REGISTERING MACRO-ORGANISMS IN GREECE

Demetra Gkilpathi
Greek Ministry of Rural Development and Food
Directorate of Plant Produce Protection
Department of Plant Protection
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”

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)
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**

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

2. TECHNICAL
   • Host Range (how detailed?)
   • Target Organism (how detailed?)
   • Application (how detailed?)
Thanks for the attention