



EUROPEAN UNION MINOR USES COORDINATION FACILITY

Second Stakeholder Advisory Forum

6 February 2018, Brussels

Executive summary

The Second Stakeholder Advisory Forum of the EU Minor Uses Coordination Facility took place on 6 February 2018 in Brussels. The event was, as in 2017, well attended with around 50 stakeholders from an important diversity of Member States and organizations.

The MUCF achieved a lot in 2017. Newsletters have been issued quarterly giving updates on different activities and the new EUMUDA was launched and is operational. The MUCF organised two series of Expert Group meetings that were well attended, by participants from more than 20 Member States. The MUCF has actively been involved in the REFIT. The MUCF attended the Third Global Minor Use Summit and is following up on the conclusions and recommendations of the event.

In 2018 the MUCF will continue to work on guaranteeing its sustainable long-term funding. Since its creation in 2015, the functioning of the MUCF has been guaranteed through a fund co-financed by the European Commission (50%) and a consortium of three Member States (France, Germany, the Netherlands, together 50%). The financing from the European Commission will expire in April 2018. In November 2017, the MUCF approached the Member States and Switzerland with a request for a voluntary assessed contribution based on their population size. At the time of the Stakeholder Advisory Forum, the MUCF received contributions or commitments from 9 Member States and Switzerland. For 2018, the funding has been secured, but for 2019 the situation is unclear.

On the short, mid-term and long-term, the MUCF will continue to develop the operational work with the Expert Groups and cooperation at EU and international level.

As seen during the Panel discussions, stakeholders aim for more harmonization in Europe, be it for the definition of minor uses, or harmonization in evaluations, crop groups, extrapolation rules, or in granting authorisations. The MUCF can play an important role in this.

From the expectations and needs of different stakeholders, and the activities and achievements of the MUCF, it is clear that the added value brought by the MUCF is acknowledged by all of the involved stakeholders.

Introduction

Mr Cramer, representative of Germany (Federal Ministry of Food and Agriculture), and member of the Minor Uses Steering Group, opened the meeting. The Second Stakeholder Advisory Forum of the EU Minor Uses Coordination Facility was, as in 2017, well attended. The Forum gathered around 50 stakeholders from an important diversity of Member States and organizations. This year representatives from DG AGRI, the EU Parliament and OECD were also present.

Achievements of the MUCF and the way forward

Mr Meeussen from the MUCF presented the main achievements since early 2017 and plans for the way forward for the short, mid- and long-term.

○ Achievements

The MUCF organises meetings of the Commodity Expert Groups and of the Horizontal Expert Group twice a year, in spring and autumn. The meetings are well attended with a high number of participants from around 20 Member States. In March 2017 meetings of all the CEGs and of HEG took place back-to-back in Brussels with 120 participants. In November 2017 the CEGs Fruits & Vegetables, Seeds, Ornamentals and Tobacco, and the HEG met in Dublin. With a total of 75 participants. Members of the CEG Hops gathered in Obernai, France, and the newly created group CEG Mushrooms have had numerous discussions by emails.

One other significant achievement was the launch of the new EUMUDA which took place during the meeting of the Minor Uses Steering Group on 28 June 2017. Fifty-one projects have already been entered in EUMUDA. For more information on EUMUDA, see page 4.

The MUCF prepared rules for membership of Expert Groups and for the establishment of a new Commodity Expert Group. These documents were approved by the Minor Uses Steering Group in November 2017. The rules for membership of expert groups state that members should have a certain level of expertise in plants, pests, regulatory affairs, or IPM. Members should actively participate in the work of the Expert Groups in meetings and/or act as project leader, add information to EUMUDA and respond to requests from the MUCF. Establishing a new Commodity Expert Group is in general possible 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. However, until the long term financial situation of the MUCF is clarified, no new CEGs can be started.

The MUCF has been involved in the REFIT of Regulation (EC) No 1107/ 2009 and Regulation (EC) No 396/2005 through the stakeholder's survey and meetings and provided, for example, the following responses to the survey:

- A harmonized EU-wide definition (instead of national definitions) would facilitate the zonal process
- Member States should move away from asking for 'national specific requirements'
- The use of residue data generated outside the EU should be supported
- MRL applications should be maximally extrapolated for minor uses
- Availability of low- risk products is insufficient to develop IPM solutions for minor uses needs.

The MUCF started to issue newsletters in 2017, on a quarterly basis. Newsletters summarize the main activities of the MUCF. They are an important tool of communication.

The MUCF attended the Third Global Minor Uses Summit (GMUS-3) in October 2017 in Montreal, Canada. The MUCF was also part of the Organizing Committee of the event. The Summit focused on

regulatory, industry and grower challenges. The MUCF is/will be involved in the follow-up of the following conclusions and recommendations of the GMUS:

- Establish minor use champions from regions, to participate in annual meetings and workshops, communicate global activities and upcoming events
- Review and publish a list of substances exempt from MRLs (such as most biopesticides and compounds of no toxicological concern)
- Explore mechanisms to have a Global MRL Database which is accessible and publicly available.
- Explore whether the EUMUDA database can also eventually host the Global Minor Uses Database
- Develop an international crop grouping scheme for efficacy/target safety data for non-food crops
- Review various definitions of minor crops and identify commonalities and differences.

The Second Global Minor Use Priority Setting Workshop was linked to the GMUS-3. The MUCF submitted a priority list on behalf of the EU (see page 4). The workshop selected three projects for research, one each in a temperate, a tropical and a greenhouse crop system: downy mildew on basil, nematodes on banana and thrips on ornamentals, respectively. Each project was selected along with backup projects for each system.

To engage with stakeholders the MUCF attended various meetings in 2017, with growers' associations, conventional and biological industry, international organisations (EPPO, OECD) as well as international conferences (ABIM, CEUREG Forum that is a technical conference for regulatory experts of Central and Eastern European countries, International Conference on Plant Protection in Hop Growing, ECPA Residues Workshop).

In addition, the MUCF contributed significantly to the preparation of the 'low- risk' EPPO Standard PP 1/296 *Principles of efficacy evaluation for low-risk plant protection products*. The Standard was published in the EPPO Bulletin in December 2017.

- Way forward

In 2018, the MUCF will continue to work on guaranteeing its sustainable long-term funding.

In the short and mid-terms, the MUCF will develop its operational work with the expert groups and the cooperation at EU and international level.

As regards expert groups, the MUCF will:

- Continue to provide administrative and technical support to the Expert Groups in organising meetings and managing ongoing projects
- Increase participation at meetings and in projects from more countries
- Organise plenary sessions with topics of general interest (e.g. IPM and residues)
- Develop work plans for the individual Commodity Expert Groups
- Review the participation of experts in Expert Groups
- Develop IPM solutions for minor use needs

At EU level, the MUCF will:

- Encourage the removal of national specific requirements for minor use applications
- Maintain and reinforce the link with the EU database PPPAMS
- Create a level playing field for EU growers of speciality crops
- Meet representatives from some of the largest Member States

At international level, the MUCF will:

- Continue to cooperate with global minor uses programmes to stimulate international harmonisation
- Play an active role in the OECD Expert Group on Minor Uses (EGMU)
- Develop an international crop grouping scheme for efficacy/crop safety data for non-food crops together with EPPO.

The MUCF also has ambitions for longer-term. It is planning to:

- Explore whether the EUMUDA database could also eventually host the Global Minor Uses Database
- Introduce national projects from all Member States, Norway and Switzerland in EUMUDA
- Organize priority setting meetings on an annual basis
- Explore the possibility to create an EU fund for minor uses.

Solving minor uses needs through EUMUDA

Ms Limache from the MUCF explained how needs on minor uses are solved through EUMUDA. EUMUDA is the European Minor Uses Database, a key tool in solving minor uses issues. Minor uses needs correspond to a lack of plant protection solutions in a crop and pest combination, in a country, e.g. on cherry against spotted-wing drosophila in France. Crops and pests are biological entities, considered preferably at species level and identified by an EPPO Code.

The process to solve a minor use need through EUMUDA was presented. Once a minor use need has been declared by a country the MUCF looks for solutions in databases for conventional and biological solutions and/or non-plant protection products (PPP) solutions under an IPM framework. When a plant protection solution is available it means an application can be submitted without data generation. When a plant protection solution has been identified, but is not available, data must be generated, and a project is started under the responsibility of a CEG. Once data is available a registration dossier can be submitted by the authorisation holder or a third party. At the end of the process, a PPP solution is authorised/available for the minor use need.

Ms Limache underlined also that work is ongoing to address ‘IPM solutions’ in EUMUDA. These solutions may not all directly correspond to authorizations of PPPs (e.g. agronomic or mechanical measures).

EUMUDA covers the whole process from the minor use need to a solution, e.g. the authorisation of a PPP. EUMUDA is linked to PPPAMS, the Plant Protection Product Application Management Systems, which as indicated by its name, is a tool for the application (registration) process.

In preparation of the Global Minor Use Summit (GMUS), October 2017, the MUCF conducted a survey to Member States, Norway and Switzerland for their minor uses needs and priorities. The MUCF presented the main (top 10) priorities for each Commodity Expert Group. In January 2018 the MUCF sent a reminder to Member States who had not replied (14 Member States). With data from as many Member States as possible, the information will be more accurate and better reflect the minor uses issues in Europe. The MUCF compiled these results in February- March 2018. The minor uses priorities identified will be used as a basis to establish work plans with CEGs.

Long-term funding

Mr Meeussen provided an update on the long-term funding situation of the MUCF. Since its creation in 2015, the functioning of the MUCF has been guaranteed through a fund co-financed by the European Commission (50%) and a consortium of three Member States (France, Germany, the Netherlands,

together 50%). The financing from the European Commission will end in April 2018, when the grant agreement for the fund expires.

However, it is clear that minor uses problems will not all be resolved in three years. A mid-/long-term plan (5-10 years) and a strategy concerning how other Member States/countries can contribute, has been prepared. The commitment of voluntary assessed contributions, where the annual amount paid by Member States is related to the size of their population, is considered the most appropriate option.

A letter from the European Commission was sent to Permanent Representations of the EU Member States in September 2017. The long-term funding of the MUCF was also discussed in the AGRI-FISH Council meeting on 9 October 2017. In November 2017, Member States, Norway and Switzerland were approached with a request for a voluntary assessed contribution.

At the date of the Forum meeting, the MUCF received contributions from Sweden, Belgium, Slovakia, Germany, Lithuania and Denmark, and commitments from Switzerland, Finland, France and the Netherlands. It must be emphasized that only with annual voluntary assessed contributions matching EUR 700 000 the continuity of the MUCF can be guaranteed. In other scenarios there will be an effect on staffing, EUMUDA and/or reimbursement of expenses for Expert Groups. For 2018, the funding has been secured, but for 2019 the situation is unclear.

Expectations and experiences from Member States and Commodity Expert Groups

Mr Bryn Bircher, representative from the UK, opened this session. Mr Bircher is from the competent authority CRD in the UK and is member of the Horizontal Expert Group (HEG). He highlighted expectations from a regulatory perspective. He stressed that evaluations for minor uses should be carried out according to uniform principles, in an agreed format and stored centrally. Information should be available to growers and contacts facilitated within each Member States. He highlighted the importance of mutual recognition for minor uses.

Mr Bircher explained that he has had very positive experience with the MUCF. There has been a transition from informal to formal work on minor uses. Thanks to the MUCF data is collected and there is a focus on databases. The importance of zonal applications is also taken into consideration. He acknowledged the developments on the guidance document for minor uses. In the future, Mr Bircher would like to see an EU application form for minor uses and a standard evaluation format, and guidance documents available. Mr Bircher would like the MUCF to have a permanent seat at the Standing Committee on Plants, Animals, Food and Feed.

He added that the general negotiations on the Brexit make the situation very unclear as regards funding of the MUCF by the UK. He encouraged the other Member States to commit to funding.

Ms Manduric from Sweden was the second representative of a Member State in this session. Sweden is member of the Commodity Expert Groups Fruits and Vegetables, and Ornamentals. Ms Manduric explained that horticulture is a sector of high value in Sweden. The total value of the Swedish horticultural production in 2016 is around 5.0 billion SEK (508 million EUR). From a production value perspective, the most important crops are carrots, strawberries and deciduous trees, while the main greenhouse crops are cucumber, tulips and aromatic plants. Farming of speciality crops stimulates local employment, and small-scale production has a positive relationship with tourism.

Many minor uses problems are due to a limited availability of plant protection products. Sweden is a small market, with high environmental protection goals, meaning that some products have never been authorised and some have been withdrawn. In addition, research on alternative methods is limited.

National and European minor uses work are indispensable lifelines for long term viability of the Swedish horticultural production. The experience of Ms Manduric with the MUCF is also very positive. She noted increased visibility, more efficient lobbying on minor uses, a clear structure and a clear mandate.

She expects from the MUCF a continuing dialogue with the PPP industry. Early information on new products and how to integrate products into IPM strategies are key information. Ms Manduric would like to see applied research encouraged to have new uses granted for both existing and new active substances and see new methods developed. She identified additional ways of working e.g. workshops on specific crops, on-line meetings, and further development of web-based tools to empower organised work.

Ms Mazier, chair of the CEG Mushrooms, continued the session. She underlined the production value of mushrooms in the EU: 2.3 billion EUR and then explained specificities of the sector. Mushrooms are grown indoors, on compost (straw and horse manure). The production cycle is short, from 2 to 3 months. There are a few diseases, but they can destroy a whole production cycle. Mushrooms are harvested by hand meaning production costs are high.

Ms Mazier indicated that the CEG Mushrooms is planning to launch an application dossier according to Article 51.

The experience of Ms Mazier with the MUCF is also positive. The MUCF is noted as a good contact point, having provided results on Homologa searches for potential solutions, and advice on regulatory procedures. Ms Mazier would like a user guide to be developed to help a project leader launch a registration dossier. A list of products authorised by Member States according to Article 53 (emergency authorisation) would be very useful. Ms Mazier expects the MUCF to be the voice of the minor uses sector and to have EU institutions on board.

Ms Kafka, co-chair of the CEG Seeds, presented specificities of the seed minor uses needs, which concern seed production, plant breeding and seed treatment products. Seeds are a small market for the crop protection companies, making the inclusion of the needs of the seed sector in the scope of the authorisation of new PPPs and extension of the authorisations difficult. The CEG seeds expects from the MUCF to establish links with:

- crop protection companies, in order to stress the importance of the availability of PPPs for the seed sector and provide advice on how the CEG Seeds can cooperate with the crop protection industry
- other CEGs as this can allow experts to join forces to solve common needs
- the Standing Committee to highlight the importance of the availability of active substance for the seed sector and show the gaps in crop protection when active substances are not renewed.

The CEG seeds asks the MUCF to support feasible and harmonised authorisations and authorisation procedures by:

- providing input to the REFIT
- stressing the importance of harmonised authorisations for minor uses
- developing a guidance document for minor uses, including a shared minor use definition which will promote cooperation in the European region and work sharing and mutual recognition
- commenting on the guidance document for authorisation of PPPs for seed treatment, with special attention paid to minor use seed treatments.

Ms Kafka found the link provided by the MUCF with the authorities very helpful. She would like to see more participation of authorities in the CEG seeds and support from the authorities on the regulatory part.

Positive listing of uses for zonal evaluation

Mr Hucorne, from Centre de Recherches Agronomiques de Wallonie (CRA-W), Belgium, presented ‘A positive listing of the uses that should be evaluated at zonal level’ in the context of Regulation (EC) No

1107/2009. This list contains uses (crop and pest combinations) proposed for evaluation at European level. When a use is on this list, it means that a zonal dossier for a plant protection product (PPP) on this use would be necessary and that data on this use should be sufficient to extrapolate to other uses.

To establish such a positive list, Mr Hucorne first considered crops which were selected based on production areas retrieved from EUROSTAT database (crops representing more than 100 000 ha in one administrative zone) as well as EPPO extrapolation rules for efficacy/crop safety (crops used as starting point for extrapolation). Pests (including diseases) to be evaluated at zonal level were selected based on economic importance¹, whether treatments are on seed, in greenhouses, post-harvest treatments, or foliar, the ubiquity of the pests, etc. Mr Hucorne also referred to official websites, companies' websites and EPPO Standards.

Mr Hucorne cited the example of the use carrot/ carrot aphid (*Cavariella aegopodii*), which is a use on the list to be evaluated in Central and Southern zones.

Overall this positive listing aims to clarify the status of the uses and the type of dossier to be submitted and evaluated in the EU.

Panel discussion

After the presentation from Mr Hucorne, a Panel discussion took place on various topics, with the following panel members: Mr Hofman (ECPA), Mr Malet (French Ministry of Agriculture), Mr Bosc (European association of cereals, rice, feedstuffs, oilseeds, olive oil, oils and fats and agrosupply trade COCERAL), Ms Lauber (Scientific Consulting Company SCC-consultancy) and Mr Hucorne. Various observers also contributed.

The panel discussion was chaired by Ms Sütterlin (Ministry of Agriculture, Nature and Food Quality of the Netherlands) and member of the Minor Uses Steering Group.

A harmonized EU definition of minor uses. The panel members agreed that a harmonized definition is required. Mr Bosc highlighted the importance of a single definition of minor uses or specialty crops at EU level, to be based on the importance of production. Mr Hofman and Ms Lauber referred to the efficacy requirements and agreed these requirements should be reduced. Mr Lynch from Ireland mentioned that the definition should follow the residue perspective to address safety. The question is how to make a list of harmonized minor uses. The positive listing by Mr Pierre Hucorne does not contain a clear definition of minor uses. It was concluded that the working group on the Guidance Document on Minor Uses or the HEG could follow up on the document from Mr Hucorne.

Acceptance of non- EU residue trials. The panellists agreed that in principle residue trials performed outside the EU, when scientifically valid, should be acceptable. Mr Malet highlighted that the limit for acceptance lies in the difference of GAPs and residue definition. He added that already for tropical crops, data from South America is used. The key point is the acceptance by EFSA of using non-EU residue trials. European Commission relies on the EFSA expertise, however provides the framework of the work of EFSA. Therefore, the decision on an acceptance of non-EU data is in the hands of the Commission. Ms Rademakers (European Commission, DG SANTE) mentioned that this point can be taken up in the REFIT process. The panel discussion concluded that a pilot study in Europe with non-EU data could be conducted, under EFSA guidance.

Crop grouping systems and extrapolation possibilities for minor crops. For efficacy the EU makes use of extrapolation rules according to EPPO Minor Uses extrapolation tables. For residues, extrapolation rules follow EU guidance document SANCO 7525/VI/95 'Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs'. There are also other (residue) crop grouping systems such as Codex crop grouping.

¹ EPPO Standard PP 1/224 (2) on 'Principles of efficacy evaluation for minor uses'.

Ms Lauber mentioned that one clear extrapolation list would be very helpful for applicants and simplify the number of trials required. According to Mr Hucorne, efficacy and residue extrapolation rules are not always aligned. He cited the example of late blight disease (*Phytophthora infestans*) in potato and tomato. It is caused by the same pathogen so from an efficacy point of view data on potato could be extrapolated to tomato. However, from a residue point of view the extrapolation clearly cannot be made. Mr Cary (IBMA) suggested that it would be useful to carry out a pilot study on crop grouping and to use EU as a single zone. He underlined that biologicals often do not require an MRL. Mr Lynch appealed for an automatic and maximized use of extrapolation rules by the applicant for an MRL setting. Mr Hofman noted this and mentioned this could be recommended by ECPA. Mr Mattaar (European Crop Care Association ECCA) highlighted that first a plant protection product needs to be authorised / a GAP must be available before extrapolation rules can be used.

Harmonization. This general topic was added to the discussion. Mr Bosc called for more exchange and cooperation and acknowledged the efforts of the MUCF towards harmonization at European and international level. The panellists agreed that a single zone concept and granting authorisations at zonal level would be very welcome and facilitate minor uses extensions. Mr Bircher recalled that a zonal procedure is already set in Regulation (EC) No 1107/2009. Ms Rademakers highlighted that the Regulation works towards harmonization and underlined it would facilitate the minor uses work. It was concluded that there is still a lot to do to achieve harmonization in Europe.

Conclusion

The concluding remarks were presented by Ms Rademakers from the European Commission, DG SANTE. Compared to 2017, the MUCF has again made a lot of progress. The new EUMUDA is now operational. One of the benefits of the MUCF is that in the Commodity Expert Groups the efforts of Member States, growers and other stakeholders are coordinated in an efficient way to find more crop protection solutions. And already more than 20 Member States are attending these Expert Group meetings. This clearly indicates the interest of the Member States to participate in the work of the MUCF.

From the expectations and needs of different stakeholders, and the activities and achievements of the MUCF, it is clear that the added value brought by the MUCF is acknowledged by all the involved stakeholders. All Member States are concerned by minor uses issues and benefit from the production of speciality crops directly, or indirectly, i.e. when they do not grow a crop on their territory but consume it.

On request of the Council of Ministers, the European Commission established in 2015 the EU Minor Uses Coordination Facility to assist farmers in the European Union in producing high quality speciality crops which make up an essential part of our diet. The Coordination Facility is partly funded by a Commission grant which is limited in time (3 years) and in amount of contribution (350 000 EUR/year). However, this grant ends mid of April 2018.

The experience gained so far in the EU, but also with similar facilities in the US and Canada, has shown that a sustained support for finding solutions for plant protection problems for speciality crops cannot be solved through a non-recurring action like a Commission grant, but requires a continuous and structural funding.

The Commission greatly appreciates the contributions made by Germany, France and the Netherlands during the initial phase of the existence of the MUCF. Contributions were already received by several Member States and Switzerland, with commitments of a few others. All Member States are strongly encouraged to contribute for this year and to commit to a continued funding of the Coordination Facility for the years to come. This to guarantee the sustainability of speciality crop production in the European Union. At least, the Commission will continue to morally support the MUCF, and if necessary and if preferred, DG SANTE will of course also continue to be a member of the Minor Uses Steering Group.