

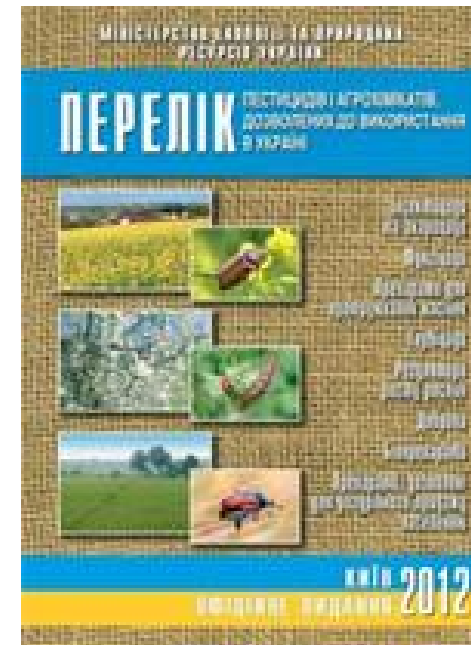
Registration of
Biopesticides (Virus based) and Microbials
in Ukraine:
Procedure and Requirements

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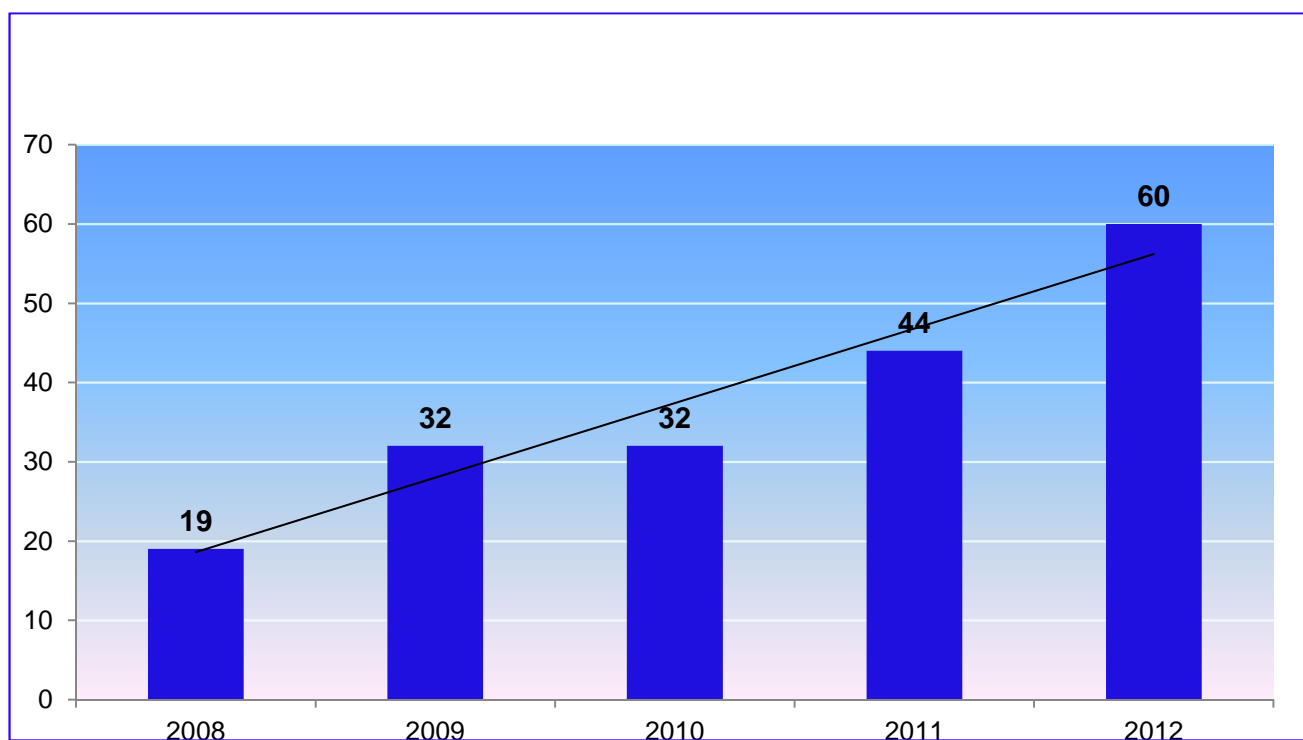
- **Market overview**
- **Overview of the registration procedure:**
 1. Timing
 2. Steps
 3. Costs
- **Registration authorities**
- **Requirements:**
 1. Application (data on pesticide)
 2. Format and language
 3. Studies
- **Some facts**



According to experts opinion, the application volumes of biopesticides constitutes 3% out of total volumes of the crop protection products used in the country in 2010

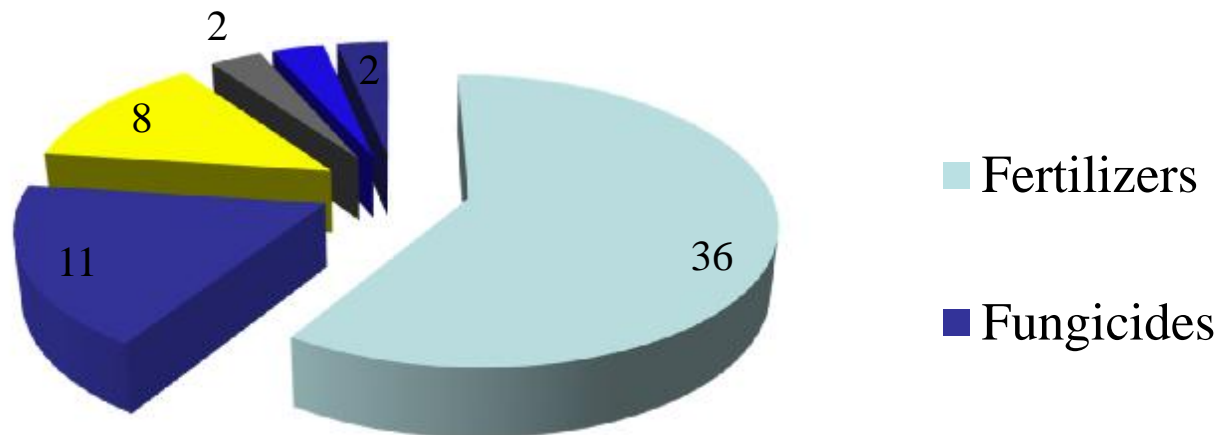
* *Govorov D. N., Zhiviyh A. V., Mirsky A. U., Ipatova N.V. Problems and perspective of the bioproducts and entomophags production at FSE “Russian Center of Agriculture”*

Number of biopesticides registered in Ukraine, 2008-2012*



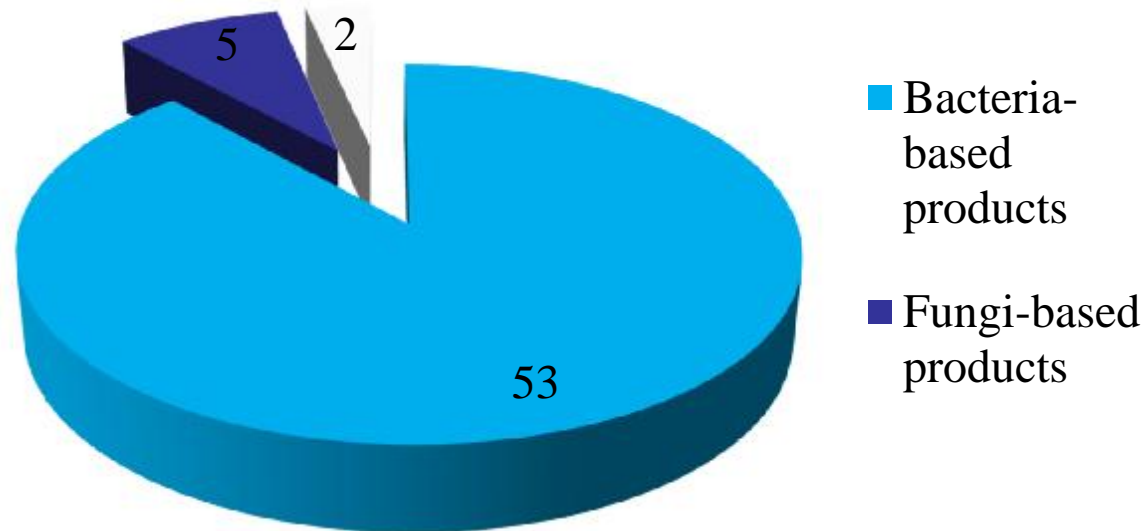
**The diagram is based on data provided in official pesticide registers of Ukraine 2008-2012*

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



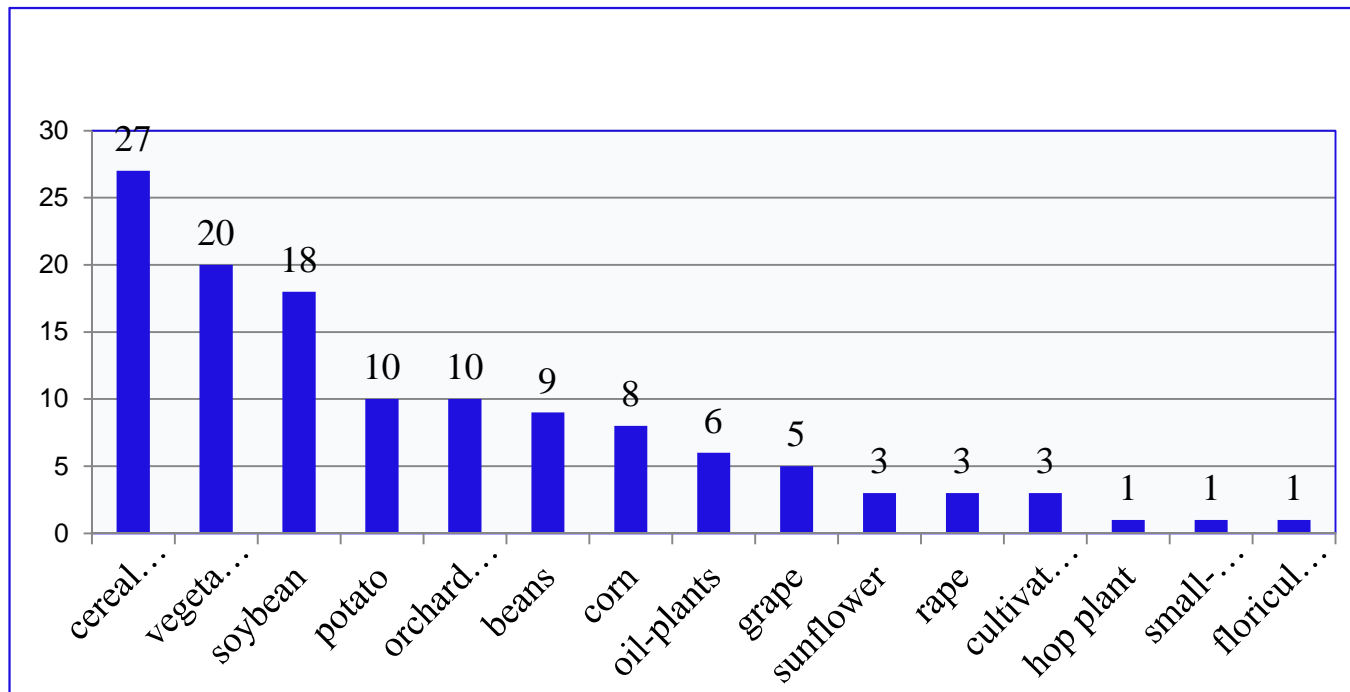
**THE DIAGRAM IS BASED ON DATA PROVIDED IN OFFICIAL PESTICIDE REGISTERS OF UKRAINE 2008-2012*

Number of products, registered in Ukraine by type of active ingredient (2012)*



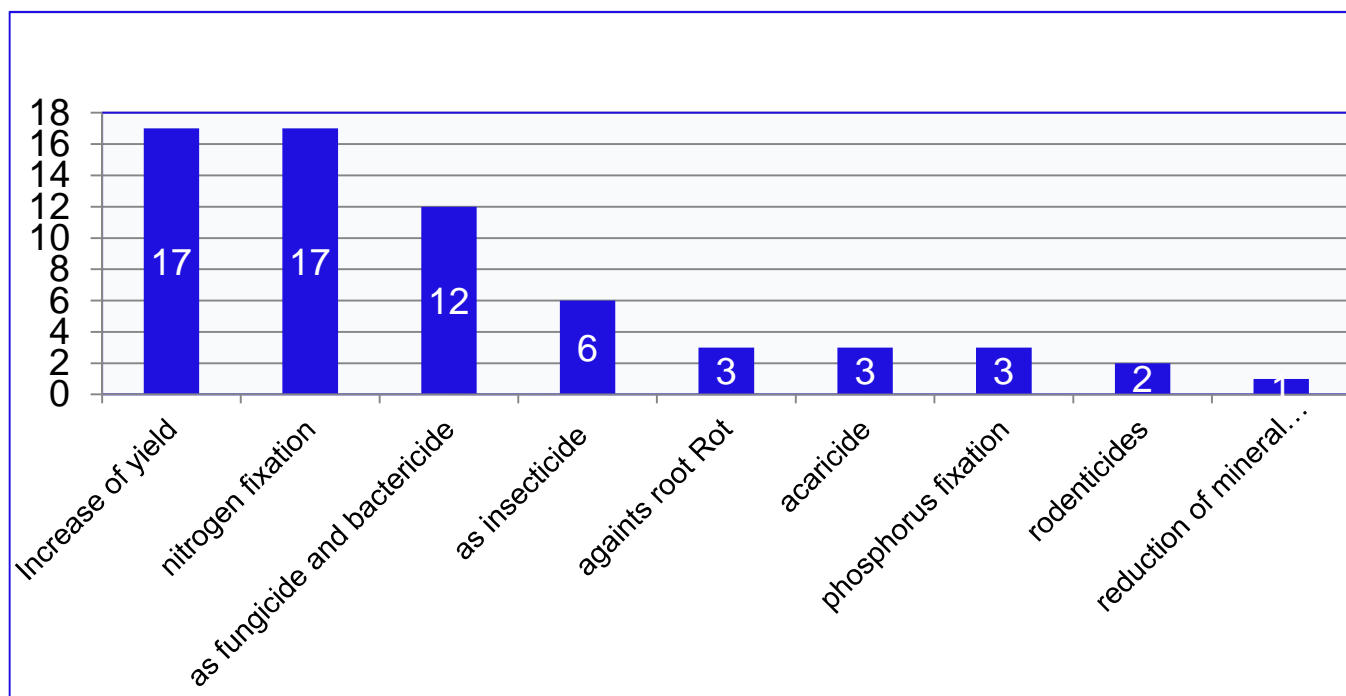
**THE DIAGRAM IS BASED ON DATA PROVIDED IN OFFICIAL PESTICIDE REGISTER OF UKRAINE 2012*

Registered biopesticides by crop (2012)*



**The diagram is based on data provided in official pesticide register of Ukraine 2012*

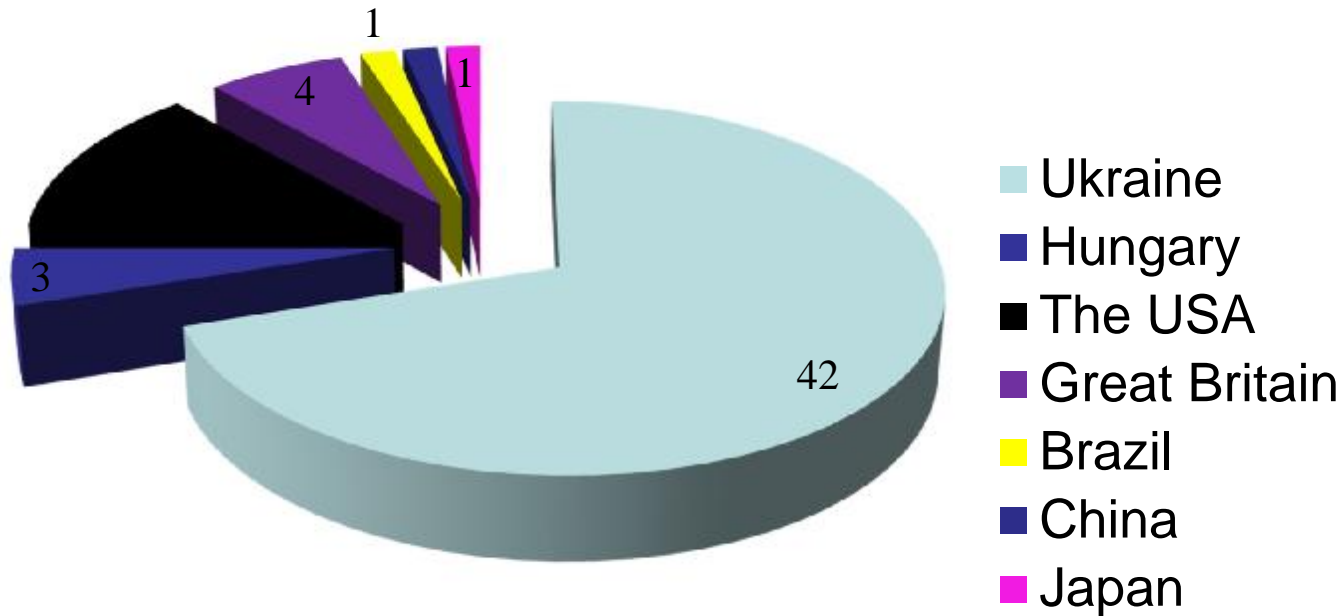
Registered biopesticides by action mode (2012)



**The diagram is based on data provided in official pesticide register of Ukraine 2012*

Market

Number of registered biopesticides by country origin of product



Introduction

- 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)



Overview: Timing

Registration usually takes around **1 year** maintenance time which includes **1 season** of biological efficiency trials.

Once results are not satisfactory, one more season of trials may be required. Usually the registration is issued for 10 years validity term as tox.requirements can be fulfill during the first year

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: 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
- Depositing of virus strain: Institute of Microbiology and Virusology n.a. Zabolotny

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. Depositing of virus strain
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

Overview: Costs

Organization	Subject	year	
		2 013	
Institute of Agroecology	Inclusion into bio-trials calendar plan	0	
	Biological effectiveness (field tests). Crops: tomato, soy-bean, pepper. Sum - 2000 x 3	6 000	
Institute of Occupational Health	Dossier expertise, expert's conclusion(report). Report reflects on pathogenicity, virulence, immunotoxicity, cummulativity	4 000	
Delivery of samples	Insurance, custom dues, broker's services		
The Ministry of Health	Expertise (approving of norms)	300	
D. Zabolotny Institute of Microbiology and Virology	Primary deposit of virus strain	400	
The Ministry of Ecology	Expertise	480	
	Registration Certificate	see below	
The Ministry of Education	Registration of brand name (application, services of patent attorney, accompaniment, issue of certificate)	not required	
		Cost of Reg.Certif	
For 2 years	1 year of trials	400	11 580
For 5 years		800	11980
For 10 years		1600	12780

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.

Application for registration of a biopesticide must include:

- Information on applicant
- Basic information of product and its application
- Info on packaging
- Toxicological and Hygienic Characteristics of product
- Influence on non-target objects
- Physical-chemical characteristics
- Safety information
- Influence on humans (poisoning)

Requirements: Format and Language

1. **Application** must be submitted as a **hard copy**
2. **Study reports** as a **hard copy or CD or via email**
3. For every document except toxicological and ecological data from other countries **the language is Ukrainian or Russian**
4. For **toxicological and ecological studies** English maybe be accepted.
5. **No German, French or any other language is accepted**
6. **Communication** with authorities and institutions is possible **in Ukrainian or Russian**

Requirements: Studies

Toxicological evaluation

There is no set of defined tox.requirements to biopesticides, no practices. Requirements vary depending on product. Preliminary expertise of dossier and foreign sources (to be provided by applicant) s performed.

Usual minimal set of data to be provided (toxicological passport):

- Toxicity and pathogenicity for haematherms
- Virulence for white mice and rats
- Acute oral toxicity
- Irritation effect on eyes and skin
- Tox. characteristics of other product components
- Sensibilization (in sub-chronic experiment)
- Hygiene of labor reports
- Tox.effect on human (poisoning)

Data from the literature may be accepted.

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, except 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
6. It is **not possible** to register a second brand name
7. **There is no “me too” registration in Russia**

Thank you!

