The off label registration process as a platform for cooperation between crop protection products producers & associations of minor crops producers.

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Do we need the off label registrations?

- High registration costs on the CPP industry:
  - Annex I a.i. inclusion (currently 540/2011 Regulation)
  - Local registration fees
- The time needed for registration
- Small acreage of crops

BUT ....
Do we need the off label registrations?

... YES!

- The high economic losses of minor crops producers

- The threat of the illegal use of crop protection products
Off label registrations – effort of solving the issue

The process as a platform of cooperation between crop protection products and minor crops producers

- Formal support from CPP industry
- Access to the dossier elements relevant to the off lable processes
- Quickness of the process!
Off label registrations – situation before 14.06.2011

- Legal basis → art. 49, Crop Protection Act of December 18th, 2003

  - Definition

  „In justified cases, the minister competent for agriculture, on the request of the state or scientific institutions specialising in the field of agriculture, social and professional farmers organisations or agricultural chambers, having obtained the consent of the applicant specified in Article 39 (1) and favourable opinion of the Commission, may allow, for a determined period, the application of the plant protection product in plants cultivated on a small area or against harmful organisms causing losses only on specific areas, if the requirements of Article 38 (1) (d) and (e) are met.”

  - Formal requirements – needed support from CPP industry
Off label registrations – situation before 14.06.2011

- „The draft list of the minor and major crops considering combination of "harmful organism/crop" for which there is no currently effective methods because of the lack of authorised crop protection products (version of 20.09.2005).”

<table>
<thead>
<tr>
<th>l.p.</th>
<th>roślina uprawna / crop (polish common name)</th>
<th>roślina uprawna - ang. / crop (english common name)</th>
<th>roślina uprawna - lac. / crop (latin scientific name)</th>
<th>organizmy szkodliwe dla których brak środków (harmful organisms for which there are no plant protection products available)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>bób</td>
<td>broad bean</td>
<td>Vicia faba</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>brokuł</td>
<td>broccoli</td>
<td>Brassica oleracea conv. botryts vr. cymosa</td>
<td>1. Czerń krzyżowych/Alternaria spp./Alternaria diseases</td>
</tr>
<tr>
<td>3</td>
<td>brukiew</td>
<td>swade</td>
<td>Brassica napus</td>
<td>-</td>
</tr>
</tbody>
</table>
State of play after 14.06.2011r.

- New legal basis → art. 51 Regulation 1107/2009 of October 21st, 2009
  - Definition – art. 3: „minor use’ means use of a plant protection product in a particular Member State on plants or plant products which are:
    (a) not widely grown in that Member State; or
    (b) widely grown, to meet an exceptional plant protection need”
  - Formal requirements – art. 51 of 1107/2009
State of play after 14.06.2011r.

- New formula of:
  - Application
  - Label

- New list of minor crops

<table>
<thead>
<tr>
<th>Lp.</th>
<th>Gatunek rośliny uprawnej/Crop species</th>
<th>Nazwa polska/polish common name</th>
<th>Nazwa łacińska/latin science name</th>
<th>Nazwa angielska/english common name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Rośliny warzywne/Vegetables</td>
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<td>Rośliny warzywne/Vegetables</td>
</tr>
<tr>
<td>1.</td>
<td>bób</td>
<td>Vicia faba L.</td>
<td>Vicia faba L.</td>
<td>broad bean</td>
</tr>
<tr>
<td>2.</td>
<td>brokuł zwyczajny</td>
<td>Brassica oleracea var.</td>
<td>Brassica oleracea var.</td>
<td>broccoli</td>
</tr>
</tbody>
</table>
State of play after 14.06.2011r. – potential risk

● New challenge:

- Annex I inclusion limitations (currently 540/2011 Regulation)
- Cut off criteria
State of play after 14.06.2011r. – new opportunities

- Mutual Recognition
- EU Fund
  - Direct support of the off label processes
  - Off label „know how”
  - Communication between stakeholders
Thank you for your attention.