APPENDIX 1

1. General Information Related to Application for Registration.
2. Applicant (firm, enterprise, address, telephone, telefax).
3. Range of applicant (in what crops it is planned to be registered, target object, Latin name).
4. Recommended dose rates and application method.
5. Recommended usage (time of application, number of treatments, interval between treatments).
6. Recommended waiting period (preharvest period in days).
7. Efficacy (field tests).
8. Results of biological effect evaluation in other countries (if there are any).
9. Residue data for other countries (if necessary).

APPENDIX 2

1. Applicant's application.
2. Applicant (firm, enterprise, address, telephone, telefax).
3. Manufacturer of a product and active substance(company name, address, telephone, telefax).
4. Name of a product (trade name), known synonyms.
5. Concentration (in g/l or g/kg).
6. Range of application (in what crops it is planned to be registered, target object, Latin name).
7. Recommended dose rates and application method.
8. Recommended use (time of application, number of treatments, interval between treatments).
9. Recommended waiting period (preharvest period in days).
10. Efficacy (field tests).
11. Results of biological effect evaluation in other countries (if there are any).
12. Residue data for other countries (if there are any).

APPENDIX 3

1. Applicant's application.
2. Applicant (firm, enterprise, address, telephone, telefax).
3. Manufacturer of a product and active substance (company name, address, telephone, telefax).
4. Name of a product (trade name).
5. Concentration (in g/l or g/kg).
6. Preparation form.
7. Range of application (in what crops it is planned to be registered,target object, Latin name).
8. Recommended dose rated and application method.
9. Recommended use (time of application, number of treatments, interval between treatments).
10. Recommended waiting period (preharvest period in days).
11. Efficacy (field tests).
12. Phytotoxicity, crop tolerance.
13. Compatibility with other products.
14. Results of biological effect evaluation in other countries (if there are any).
15. Residue data for other countries (if there are any).

APPENDIX 4

1. Applicant's application.
2. Applicant (firm, enterprise, address, telephone, telefax).
3. Manufacturer of a product and active substance (company name, address, telephone, telefax).
4. Name of a product (trade name).
5. Function of all active substance.
6. Concentration (in g/l or g/kg).
7. Preparation form.
8. Range of application (in what crops it is planned to be registered, target object, Latin name).
9. Recommended dose rates and application method.
10. Recommended use (time of application, number of treatments, interval between treatments).
11. Recommended waiting period (preharvest period in days).
12. Compatibility with other products.
13. Efficacy (field tests).
14. Registration in other countries (registration number, date, crops, use instructions).
15. Result of biological effect evalution in other countries (if there are any).
16. Residue data for other countries (if there are any).

APPENDIX 5

MICROBIOLOGICAL PREPARATIONS

Information about composition and properties of an active ingredient and preparation form (of bacterial, fungous, viral, microsporodial products baced on products of microorganisms activity).

Properties of a Producer Strain

1. Name of microorganisms class (Latin name).
2. Number and name of a strain (isolate).
3. Source of strain isolation.
4. Cultural, morphological and biochemical properties, tests and criteria of identification (state an institution responsible for indentification).
5. Pathogenicity or antogonism to a target object.
6. Difference from already available strains of the same class (including in other countries).
7. Relation to phages lysing cells of other strains of the same class of microorganisms.
8. Manner, conditions and environment composition for strain storage.
9. Manner, conditions, and environment composition for microorganisms reproduction, state characteristics of a specific medium for viruses and microsporodia inclubation.
10. Method of microorganism identification in microbal associations of the environment and in the biomaterial.
11. A product synthesized by the strain (chemical composition, structural formula, stability, method of residue analysis).
12. Composition of a preparation: active substance, content (titer of active cells or of a product of their activity, titer of viral or inclusion bodies), content of auxillary substances and their function.
13. Aggregate state.
14. Wettability.
15. Water content.
16. Foreign microflora content.
17. Method of active substance determination.
18. Shelf life and storage conditions.
19. Method or spray liquid preparation.
20. Decontamination or cleaning of clothing, packing material, transport means: disposal of the remaining product not good for reuse, spill and leak disposal.
21. Compatibility with other pesticides.

APPENDIX 6

PHYSICAL AND CHEMICAL PROPERTIES

a) Physical and Chemical Properties of an Active Substance

1. Active substance (according to ISO, JUPAC, GAS No.).
2. Structural formula (state optical isomers).
3. Empirical formula.
4. Molecular mass.
5. Aggregate state.
6. Color, odor.
7. Vapor pressure in mm Hg at 20°C and 40°C.
8. Solubility in water.
9. Solubility in organic solvents in mg/100 ml.
10. Partition coefficient n-octanol/ water.
11. Melting point.
12. Boiling/ freezing point.
13. Flash/ ignition point.
14. Stability in water solutions (pH 3-5, 7, 10) at 20°C including low concentrations (less than 1 mg/ dm^3).
15. Density (for gas substances state density at 0°C and 760 mm Hg).

b) Physical and Chemical Properties of a Technical Product

1. Purity of technical product, qualitative and quantitative characteristics of impurities.
2. Aggregate state.
3. Color, odor.
4. Melting point.
5. Flash/ ignition point.
6. Density (for gas substances state density at 0°C and 760 mm Hg).
7. Therma/ photostability.
8. Analytical method of purity identification allowing to identify a composition of a technical product, isomers, impurities, ets.

c) Physical and Chemical Properties of a Preparation form

1. Aggregate state.
2. Color, odor.
3. Stability of water emulsion or syspension.
4. pH acidity.
5. Water content (%).
6. Viscosity.
7. Dispersibility.
8. Density.
9. Particle size (powder, granules, etc).
10. Wettability.
11. Flash point.
12. Crystallization point, resistance to cold.
13. Volatility.

14. Data on caking.
15. Corrosive properties.
16. Qualitative and quantitative characteristics of impurities.
17. Storage stability.

APPENDIX 7

TOXICOLOGICAL AND HYGIENIC CHARACTERISTICS

a) Toxicology of an Active Substance (Technical Product)

1. Acute oral toxicity (mice, rats) — LD_{50}, thres hold of acute effect (for products manufactured in countries of CIS).
2. Acute dermal toxicity — LD_{50}.
3. Acute inhalation toxicity — CL_{50}, threshold of acute effect (for products manufactured in countries of CIS).
4. Mechanism of toxicological effect (organs target) clinical signs of acute and chronic intoxication.
5. Skin and mucous membranes irritation.
6. Delayed neurotoxic effect in hens (a must for organophosphorus pesticides, for the rest-if needed).
7. Subacute oral toxicity (cumulative properties), cumulation coefficient (for products manufactured countries of CIS using Kagan method).
8. Subacute epidermal toxicity.
9. Sensitization, immunotoxicity.
10. Chronic toxicity (NOEL, NOAEL).
11. Carcinogenicity determined by administering a test agent to two types of animals (mice and rats) for two years. Applicants must submit data on survival rate (tables and curves); incidence of malignant and benign tumors of all hystological types and localizations determined by their effective value (number of animals surviving to the, first tumor occurence of discovery) taking into account intercurrent mortality (Kaplan-Meier test); experimental control and follow-up data.
12. Teratogenicity and embriotoxicity, using methods allowing to reveal embryo/ fetal anomalies or any signs of toxicity.
13. Reproductive toxicity using 2-generation studies and gonadotoxicity.
14. Mutagenicity:

— Ames test for gene mutations with and without metabolic activation;
— cytogenetic test in vitro in human peripheral blood lymphocyte culture (chromosomal aberrations);
— cygenetic test in vivo in bone marrow cells of rodents (chromosomal aberrations, micronuclei):

Other tests can be used but not less than three including Ames test and test in mammals in vivo.

15. Metabolism in mammals, major matabolites, their toxicity, toxicokinetics and, if necessary, toxicodynamics.
16. Limiting factor of adverse effect.
17. Allowable daily intake (ADI) mg/kg of human body weight.
18. Metabolism in environmental objects including agricultural plants.

b) Toxicological Characteristics of a Preparations form

1. Acute oral toxicity (mice, rats), LD_{50}.
2. Acute dermal toxicity, LD_{50}.
3. Acute inhalation toxicity, CL_{50}.
4. Skin and mucous membranes irritation.

5. Subacute oral toxicity (cumulative properties), cumulation coefficient (for products manufactured countries of CIS).
6. Subacute epidermal toxicity (for products with pronounced dermal toxicity).
7. Subacute inhalation toxicity (for products with pronounced inhalation toxicity).
8. Sensitization.
9. Toxicology of the preparation form ingredients (fillers, emulsifiers, stabilizers, solvents, etc).

In the presence of a toxic ingredient able to increase the toxicity of a pesticide compared with that of an active substance, toxicology data on a preparation form can be extended to include the properties of an active substance and other preparation form constituents and also their metabolism.

c) Hygienic Characteristics of a Preparation form

1. Effect on the quality and nutritional value of crops.
2. Degradation of a pesticide during agricultural products storage and processing.
3. Possibility of finding a pesticide in milk (for products used on fodder crops and in animal husbandry).
4. Recommended hygienic normatives and waiting periods.
5. Recommendations on diagnosis and treatment in cases of acute poisoning including first aid measures in poisoning, antidotes.
6. Risk, factors evaluation — data of Expert Committees of FAO/WHO, EPA, European Community.
7. Recommended precautions in handling, storage, transportation, production (if a product is manufactured by countries of CIS).

APPENDIX 8

VETERINARY AND SANITARY ECOTOXICOLOGICAL EVALUATION OF PESTICIDE HAZARDS FOR BEEKEEPING AND CATTLE BREEDING

Laboratory Texts of Toxicity for Honeybees (not required for seed and planted material treaters and pre-em herbicides)

1. Acute and chronic contract toxicity of an active substance and a preparation form — LD_{50} (mg/bee) and LC_{50} (%).
2. Acute and chronic oral toxicity of an active substance and a preparation form — LD_{50} (mg/bee) and LC_{50} (mg/cm2).
3. Duration of a residual effect of a products (at a level of LC50) ob a glass surface (days — %).
4. Fumigant toxicity of a product LD_{50} — (mg/cm2).
5. Repellent effect of a product — coefficient of protective effect (CPE) (%).
6. Toxicity class of an active substance and product for honeybees in laboratory conditions.
7. Toxicity class of a product for honeybees in field conditions (within the recommended dose and time range).
8. Use instructions safe for honeybees and decrease in potential risk after a product application.

Pavilion and Field Tests of Toxicity for Honeybees

(for products with LD_{50} of less than 1,0 mg/bee under acute contract effect and products applied at bud and flowering stages)

1. Number of visits of bees to treated plants: activity in collecting nectar and pollen from treated plants.
2. Death dynamics in flying, hive bees and the brood: changes in major behavioral reflexes of bees.
3. Toxicity of collected nectar and pollen to young hive bees and the brood.
4. Terms of a product detoxication on treated plants.
5. General physiological (zootechnical) condition of bee families during trial and post-trial period (including wintering).
6. Methods or residue analysis in fodder of wintering bees (fodder honey, deposited pollen).
7. Dynamics of residue accumulation/ degradation in beekeeping products.
8. MRL (maximum residue level) in fodder of wintering bees.

Veterinary and Sanitary Evaluation of Toxicological Danger for Cattle Breeding

(for products applied on fodder crops)

1. Parameters and class to toxicity of a product to warm-blooded animals and birds: clinical signs of toxicity, symptoms in poisoning.
2. Method(s) of residue analysis in fodder of agricultural animals and birds (hay, straw, cereals, root crops) (only methods developed for marketable are accepted).
3. Dynamics of residue accumulation/ degradation in fodder of agricultural animals and birds).
4. MRL in fodder of agricultural animals and birds (hay, straw, cereals, root crops) (normatives developed for marketable products can be accepted).
5. Recommendations on possible decrease of residue contamination level in fodder of animals and birds when MRL was exceeded.

APPENDIX 9

TOXICOLOGICAL—FISH—INDUSTRY EVALUATION OF PESTICIDES

1. Techniques of a product indentification in water.
2. Stability of a product in water at pH 7-8 (DT_{50} and DT95).
3. Mean lethal concentration of a product (LC_{50}) inducing death of 50% of Daphnia Magna within 48 h.
4. LC_{50} inducing fatal outcome in 50% fishes within 96 h.
5. LC_{50} inducing fatal outcome in 50% of larvae of sturgen and other fish species within 48 h.
6. Solubility, stability and detoxication periods of a product and its metabolites in water.
7. Analysis of a product effect on chemical composition and selfpurification processes in water medium (pH, dissolved oxygen, nitrogen of: ammonium, nitrates, nitrites; biological oxygen consumption within 5 days (BOC-5); population of saprophyte microflora, organoleptic properties).
8. Analysis of a product effect on processes of primary production of cultures of mass types of monocelled algae. Duration of experiments is 30 days.
9. Toxicity to zooplankton organisms, registration of survival rate, general fertility in 2-4 plankter generations and also physiological, biochemical and morphological anomalies. Duration of experiments is 30-40 days.
10. Toxicity to molluscs, registration of survival, grouth rates, general fertility.
11. Toxicity to fish:

— analysis of material and physiological cumulation;
— analysis of a product effect on developing spawn and larvae of sturgen and other fish species (survival, growth rates, morphological anomalies);
— recent fry and nature fishes (carp, trout, salmon species), survival rate, physiological, biochemical, morphological and other changes.

Duration of experiments is 1-6 months.

12. Mutagenicity to hydrobionts (if necessary).
13. Gonadotropic effect on hydrobionts (if necessary).
14. Immunological effect on hydrobionts (if necessary).
15. Carcinogenicity to hydrobionts (if necessary).

Data for points 1-15 are provided on an active substance (technical product) and preparation form. Studies are carried out on the preparation form.

If data is not provided by an applicant, studies are carried out at one of relevant institutions countries of CIS.

For point 7 data obtained by medical institutions countries of CIS developing MAC for water of Community reservoirs can be accepted.

Tentative safe effect level (TSEL) in water of fish-producing reservoirs is calculated using data of points 1-6. This normative will remain effective for two years.

Maximum allowable concentration (MAC) a product in water of fish-producing reservoirs is determined using data of points 1-15.

APPENDIX 10

ECOLOGICAL—TOXICOLOGICAL EVALUATION OF PESTICIDES

1. Degradation rate of active substance (T_{50} and T_{90}) in soil:
1.1. in laboratory conditions in 2 soils: black soil and grey soil or in similar soils with pH 6.5-7.5 and organic matter content from 1% to 4%. t^{o} — humidity;
1.2. in laboratory anaerobic conditions in one soil (any);
1.3. in field conditions in soils of not less than 2 soil-climatic zones.
2. Content and percentage of metabolites formed during active substance degradation (laboratory anaerobic and aerobec conditions, any one soil).
3. Percentage of bound residues of active substance (laboratory conditions, any one soil).
4. Sorption /desorption index for active substance in 2 soils: black soil and grey soil or similr soils with pH 6,5-7,5 and organic matter content from 1% to 4% (laboratory conditions).
5. Parameters of active substance migration in soils:
5.1. in laboratory conditions in 2 soils: black soil and grey soil with pH 6,5-7.5, and organic matter content from 1% to 4% (thin layer chromatography. TLC, or column tests);
5.2. in field conditions in soils of not less than 2 soil-climatic zones;
6. Evaporation index for active substance (for volatile products) from one soil (any type) (laboratory conditions).
7. Degradation rate of active substance in water (T_{50} and T_{90}, hydrolysis and photolysis in laboratory conditions).
8. Content and percentage of metabolites formed during active substance degradation in water (laboratory conditions).
9. Behavior of a product within elements of rice irrigation system (RIS):
9.1. border check (dynamics of a product content in irrigation water layer and soil);
9.2. collector-drainage system (determination of the amount of product taken away from the border check and away from RIS by surface and underground flow);
9.3. level of active substance vertical migration with filtration flow;
9.4. sorption/ desorption index of active substance in sapropel (laboratory conditions).
10. Toxicity to birds:
10.1. acute oral toxicity (LD_{50});
10.2. eight day dietary toxicity (LC_{50});
11. Toxicity to earthworms (LC_{50}).
12. Toxicity to soil microflora (evaluated by the intensity of soil respiration and nitrogen transformation processes).
13. Phytotoxicity of a product to crops within crop-rotation system and its translocation in a plant.
14. Toxicological and fish-industry evaluation of a pesticide
(Conclusion of Department).
15. Toxicity and danger to honeybees (Conclusion of Department).
16. Spill/leak disposal information. Decontamination and disposal of small quantities of unused product and empty containers. Data for points 1-8 are submitted on active ingredient: for points 1.3, 5.2, 9.1, 9.2, 9.3, 10—13 — on a preparation form. Behavior of a pesticide in conditions specified in points 1.3 and 5.2 must be tested in Countries of CIS.

Data for point are necessary for products planned for registration on rice. Studies necessary for points 9.1, 9.2, 9.3 are carried out countries of CIS.

If data for points 1-16 are not submitted by an applicant then studies are carried out by the research institutions countries of CIS.

APPENDIX 11

METHODICAL INSTRUCTIONS FOR DETERMINATION RESIDUE QUANTITY OF PESTICIDES

An applicant must adapt residue test methods to the conditions of countries of CIS and Republic of Kazakstan according to the requirements of these Regulations.

Residues in or on Food Products, Fodder, Environmental Objects and Biological Environment. (already adapted methods are acceptable).

Methods of Residue Analysis in Agricultural Products (Processed Products) and other Plants (already adapted methods are acceptable).

Methods of Residue Analysis in Soil
(already adapted methods are acceptable).

Methods of Residue Analysis in Water
(already adapted methods are acceptable).

Methods of Residue Analysis in Air
(already adapted methods are acceptable).

Methods of Residue Analysis in Biological Environment
(already adapted methods are acceptable).

APPENDIX 12

INSTRUCTIONS FOR PESTICIDE USAGE

1. Name, manufacturer (applicant).
2. Active substance (according to ISO), (species name of a microorganis, name of a strain or isolate).
3. Concentration (in g/l or g/rg), (titer of active cells or products of their activity, titer of viral bodies, inclusions).
4. Preparation form.
5. Function.
6. Compatibility with other products.
7. Duration of protective effect.
8. Speed of action.
9. Phytotoxicity.
10. Risk of resistance.
11. Recommendations for protection of fauna and flora beneficial objects.
12. Precations related to handling pesticide.
13. First aid in poisoning.
14. Precations related to handling, transportation and storage.
15. Spill, leak and disposal information.
16. Technology of application.

16.1. Preparation of spray solution.

APPENDIX 13

ORDER FOR SUBMITTING AND GETTING AN APPROVAL OF TECHNOLOGICAL REQUIREMENTS FOR PESTICIDES

This document establishes a uniform order of submitting and circulating Technological Requirements (TR) on pesticides and amendments to them. This procedure is valid for all products developed and manufactured by national and other agencies irrespective of their forms of property and subordination.

1. Technological Requirements on pesticides should accompany:
— test samples for registration;
— a test — industrial sample for production-scale tests in cases of temporary registration:
— industrial production of plant protection chemicals included into «The List of chemicals and biological products to control pests, diseases and weeds, growth regulators, pheromones, allowed for usage in agriculture, wood industry and public service...» (hereinafter referred to as «the List»...) for permanent registration.
2. Composition of a formulation should be annexed to Draft TR and it is circulated together with TR.

Composition of a formulation is the property of those who have developed it cannot be passed to any third party without prior consent of the owner. Then approved TR are sent to other organizations for consideration, composition of a preparation form is annexed to a covering document.

3. Draft TR are forwarded for consideration to all interested organizations.
4. Minzdrav (Ministry of Health Care) accepts TR for consideration only with Commission presentation.
5. Commission will get agreement on TR after positive conclusions from all interested organizations have been received. Draft TR (and amendments to them) should be considered by an organization within 30 days from a date of receipt. Agreement of an organization should be in a form of a letter signed by a manager (or his deputy) stamped and sealed. This letter should accompany the documentation or a sertificate should be given.
6. Amendments, extension TR effect of their cancellation should be agreed in a way established for TR.
7. A term of TR effect can be limited, if appropriate, after getting an agreement of Commission and Minzdrav.
8. If additional tests are necessary a developing company sends to authorities a draft notification for extension of TR effect for a test or test-industrial sample.
9. The original (first copy) of approved TR remains in the company where the product was developed.

Another copy having original signatures and a seal is forwarded to Commission within a month after TR approval.

A developing company sends positive conclusions of interested organizations to a manufacturer.

10. TR developed to replace the existing documents (revision) notifications on amendments in TR for manufactured products are circulated in the same way in 30 days.

APPENDIX 14

LABEL
READ CAREFULLY BEFORE USE!

Manufactured and labelled by (name, company and its address)

1. Name, manufacturer (applicant).
2. Active substance (according to ISO), (species name of a microorganism, name of a strain or isolate).
3. Concentration (in g/l or g/kg), (titer of active cells or products of their activity).
4. Preparation form.
5. Function
6. Restrictions
7. Toxicity (indicate Hazard class).
8. Registration number of the label.

A label should contain information on all these points. There is no regulation for its design. It is possible to combine a label for use in one document if technically it can be attached to a pack.

APPENDIX 15

TOXICOLOGICAL EVALUATION OF MICROORGANISMS (Bacteria, Fungi)

1. Pathogenicity (virulence, toxicity, toxigenicity, dessemination) of bacteria, fungi is analyzed in two types of laboratory animals using single intraperitoneal, intragastric administration or exposure to a product by inhalation. Effects on aya mucous membranes should be also analysed.
2. Effects of microorganisms on the immune system (sensitizing, allergic, immunotoxic, immunomodulating) administered through inhalation for one month.

a) Toxicological Evaluation of Microbic Synthesis Products

1. Acute oral toxicity (mice, rats) — LD_{50}, threshold of acute effect (for products manufactured countries of CIS).
2. Acute dermal-toxicity — LD_{50}.
3. Acute inhalation toxicity — CL_{50}, threshold of acute effect/ for products manufactured countries of CIS).
4. Clinical signs of acute intoxication.
5. Skin and mucous membranes irritation.
6. Subacute oral toxicity (cumulative properties), cumulation coefficient (for products manufactured countries of CIS).
7. Subacute epidermal toxicity.
8. Sensitization, immunotoxicity.
9. Chronic toxicity (NOEL, NOAEL).
10. Carcinogenicity (primary summary data on tumor occurence in test animals in absolute values in respect to their effective value, incidence of tumors per one animal, quantity and incidence of histological tumors for different situes, metastasis, survival rate, risk on cogenicity factor, the term of the first tumor occurence, experimental and historical control of experimental animals, etc).
11. Teratogenicity and embriotoxicity, using methods allowing to revela embryo/ fetal anomalies or any signs of toxicity.
12. Reproductive toxicity using 2-generation studies and gonadotoxicity.
13. Mutagenicity:

— Ames for gene mutations with and without microsomal activation;
— chromosomal abberrations (in vivo in laboratory animals);
— in vitro in human peripheral blood lymphocyme culture:

Other tests can be used but not less than three including Ames test.

14. Metabolism in mammals, major metabolites, their toxicity, toxicokinetic and, if appropriate, toxicodynamics.
15. Limiting factor of toxicity.
16. Allowable daily intake (ADI) mg/kg of human body weight.
17. Other information.

b) Toxicological Evaluation of Preparation Form of Microbiological Preparation

1. Acute oral toxicity (mice, rats) — LD_{50}.
2. Acute inhalation toxicity — LC_{50}.
3. Irrigative and resorptive (if appropriate) effect on skin and mucous membranes.

4. Sensitization.
5. Cumulative properties (for pesticides based on products of microorganism activity).
6. Disbacterial effect.
7. Composition of contaminant microflora (for viral and microsporodial products) and pathogenicity for warm-blooded species.
8. Follow up effects (for toxin containing products) mutagenicity (Ames test), teratogenicity.

c) Establishment of Hygienic Nnormative Usage and Production of Microbiological Preparations

1. Analysis of residue dynamics meeting the requirements of these Regulations if it is necessary to develop hygienic normatives.
2. Hygienic analysis of labor conditions during product application taking into account maximum dose rates and various technologies.

In greenhouses analysis of labor conditions is performed irrespective of the available data on field conditions.

3. Some grounds for the necessity of hygienic normatives and their development providing the safety for population and for employees involved in manufacture and use of pesticides (if appropriate):

— MRL in food products;
— MAC in water of community reservoirs:
— MAC in the air of a working zone (for products manufactured countries of CIS);
— TSEL in the air of a working zone (for imported products);
— MAC in soil (for stable products able to translocate within a plant and migrate into other systems);
— TAC in soil for the rest of products.

APPENDIX 16

ESTABLISHMENT OF HYGIENIC NORMATIVES, SANITARY NORMS AND INSTRUCTIONS FOR USAGE AND PRODUCTION OF PESTICIDES

1. Study of residue meeting the requirements of these Regulations and substantiation of expectation terms for each crop.
2. Hygienic analysis of labor conditions under product application taking into account maximum dose rates, number of treatments and various technologies. Proposals supported by appropriate data on re-entry periods. In greenhouses analysis of labor conditions is perfirmed irrespective of the available data on field conditions.
3. Some grounds for the necessity of hygienic normatives and their development proving safety for population and employees involved in manufacture and use of pesticides:

— maximum residue level (MRL/ temporary MRL) in food products and agricultural raw material:
— maximum allowable concentration (MAC) in water of community use;
— MAC in the air of a working zone (for products manufactured and packaged in CIS countries and for imported products with pronounced inhalation toxicity). TSEL in the air of a working zone for the rest of products:
— tentative safe effect level (TSEL) in atmospheric air (if appropriate);
— MAC in atmospheric air (for products manufactured in CIS countries):
— MAC in soil (for stable products able to translocate within a plant and migrate into neighboring environment);
— tentative allowable concentration (TAC) in soil for the rest of products.

4. Hygienic analysis of pesticide hazards, recommendations for a label, use instructions, precautions.

In the development of Hygienic normatives for water reservoirs, data on the effect of a product on chemical composition and selfpurification processes in water environment obtained at a research institution or at the other organization, responsible for ecological evaluation of pesticides can be accepted it this evaluation is carried out according to uniform methods.

In the development of hygienis normatives for soil, data on pesticide behavior in soil obtained by a research institution or at the other organization responsible for ecological evaluation of pesticides can be accepted if this evaluation is carried out according to uniform methods.

APPENDIX 17

UNIFORM REQUIREMENTS TO ANALYSIS OF PESTICIDE RESIDUES AND TO COMPOSING REPORTS

Field tests analysing pesticide residues in dynamics are carried out according to relevant «Methodological Instructions on Registration Tests...» for each group of pesticides (insecticides, fungicides, herbicides, etc).

If can be either 2-year experimental tests establishing biological parameters of pesticide application, or 2-year special tests in zones, where registration tests are carried out.

A report on the results of analysis of pesticide residue dynamics should include the following parts and information:

1. Brief description of objects and tasks or a test.

2. Brief characteristics of an analyzed product and his functions.

3. General description of a test with information about locations, type and duration of tests, size of plots and number of repetitions, type of samples in which pesticide were analyzed in dynamics.

4. Characteristics of soil, weather and climatic conditions with many-year averages for vurious meteorological parameters and analysis of conditions during test periods.

5. Information about application of the analysed product: a preparation form, way and number of treatments, timing and dose rates by product and by active substance.

6. Methods of taking samples and their storage conditions: Samples are taken and stored according to «Unified Rules of Taking Samples of Agricultural, Food products — and Environment Objects to Control Pesticide Microquantities» of 21.08.1979, № 2051-79.

Samples are taken separatelly from each repetition (a total of 4 repetitions) including untreated control. An average sample is prepared from these samples. Two analytical samples are taken from an average sample for analysis.

Usually average samples are taken to a laboratory on the same day and kept frozen to the moment of analysis.

Long distance transportation of samples is possible only in special containers (thermos) with dry ice or cooled-by cooling element to temperature of maximum -2°C.

Specific details on sample storage and transportation are written in the report.

7. Techniques of residue analysis.

The following methods can be used for analysis of residue dynamics and residue content in yield elements:

— methods of a manufacturer (an applicant) or internationally accepted methods accuratelly reproduced in a laboratory;

— methods of a manufacturer (an applicant) adapted to conditions of laboratories and tested at least once;

— methods either under approval or already approved.

In the report an executor of the test should refer to approved methods. Description of unapproved methods is arranged according to requirements and annexed to the report.

8. Trade mark of a chromatograph (other instrument or plates), limits of accuracy, limits of extraction and existing hygienic normatives for the pesticide.

9. Data on the dynamics of analysed pesticide residues in tested objects under maximum dose rates and number of treatments during two seasons tests in all soil-climatic zones where biological evaluation is carried out and where this pesticide is planned to be registered. To secure accurate analysis of results

and the possibility of calculating degradation rate pesticides. samples are taken for analysis within the following terms:

Recommended time of last treatment (waiting period)	Terms of sample selection (days)
2 days	0*. 1. 2. 3. 4
3 days	0. 1. 2. 3. 5
7 days	0. 3. 5. 7. 10
10 days	0. 4. 8. 10. 12
15 days	0. 5. 10. 15. 20
21 days	0. 7. 14. 21. 28
30 days	0. 10. 20. 30. 40
40 days	0, 14. 28. 40, 50
50 days	0. 20. 35. 50. 60
60 days	0. 20. 40. 60. 70
More than 60 days	on harvest day **

0*, day of the last treatment, samples are taken after 2-3 hours of treatment.

0** for pesticide used for pre-plant seed treatment, applied before seeding, immediately after seeding. before flowering (orchards, and berry crops), post-em if last treatment was done more than 60 days before harvest. In this case residues are evaluated only in the elements of the yield.

For pesticides recommended for use on fodder crops or crops whose green mass can be immediately used as animal fodder it is necessary to study active substance degradation dynamics (all active substance for mixtures) according to the above scheme and waiting period recommendations of an applicant company.

For pesticides recommended for use on open-field vegetables harvested several times during season (cucumbers. tomatoes, eggplant, pepper, early varieties of cabbage) first samples should be selected when the crops were treated at a friut-or head-forming stage according to the above scheme with a recommended 7-day waiting period (a third line in the table: 0, 3, 5, 7, 10 days after treatment).

If treatments are alternating with harvests samples are taken separately for each harvest according to the same scheme (5 samples after each treatment). When pesticides are tested in production fields where nature crops are harvested once samples are taken according to a general scheme.

For pesticides recommended for use on vegetables in glass-houses harvested many times during season (cucumbers, tomatoes, eggplant, pepper) first samples are taken when the crops are treated at a fruitor head forming stage according to the scheme with a recommended 3-day waiting period (a 2-nd line in the table: 0, 1, 2, 3, 5 days after treatment). If treatments are alternating with harvests samples are taken separately for eash harvest according to the same scheme (5 samples after each treatment).

For pesticides treatment for use on greens green peas, table beets, crops with vegetation period less than 60 days (garden radish, beets and carrobs, etc.) analysis of active substance degradation dynamics is carried out according to a general scheme. In all cases analysis of final products by yield elements (and of processed if appropriate) is necessary.

Residue analysis is not needed for pesticides applied on plants used for multiplication, seed-producing crops, in nurseries, on medicinal and ether-oil herbs used for individual substance extraction, on medicinal and ether-oil herbs harvested a year after treatment, on ornamentals.

Results of analysis are presented in the form of a table:

Product (Variant of the experiment) Data of treatment Dose rates including by a.i. Number of treatments	Terms of sample selection	Data when samples are selected	The content of the substance in the analyzed object	Data of analysis

10. Conclusions on the analysis results.

A report should be signed by executors, approved by a chief administrator and sealed by the seal of an institution (copies are not accepted). Acts on sample taking (originals), copies of typical chromotograms on all variants, objects, terms of sample selection or any other technical information supporting the results of experiment should be attached to the report.

An separate report is done on each product planned for registration.

The report should be arranged according to the Regulation.

APPENDIX 18

UNIFORM REQUIREMENTS TO TECHIQUES OF RESIDUE AND PESTICIDE METABOLITES ANALYSIS IN FOOD PRODUCTS AND ENVIRONMENTAL OBJECTS

These Regulations are valid for techniques used for analysis of pesticide content in air, water, soil, food products, fodder, biological material.

This document sets forth uniform requirements to the arrangement contents, idea of normative documents (certificates, methodological instructions) for technique of pesticide residue analysis in food products, fodder and environmental objects, requirements to instruments, reagents, preparation for tests and to tests themselves, processing of results, metrological background.

1. GENERAL INFORMATION

1.1. Methodological instructions on residue analysis in agricultural raw material, food products, fodder and environmental objects must meet the requirements to scientific-technical documents.

1.2. Methodological instructions should be developed for products included into the list of pesticides allowed for use, and also products recommended for registration tests.

1.3. Methodological instructions must:

1.3.1. employ modern physical and chemical techniques including photometry, chromatography, etc, tested experimentally and practically and supported metrologically;

1.3.2. recommended to work with instruments that have passed state tests and were included into a national catalogue CIS and produced in big quantities, and also instruments requirements to which were set forth by national standards and technical normative documents;

1.3.3. recommended to use instruments recording data in a form convenient for statistical analysis including instruments connected to computers;

1.3.4. employ doubling techniques similar in accuracy to increase significance of identification and to provide a possibility of using available instruments;

1.3.5. include requirements to the safety of labor conditions and occupational sanitation.

1.4. Methodological instructions are in effect without any time limit. Techniques are reconsidered and reapproved with improvement of analysis procedures.

2. UNIFORM REQUIREMENTS TO TECHNIQUES

2.1. Methodological instructions should have an introduction and description of a technique (or techniques) containing the following information:

- general information;
- reagents and materials (instruments, equipment, vessels, glassware);
- sample taking;
- preparation to tests;
- testing;
- processing of resilts;
- safety measures;
- authors.

2.2. The title of methodological instructions should include a name of an active substance of a product (according to ISO) or a name of a chemical group, target objects and a principle of analysis. For example, «Methodological instructions on the analysis of chloro-organic pesticides residues in soil using thin-layer chromatography»; «Methodological instructions on the analysis of Methylparathion residues in plants using gas-liquid chromatography».

2.3. Introductory part of the document must describe the purpose and the field of technique(s) application and should be formulated in the following way: «These methodological instructions are developed for agencies and instructions of sanitary and epidemiological inspection or Ministries of Health Care and also for veterinary, agrochemical, Control-toxicological laboratories of Ministry of Agriculture and laboratories included into a system of other ministries and departments, responsible for pesticide residue analysis in food products, fodder and environmental objects».

2.3.1. Introduction should contain:

— name of a manufacturer;

— trade name of a product (if there are synonyms name only those whose residues could by analyzed using the same technique(s);

— name of an active substance according to ISO (International Standardization Organization);

— name of active substance according to IUPAC (for products of CIS countries according to commonly accepted standards);

— structural formula;

— empirical formula;

— molecular mass;

— specific gravity;

— isomers;

— refraction index (for liquids);

— aggregate state;

— color, odor;

— volatility (vapor pressure in mm Hg at 20°C and 40°C);

— soludility in water and major organic solvents;

— emlting point;

— boiling/ freezing point;

— partition coefficients if known;

— brief toxicological characteristics: ADI, acuta peroral toxicity; acute dermal toxicity, acute ihalation toxicity, specific toxicological properties (possibility of forming more toxic metabolites and ieir characteristics);

— hygienic normatives;

— area of application;

— pesticide group according to classification by its mode of action and object of application, or ant and crop growth regulator (eg, post-em herbicide in potatoes).

2.3.2. First part of the document should have a title: «Techniques of analyzing (ISO name of an tive substance)... (object)... using (technique). For example: «Lindane analysis in soil using thinlayer iromatography», «Methods of Simazine, analysis in soil using spectrophotometry».

2.3.3. Subsection «General Information» should describe a principle on which the technique is sed and state major parameters of determination and possibility of detecting major toxic metabolites. ir example, «The method is based on Lindane chromatography in a thin layer of silica gel in n-xane-aceton system and purification of the extract using concentrated sulfuric acid», «The technique based on Lindane analysis using gas chromatography with a detector of contact recombination rate of SE-30 immobile phase after extraction — by n-hexane-aceton mixture and purification of the extract a column with silica gel», «The method is based on optical density measurement in Simazine ntaining solution».

If an active substance is analyzed together with its toxic metabolites, they should be listed.

Metrological characteristics of a method should be also described in this subsection:

— range of analyzed concentrations;

— limit of detection in mg;

— limit of detection in mg/kg, mg/l, mg/m3; except otherwise specified, limits of detection should not exceed normatives;

— average values of standard pesticide residues in a sample in per cent.

In order to fix a determination percentage in various crops it is necessary to conduct analysis of typical representatives (see Table 2), and in case of narrow sphere of pesticide application -in those crops for which the preparation is designed for. From each environment 4 concentrations with 6 tests a within the range of the measured concentrations are taken. (i.e. 24 tests) sufficient for standardization.

The following values should be calculated:

— average limit of extraction for each environment in per cent;

— confidence interval for six parallel determinations (minimum number of parallel determinations (n) is 6);

— standard deviation (S);

— relative standard deviation (DS);

confidence interval of a mean value at p=0,95 and n=57

Average of the determination of standard quantities and confidence interval of a mean value should be given for 4 concentrations;

— equal to a hygienic normative;

— equal to a doubled detection limit;

— equal to half of a hygienic normative if it is higher than the limit of detection;

— equal to determination maximum.

If hygienic normatives are not yet set, then an average value is determined in 4 concentrations within a tested range.

Selectivity of a technique in the presence of pesticides close by their chemical structure and field of application.

If some impurities are interfering with determinations it is necessary (if possible) to describe them and indicate concentration where their influence starts to show.

2.4. Subsection «Reagents and Materials» should contain a list of reagents and materials used for residue analysis and also information on their purity in relation to the existing standards, normative-technical documentation (NTD) and also solutions with information on their shelf-life and the necessary quantity for one test or measurement, or for what number of tests the volumes of these or those solutions (including standards) prepared according to this technique could be used.

Description of a gas-chromatography technique for residue analysis should contain information on the type of chromatograph, type of detector and its selectivity, column material, length and diameter, sorbent-carrier and type of steady (stationary) phase.

Information on thin-layer chromatography in residue analysis should include size of plates, thickness of a layer, a sorbent mark and its graining.

Information on optical methods of pesticide residue analysis should state type of the instrument, type and size of cuvettes and type of a catode lamp.

2.5. Subsection «Preparation to Analysis» should include requirements to all types of activities preceding pesticide residue analysis including preparation of standard, calibration and other solutions with information on their shelf-life, perifacation of solvents, preparation of chromatography plates, packings— and conditioning of columns, plotting calibration curves.

— the way and the extend mobile solvent saturation with vapors;

— path length of a solvent;

— developing reagent:

way of treating chromatograms (heating, UV radiation, etc).

— R_f value (an average of live determinations):

quantitative analysis:

— linear range of concentrations:

— stability of stains in time and the way of chromatogram fixation.

If densitometer is used its major parameters are given in section.

For high-performance liquid chromatography of pesticide residues the following information is necessary:

— composition of a washing agent:

— its flow velocity:

— type of detector:

— volume of a sample:

— refention time:

— linear range of detection;

— quantitative analysis:

— electrometer scale readings;

— recorder strip feed rate.

In photocolometric and spectrographic analysis the way or preparing calibration solutions should be presented as a table and a wave length at which optical density of calibration solutions. Is measured should be stated.

For example:

Components	Number of calibrating solutions						
of calibrating solutions, their volume	1	2	3	4	5	6	7
Standard simazine solution, ml	0,0	0,1	0,2	0,4	0,6	0,8	1,0
Simazine content mg/ml	0,0	10	20	40	60	80	100

To increase reliability of a product identification the technique must include other alternatives for extract purification.

Residue analysis using gas chromatography should include analysis on at least two columns filled with immobile phases of different polarity.

As a rule residue determinations using thin layer chromatography should include alternative conditions of chromatography (different sorbents, developing reagents, at least two mobile solvents).

2.6. Subsection «Analysis of results» should describe how the obtained results were analysis and what equations were used for calculation of analysis results. Content of pesticide residues in analyzed samples is calculated as an average of two-three parallel determinations.

2.7. Part «Safety requirements» must contain specific recommendations on safety measures while performing residue determinations which should meet the requirements of «Rules of ogranization, safety engineering, occupational sanitation; antiepidemiological measures and personal hygiene when working at medical, sanitary and epidermiological institutions within the system of the USSR of Health № 2455-81 dated 20.10.81.

2.8. Part «Designers» should offer information of the author(s) who took part in the development of a technique: family name, name, place of work, mailing address, telephone.

If several author groups were developing the technique they are numerated and the number of each group is shown in a relevant part of the text describing the technique and references are given in brackets.

2.9. The document must have information on techniques before (if available) but without effect since the approval of these Regulations. If any part of the technique was approved before, the number, date and body of authorization should be stated.

Table 2

Substance	Typical representatives
1	2
Water	from drinking open reservoirs.
Soil	loamy containing small large amount of numus
Air	of working zone and atmospheric
Products of animal origin	muscular tissue (meat), liver, fat, eggs, milk and milk products
Field crops:	
— grain	wheat, rye, corn, barley, oats, rice
— bean	peas, soy bean
— oil-yielding	sunflower, cotton
— technical spinning	cotton, flax
— technical	sugar beet
— fodder	perennial grass, lucerne, corn
Potato	potato
Root plants	carrot, beet
Perennial friutful:	
— seed plants	apples, pears
— plants with pits	plum, cherry, apricot
— citrus	tangerine, lemon
Grapes	grape
Berry plantations	black red currants, raspberry, strawberry
Vegetables:	
— cucumbers	cucumbers
— tomatoes	tomatoes
— green	dill, parsley; celery, lettuce, spinch
— cabbage	white-headed cabbage
Vegetables of closed ground	cucumbers, tomatoes, pepper, green crops
Melon crops	water melon, melon, gourd
Special crops	defined according to the Sphere of preparation application

UNIFORM REQUIREMENTS TO STANDARD SPECIMEN (SAMPLE)

Pesticide standard specimen (sample) must be homogeneous upon chemical composition containing the main substance not lower than 97—99%.

Contents of standard specimen elements is not to be altered in the process of measurement (analysis) as well as in storage during 2—3 years.

In standard titrated solutions precise concentration of active substances, reagents must be indicated.

APPENDIX 19

ORDER

FOR DEVELOPMENT, ADAPTATION, TESTING AND CONFIRMATION OF TECHNIQUES OF ANALYSING MICROQUANTITIES OF PESTICIDES AND THEIR METABOLITES IN AGRICULTURAL, FOOD PRODUCTS, BIOLOGICAL MEANS AND ENVIRONMENTAL OBJECTS

1. All activites in development, adaptation, approbation of techniques and preparation of document for confirmation affirmation are carried out on the contractual basis between a firm-manufacturer, Comission and a executor. The amount and terms of activities implementation are determined in the contract and are found to be a prerogative of the parties. Total cost of the work is fixed by the agreement of the parties but is not to lower than minimal costs taking into account all expenses and qualification of the executor. Costs of developing and adapting techniques should include expenses on testing and expertise.

2. Priority right to develop, adapt and test techniques is granted to organizations and specialists indicated in «The List of institution and registration of test system». This list can be annually revised and added by the experts group with following confirmation by the Commission.

3. At the end of development and adaptation technique the executor activities submits to the Commission the detailed description, edited and arranged according to uniform requirements (to this Appendix18) and supplemented with reviews of those who have tested them.

4. For testing the technique is submitted by the firm-manufacturer. Commission signs a contract and then sends it to a scientific-research institute, laboratory of the Ministry of Agriculture and one to control toxicological laboratory or Design and Survey chemization Station of the Ministry of Agriculture, which are included into the system of registration tests (totally there should be two acts of approbation).

5. Approbator submits a detailed conclusion stating its advantages and disadvantages, the possibilities of its reproduction in conditions of a practical laboratory. The conclusion should be sumplemented by copies of chromatograms or other technical documentation on the results of analysis of three tests in three times repetitions (1-idle, 0,5 MAC or MRL, MAC or MRL or three lowest detection limit) in two most complex environments.

7. Having received approbation acts the technique of the firm-manufacturer is affirmed as the official one by the Commission upon the Board experts conclusion.

APPENDIX 20

MINISTRY OF HEALTH CARE OF THE REPUBLIC OF KAZAKSTAN

HYGIENIC SUBSTANTIATION №:_____

on toxic-hygienic esmation of chemical, biological protection means and plant growth regulators.

Ministry of Health Care of the Republic of Kazakstan considering the materials of toxic-hygienic estimation

_____

(name of the preparation being registered)

permits its application in agriculture observing sanitary rules, norms and hygienic normatives _____

_____

(to point out the application sphere, limitations and etc)

and grants №:_____ of state hygienic registration.
The present hygienic substantiation is valid for_____years.

On altering prescription, technology of receiving, conditions and application sphere or discovery of features dangerous for human health, the present hygienic substantiation can be cancelled.

The hygienic substantiation is issued by _____

_____

(name of the organization, institution, establishment)

Chief State Sanitary Doctor
of the Republic of Kazakstan
(deputy) _____

«___»_____19_____