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Termőföldtől az asztalig

Authorisation of ‘other products’ in Hungary (not PPPs and yield enhancers)

Gábor Tőkés

Food Chain Safety Office

**Directorate for Plant Protection, Soil Conservation
and Agri-Environment**



Products used in agriculture:

PPP
Plant Protection Products

Not PPPs
e.g. adjuvants,
traps

YES
Yield Enhancing Substances

Others

EC Fertilisers

EU

Dir. 91/414 EEC

Reg. 1107/2009

2003/2003 EC Regulation

National legislation

EU regulation is being prepared for YES

Each product is to be registered in Hungary

**With the exception of
Water, untreated manure, and EC fertilisers**



Products subject to authorisation

Plant protection products (PPP)

Herbicides, Fungicides, Zoocides, Plant growth regulators

+ later on: Safeners, Synergists, Co-formulants, Adjuvants in 1107
(till COM regulation : light Annex III on national level)

NOT PPPs

e.g. Traps with stickers or pheromones, leaf sprayers etc.

In many countries not to be registered !

DG SANGO

Yield enhancing substances (YES)

1. Fertilizers,
2. Organic fertilizers,
3. Mineral fertilizers,
4. Composts,
5. Earthworm humus,
6. Soil improving substances,
7. Soil-conditioners,
8. Microbiological products (living)
9. Growing media
10. Plant-strengtheners

DG Enterprise

In many countries YESs are not to be registered !

What are 'other products'?

- I. Products used in plant protection but not to be considered as PPP (notPPPs)
 - - regulated in decree 89/2004 FVM about PPP authorisation

- II. Yield enhancing substances (fertilisers and many types of organic yield improvers)
 - - regulated in decree 36/2006 FVM

■ I. Products used in plant protection but not to be considered as PPP

- regulated in decree 89/2004 FVM about PPP authorisation

a) Safeners, Synergists, Co-formulants, Adjuvants They will go under 1107 after COM regulation
Cleaners, stickers, additives etc.



b) Plant protection tools (e.g. traps)



c) Macro organisms



Simple and cheap procedure (compared to PPPs)

I a) Safeners, Synergists, Co-formulants, Adjuvants Cleaners, Stickers, Additives etc.

- Data requirement similar to PPP but much lighter
- Less data needed and non GLP accepted
 - Identity
 - Phy-chem properties
 - Toxicology
 - Ecotoxicology
 - Efficacy
- In case of well-known substances literature data are accepted



I b) Plant protection tools (e.g. traps)

- Traps without feromones or with feromones but not used for mass trapping are not PPPs
- Tools containing repellents against wild animals, moles
- Simplified data requirement
description of tool and substance,
description of application
efficacy



I c) Macro organisms



- Despite of plant protection purpose, not considered as PPP in the 1107
- Data requirement:
 - *Identity of the formulation containing macro-organisms*
 - *Biological properties*
 - *Biological activity, mode of action, efficacy*
 - *Effects on human health, non-target organisms and the environment*

In case of newly introduced organism the opinion of environmental authority is essential (bad example of *Harmonia axyridis* - harlequin ladybird)



II. Yield enhancing substances (YES)

To be registered under 36/2006 FVM decree

1. Fertilizers (except EC fertilizers),
2. Organic fertilizers,
3. Mineral fertilizers,
4. Composts,
5. Earthworm humus,
6. Soil improving substances,
7. Soil-conditioners,
8. Microbiological products (living)
9. Growing media
10. Plant-strengtheners (biostimulants)



EC fertilizers

Not to be registered under 36/2006 FVM decree

if fulfilling the conditions and parameters of 2003/2003 EC regulation

Generally must not contain organic materials (with special exceptions)

Control on market

Data requirements

Physical properties and chemical composition	<i>for all type</i>
Toxic elements (As, Cd, Cr, Co, Cu, Hg, Ni, Pb, Se) – strict limits -	<i>for all type</i>
Organic contaminants (PAH)	<i>if necessary</i>
Germination inhibition (white mustard test)	<i>not for fertilizers and mineral fertilizers</i>
Hygienic microbiological tests (human pathogenity)	<i>not for fertilizers and mineral fertilizers and soil conditioners</i>
Biological efficacy	<i>Basically at microbiological products and plant-streghteners</i>

General requirement : Freedom from plant pathogen pests

Efficacy is often tested on *Sinapis alba* and *Lolium perenne*



Testing institutes

- All tests are accepted from accredited laboratory of European Economic Area
- Open field efficacy tests are accepted from S-E EPPO zone - GEP accreditation is necessary



Border-line cases

- The same substance can be PPP or YES (or even biocide)

- Claim is essential

- Examples:

plant extract, algae extract, Ag^{++} , Fe^{++} , Cu^{++} , S, Trichoderma and other microbiological products

- Registration practice :

- If claim is PGR or PP → 1107/2009

- In case of YES registration, no hormonal or plant protection effect can be put on the label



Mutual recognition of YES

- **764/2008/EC regulation about mutual recognition of goods traded in other MS**
- **no technical obstacle is possible**
- **the equivalence of protection level (of human, animal and plant health as well as consumer and environmental protection) can be considered**
- **authorisation in Hungary can not be automatically avoided because:**
 - if no authorisation in the other MS – no protection level exists**
 - if not then same requirement in the other MS, protection level is lower – missing tests must be supplied**



Deviating ways for PPPs and YESs



An EC fertiliser contains more Cd than a general registered one !

