EUROPEAN UNION MINOR USES COORDINATION FACILITY

Meeting "Horizontal Expert Group", 27 April 2016

The main conclusions of the meeting of the "Horizontal Expert Group", held on 27 April 2016 in Brussels, are listed below.

- The meeting was attended by 26 people from 13 EU Member States and 5 different stakeholder organisations.
- Over the past months the Coordination Facility had a number of **meetings with different stakeholders** to get a better understanding of their needs and expectations. In this respect, the Coordination Facility has attended the Canadian Biopesticides and Minor Uses Pesticides Priority Setting Workshops in Ottawa, Canada. The Workshops were very well organised. It was a smooth and transparent process. These workshops are the result of a selection process that already starts in the autumn prior to the year of the meetings. In the Canadian programmes the priorities are based on pest, disease and weed control needs rather than identification of active ingredients. It will be considered if some elements of this process can be introduced in the EU.
- The proposal to have 'biocontrol' as topic for the **plenary session in September 2016** was generally supported.
- The **Terms of Reference (ToR) for the Horizontal Expert Group** has been approved by the Steering Group. The following points from the ToR were highlighted:
    - The Horizontal Expert Group will act for all EU Member States.
    - Members of the HEG should have an EU mind set.
    - The chair will make the draft-agenda timely available prior to the meeting for commenting.
- At the **Global Minor Uses workshop** (Chicago, September 2015) ´A-priorities´ were selected for a glasshouse crop, temperate crop and tropical crop. The EU, together with Canada and Australia, is involved in the temperate project ´downy mildew on leafy vegetables´. IR-4 (US) has the lead for the tropical project. Currently there is no further news on the 'glasshouse' project.
- What are the **criteria to start a new Commodity Expert Group**? In general, when a certain number of Member States and growers' associations representing a substantial percentage of the EU-production of that commodity are willing to comply with the Terms of Reference of a CEG it should be possible to start a new CEG. In all cases the Steering Group should be consulted for final approval.
- The experience that EU Member States and industry have with the **zonal system** differs, but it is clear that in general the zonal procedure and Mutual Recognition is not working as anticipated. The Commission will take this point up in light of the upcoming review of Regulation (EC) No 1107/2009, where the Commission is asked to evaluate the functioning

of mutual recognition and the division of the European Union in three zones. The revision of Regulation (EC) No 1107/2009 is expected to start in 2016.

- The **provisions for data protection** are not correctly applied by all Member States as they do not extend the period of data protection with an additional 3 months for every minor uses extension.
- The **treatment of seeds** is considered as one of the possible uses of plant protection products and the notion of "use" covers the treatment of seeds and not the sowing of treated seeds. Also for minor uses extensions for seed treatment the inter-zonal procedure needs to be followed, even if the application is only intended for one Member State. The Zonal RMS prepares an evaluation and circulates the evaluation for commenting to all other Member States.
- The Coordination Facility has recruited an **IT-officer** to work on the database. First task will be transfer of EUMUDA. It will be important for EUMUDA that more countries will contribute to the database (e.g. for crop acreages). Currently the information on ongoing projects is available in different types of documents and formats. The new IT-officer of the Coordination Facility, will work on such a template to be used by all CEGs. The aim is also to produce a template for a ´project agreement´ for future EU trials. Although such a template would have no legal status it should clearly capture the parties involved, their tasks and the agreed timelines.
- It is planned that a **Guidance Document on Minor Uses** will be developed. Such a document should comprise of two parts. Part 1 should cover the process from identifying a crop-pest combination until the generation of the data; Part 2 should cover the submission process from application till decision. The Guidance Document should not just repeat the provisions of Regulation (EC) No 1107/2009, but should preferably be built step by step based on 'real' problems encountered in the different Member States. Case studies could be used for this purpose. Eventually the Guidance Document should be noted by the Standing Committee to ensure an official EU-status of the document.
- A tour de table was done to see how member States apply **comparative assessment**. There is a diversity of interpretations:
    - When there is a minor use on the label/off label this will not be assessed; only the major uses will be assessed.
    - When a minor use is on the label all major uses will also not be assessed and be kept on the label.
- Due to the **(non)renewal of the approval of active substances** less active substances will become available for EU agriculture. As a consequence, PPPs will disappear from the market which will have a negative impact on 'minor uses'.
- The **'ECPA-ECCA Crop Protection European Regulatory Conference'** (10-11 March 2016, Brussels), was very well attended with more than 300 participants. All presentations given at the Conference can be found at the ECPA website: http://www.ecpa.eu/event/regulatory-affairs/crop-protection-european-regulatory-conference-0
- The results of the **'Workshop on efficacy requirements and evaluation of plant protection products based on low-risk active substances'** (6-7 April 2016, Ede, NL) were

presented. Currently the efficacy of low-risk products is evaluated in the same way as standard chemical products. To accelerate their acceptance, it was discussed whether a customised approach is possible for low-risk products. EPPO will start preparing a new guideline on the efficacy requirements for low-risk products. This has to be approved by the EPPO Working Party on PPP in May 2016. It is envisaged that the guidelines will be finalised and adopted by the EPPO Council meeting in September 2017.