



# **SETAC Europe Special Science Symposium**

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# **Objectives and regulatory context of risk mitigation measures applied to pesticides**

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# Environmental risk mitigation

## Relevant legislation

- Reg. (EC) No 1272/2008: General harmonised standard phrases for safety precaution
- Reg. (EC) No 547/2011: Harmonised standard phrases for safety precautions, specific for PPP
- Dir. 128/2009/EC
- Reg. (EC) No 1107/2009
  - Article 4: harmful effect on groundwater, no unacceptable effects on the environment
  - Article 65 (3): Additional national safety phrases to be notified to MS and COM, they shall be considered for inclusion into Reg. 547/2009
- Directive 2000/60/EC (Water framework Directive)
- Directives 2006/118/EC (groundwater)

# Risk Mitigation in Regulation 1107/2009

## Legal framework

- No definition of RMM given in the Regulation
- Art. 4(3) A PPP shall only be authorised if it has:
  - no harmful effect on human and animal health and groundwater
  - no unacceptable effect on plants and plant products
  - no unacceptable effect on the environment
  - on application of good plant protection practice (GPP) and *realistic conditions of use*
- Art. 3(18) GPP = Application in conformity with conditions of use and applied in a way to ensure acceptable efficacy with the minimum quantity necessary
- Art. 31(2) Authorisation sets out requirements relating to the use of the PPP
- Art. 31(4e) These requirements may include the approved label

# Risk Mitigation in Regulation 1107/2009

## Realistic conditions of use

- RMM part of realistic conditions of use
- Proper implementation crucial for meeting the safety level established in the authorization
- RMM are a risk managers' tool, but risk assessors must know about them when identifying safe use scenarios
- Label informs the user which RMM have to be applied for a safe use
- The effective implementation of RMM involves the user of the PPP, who shall:
  - decide on whether to apply the measure;
  - carry out the measure correctly; and
  - adapt the measure, if necessary, in order to achieve the intended effect
- Operators, industry and regulators must be involved to achieve efficient implementation of RMM

# Risk Mitigation in Regulation 1107/2009

## Labelling

- The label of a PPP shall contain hazard and precautionary statements
- Art 65 distinguishes 3 types of statements:
  1. General phrases coming from Regulation 1272/2008/EC
  2. Specific phrases included in Regulation 547/2011/EC (on labelling requirements of PPP)
  3. Temporary national phrases
    - to be notified to MS and COM
    - to be considered for inclusion in Regulation 547/2011/EC

# Risk Mitigation in Regulation 1107/2009

## Zonal authorisations

- RMM must be compatible amongst Member States, otherwise mutual recognition of authorizations is difficult
- A full harmonization would be the most easy and simple way to get to mutual recognition
- However, full harmonization is admittedly not possible for the whole area of use of many PPP
- Nota bene: the regulatory purpose of a RMM is the reduction of a risk by a certain factor, not the application of a certain technique.
- A possible solution is standardization instead of harmonization:
  - Establish a catalogue of available RMM;
  - Classify RMM according to their effectiveness; and
  - Emphasize in the risk assessment the degree of risk reduction required

# Risk Mitigation in Regulation 1107/2009

## Against the current backlog in implementation

- COM audits in MS have established that mutual recognition and the zonal system are largely ignored by MS
- Environmental concerns are widely used by MS in refusing mutual recognition
- At the same time, the degree of harmonization of RMM is low and there is no system to standardize RMM
- Upon request from COM, only 2 out of 28 MS officially confirmed and notified the use of national R/S phrases on product labels

# Risk Mitigation in Regulation 1107/2009

## Recommendations from MAgPIE

- Registration reports should not identify measures, but the necessary degree of risk reduction
- Fixed reduction classes (50%, 75%, 90%,...) might facilitate implementation
- Maximum acceptable degree of risk reduction must be agreed (at minimum) on zonal level
- Risk assessment and RM efficacy assessment must use the same reference points (e.g. field length for runoff)
- A toolbox is recommended; possible elements were identified at the workshop
- Toolbox should be adopted by COM in close cooperation with Member States
- Member States shall be prudent about national measures
- Harmonized statements in Regulation 547/2011 should be rephrased in order to reflect the toolbox approach





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