State Plant Protection Station Translation January 1995 LATVIA

The Law of the Plant Protection

REGULATIONS

on Registration of Plant Protection Products
in Republic of Latvia

The Terms used in the Law

Plant protection - a field of crop production, which studies the biological and ecological factors of harmful and competitive organisms of crop, works out and performs restriction and control measures of these organisms.

Plant Protection Machinery - especially constructed and manufactured machinery (sprayers, aerosol generators, devices for work into the ground granules of the pesticides, machinery for preparation the spray liquid and seed dressers etc.) for application of plant protection products.

Plant protection product - biological, chemical or physically mechanical plant protection product for controlling harmful and competitive organisms of crop and weed control or to decrease their negative influence.

Plant protection measures - the man's effect on the harmful organisms or initiators of the disturbance of physiological functions of the plants; to protect plants, to insure the normal growth of them and not to allow the possible loss of the yield.

Plant infestation - the beginning of the disease which is setting in with the entrance of phytopathogen in the plant and goes on until stable parasitic relations are formed between the phytopathogen and the host of parasite.

Harmful organisms - pests of plant or plant products belonging to the animal or plant kingdom, and also viruses, bacteria and mycoplasmas and other pathogens, weeds etc., which directly or indirectly damage the plants or cause their disease, thereby reducing the crop yield.

Pests - any species, strain or biotype of plant, animal, or pathogenic agent which directly or indirectly damage the plants, thereby reducing the crop yield and quality.

Prevalence of plant pests (diseases) - occurance of the plant pests (pathogen agents) in an area in the definite time period.

Plant quarantine - the State organized measures to secure the plant protection, don't allow to import and spread the quarantine objects and other particularly harmful organisms for plants which are determined by the corresponding state institutions.

Plant diseases - disturbance of metabolism of the plant, its organs or cells which is caused by unfavourable growth conditions or phytophatogenic organisms (fungus, bacteria, viruses etc.), thereby reducing the crop yield or causing their damage.

Growth regulators - the biologically active substance, which influences the plants vegetation or development.

Environment - totality of the nature's factors which directly or indirectly affect the human life and their economic activities.

Fungicide - the chemical substance for the control of the plant diseases initiated by fungus.

Herbicide - the chemical product for weed control.

Insecticide - the chemical product for insect control.

Cultivated substrate - artificially formed substrate.

Mycotoxin - a product of the metabolism which has cropped up during the life processes of the microscopic fungus, which is toxic to plants, people and animals.

Unparasitic plant disease - the disturbance of the physiological functions of the plants due to unfavourable conditions. The main factors which make the negative influence to the plant development are the metereological and soil conditions (the temperature, humidity, structure of the soil, the ensuring with nutrients for plants etc.), as well as choice of the place of cultivation and alongside plants.

Pesticide - a chemical product (any substance or mixture of substances) intended for preventing, destroying or controlling any pest and weed.

Retardant - a chemical substance which increases the plant stability against lie down.

Substrate - nutrition setting in which various organisms live.

I Chapter

The General Conditions

Article 1 The Tasks of the Plant Protection

The tasks of the plant protection are :

- to ensure the protection of the plants, especially crops and their yield against plant diseases, pests and weeds as well to protect the plants against unparasitic plant diseases;
- 2) to safeguard the plant products against mycotoxins and other dangerous admixtures in quantities which are risky for human and animal health;
- 3) not to allow the taken measures of the plant protection unfavourably influence the environment and to accumulate the residues of the used pesticides in the plant products, soil and water over the permitted rates;

Article 2 The Sphere of Action of the Law of the Plant Protection

- i) All the land areas the landowners possess regardless the land area quantity or kind of usage, are subordinated to the plant protection against plant diseases, pests, weeds and unparasitic plant diseases.
- 2) The land owner, in hired areas the hirer are responsible for the performance of the plant protection measures, if in the contract of hiring is not envisaged otherwise.

II Chapter

The Plant Protection Service

Article 3 The Structure of the Plant Protection Service

- (1) The Plant Protection in the State is organized, directed and controlled by the state institution the State Plant Protection Station, which is the status legal person, subordinated to the Ministry of Agriculture. The Statute of the State Plant Protection Station is cofirmed by the Minister of Agriculture.
- (2) The State Plant Protection Station is managed by the Director, who simultaneously is the Main State Inspector of the Plant Protection in Latvia. He is appointed and dismissed from the position by the Minister of Agriculture.
 - (3) The Director of State Plant Protection Station:
- i) is responsible for the plant protection undertakings in State and follows that the Plant Protection Service in its activities observes the requirements referring to work, environmental protection and other spheres stated in the legal documents;
- 2) ensures the observation of law and legal documents of Cat net in the sphere of the plant protection and in the work of Plant Protection Service.

Article 4 The Competence of the Ministry of Agriculture in Plant Protection

The Ministry of Agriculture in Plant Protection:

- 1) prepares the Law and the draft issues of the Cabinet on problems of the plant protection;
- 2) issues the regulations and recommendations on the use of the plant protection products and the performance of corresponding plant protection measures;
 - 3) supervises the Plant Protection in Latvia;

- 4) controls the reserves of the pesticides in the State, not to allow to purchase and accumulate the preparations in groundless quantities, which turning into toxic unliquides endanger the environment and are risky for human and animal health; on State bugdet's resources forms the States pesticides reserve and coordinating with the National Centre of Environmental Health defines the assortment and quantity of such preparations which are necessary for control of harmful organisms of unexpected and in particularly dangerous multiplying cases.
- 5) Cancels the instruction of the Director of the State Plant Protection Station if he violates the Statutes of the State Plant Protection Station and the authority stated in this Law and if the performance of these instructions could do harm to human and animal health, environment and promote the spreading of the plant pests and diseases as well as the deterioration of the quality of plant products.

Article 5 The competence of the State Plant Protection Station

- (1) The duty of the State Plant Protection Station is to ascertain the appearance of the plant pests and diseases in the State, in due time to forecast their development and promote the measures of the plant protection and quarantine in such quantities which would restrict the spreading of the plant pests, diseases and weeds and decrease their negative influence.
- (2) The State Plant Protection Station for this purpose has the rights:
 - 1) to form the Register of Plant Protection Products;
 - 2) to confirm The Regulations of Plant Quarantine;
- 3) to confirm The Regulations of trade and use of Plant Protection Products, coordinating them with the National Centre of Environmental Health;
- 4) to issue phytosanitary export certificates for the plants and plant products.
- 5) to organize the practice for the land users how to perform the plant protection measures, to define the necessary knowledge minimum in plant protection and hand out them certificate which gives the rights to purchase and use the necessary pesticides against plant diseases, pests and weeds;
- 6) to inspect and check the plants and plant production in warehouses, in means of transport, production premises, as well as in land areas due to the form of managing, ownership, season and other conditions;
- 7) to take samples of plant products, plant seedling, soil as well as the other samples for analyses without compensation in quantities determined in the The Regulations of Plant Quarantine;

- 8) to demand and gain the information from the land users (owners) about emergence of the plant diseases and pests, their distribution and the performed plant protection measures;
- 9) to give task to the land users (owners) and the processors of plant production to ensure the destruction of noxious organisms or exposed to danger objects, the desinfection and desinsection of the soil, substrates and premises, the application of appointed plant protection products, devices and methods of treatment;
- 10) to forbid the cultivation of definite plants, to exploitate the soils which are polluted with noxious organisms temporary or all the time, utilization the infected seed or seedling as well as transportation and sale of infected plants or plant products, or import and use of nonregistered plant protection products.
- 11) if necessary, to state (perform) quarantine in some farm, pagasts (small rural district), district or in all the State, coordinating it with the corresponding self-government or government (if quarantine is stated in all the State).

III Chapter

Plant Protection Products, Undertakings and Machinery

Article 6 Use of Plant Protection Products

- (1) In Latvia there are allowed to use only plant protection products which are included in the Register of Plant Protection Products. The Regulations on Registration of plant protection products are comfirmed by the Minister of Agriculture, coordinating it with the Ministry of the Environmental Protection and Regional Development and National Centre of Environmental Health. This order doesn't concern to plant protection products which are intended:
- 1) for export or transit and are situated in free port or in customs as customs goods;
 - 2) for use as growth regulator for cut ornamental plants;
- 3) for application against microorganisms in closed premises of plants and enterprises, pipelines or for sanitary purposes.
- (2) The plant protection products which are not registered may be imported only with the permission of the State's Plant Protection Station and after coordination with the National Centre of Environmental Health in the following cases:
- for tests, trials and testing the dynamics of decomposition of the pesticides;
- 2) if there is danger to protect plants against harmful organisms.
- (3) in the 1-st point second part of this Article (1.2.) the mentioned residue limits in the agricultural products before realization to consumers are controlled by the National Centre of Environmental Health.

(4) Seeds. live plants and live parts of plants which contain the plant protection products or are found there may be imported and realized if these products are registered or the active substance and its influence correspond to any form of the registered plant protection product. The trade name of pesticide should be shown on the overpack of goods.

Article 7 Information on Plant Protection Products

- (1) The State Plant Protection Station ensures all the persons concerned the possibility to get information on the Register of Plant Protection Products and use of there included preparations.
- (2) On the packaging of the plant protection products must be clearly showed the trade name of the plant protection product, registration number, name of active substance and its concentration in the preparation, shelf life, directions for use and information on first aid and advice to medical doctors.
- (3) The plant protection products may be imported if on the packaging are showed data, mentioned in this Article's second part.
- (4) The information shown in the advertisment of plant protection product can't be contradictory with the Register of the Plant Protection Products.

Article 8 Control on Trade and Use of Plant Protection Products

- (1) The enterprises may realize the Plant Protection Products after they have got the Certificate from the State Plant Protection Station.
- (2) The chemical Plant Protection Products which are useless should be liquidated in accordance with the law "About Dangerous remains".
- (3) The trade and use of Plant Protection Products are controlled by the State Plant Protection Station.

Article 9 The Plant Protection Machinery

The plant protection machinery are allowed to exploit, if they are up to the requirements which are obligate concerning to the human's life, health as well as to ensure the regulations of environmental protection and exploitation.

Article 10 The Obligations for the Land Users (Owners) in the Branch of the Plant Protection

The land users (owners) must conscientiously perform the plant protection measures, ensure registration of pesticides and inform the State Plant Protection Station about emergence of plant diseases and pests.

Article 11 Plant Quarantines Measures on Custom-houses (Control posts)

The State Plant Protection Station together with the concerned State institutions organize the control of import and export of the plant products as well as the phytosanitary control of such transit goods on custom-houses (controlposts).

Article 12 Responsibility on Trespass this Law

The guilty person who ignores the demands of this Law is called to account according to the order of the law.

The Law is accepted in Saeima on 5-th October, 1994.

The State President G. Ulmanis Riga, 20-th October, 1994

CONFIRMED

The Minister of Agriculture of Latvian Republic

A. Udris

5-th January, 1995

REGULATIONS

on Registration of Plant Protection Products

in Republic of Latvia

- 1. These regulations are worked out according to the Law of Plant Protection in Latvia accepted on October 5, 1994, requirements of Council Directive 91/414/EEC and is obliged for all legal and physical persons who manufacture, import, sale and use the plant protection products in Republic of Latvia.
- 2. In Latvia there are allowed to distribute and use only plant protection products and growth regulators which are included in the Register of Plant Protection Products and in accordance with "The Regulations of trade and use of Plant Protection Products".
- 2.1. The Register of Plant Protection Products consists of the list of preparations and the list of active substances (Annex I).
- 2.2. The Regulations of Plant Protection Products don't concern to plant protection products which are intended:
- a) for export or transit and are situated in free port or in customs as customs goods;
 - b) for use as growth regulator for cut ornamental plants;
- c) for application against microorganisms in closed premises of plants and enterprises, pipelines or for sanitary purposes.
- 2.3. The plant protection products which are not registered may be imported only with the permission of the State's Plant Protection Station and after coordination with the National Centre of Environmental Health in the following cases:
- a) for tests, trials and testing the dynamics of decomposition of the pesticides;
- b) if there is danger to protect plants against harmful organisms.
- 3. Seeds, live plants and live parts of plants which contain the plant protection products or are found there may be imported and realized if these products are registered or the active substance and its influence correspond to any form of registered plant protection product. The trade name or proposed trade name of pesticide should be shown on the overpack of goods.

- 4. The plant protection product is registered, if :
 - its active substance is mentioned in the Register of Plant Protection Products and the following conditions are observed:
- a) it is ascertained, that with correct use and observation of the normal application conditions, the aftereffects of this usage at the current level of science and technics are generally acceptable and it is approved that:
 - it is sufficiently effective;
 - it has no unacceptable effect on plants or plant products;
 - it doesn't cause unnecessary pain and suffering to the controlled verterbrate animals;
 - it has no harmful effect on human or animal health due to the contamination of drinking water, soil, food, feed or groundwater, has no unacceptable influence on the environment and doesn't impact on non-target species;
- b) the nature and quantity of its active substances and where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants can be determined by appropriate methods:
- c) its residues, resulting from the authorized uses, and which are of toxicological or environmental significance, can be measured and determined;
- d) its physical and chemical properties have been determined and deemed acceptable for the purposes of the appropriate use and storage of the product;
- e) maximum residue limits (MRLs) in the agricultural products referred to in the authorization have been provisionally established by the European Community States and notified to the Commission of Registration of Plant Protection Products.
 - Remark: The Commission after that notification in three months' time must decide if in Latvia is acceptable this maximum residue limit (MRLs), provisionally established by the European Communi y States or provisional maximum residue limit must be defined.
 - 5. The application on registration should be submitted by :
 - 5.1. manufacturer;
 - 5.2. trade firm authorized distributor of the manufacturer;
 - 5.3. legal or physical person who is interested in use of the plant protection product in Republic of Latvia.
- 6. The application on registration of preparation should be submitted to the Ministry of Agriculture State Plant Protection Station.
- 7. The application on registration of preparation should be submitted in duplicate and should be written in Latvian or after the agreement with State Plant Protection Station in English or Russian according to the form shown in Annex 2., with

additional data of the results of the biological trial as well as the results of the pesticide residual tests in the yield (if it is necessary in soil too) in conditions of Latvia, which are estimated in the laboratory of National Centre of Environmental Health, independent laboratory or in the accredited laboratory.

- 7.1. If preparation is registered with a new active substance not registered in Latvia an application and the data of the biological trial as well as the results of the pesticide residual tests in yield (soil) in Latvia during 2 years' period should be submitted.
- 7.2. If the active substance is registered in Latvia there is necessity of one year's trial of the preparation.
- 7.3. The active substances and products permitted for application in 1994 in Latvian Republic should be reregistered and documents should be submitted till the 1st of October, 1995 (data of the biological trials as well as the results of the pesticide residual tests in yield (soil) aren't obligatory).
- 7.4. After expiration of this date for not reregistered preparations it is permitted to use only the remnant quantities of them in Latvia.
- 8. The application on the registration of preparation is considered by the Commission of Registration of Plant Protection Products, consisting of 5 7 people: representatives from State's Plant Protection Station, National Centre of Environmental Health, Ministry of the Environmental Protection and Regional Development and representatives of agricultural sciences (Annex 3). The Commission is managed by chairman the director of State's Plant Protection Station. For the examination of the application may be invited specialists who have taken part in trials of the preparation in Latvia, if necessary the experts.
- 8.1. The sessions of Commission of Registration of Plant Protection Products are summoned by chairman.
- 8.2. State Plant Protection Station's department of Registration the Plant Protection Products provides the Commission members with the application documents and with the trial results of preparations and make ready the draft projects.
- 8.3. The Commission of Registration of Plant Protection Products with 2/3 participate members by a majority vote decide to register the preparation or postpone the decision of the issue until the examination of the additional data.
- 9. The Commission examines the application in 3 months' time if there is no necessity of additional information on the preparation or its active substance.

The decision on registration is accepted after the analysis of usefulness and the risk of use of preparation. The Commission determines the list of treated crops, the list of harmful organisms, doses, pre-harvest interval and accepts the preparation's label text.

Simultaneously is determined in which registration class the plant protection product should be included:

2nd class - preparation for landowners and land users who are trained and have a certificate of knowledge minimum of plant protection;

3rd class - preparation for application against pests whithout limitation.

10. The registration of the new preparation is in force for 10 years (in exceptional cases the preparation can be registered for shorter time, which is coordinated with the submitter). The registered preparation is written in "Register of the Plant Protection Products in Republic of Latvia" (form is in Annex I) with number consisting of four digits. Simultaneously is written the active substance (active substances) with number of three digits. The State Plant Protection Station issues to the submitter of application on registration of the preparation "The Registration Certificate of the Plant protection Product" (form is in Annex 4) in Latvian with the registration number Nr. . If the submitter wishes there is a possibility to get the duplicate of the Registration Certificate in the language the application is submitted.

The "Register of the Plant Protection Products in Republic of Latvia" is kept in the State Plant Protection Station.

The registration of the product doesn't guarantee the purchase of the preparation but insures the rights to get the permission from the State Plant Protection Station to import the product in Latvia. After the expiry of the registration term the product could be reregistered, if such a wish is expressed by the owner of the Registration Certificate - the application of the reregistration should be submitted 6 months before the expiry of the registration term.

- 11. The owner of the Registration Certificate must lamediately inform The State Plant Protection Station about 'e changes in the documents or in data which are submitted in the application of the registration.
- 12. The State Plant Protection Station has the rights during the term of action the registration of preparation (10 years from the date of registration) to claim from the owner of "The Registration Certificate of the Plant protection Product" additional data or trial results, if new scientific investigations demand for checking-up the registration. If such data in term, which is fixed to come to agreement with Commission of Registration of Plant Protection Products, are not submitted the Commission has the rights to annul the Registration Certificate.
- 13. If the owner of "The Registration Certificate of the Plant protection Product" stops his activities or changes the name, he must inform the State Plant Protection Station about these changes and together with it decide about further status of the Registration Certificate.

- 14. Organizations concerned and the owner of "The Registration Certificate of the Plant protection Product" have the rights during the term of action the registration of preparation to change the spectre of using the preparation, doses etc. (look 7.2.). The Commission of Registration of Plant Protection Products additionally enter the decision about changes in the "Register of the Plant Protection Products in Republic of Latvia".
- 15. The information shown on the label and advertisment can't be contradictory with the Register of the Plant Protection Products. It doesn't concern to the publications of the scientific papers.
- 16. If the preparation is registered the receiver of "The Registration Certificate of the Plant protection Product" pays the registration fee to the State Plant Protection Station Ls 500, for reregistration Ls 200. If the preparation is registered for use in glasshouses as well the biological products, entomophages and pheromones the registration fee is Ls 100.

The means from the registration fee are used for provision of the registration actions, for publishing the information about Register of Plant Protection Products and the usage of the included preparations.

If the procedure of registration is started on behalf of any legal or physical person, the registration fee is payed according to the mutual agreement between the submitter of the application and the mover.

- 17. The submitter of the application before the registration of the preparation informs the State Plant Protection Station about the proposed trials of the preparation its general data and active substance by a letter. The State Plant Protection Station comes to an agreement with the submitter of the application concerning the plan of the biological trials and legal or physical person whom to trust the carrying out of the field trials of estimation of biological efficacy and dynamics of decomposition of the residuals of the active substance.
- 18. Pre-registration trials should be arranged following the recommendations of the European Plant Protection Organization (EPPO) and the expierence in Latvia.

The trials of the 2-nd year could be used as demonstration trials.

- 19. The submitter of the application on registration submits the State Plant Protection Station the results of pre-registration trials by the 1-st December. The State Plant Protection Station sends out the potential submitter of the application:
 - a summon to carry out the trials of the 2-nd year by 15-th January;
 - appeal to submit all the data for registration of the preparation.

- 20. The expenditures of the pre-registration trials of the preparation as well as the estimation of the residuals of active substance in yield (soil) are paid by the submitter of the application.
- 21. If the owner of "The Registration Certificate of the Plant protection Product" after some time of the registration of the preparation wishes to realize the product with a different percentage or with another form of preparation than registered before, it is necessity to perform one year's trials and cover the expenditures of the reregistration (look 16.).

The new preparation is to be marked with a new registration number.

- 22. The Commission of Registration of Plant Protection Products can't use the data for the benefit of the second pretender (is mentioned in Annex 2), before it has not come to an agreement with the first pretender and got a Letter of access. This condition is valid also after the expiry of the patent rights.
- 23. State Plant Protection Station and the members of the Commission of the Registration of Plant Protection Products must ensure the necessary confidence of the data. It doesn't concern to:
 - the name and composition of the active substance or substancies and the trade name of the plant protection product;
 - preparations containing other substances, which by the Directive 67/548/EEC, 78/631/EEC and other directives are considered as dangerous;
 - physically chemical data, which concern to the plant protection product and actve substance;
 - any method to make the active substance or the plant protection product harmless;
 - the summary of the trial results, which clear up the effectivity or harmlessness of the active substance or products to animal and human body, plants and environment;
 - recommended methods and safety precautions for decreasing hazard potential of pesticide in storage, transportation and usage;
 - analytical methods for determining the nature and quantity of their active substances, toxicologically or ecotoxicologically significant impurities and co-formulants, their residues, resulting from the authorized use;
 - methods for destruction of the plant protection product and its packaging;

- procedures for cleaning to be followed after casual spillages or outflow of pesticides;
- proposed first aid measures, medical treatment in case of poisoning the personnel.

The State Plant Protection Station Director

G. Galvipš

Coordinated

The Ministry of Welfare
Director of the Department
of Environmental Health

A. Jurēvics

1994. g. "27." dec.

Coordinated

The Minister of the Environmental Protection and Regional Development

J. lesalnieks

1994. g. "29." decembrī