

Exchange of Experience - Proposed solutions for the Southern Zone

ECPA opinion

Vassilia Sgouri- April 30th, 2010

Learning from the past - creating the future

- ❖ The EU legislation (s) on minor uses - key issues
- ❖ The people and their means-cooperation with Key partners
- ❖ The need to continue improvements

European legislation :The past of the Minor uses in Europe

- ❖ Authorisation of use of a PPP on plants/plant products
 - a) not widely grown in a Member State (art. 9 Directive 91/414) or
 - b) any crop to meet an exceptional or punctual plant protection need
 - ❖ Different definitions, “minor use” case by case
 - ❖ Different authorization types
 - ❖ data requirements
 - ❖ investment required
- ⇒ high cost of authorization, dissuasive to invest in minor uses.**

European Regulation 1107/2009: Minor uses as integral part

- ❖ Common legal basis and definition
- ❖ Industry incentive and opportunities for developing minor uses
- ❖ All uses follow MRL setting Regulation 396/2005.
- ❖ Member State defines the minor uses and facilitates authorisation
- ❖ Minor uses in the zonal approach: Strengthening Mutual Recognition
- ❖ Who deals with Minor uses in Europe?

Key issues: Definition in Regulation 1107/2009

The definition Article 3 point 26: Use of a PPP in a particular MS on plants or plant products which are:

- a) not widely grown in that Member State
- b) widely grown to meet an exceptional plant protection need

=>Industry to prepare a data package /crop for different countries.

Provided MSs' defined minor uses are known, anyone proposes solution, but needs **a clear process,**

**harmonised data requirements and
quality of dossier.**

Key issue: incentives and opportunities

- ❖ Extension of PPP authorisations for minor uses (art. 51)
- ❖ Towards a minor use fund (art. 51 §7)
- ❖ Data protection only for new compounds or new formulations submitted within the 5 years of 1st registration (art. 59)
- ❖ No data protection for label extension of renewals, while investment continues
 - ❖ Support during reviews
 - ❖ Cost of additional data and authorisation
 - ❖ MRLs adaptation - support
- ❖ Will be taken into account for the comparative assessment (art. 50)

Key issue: incentives and opportunities

... some potential blockers, given major and minor uses link

❖ Length of authorization processes impact investment and priorities
=>a quicker approval in Europe will support broader investment on uses

❖ Additional data requirements. Necessity ?
=>additional requirements need higher investment in time and capacities

❖ Comparative assessment: complex processes impact resources and costs
=> removal of major uses (through substitution) will impact the product availability for minor uses

The people and the means: Cooperation experiences - Key partners

- ❖ Identification of needs: MS authorities, farmers, Institutes, Food Chain, Industry.
Collaboration: national minor uses and existing practices, correct-use control
-> minor uses project's selection – prioritization - realization and authorization
- ❖ Collect solutions - Project planning: Industry, Institutes, MS authorities, Food Chain, professionals, farmers association, TEG (Region) and COM
Coordination: role of TEG and Steering committee at European level.
-> intensive cooperation on technical issues and countries coordination
-> European project's selection – compilation - prioritization – realization
- ❖ Authorization processes: Industry and other requestors, MS authorities, TEG (Region), RMS and COM
-> minor uses authorization requests fitting to national system

The people and the means: Cooperation experiences - Key partners

European funding: guarantees co-ordination in Europe, process coherence, safety control (consumer and environment). Assures the support of MS's authorities.

Improved extensive cooperation- Collaboration

Farmers & Food Chain: give the pragmatic view of priority needs and existing solutions. Support the implementation for quality production and safe use.

Industry: Brings innovation, support authorization and implementation of safe uses.

Experience: Issues identified & process improvement proposals

- ❖ **Data base: Public availability of Minor uses lists**
Evaluation and Prioritisation of available solutions/country
- ❖ **Development of solutions for minor uses, in cooperation with industry:**
 - Include minor uses in the early development planning
 - Use of extrapolation or complementarily to major uses/country
 - Technical coordination for development of common solutions
- ❖ **Successful use of existing capacities: Cooperation – Strong Coordination**
- ❖ **Adaptation to zonal authorization with inter-zonal cooperation, Improve Mutual recognition**
- ❖ **Simplification and harmonization of authorization process (European level).**
Support MSs to facilitate and encourage the applications of minor uses

... improvement proposals: Data requirements potential simplifications

❖ **Need to reduce significantly the workload for minor uses -**

Usually minor use are widely distributed on small areas, with probably different exposure scenarios. Would it mean different risk-assessments ?

- ❖ Need an overview of Minor uses and specialty crops (type of crop, cultivation locations, techniques)
- ❖ Solutions to fit the nature and geographic distribution of specialty crops
- ❖ Harmonize risk assessments and control measures

Solution proposal

- ❖ Use “flexible” extrapolation from major uses per type of crop/use
- ❖ Define basic extrapolation guidelines- avoid specific national requirements
- ❖ Include Minor uses in the concept of “Risk Envelope” too.

Key conclusions of Stakeholders Conference November 4th, 2009

Conference as catalyst of existing situation for speciality crops:

- ❖ Producing quality food includes better protection of specialty crops
 - ❖ Protect of high value specialty crops
 - ❖ Support European Agriculture
 - ❖ Produce of high-quality healthy and affordable food for all consumers
 - ❖ Promote sustainable farming and biodiversity

- ❖ Greater Coordination: specific EU workgroups and coordination units for minor use issues
 - ❖ Sharing information-Technical coordination & work-sharing
 - ❖ Clear and harmonized process
 - ❖ Pragmatic data requirements for authorization (Europe)
 - ❖ Guidance and process Coordination (Europe)

Key conclusions of Stakeholders Conference November 4th, 2009

- ❖ Towards Improved cooperation:
 - ❖ Trust and cooperation between public and private sector
 - ❖ Holistic understanding of minor use situation
 - ❖ Intensify cooperation with third countries and international bodies (OECD, IR4)

- ❖ Use of Minor Use Fund (report by end 2011) to ensure
 - ❖ Coordinated approach towards PPP authorisation across EU
 - ❖ Enhanced cooperation and information sharing
 - ❖ Provisional solutions for growers in the meantime

More than 100 participants from National authorities-Commission and Food value chain

⇒ **Keep the momentum of the 4 November 2009**

Thank you for your kind attention

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