



10th Annual Biocontrol Industry Meeting ABIM

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Low risk substances and products – where now?

Wolfgang Reinert

European Commission

DG Health and Food Safety

Unit Pesticides and Biocides

Regulation (EC) No 1107/2009

- Regulation introduces a new system of approvals, tiered by risk
- Criteria for low risk (Annex II) are only negative
- Low risk products shall be authorised in 120 days (article 47)
 - but MS do not find that feasible
- Extended period of data protection (article 59)
 - but industry does not find that sufficient
- The use of such substances in PPP should be favoured (recital 17)
 - but "low risk" must not be advertised as a property or used on the label as a claim (article 66)
- Is the concept fully mature?
- Is it all about low risk or low hazard?

**...an important step
into the right
direction!**

EU expert Group on low risk active substances

- Experts from MS, academia and stakeholders
- Start in October 2012: Long-lasting, but good discussions
- Set of possible criteria was identified
- Separate criteria for chemicals and microorganisms proposed
- These criteria are currently tested against approved substances
- A draft for amending the low risk criteria in Regulation 1107/2009 can be produced in relatively short time on service level
- Adoption process must be compatible with Better Regulation toolbox

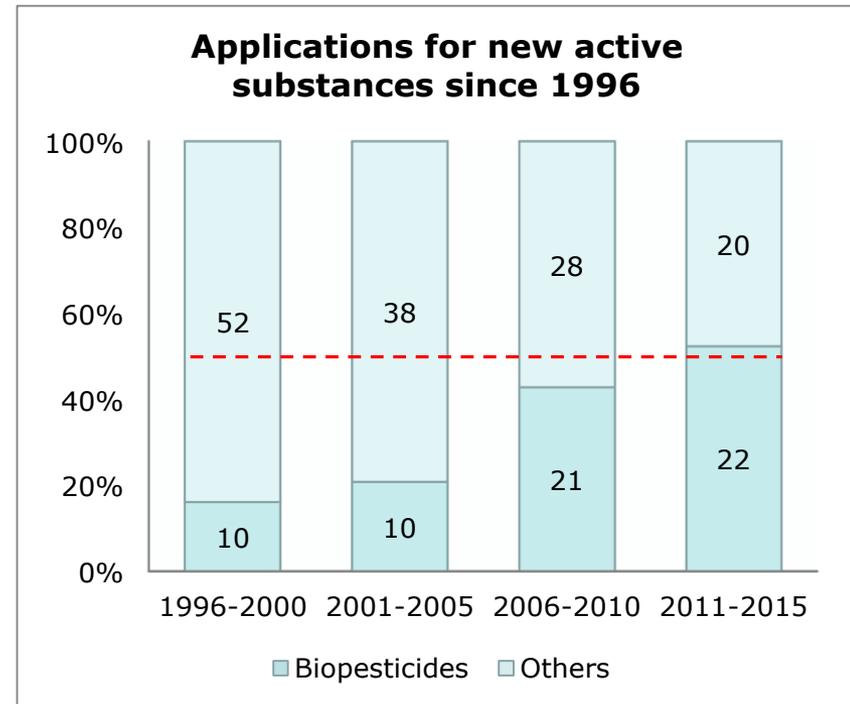
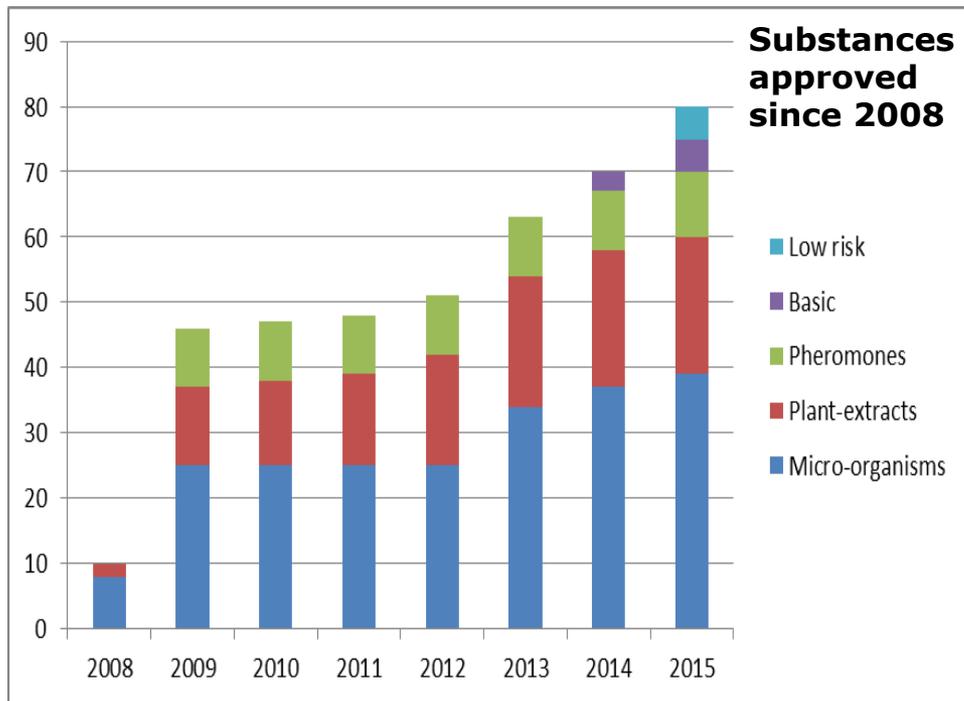
Emerging political interest

- Potential in overall plant protection:
 - Amateur uses
 - Organic agriculture
 - IPM
- On the agenda of the Agriculture/Fisheries Council meeting on 22 October as AOB point by NL
- COM informed by letter about plans to initiate a Motion for a Resolution

where tomorrow?

- Trinity of low risk:
 - Criteria
 - Guidance
 - Incentives
- Amendment of criteria ongoing
- Room for drafting of guidance
- Amendment of enacting terms through co-decision procedure
- Ex-post evaluation of Regulation 1107/2009 to be launched in 2016

The implications for biopesticide industry



- 5 Low risk substances approved so far; 4 of them are biopesticides
- In addition 33 applications for basic substances



Thank you very much
for your attention!