

# **BORDERLINE CASES**

## **(SCOPE OF THE PPP LEGISLATION)**

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# SCOPE OF THE PPP DIRECTIVE 91/414 *Article 2*

## **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**



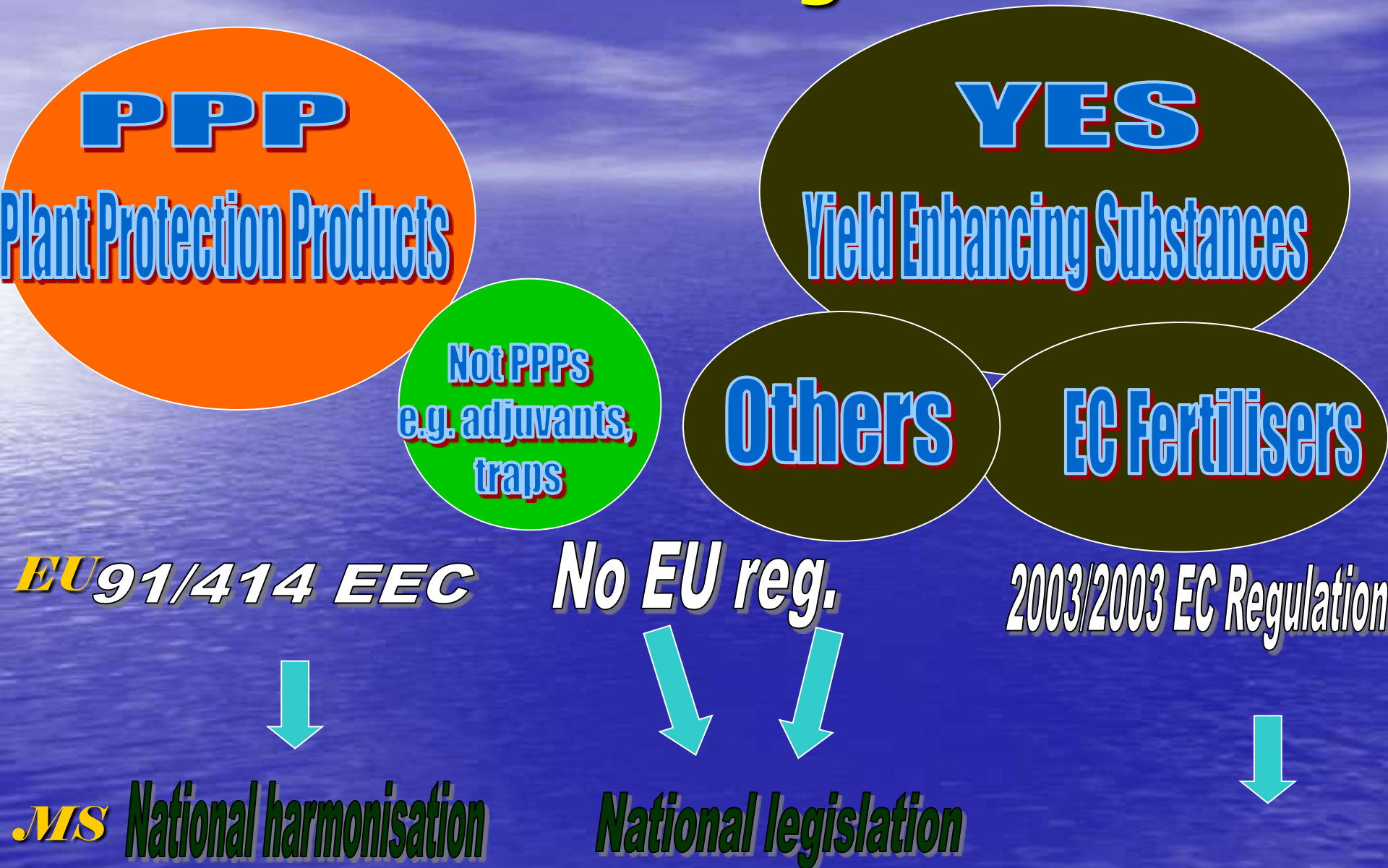
# UNCERTAIN CASES

*Plant  
Protection  
Products*

*Other Products*

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

# Products used in agriculture:



# 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

SANCO Doc 6621-99 rev 42 dd 16.10.2009

- 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.

SANCO Doc 6621-99 rev 42 dd 16.10.2009

	Active substance or product	Date discussed	Doc. Reference	Comments – Uses	Conclusions
	Lipid tarpaulin	Letter of 11. April 1994		Liquid polymer that forms physical barrier after evaporation	Not PPP
	Insecto –diatomaceous earth-	Letter 24/01/1995 of C. KAUL		Authorized in DK	PPP
	CROP-SET	Letter of 4.June 1996		Growth stimulant	Not PPP
	Azibenzolar-S-methyl	Application 18/6/1997		New active substance	PPP
	Insecticides used on potplants	10-11/7/1997		Insecticides used on potplants	PPP
	Beauveria brongniartii	10-11/7/1997 18. Oct. 2000	Sanco/2945/00 (email print-out)	Existing active substance.	PPP
	Dimethenamid-P	21-22/4/98		New active substance	PPP
	Phosphoric acid	6-7/7/1998 21-22/4/98		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/VI/98)	PPP



# 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** **not PPP**  
**Application as a fertiliser, no claims of pesticidal activity on the label**
- **Sea algae extracts on 4th list** **PPP**  
**Growth regaulating activity**

- **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)



# 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



**4<sup>th</sup> 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



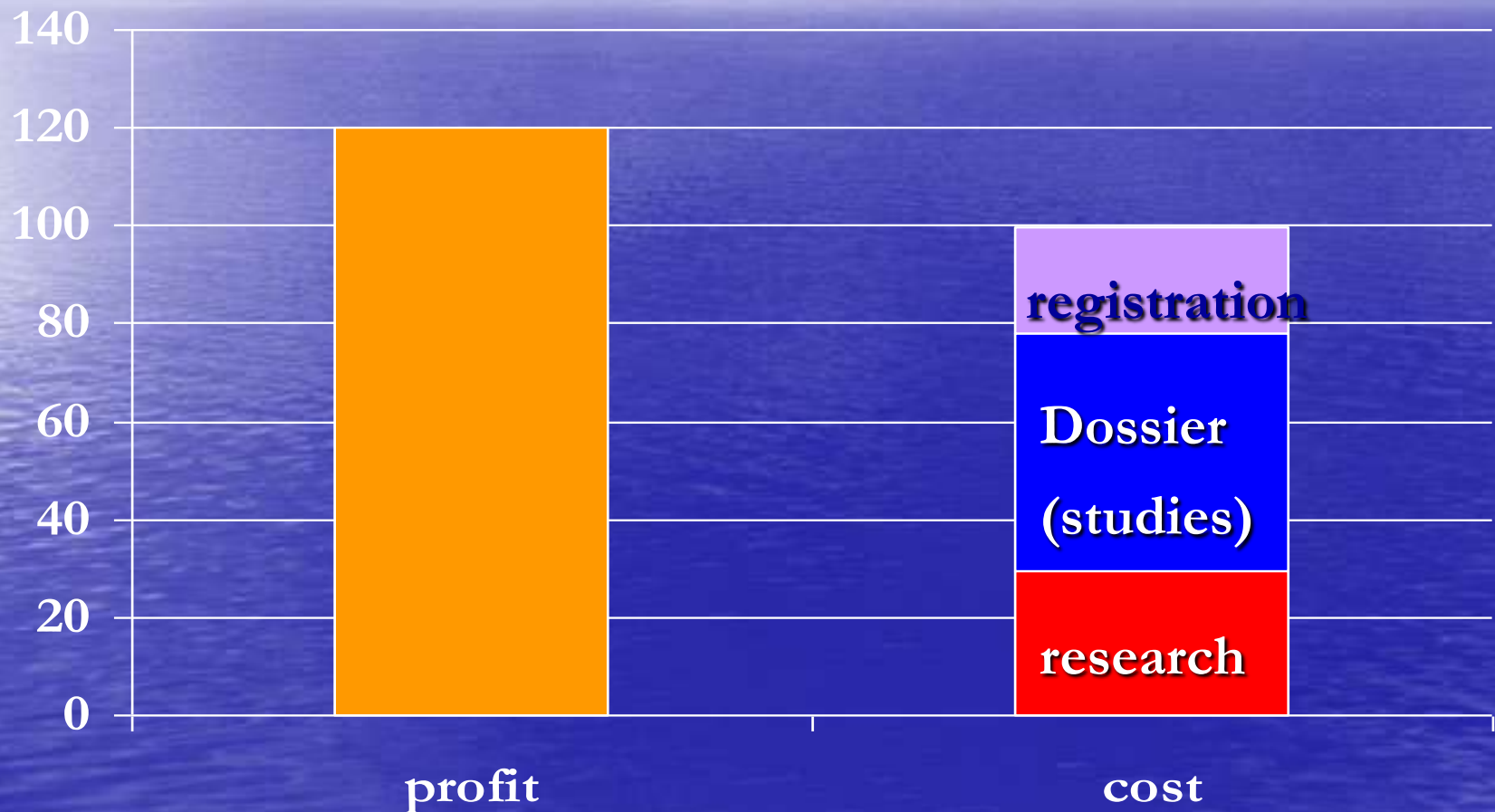
# PRODUCTS OF 4th list substances

- 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 & seaweed 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 hormon levels)
  - Repellents, feromons (except forcastig 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

CLAIM

*Not plant protection*

*Not hormonal effect*

a.i. Notification for positive  
list with AII dossier

Not PPP

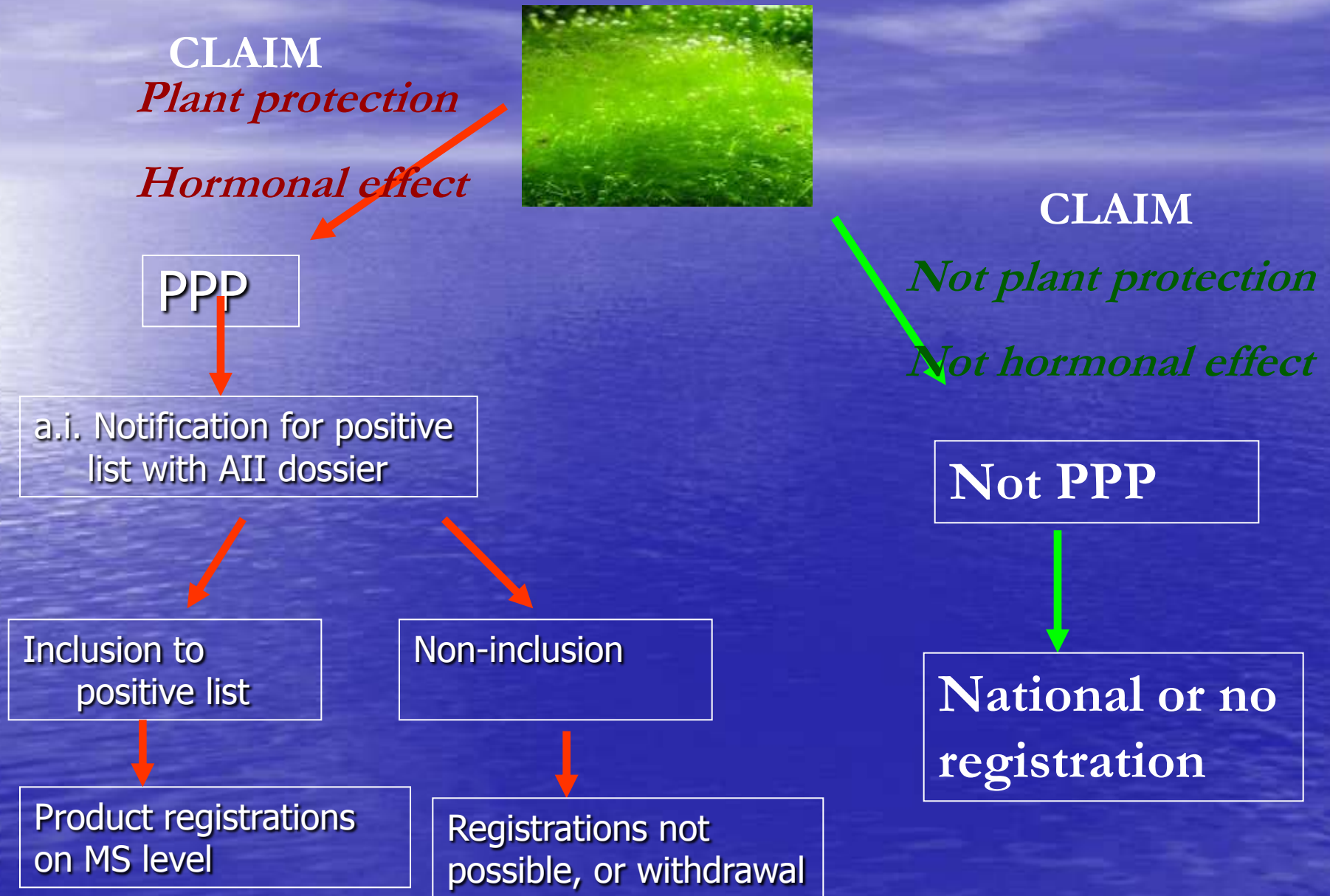
Inclusion to  
positive list

Non-inclusion

National or no  
registration

Product registrations  
on MS level

Registrations not  
possible, or withdrawal



# 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)
- $\text{Cu}^{++}$  can be used as EC fertiliser no registration needed
- $\text{Cu}^{++}$  can be used as fungicide (Annex I listed)



- If I have no dossier, I can sell it as fertiliser ☺

# Deviating legislations

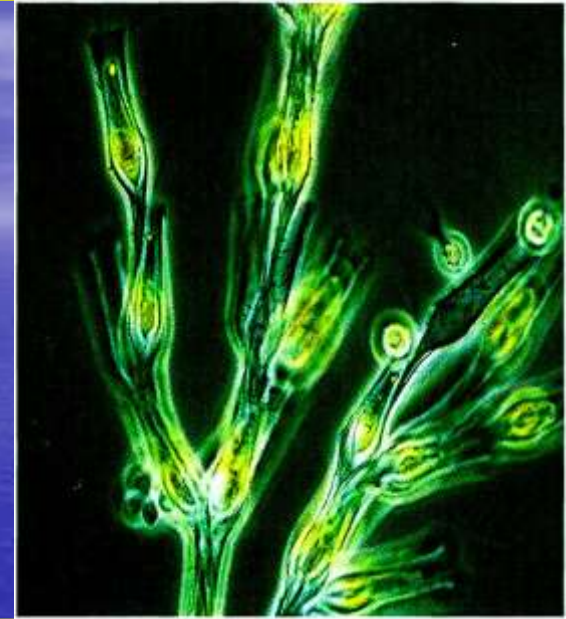
- For fertilisers very liberal (DG ENTERPRISE)  
(Cadmium problem)
- For PPPs very strict (DG SANCO)

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 registered as Y.E.S. (national level)
- As PPP, it can be registered 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



