European Commission

Unacceptable co-formulants in PPPs

Jeremy Pinte, E4

Advisory Group, 29/04/2016

Food Safety

European Commission

Content

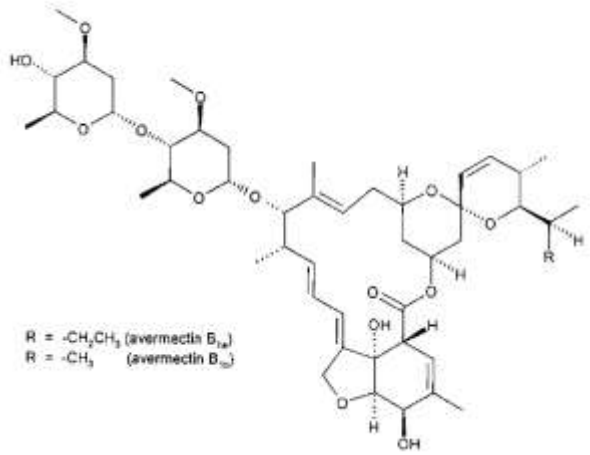
- Context
- Setting Annex III
  - Criteria
  - Procedure
- Next steps
- Q&A

European Commission

Context (1/2)

- PPP: formulated products

=



Abamectin

+

fillers

preservatives

Context (2/2)

 = AS + co-formulants

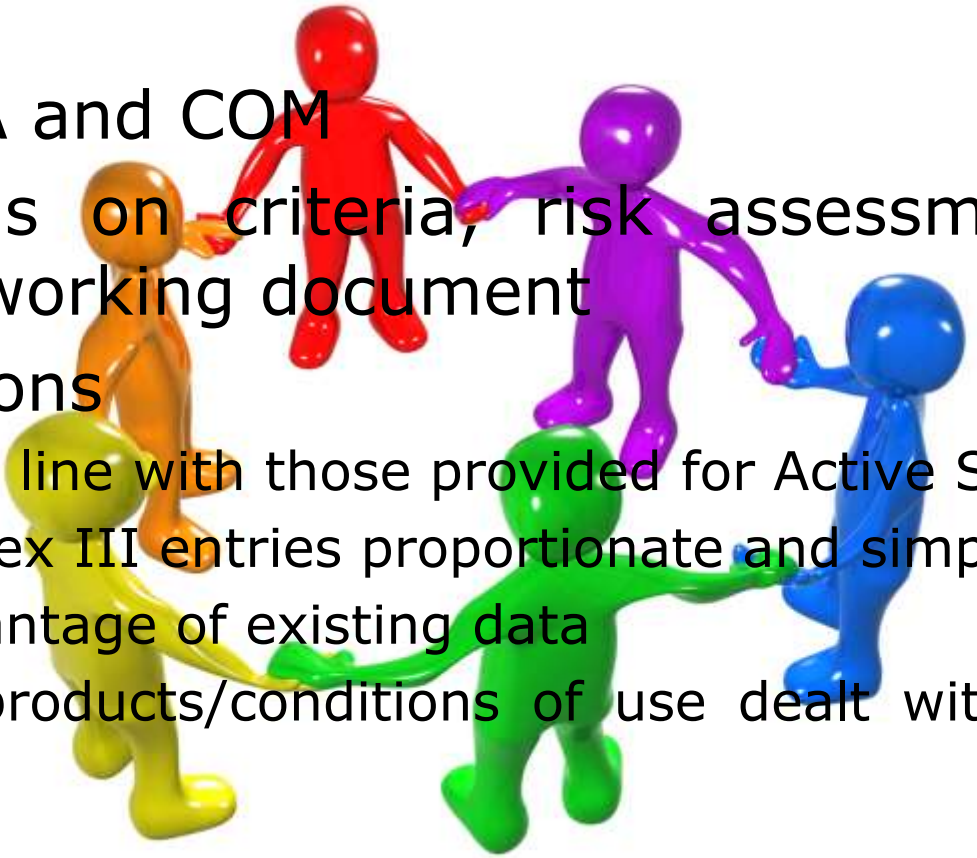
Chemical reg.	REACH – CLP – POP …		
PPP Reg.	1107/2009	1107/2009	1107/2009 (Art. 27)
Risk Management	National authorisations	European approval	European negative list (Annex III) Where risk identified
Risk Evaluation	Zonal assessment EU Requirements	European assessment EU requirements	Zonal and European assessment EU Requirements
Toxicology	Combined tox.	Single mol. tox.	May alter AS tox. or have specific tox. properties

European Commission

Setting Annex III

- Art. 27 mandates EC to set a list of unacceptable co-formulants as Annex III to Reg. (EC) 1107/2009. These unacceptable coformulants, or their residues cause a risk to human or animal health or to the environment, including ground waters.

WG on co-formulants



- MSs, EFSA and COM
- Discussions on criteria, risk assessment and procedure: working document
- Key decisions
  - Criteria in line with those provided for Active Substances
  - Keep Annex III entries proportionate and simple
  - Take advantage of existing data
  - Specific products/conditions of use dealt with at zonal level

European Commission

Criteria

- A Tiered approach, considering the criticality of the concerns
  - Tier1: triggers based (only) on hazard classification ☞ Annex III
    - Extrapolation from AS criteria (Annex II): CMR 1A/B, (ED)…
    - Extrapolation from REACH Annexes XIV/XVII: POP, PBT, SVHC…

European Commission

Criteria

- Tier2: triggers based on hazard classification ☞ Risk assessment ☞ Annex III ?
  - CMR2, STOT RE1&2, Skin/Resp. Sens. 1, two criteria PBT…
- Tier3: triggers based on other informations ☞ Risk assessment ☞ Annex III ?
  - Risk concerns, new scientific information, unsubmitted preservatives (Reg. 528/2012)…

European Commission

Procedure

Zonal assessment taking into account the toxicity of relevant co-formulants

- Notification by MS noted in PAFF
- Assessment by a RMS
- Peer-review
- Vote PAFF (PRAC)
- Annex III, with w/o specific conditions

European Commission

Next steps

- Working document from the Working Group
  - ☞ Stakeholders to comment: 30/05/2016(in writing)
    SANTE-Advisory-Group@ec.europa.eu
- Impl. Act to set detailed rules for Annex III
- Setting Annex III (PRAC 3 months)
  - ☞ MSs to identify candidates: 30/04/2016

☞ Discussion: May/July PAFF

☞ TBT during the summer break

☞ Vote Q4 2016 at the earliest

Thank you for your attention

Any questions ?

European Commission