EUROPEAN UNION MINOR USES COORDINATION FACILITY

Meeting "Horizontal Expert Group", 29 September 2016

The main conclusions of the meeting of the "Horizontal Expert Group", held on 29 September 2016 in Freising (Germany), are listed below.

- The meeting was attended by 41 people from 16 EU Member States and 4 different stakeholder organisations.
- The conclusions from the meeting of the "Chairs of the Commodity Expert Groups" on 27 September were reiterated in the meeting of the "Horizontal Expert Group".
- As from 1st November 2016 the **EUMUCF will be fully staffed** with the coordinator, administrator, IT-expert and the technical expert.
- **Homologa** is a Global Crop Protection Database about plant protection products and their Maximum Residue Limits (MRLs). Homologa may be a useful tool to close minor use gaps. The Minor Uses Steering Group will discuss in its meeting on 5th October 2016 if a subscription will be taken by the Coordination Facility.
- As it is clear that minor uses problems in the EU will not all be resolved in three years, the MUCF had prepared an initial proposal for the **long-term funding** of the Coordination Facility. The option to ask for contributions from Member States according to their population (equal to the voting system in the Standing Committee on Plants, Animals, Food and Feed) is considered the most feasible option. This proposal will be discussed in the meeting of the Minor Uses Steering Committee on 5th October 2016.
- For transparency and clarity reasons, some information on the tasks of the MUCF is laid down in a document **"Overview of Tasks of MUCF"**. After agreement by the Minor Uses Steering Group this document will be put on the MUCF website.
- Regarding the **organisation of future meetings**, the following general comments were made:
    - The spring meeting should preferably be held in Brussels.
    - A number of plenary sessions related to topics of interest to all CEGs should be organised during the spring meeting.
    - During the spring meeting, all CEGs should also have the opportunity to have a meeting of their group, especially to discuss ongoing projects.
    - The autumn meeting can be organised by CEGs individually. In this meeting especially new projects should be discussed. Of course, CEGs still can decide to organise their meeting back-to-back to the meeting of another CEG. In all cases meetings should be organised by using the MUCF registration system and the Minor Uses Extranet.
- The benefits of the **new EUMUDA** will be a new tool for CEGs, using the same structure and the same information as before, but with a more detailed follow up of each project.

More accurate and consistent information for each case/project will also be available. Information can be entered with selective lists (drop down menus) and the fields for the GAP will be similar as used in PPPAMS, for better exchange of information. A trial phase will be organised in October/November. In November the 'new' EUMUDA will be revised based on comments received, followed by a final discussion with chairs CEGs in January. The launch of 'New' EUMUDA is planned for February 2017. When the 'New' EUMUDA is operational, the 'old' EUMUDA will be 'switched off'.

- The **'regulatory hurdles'** raised by the MUCF on definition of 'minor use', zonal procedure, renewal programme and data protection, were noted by the SCoPAFF. Different interpretations and approaches that are taken by Member States in applying Comparative Assessment were also highlighted.
- Member States highlighted that according to Regulation (EC) No 1107/2009 no **efficacy data** are necessary to grant extensions for minor uses authorisations.
- Member States supported the use of **residue data generated outside the EU**, and when scientifically valid, in granting minor uses extensions. Reference was made to the current active substance data requirements (Regulation (EC) No 283/2013) which states under Part A Section 6.3: *Part of the trials may be replaced by trials performed outside the Union, provided that they correspond to the critical GAP and that the production conditions (such as cultural practices, climatic conditions) are comparable*.
- As regards new or other **experiences with zonal evaluation for minor uses** since the last meeting in April, the following points were raised:
    - In general Art. 51 applications are submitted by industry/companies as it is considered too difficult by third parties. However, in the northern zone mainly growers apply for an extension of use.
    - Some Member States apply shorter timelines for Art. 51 (which are different from the timelines in Regulation (EC) No 1107/2009).
    - When an application for Art. 51 is received some Member States apply the regulatory framework (= Guidance Documents) applicable at the time of application; other Member States use the regulatory frame work applicable at the time of authorisation of the reference product.
    - Some Member States, when issuing a national authorisation, will 'automatically' extend the label with minor crops/uses.
    - The development of a dRR for minor uses (based on the DE draft), as well as the issue who would complete the dRR for minor uses, will be taken forward by the MUCF.
    - It was emphasized that also for minor use applications the normal rules for data protection apply.
- An information session for stakeholders on the **EFSA Scientific Opinion "GD on the establishment of the residue definition to be used for dietary risk assessment"** was organised on 26-27 September 2016 in Parma. Based on the results of this session and comments received EFSA will prepare a final version of this document. This document will only get a regulatory status after discussion and note taking in the Standing Committee on Plants, Animals, Food and Feed. When this document will become applicable it can have a

huge impact on the availability of PPPs for minor uses as extrapolation for new minor uses may no longer be possible.

- In Article 50 of Regulation (EC) No 1107/2009 it is indicated that when member States apply **Comparative Assessment (CA)** that they should take into account the consequences on minor use authorisations. CA needs to be done at crop level. There is a diversity of interpretations as discussed in the meeting of 27 April 2016 (i) When there is a minor use on the label/off label this will not be assessed; only the major uses will be assessed; (ii) When a minor use is on the label all major uses will also not be assessed and be kept on the label; (iii) Only major uses will be evaluated. As regards minor uses comparative assessment will be stopped when a certain % or number of the authorised uses are minor uses without sufficient alternatives and the product can stay on the market. Most MS indicated that the CA process is foremost time consuming with little or no results until now.
- Due for example to the **(non)renewal of the approval of active substances** or for other reason, less active substances will become available. As a consequence, PPPs or uses will disappear from the market which will have a possible negative impact on 'minor uses'. The EFSA-conclusion is issued in general 12-18 months before the expiry date of the active substance, but that does not leave sufficient time for action.
- EFSA has published their **"Protocol for the evaluation of data concerning the necessity of the application of herbicide active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods"** (http://www.efsa.europa.eu/en/supporting/pub/1060e). EFSA has been asked to develop a similar protocol for insecticides (to be delivered in December 2016).
- Fees can also be a blocking factor for more specific products. In this light an **OECD-BPSG seminar** will be held on "Niche Uses of Highly Specific Biocontrol Agents" end of June 2017.
- A **Guidance Document on Minor Uses** is under development. This document comprises of two parts. Part 1 will cover the process from identifying a minor-use need until the generation of the data; Part 2 will cover issues related to the submission process from the application till decision. A small drafting group has started working on the document. A first meeting of the Expert Group was held on 15-16 September 2016 in Brussels. The steps from a minor-use need till authorisation/solution were identified, including a 'check list' containing issues that should be checked for every project. Also elements for a 'project agreement' (an overview of who is doing what and when) were identified. At regular intervals drafts will be circulated for comments. It is envisaged that eventually the Guidance Document will be noted by the Standing Committee to ensure an official EU-status of the document.
- The **C-IPM questionnaire** has to be completed individually per IBMA company with the aim to have a general overview of possible biocontrol solutions available (or in near future available) for specific minor use problems at EU-level. The result of the questionnaire will be a confidential database that will be maintained by the EU Minor Uses Coordination Facility.
- The Pest Management Centre, Agriculture and Agri-Food Canada in partnership with the IR-4 Project, US Department of Agriculture and other organizations is pleased to announce

that the **Third Global Minor Use Summit (GMUS-3)** and the Second Global Minor Use Workshop will be held in Montreal, Quebec, Canada from October 1st – 4th, 2017 at the Fairmont Queen Elizabeth Hotel.

- The **next meeting** of the Horizontal Expert Group will be organised end of March 2017 in Brussels.