Expert group on Sustainable Plant Protection

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- The work of the Expert Group on Sustainable Plant Protection
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Low-risk in 1107/2009

- To favour inclusion of a low risk substance in PPP's it is appropriate to [...] facilitate the placing on the market of PPP's containing them.
- Incentives should be given for the placing on the market of low-risk plant protection products (recital 17)
- Use of PPP's shall comply with general principles of IPM as defined in SUD (art 55, 1107/2009)

Low-risk in 1107/2009

- Substances can be approved as low-risk when they meet criteria (art 4 + low risk criteria!)
- Products can be authorized as low risk if they contain only low risk, no substances of concern, no specific risk mitigation measures
- Low-risk incentives:
  - First approval period of 15 years (vs 10)
  - Data protection of 13 years (vs 10)
  - 120-day authorization procedure
  - Possibility to mention in advertising

Low-risk in Sustainable Use Directive (SUD)

- Objectives at use level:
  - reducing risks and impacts of pesticide use on human health and the environment and
  - Promoting the use of IPM and of alternative approaches or techniques such as non-chemical alternatives to pesticides (art 1).

Low-risk in Sustainable Use Directive

- MS shall take all necessary measures to promote low pesticide-input pest management, giving where possible priority to non-chemical methods, so that professional users switch to practices and products with the lowest risk to human health and the environment […] (art 14)
- In sensitive areas: low-risk and biological control measures shall be considered in the first place. (art 12)

State of play low-risk

- 5 low-risk actives approved
- Also substances already on market that may be low-risk.
- Upcoming renewal program (AIR-4)
- Start-up years: lots of work done to gain experience, create guidance documents etc.
- Work on proposal to amend low-risk criteria

Expert group Sustainable Plant Protection

- NL initiative, supported by Commission, EFSA and 19 Member States
- December 2015 – June 2016
- Identify short term and long term actions to:
  - Increase availability of low-risk products
  - Accelerate implementation of IPM in MS
- Implementation plan in Council next June

Work so far

Four areas:

1. Increasing the availability of low-risk products
2. Accelerating the implementation of IPM in Member States
3. Supporting the research and development of alternative methods
4. Recommendations for the future review of 1107/2009 regarding low-risk and basics

Work so far

1. Increasing the availability of low-risk products:

- Accelerating procedures for low-risk
- Measures to support businesses with their applications
- Clarification and guidance on regulatory requirements

Work so far

2. Accelerating the implementation of IPM in Member States:

- Easier access to available information
- Demonstration farms
- Advisory support

Work so far

3. Supporting the research and development of alternative methods:

- Make better use of what is already available
  - Completed and ongoing Framework Programme projects, like Endure, Pure, Biocomes …
  - C-IPM Eranet
  - Horizon 2020: ongoing projects and upcoming work programme calls

Work so far

4. Recommendations for the future review of 1107/2009 regarding low-risk and basics

- Input for upcoming review of 1107/2009
- Gaps and incoherencies?
- Proposals to change procedures?

Exploratory phase

So, what about efficacy?

- The expert group identified this workshop as important short term action
- Agreed-on follow-up actions may be included in implementation plan
- Commission welcomes initiative for further harmonisation in this area.

Efficacy in EU legislation

- Substances and products should present clear benefit for plant production (recitals 10 & 24)
- Active substance, art 4(3): a PPP, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:
  - is sufficiently effective
  - shall not have any unacceptable effects on plants or plant products
- Annex II, 3.2

Efficacy in EU legislation

- Products: uniform principles (reg 546/2011)
  - **Evaluation**
  - **Decision making**
- Data requirements (reg 284/2013)
  - **Reference to EPPO guidelines on trial design**
- Guidance documents
  - **Active substances (SANCO/10054/2013)**
  - **Products (SANCO/10055/2013)**
  - **Botanicals, semiochemicals (upcoming)**

Relevance to low-risk substances

- Level of effectiveness: what level is "sufficient"?
  - EPPO/EC guidance documents recognize that some products may have lower effectiveness than reference product
  - This can be acceptable if other characteristics have an advantage over reference product
  - Low risk products may have such advantages – explain and justify.

(e.g. See Guidance Doc SANCO/10054/2013, page 5)

Relevance to low-risk substances

- Way to demonstrate efficacy:
  - Guidance documents recognise that efficacy data shall be generated in trials performed to appropriate EPPO standards (or equivalent).
  - Deviation from the standards is possible in some cases, but must be justified.
  - Specific info on efficacy in guidances for microorganisms, semiochemicals, botanicals.

Expectations

- Work towards harmonization and simplification
- Make use of available room in current regulation and EPPO and EC guidance documents
- For EU Member States that take part in the expert group: take home results and share them with your representative.