The new EU PPP legislation and the challenge for minor use registration

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Overview

- About ECPA
- Regulation 1107/2009
- Key provisions concerning minor uses
- Food Chain and industry views
- Conclusion
About ECPA:

ECPA Network – reaching across Europe

Based in Brussels, ECPA represents both member national associations and member companies throughout Europe, extending to include the Accession Countries in Central and Eastern Europe.

ECPA’s secretariat & working groups come together to provide expertise & strategic direction to the network.

- 18 member multinational companies
- 31 member national associations
- Gapeg members
- + ECPA and it’s 33 working groups

The ECPA Network
Regulation 1107/2009

- Regulation developed to replace Directive 91/414/EEC
- Full application from 14th June 2011
- Many implementation measures being put in place
- Developed in parallel to the Directive on the Sustainable Use of Pesticides
Main new provisions from the Regulation

- **Cut-off criteria** introduce hazard based decisions for active substances – which could impact availability
  - Industry experts still maintain that decisions should be risk & science based

- **Comparative assessment** for products containing a ‘candidate for substitution’
  - Need proportionate and predictable implementation to limit workload

- **The zonal process** offers an important opportunity for worksharing
  - Remove unnecessary national requirements to allow actual worksharing!
Minor Uses – A Common goal of the food chain

**Overall goal of the food value chain:**

- Meeting consumer’s right for high quality healthy and affordable food

- **Speciality crops are a prerequisite for healthy nutrition**

- **Minor use authorisations therefore play an essential role to ensure speciality crops have adequate protection**
Minor Uses – A Common need of the food chain

The fact: Increasing lack of economically viable crop protection solutions

The consequences:

- Lower productivity, lower quality, higher risk of resistances; leading to decreased return on investments

- Difficult to continue to grow certain crops in the EU with likely effects on availability and affordability of food and endorsing land grabbing outside the EU

- Increasing problems with crop rotation and biodiversity

The need: Maintain production of speciality crops and minor uses as a cornerstone of a competitive European food value chain
Key challenges and opportunities

What can be done at the EU level to ensure availability of crop protection products for minor uses?

**Overall aim:**
Ensure sustainable solutions for minor uses and speciality crops as it concerns the whole food chain

- Seize opportunities and transform potential blockers from Regulation 1107/2009
- Identify practical supporting measures
- EU fund to support initiatives on minor use authorisation
Seize opportunities and transform blockers from Regulation 1107/2009

Seize opportunities

- Art 51
  Extension of PPP authorisations

- Art 51§9
  Minor use fund

- Art 59§1
  Additional data protection: 3 months per minor use authorised

Transform blockers

- Long process/delayed approval of new active substances

- Costs of unnecessary additional requirements

- Comparative assessment

Crop protection industry will continue to make significant investments for crop protection solutions for minor uses and in speciality crops
Article 51(9) requires the Commission to present a report on minor uses

Consultants evaluation finalised
- Recognition of importance of minor uses & insufficiency of available crop protection
- 4 options: Strong EU support to strengthen coordination and project execution is key!
- Key as well will be communication from all stakeholders on this need

Commission report in early December
- With minor use fund proposal?
- Key for future of speciality crops!
Food Chain Joint Views

**To help minor use authorisations?**
1. EU/zonal list of minor uses
2. EU database (products/uses)
3. Common system for extensions: “off label”
4. Use of mutual recognition
5. Simplified minor use study protocols

**To help minor use coordination?**
a) Inventory of MS problems and solutions
b) EU coordination forum
c) Co-financing for authorisation data
d) Advisory Group to assess future needs
Conclusions

- Needs attention given their importance for a healthy diet and value of €1 billion +
- Regulation 1107/2009 has some opportunities
  - But also numerous threats
- An EU fund is needed to ensure coordination knowledge and cost sharing

**But let’s get to the root of the problem**
- The growing complexity of the regulatory process, and the difficulty in getting support to communicate the benefits and need of crop protection products, where EU communication would be helpful
Food Chain Joint Conference – 7 November

**Overall goals**
- Maintain EU viability of speciality crops for available high quality healthy food at affordable prices
- Ensure available PPP solutions for speciality crops and minor uses

**Objectives of the Conference**
- Consider the progress made by EC and consultant
- Progress the discussions of the 2009 Conference
- Awareness raising towards stakeholders (growers, food chain, public)
- Get more clarity on the uses of the fund

*Thank you*