POLGAR ACRO
Agrochemical Consulting and Registration Office

Registration of Pesticides in Ukraine: Procedure and Requirements

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Introduction

- Registration mantanence time, steps and requirements are defined in the Procedure for State Registration of Pesticides and Agrochemicals (Approved by Resolution of the Cabinet of Ministers from 04.03.1996 № 295)

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Overview: Timing

1) Temporary registration for 1-2 years.
Takes 1 – 1,5 years to get.
Allows to start import and sell a product
Needs 1 season of bio.effic. trials

2) Permanent registration for 5-10 years
Takes 2 – 2,5 years (including 1 – 1,5 for temporary)
Does not need 2nd season of bio.effic. trials

* Most of toxicological studies are required only during the second year (for permanent registration)

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Overview: Steps

1. Application is submitted to the Ministry of Environment (January)
2. Inclusion into **biological efficiency trials plan of the Ministry of Environment (January-February)**
3. **Communication of trials programme** and calendar plan (March)
4. Submission of toxicological dossier
5. Submission of eco toxicological dossier
6. ADI, Hyg.of labor trials, residue
7. Collection of biological efficiency reports and submission of this reports to toxicologists (October)
8. Collection of toxicological conclusions (November)
9. Preparation of new Application
10. Submission of all documentation to MoE
11. Expertise of MoH (tox), Expertise of MoE (comprehensive)
12. Scientific Expert Council approval (MoE)
13. Registration issued

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Costs

Country	Pesticide with 1 A.I. for 2-3 crops and several pests	Pesticide with 2 and more A.I. for 3-4 crops and several pests	Highest cost belongs to
	Cost of registration	Cost of registration	
Ukraine	App.from 30.000 euro	App.from 40.000 euro	Hygienic studies and residues

* **Costs vary greatly depending on number of crops and pests.** Costs are given assuming that a company has complete toxicological dossier of both A.I. and product formulation. Otherwise additional expenses will follow. Costs are given for **permanent** registration.

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Authorities and institutes

Authorities

- Ministry of Environment and Natural resources (MoE)
- Ministry of Health (MoH)

Expert Institutions

- Efficiency trials: Crop protection Institute, Institute of Agroecology, Beetroot Institute, Potato Farming Institute, etc
- Toxicology, residue, hygiene of labor: Institute of Hygiene and Ecotoxicology n.a. Medved, Institute of Labor Medicine, National Medical University
- Eco Toxicology: Institutes belonging to the National Academy of Sciences, National Academy of Agricultural Sciences, Medical Institutes, etc

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Requirements

2 things to remember!

- Ukrainian authorities accept “foreign” tox and eco.-tox. studies if all requirements are kept and quality is acceptable. GLP is highly appreciated.
- Some studies can be made in Ukraine only (for example, same as in Russia bio.effic.trials and residue)

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Requirements: Application

Application or Data on Pesticide or Dossier Summary must be prepared in Ukrainian according to an established format and submitted to the Ministry of Environment

Data on pesticide must include:

- Data on applicant and producers
- Data on application of product
- Phys.-chem. information for A.I. And products
- Influence on non-target objects
- Data on Biological Efficacy and Safety of product
- Toxicological and Hygienic Characteristics of A.I. and product
- Residue
- Hygienic analysis of pesticide manufacturing and application
- Ecological Characteristics of Pesticide (both A.I. and product)
- Ecotoxicology

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Requirements: Format and Language

1. **Application** must be submitted as a **hard copy**
2. **Study reports** as a **hard copy or CD**
3. All documents must be delivered **from hands to hands**, it is better to avoid sending by post.
4. All **expert conclusions** must be collected and delivered to other institutes (as required by the procedure) by an applicant
5. For every document except toxicological and ecological data from other countries **the language is Ukrainian or Russian**
6. For **toxicological studies English is allowed**.
7. **No** German, French or **any other language is accepted**
8. **Communication** with authorities and institutions is possible **in Ukrainian and Russian**

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Requirements: Studies

Every new applicant has to generate full kit of studies. Situation is identical to Russia

Toxicological evaluation

Product:
Acute oral, acute dermal, acute inhalational toxicity, skin and eye irritation, sensibilization

A.I.:
Acute oral, acute contact toxicity, skin and eye irritation, sensibilization
Sub-chronic toxicity (90 days) – oral, inhalation, dermal, etc
Cancerogenicity, mutagenicity, reproductve toxicity, neurotoxicity, metbolite toxicity

First and up to now the only GLP certified Laboratory is located in Kyiv at Institute of Hygiene and Ecotoxicology n.a. Medved

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Requirements: Studies

Influence on non-target species

- The risks to insect pollinators, acute oral, acute contact
- Acute toxicity to fish, Chronic toxicity to fish, eggs, juvenile fishes
- Reproductive studies on fish (eggs, juvenile fishes, commercial fish)
- Bioaccumulation,
- Acute toxicity to daphnia, reproduction studies on daphnia
- Inhibition of the algae growth
- Effects on beneficial insects (save for the marked above)
- Acute toxicity to birds, effects on wildlife birds
- Toxicity to earthworms
- Effects on soil microorganisms
- Degradation and transformation in soil, in water

*Data from the literature sometimes **may be accepted.***

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Requirements: Studies

Toxicological evaluation

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Challenges and particularities

- Procedure is **complicated**, often uncertain, **frequently changing** and very **different from reg.procedure in USA and EU**
- Many things including required studies and costs is a **matter of negotiation**
- Communication with reg.authorities is possible only in national language
- Applicants or reg.agent's **previous registrations record matters**!
- Personal contacts matter, too.

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Some facts

1. There are 3 declared actors in a registration: 1) holder 2) producer of a formulation 3) producer of AI
2. It is possible to declare several of each producer, but only one reg. holder
3. It is possible to sell a registration or to shift from one company to another
4. Foreign company can be a registration holder
5. It is not possible to change a producer without performing majority of studies again, but possible to register additional producer (equivalence must be proved)
6. It is not possible to register a second brand name
7. There is no “me too” registration

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Q&A

Thank you!


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ПОСВІДЧЕННЯ

про державну реєстрацію

Серія А № 03552

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