



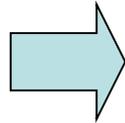
8th ABIM Meeting, Basel, Switzerland

Issues with Regulation 1107/2009 and the SUD

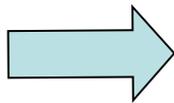
**Dr. Michael Flüh
European Commission
DG SANCO**

EU legislative frame

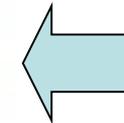
**Placing on
the market
of plant
protection
products**



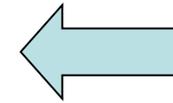
**Collection
of statistics**



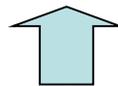
**Sustainable
use of
pesticides**



**Maximum
residue
levels of
pesticides**



**Technical requirements for
machinery**





Structure of this presentation

- ❑ Basic substances
- ❑ Low risk substances
- ❑ Other issues related to 1107/2009
- ❑ Sustainable Use Directive
 - ❑ National Action Plans
 - ❑ Integrated Pest Management



Basic substances - Pilot project

- *DG SANCO pilot project: with 5 applications*
- *Working procedure with Member States and EFSA established*
 - **EFSA co-ordinates commenting and finalises reporting table**
 - **If required, COM asks EFSA for focussed peer review or conclusion on open points**
 - **COM prepares review report and legal act**
 - **Overall 12-15 months**



Low Risk Substances

Regulation 1107/2009

- favours the inclusion of low risk substances in plant protection products and
- facilitates their placing on the market

Incentives and facilitated market access

- Approval up to 15 years
- Data protection up to 13 years
- Low risk PPP: Member States to decide in 120 days
- Separate listing
- Allowed to be mentioned in advertising



Low Risk – current issues/IBMA request 1

- More suitable criteria
 - Review and specification of new criteria legally possible
- Establishment of list of low risk substances
- Specific data requirements for biopesticides
- Preferential treatment in approval/authorisation process

Low Risk – Criteria for identification

*An active substance shall **not** be considered of low risk where it is or has to be classified as at least one of the following:*

- carcinogenic,*
- mutagenic,*
- toxic to reproduction,*
- sensitising chemicals,*
- very toxic or toxic,*
- explosive,*
- corrosive.*



Low Risk – Criteria for identification

*It shall also **not** be considered as of low risk if:*

- persistent (half-life in soil is more than 60 days),*
- bioconcentration factor is higher than 100,*
- it is deemed to be an endocrine disrupter, or*
- it has neurotoxic or immunotoxic effects.*



EU-expert group on "low risk"

Expert group of EU-Member States, Commission, Growers Organisations, NGOs and Industry.

Points to consider:

- *Consistency with other regulatory frames;*
- *Compare with criteria for 'green track active substances';*
- *Adjust current 'negative' criteria - formulate positive criteria;*
- *Develop further guidance;*
- *Discuss current incentives.*



Low Risk – current issues/requests IBMA – 2

- Establishment of list of low risk substances
 - Early review of already approved substances

- Specific data requirements for biopesticides

- Preferential treatment in approval/authorisation process
 - Accelerated approval/authorisation
 - Provisional/conditional approval
 - Unlimited approval/authorisation
 - Fees - exemption



Regulation 1107/2009 – other relevant issues

Minor uses

- Report to Council and Parliament delayed
- Report foresees establishment of secretariat with co-ordination role
- No funding of studies and research foreseen

Candidates for substitution

- Legal deadline to establish list
- External study carried out



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Objectives of Sustainable Use Directive

Achieve sustainable use of pesticides by

- reducing risks and impacts on human health and the environment and
- promoting the use of IPM and of alternative approaches or techniques such as non-chemical alternatives



SUD transposition and implementation

- Transposition date : 26 November 2011
- Today: transposition completed by **26** Member States
- Submission of **National Action Plan**: 26 November 2012
- Today: **27** Member States have submitted up to now



National action plans (NAP)

- Quantitative objectives, targets, measures and timetables
 - to reduce risks and impacts of pesticides uses and
 - to encourage development of IPM and alternative techniques to reduce dependency on the use of pesticides
- Indicators to monitor the use of active substances
- Description of implementing measures such as
 - IPM
 - Training and information
 - Controls of equipment and others



Follow up on implementation NAP

- First analysis available beginning 2014 together with FVO
- Report to European Parliament and Council by 26 Nov 2014
 - on the information communicated by MS in relation to NAPs
 - on methods used and
 - implications concerning the establishment of different targets to reduce the risks and use of pesticides
- NAP are not to be approved by Commission!



Follow up on implementation of IPM

- Member States shall report by 30 June 2013
 - on the measures to promote low pesticide-input pest management
 - on the establishment of necessary conditions for the implementation of IPM
 - In particular if farmers have at their disposal information and tools for monitoring and decision making as well as advisory services

- Already NAP shall describe
 - How MS ensure that the general principles of IPM are implemented and
 - Followed by all professional users as of 1 Jan 2014



Implementation of IPM - 1

- Submission of IPM reports by 30 June 2013
- SANCO offered electronic questionnaire to facilitate process
- Today: reports from **21** Member States
- Translation of reports in progress
- Project planned under BTSF (« train the trainer »)

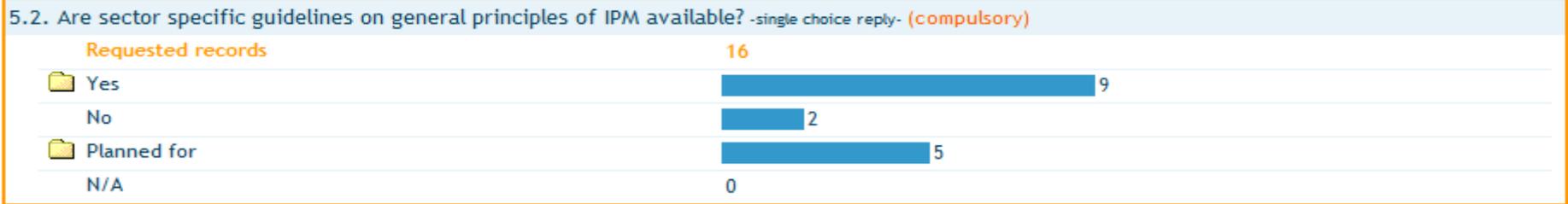
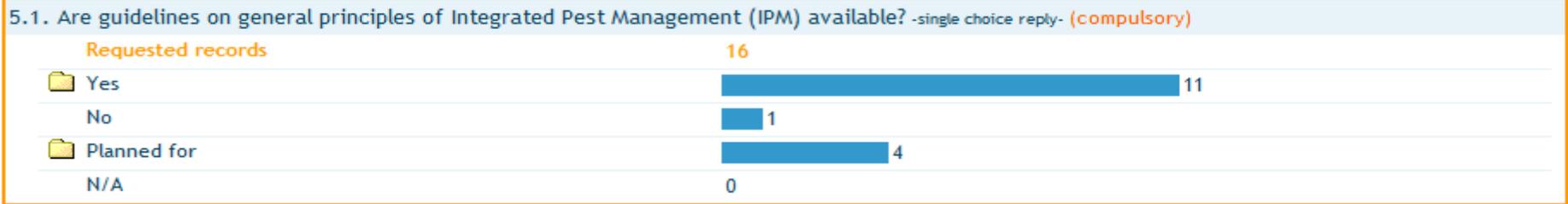


Structure IPM questionnaire

- *Planning, governance and coordination*
- *Communication and certified training*
- *Advisory services, pest monitoring and decision making tools for professional users*
- *Guidelines and other documentation*
- *Measure the progress achieved*
- *Promotion of low pesticides input pest management*
- *Complementary related policies*

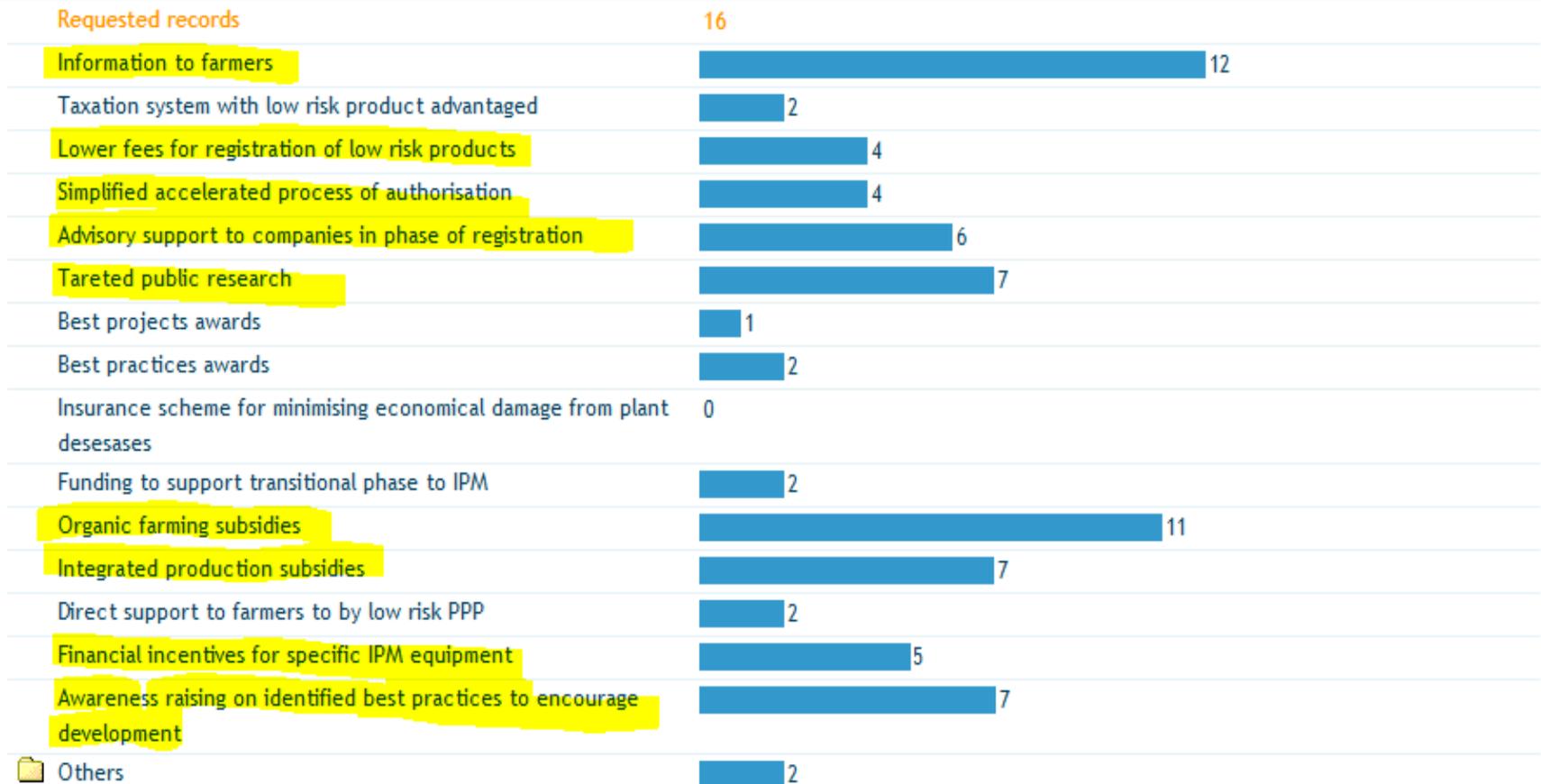
Draft overview of Guidelines and other informative technical documentation

5. Guidelines and other informative technical information



Draft overview on promotion of low pesticides input pest management

7.1. What are the measures put in place to promote low pesticide-input pest management? (*more than 1 answer possible*) -multiple choices reply- (optional)





Implementation of IPM - 2

- Submission of IPM reports by 30 June 2013
- SANCO offered electronic questionnaire to facilitate process
- Today: reports from **21** Member States
- Translation of reports in progress
- **Project planned under BTSF (« train the trainer »)**



Impact on work progress

- Unforeseen issues:
 - Bees/NNI
 - Endocrine disruptors
- Court cases
- Requests for access to documents
- Commission-wide reduction in staff



Thank you for your attention !