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Agrochemical Consulting and Registration Office

Registration of Agrochemicals in Russia: Requirements to Dossier and Application Procedure

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Contents

- **Overview of the registration procedure:**

1. Timing
2. Steps
3. Costs

- **Registration authorities**
- **Requirements:**

1. Application (data on pesticide)
2. Format and language
3. Studies

- **Data ownership and data protection**
- **Some facts**

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Introduction

- 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)

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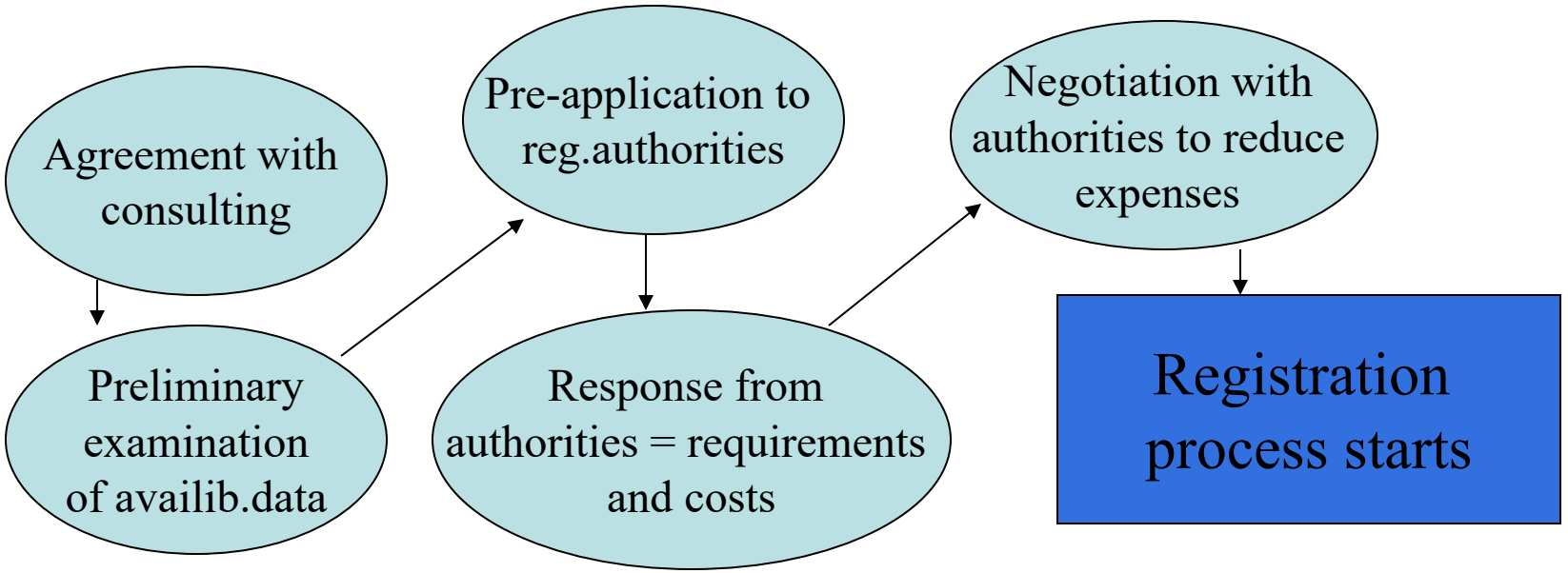
Introduction

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)

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Overview: Timing

Two types of registration exist:

1) **Temporary or „experimental”**. **Issued for 2 years.** Requires **1 season of biological efficiency trials** and **1 season 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.

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Overview: Steps

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)
3. **Communication of trials programme** and calendar plan with MoA, MSU and Toxicological Institute n.a. Erisman (Erisman Institute) + delivery of samples
4. **Hygiene of labor trials** (Erisman Institute), tox. assessment of product formulation and active ingridient
5. First year of biological efficiency trials and residue evaluation (VIZR)

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Overview: Steps

Second year

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

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Overview: Costs

Registration in Russia is rather **expensive** because many studies must be performed only in the country and only by **state certified institutions**. Thus, there are **not many alternatives** where to make hygiene of labor or biological efficiency trials. Toxicological evaluation is made always by Erisman Institute and their prices are very high.

Cost of the registration depends greatly on crops and pests on the label.
Biological efficiency trials take major part of the expences.

Cost can vary from **$90.000** to **$300.000** and, in exceptional cases (like new molecule or very wide range of crops and pests) more. Average cost for generic product, herbicide, 1 A.I., 2-3 crops – around **$160.000**

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Registration authorities

Authorities:

- Ministry of Agriculture
- RosPrirodNadzor
- RosPotrebNadzor

Expert Institutions:

- 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.

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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 MoA

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Requirements: Format and Language

1. **Application** must be submitted as a **hard copy**
2. **Study reports** as a **hard copy**
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 Russian**
6. For **toxicological and ecological studies** submitted to the Erisman Institute and MSU **English is allowed**.
7. **No** German, French or **any other language is accepted**
8. **Communication** with authorities and institutions is possible **only in Russian**

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Requirements: Studies

Must be made in Russia:

1. Biological efficiency trials
2. Residue evaluation
3. ADI
4. Hygiene of labour

6. Ecological expertise

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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, sensibilization, inhalation toxicity
3. Reports on subacute oral toxicity, subacute dermal toxicity, subacute 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, sensibilization, 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.

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Data ownership and data protection

There are no any special rules or Laws regarding **confidentiality of data** submitted to the authorities. It is assumed, that this **information 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 even if a product is generic and has 20 analogues registered in the country.

All data, generated in the registration process belongs to the registration holder, even if it is a study on toxicology of active ingridient and the producer of A.I is different from the registration holder.

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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. This information is public.
2. It is possible to declare several of each.
3. It is not 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
6. It is not possible to register a second brand name
7. There is no “me too” registration in Russia

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Q&A

Thank you!

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