

Registration of Biopesticides (Virus based) in Russia

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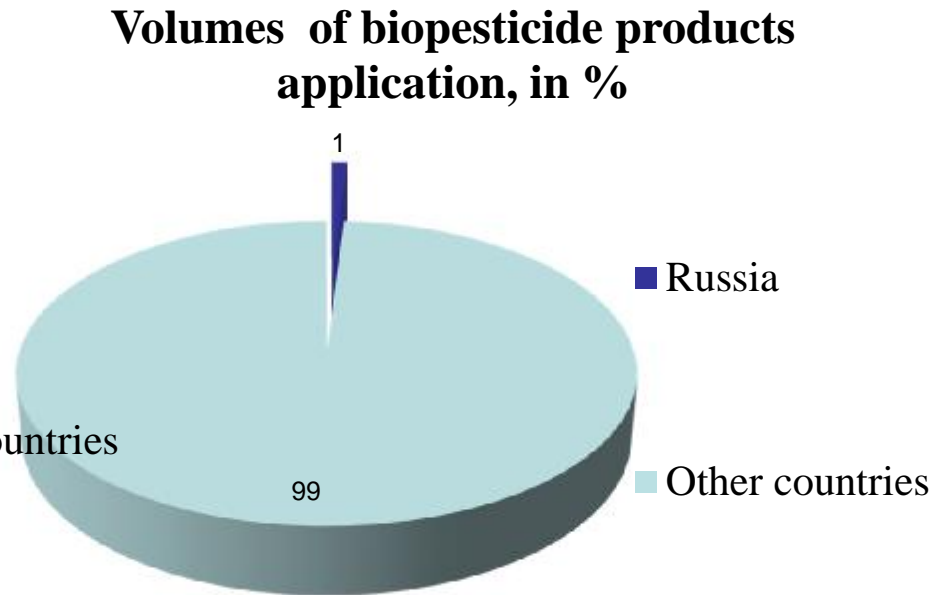
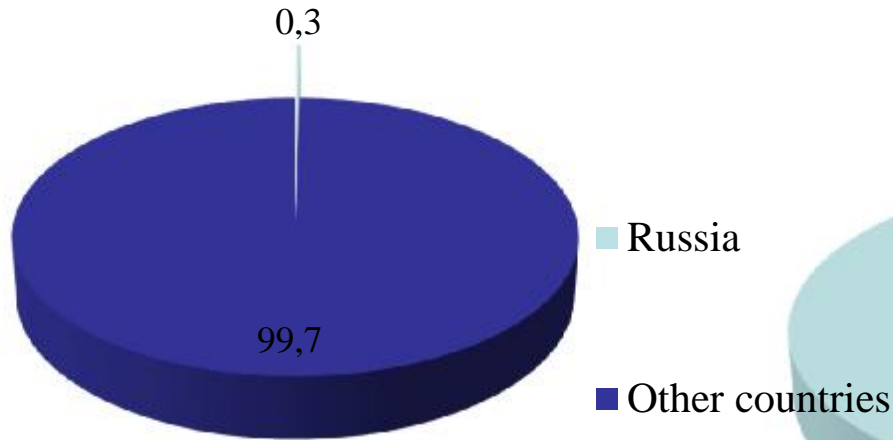
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- **Market overview**
- **Registration authorities**
- **Overview of the registration procedure:**
 1. Timing
 2. Steps
 3. Costs
- **Requirements:**
 1. Application (data on pesticide)
 2. Format and language
 3. Studies
- **Data ownership and data protection**
- **Some facts**

Market

- The position of Russia on the world biopesticides market (2011)**



General overview of the Russian biopesticide market

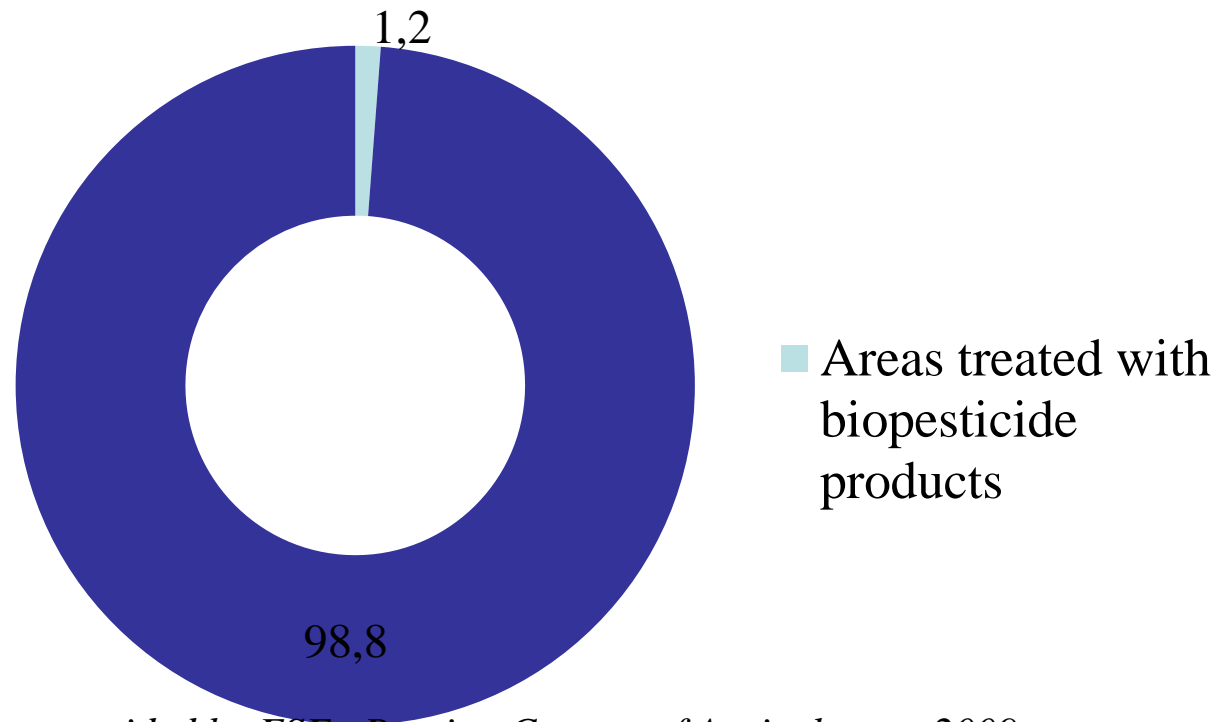
- **Total amounts of biopesticides application were low in 2010** (1% out of overall amount of applied CPP).
- In 2010 **less than 1,5%** (total areas of $961,9 \cdot 10^3$ ha) of farmlands were treated with biopesticides. However these numbers surpass 2009 year data for 12 %.
- In some regions (Stavropolskaja, Krasnodarskaja, Rostovskaja areas, Republic of Tatarstan, Voronezhsky region) the percent of treated lands consists of 10%.
- **The demand of biopesticide products exceeds the supply**, for protected grounds it is covered only on **10-20%**, even less for the fieldproduction* (2011)

**Sources: The demand on biopesticides is growing in Russia <http://regreenhub.ru/2011/10/spros-na-biopesticity-v-rossii-rastet/> October 30, 2011*

Andrej Evplanov, The demand of biopesticides are covered only on 10-20 % 31.05.2011, 00:42

"Российская Бизнес-газета" №800 (18)

Farm lands treated with biomethod in Russia, in %*

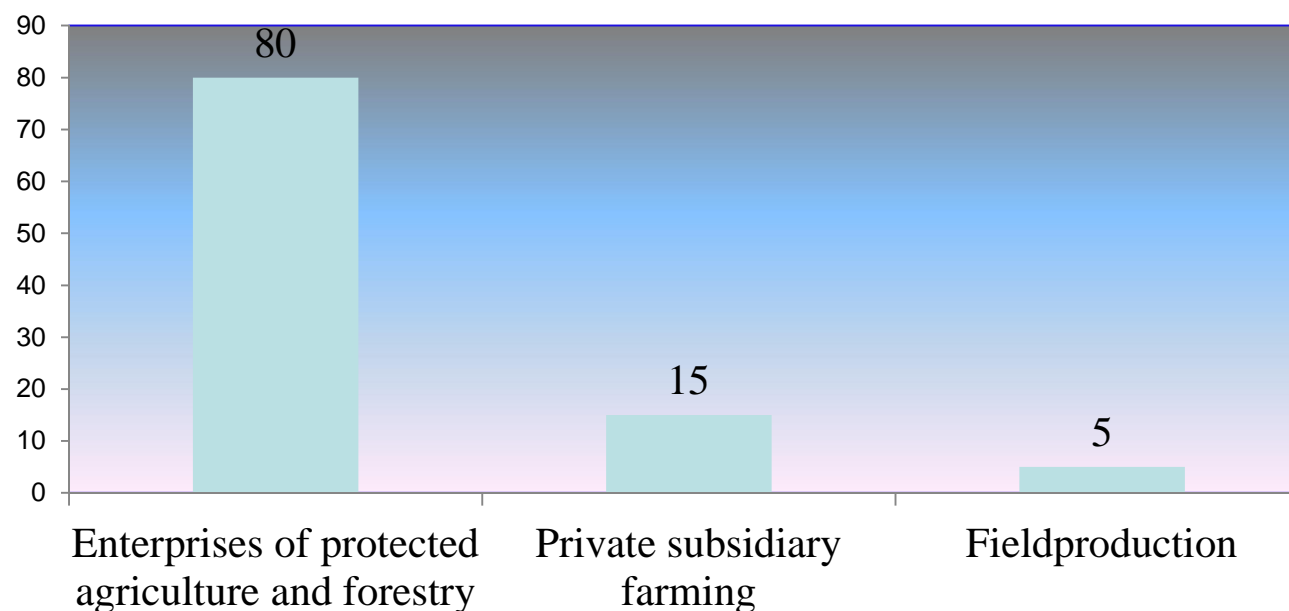


**Data provided by FSE «Russian Center of Agriculture», 2009*

- **Volumes of Russian biopesticides market, 2010**

- Microbiological pesticides market amounts 11,7 MIO USD.
- The supply volume of ready product formulation - 1 665 tones
- 80 % of the products amount consists of fungicides (1 290 tones).
- Dominated type of active ingredients: bacteria - *B. subtilis*, *Pseudomonas* and *B. thuringiensis*; biofungicides – *Trichoderma*.

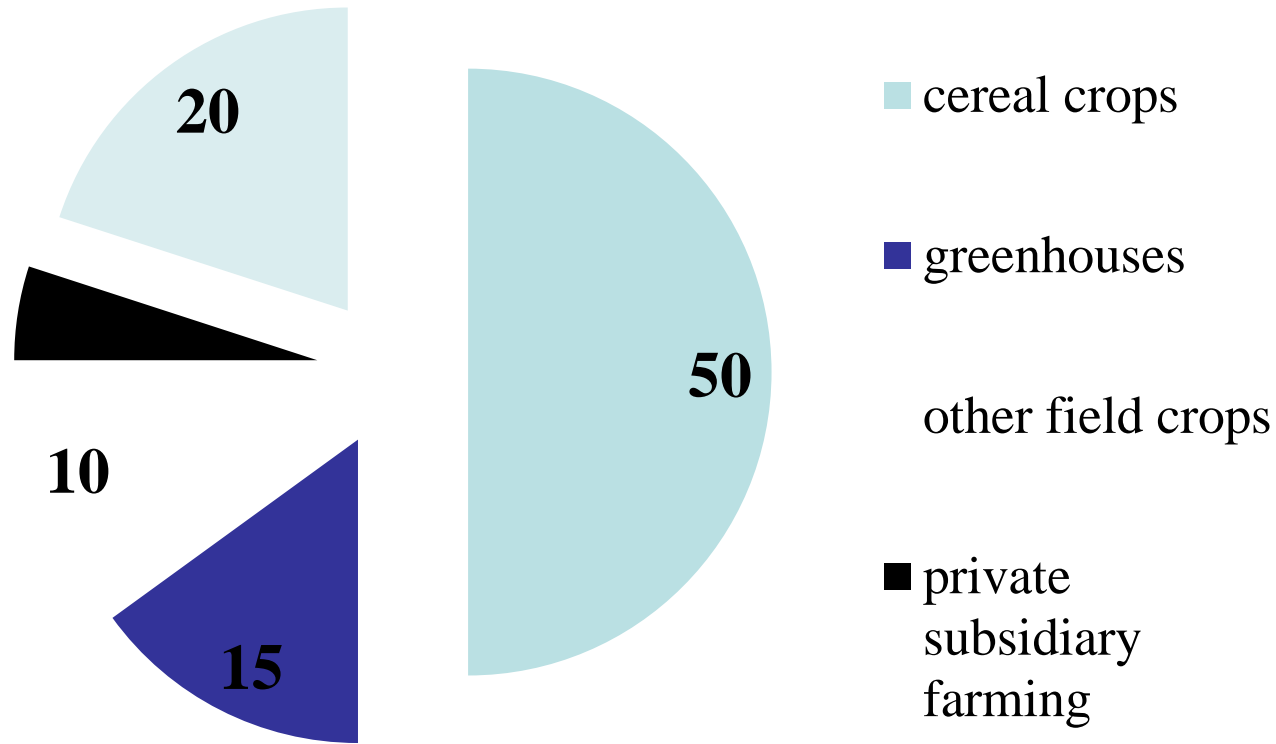
Position of Russia on the world biopesticide market (2011)



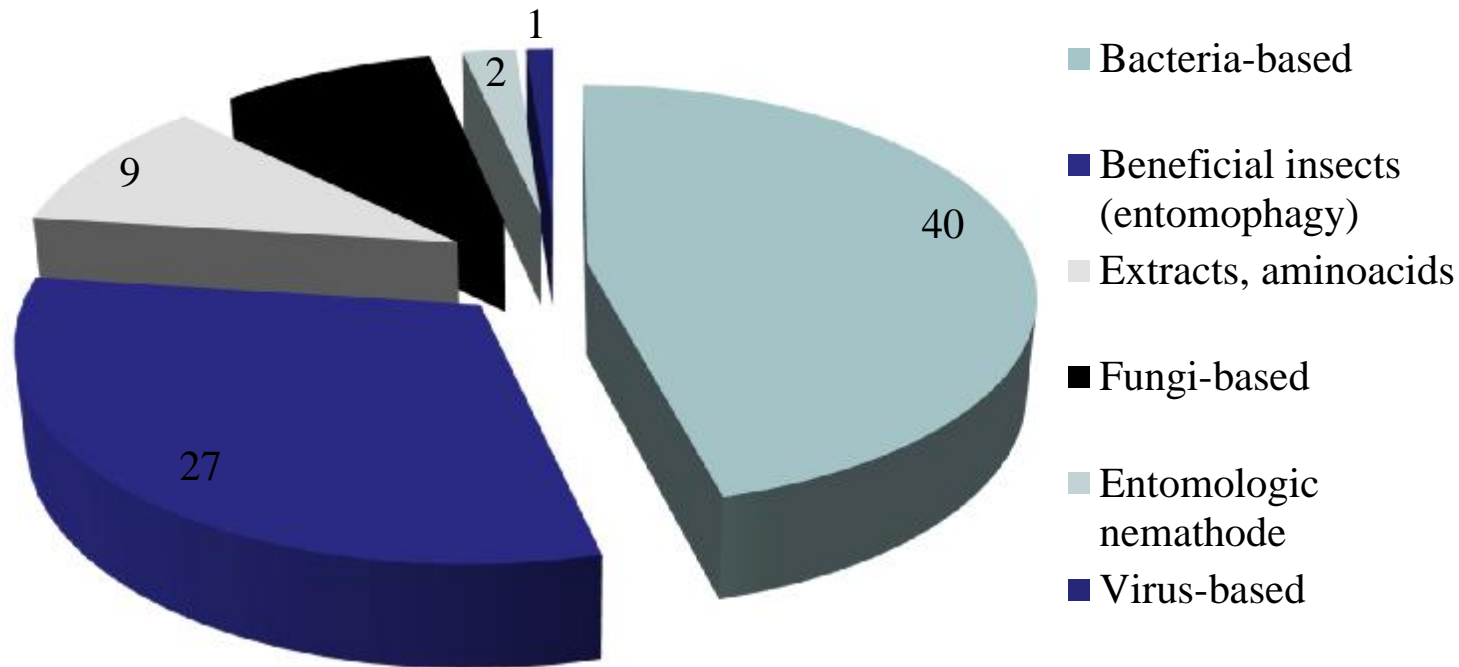
**DATA PROVIDED BY FSE «RUSSIAN AGRICULTURAL CENTER», 2009*

Market

Application of biopesticides, 2010 (in % out of total volumes used)



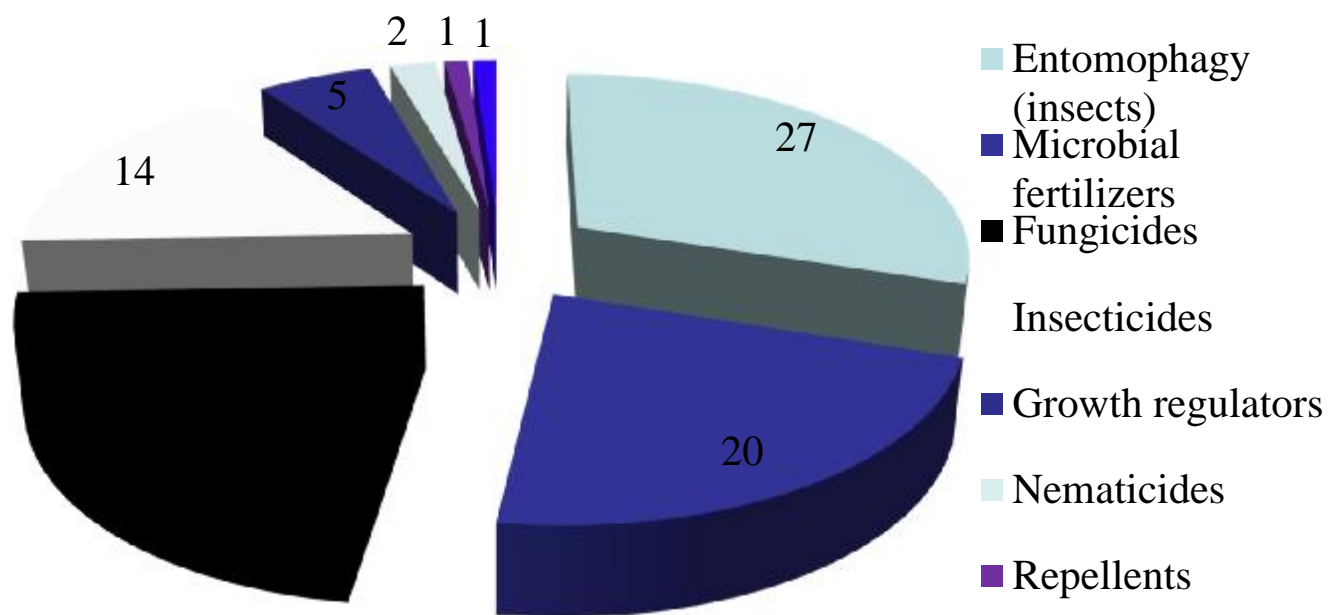
Number of products registered in Russia by the type of a.i. (2012)*



**The chart is based on data provided in official pesticide register of Russia (2012). Total amount of registered biopesticide products - 87*

Market

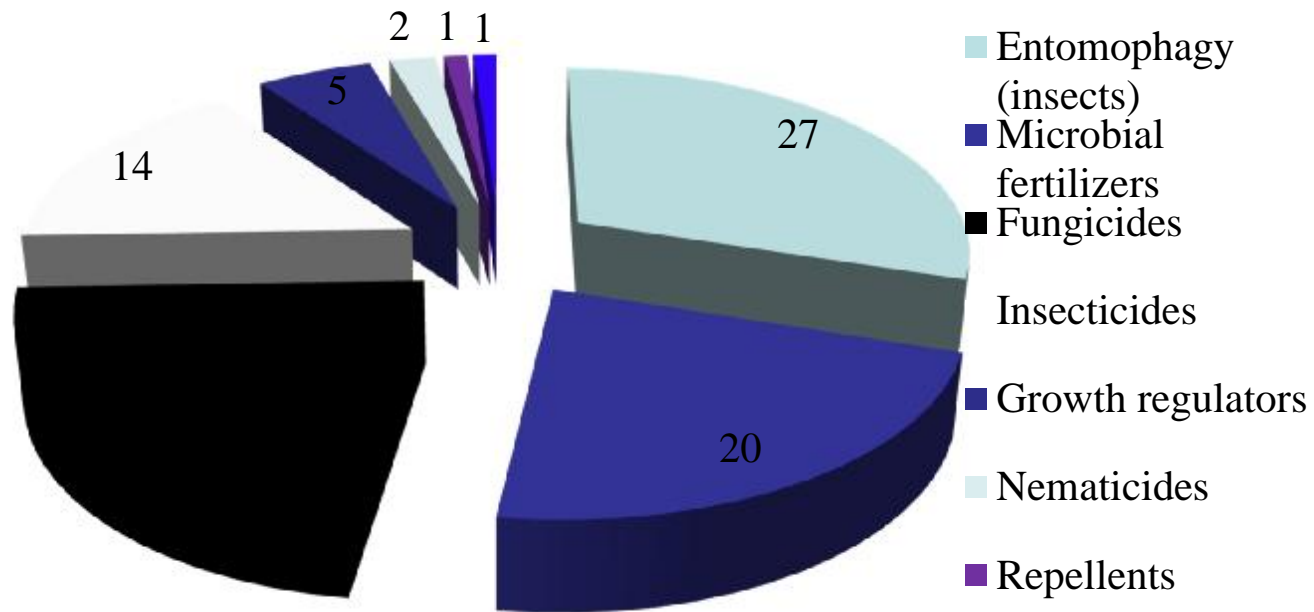
Number of products registered in Russia according to application purpose (2012)*



**The chart is based on data provided in official pesticide register of Russia (2012). Total amount of registered biopesticide products - 87*

Market

Number of products registered in Russia by application (2012)



**The chart is based on data provided in official pesticide register of Russia (2012). Total amount of registered biopesticide products - 87*

- 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)



Registration authorities

Authorities:

- RosPrirodNadzor
- RosPotrebNadzor
- Ministry of Agriculture

Expert Institutions:

- Centre of Grain Quality Research (+/-)
- VIZR (where analogue is made)
- Research Centre for Toxicology and Hyg products
- MSU



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.

Overview: Timing

Two types of registration:

- 1) **Temporary or „experimental”**. Issued for 2 years. Requires 1 season of biological efficiency trials. From the moment of application the whole process usually takes a bit more than 2 years
- 2) **Permanent registration**. Issued for 10 years term. Requires 2 seasons of biological efficiency trials. Takes 2,5 years to receive

Some other types of biopesticides like, for example, products based on non-pathogenic soil-born bacteria may get certified for 10 year after 1 season of efficiency trials. Since trials results are satisfactory, there is not need for the second season.

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 and **Research Centre for Toxicology and Hygienic Regulation of Bio products** at Federal Medico-biological Agency (SFES RCT&HRB at FMBA of RF, so called “Serpukhov”)
4. Tox. assessment of product formulation and active ingredient at “Serpukhov”
5. Depositing of virus strain (VIZR)
6. First year of trials (VIZR)

Second year

1. Second year of **biological efficiency trials** (VIZR)
2. **Ecological evaluation** (MSU)
3. Development and approbation of **method of determination** of A.I. in product formulation (Grain quality research Center (Ramenskoe))
4. **Approval of RosPotrebNadzor** (All Russia Consumer Rights Inspection)
5. Collection of all **conclusions**
6. **Ecological expertise** (RosPrirodNadzor (All Russia Environmental Inspection)) – maybe canceled
7. **Joint Committee for Microbial Agents and Biofertilizers of Russian Academy of Agricultural Sciences**
8. **Expertise of MoA**
9. Registration

Steps: Ecological Expertise

- 1) Required for **biopesticides and pesticides**
- 2) Independent from ecological evaluation by MSU
- 3) **Consists of 3 stages:**
 - **EIA**
 - **Public hearings**
 - **Evaluation by RosPrirodNadzor**
- 4) Evaluation is made by regional departments of **RosPrirodNadzor** at the place of publications
 - Made by a committee of ecologists
 - Requires very serious preparation
 - Can happen only when everything else is ready: requires submission of all expert conclusions from all expert institutions
- 5) Together with a Joint Committee this is the **most complicated and unregulated part of reg.procedure**. Until 2011 it was only required for new products. At present time the necessity of eco expertise for generic products analogue to already registered and evaluated is constantly being questioned. Since reg.authority is transferred back to MoA there is hope for going back to old approach.

Steps: Joint Committee

- 1) Required only for biopesticides
- 2) Takes place in St. Petersburg
- 3) **Requires separate dossier in Russian language**
- 4) Led by the director of Crop Protection Institute and consist of member of the Academy of Sciences, Institute of Microbiology and other “people from science”
- 5) Some of them are very far from the registration so questions can come literally about anything, including purely confidential commercial information about production, which is causing difficulties sometimes
- 6) Reminds thesis defense

Steps: Joint Committee



Overview: Costs

Costs on registration on biopesticides vary greatly depending on product and may start from 35.00 euro (some types of microbial fertilizers) to 100.000 euro (virus based insecticides)

EXAMPLE

Requirements: Application

- Data on applicant and product
- Specification on producing strain and isolate
- Cultural, morphological and biochemical characteristics, identification tests and criteria
- Data on Biological Efficacy and Safety of product
- Toxicological and Hygienic Characteristics
- Hygienic analysis of pesticide manufacturing and application
- Ecological Characteristics
- Ecotoxicology

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

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**

Requirements: Studies

Certain sections of the Application (data on biopesticide) must be supported by study reports on a particular products and be generated by an applicant

They are:

Acute oral and acute inhalation toxicity, irritation on skin and eyes,
Sensibilization

Reports on delayed effects can be provided from the literature

For biopesticides list of requirements can be discussed on case by case basis. Negotiation is possible.

Data from the literature may be accepted.

Requirements: Studies

Must be made in Russia:

1. Biological efficiency trials
2. Approbation of method of determination of A.I. in product
3. EIA (OVOS)



Data protection

Same, as in Ukraine, there is **no data protection expiration period in Russia**. All studies are to be kept confidential forever. There is **no mandatory procedure for data sharing**. All reports remain property of an applicant/producer and only the data owner can give access to these studies to another company. No matter how old a product is and how many analogues are on the market, **every new applicant must generate new studies**.

Pesticides vs. Biopesticides registration

1. To register a biopesticide is usually **twice cheaper** than a pesticide alternative of this product
2. However, the **procedure is much more complicated**
3. Different Institutions make evaluation: in the case of a biopesticide it is much **easier to negotiate**
4. Specific procedure – **Joint Commission**
5. Data ownership and protection rules are the same
6. Market size

Thank you!

