BORDERLINE CASES
(SCOPE OF THE PPP LEGISLATION)

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Plant Protection Product (PPP):

containing one or more active substances, intended to:

1. **protect plants** or plant products against all harmful organisms or prevent the action of such organisms,

2. influence the **life processes** of plants, other than as a nutrient, (e.g. growth regulators);

3. **preserve** plant products

4. **destroy** undesired plants; or

5. **destroy parts of plants**, check or prevent undesired growth of plants;
Scope of the new regulation 1107/2009

PPPs as in 91/414

- At 4.-5.def. except algae
- Safeners
- Synergists
- Co-formulants
- Adjuvants
UNCERTAIN CASES

**Plant Protection Products**

- PRODUCTS WITH NUTRIENT EFFECTS, PLANT STRENGTHENERS
- PHYSICAL MODE OF ACTION
- NOT KILLING BUT INFLUENCING ANIMALS
- BIOCIDES/PPP BORDER LINE PRODUCTS

**Other Products**
Products used in agriculture:

PPP: Plant Protection Products
- Not PPPs: e.g. adjuvants, traps

YES: Yield Enhancing Substances

Others

EC Fertilisers
- 2003/2003 EC Regulation

EU 91/414 EEC
- National harmonisation

No EU reg.
- National legislation

.MS
Products subject to authorisation

*Plant protection products (PPP)*
- Herbicides, Fungicides, Zoocides, Plant growth regulators

*NOT Plant protection products (PPP) with plant protection concern*
- e.g. Traps with stickers or pheromones, adjuvants, safeners, leaf sprayers etc.  *In many countries not to be registered!*

*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-conditional products

*In many countries YESs are not to be registered!*
Scope list of EU

- Case by case decision about border line issues
- COM proposal, Standing Committee decision
- Not legally binding
- Since 1994
- Contradictory decisions
- Tendency towards to be PPP for more a.i.
## Working document

**DIRECTIVE 91/414/EEC – SCOPE AND BORDERLINE ISSUES**

**DISCLAIMER:** The answers to the various questions reflect the conclusions reached within the working group of governmental experts responsible for the application of Directive 91/414/EEC (“Working Group Legislation”). They do not necessarily represent the views of the Commission services and are not legally binding. Only the European Court of Justice has the highest authority to give authoritative interpretations on the contents of Community law.

<table>
<thead>
<tr>
<th>Active substance or product</th>
<th>Date discussed</th>
<th>Doc. Reference</th>
<th>Comments – Uses</th>
<th>Conclusions</th>
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</thead>
<tbody>
<tr>
<td>Lipid tarpaulin</td>
<td>Letter of 11. April 1994</td>
<td></td>
<td>Liquid polymer that forms physical barrier after evaporation</td>
<td>Not PPP</td>
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<tr>
<td>Insecto –diatomaecous earth-</td>
<td>Letter 24/01/1995 of C. KAUL</td>
<td></td>
<td>Authorized in DK</td>
<td>PPP</td>
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<tr>
<td>Azibenzolar-S-methyl</td>
<td>Application 18/6/1997</td>
<td></td>
<td>New active substance</td>
<td>PPP</td>
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<tr>
<td>Insecticides used on potplants</td>
<td>10-11/7/1997</td>
<td></td>
<td>Insecticides used on potplants</td>
<td>PPP</td>
</tr>
<tr>
<td></td>
<td>(email print-out)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Dimethenamid-P</td>
<td>21-22/4/98</td>
<td></td>
<td>New active substance</td>
<td>PPP</td>
</tr>
<tr>
<td>Phosphoric acid</td>
<td>6-7/7/1998 21-22/4/98</td>
<td></td>
<td>Finland indicated that it had registrations in 1993 therefore it should be included as an existing active substance. Already on the market. Phosphoric acid (doc. 5072/V1/98)</td>
<td>PPP</td>
</tr>
</tbody>
</table>
Decision examples – scope list

- Anti-stress Acrylic Latex Foliar Spray Polymer, physical protection as the product. Not PPP

  Yucca extract
  physical action and not a repellent; does not kill Not PPP

- Plastic mulch
  acts as a physical barrier Not PPP

- **Lignosilicon**
  organo-silicon compound of unknown but beneficial action, including the increase in plant resistance towards diseases and other stresses. PPP

- **Kaolin**
  Clay, forms a physical barrier against insects, mites, fungi and bacteria PPP
Physical barrier to protect trees.
Is it a PPP?
Decision examples (2) – scope list

- **Mycorrhiza product 1999**
  Biostimulant. Increases growth of plant and yield  
  Not PPP

- **Mycorrhiza product 2003**
  Claim against fungi  
  PPP

- **Mycorrhiza product 2008**
  Protective effects due to the colonisation of the roots  
  PPP
Decision examples (3) – scope list

TRAPS

- Attractants used for monitoring                  not PPP
- Attractants used together with an insecticide   not PPP
- Attractants used for mass trapping              PPP
- Glues on colored plastics panes                 not PPP
Decision examples (4) – scope list

ALGAE

- **Sea algae extracts**
  - Application as a fertiliser, no claims of pesticidal activity on the label
  - not PPP

- **Sea algae extracts on 4th list**
  - Growth regulating activity
  - PPP
• Same product can be PPP or not PPP depending on the claim

• Difference is high!

PPP: AII + AIII dossier

Not PPP: national registration or no registration
BORDER LINE CASES (scope list)

- EU Standing Committee on the Food Chain and Animal Health (SCFCAH)

EC fertilizer?  
- Biocide directive: no
- National competence: no
- 2003/2003 EC regulation: yes, no registration

Decision
- PPP?: yes
- Registration according to 91/414 EEC directive, 4th list
Aim of PPP legislations

- The basic principle is the high level of protection for humans and the environment from pesticides
  - It is not always relevant at border-line cases
  - Originally the Directive was planned only for pesticides and PGRs
  - Huge number of "soft" PPPs was not predicted

4th list
EU 4th list examples

- 1-Decanol
- Aluminium sulphate
- Amino acids: Cystein
- Amino acids: gamma aminobutyric acid
- Amino acids: L-glutamic acid
- Amino acids: L-tryptophan
- Azadirachtin
- cis-Zeatin
- Citrus extract
- Fatty acids / Isobutyric acid
- Fatty acids / Isovaleric acid
- Gibberellic acid
- Gibberellin
- Indolylacetic acid (aka auxins)
- Indolylbutyric acid
- Paraffin oil
- Plant oils / Eucalyptus oil
- Sea-algae extract
- Seaweed

No officially reduced data requirement
PRODUCTS OF 4th list substances

- Legally no lighter dossier than synthetic pesticides
- RMS can set aside from certain tests
- Simplified process can be applied by MSs (product)
- Small companies or single inventors
- Small capital, small trade, no source for expensive studies
RESULT OF AII evaluation

- **Non-inclusion**: Products must be withdrawn in the MSs
- **Inclusion**: Products must be registered as PPP in the MSs

Notifier has data protection rights
Monopol situation for simple substances,
Letters of access are not given or extreme high price
Withdrawal of similar products without data acces
The profit of the product must be more within 5-10 years than the costs.
Can the alga keep such dossier?
Plant & seeweed extracts

- Primarily nutrients
- BUT
- Can contain plant hormones at mg/l level
- Can have plant protection effect

Registration practice in MSs:
- If claim is PGR or PP 91/414 (1107)
- If registration is not as PPP, no PGR or PP effect can be on the label
PPP or not PPP? Claim is essential

- Basis of decision for being PPP:
  - Protect plants from pests
  - Influence plant processes other than nutrients (effect generally complex, nutrients also modify hormone levels)
  - Repellents, feromons (except forcecastig traps)

Product is dead if not supported with dossier

New developments cannot reach market
Registration of plant and seaweed products

CLAIM
Plant protection
Hormonal effect

PPP
a.i. Notification for positive list with AII dossier

Inclusion to positive list
Product registrations on MS level

Non-inclusion
Registrations not possible, or withdrawal

CLAIM
Not plant protection
Not hormonal effect

Not PPP
National or no registration
BASIC SUBSTANCES in 1107/2009

- Inclusion unlimited (not for 10 years)
- Simple process, based on existing data or other legislations

- WILL IT BE A SOLUTION?
BASIC SUBSTANCES in 1107/2009

– is not a substance of concern; and

– does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects; and

– is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent; and

– is not placed on the market as a plant protection product
Relation to fertiliser regulation 2003/2003

- For EC fertilisers no registration is needed (criteria in the tables of regulation)
- Cu$^{++}$ can be used as EC fertiliser no registration needed
- Cu$^{++}$ can be used as fungicide (Annex I listed)
- If I have no dossier, I can sell it as fertiliser 😊
Deviating legislations

- For fertilisers very liberal (DG ENTERPRISE) (Cadmium problem)
- For PPPs very strict (DG SANCO)

Active substance can be same!
Consequences of A I decisions

- Inclusion: Product is PPP, all MS registrations
- If a product is not used as PPP, it can be registrated as Y.E.S. (national level)
- As PPP, it can be registrated only in case of EU inclusion
- EU decisions are tending towards PPP

- Safe but „small” products are disappearing
- New developments cannot jump the obstacles
Solution?

- More flexible approach at borderline cases if human and environmental risk are obviously not relevant.