ANNEX I

Regulations on Registration
of Plant Protection Products
in Republic of Latvia

5-th January, 1995

The Register of Plant Protection Products in Republic of Latvia

Part I

PREPARATIONS

Registration		Preparation is registered till (year)	The submitter of the application on registration (Name, address)	The manufacturer firm, State, address	Trade name of preparation, type, active substance	The registration class	Crop	Harmful organism	The dose rate kg, l/ha kg, l/t	Application frequensy per season	Preharvest interval (days)
Nr	Date										
1	2	3	4	5	6	7	8	9	10	11	12

The Register of Plant Protection Products in Republic of Latvia

Part II

BIOLOGICAL PREPARATIONS

Registration		The submitter of the application on registration (Name, address)	The manufacturer firm, State, address	Trade name of preparation	Taxonomic name, strain for bacteria protozoa and fungi; for viruses taxonomic designation of the agent, serotype	Crop	Harmful organism	The dose rate kg, l/ha kg, l/t	Application frequency per season	Pre-harvest interval (days)
Nr	Date									
1	2	3	4	5	6	7	8	9	10	11

The Register of Plant Protection Products in Republic of Latvia

Part III

ACTIVE SUBSTANCES

Registration		The submitter of the application on registration (Name, address)	The manufacturer firm (name, address)	Common name proposed or ISO - accepted, and synonyms	Chemical name (IUPAC nomenclature)	Empirical formula	Molecular mass	Manufacturer's code Nr	CAS and EFC Nr	Sphere of application	The active substance registered in Europe (State, year)
Nr	Date										
1	2	3	4	5	6	7	8	9	10	11	12

A N N E X II

Regulation on Registration
of Plant Protection Products
in Republic of Latvia
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REQUIREMENTS FOR THE DOSSIER TO BE SUBMITTED FOR THE AUTHORIZATION OF PLANT PROTECTION PRODUCTS

PART I

Chemical substances
(Active ingredients)

1. Identity of the active substance

1.1. Applicant (name, address, etc.)
1.2. Manufacturer (name, address, including location of plant)
1.3. Common name proposed or ISO-accepted, and synonyms
1.4. Chemical name (IUPAC nomenclature)
1.5. Manufacturer's development code number(s)
1.6. CAS and EEC numbers (if available)
1.7. Empirical and structural formula, molecular mass
1.8. Method of manufacture (synthesis pathway) of the active substance
1.9. Specification of purity of the active substance in g/kg or g/l as appropriate
1.10. Identity of isomers, impurities and additives (e.g. stabilizers), together with the structural formula and the possible range expressed as g/kg or g/l as appropriate

2. Physical and chemical properties of the active substance

2.1. Melting point, boiling point, relative density (1)
2.2. Vapour pressure (in Pa) at 20 ° C, volatility (e.g. Henry's law constant) (1)
2.3. Apperance (physical state, colour and odour; if appropriate, threshold concentrations for substances with intense odour or taste in water (2)
2.4. Absorption spectra (UV / VIS, IR, NMR, MS), molecular extinction at relevant wavelengths (1)
2.5 Solubility in water including effect of pH (5 to 9) and temperature on solubility (1)
2.6. Solubility in organic solvents including effect of temperature on solubility (1)

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(1) These data must be submitted for the purified active substance of stated specification.
(2) These data must be submitted for the active substance and the purified active substance of stated specification.

2.7. Partition coefficient N-octanol/water including effect of pH (5 to 9) and temperature (1)
2.8. Stability in water, hydrolysis rate, photochemical degradation, quantum yield and identity of breakdown product(s), dissociation constant including effect of pH (5 to 9) (1)
2.9. Stability in air, photochemical degradation, identity of breakdown product(s) (2)
2.10. Stability in organic solvents used in preparations (3)
2.11. Thermal stability, identity of breakdown products
2.12. Flammability including auto-flammability and identity of combustion products
2.13. Flash point
2.14. Surface tension
2.15. Explosive properties
2.16. Oxidizing properties
2.17. Reactivity towards container material

3. Further information on the active substance

3.1. Function, e.g. fungicide, herbicide, insecticide, repellant, growth regulator
3.2. Effects on harmful organisms, e.g. contact poison, inhalation poison, stomach poison, fungitoxic or fungistatic, etc., systemic or not in plants
3.3. Field of use envisaged, e.g. field, glasshouse, food or feed storage, home garden
3.4. Where necessary, in the light of the test results, any specific agricultural, plant health or environmental conditions under which the active substance may or may not be used.
3.5. Harmful organisms controlled and crops or products protected or treated
3.6. Mode of action
3.7. Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies
3.8. Recommended methods and precautions concerning handling storage, transport or fire
3.9. In case of fire, nature of reaction product, combustion gases, etc.

3.10. Emergency measures in the case of an accident
3.10.1. Procedures for destruction or decontamination of the active substance
3.10.2. Possibility of recovery
3.10.3. Possibility of neutralization
3.10.4. Controlled discharge
3.10.5. Controlled incineration
3.10.6. Water purification
3.10.7. Others

4. Analytical methods

4.1. Analytical methods for the determination of pure active substance and, where appropriate, for relevant breakdown products, isomers and impurities of the active substance and additives (e.g. stabilizers)

4.2. Analytical methods including recovery rates and the limits of determination for residues in, and where relevant on, the following :

4.2.1. Treated plants, plant products, foodstuffs, feedingstuffs
4.2.2. Soil
4.2.3. Water (including drinking water)
4.2.4. Air
4.2.5. Animal and human body fluids and tissues

5. Toxicological and metabolism studies on the active substance

5.1. Acute toxicity
5.1.1. Oral
5.1.2. Percutaneous
5.1.3. Inhalation
5.1.4. Intraperitoneal
5.1.5. Skin and where appropriate eye irritation
5.1.6. Skin sensitization

5.2. Short-term toxicity

5.2.1. Oral cumulative toxicity (28-day study)
5.2.2. Oral administration - two species, one rodent (preferably rat) and one non-rodent, usually 90-day study
5.2.3. Other routes (inhalation, percutaneous as appropriate)

5.3. Chronic toxicity
5.3.1. Oral long-term toxicity and carcinogenicity (rat and other mammalian species) - other routes as appropriate

5.4. Mutagenicity - test battery to assess gene mutations, chromosomal aberrations and DNA perturbations

5.5. Reproductive toxicity

5.5.1. Teratogenicity studies - rabbit and one rodent species, oral and when appropriate percutaneous
5.5.2. Multigeneration studies in mammals (at least two generations)

5.6. Metabolism studies in mammals

5.6.1. Absorption, distribution and excretion studies - following both oral and percutaneous administration
5.6.2. Elucidation of metabolic pathways

5.7. Neurotoxicity studies - including where appropriate delayed neurotoxicity tests in adult hens

5.8. Supplementary studies

5.8.1. Toxic effects of metabolites from treated plants in case where different from those identified in animal studies

5.8.2. Any mechanistic studies needed to clarify effects reported in toxicity studies

5.9. Toxic effects on livestock and pets

5.10. Medical data

5.10.1. Medical surveillance on manufacturing plant personnel

5.10.2. Direct observation, e.g. clinical cases and poisoning incidents

5.10.3. Health records, both from industry and agriculture

5.10.4. Observations on exposure of the general population and epidemiological studies if appropriate

5.10.5. Diagnosis of poisoning (determination of active substance, metabolites), specific signs of poisoning, clinical tests

5.10.6. Sensitization/allergenicity observations

5.10.7. Proposed treatment : first aid measures, antidotes, medical treatment

5.10.8. Prognosis of expected effects of poisoning

5.11. Summary of mammalian toxicology and conclusions (including no observable adverse effect level (NOAEL), no observable effect level (NOEL), acceptable daily intake (ADI)). Overall evaluation with regard to all toxicological data, and other information concerning the active substance

6. Residues in or on treated products, food and feed

6.1. Identification of breakdown and reaction products and of metabolites in treated plants or products

6.2. Behaviour of residue of the active substance and its metabolites from the time of application until harvest or outloading of stored products - uptake and distribution in, and where relevant on, plants, kinetics of disappearance, binding to plant constituents, etc.

6.3. Overall material balance for the active substance. Sufficient residue data supervised trials to demonstrate that residues likely to arise from the proposed treatments would not be of concern for human and animal health

6.4. Estimation of the potential and actual exposure through diet and other means, such as residue monitoring data for products in the distribution chain, or such as data concerning exposure via air, water,etc.

6.5. Feeding and metabolism studies in livestock (if residues remain in or on crops or parts of crops used for feed) to permit evaluation of residues in foodstuffs of animal origin

6.6. Effects of industrial processing and/or household preparation on the nature and magnitude of residues

6.7. Summary and evaluation of residue behaviour resulting from data submitted pursuant to points 6.1 to 6.6

7. Fate and behaviour in the environment

7.1. Fate and behavoir in soil

7.1.1. Rate and route of degradation (to 90 per cent degradation) including identification of the process involved and identification of metabolites and breakdown products in at least three soil types under appropriate conditions.

7.1.2. Adsorption and desorption in at least three soil types and where relevant adsorption and desorption of metabolites and breakdown products

7.1.3. Mobility in at least three soil types and where relevant mobility of metabolites and breakdown products

7.1.4. Extent and nature of bound residues

7.2. Fate and behaviour in water and air

7.2.1. Rate and route of degradation in aquatic systems - biodegradation, hydrolysis, photolysis (as far as not covered by point 2.8), including identification of metabolites and breakdown products

7.2.2. Adsorbtion and desorption in water (sedimentation) and where relevant adsorption and desorption of metabolites and breakdown products

7.2.3. Rate and route of degradation in air (for fumigants and other volatile active substances) (as far as not covered by point 2.9)

8. Ecotoxicological studies on the active substance

8.1. Effects on birds

8.1.1. Acute oral toxicity

8.1.2. Short-term toxicity - eight-day dietary study in at least one species (other than chicken)

8.1.3. Effects on reproduction

8.2. Effects on aquatic organisms

8.2.1. Acute toxicity to fish

8.2.2. Chronic toxicity to fish

8.2.3. Effects on fish reproduction and growth rate

8.2.4. Bioaccumulation in fish

8.2.5. Acute toxicity for Daphnia magna

8.2.6. Daphnia magna reproduction and growth rate

8.2.7. Effects on algal growth

8.3. Effects on other non-target organisms

8.3.1. Acute toxicity to honeybees and other beneficial arthropods (e.g. predators)

8.3.2. Toxicity to earthworms and to other soil non-target macro-organisms

8.3.3. Effects on soil non-target micro organisms

8.3.4. Effects on other non-target organisms (flora and fauna) believed to be at risk

8.3.5. Effects on biological methods for sewage treatment

9. Summary and evaluation of points 7 and 8

10. Proposals including justification for the proposals for the classification and labeling of the active substance according to Council Directive 67/548/EEC

- Hazard symbol(s)
- Indications of danger
- Risk phrases
- Safety phrases

11. A dossier as referred to in part 3, for a representative plant protection product

PART 2

Micro-organisms and viruses

1. Identity of the organism

1.1. Applicant (name, address, etc.)
1.2. Manufacturer (name, address, including location of plant)
1.3. Common name or alternative and superseded names
1.4. Taxonomic name and strain for bacteria, protozoa and fungi, indication whether it is a stock variant or a mutant strain; for viruses the taxonomic designation of the agent, serotype, strain or mutant
1.5. Collection and culture reference number where the culture is deposited
1.6. The appropriate test procedures and criteria used for identification (e.g. morphology, biochemistry, serology)
1.7. Composition - microbiological purity, nature, identity, properties, content of any impurities and extraneous organisms

2. Biological properties of the organism

2.1. Target organism. Pathogenicity or kind of antagonism to host, infective dose, transmissibility and information on mode of action
2.2. History of the organism and its uses. Natural occurrence and geographical distribution
2.3. Host specificity range and effects on species other than the target harmful organism including species most closely related to the target species - to include infectivity, pathogenicity and transmissibility
2.4. Infectivity and physical stability when used according to the proposed method. Effect of temperature, exposure to air radiation, etc. Persistance under the likely environmental conditions of use
2.5. Whether the organism is closely related to a plant pathogen or to a pathogen of a vertebrate species or

2.6. Laboratory evidence of genetic stability (i.e. mutation rate) under environmental conditions of proposed use

2.7. Presence, absence or production of toxins as well as their nature, identity, chemical structure (if appropriate) and stability

3. Further information on the organism

3.1. Function, e.g. fungicide, herbicide, insecticide, repellant, growth regulator

3.2. Effects on harmful organisms, e.g. contact poison, inhalation poison, stomach poison, fungitoxic or fungistatic, etc., systemic or not in plants

3.3. Field of use envisaged, e.g. field, glasshouse, food or feed storage, home garden

3.4. Where necessary, in the light of the test results, any specific agricultural, plant health or environmental conditions under which the active substance may or may not be used

3.5. Harmful organisms controlled and crops or products protected or treated

3.6. Method of production with descriptions of the techniques used to ensure a uniform product and of assay methods for its standardization. In the case of a mutant, detailed information should be provided on its production and isolation, together with all known differences between the mutant and the parent wild strains.

3.7. Methods to prevent loss of virulence of seed stock

3.8. Recommended methods and precautions concerning handling, storage, transport or fire

3.9. Possibility of rendering the organism uninfective

4. Analytical methods

4.1. Methods for establishing the identity and purity of seed stock from which batches are produced and results obtained, including information on variability

4.2. Methods to show microbiological purity of the final product and showing that contaminants have been controlled to an acceptable level, results obtained and information on variability

4.3. Methods used to show that there are no human or other mammalian pathogens as contaminants in the active agent, including in the case of protozoa and fungi, the effects of temperature (35 o C and other relevant temperatures)

4.4. Methods to determine viable and non-viable (e.g. toxins) residues in or on treated products, foodstuffs, feedingstuffs, animal and human body fluids and

tissues, soil, water and air, where relevant

5. Toxicological, pathogenicity and infectivity studies

5.1. Bacteria, fungi, protozoa and mycoplasma
5.1.1. Toxicity and/or pathogenicity and infectivity
5.1.1.1. Oral single dose
5.1.1.2. In cases where a single dose is not appropriate to assess pathogenicity, a set of range-finding texts must be carried out to reveal highly toxic agents and infectivity
5.1.1.3. Percutaneous single dose
5.1.1.4. Inhalation single dose
5.1.1.5. Intraperitoneal single dose
5.1.1.6. Skin and, where necessary, eye irritation
5.1.1.7. Skin sensitization

5.1.2. Short-term toxicity (90 days exposure)
5.1.2.1. Oral administration
5.1.2.2. Other routes (inhalation, percutaneous as appropriate)

5.1.3. Supplementary toxicological and/or pathogenicity and infectivity studies
5.1.3.1. Oral long-term toxicity and carcinogenicity
5.1.3.2. Mutagenicity - (tests as refered to under point 5.4 of part I)
5.1.3.3. Teratogenicity studies
5.1.3.4. Multigeneration study in mammals (at least two generations)
5.1.3.5. Metabolic studies - absorption, distribution and excretion in mammals including elucidation of metabolic pathways
5.1.3.6. Neurotoxicity studies, including where appropriate delayed neurotoxicity tests in adult hens
5.1.3.7. Immunotoxicity, e.g. allergenicity
5.1.3.8. Pathogenicity and infectivity under immunosuppression

5.2. Viruses, viroids
5.2.1. Acute toxicity and/or pathogenicity and infectivity. Data as outlined under point 5.1.1 and cell culture studies using purified infective virus and primary cell cultures of mammalian, avian and fish cells
5.2.2. Short term toxicity
Data as outlined under point 5.1.2 and tests for infectivity carried out by bio-assay or on a suitable cell culture at least seven days after the last administration to the test animals
5.2.3. Supplementary toxicological and/or pathogenicity and infectivity studies as outlined under point 5.1.3

5.3. Toxic effects on livestock and pets

5.4. Medical data
5.4.1. Medical surveillance on manufacturing plant personnel
5.4.2 Health records, both from industry and agriculture
5.4.3. Observations on exposure of the general population and epidemiological data, if appropriate
5.4.4. Diagnosis of poisoning, specific signs of poisoning,

clinical tests, if appropriate

5.4.5. Sensitization/allergenicity observations, if appropriate

5.4.6. Proposed treatment : first aid measures, antidotes, medical treatment, if appropriate

5.4.7. Prognosis of expected effects of poisoning, if appropriate

5.5. Summary of mammalian toxicology and conclusions (including NOAEL, NOEL and ADI, if appropriate). Overall evaluation with regard to all toxicological pathogenicity and infectivity data, and infectivity and other information concerning the active substance

6. Residues in or on treated products, food and feed

6.1. Identification of viable and non-viable (e.g. toxins) residues in or on treated plants or products, the viable residue by culture or bio-assay and the non-viable by appropriate techniques

6.2 Likelihood of multiplication of the active substance in or on crops or food together with a report on any effect on food quality

6.3. In cases where residues of toxins remain in or on an edible plant product, data as outlined under points 4.2.1 and 6 of part I are required

6.4. Summary and evaluation of residue behaviour resulting from data submitted under points 6.1 to 6.3

7. Fate and behaviour in the environment

7.1. Spread, mobility, multiplication and persistance in air, water, soil

7.2. Information concerning possible fate in food chains

7.3. In cases where toxins are produced, data as outlined under part I, point 7 are required, where relevant

8. Ecotoxicological studies

8.1. Birds - acute oral toxicity and/or pathogenicity and infectivity

8.2. Fish - acute toxicity and/or pathogenicity and infectivity

8.3. Toxicity - Daphnia magna (if appropriate)

8.4. Effects on algal growth

8.5. Important parasites and predators of target species; acute toxicity and/or pathogenicity and infectivity

8.6. Honey-bees: acute toxicity and/or pathogenicity and infectivity

8.7. Earthworms: acute toxicity and/or pathogenicity and infectivity

8.8. Other non-target organisms believed to be at risk: acute toxicity and/or pathogenicity and infectivity

8.9. Extent of indirect contamination on adjacent non-target crops, wild plants, soil and water

8.10. Effects on other flora and fauna

8.11. In cases where toxins are produced, data as outlined under Part I, points 8.1.2, 8.1.3, 8.2.2, 8.2.3, 8.2.4, 8.2.5, 8.2.6, 8.2.7 and 8.3.3 are required, where relevant

9. Summary and evaluation of points 7 and 8

10. Proposals including justification of the classification and labelling of the active substance in accordance with Directive 67/548/EEC

- Hazard symbol(s)
- Indications of danger
- Risk phrases
- Safety phrases

11. A dossier as referred to in part 4, for a representative plant protection product.

PART 3

Chemical preparations

1. Identity of the plant protection product

1.1. Applicant (name, address, etc.)
1.2. Manufacturer of the preparation and active substance(s) (name, address, etc. including location of plants)
1.3. Trade name or proposed trade name, and manufacturer's development code number for the preparation, if appropriate
1.4. Detailed quantitative and qualitative information on the composition (active substance(s), impurities, adjuvants, inert components, etc.)
1.5. Physical state and nature of the preparation (emulsifiable concentrate, wettable powder, solution etc.)
1.6. Use category (herbicide, insecticide, etc.)

2. Physical, chemical and technical properties of the plant protection product

2.1. Appearance (colour and odour)
2.2. Explosivity and oxidizing properties
2.3. Flash point and other indications of flammability or spontaneous ignition

2.4. Acidity/alkalinity and if necessary pH value (1 % in water)
2.5. Viscosity, surface tension
2.6. Relative density
2.7. Storage stability - stability and shelf-life. Effects of light, temperature and humidity on technical characteristics of the plant protection product

2.8. Technical characteristics of the plant health product

2.8.1. Wettability
2.8.2. Persistent foaming
2.8.3. Suspensibility and suspension stability
2.8.4. Wet sieve test and dry sieve test
2.8.5. Particle size distribution, content of dust/fines, attrition and friability
2.8.6. In the case of granules: sieve test and indication of weight distribution of the granules, at least of the fraction with particle sizes bigger than 1 mm
2.8.7. Content of active substance in or on bait particles, granules or treated seed
2.8.8. Emulsifibility, re-emulsifiability, emulsion stability
2.8.9. Flowability, pourability and dustability

2.9. Physical and chemical compatibility with other products including plant protection products with which its use is to be authorized

2.10. Wetting, adherence and distribution to target plants

3. Data on application

3.1. Field of use, e.g. field, glasshouse, food or feed storage, home garden

3.2. Effects on harmful organisms, e.g. contact poison, inhalation poison or stomach poison, fungitoxic or fungistatic, etc., systemic or not in plants
3.3 Details of intended use, e.g. types of harmful organisms controlled and/or plants or plants products to be protected
3.4. Where necessary, in the light of the test results, any specific agricultural, plant health and/or environmential conditions under which the organism may or may not be used
3.5. Application rate
3.6. Concentration of active substance in material used (e.g. in the diluted spray, bait or treated seed)
3.7. Method of application
3.8. Number and timing of applications and duration of protection
3.9. Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding crops
3.10. Proposed instructions for use

4. Further information on the plant protection product

4.1. Packaging (type, materials, size, etc.), compatibility of the preparation with proposed packaging materials
4.2. Procedures for cleaning application equipment
4.3. Re-entry periods, necessary waiting periods or other precausions to protect humans and animals
4.4. Recommended methods and precautions concerning handling, storage, transport or fire
4.5. Emergency measures in case of an accident
4.6. Identity of combustion products relevant to cases of fire

4.7. Procedures for destruction or decontamination of the plant protection product and its packaging

4.7.1. Possibility of neutralization
4.7.2. Controlled discharge
4.7.3. Controlled incineration
4.7.4. Water purification
4.7.5. Others

5. Analytical methods

5.1. Analytical methods for determining the composition of the plant protection product

5.2. In so far as not covered by Annex I, Part I, point 4.2, analytical methods including recover rates and the limits of determination for residues in and where relevant on, the following :

5.2.1. Treated plants, plant products, foodstuffs, feedingstuffs
5.2.2. Soil
5.2.3. Water (including drinking water)
5.2.4. Air
5.2.5. Animal and human body fluids and tissues

6. Efficacy data

6.1. Preliminary range-finding tests
6.2. Field experimentation
6.3. Information on the possible occurrence of the development of resistance
6.4. Effects on the quality and where appropriate on the yield of treated plants or effects on the quality of treated plant products
6.5. Phytotoxicity to target plants (including different cultivars), or to target plant products
6.6. Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms, on succeeding crops, other plants or parts of treated plants used for propagating purposes (e.g. seeds, cuttings, runners)
6.7. Summary and evaluation of data presented under points

	6.1 to 6.6
7.	Toxicological studies
7.1.	Acute toxicity
7.1.1.	Oral
7.1.2.	Percutaneous
7.1.3.	Inhalation
7.1.4.	Skin and, where relevant, eye irritation
7.1.5.	Skin sensitization
7.1.6.	Where appropriate, acute dermal toxicity, skin and eye irritation for combinations of plant protection products for which authorization is sought for use in such combinations
7.2.	Operator exposure
7.2.1.	Dermal absorption
7.2.2.	Likely operator exposure under field conditions, including where relevant quantitative analysis of operator exposure
7.2.3.	Available toxicological data relating to non-active substances
8.	Residues in or on treated products, food and feed
8.1.	Data from supervised trials in crops, food or feedingstuffs, for which authorized use is sought, giving all experimental conditions and details, including residue data concerning the active substance, relevant metabolites and relevant other constituents of the plant protection product, from time of application until harvest, or in the case of post-harvest treatment, breakdown of residues during storage and levels of residues at time of release from storage for marketing. Data should be available for the range of climatic and agronomic conditions likely to be encountered in the proposed area of use
8.2.	Effects of industrial processing and/or household preparation on the nature and magnitude of residues
8.3.	Effects on taint, odour, taste or other quality aspects due to residues in or on fresh or processed products
8.4.	Estimation of residues in products of animal origin resulting from ingestion of feedingstuffs or resulting from contact with bedding, on the basis of residue data referred to in point 8.1 and studies in livestock referred to in Annex I, Part I, point 6.5
8.5.	Residue data in succeding or rotational crops where presence of residues might be expected
8.6.	Proposed pre-harvest intervals for envisaged uses, or witholding periods or storage periods, in the case of post-harvest uses
8.7.	Proposed maximum residue levels (MRLs) and justification of the acceptability of these residues
8.8.	Summary and evaluation of the residue behaviour on the basis of the data submitted under points 8.1 to 8.7

9. Fate and behaviour in the environment

The information provided must, where relevant, include that referred to in Annex I, Part I, point 7, and

9.1. Testing for distribution and dissipation in soil
9.2. Testing for distribution and dissipation in water
9.3. Testing for distribution and dissipation in air

10. Ecotoxicological studies

10.1. Effects on birds
10.1.1. Acute oral toxicity
10.1.2. Supervised trials to assess risks to avian species under field conditions
10.1.3. If appropriate, studies on acceptance of bait, granules, or treated seeds by birds

10.2. Effects on aquatic organisms

10.2.1. Acute toxicity to fish
10.2.2. Acute toxicity to Daphnia magna
10.2.3. Overspray study (if toxic to fish or other aquatic organisms and persistent in water) to assess risks to aquatic organisms under field conditions

10.2.4. In case of application in/at surface waters

10.2.4.1. Particular studies with fish and other aquatic organisms
10.2.4.2. Residue data in fish concerning the active substance and including toxicologically relevant metabolites

10.2.5. The studies referred to in Annex I, Part I points 8.2.2, 8.2.3, 8.2.4, ,8.2.6, and 8.2.7 may be required for particular plant protection products

10.3. Effects on other non-target organisms

10.3.1. Effects on terrestrial vertebrates other than birds
10.3.2. Toxicity to honey-bees
10.3.3. Toxicity to foraging bees under field conditions
10.3.4. Effects on beneficial arthropods other than bees
10.3.5. Effects on earthworms and other soil non-target macro-organisms, believed to be at risk
10.3.6. Effects on soil non-target micro-organisms
10.3.7. Available data from biological primary screening in summary form

11. Summary and evaluation of points 9 and 10

12. Further information

12.1. Information on authorizations in other countries
12.2. Information on established maximum residue limits (MRL) in other countries

12.3. Proposals including justification for the classification and labelling proposed in accordance with Directive 67/548/EEC and Directive 78/631/EEC

- Hazard symbol(s)
- Indications of danger
- Risk phrases
- Safety phrases

12.4. Proposals for risk and safety phrases and proposed label

12.5. Speciments of proposed packaging

PART 4

Preparations of micro-organisms or viruses

1. Identity of the plant protection product

1.1. Applicant (name, address, etc.)

1.2. Manufacturer of the preparation and the active agent(s) (names, addresses, etc., including location of plants)

1.3. Trade name or proposed trade name and manufacturer's development code number/or the plant protection product, if appropriate

1.4. Detailed quantitative and qualitative information on the composition of the plant protection product (active organism(s), inert components, extraneous organisms, etc.)

1.5. Physical state and nature of the plant protection product (emulsifiable concentrate, wettable powder, etc.)

1.6. Use category (insecticide, fungicide, etc.)

2. Technical properties of the plant protection product

2.1. Appearance (colour and odour)

2.2. Storage stability - stability and shelf-life. Effects of temperature, method of packaging and storage, etc. on retention of biological activity

2.3. Methods for establishing storage and shelf-life stability

2.4. Technical characteristics of the preparation

2.4.1. Wettability

2.4.2. Persistent foaming

2.4.3. Suspensibility and suspension stability

2.4.4. Wet sieve test and dry sieve test

2.4.5. Particle size distribution, content of dust/fines, attrition and friability

2.4.6. In the case of granules, sieve test and indications of weight distribution of the granules, at least of the fraction with particle sizes bigger than 1 mm

2.4.7 Content of active substance in or on bait particles, granules or treated seed

2.4.8 Emulsifiability, re-emulsifiability, emulsion stability
2.4.9. Flowability, pourability and dustability

2.5. Physical and chemical compatibility with other products including plant protection products with which its use is to be authorized
2.6. Wetting, adherence and distribution to target plants

3. Data on application

3.1. Field of use, e.g. field, glasshouse, food or feed storage, home garden
3.2. Details of intended use, e.g. types of harmful organism controlled and/or plants or plant products to be protected
3.3. Application rate
3.4. Where necessary, in the light of the test results, any specific agricultural, plant health and/or environmental conditions under which the product may or may not be used.
3.5. Concentration of active substance in material used (e.g. % concentration in the diluted spray)
3.6. Method of application
3.7. Number and timing of applications
3.8. Phytopathogenicity
3.9. Proposed instructions for use

4. Further information on the preparation

4.1. Packaging (type, materials, size, etc.), compatibility of the preparation with proposed packaging materials
4.2. Procedures for cleaning application equipment
4.3. Re-entry periods, necessary waiting periods or other precautions to protect humans and animals
4.4. Recommended methods and precautions concerning handling, storage, transport
4.5. Emergency measures in case of an accident
4.6. Procedures for destruction or decontamination of the plant protection product

5. Analytical methods

5.1. Analytical methods for determining the composition of the plant protection product
5.2. Methods for determining residues in or on treated plants or in or on plant products (e.g. biotest)
5.3. Methods used to show microbiological purity of the plant protection product
5.4. Methods used to show the plant protection product to be free from any human and other mammalian pathogens or, if need be, from honey-bee pathogens
5.5. Techniques used to ensure a uniform product and assay methods for its standardization

6. Efficacy data

6.1. Preliminary range-finding tests
6.2. Field experimentation
6.3. Information on the possible occurrence of the development of resistance
6.4. Effects on the quality and where appropriate on the yield of treated plants or effects on the quality of treated plant products
6.5. Phytotoxicity to target plants (including different cultivars), or to target plant products
6.6. Observations concerning undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms, on succeeding crops, other plants or parts of treated plants used for propagation purposes (e.g. seeds, cuttings, runners)
6.7. Summary and evaluation of data presented under points 6.1 to 6.6

7. Toxicity and/or pathogenicity and infectivity studies

7.1. Oral single dose
7.2. Percutaneous single dose
7.3. Inhalation
7.4. Skin and where relevant eye irritation
7.5. Skin sensitization
7.6. Available toxicological data relating to non-active substances

7.7. Operator exposure

7.7.1 Percutaneous absorption
7.7.2. Likely operator exposure under field conditions, including where relevant quantitative analysis of operator exposure.

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

8.1. Residue data concerning the active substance including data from supervised trials in crops, food or feedingstuffs for which autorization for use is sought, giving all experimental conditions and details. Data should be available for the range of different climatic and agronomic conditions encountered in the proposed area of use. It is also necessary to identify viable and non-viable residues in treated crops
8.2. Effects of industrial processing and/or household preparation on the nature and magnitude of residues, if appropriate
8.3. Effects on taint, odour, taste or other quality aspects due to residues on or in fresh or processed product, if appropriate
8.4. Residue data in products of animal origin resulting from ingestion of feedingstuffs or contact with bedding, if appropriate
8.5. Residue data in succeeding or rotational crops where

presence of residues might be expected

8.6. Proposed pre-harvest intervals for envisaged uses or witholding periods, or storage periods, in the case of post-harvest uses

8.7. Proposed maximum residue levels (MRLs) and the justification of the acceptability of these levels (for toxins), if appropriate

8.8. Summary and evaluation of the residue behaviour on the basis of the data submitted under points 8.1 to 8.7

9. Fate and behaviour in the environment

9.1. In cases where toxins are produced, data as outlined under Part I, point 9 are required, if appropriate

10. Ecotoxicological studies

10.1. Effects on aquatic organisms
10.1.1. Fish
10.1.2. Studies in Daphnia magna and in species closely related to the target organisms
10.1.3. Studies in aquatic micro-organisms

10.2. Effects on beneficial and other non-target organisms
10.2.1. Effects on honey-bees, if appropriate
10.2.2. Effects on other beneficial organisms
10.2.3. Effects on earthworms
10.2.4. Effects on other soil fauna
10.2.5. Effects on other non-target organisms believed to be at risk
10.2.6. Effects on soil microflora

11. Summary and evaluation of points 9 and 10

12. Further information

12.1. Information on authorizations in other countries
12.2. Information on established maximum residue limits (MRLs) in other countries
12.3. Proposals including justification for the classification and labelling proposed in accordance with Directives 67/548/EEC and 78/631/EEC

- Hazard symbol(s)
- Indications of danger
- Risk phrases
- Safety phrases

12.4. Proposals for risk and safety phrases and proposed label

12.5. Specimens of proposed packaging

REQUIREMENTS FOR LABELS AND LEAFLETS OF PLANT PROTECTION PRODUCTS IN LATVIA

LABEL FOR OVERPACKS :

1. Trade name of the plant protection product
2. Type of preparation (e.g. wettable powder, emulsifiable concentrate etc.)
3. Type of action (e.g. insecticide, growth regulator, etc.)
4. Hazard symbols
5. Name and address of holder of the authorization
6. Name and address of manufacturer, distributor or agent
7. Registration number.
8. Batch number
9. Date of formulation
10. Net weight
11. Storage conditions
12. Safety statements

LABEL FOR INSIDE CONTAINERS :

1. Trade name of the plant protection product
2. Active ingredient(s) and amount of each
3. The type of preparation (e.g. wettable powder, emulsifiable concentrate, etc.)
4. The type of action (e.g. insecticide, growth regulator, etc.)
5. Hazard symbols
6. Name and address of holder of the authorization
7. Name and address of manufacturer, distributor or agent
8. Registration number
9. Distribution group
10. Batch number
11. Date of formulation
12. Net weight
13. Storage conditions
14. Shelf life
15. Safety precautions for the protection of humans, animals or the environment in the form of standart phrases
16. Information on first aid and advise to medical doctors
17. Summary of uses for which the plant protection product has been authorized.
18. Directions for safe disposal of the plant protection product and of the packaging

19. Directions for use :
- crop,
- pests, diseases, weeds controlled,
- dose rates, timing, frequency,
- re - entry period,
- method of application,
- application conditions,
- use restrictions,
- pre - harvest interval,
- mixing instructions.
- warning statement for good agricultural practice:

where necessary, the safety interval for each use between application and :
- sowing or planting of the crop to be protected,
- sowing or planting of succeding crops,
- access by humans or animals,
- harvesting,
- use or consumption;

particulars of possible phytoxicity, varietal susceptibility, and any other direct or indirect adverse side effects on plants or products of plant origin together with the intervals to be observed between application and sowing or planting of :
- the crop in question, or
- subsequent crops.

20. Legal responsibilities

21. If accompanied a leaflet, the sentence "Read accompanying instructions before use"

REQUIREMENTS FOR LEAFLET

If the space available on the package is too small, regulations permit that requirements in paragraph 19, 20 may be printed on leaflet. Such a leaflet shall be regarded as part of the label.

The leaflet should contain information provided in paragraphs 1, 2, 3, 4, 13, 15, 16, 17, 18.

ANNEX 4

Regulations on Registration
of Plant Protection Products
in Republic of Latvia

5-th January, 1995

(Coat of Arms)

The Ministry of Agriculture of Latvian Republic

The State Plant Protection Station

The Registration Certificate

of the Plant Protection Product

Nr ....

This Certificate is handed out .....

.....

that according to the "Regulations on Registration of Plant Protection Products in Republic of Latvia"
is registered the preparation

.....

with the active substance (es) .....

Reg. Nr ....., ... Reg. Nr .....

_____ is registered in .... class.
(plant protection product)

The term of action of this Certificate is till .....

..... Director .....
(date)