

Polgar ACRO
Registration of Pesticides
in Russia and Ukraine:
Applicants feedback

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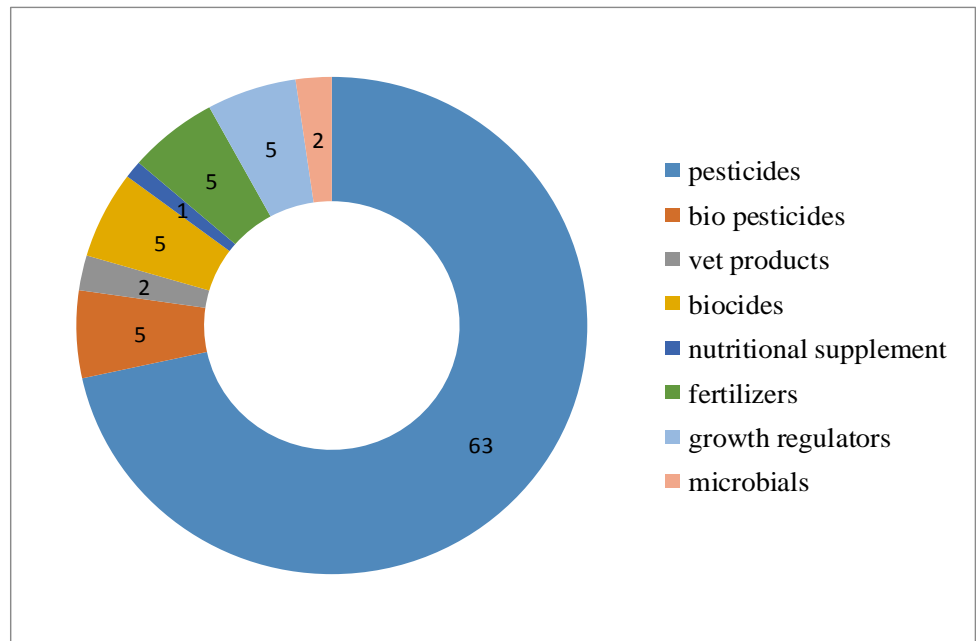
- **Who we are**
- **Introduction: Ukraine**
- **Overview: timing, steps**
- **Costs**
- **Authorities and institutions**
- **Requirements: application, language, studies**
- **Russia (same outline)**
- **Issues to discuss**



- **Locations**

Products registered in CIS

- 63 pesticides (including 1 new A.I.)
- 5 bio pesticides
- 2 vet products
- 5 biocides
- 1 nutritional supplement
- 5 fertilizers
- 5 growth regulators
- 2 microbials



Introduction: Ukraine

- Registration maintenance 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)



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 (if demonstrates good results)

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

* Tox. studies on A.I. are required only during the second year
(for permanent registration)

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

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 , etc
- Eco Toxicology: Institutes belonging to the National Academy of Sciences, National Academy of Agricultural Sciences, Medical Institutes, etc

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)

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

Requirements: Format and Language

1. **Application** must be submitted as a **hard copy**
2. **Study reports** as a **hard copy or CD**
3. It is better to deliver documents from hands to hands, in our experience it is better to avoid sending by post.
4. For every document except toxicological and ecological data from other countries **the language is Ukrainian or Russian**
5. For toxicological studies English is allowed.
6. **No** German, French or any other language is accepted
7. **Communication** with authorities and institutions is possible in Ukrainian and Russian mainly, sometimes in English

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, sensitization

A.I.:

Acute oral, acute contact toxicity, skin and eye irritation, sensitization
Sub-chronic toxicity (90 days) – oral, inhalation, dermal, etc
Carcinogenicity, mutagenicity, reproductive toxicity, neurotoxicity, metabolite toxicity

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

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.

Introduction: Russia

- Registration maintenance time, steps and requirements are defined in the Procedure for State Registration of Pesticides and Toxic Chemicals (Approved by Order of the Ministry of Agriculture of the Russian Federation No. 357 of July 10, 2007)



Two types of registration exist:

- 1) Temporary or „experimental”.** Issued for **2 years**. Requires **1 season of biological efficiency trials** and **2 seasons of residue evaluation**. From the moment of application the whole process usually takes **2,5-3 years**
- 2) Permanent registration.** Issued for **10 years term**. Requires **2 seasons of biological efficiency trials**, **2 seasons of residue evaluation** and **full tox.evaluation** of product and AI. From the moment of application the whole process usually takes **3 - 3,5 years**
That is not complete list of requirements but difference of those for 2 and 10 years registration.

First year

1. Preparation of **Application** (data on pesticide), dossier and recommendations.
2. Inclusion into **biological efficiency trials plan of the Ministry of Agriculture** (MoA) (3 month before trials start) + residue evaluation
3. **Communication of trials programme** and calendar plan with MoA, MSU and Toxicological Institute n.a. Erisman (Erisman Institute) + delivery of samples
4. **Higiene of labor trials** (Erisman Institute), tox. assessment of product formulation and active ingredient
5. First year of trials and **residue** (VIZR)
6. Development of **ADI**



Second year

1. Second year of **biological efficiency trials and residue** (VIZR)
2. **Ecological evaluation** (effect on Bees, etc) (MSU)
3. **Approval of RosPotrebNadzor** (All Russia Consumer Rights Inspection)
4. Collection of all **conclusions**
5. **Ecological expertise** (RosPrirodNadzor (All Russia Environmental Inspection)) – maybe canceled
6. **Expertise of MoA**
7. Registration

Registration authorities

Authorities:

- Ministry of Agriculture
- RosPrirodNadzor
- RosPotrebNadzor

Expert Institutions:

- Centre of grain quality
- VIZR, TSHA, etc
- FNCG n.a. Erisman
- MSU
- And others



The division for authorities and expert institutions is conditional, as many institutes issue expert conclusion for the registration after performing a study and make official evaluation of the dossier submitted by an applicant.

Requirements: Application

Application or Data on Pesticide or Dossier Summary must be prepared in Russian according to an established format and submitted to the Ministry of Agriculture, Erisman Institute, MSU.

Data on pesticide must include:

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

Data on pesticide is being constantly edited in the registration process, new, generated data added. Final version shall be prepared before submission of all documents to the MoA

Requirements: Format and Language

- 1. Requirements are pretty similar to Ukrainian, except:**
- 2. All expert conclusions** must be collected and delivered to other institutes (as required by the procedure) by an applicant
- 3. For every document except toxicological and ecological data from other countries the language is Russian**

Must be made in Russia:

1. Biological efficiency trials
2. Residue
3. ADI
4. Hygiene of labour
5. Approbation of method of determination of A.I. in product (?)
6. Ecological expertise

Requirements: Studies

Can be made in Russia or imported:

1. 5-batch analysis
2. Reports on acute toxicology of technical product: acute oral, dermal toxicity, irritant effect on skin and eye mucosa, sensitization, inhalation toxicity
3. Reports on subchronic oral toxicity, subchronic dermal toxicity, subchronic inhalation toxicity
4. Reports on chronic toxicity, carcinogenicity, teratogenicity, mutagenicity
5. And toxicology of product formulation: acute oral, dermal toxicity, irritant effect on skin and eye mucosa, sensitization, inhalation toxicity according to GLP

In particular many things are decided by Institutes on case by case basis.
Negotiation is possible.
Data from the literature may be accepted.

Data ownership and data protection

It is assumed, that **data** submitted to the authorities **shall never be disclosed to a third party but there is no defined data protection mechanism**. There is no data protection term and no expiration of data protection term is assumed. Thus, data generated for a certain registration is never supposed to become public. Every applicant shall provide same studies again and again.

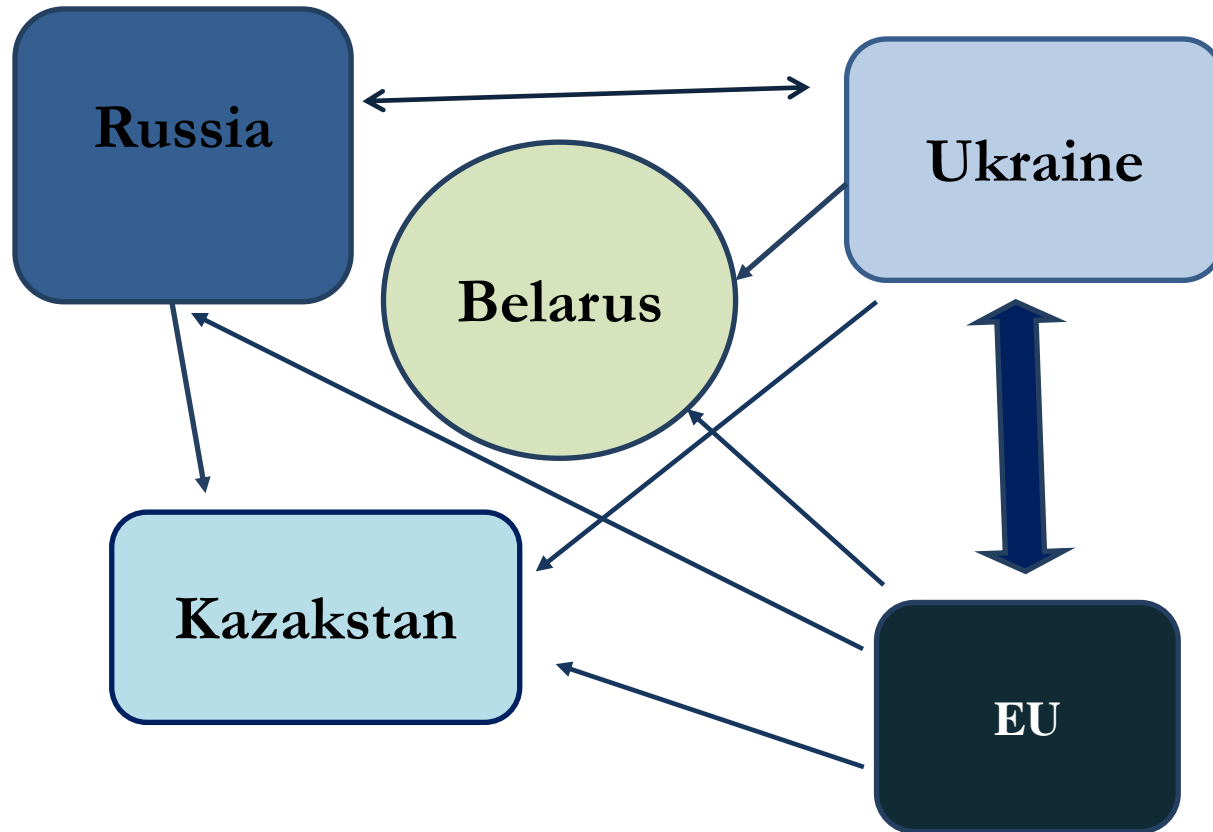
Some facts: RU and UA

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
3. It is possible to sell a registration or to shift from one company to another in Ukraine and not possible in Russia
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 allowed to register a second brand name
7. There is no “me too” registration

Under discussion

- **Harmonisation of study requirements (RU, UA, BY, RK etc)**
Guidance?
How to foresee where to order studies to optimize expenses?
Partial acceptance of efficacy trials results?
Sharing of methods developed on state level?
- **Availability of tox reports in English (RU)**
Ukraine has solved this, what about Russia?

- Mutual recognition for tox studies



Under discussion

- **Data protection (RU, UA), studies**
What about data protection expiration term
Why to repeat studies again and again
- **Mandatory data sharing (vertebrates?) (RU, UA)**
Any plans on that?
- **Communication between authorities (RU)?**
- **Guidelines?**
Lots of things are defined by experts, not published anywhere,
laws are not detailed enough
- **Studies, evaluation and approval are made by the same institutions (RU)**

Under discussion

- **Transfer of the registration (RU)**

Not possible to change the owner of the registration if the producers (product qualities) say the same?

It is required to get again opinion of all expert institutions and can not be decided on the level of MoA if this is purely commercial issue.

- **Timing (RU)**

Registration takes more and more time: new requirements appear, institutes increase time of evaluation

- **Ecological expertise (RU)**

The applicant is facing the following problems:

- Need to repeat expertise for each generic products even if they are identical
- Need to go through expertise twice for same product in case if temporary registration obtained first
- Regional divisions of RosPrirodNadzor are not prepared, experts have general understanding and no special knowledge on pesticides
- Collision of MSU and RosPrirodNadzor's expertise
- Time-consuming, no deadlines defined

Since registration authorities were shifted back to the MoA from RosSelkhozNadzor , the reg.procedure in Russia became easier, however we expect still some actions from MoA to be made about eco expertise

Thank you!

