

Plant Protection Products and Fertilizers trials for state registration in the Republic of Belarus

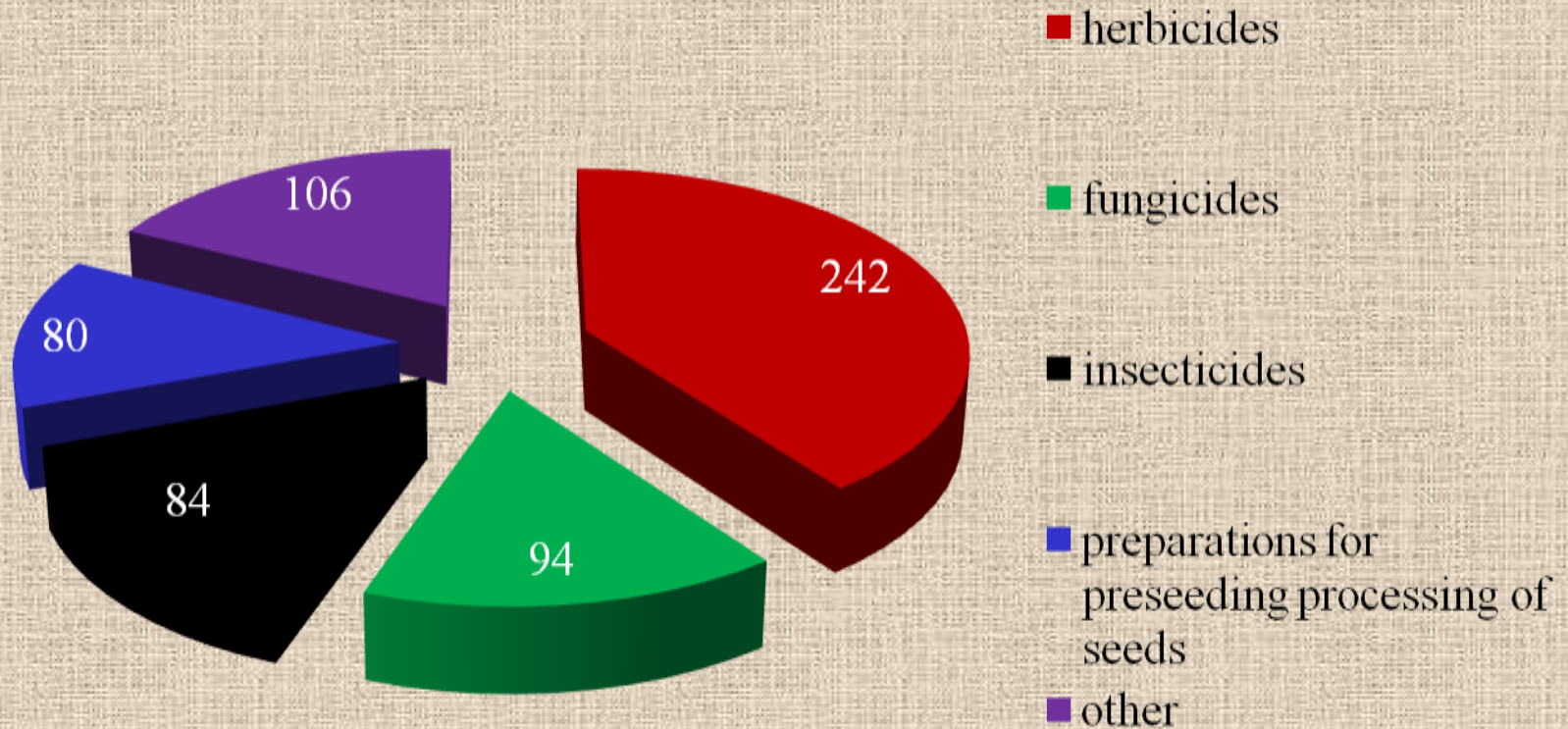
Belarus, 2009 год

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The state registration of pesticides in the Republic of Belarus



Total: 606 plant protection products and 256 active ingredients



The obligatory condition for state registration of pesticides and fertilizers is their trials, which include state hygienic regulation, assessment of biological and economic efficacy and development of their application regulations.

Trials for plant protection products and fertilizers for evaluation of biological and economical efficiency are performed by legal institutions that passed assessment in accordance with “Instruction on order of carrying out trials of plant protection means and fertilizers, which are subjected to state registration” and “Instruction on order of carrying out certification of legal institutions conducting trials of plant protection means and fertilizers, which are subjected to the state registration”.

The certification is carried out by the Ministry of Agriculture and Food of the Republic of Belarus .

Biological and economical efficiency trials of Plant Protection Products, with new or registered earlier active ingredients and their combinations, must be carried out during two-seasons for each crop.

One season trial is necessary to extend the registration for a new crop.

Biological and economical efficiency trials can be prolonged for one more vegetation season in case of unusual conditions. Residues of Plant Protection Products in plant production are determined during biological and economical efficiency trials of Plant Protection Products.

The rules of Plant Protection Products and Fertilizers use for including into the “State Catalogue of Plant Protection Products (Pesticides) and Fertilizers allowed for usage in the Republic of Belarus” are discussed by experts for evaluation of biological efficiency of herbicides, insecticides, fungicides and seed treatment products, biological products, pheromones, growth regulators and fertilizers during their workgroups meetings.

The members of expert workgroups

The Ministry of Agriculture and Food

The Ministry of Forestry

The State Enterprise “The Main State Inspection for Seed-Growing, Quarantine and Plant Protection”

The National Academy of Sciences of Belarus



Information on legislation about plant protection of the Republic of Belarus can be obtained on the sites: www.pravo.by, ggiskzr.by.

The basic technical normative legal certificates (acts)

- SR № 2.2.3.12-17-2003 “Hygienic requirements to storage, application and transportation of pesticides and agrochemicals”
- The instruction № 2.2.3.10-24-81-2006 “Requirements to carry out state sanitary-and-hygienic expertize of plant protection means”

Functions of State Institution «Republican scientific - practical center of hygiene» Ministry of Health of Republic of Belarus on pesticides safe handling on the territory of Republic of Belarus

- Full toxico-hygienic expertize of pesticides data for their hygienic registration in BY;
- Adaptation of methods for pesticides active ingredients determination in environment and agricultural production (the purposes are:
 - to implement state sanitary inspection of manufacture and application of pesticides,
 - to check pesticides residue content in food stuffs,
 - to reveal possible contamination sources of environment,
 - to monitor inhabitant surroundings);
- Development of pesticides hygienic specifications (provides their safe use, an opportunity to control their contents in environment);
- Development of recommendations for pesticides safe application;
- Investigation of labour conditions during pesticides application to estimate risk of adverse influence on workers;
- Toxicological investigation of new synthesized pesticides formulations and their active ingredients.

Toxico-hygienic expertise of pesticides

- The manufacturer of a pesticide and active ingredient
- Trade name
- Function
- Active ingredient. Chemical class. Concentration (in g/l or g/kg). Formulation
- Sphere of application (on what crops it is supposed).
- Recommended rate and way of application. Recommended rules of application. Recommended pre-harvest period.
- Physical and chemical properties of active ingredient (structural formula, the empirical formula, molecular mass, aggregate state, solubility in water, solubility in organic solvents, color, odor, etc.). Purity of a technical product, qualitative and quantitative composition of impurity.
- Physical and chemical properties of formulation (aggregate state, color, odor, a hydrogen index, water content (%), qualitative and quantitative composition of impurity, storage stability).
- Physical and chemical characteristics, percentage and function of constituents in formulation.

- The toxicological characteristic of active ingredient:
- Acute oral toxicity, a threshold of acute action. Acute dermal toxicity acute inhalation toxicity. A threshold of acute action. Clinical signs of acute intoxication
- Skin and mucous membranes irritation
- Delayed neurotoxic effect in hens (it is necessary for phosphorus-organic pesticides, for others - if necessary);
- Subacute oral toxicity (cumulative properties), cumulative coefficient.
- Subacute epidermal toxicity
- Sensitization, immunotoxicity
- Chronic toxicity (NOEL, NOAEL)
- Carcinogenicity determined by administering a test agent to two types of animals (mice and rats) for two years.
- Teratogenicity and embryotoxicity, using methods allowing to reveal embryo/fetal anomalies or any signs of toxicity.
- Reproductive toxicity using 2-generations studies and gonadotoxicity

- Mutagenicity: (not less than three tests, including Ames test and mammal test in vivo)
- Metabolism in mammals, major metabolites
- Limiting factor of adverse effect allowable daily intake (ADI) mg/kg of human body weight
- Metabolism in environmental objects including agricultural plants.
- Toxicology of a Formulation and its constituents
- Product Composition (Chemical names of each constituent of a product, function of constituents in a formulation)
- Acute oral toxicity , acute dermal toxicity, acute inhalation toxicity;
- Skin and mucous membranes irritation
- Subacute oral toxicity (cumulative properties), cumulative coefficient. Subacute epidermal toxicity
Subacute inhalation toxicity
- Sensitization;
- Toxicology of the formulation ingredients (fillers, emulsifiers, stabilizers, solvents).
- Hygienic Characteristics of a Formulation: Effect on the quality and nutritional value of crops

- Recommended hygienic normatives of residual quantities of pesticides in foodstuff and environment, waiting periods (for persistent formulations capable to translocate into plants and migrations in adjacent environments maximum allowed concentration for soil is submitted, for other formulations - approximate allowable concentration in soil is submitted).
- Recommendations on diagnosis and treatment in case of acute poisoning including first aid measures in poisoning, antidotes
- Residues data and data on waiting periods for each crop
- Hygienic analysis of labour conditions during product application taking into account maximal dose rates, number of treatments and various technologies in conditions of Republic of Belarus/ Proposals supported by appropriate data on re-entry periods
- Speed of decomposition of active ingredients (T50 and T90) in soil and water;
- The name of toxic metabolites if those are available;
- Methods of residue analyses in environment and food

Experimental toxico-hygienic researches

- For active ingredient and formulation of foreign pesticide:
determination of danger class on base of acute oral toxicity and dermal toxicity on laboratory animals with estimation of a clinical picture of toxic action and establishment of LD50, LD50cut and comparative characteristic of a clinical picture of acute intoxication and parameters of acute toxicity with the original data (in dossier of the firm).
- For locally produced pesticide (formulation is produced on the territory of Belarus using foreign active ingredients): laboratory experiment on acute toxicity of formulation (oral, dermal, inhalation) using laboratory animals with estimation of clinical picture of toxic action, establishment parameters of acute toxicity and a class of danger; studying irritating influence on eyes; researches on subacute toxicity of formulation in two-months experiment on skin and mucous membranes of laboratory animals; an estimation of sensibilizing effect of formulation.

For locally produced pesticides **(formulation and active ingredient are** **produced on the territory of Belarus)**

- Laboratory experiments on acute toxicity of formulation and active ingredient (oral, dermal, inhalation) on laboratory animals with estimation of a clinical picture of toxic effect and an establishment of parameters of acute toxicity and a class of danger;
- Studying irritating effect of formulation and active ingredient on skin and mucous membranes of eyes of laboratory animals;
- Studying subacute toxicity of formulation and active ingredient in two-months experiments on laboratory animals;
- An estimation of sensibilizing effect of formulation and active ingredient of pesticide;
- Studying chronic toxicity, the remote effects (embryo-and gonadotoxic effect, reproductive toxicity, mutagenic and cancerogenic properties)of active ingredient with an establishment of maximum invalid dozes, calculation of an allowable daily doze and a substantiation of hygienic specifications.

For all categories of pesticides conduct

- A hygienic estimation of labour conditions with calculation of all allowable risk at application of a pesticide taking into account maximal rates, applications number and various technologies in conditions of Belarus, a substantiation of terms of a safe re-entry periods
- Studying labour conditions for pesticides used in green houses is carried out irrespective of labour conditions results availability in conditions of an open air .
- Labour condition trials are conducted for private and state firms separately in each case;
- Residue determination of pesticide in agricultural products .
- Active ingredient amount determination in formulation
- Approval and adaptation methods of active ingredient residue amount determination in environment and agricultural products.

Supervision of plant protection means application in agriculture is carried out

- At storage and delivery of pesticides and agrochemicals
- At work with machines and equipment
- At application of pesticides and agrochemicals using ground equipment
- At application of pesticides and agrochemicals using aviation equipment
- At application of pesticides and agrochemicals in green houses
- At seed treatment, their storage, transportation and sowing
- At application of pesticides and agrochemicals in private farms
- At use of individual protection means by workers contacting with pesticides and agrochemicals
- At disinfection of transport means, equipments, containers, premises and overalls
- At performance of environment protection actions and maintenance of release of qualitative food production
- At transportation of pesticides and agrochemicals.

Main principles of the state sanitary- and-hygienic expertize

- It is compulsory
- Its conclusions are scientifically based;
- Independence of experts;
- It's complete
- It's confidential



THANK YOU FOR YOUR ATTENTION