

Registration procedure for
agrochemicals in CIS:
Russia and Ukraine
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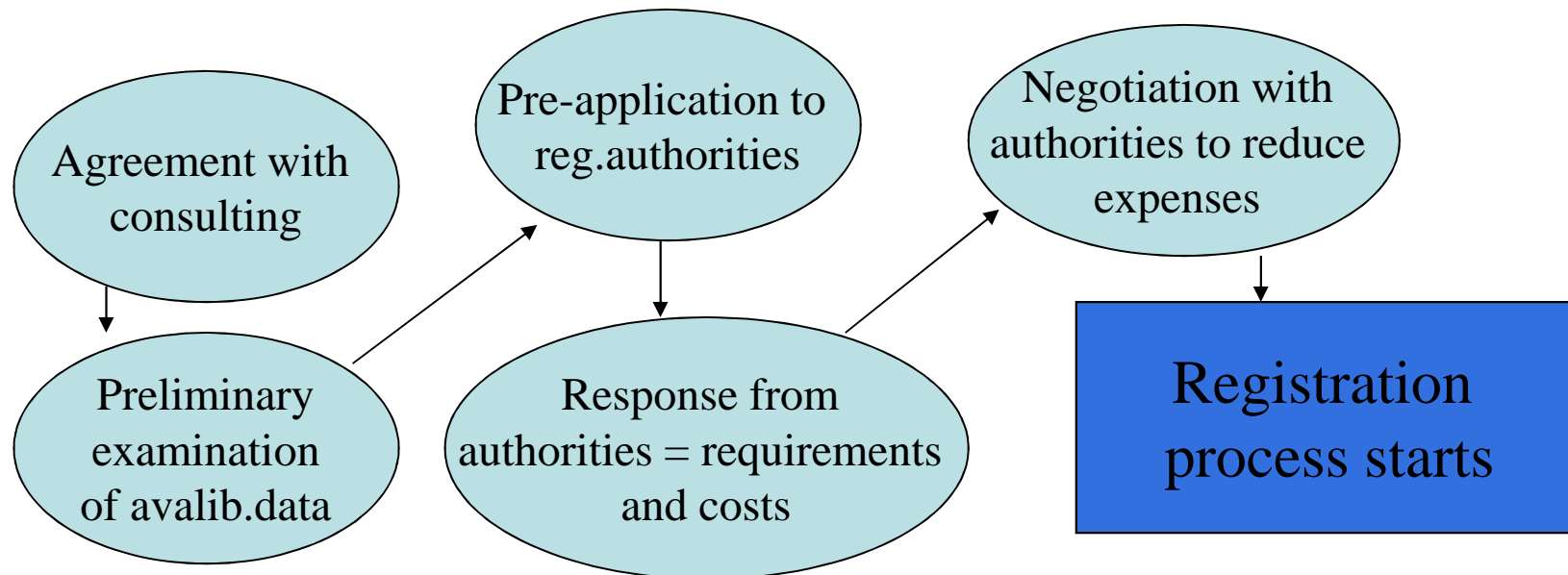
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- Introduction: Where to start?
- Overview
- Procedure: Registration authorities, main steps, timing
- Requirements
- Costs
- Challenges and particularities
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Intorduction

For both Ukraine and Russian once the decision to register the product is made an applicant should start with a background search. The results of this investigation will form future procedure.



* Here and further we assume that registration service is provided by a consultancy (further – registration agent, authorized representative)

1) Temporary registration for 1-2 years.

- Takes 2 years to get
- Costs app.60% of the whole registration budget
- Allows to start import and sell a product
- Needs 1 season of bio.effic. trials and 1 season of residue

2) Permanent registration for 5-10 years

- Takes 2,5 – 3 years (including 1,5 for temporary)
- Costs app.40% of the whole registration budget (excluding costs for temporary)
- Needs additional studies and 2 seasons of bio.effic. trials

Procedure I: Russia

- 1) Background study (slide 3). On this stage applicant knows which parts of his dossier can be accepted and what studies must be made additionally (ordered in Russia)
- 2) Development and submission of application and dossier
- 3) Applications to responsible institutions and authorities (Ministry of Agriculture, Russian Research Institute of Crop Protection (VIZR), Rosselkhoznadzor, etc and requesting for all necessary studies and experts conclusions (equivalence check, toxicological and hygienic expertise, development of methods, studies on bees etc)
- 4) Inclusion into the state plan on biological efficiency trials (made by few state organizations only)

Procedure II: Russia

- 5) Collection of all the experts conclusion and evaluation reports
- 6) Ecological expertise (if required)
- 7) Conclusion of the Ministry of Agriculture and Rospotrebnadzor
- 8) Registration certificate

In Russia most required studies can be made after the application is submitted.

Moreover, an applicant might be asked for additional data on any stage of the registration process

Requirements: Russia

2 things to remember!

- 1) Russian authorities accept GLP studies only or studies made in certified Russian institutions (toxicological studies)
- 2) Some studies can be made in Russia only (for example bio.effic.trials and residues)

- Most documents must be handled to registration authorities as a hard copy, in hands, personally
- Reports and conclusions must be collected from the reg.institutions in the same way
- Applications must be made in Russian language
- Communication language is Russian only
- Reports on some studies are accepted in English (no German, French or another language is accepted)

Overview: Ukraine

1) Temporary registration for 1-2 years.

- Takes 1 – 1,5 years to get.
- Costs app.30% of the whole registration budget
- 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)
- Costs app.70% of the whole registration budget
- **Does not** need 2nd season of bio.effic. trials

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

Procedure: Ukraine

- 1) Background study (same as for Russia)
- 2) Development and submission of application and dossier
- 3) Application for bio.effic. trials
- 4) Contracts for studies are made with the Medved's Institute of Hygiene and Toxicology (Ecogintox): toxicological studies, hygienic studies, residues and with Institute of Crop Protection (IZR): biological studies

Procedure II: Ukraine

- 5) Simultaneously toxicological and hygienic studies are made
- 6) Reports and conclusions are collected and submitted to the Chemical Commission of the Ministry of the Environment (CCMoE)
- 7) If conclusion of CCMoE is positive registration is issued.

In Ukraine, same as in Russia most required studies can be made after the application is submitted.

And, same as in Russia, an applicant might be asked for additional data on any stage of the registration process

Requirements: Ukraine

2 things to remember!

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

! All other requirements are identical with the discussed above requirements to the registration of pesticides in Russia

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	
Russia	App. from 150.000 USD	App. from 170.000 USD	Bio.eff.trials
Ukraine	App. from 40.000 USD	App. from 50.000 USD	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.

Challenges and particularities

For both Russia and Ukraine:

- 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 in **Russian only** (or Russian and Ukrainian for Ukraine)
- Applicants or reg.agent's **previous registrations record matters!**
- Personal contacts matter, too.
- **Authorities hardly communicate between with other.** To push the document flow is a responsibility of an applicant or his representative.
- In most cases local institutes performing the studies are also same state organizations issuing expert's conclusion on registered products

Conclusion

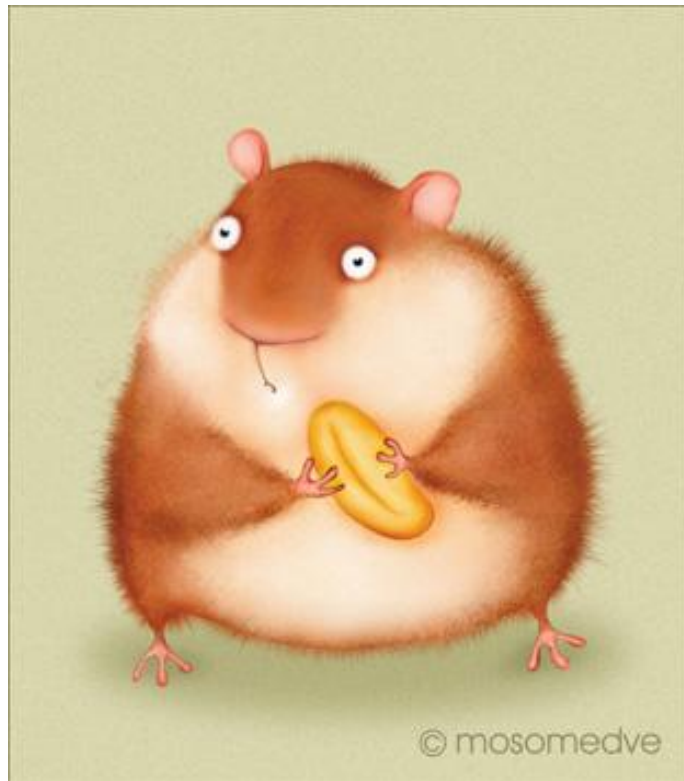
For both countries:

- There are possibilities to obtain temporary registration to try out the market with less expenses
- Permanent registration takes 2-3 years
- For applicant or reg.agent registration process is more about communication, negotiation then about evaluation of data
- Registration costs are constantly growing
- Requirements are getting more and more strict

Differences:

- Registration in Ukraine is cheaper and faster, but more sophisticated to get through and harder to understand
- Registration requirements in Russia are changing in a way more often then in Ukraine

Questions?



Thank you!