an application for the registration of plant protection products, establishes that the active substances, produced by other producers or using other manufacturing processes, differ from those indicated in the documents on the basis of which the active substances were first included in the list of active substances referred to in paragraph 3 of Article 5 of this Law, it shall inform the European Commission thereof.

4. Applicants who intend to apply for the registration of plant protection products, the active substances of which are included in the list of active substances referred to in paragraph 3 of Article 5 of this Law, shall, before carrying out experiments involving vertebrate animals, enquire of the Service whether the plant protection product for which an application for registration is to be made is identical to a plant protection product already registered. The Service shall indicate to the applicants the names and addresses of holders of registration of the former plant protection products and shall inform the holders of registration of plant protection products the names and addresses of prospective applicants.

5. Where information is requested with a view to inclusion of active substances in the list of active substances approved by the European Commission, where the active substances in question are already on the Lithuanian market before the entry into force of this Law, the Service shall encourage the holder of registration of plant protection products and the applicant to share information so as to avoid the duplication of testing on vertebrate animals.

6. Applicants and holders of registration of previously registered plant protection products must seek agreement on sharing of information so as to avoid the duplication of testing on vertebrate animals. If they fail to reach an agreement, the Service shall inform the Commission on ethics of the use of laboratory animals under the State Health and Veterinary Service accordingly.

Article 16. Derogations to the application of protection and confidentiality to data submitted for the registration of plant protection products

1. The Service shall ensure, upon request of the applicant, the confidentiality of data relative to industrial and commercial secrets. The provision on confidentiality shall be applied without prejudice to the provisions of the Convention on access to information, public participation in decision-making and access to justice in environmental matters, ratified by the Republic of Lithuania.

2. The following data shall not be considered confidential:

1) the names and content of the active substance or substances and the names of the plant protection products;

2) the names of other substances, which are classified and must be indicated in accordance with the legislation on the classification, labelling and packaging of chemical substances and preparations;

3) physical and chemical properties of the active substances and the plant protection products;

4) any ways of rendering the active substances or plant protection products harmless;

5) summaries of the results of tests carried out to establish the substance's or product's efficacy and harmlessness to humans, animals, plants and the environment;

6) recommended methods and precautions to reduce the hazards of use, storage, transport, loading, unloading, fire, etc.;

7) methods of analysis referred to in paragraph 1 (3) and (4) of Article 6 of this Law;

8) methods of disposal of the plant protection products and of their packaging;

9) decontamination procedures to be followed in the case of accidental spillage or leakage of plant protection products;

10) first aid and medical treatment to be given to persons in the case of poisoning or injury.

3. If the applicant subsequently discloses previously confidential information, he shall be required to inform the Service accordingly.

Article 17. Information provided on the labels of plant protection products

1. The following information must be legibly and indelibly indicated on the labels affixed to the packaging of plant protection products:

1) the trade name of the plant protection product;

2) the names and addresses of holders of registration of plant protection products, registration numbers and, if different, the names and addresses of persons responsible for the final packaging and labelling of plant protection products or for the final labelling of plant protection products on the market;

3) the names and quantities of active substances. The names must be as those given in the List of classified chemical substances approved by the Minister of the Environment and the Minister of Health or, if the substances are not included therein, the common name established by the International Organization for Standardization (ISO) shall be indicated. If the latter is not available, the active substances shall be designated by their chemical designations according to the nomenclature of chemical substances of the International Union of Pure and Applied Chemistry (IUPAC);

4) the quantity of plant protection products in grams, kilograms, millilitres or litres;

5) batch number;

6) information on the composition of the plant protection product, presented in accordance with the procedures for the classification, labelling and packaging of chemical substances and preparations adopted by the Minister of the Environment and the Minister of Health, and information concerning first aid to be given in the case of an accident;

7) nature of a possible risks for humans, animals or the environment, by means of relevant risk phrases;

8) safety precautions for the protection of humans, animals or the environment, by means of relevant risk phrases, and the personal safety measures of the operator;

9) the type of action of the plant protection products (e.g. insecticide, growth regulator, weedkiller, etc.);

10) the type of the plant protection products (wetable powder, emulsifiable concentrate, etc.);

11) the plants or plant products for which the plant protection product is intended and any specific agricultural, plant health and environmental conditions under which the product may be used or should not be used;

12) recommendations on the use of the plant protection product;

13) where necessary, the safety interval for each use between application and sowing or planting of the crop, sowing or planting of succeeding crops, access by humans or animals into the treated areas, harvesting, consumption or use as feed;

14) particulars of possible phytotoxicity, varietal susceptibility, and any other direct or indirect adverse side effects on plants or plant products together with the intervals to be observed between the use of plant protection products and the sowing or planting of crop which may be susceptible to the plant protection products, or in crop rotation;

15) if accompanied by a leaflet referred to in paragraph 2 below, the indication 'Read accompanying instructions before use';

16) directions for safe disposal of the unused plant protection product and of the packaging;

17) the expiry date relevant to the established conditions of storage;

18) the users of the plant protection products: professional or individual.

2. If the space available on the label is insufficient for the requirements of paragraph 1 above, the Service may permit the requirements laid down in paragraph 1 (12), (13) and (14) above to be indicated on a separate leaflet accompanying the package. Such leaflets shall be regarded as part of the labels.

3. In no circumstances may the label of the packaging of a plant protection product bear the indications 'non-toxic', 'harmless', or similar indications. However, information to the effect that the plant protection products may be used when bees or other species are active, or when crops or weeds are in flower, may be given on the label, if they present only a minimal hazard to them.

4. Plant protection products placed on the Lithuanian market must be labelled in Lithuanian. The applicant must submit the proposed labels to the Service for approval.

5. The Service shall be entitled to require additional information to be clearly and indelibly marked on the packaging when it is deemed to be necessary for the protection of human beings, animals or the environment. The Service shall immediately inform the other institutions authorized by the Member States of the European Union and to the European Commission of every exceptional requirement and shall provide additional information, as well as the reasons for these requirements. The decision in this matter shall be taken in accordance with the procedure established by the European Commission. The Service shall be entitled to maintain its requirement until such time as a decision has been taken.

Article 18. Research on plant protection products

1. Research on unregistered plant protection products, which may have an impact on the environment, shall be authorized only when the Service includes them in the list of plant protection products used for research and only under determined conditions.

2. Applicants shall, within a period of six months prior to the beginning of research, submit to the Service an application and available data to permit an assessment of possible effects on human and animal health and impact on the environment, except in cases when the institutions carrying out the research are entitled to carry out certain research and the conditions thereof are established.

3. If the research is liable to have harmful effects on human or animal health or on the environment, the Service may prohibit them or permit them subject to such conditions as it determines.

4. The research on plant protection products containing genetically modified organisms shall be governed by the Law on Genetically Modified Organisms.

Article 19. Consultative commission

1. The Consultative commission shall be composed of representatives of scientific and other institutions. Commission, in submitting to the Service proposals and recommendations on the registration of plant protection products, shall act in accordance with the evaluation and decision-taking procedure with regard to plant protection products referred to in paragraph 13 of article 3 of this Law.

2. The composition and the rules of procedure of the Consultative Commission shall be approved by the Ministry of Agriculture.

Article 20. Submission of information

1. Within a period of one month at the end of each quarter, the Service shall notify the Member States of the European Union and the European Commission in writing of any plant protection products registered or any withdrawal of registration in accordance with the provisions of this Law, indicating:

- 1) the name of the holder of registration of the plant protection products;
- 2) the trade name of the plant protection products;
- 3) the type of action of the plant protection products;
- 4) the names and quantities of all active substances contained therein;
- 5) plants and plant products, for which the registered product is intended;

6) maximum authorized residue levels provisionally established where they have not already been set by the legislation of the European Union;

7) reasons for the withdrawal of registration of plant protection products;

8) information necessary for the evaluation of the maximum authorized residue levels provisionally established.

2. The Service shall draw up an annual list of registered plant protection products. The list shall be communicated to the institutions authorized by the Member States of the European Union and to the European Commission.

Article 21. Trade in analogous plant protection products

1. Trade in analogous plant protection products shall be allowed if these products are supplied and placed on the market from the Member States of the European Union.

2. Rules on the trade in analogous plant protection products shall be adopted by the Minister of Agriculture.

Article 22. State charges for the registration, re-registration, modification of regulations on use, extension for minor crops

Applicants, at the time of submitting their applications for registration of plant protection products, their re-registration, modification of regulations on use, extension of use for minor crops, shall pay a charge as laid down in relevant legislation.

SECTION THREE

COMPETENCE AND FUNCTIONS OF STATE INSTITUTIONS

Article 23. System of state administration of plant protection products

The state administration of registration of plant protection products, their import, storage, trade in, use and control shall be carried out by the institution authorized by the Ministry of Agriculture – the State Plant Protection Service, as well as by the Ministry of the Environment and the Ministry of Health and/or institutions authorized by them in accordance with their competence.

Article 24. Competence of the State Plant Protection Service

The Service shall:

- 1) implement the state policies on plant protection;
- 2) develop international cooperation;
- 3) draft projects of legislation governing the registration, import, storage, trade in, use and control of plant protection products;
- 4) draw up plans and programs for the implementation of plant protection and coordinate their implementation;
- 5) carry out the assessment of the effects on human health and risk for the environment, the physical and chemical properties, validity of analytical methods and biological efficiency of plant protection products presented for registration;
- 6) register plant protection products;
- 7) draw up and publish lists of registered plant protection products;
- 8) administer the implementation of the provisions on good experimental practice;
- 9) carry out the control of the labelling, import, storage, trade in and use of plant protection products;
- 10) issue onetime permits for the import of plant protection products and trade permits;
- 11) prepare statistic summaries on the import and use of plant protection products;
- 12) organize the certification and technical inspections of plant protection sprayers and carry out their control;
- 13) carry out the observation of crop diseases and pests, evaluate the manifestation of diseases and pests and inform land users of the best time for the application of protection measures;
- 14) instruct users and traders of plant protection products, together with other institutions, according to approved programs;
- 15) perform other functions as laid down in this Law and other laws and regulations.

Article 25. Competence of the Ministry of the Environment

The Ministry of the Environment and/or institutions authorized by it shall:

- 1) issue permits for the repackaging of plant protection products;
- 2) draw up and approve legislation concerning the determination of safety strips and zones on the shores of surface water bodies with regard to the use of plant protection products;

3) controls the compliance with environmental requirements as regards the storage and use of plant protection products, in accordance with the procedures laid down in this Law and other Laws and regulations.

Article 26. Competence of the Ministry of Health

The Ministry of Health and/or institutions authorized by it:

- 1) evaluate the data on residue testing submitted for the registration of plant protection products, determine and approve the maximum admissible residue concentration in plant and plant products;
- 2) draw up and adopt lists of prohibited and restricted active substances of plant protection products;
- 3) issue permits for the trade in and storage of plant protection products (hygiene passports);
- 4) draft and adopt legislation governing sanitary protection zones for the storage of plant protection products;
- 5) establish medical examination requirements for workers working with plant protection products and examine their health.

SECTION FOUR

STATE CONTROL OF PLANT PROTECTION PRODUCTS

Article 27. State control of plant protection products

1. The state control of plant protection products shall be carried out, in accordance with procedures laid down in relevant legislation, by the institution authorized by the Ministry of Agriculture (the State Plant Protection Service) and by the Ministry of the Environment and institutions authorized by it.
2. The Regulations on the control of plant protection products for the plant protection inspectors shall be adopted by the Minister of Agriculture.
3. Every year before 1 August the Service shall inform the institutions authorized by the Member States of the European Union and the European Commission of the results of the placing on the market of plant protection products and of the inspection of their use.

Article 28. Officers carrying out the state control of plant protection

Officers of the institution authorized by the Ministry of Agriculture (the State Plant Protection Service) and officers of the Ministry of the Environment carrying out the state control of plant protection, upon presentation of their certificate of employment, shall be empowered to:

1) freely access agricultural and commercial buildings and land of all undertakings, agencies, organizations, agricultural holdings, where plants are grown, and to verify the compliance with the requirements on the import, trade in, storage and use of plant protection products and environmental and hygiene requirements;

2) examine documents attesting to the legality of purchase of plant protection products, their quantities and quality;

3) take samples of plant protection products, free of charge, with a view to determining their quality, and to present them to a laboratory in accordance with the procedures laid down in relevant legislation;

4) receive information on the spread of plant diseases, pests, weeds and their control using plant protection products;

5) suspend or prohibit the use of and trade in plant protection products in the case of violation of the requirements laid down in relevant legislation;

6) draw up protocols, examine cases of administrative infringements in accordance with the procedures laid down in relevant legislation and impose administrative penalties.

SECTION FIVE

USERS OF PLANT PROTECTION PRODUCTS

Article 29. Users of plant protection products and their obligations

1. Professional and individual users of plant protection products must:

- 1) act in accordance with this Law and other legislation;
- 2) comply with the requirements for storage and use of plant protection products;
- 3) comply with hygiene and environmental requirements.

2. Professional users must keep a register of the purchase and use of plant protection products and provide information on the use of plant protection products to the Service and other institutions concerned in accordance with procedures laid down in relevant legislation.

SECTION SIX
PROCEDURES FOR THE IMPORT, STORAGE, TRADE IN AND USE OF
PLANT PROTECTION PRODUCTS

Article 30. Procedures for the import, storage, trade in and use of plant protection products

1. Rules governing the storage, trade in and use of plant protection products shall be adopted by the Minister of Agriculture after consulting the Minister of the Environment and the Minister of Health.

2. Rules on the good plant protection practice and the inspection of sprayers shall be adopted by the Minister of Agriculture.

Article 31. Derogations of the use of plant protection products

If harmful organisms that cannot be eradicated using the existing registered plant protection products appear in the country, the Service shall be entitled to place on the market, for a period not exceeding 120 days, plant protection products on such conditions of use as it may determine. The Service shall immediately inform of such cases the other institutions authorized by the Member States of the European Union and the European Commission. Such derogations may be extended for a determined period or recalled in accordance with the procedure established by the European Commission.

Article 32. Import of plant protection products from states other than the Member States of the European Union

1. All import of plant protection products from states other than the Member States of the European Union shall be subject to the possession of a onetime permit issued by the Service.

2. Onetime permits shall be issued in accordance with the procedure established by the Minister of Agriculture.

SECTION SEVEN
FINAL PROVISIONS

Article 33. International cooperation in the field of plant protection

The Head of the Service shall represent the Republic of Lithuania in international organisations and perform other actions necessary to implement international obligations in the field of plant protection.

Article 34. Legal responsibility

Natural and legal persons, which have been in violation of the requirements of this Law, shall be held liable in accordance with the procedure established by laws.

Republic of Lithuania
Law on Plant Protection
No IX-1069
Annex

Legislation of the European Union implemented

Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (as last amended by the Commission Directive 2003/82/EC of 11 September 2003).

Article 2. Proposal to the Government

Propose to the Government to draw up and adopt before 30 April 2004 the legislation necessary for the implementation of this Law.

Article 3. Entry into force

This Law, with the exception of Article 2, shall enter into force on 1 May 2004.

I hereby promulgate this Law passed by the Seimas of the Republic of Lithuania.

PRESIDENT OF THE REPUBLIC

ROLANDAS PAKSAS