Pesticide risks for pollinators
8th SETAC Europe Special Science Symposium
Brussels, 16-17 October 2013

Regulatory framework for seed treatments in the EU

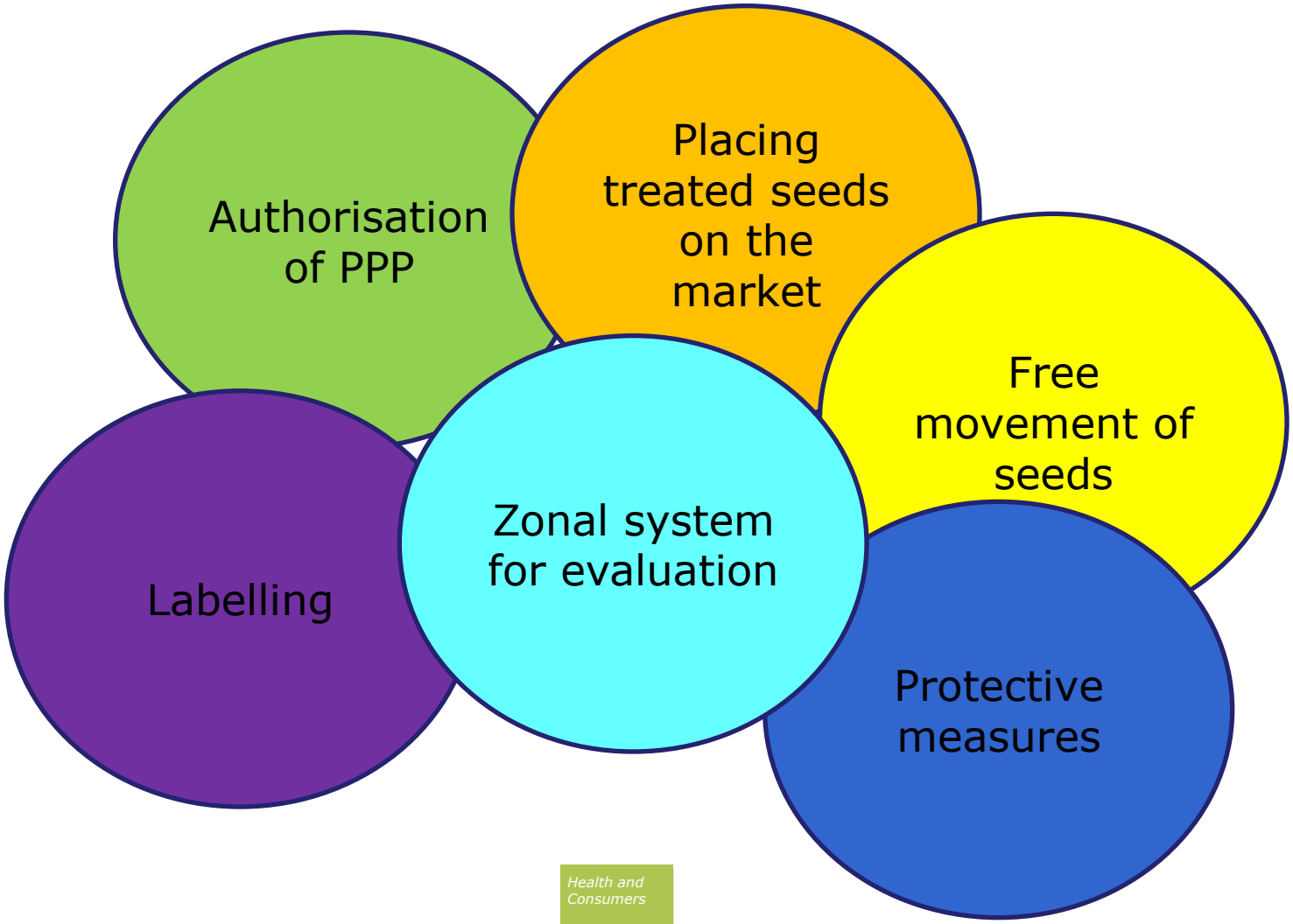
Gunilla Ericson
European Commission
Health and Consumers Directorate General

Health and Consumers

European Commission

Contents

- Treatment of seeds
- Placing on the market of treated seeds
- Labelling
- Zonal evaluation
- Data requirements
- Decision making and Uniform principles


Authorisation of PPP
Placing treated seeds on the market
Free movement of seeds
Zonal system for evaluation
Labelling
Protective measures

European Commission

Regulation (EU) No 1107/2009

Art. 28

Authorisation and placing on the market and use

Art. 49

Placing on the market of treated seeds

Treatment of seeds

Art. 28: Autorisation and placing on the market and use

- A national autorisation is needed to treat seeds
- Comparable to a treatment of a crop
- Treated seeds are not considered as plant protection products

Placing on the market of treated seed

Art. 49

- Free movement of treated seed
- Protective measures
- Labelling of treated seeds

European Commission

Placing on the market, Art. 49 (1)

'Member States shall not prohibit placing on the market and use of seeds treated with plant protection products authorised for that use in at least one Member State'

Protective measures, Art. 49(2)

- Substantial concerns ➔ serious risk to human or animal health or to environment
- Measures to restrict or prohibit the use and/or sales of such treated seeds (Regulatory procedure)
- Commission shall examine evidence and may request an opinion from EFSA

Labelling of treated seeds, Art. 49(4)

Label and documents accompanying treated seeds shall include:

- Name of PPP with which the seeds were treated
- Name of active substance(s) in that product
- Standard phrases for safety precautions
- Risk mitigation measures set out in the authorisation

Standard phrases for safety precautions

'Standard phrases for safety precautions as provided for in Directive 99/45/EC'

=

'Safety advice (S phrases)' referred to in Article 10 paragraph 2.6 of Directive 99/45/EEC

Those can be found in Directive 67/548/EEC (Dangerous substance directive)

Health and Consumers

Evaluation of application

Art. 33.2 (b)

"..for seed treatment, only one Member State shall be proposed, which evaluates the application taking account of all zones."

Differences between MS

- Sowing practice
- Climatic conditions
- Dissipation/degradation in environmental compartments
- Available risk mitigation measures

European Commission

Data requirements

- Regulation (EU) No 283/2013 active substances
- Regulation (EU) No 284/2013 for products

New Data requirements (a.s.)

When bees are likely to be exposed

- Acute oral and contact toxicity (LD_{50} and NOEC)
- Chronic toxicity (EC_{10},EC_{20},EC_{50},NOEC)

If sub-lethal effects cannot be excluded

- Effects on honeybee development and other honeybee life stages (EC_{10},EC_{20},EC_{50},NOEC)
- Sub-lethal effects (behavioural, reproductive)

Data requirements (PPPs)

Testing required if:

- More than one a.s.
- Toxicity not reliably predicted to be same or lower as for a.s.

Seed treatment and granules: Dust drift

Systemic and acute oral toxicity <100 µg/bee:

- Residues in nectar, pollen and water

Data requirements (PPPs)

When acute or chronic effects on colony survival and development cannot be ruled out:

- Cage and tunnel tests
- Field tests with honeybees

Decision making at MS level (UP)

If exposure possible:

HQ > 50 ⟶ no authorisation

……..unless it is clearly established through an appropriate risk assessment that under field conditions there are no unacceptable effects on:

- ✓honeybee larvae
- ✓honeybee behaviour, or
- ✓colony survival and development

European Commission

Wrap up

- A national autorisation is needed to treat seeds
- Treated seeds are not considered as plant protection products
- Free movement of treated seeds in EU
- One zone for the evaluation
- Serious risk ⟶ MS protective measures
- Treated seeds shall be labelled, including safety phrases and risk mitigation measures

European Commission

Thank you for your attention

Health and Consumers