Importance of minor uses for the chemical industry and initiatives

Regulation 1107/2009 on the authorisation of Minor Uses in Europe - Opportunities and constraints.

Conference on keeping plant protection solutions available for speciality crops & minor uses in the Central & Northern Zone of the EU
18-19 May 2011 - Wageningen, the Netherlands -.
Vassilia Sgouri – BCS - European Stewardship Strategy
Content - important points

-State of play: importance of the Minor Uses and speciality crops, market, legislation.

- Authorisations on Minor Uses: implementing regulation 1107/2009 on authorisation and 396/2005 on MRLs setting

- Implementation of 1107, needs to further define
  1. Definition of Minor Uses
  2. Incentives
  3. Initiatives
  4. Organisation & European fund
State of play: importance of the minor uses and speciality crops

Huge variety of minor uses exist in Europe with poor means to achieve crop protection and quality production.

Dr M. Flueh –Com, SANCO, unit E3 director, in his introduction on 5th May 2011 meeting “Minor uses history”

- persistent by-product of legislation
- reason: economy versus law
- effects: illegal uses, persistent demands for derogations, economic loss for growers, unrest with consumers

“Output of Speciality crops, which include most vegetables, fruits, nurseries and flowers, accounts for more than 25% of the value of EUs total agricultural production-2007 values”.

Despite the need to have quality and affordable production is recognized, we still need to build on common practice with all stakeholders in Europe, on the way towards a

- sustainable system of production, including the development of crop protection solutions,
- giving access to innovation and safe crop production to farmers
- affordable quality food to consumer while keeping food and landscape bio-diversity
State of play: importance of the core horticultural products

Table 3: Crop output as share of agricultural goods output 2007 (%)

<table>
<thead>
<tr>
<th>Product</th>
<th>EU15</th>
<th>NMS12</th>
<th>EU27</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cereals</td>
<td>13.6</td>
<td>20.9</td>
<td>14.8</td>
</tr>
<tr>
<td>Industrial crops</td>
<td>3.9</td>
<td>6.9</td>
<td>4.4</td>
</tr>
<tr>
<td>Forage plants</td>
<td>6.2</td>
<td>8.3</td>
<td>6.5</td>
</tr>
<tr>
<td>Vegetables*</td>
<td>15.7</td>
<td>10.2</td>
<td>14.8</td>
</tr>
<tr>
<td>Potatoes</td>
<td>2.8</td>
<td>5.9</td>
<td>3.3</td>
</tr>
<tr>
<td>Fruits</td>
<td>7.2</td>
<td>4.8</td>
<td>6.8</td>
</tr>
<tr>
<td>Wine</td>
<td>5.4</td>
<td>1.0</td>
<td>4.8</td>
</tr>
<tr>
<td>Olive oil</td>
<td>1.7</td>
<td>0.0</td>
<td>1.4</td>
</tr>
<tr>
<td>Other crop products</td>
<td>0.9</td>
<td>0.5</td>
<td>0.8</td>
</tr>
<tr>
<td><strong>Crop output, total</strong></td>
<td><strong>57.4</strong></td>
<td><strong>58.5</strong></td>
<td><strong>57.5</strong></td>
</tr>
</tbody>
</table>

* The full name is **Vegetables and horticultural products**, which includes plants and flowers.

... vegetable and fruit growing is a major agricultural activity in southern Europe. In Netherlands, the share accounted for by vegetables, plant and flowers and fruits is more than 40%. ... production of ornamental plants and flowers in the Netherlands, accounting for some two thirds of the country's output of vegetables, horticultural products and fruits. In fact, roughly one third of the EU-27 total output of plants and flowers comes from the Netherlands.
Vegetables, horticultural products and fruit output as share of agricultural goods output 2007 (%)
Global Seed, Trait & Crop Protection Market

2009: > 1 in 4 € spent on Fruits & Vegetable crops globally

Commercial S&T market: 22.8 bn €

- Corn: 37%
- Soy: 15%
- Cereals: 8%
- Sugar Crops: 3%
- Rice: 7%
- Cotton: 5%
- Rapeseed: 3%
- Others: 9%
- Vegetables: 13%

Crop Protection market: 29.5 bn €

- Corn: 37%
- Soy: 15%
- Cereals: 17%
- Sugar Crops: 4%
- Rice: 9%
- Cotton: 4%
- Rapeseed: 4%
- Others: 7%
- Vegetables: 15%
- Fruits: 17%

Sources: Tricast Aug 2010/ Seed – Context Network 2010

Fruit: Fruits & Nuts, Grapes & Plantations; Vegetables: Vegetables, Potatoes & Flowers
Fungicide value market in Europe – Development / authorisation efforts


Total market value: 1242 m€ in 2008 and 1131 m€ in 2009

Total Fungicide market G/F/V = 1.039 M€ in 2009

Development effort to cover the cereals’ group of crops:
2 crop groups X pest

Development effort to cover groups of crops:
vegetable crops 20 groups X pest
fruits 11 groups of crops X pest
grapes 2 groups X pest
Disease segments (M€, Agrowin 2009)

- **Bot+(Scle+Mo.)** 14%
- **Leaf spot** 14%
- **Others** 16%
- **Downy/Pythium** 38%
- **Powdery** 18%

Total Fungicide market = 1.039 M€
Authorisations on Minor Uses -1107/2009
MRLs setting on Minor Uses-396/2005

1107/2009

• The definition of minor uses in 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
• To consider also that facilitation of registration will be applicable if
  a) the intended use is minor in nature;
  b) provided that the conditions referred to in Article 4(3) are satisfied: PPP should have no harmful effect to humans, shall not cause unnecessary pain to vertebrates and have no unacceptable effects to environment, and Art. 29(1) p. (i) are satisfied;
  c) the extension is in the public interest; and
  d) the documentation and information to support the extension of use has been submitted by the persons or bodies referred to in paragraph 1, especially data on the magnitude of residues and where necessary on the risk assessment to the operator, worker and bystander (and resident).

396/2005

• MRLs are needed for all food /feed crops, either produced in Europe or Imported.
• The number of trials varies to Major/minor (according to acreage, production and consumption) – trials requested 8/region for Major and 4/region for minor crops.
1. Definition of Minor Use

Definitions of minor and speciality crops and minor use are critical precursors to the development of programmes to encourage the availability of crop protection solutions!

Definitions …

CROPS are Major or minor, linked to the production – compared to cultivated acreage or tonnage produced.

“Minor crops” includes both food and ornamental crops of low cultivated acreage. “Speciality crops” often refers to a narrower group of minor crops.

- OECD: definition should reflect production variables, dietary significance and economic return.
- 1107/2009: Minor USE is Crop X Plant Protection need against a pest

Article 51(8): “Member States shall establish and regularly update a list of minor uses”.

- The guidance document SANCO 7525/VI/95 defines Minor Crops for residue data needs, considering cultivated area, production and consumption.
1. Definition of Minor Use

In Europe, Article 3 point 26, there is a general definition and MSs are requested to give definition of minor use lists per MS, Article 51(8).

- Combination of minor uses at the EU or zonal level would allow better response to a compiled need, with viable solutions.

Need European guidance to establish common terminology on what is a minor use:

- to ensure common approaches in establishing MSs lists of minor uses.
- to develop criteria that allow crops and uses to be defined as minor, especially for minor uses on Major crops
  - ‘minor’ at the EU or
  - ‘minor’ zonal level
Criteria proposed by ECPA and Food Chain Partners

Definition of Minor Crops = Minor uses: should be considered as minor

- in Europe, all crops grown on < 200,000 hectares (~ 0.2% of cropped area) in the whole of the EU
- per zone, crops grown on a small percentage of the zonal land area (~ 0.5% of cropped land in that zone), and
- per individual Member State, crops grown on a small percentage of the national land (~ 1.0% of cropped land in that country)

Develop a definition of minor use where it is linked to a major crop, linked to a number of specific conditions as,

a) there are insufficient efficacious alternatives for the use,
b) alternatives pose greater risks,
c) the minor use is significant in managing pest resistance, or
d) the minor use plays a significant part in integrated pest management.

Some of the above criteria apply in specific countries but there is important diversity in definitions…

In principle, all definitions of minor uses are based on the PPP use pattern being so limited that revenues from the expected sales may not justify an investment.
2. Incentives

- Extension of data protection for PPP submissions including minor uses
  
  BUT…only for new compounds or new formulations submitted within the 5 years of 1st registration in a MS (art. 59)

  …No incentive while investment continues during
  
  • Support of authorisation reviews, renewals
  • Preparation of additional data and authorisation support
  • MRLs adaptation – modifications support

  Additional motivation
  
  - European minor use fund (art. 51 §7)

  Will be taken into account for the comparative assessment (art. 50)
2. Incentives: protection of data

- Incentive to prolong the protection period, if an application includes minor uses, in each MS

  - 3 months for each minor use up to a max of 3 years in each MS for ‘normal’ substances (ie for new actives 10 + 3 years), for ‘low risk’ substances (ie 13 + 2),

- Conditions:

  Applications for minor uses must be made within 5 years of the first registration in each MS level, and therefore will apply primarily to submissions for new active substances or new products (Article 59.1)

  No protection for minor uses submitted for a renewal of approval of a product, because application must be made within 5 years, but could help in comparative assessment
Two new PPPs based on same AS (with minor uses)

1. New file PPP-A
   - New data PPP-A: 10 years data protection
   - 10 years
   - Data protection
   - DP

2. New file PPP-B
   - New data PPP-B: 10 years data protection
   - 2 years
   - Data protection
   - DP

More uses

Minor use x8

Authorisation

DP – from PPP-A

Bayer CropScience
Product Registration – **Minor Crop Use Data Protection**

The minor crop use situation (data protection) represents an interesting facet for minor crops CP registrations.

**Canada: Regulatory Directive DIR 2007-03**
Up to 5 additional years for minor uses

**USA: Food Quality Protection Act 96**
1 year for each 3 minor uses up to a total of 3 additional years

- LA realizes interest in minor crops – discussion starting

**EU Regulation 1107/2009 up to 3 additional years**

**Brazil – South Africa:**
To be clarified

**Australia/ APMVA**
1 year for each 5 minor uses up to 3 additional years

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Source: Isidro Bailo – BCS Generic Affairs
2. Incentives: Industry’s position

Industry supports the use of appropriate incentives for the effort to authorise and support minor uses authorisations

- 10 years minimum protection for regulatory data, plus additional periods of protection of regulatory data for minor use registrations
- Incentives to support the continued availability of crop protection solutions for minor uses i.e. during authorisation renewals and review programmes.
- Reduced administrative fees
- Stimulate inter-zonal Mutual Recognition

Improved mechanisms to facilitate the registration of Minor uses

- Extended scope of extrapolations to crops and crop-groups
- Reduced number of trials based on the principles of sound science for the protection of humans and environment. i.e. use 50% residue trials from non EU countries with comparable conditions.
- Expedited reviews to facilitate applications, provide economic stimulus to register and increase the availability of new crop protection technologies to growers.
- Ask registrants’ consent before granting third party authorisations for minor uses. Clear the question on liability.
3. Initiatives

Cooperation experiences have shown that **Key issues**

- Identification of needs
- Evaluation of the importance and priority
- Elaboration of projects
- Authorisation of solutions

Need collaboration and strong coordination between the **Key partners**

- Authorities
- Growers
- Industry
- Food Chain partners
- Academia and experts
4. Organisation & European fund

Process improvement proposals include

- **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
  - Extended use of extrapolation or complementarily to major uses/country
  - Technical coordination for development of common solutions

- **Simplification and harmonization of authorization process**: adapted to zonal authorization, improved inter-zonal cooperation and mutual recognition

- **Successful use of existing capacities**: Cooperation – Strong Coordination
4. Organisation & European fund

🌟 Use of the European Fund:

- To keep together the key partners and a managing team
- Create transparent and easy process from data collection to authorisation
- Create appropriate tools to support information collection and evaluation, transparency and efficacious authorisation
- Give appropriate incentives to keep innovative and safe solutions for the farmers of minor crops and minor uses.
4. Proposals - Industry’s contribution

Minor uses issues is a challenge to all stakeholders involved, and in particular regulatory authorities.

Therefore, in order to improve availability of crop protection products for minor uses, Industry

- supports initiatives and specific arrangements to facilitate and improve authorisation for minor uses.
- can contribute expertise and knowledge to ongoing efforts to increase the availability of crop protection products.
- supports the use of systems, processes and tools which provide transparency and availability of information for all stakeholders.
THANK YOU FOR YOUR ATTENTION!

For any questions, please contact vassilia.sgouri@bayer.com