



# REGISTERING MACRO-ORGANISMS IN GREECE

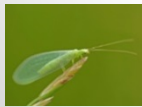
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**[www.minagric.gr](http://www.minagric.gr)**





# Legal Base

- **Organisms Not under** the Scope of Regulation 1107/2009/EU

- **National Legislation**

Law 4036/2012 (O.J.A'8)

“Pesticide marketing, sustainable use and other provisions”

[http://www.minagric.gr/images/stories/en\\_docs/plant\\_protection/L4036\\_2012\\_EN.pdf](http://www.minagric.gr/images/stories/en_docs/plant_protection/L4036_2012_EN.pdf)





Legal base

Article 6 and Article 48 of Law 4036 Official Journal A'8

**art. 6 : FEES**

**art 48 par.1**

Macro-organisms?

*“ Plant protection formulations that contain macro-organisms means formulations containing only organisms visible by naked eye and used in integrated pest management programs”*





## Legal base

### Article 48 of L.4036 O.J A'8:

#### **Art.48 par. 2**

Competent authorities:

- Ministry of Rural Development and Food (Directorate of Plant Produce Protection and Directorate of Organic Farming)

#### **Art 48 par. 3**

- National List
- Submission: Legal entities based in Greece
- Criteria: Evaluation, environment and human safety , efficacy

#### **Art 48 par. 4 :**

- Delegation to the Minister of Rural Development and Food for implementing decisions
- Licensing manufacturing of formulations





# Legal base

Ministerial Decision 10522/117908/22-09-2014, O.J. B'2622

*“Draw up the national list of formulations that contain macro-organisms and licensing production units of micro-organisms formulations”*

## **Section 1**

### **art. 1 Subject and Purpose**

- a) Setting data and studies required
- b) Setting the framework of market release
- c) Define the competent authority for formulation evaluation
- d) Define the competent authority for evaluation the application for manufacturing macro-organisms
- e) Define the competent authority for safeguarding the implementation of the Decision





# Legal base

Ministerial Decision 10522/117908/22-09-2014, O.J. B'2622

- **Section 2 art. 2**

1. **National List of Formulations**

- a) **Commercial Product Name**
- b) **Macro-Organism( Family, Genus, Species)**
- c) **Target Pest ( Family, Genus, Species)**
- d) **Crop/cultivation**
- e) **Distributor**

2. **Registration is open-ended**

3. **If not registered in the list, is prohibited to produce, to import and place in the market (even for personal use)**

4. **National List is uploaded**

5. **National List of Macro-Organisms ( macro-organisms that are native, or have been imported, or have been imported and established)**





# Legal base

Ministerial Decision 10522/117908/22-09-2014, O.J. B'2622

## **Art. 3 Application procedure for registering a macro-organism formulation in the National List**

- 1) Application: Entities based in Greece or by a representative (proxy) based in Greece (even for own-use)
- 2) Application to the Competent Authority (Ministry of Rural Development and Food –Directorate of Plant Produce Protection)
- 3) Deadline 01-11-2015





# Legal base

Ministerial Decision 10522/117908/22-09-2014, O.J. B'2622

## Art. 4.1 Type of Applications-Data & Info Required

a/a	Type of Applications Formulations containing Macro-Organism	Fees (in €)
a	In the National or EPPO List ( <i>Application model 1</i> )	100
b	<b>Not</b> in the National or EPPO List <b>but</b> present (originate from) the EPPO Region ( <i>Application model 2</i> )	500
c	<b>Not</b> in the National List or EPPO List <b>and Not</b> present (originate from) the EPPO Region ( <i>Application model 3</i> )	2000







# Legal base

Ministerial Decision 10522/117908/22-09-2014, O.J. B'2622

- **Art. 4.2 Type of Applications-Data & Info Required**
  - a) **Fee**
  - b) **Formal Statement (*Law 1599/1986*) stating that the organism is not a product of genetic modification**
  - c) **Formal Statement stating the completeness of the application dossier**
  - d) **Manufacturer letter stating the species**
  - e) **Label**
- **Art 4.3:** If the formulations are manufactured in Greece then for registration the manufacturing company shall hold a license
- **Art 4.4:** Competent authorities during evaluation they may require additional data
- **Art 4.5 :** Directive 2008/61/EC is implemented in case of introduction of exotic species for research





# Legal base

Ministerial Decision 10522/117908/22-09-2014, O.J. B'2622

- **Art 5 Evaluation of the application and Decision**
  1. Evaluation of the data, studies etc. : **Benaki Phytopathological Institute– Biological Control Lab ([www.bpi.gr](http://www.bpi.gr))**
  2. Evaluation regarding the use of formulation in Organic Farming : **Ministry of Rural Development and Food , Department of Organic Farming**
  3. Decision by the **Ministry of Rural Development and Food Directorate of Plant Produce Protection ([www.minagric.gr](http://www.minagric.gr))**





# Legal base

Ministerial Decision 10522/117908/22-09-2014, O.J. B'2622

- **Art 6 –Placing on the market, Distribution- Obligations of distributors**

1. Label of the formulation

- Commercial Name
- Genus-Species of Macro-Organism
- Number of adults/or other life stages per package
- Storage conditions (pictograms can be used)
- Company name or distributor name
- Registration Number

2. Any changes to the registered formulation have to be communicated to the CA within one month (not changes in the number in the package)





## Art 6 –Placing on the market , Distribution- Obligations of distributors

3. Transit : allowed if organisms are in the National or EPPO List
4. Obligations of the registration holder
  - a) Webpage with detailed info in Greek ( at least the ones in the label
  - b) Give to CA statistic data if asked
  - c) Inform CA of any side-effects of the release of the macro-organism
  - d) In case of exotic macro-organism the dates of the release will be required





# Legal base

Ministerial Decision 10522/117908/22-09-2014, O.J. B'2622

- **Art 7 – Penalties and Official Controls**

In case of infringement penalty ( 1000 to 10.000€) withdrawal of the formulation from the market

- **Art 8 : Transition period**

- for label and webpage ( of formulations in the market prior to the national legislation) one year after the inclusion of the formulation in the National Catalogue and the uploading in the CA's website





# Questions and Problems so far

## 1. LEGAL

- Who is the registration holder?
  - Data holder?
  - Different registration per commercial name? even if the product is the same?
  - What kind of letter the manufacturer should give?
  - If there are more than one manufacturer ?
  - If producer is different from where the formulation is packaged?
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## 2. TECHNICAL

- **Host Range ( how detailed?)**
- **Target Organism ( how detailed?)**
- **Application ( how detailed?)**



