



Report of the Workshop on "Minor Uses and Speciality Crops: The way forward in Europe", 18- 20 February 2020, Paris

Hosted by the French Ministry of Agriculture and Food



Minor uses across borders: A United Europe from space

(Source: ESA- European Space Agency)

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1. INTRODUCTION

This report presents the proceedings of the Workshop on "Minor Uses and Speciality Crops: The way forward in Europe", held in Paris, France from the 18th to the 20th of February 2020. It includes summaries of presentations given at the workshop¹, a summary of the workshop discussions and the overall workshop conclusions and recommendations.

The Workshop brought together key European stakeholders, minor use specialists from EU Member States and policy-makers on minor uses and speciality crops. The workshop allowed growers' organisations, the Member States and other stakeholders to exchange on their experiences and expectations on minor uses work and the EU Minor Uses Coordination Facility. The workshop aimed to enhance regulatory harmonisation, come to a sustainable European way forward for minor uses work and establish a roadmap containing a list of concrete actions regarding the future organisation for minor uses work, and the role therein of the EU Minor Uses Coordination Facility, European Commission, Member States and other stakeholders.

The workshop was planned as an event organized by the EU Minor Uses Coordination Facility (MUCF). A workshop organising committee (see Annex 1) consisting of representatives of the main organisers (MUCF), regulators from EU member countries and representatives of a growers organisation (Copa-Cogeca) and industry (ECPA and IBMA) was set up to develop the concept for this workshop, its overarching theme and its detailed programme.

The workshop was hosted by the French Ministry of Agriculture and Food, location Rue de Varenne, Paris, France. It was chaired by Jeroen Meeussen and co-chaired by Flora Limache, both MUCF, and was attended by 65 participants from 17 different countries. The participants were representatives of regulatory agencies, as well as regional and international organisations including the European Commission (DG SANTE and DG AGRI), growers' associations (Copa-Cogeca), the International Biocontrol Manufacturers Association (IBMA) and the European Crop Protection Association (ECPA), advisory services and research institutes. The list of workshop participants is attached in Annex 2.

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¹ Presentation slides are available in a separate document

1.1 Speciality crops

Speciality crops represent a fundamental sector in agriculture for many European countries. These crops include most vegetables, fruit, nurseries, flowers, forest trees, seed production crops and some arable crops.

It is estimated that overall speciality crops represent a value of more than € 70 billion per year, which equates to 22% of the total EU plant production value. The sustainable production of speciality crops is important for food security, food safety, biodiversity and mental wellbeing –particularly as regards ornamentals– in Europe.

Speciality crops are considered minor in terms of production scale when compared to the overall agriculture production. In the Regulation (EC) No 1107/2009, Article 3, paragraph 26, 'minor uses' are defined as the use of a plant protection product on a crop which is not widely grown in a Member State or against pest problems which are not routinely encountered but may on occasions be very damaging in major crops.

Growers face increasing difficulties in having solutions available for speciality crops.

As the ultimate goal of minor uses work is to find solutions for the growers, it is considered necessary to get more insight in their expectations, to discuss how they can be more engaged in minor uses work and to define the future organization of the minor uses work in Europe.

The lack of harmonisation in the regulatory framework in Europe is a major hurdle that applicants and other stakeholders have to overcome. One of the predominant issues is to establish an EU-wide or zonal uniform status of a crop in relation to the current definition of a minor use. As the lack of harmonisation hampers the zonal system and mutual recognition this can lead to delays in the evaluation of dossiers and decisions on the authorisation of plant protection products for speciality crops.

To follow the principles of Integrated Pest Management (IPM) is mandatory in the EU Member States. A lot of research is ongoing in the field of IPM, but minor uses and speciality crops are not always addressed sufficiently. Several projects on minor uses that are carried out under the C-IPM ERANET umbrella are still ongoing. The next step is to translate the results of IPM research into practical solutions available for growers. In that aspect, advisory services play a key role.

A lot has been achieved thanks to the work and involvement of many minor uses' experts and stakeholders coordinated by the MUCF. Now, almost 5 years after the establishment of the MUCF, it is time to take stock and to gather the different stakeholders to learn about their experiences, to know their expectations and define a common way forward for the work on minor uses in Europe.

1.2 EU Minor Uses Coordination Facility

Minor uses of plant protection products are usually of low economic interest for the crop protection industry due to their small-scale use, based on small acreage of the crops or on the type of application (for example seed treatment). This leads to a lack of authorized products on the market for farmers and growers to use on these crops.

To address this problem in a more coherent way the European Minor Uses Coordination Facility (MUCF) was established in April 2015, initially funded by the EU Commission (DG SANTE) and three Member States (France, Germany and the Netherlands). Since April 2018, the MUCF is fully relying on voluntary contributions from the Member States. The MUCF is hosted by the European and Mediterranean Plant Protection Organisation (EPPO) in Paris. The mission of the Facility is 'to enable farmers in the EU to produce high-quality crops by filling minor uses gaps through efficient collaboration to improve the availability of chemical and non-chemical tools within an integrated pest management (IPM) framework'.

Since its establishment, a lot has been achieved by the MUCF. A revised version of the European Minor Use Database EUMUDA was launched in 2017 and now contains a consolidated and updated list with the minor use needs and priorities from 28 European countries. Also, more than one hundred projects have been included in EUMUDA.

Minor uses work comprises the identification of minor uses needs, the search for possible solutions, the generation of data (residue/efficacy) in projects, the application for registration of plant protection products, and the bringing of solutions to the grower.

Different actors are involved in minor uses work: governments (representatives from Ministries and competent authorities), policy-makers, growers' organisations, national minor uses experts, industry (conventional and biological), research centres, advisory services, European and international partners.

The European Commission is currently carrying out a REFIT evaluation of the EU pesticide legislation to assess if the legislation in place is still fit for purpose. As is stated in the final report of the REFIT consultant, the definition of minor uses is not sufficiently clear and procedures are often not clearly established. Besides, the PEST Committee of the European Parliament calls in a resolution for a harmonized definition of 'minor use' and recommends creating a single EU list of major crops. In this respect, the survey that was conducted in 2017 by the MUCF on how the Member States organise minor uses work and how they evaluate and define minor uses already contains very useful information.

The MUCF organises twice a year meetings of minor uses experts. One of the greatest benefits of the work of the MUCF is the coordination of the minor uses work and building trust between governments of European countries, growers, industry, research and other international partners such as OECD, IR-4 and PMC.

1.3 Scope of the workshop

The workshop covered minor uses' work in Europe. It focussed on the organisation of the work and the regulatory problems linked to minor uses work. Regulatory aspects are limited to authorisation procedures and status of a crop in relation to the definition of minor uses, in the framework of Regulation (EC) No 1107/2009.

2. WORKSHOP OBJECTIVES

The main workshop objectives were to:

- Raise awareness on minor uses' work in Europe and on the work of the MUCF
- Increase the trust and collaboration between the Member States and between stakeholders.
- Exchange on experience and expectations on minor uses work and on the MUCF of stakeholders, with a focus on growers and the Member States.
- Define the future organisation of the minor uses work in Europe and the way to secure funding of minor uses activities and the MUCF.
- Identify how to solve problems related to minor uses, including IPM research and implementation, regulatory problems, and define the role of the MUCF, European Commission, Member States and other stakeholders in solving these problems.
- Develop a concept, criteria and a way forward to establish an EU-wide (or zonal) uniform status of a crop in relation to the current definition of a minor use.

3. STRUCTUR OF THE WORKSHOP

The 2.5-day workshop was organised in alternating plenary and break-out group (BOG) sessions, as described below. Plenary sessions consisted either of presentations, BOG feedback or discussion sessions amongst all participants. Four BOGs met at four BOG sessions. The agenda for the Workshop can be found in Annex 3. Two sets of background documents with topics and questions were prepared by the organising committee for use in BOGs (see Annex 4a and 4b).

3.1 Plenary Sessions

The initial plenary session on the morning of day 1 included a welcome address by the workshop host the French Ministry of Agriculture and Food followed by a presentation from the MUCF. The Chair of the workshop gave a presentation on the achievements and plans for the future of the MUCF. This was followed by an introduction of the Co-chair of the workshop on the aims of the workshop and its logistics. Copa-Cogeca gave insight on their perspective on the production of speciality crops in Europe. From the European Commission, there were presentations from DG SANTE and DG AGRI.

The next plenary sessions were comprised of the following presentations:

- One grower's organisation, two regulatory authorities and three Commodity Expert Groups (CEGs) shared their experiences and expectations in the field of minor uses.
- Three related presentations followed, covering: experiences from the European Crop Protection Association (ECPA), the International Biocontrol Manufacturers Association (IBMA) and an individual company.
- Two presentations covered experiences from research networks
- Three related presentations followed, covering an overview of how the Member States organise minor uses work, experience and expectations from an advisory service and experience of the minor uses work in North America.

There was a short period for questions and answers after each presentation.

Short summaries of all presentations can be found in section 6 and presentation slides in Annex 5 (as a separate document).

At the beginning of the second-day, Chairs of each of the four BOGs gave their initial feedback orally in plenary, with a short period for questions and answers after each report. Then, at the beginning of the final morning of the workshop, the four BOG Chairs gave longer presentations on the discussion, conclusions and recommendations from their groups. Again, there was a short period for questions and answers with the audience after each presentation.

Finally, there was a plenary discussion on the overall workshop conclusions and recommendations which had been developed from the findings of the four BOGs. This session was concluded by a short presentation on the next steps and closing remarks by the workshop's Chair.

3.2 Break-Out Group (BOG) Sessions

During four break-out group (BOG) sessions that lasted for about seven hours in total, participants met in four BOGs of about 15 people each. All four BOGs discussed issues related to obstacles in minor uses work and possible ways forward, and the future organisation of minor uses' work in Europe. Besides, two BOGs were tasked with addressing the topics and questions given in the background document with a focus on IPM research and implementation, whereas the other two BOGs were to address topics and questions related to regulatory procedures and a harmonized status of a crop.

The membership of each BOG was tailored so that each BOG had a mix of participants from regulatory authorities, industry, growers' organisations, advisory services and research institutes.

Each BOG produced a set of slides that their Chair or rapporteur presented in the plenary session on the second and the last day of the workshop (see Annex 6, as a separate document). A report of the discussions of the different BOGs is presented in section 7. These BOG reports formed the basis for the conclusions and recommendations described in section 5 of this report.

4. WORKSHOP ISSUES

The background documents (Annex 4a and 4b) were prepared before the workshop to aid discussions in the BOGs. It lists topics and, within each topic, questions which were felt to be the main technical and regulatory issues that should be addressed at the workshop.

The main topics covered in the background documents are as follows:

- Obstacles in minor uses work and possible ways forward.
- IPM research and integration in minor uses work.
- IPM implementation and how to bring results of IPM research to growers.
- Regulatory procedures: how to facilitate authorisations for minor uses.
- Harmonized status of crops in relation to the definition of minor uses
- The future organisation of minor uses' work in Europe.

The presentations (see separate Annex 5) made reference to many of these topics, covering some in more detail but also raising additional topics and questions that fed into the BOG discussions. These topics are dealt with in the individual sections in chapter 7.

5. CONCLUSIONS AND RECOMMENDATIONS

The Workshop brought together key European stakeholders and policy-makers on minor uses and speciality crops. The workshop allowed growers' organisations, the Member States and other stakeholders to exchange on their experiences and expectations on minor uses work and the EU Minor Uses Coordination Facility. The workshop aimed at enhancing regulatory harmonisation, coming to a sustainable European way forward for minor uses' work, and establishing a roadmap containing a list of concrete actions regarding the future organisation of the minor uses' work in Europe.

<u>Growers</u> face a future where less active substances and plant protection products (PPPs) are available. Forecast studies on the availability of active substances and PPPs are welcomed so that the future for growers regarding the availability of active substances and PPPs becomes more predictable. Research programs on alternatives, especially for minor uses are considered necessary. Living labs and demonstration farms can provide more knowledge and acceptance of these alternatives.

<u>Policy-makers</u> should be made aware of the (economic) importance of speciality crops. They should facilitate the implementation of the Regulation (EC) No 1107/2009; the purpose of which is to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competiveness of Community agriculture. Trust between the Member States should be increased so that the zonal system and mutual recognition will work as it is meant to be. The administrative burden should be reduced so that available capacity can be better used, and that duplication of work is avoided. A 'Pan-European authorisation' requires strong zonal cooperation and having a common procedure to facilitate interzonal authorisation for Art. 51 extensions could be explored and e.g. taken up as a pilot project.

<u>The industry</u> should better facilitate the authorisation of minor uses. Sufficient incentives (e.g. timelines, fees, data protection) should be installed to stimulate industry to apply for minor uses. At the time of submission applications should already have as many minor uses on the label as possible (e.g. based on extrapolation rules). One evaluation done on an agreed (zonal) GAP will eventually lead to more available products for the farmers of speciality crops.

Governments should minimize the requests for 'national specific requirements'. These 'national specific requirements' are additional requirements outside the EU agreed data requirements and guidance, and these should only be applied when justified. Member States should create a level playing field for EU farmers. Harmonisation of the status of crops on zonal or EU level would allow for more mutual recognitions for minor uses. As a first step, a discussion paper on this topic should be prepared by the MUCF, followed by a pilot project.

<u>Research</u> is often performed on major crops and projects should focus more on minor uses/speciality crops. Researchers should engage with farmers at an early stage to guarantee that the outcome of the research will address the needs of the growers as much as possible. Researchers should also liaise with the Commodity Expert Groups (CEGs) to know about the most important minor uses needs and the area(s) in which

research is most needed. Dissemination of the results of research to growers is considered crucial.

Advisors play an important role in the communication between research, farmers, growers and industry. Advisors do understand farmers and farming and they should be able to enforce trust between farmers and researchers. Demonstration farms and pilot farms can contribute to an early adoption of (new) solutions by farmers. Advisers should make farmers aware of the possibility of CAP-payments when applying IPM systems or when using biocontrol instead of conventional plant protection products. Advisory services can assist farmers in developing useful tools (e.g. 'IPM-profiles') to disseminate relevant information to growers.

The <u>MUCF</u> should, according to its mission, be in contact will all different stakeholders and aiming to bring solutions for minor uses needs to the farmers by filling minor uses gaps through efficient collaboration between all stakeholders and to improve the availability of chemical and non-chemical tools within an integrated pest management (IPM) framework.

In addition, the MUCF should expand its activities and:

- have a more steering role in the preparation of the agendas and work plans of CEGs.
- display realized solutions in EUMUDA to increase the visibility of the work of the MUCF.
- list all Art 51 authorisations granted in the different Member States in EUMUDA.
- play an active role in harmonising and coordinating research programmes aiming to disseminate information and to avoid any duplication of research (e.g. by setting up a centralised website).
- become (more) involved in projects for data generation.
- develop a model for 'IPM-profiles 'and provide this on its website.
- enhance communication e.g. via info on MUCF website.

6. SUMMARIES OF PRESENTATIONS

Ms Anne-Cécile Cotillon (Ministry of Agriculture and Food, France) welcomed all participants and introduced the topic of the workshop by highlighting the importance of minor uses for the EU food production. Solutions have to be based on IPM principles and priority should be given to solutions with low impact like biopesticides. The role of MUCF is important to ensure coordination between Member states and to establish a work programme that has to be in line with Member States expectations. However, this can only be achieved with a sustainable funding. She recalled that France adopted in 2018 a national plan aiming to withdraw the substances of most concern and to promote their substitution with alternatives of less concern, like biopesticides. This big challenge is fully in line with the Green Deal and the Farm to Fork strategy for sustainable food that is being developed by the European Commission. This transition by European farmers is essential to meet consumers requirements to better protect human health and the environment.

Mr Jeroen Meeussen (MUCF) introduced the EU Minor Uses Coordination Facility. A lot has been achieved by the MUCF. A revised version of the European Minor Use Database EUMUDA was launched in 2017 and contains a consolidated and updated list with the minor use needs and priorities, as well as more than one hundred projects. One of the greatest benefits of the work of the MUCF is the coordination of the minor uses work and building trust between governments of European countries, growers, industry, research and other (international) partners. The challenges for 2020 are to (i) assist CEGs in preparing work plans, (ii) work on the harmonisation of the status of a crop, (iii) work on an Extrapolation Databases for efficacy crop safety and residue, (iv) display plant protection (IPM) solutions in EUMUDA, (v) linking of emergency authorisations with minor uses needs, (vi) work towards a multilateral agreement for funding. This was followed by an introduction to the objectives of the Workshop by Ms Flora Limache (MUCF). She indicated that after 5 years of MUCF it is time to take stock and highlighted the main objectives of the Workshop and the envisaged outcome of the Workshop. The purpose of the workshop is to develop (i) a roadmap containing a list of concrete actions regarding the future organisation for minor uses work and the role herein of the MUCF, European Commission, the Member States and other stakeholders, (ii) a proposal on a concept, criteria and a way forward to establish an EU-wide (or per zone) uniform status of a crop in relation to the current definition of minor use, (iii) a proposal to facilitate zonal authorisations and mutual recognition of plant protection products for speciality crops within the current regulatory framework, and (iv) a list of practical proposals for common solutions to minor uses problems. She invited participants to look at minor uses from a wider perspective, to look at minor uses across borders.

Ms Paula de Vera (Copa-Cogeca) introduced the organisation of EU farmers (Copa) and agri-cooperatives (Cogeca). The mission of Copa-Cogeca is to ensure a viable, innovative, competitive EU agriculture and agri-food sector guaranteeing food security to half a billion people throughout Europe. Farmers are ready for the implementation of the European Green Deal and Farm to Fork Strategy. Copa-Cogeca favours sustainable crop protection. She presented some figures on the cultivated area

and/or total yield for two speciality crops produced in the EU: rice and hops. The main bottlenecks for farmers are that there is no common EU approach, a lack of harmonisation, different interpretations on the definition of a 'minor use', and there are not enough tools available for farmers. The MUCF is doing highly important work for EU farmers by tackling the lack of plant protection products available for speciality crops, by building trust among national authorities and identifying needs and avenues for cooperation among the Member States. A continuous and long-term support for the MUCF is indispensable by both the European Commission and the Member States.

Ms Desislava Ivanova from the European Commission (DG SANTE) indicated that, due to the high value of speciality crops, minor uses are today internationally recognised as a priority topic requiring solutions. A lack of plant protection products may lead to insufficient protection of crops against harmful organisms and this may endanger the production of certain high-value food crops within the EU and finally may affect the competitiveness of EU agriculture. This could lead to improper use of emergency authorisations under Article 53 of Regulation 1107/2009. In the REFIT evaluation, it is indicated that 54% of all emergency authorisations are for minor uses. To solve minor uses needs the Member States should make full use of the possibilities offered in Regulation 1107/2009 e.g. Article 51 extensions and mutual recognition. Also, better communication and information should be provided to farmers, growers' organisations and scientific bodies. Regular financing of the Minor Uses Coordination Facility is key to achieve these goals.

Mr Aymeric Berling from the European Commission (DG AGRI) provided an insight how the Common Agriculture Policy (CAP) can promote alternatives to the use of pesticides. Farmers and other CAP beneficiaries may benefit from advisory systems set up by national authorities for advising in particular on the sustainable use of pesticides and IPM. Conditionality (currently named cross compliance) links CAP payments to farmers to the respect of legal rules, including for pesticides. Farmers may also benefit from CAP financial support for sustainable use of pesticides or alternative to their uses, beyond legal requirements. To note that many farmers growing speciality crops are currently not or little beneficiaries of CAP payments. Research and innovation projects are also available to promote the use of IPM.

The environmental ambition of the future CAP will be strengthened, in particular for the sustainable and reduced use of pesticides. Conditionality will include the SUD, including the relevant general principles of IPM and Member States will have more possibilities to develop support schemes. CAP payments, paid to farmers, can indirectly benefit the work of the MUCF e.g. by farmers using biocontrol instead of conventional plant protection products or by assisting advisory services in developing useful tools (e.g. 'IPM-profiles', see pages 24-25) to disseminate relevant information to growers. As regards research, Horizon Europe will replace Horizon 2020 for the period 2021 – 2027 with a higher budget.

Experience and expectations from a Northern grower organisation were presented by **Ms Agneta Sundgren** from the Federation of Swedish Farmers. Swedish horticulture comprises more than 2 000 enterprises in which 14 800 people are employed. Minor

uses projects are financed by the Swedish government but carried out by the Federation of Swedish Farmers. Most of the reports are available in English. Within projects, the Federation of Swedish Farmers can (i) apply for an extension of authorisation, emergency use, or mutual recognition, (ii) perform trials to control efficacy and phytotoxicity, (iii) residue trials, (iv) buy service from advisers to get information, (v) arrange meetings. In 2019 a total of 41 trials were performed and 13 extensions of authorisations for minor uses were granted. An example of a problem solved by the Federation of Swedish Farmers is mildew in greenhouse cucumber that was solved by performing 2 years of efficacy trials in greenhouses, together with residue and exposure data from the company.

Experience and expectations from an Eastern European country from the Central Zone were presented by **Ms Malgorzata Flaszka** from the Ministry of Agriculture and Rural Development in Poland. The Polish national regulation contains a long list of minor uses. Only a few crops are classified as a major crop. Poland has introduced several measures to stimulate applications for minor uses, e.g. reduced fee, presubmission meetings free of charge, a separate line for minor uses applications. Since 2016 minor uses are in Poland granted at the same time when a Zonal Registration or Mutual Recognition authorisation is granted. A prerequisite is that the crop must be on the list in the Polish national regulation on minor uses, that the evaluation is conducted in the core dossier, and that a separate application for minor uses is submitted. This has led to a considerable increase in the number of minor uses applications and authorisations in Poland. Current problems are still the lack of plant protection products in certain minor crops and the limited number of applications done by growers' organisations. Reduced residue requirements for minor uses (GLP standards, number of trials) is a wish for the future.

Mr Donal Lynch from the Ministry of Agriculture, Food and Fisheries of Ireland presented experience and expectations from Ireland. In Ireland, more than 4 000 product/crop combinations are authorised on 140 different minor crops. The Irish authorities have a proactive policy regards minor uses resulting in a large number of off-label uses. Ireland is a firm believer in mutual recognition. Access to data is considered one of the major obstacles to getting authorisations for minor uses as no residue trials are conducted in Ireland and only limited funding is available to purchase data. Besides, there is a reluctance of companies to register products for Ireland due to the small market size. There is also a lack of non-chemical solutions, particularly in field situations. In 2019, 16 active substances have been removed from the Irish market and more are expected to be withdrawn shortly. Ireland will continue to actively participate in the CEGs and Horizontal Expert Group (HEG) of the MUCF and contribute financially to support the work of the MUCF. Authorisation holders are encouraged to apply for minor uses products through mutual recognition. Aspects of the way forward are (i) contribution to the funding of residue trials, (ii) project collaboration with some other Member States, (iii) encourage authorisation holders to apply for minor uses products through Mutual Recognition, (iv) communication with Irish horticultural industry in identifying problems and solutions.

Mr Jean-Claude Malet from the French Ministry of Agriculture and Food presented experience and expectations from the Commodity Expert Group Fruit & Vegetables. Fruits and vegetables comprise a large group of crops that have a different status (major/minor) in the different Member States. There is a variety of phytosanitary problems in this sector with emerging pests as Tuta absoluta on tomatoes, Drosophila suzukii on red fruits and strawberries, and soon maybe Bactrocera dorsalis on fruits. The fruits and vegetables' sector is important in the majority of the European Member States of which the Southern Member States have the largest diversity of crops. Minor uses are an important issue for all Member States and each country develops action plans dedicated to minor crops. CEG F&V has initiated already many projects that are entered in the EU Minor Uses Database EUMUDA. This approach is based on worksharing, but there is still a lack of visibility and concrete results. The CEG is working on an action plan with concrete timelines and responsibilities. The projects should respond to the selected priorities in the list of minor uses needs as listed in EUMUDA and as such involve a maximum number of interested Member States. Discussion on some technical issues, e.g. residue extrapolation, metabolism, research can still be improved between the CEG and the MUCF. The Coordination Facility is considered the 'spokesperson' in the EU regarding minor uses, especially in looking for financing and to express minor uses issues to European authorities.

Ms Magda Rak Cizej from the Slovenian Institute of Hop Research and Brewing presented experience and expectations from the Commodity Expert Group on Hops. The hop industry is an important economic/agricultural industry with a long tradition. Most hops are exported to global markets. Around 20 countries are responsible for the global hop production from which USA and Germany produce more than 70%. Slovenia already produces hop under IPM-conditions for more than 60 years. For the most important hop diseases (e.g. downy mildew, powdery mildew, grey mould) are forecasting systems in place. The most significant pests like hop damson aphids, twospotted spider mite and hop flea beetle are also monitored. An emerging problem is the development of resistance in hop varieties. In Slovenia, no herbicides are used in the hop production. Harmonisation of pesticide registrations and MRL regulations for hops worldwide is considered necessary to avoid trade disruptions. Eight EU Member States and the USA are members of the CEG Hops and they meet twice a year. Main future challenges are: (i) find solutions to manage invasive pests, (ii) manage pest resistance, (iii) reduce pesticide residue levels to enhance trade, (iv) increase the role of bio-pesticides and bio-stimulators in plant protection. The point of attention is how the use of micro-organisms influences the beer production.

Ms Gea Bouwman from Plantum (Netherlands; also representing Euroseeds) presented experience and expectations from the Commodity Expert Group on Seeds. CEG Seeds is dealing with 'seed production' as well as 'seed treatment'. The aim of 'seed production' is to have good starter material, whereas 'seed treatment' aims to have crop protection through the treatment of seeds. Seed treatment is a more targeted way of applying plant protection products as up to 99% less active ingredient can be used. European seeds are sold all over the world, therefore the seeds sector needs European solutions and an EU Minor Uses Coordination Facility. The CEG Seeds provide input for the list of minor uses needs. CEG Seeds exchanges information on possible solutions (crop protection products and methods, agricultural practices),

maintain the list of projects and exchange with CEG Fruits & Vegetables on different kind of solutions for shared minor use needs. Working in the framework of the MUCF (i) enlarges the network to work on solutions, (ii) provides guidance and harmonisation, (iii) enables to have a spokesman, knowledge centre and coordinator for minor uses, and (iv) provides practical help and tools (e.g. EUMUDA, Homologa searches).

Ms Sheridawn Shoeman presented on behalf of the European Crop Protection Association (ECPA) the experience and expectations from the conventional/biopesticide industry. ECPA represents the highly innovative R&D driven crop protection industry in Europe consisting of 22 multinational companies, 32 national associations within total 26,000 people. Crop protection is necessary as annual crop losses caused by insects, diseases and weeds are estimated up to 40% according to the UN FAO. Currently, there is a broad discussion on sustainable agriculture and food (e.g. REFIT, Green Deal, Farm-to-Fork Strategy). What are the implications for minor uses? The availability of plant protection products for minor uses is negatively affected by a lack of clarity on the rules for authorisation and harmonisation between the Member States. Procedures are often not established, and alternative ways are used by the Member States to ensure that products can be made available in their national markets. And the Member States tend to establish their procedures. The Agri-Food Chain Round Table for Plant Protection provides for a common position from all major EU agri-food chain associations including ECPA to support minor uses and the role of the EU Minor Uses Coordination Facility and its sustainable funding. ECPA listed the following considerations on the way forward: (i) the MUCF role is recognized as essential by the European Commission, national governments, industry and growers, (ii) actions taken by MUCF over the last 4 years are allowing greater collaboration and practical solutions to be found, and (iii) lack of sustainable financing is putting the mission of the MUCF at risk. As Health Commissioner Stella Kyriakides said, "We all agree the minor use facility is extremely important and needs to be supported".

Mr Ulf Heilig presented on behalf of the International Biocontrol Manufacturers Association (IBMA) the experience and expectations from the biocontrol industry. IBMA has more than 250 members of which the majority (around 80%) are SMEs. IBMA a member of the global federation of biocontrol associations (BPG). IBMA has partnerships with Copa-Cogeca (Roadmap for collaboration) and IFOAM EU (Roadmap for organic farming). The Copa-Cogeca-IBMA Roadmap contains a specific platform on the cooperation on EU Minor Uses & Specialty Crops. The IBMA-IFOAM EU Roadmap supports the authorisation of substances/products in small markets (=minor uses and specialty crops). IBMA proposals include: (i) establish a harmonised EU wide common minor use status, (ii) give priority in assessment and reduce time to market for low-risk and biocontrol products, (iii) grant EU wide authorisations for biocontrol & low-risk plant protection products for minor uses, and (iv) grant derogations for niche uses. IBMA recognises the MUCF's essential role in filling minor use gaps by coordinating the work, facilitating information exchange, setting priorities and representing minor uses interest. The MUCF has an essential role in Minor Uses/speciality crops protection by coordinating and contributing to the optimisation of the availability of tailored solutions. The existence of the MUCF is vital for all stakeholders.

Ms Elisabeth Douce presented on behalf of UPL the experience and expectations from an individual company. There is a huge diversity of definitions and classification of 'Minor Uses' that differ from one Member State to another. In this respect, there is no 'zonal approach'. This hampers the use of Article 51 extensions of authorisations for minor uses. Obtaining a minor uses authorisation can take several years and delays can even be added up. Complex extrapolation rules and additional data requirements lead to a substantial increase in cost and time. An example is the risk envelope where it is very difficult to determine in advance if the intended minor use falls within the risk envelop of already registered crops. Proposals for improvement include (i) harmonise the classification of minor uses at EU or zonal level, (ii) simplify efficacy data extrapolation rules for minor uses preferably at crop level, (iii) clarify and ease the risk envelop approach for minor uses, (iv) facilitate evaluation timelines for minor uses in parallel to other processes (EU approval, Art. 43 evaluation), (v) reduce administrative burden wherever possible, and (vi) make it possible to submit minor uses at the national level and not necessarily at the zonal level.

Mr Johannes Fahrentrapp (Zurich University of Applied Sciences) presented his experience and expectations from the C-IPM research network. When the MUCF was established it was indicated that it should work mandatory together with the C-IPM ERANET as Work Package 3 dealt with the 'mapping and analysis of minor use problems and possible IPM solutions'. ERANETs aim to step up the cooperation and coordination of research activities carried out at National or regional levels (duration 2014-2016). The ERANETs are followed up through SusCrop calls. SusCrop is an ERANET Cofund Action under H2020, which aims to strengthen the European Research Area (ERA) in the field of Sustainable Crop Production through enhanced cooperation and coordination of different national and regional research programmes. Further cooperation is needed on different levels as pests ignore borders. More interdisciplinary IPM research is necessary as well as an upscale from specific crop pest solutions to sustainable cropping systems. The AAPM (Automated Airborne Pest Monitoring) project on detection and monitoring with drones of Drosophila suzukii was given as an example of a C-IPM project. Some of the conclusions are that (i) improvement is needed regarding the trap performance, (ii) deep learning and highresolution imagery has a high potential for insect counting, and (iii) improvement is needed regarding optics and autonomous positioning for the landing of the drone on the platform.

Ms Rosemary Collier (University of Warwick) presented her experience and expectations with EUVRIN, the European Vegetable Research Institutes Network. EUVRIN is an informal, voluntary organization of research institutes or departments that specialize in research, development, and extension on vegetable production. Most vegetables are considered minor crops. There are several EUVRIN Working Groups, e.g. IPM for vegetable production, European Mushroom Working Group. Exchange of ideas and information takes place at annual meetings in different locations. The priorities of the EIP AGRI Focus Group on IPM in Brassica are (i) control strategies with fewer side effects on beneficial, (ii) new and emerging pests and diseases and

climate change, (iii) exploiting soil microbiome diversity to prevent/control soil-borne diseases, (iv) reliable, cost-effective and simple monitoring and decision support systems, (v) breeding for pest resistance, (vi) applied research on plant defence elicitors, (vii) better understanding which crops and wild hosts are reservoirs for pests and diseases, and (viii) how to implement and manage functional biodiversity.

Ms Flora Limache (MUCF) presented the results of a survey on how the Member States organise minor uses' work. The survey was carried out in 2017 and responses were received from 24 EU Member States, Norway and Switzerland. The report is available on www.minoruses.eu. A majority (73%) of the national contact points responsible for minor uses come only from the national competent authority dealing with authorisation of plant protection products (PPPs). For more than half of the Member States (54%) all the applicant categories that are mentioned in Article 51 of Regulation (EC) No 1107/2009 can or do apply for a minor use extension. More than half of the Member States (54%) indicated that they have a national list on minor uses available. Overall the criteria given by the Member States they use to define a minor use are very diverse and of quantitative and/or qualitative nature. To qualify a use as minor, Member States use primarily criteria linked to the crop: surface, production volume, type of crop (e.g. speciality) or dietary intake. Some Member States also consider the pest occurrence. It should be noted that various Member States use more than one criterion. Overall 34% of Member States have set up a group-specific to minor uses. A majority of Member States does not charge a fee or charge a low fee, between 10 to 800 euros, for an article 51 minor use extension. Overall, a high proportion of Member States (81%) do not require efficacy data for minor uses extensions.

Mr Niels Enggaard Klausen from HortiAdvice, Denmark presented the experience and expectations of advisory services. HortiAdvice is a private horticultural advisory service that advises gardeners and growers of all horticultural crops in Denmark. In Denmark, there is a strong tradition, both in agriculture and horticulture, for private and independent advice. There is also a strong tradition for working together with the universities in research and development projects. The advisory service plays a central role in applying for minor uses. The advisory service is the link between the practise/growers and the universities. HortiAdvice conducts practical tests of alternative products as biostimulants and biopesticides, also as part of IPM strategies. This close interaction between gardeners, advisory service and universities ensure good results when applying for minor uses. Recently, a close collaboration of a Scandinavian cross-border co-operation between Denmark, Sweden and Norway has started. This Interreg project, from 1st January 2020 to 30th September 2022, aims of improving co-operation in the work of minor use applications. The results from trials in one country could also be used in the other two countries. Besides the economic advantage in not doing the same trials in similar countries, the idea is also to speak with one voice when trying to get new products into the Northern zone. Three countries have a louder voice than one.

Mr Dan Kunkel (IR-4, USA) presented his experience of the minor uses work in North America. The IR-4 Project is a US government-funded research programme facilitating the regulatory approval of sustainable pest management technology for

specialty crops and specialty uses to promote public well-being. The vision of IR-4 is to establish a global network of capable minor use programs working together to solve the Minor Uses Problem. Within NAFTA there is an intensive collaboration between the US and Canada resulting in a 'Win-Win' situation. This model (i) addresses grower pest control needs with safe effective products in a manner that does not affect trade markets, (ii) provides for conducting Joint Residue Studies and provide simultaneous submissions to both regulatory agencies (EPA in US and PMRA in Canada), and (iii) allows for submissions are reviewed and registrations approved in both countries at approximately the same time with harmonized tolerances/MRLs. Regarding its global activities IR-4 is actively involved in the Codex Committee on Pesticide Residues, Global Minor Use Summit, OECD-Expert Group on Minor Uses, and IR-4 Global Residue Studies, training and capacity development. IR-4, together with partners, has set up the 'Global Minor Use Foundation' that will provide funding for research to other qualifying organizations based on priorities resulting from the Global Minor Use Workshops. IR-4 Food and Global Minor Use Priority Setting Workshops will be held from September the 14th to the 17th, 2020, Minneapolis, Minnesota, USA. The Biopesticide and Organic Support Programme currently covers 5% of the IR-4 projects' efforts and resources. The focus of the work is on the integration of bio-pesticides into conventional systems.

7. SUMMARIES OF BREAK-OUT GROUP SESSIONS

7.1 Session 1: Obstacles in minor uses work and possible ways forward

This topic was discussed by all four BOGs.

Different stakeholders are involved in minor uses work: governments (representatives from Ministries and competent authorities), EU policy-makers, growers' organisations, national minor uses experts, industry (conventional and biological), research centres, advisory services, and international partners.

Different groups of stakeholders face different obstacles in their day-to-day work on minor uses.

In this session, the views of the stakeholders on the obstacles they encounter were compiled and possible ways forward were identified.

Topics for discussion:

- 1. What are the obstacles faced by growers in relation to the protection of speciality crops and major (arable) crops?
- 2. What are the obstacles faced by EU and national (both Ministry and competent authorities) policy-makers in relation to minor uses?
- 3. What are the minor uses obstacles faced by the other stakeholders, industry, research, advisory services?
- 4. How could these obstacles be overcome?

Summary of discussion:

For growers' one of the main obstacles is the non-availability of plant protection products (PPPs) in combination with the uncertainty on the status of active substances and which PPPs will be available for the next growing season. This is mainly due to renewal programmes and the implementation of new (approval) criteria. These obstacles can, at least partly, be overcome by carrying out forecast studies on the availability of active substances and PPPs.

Besides, there is a difference in the availability of PPPs in the different zones. As the market in the Northern zone is rather small, there is a low interest of the industry to submit applications and therefore too few products are authorized in the Northern zone. In the Southern zone, there is an important number of minor crops and hence more products are available. Common solutions for greenhouses are generally found acceptable and exchangeable between zones. Contrary, for field's uses in most cases there is a need for additional specific data for a specific zone.

Complex procedures, national specific requirements and different interpretation of the regulatory framework lead to different (national) decisions and thus creating an uneven level playing field for EU farmers. Farmers have a difficulty to compile a dossier and prepare the application in the correct way. When submitted, it may be

difficult for farmers to follow their submissions for minor uses (where is my application in the process and when can I expect a decision). Possible benefits on clarity and transparency may be expected from the new General Food Law including further transparency provisions (applicable from March 2021). The MUCF could assist growers and farmers organizations to find their way in these complex procedures and to make the best use of the transparency provisions for their applications.

"Minor Uses" can easily be considered as a "Minor Problem" by policy-makers. These should be aware of the importance of minor crops and the high economic value of these crops. There was agreement at the workshop to use 'speciality crops' rather than minor crops as this better reflects the status/value of these crops.

Growers livelihood depends on securing harvest with high yields and high crop's quality and growers need both safe and efficient solutions, whether conventional or biological, to control pests and diseases. Market requirements are very strict on damage on the products to be sold which makes it even more difficult for IPM growers. Multiple IPM actions may be necessary to replace one conventional PPP. The use of IPM practices represents an economic risk for growers which is not balanced by a corresponding increased market price. However, not all farmers are aware of the possibility to get financial compensation via CAP-payments when growing crops within an IPM framework. On the other hand, not all speciality crop growers may be eligible to receive CAP-payment (for example specialised horticultural crop growers).

To have two residues zones in EU is, especially for minor crops, an obstacle and it was suggested to revisit this concept. It should also be considered to update the Guidance Document on residue extrapolations (SANCO 7525/VI/95) and to ask only residue trials from the region where the crop is mainly cultivated. Then the residue trials and MRL from the main cultivation region can be used for authorisations in all zones. In this way, better use can be made of the available data. Besides, the use of residue data generated outside the EU, when scientifically valid, in granting minor uses extensions, should be acceptable. In this respect, the findings of the Global Residue Data Exchangeability project (carried out by IR-4 in the USA) are very convincing in terms of data comparability. These finding can be used to explore if for minor uses the EU can be considered as one zone for residues (and not two as it is currently: north and south).

Although the principle that applications for MRL's should always be maximally extrapolated to the entire crop group was embraced, it was indicated that food basket needs to be considered to prevent an exceedance of the MRL.

It was highlighted that in general for biologicals no MRL needs to be set.

Retailers set additional requirements to the level of residues which can be below the accepted MRL, sometimes far from it. This creates an uneven level playing field and is disruptive mostly for local trade, but also the trans-national and international one.

From a regulatory perspective, there is a recommendation to make better use and maximize the use of Mutual Recognition. The fact that crops can have a different

status in each Member State makes it difficult to extrapolate from a speciality crop/minor use to a major crop/major use. This does not only hamper the zonal procedure but more specifically the mutual recognition of minor uses authorisations between the Member States, even in the same zone. Better implementation of the zonal system is necessary, limit the requests for national specific requirements, and build and foster the trust of regulators with regards to acceptance of evaluations performed by other regulatory authorities. Within authorities, specific teams for minor uses could be established to accommodate the zonal system and to facilitate applications for minor uses.

A lot of research is ongoing in different networks. Research is often done on major crops and not on minor crops (biological alternatives). Research on extrapolation possibilities (efficacy/residues) is considered crucial. The results of C-IPM and other research networks should be communicated to growers. Currently, there is a lack of technical translation of results of research to growers and communication between growers, advisors and researchers on future needs and available knowledge need to be improved.

Currently, the funding of the MUCF fully relies on voluntary contributions from member countries. A prerequisite to getting more countries on board to fund the work of the MUCF is good communication on the benefits of the work of the MUCF for consumers and other stakeholders. What are the concrete benefits for a specific Member State of funding the MUCF? Regarding financial sustainability, it is recommended to link the work on minor uses to other policy initiatives (e.g. Green Deal, Farm-to-Fork Strategy, Horizon Europe) so that within the European Commission a separate budget line can be created that should facilitate the mid- and long-term funding of the MUCF.

7.2 Session 2A: IPM research and integration in minor uses work

This topic was discussed by BOG 1 and BOG 2.

This session focussed on research in Integrated Pest Management (IPM) and projects to generate data on efficacy/crop safety and residues.

A lot of research on IPM is ongoing, but minor uses and speciality crops are not always addressed sufficiently. This issue has been identified by the ERANET C-IPM (Coordination Integrated Pest Management) and is also described in the Strategic Research Agenda.

The projects under the Commodity Expert Groups (CEGs) are run to generate data on efficacy/crop safety or residues for authorisation of plant protection products on minor uses.

In this session, ways were discussed how to integrate research on Integrated Pest Management (IPM) and their results in minor uses work and how to integrate this into projects done under the supervision of the Commodity Expert Groups (CEGs).

Topics for discussion:

- 1. How to make an inventory of existing solutions and/or new solutions coming from IPM research for minor uses?
- 2. How to increase collaboration with IPM research networks?
- 3. How to integrate IPM research in minor uses work?
- 4. How can researchers in IPM benefit from the work of the Commodity Expert Groups?

Summary of discussion:

Integrated Pest Management (IPM) is complex of measures that need more resources, communication and training, including a change of mindset compared to 'traditional agriculture'. An inventory on IPM measures should be done at different levels of detail: inventory per country (e.g. Ecophyto), inventory per crop, and inventory per pest/disease. This all based on the 8 steps of IPM.

Researchers should engage with farmers at an early stage to guarantee that the outcome of the research will eventually address the needs of the growers. Researchers should also liaise with the CEGs to know about the most important minor uses needs and the area(s) in which research is most needed.

The MUCF should keep track of ongoing research and an IPM research platform should be established that gathers information on activities and results of IPM research programmes. The MUCF should play an active role in harmonising and coordinating research programmes aiming to disseminate information and to avoid any duplication of research. A centralised website, covering research programmes in Europe, could be operated by the MUCF. In this respect, the MUCF should link as

much as possible with existing platforms and networks and in this way optimise the exchange of knowledge and information on innovation.

Different Research Networks are operational. The work of these networks (e.g. CostAction, Euphresco, C-IPM ERANET) should be promoted, and the knowledge should be exchanged among relevant stakeholders. It is proposed to organise a workshop with several research networks instead of every research network having its workshop. This would greatly increase the value of all of these research programmes. Copa-Cogeca and its members can act as a facilitator for such workshops. Co-funding of research on minor uses/IPM via Horizon Europe should be explored.

Advisors and advisory services play a key role in the communication between research and growers. Advisors do understand farmers and farming and they should be able to enforce trust between farmers and researchers. Demonstration farms and pilot farms can contribute to an early adoption of (new) solutions by farmers.

Social science is the branch of science devoted to the study of human societies and the relationships among individuals within those societies, including agriculture. Until now, social science has been neglected but it should be considered as an entire part of the agricultural issues and therefore social scientist should be more involved in collaborative research.

Farmers can claim CAP payments, in particular for the sustainable and reduced use of pesticides by applying the relevant general principles of IPM.

7.3 Session 3A: IPM implementation

This session covers 'IPM implementation and how to bring results of IPM research to growers' and was discussed by BOG 1 and BOG 2.

IPM implementation is mandatory in every Member State according to the Sustainable Use Directive. However, to date, IPM implementation and reduction of the use of conventional (chemical) pesticides do not yet meet the expectations of the Sustainable Use Directive in all Member States.

It is needed to improve the link between the results of IPM research and practical solutions available for growers. In that aspect, advisory services play a key role.

Research results can quickly be translated into practice if they are efficient, economically viable and where relevant, have passed the regulatory process for authorisation.

'Crop profiles' provide baseline information (e.g. per zone on crop production and IPM practices) and record the pest management needs and issues faced by growers; hence they could be useful tools to disseminate relevant information to growers.

This session discussed and proposed ways to improve the link between results of IPM research, CEG projects and how practical solutions can be made available for growers. In this session also the usefulness and feasibility of 'crop profiles' should be discussed.

Topics for discussion:

- 1. What is the experience of stakeholders (growers, advisory services) in the implementation of IPM in general?
- 2. How to translate the work from IPM research and CEG projects into practical solutions for growers?
- 3. How can data obtained through CEGs (projects) be used for setting IPM strategies for growers?
- 4. How to disseminate results from IPM research programmes and their progress to relevant stakeholders?
- 5. How to increase the collaboration of stakeholders (research institutes, Ministries, MUCF) with advisory services?
- 6. Are there alternative approaches to 'crop profiles'?
- 7. Are crop profiles or similar approaches useful for finding solutions for minor uses?
- 8. What would be the benefits of preparing 'crop profiles' or similar approaches?
- 9. What would be the drawbacks of preparing 'crop profiles' or similar approaches?
- 10. How can the work on crop profiles or similar approaches be supported and developed?
- 11. Who should be the actors involved in the development of crop profiles or similar approaches?

Summary of discussion:

The knowledge and experience that growers have gained on IPM methods need to be communicated more widely. To achieve this appropriate communication tools need to be used (e.g. forecasting advice, warning systems).

The objective of CEG projects is to provide a solution for a minor crop or minor use/pest/disease/weed for which an IPM strategy was not yet developed. The aim is to provide solutions to the growers.

In this respect, it is important to link (innovative) research at Universities and Research Institutions (scientific publication *vs.* applied science results) more widely with the research at stations that in general is more related to 'how to grow a crop' and farming.

Advisors are the link between growers and research and play a key role in communication and the dissemination of information. 'IPM Profiles' can become important tools to achieve these goals. 'IPM Profiles' should provide baseline information at different level (e.g. EU, zonal, national, regional) on crop production and IPM practices and the issues faced in this respect by growers. To produce such comprehensive information there is a need for coordinating, updating and disseminating. To ensure harmonisation the MUCF can develop a model, provide this on its website and then Member States can be encouraged to prepare these 'IPM Profiles'. These documents can also be good opportunities to prepare farmers for new solutions that they may need in several years (e.g. resistant varieties). When farmers start using these 'IPM Profiles' and indicate that these are important tools for their business operation they can claim contributions via CAP payments.

7.4 Session 2B: Regulatory procedures

This session covers 'Regulatory procedures: how to facilitate authorisations for minor uses' and was discussed by BOG 3 and BOG 4.

An applicant can apply for an authorisation for a minor use according to Article 33, Article 40 or Article 51 of Regulation (EC) No 1107/2009.

Although in general, the application for an extension for minor uses according to Article 51 follows the same zonal procedure as other applications, there are currently differences in the situation of implementation of the minor use provisions of Regulation (EC) No 1107/2009 and this creates uncertainty and divergence between the Member States. The availability of plant protection products for minor uses is negatively affected by a lack of clarity regarding the rules for authorisation and of harmonisation between Member States.

The Agri-Food Chain Round Table for Plant Protection favours an 'EU-wide authorisation' for Speciality Crops and minor uses. Whilst the current legislation neither requires nor prescribes such an 'EU level authorisation', there is scope for the Member States to make better use of the zonal and mutual recognition system to ensure that minor use authorisations are granted throughout the EU.

This session covered the zonal evaluation and mutual recognition. Member States exchanged on the way they deal with minor uses applications and how to facilitate solutions for minor uses in the current regulatory framework. Solutions that require pragmatic legislative changes were also discussed in the light of a 'vision for the future'. There were also discussions on ways to improve data access and sharing.

Topics for discussion:

- 1. How do Member States and applicants (industry and third parties) deal with minor uses applications? What are the obstacles they encounter in the zonal procedure?
- 2. What is the view of the other stakeholders on the procedures to get plant protection products registered for minor uses?
- 3. How to improve procedures and practices to authorise minor uses? What options can be identified, within the existing legal framework, by better implementation of existing rules? As part of a 'vision for the future' explore the benefits/drawbacks of a Pan-European authorisation for minor uses (Article 51) applications.
- 4. Authorisation of plant protection products-how to stimulate applications by industry and by third parties?
- 5. How can data sharing be increased especially for efficacy/crop safety and residue trials?

Summary of discussion:

Some obstacles stakeholders encounter in the zonal procedure are: (i) different requirements by the Member States, e.g. number of efficacy trials, (ii) different ways

of applying the risk envelop, (iii) different interpretation of the national definition of minor uses or no definition at all, and consequent lack of a proper procedure, (iv) different extrapolation rules for efficacy and residue data, (v) lack of clarity of the GAPs that support minor uses requests, (vi) a change of the residue definitions blocks the renewal of authorisations and the registration of authorisations for minor crops, (vii) as submissions for applications for minor crops are complex and costly there are only a limited number of farmers' requests for minor crops authorisations, (viii) lack of willingness to share data, "protectionism" – either from the Member States, industry or growers –, (ix) limited access to registration reports (dRRs) of other Member States, being final documents of drafts.

These obstacles can be overcome by (i) harmonized definition for minor crops/minor uses in EU, (ii) extended MRL extrapolation rules and further development of the EPPO tables for extrapolation of efficacy data, (iii) acceptance of residue data from non-EU countries for authorisations of minor uses, (iv) facilitate evaluation timelines for minor uses in parallel to other processes (e.g. renewal), (v) reduce the administrative burden for minor uses, whenever possible, (vi) prepare a so-called 'dormant authorisation' for emerging pests (see next paragraph), (vii) introduce a pan-European authorisation for minor uses (see next paragraph), (viii) introduce better information exchange system (especially for dRRs) before PPPAMS is fully implemented.

It was suggested to register the already so-called 'dormant authorisation' for issues that have not yet arrived in some countries ('emerging pests'). In this way, national authorities can act proactively and the number of requests for emergency authorisations will decrease.

According to the provisions of Regulation (EC) No 1107/2009 the approval period for active substances is limited to generally 10 or 15-years. An unlimited approval period for certain categories of active substances (e.g. low risk and biologicals) would facilitate and stimulate the authorisation of these plant protection products (as is promoted in the Green Deal). Speciality crops would also benefit from such a regime.

It is considered important that there is a proactive communication with stakeholders, especially between industry and grower groups on the status of active substances and the availability of plant protection products. Preferably, before submission, the GAP requested should be agreed with farmers to better meet their needs. Increased collaboration would increase trust.

In most Member States there is no authorisation possibility by Mutual Recognition of a minor crop if the PPP is not already authorised in that Member State on a major crop. That may lead to double work as first, the major crop needs to be authorised followed by the authorisation of the minor crop based on the major authorisation. This issue can be overcome by the introduction of the application of a 'one zone concept' and not just for evaluation but also for authorisation. Such a 'one zone concept' would be helpful for minor uses. The provision for a one-zone evaluation already exists within Regulation (EC) No 1107/2009 for plant protection products used in greenhouses –protected crops–, in storage or as a seed treatment. Through this provision, an evaluation by one Member State enables an authorisation throughout the EU, through a zonal application or mutual recognition. The application of such

provision should provide benefits to specialty crops and other minor uses. A next step, which would require legislative change, would be a true one-zone concept, i.e. including one-zone authorisation, where the result of the evaluation of any minor use, would be a European authorisation for this use. This would save time and money consuming procedures for zonal application and mutual recognition and would be justified, as all risks would already be evaluated, and be minor since it concerns minor uses. Such a 'Pan-European authorisation' requires a strong zonal cooperation. Having a common procedure to facilitate interzonal authorisation for Art. 51 extensions might be a positive realistic step forward and could be taken up as a pilot project.

When data (studies) are shared, duplication of the work can be avoided and costs saved. However, data is not always shared due to data protection rules. Mandatory data sharing, for all studies and not only for vertebrate studies, could be a solution to this issue. A step forward can be to provide MUCF access to PPPAMS to have information on efficacy/residue studies.

To address several of the aforementioned obstacles it can be explored to expand the scope and ambition of the Guidance Document on Minor Uses.

7.5 Session 3B: Harmonized status of crops

This session covers 'Harmonized status of crops in relation to the definition of minor uses' and was discussed by BOG 3 and BOG 4.

The following definition of a 'minor use' is provided in Article 3(26) of Regulation (EC) No 1107/2009. A 'minor use' means a 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.

Different definitions of 'minor/major' are used in different regulatory structures. The definition in Regulation (EC) No 1107/2009 refers clearly to the <u>cultivation area</u> (".... plants or plant products which are not widely grown").

In EPPO standard PP 1/224(2) on the 'Principles of efficacy evaluation for minor use,' it is indicated that "Minor uses are those uses of PPPs in which either the crop is considered to be of low economic importance at national level (minor crop), or the pest (minor pest) is not important on a major crop". In this case minor/major refers to economic importance.

In the Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs, SANCO 7525/VI/95, Rev. 10.3, 13 June 2017 the following are the criteria used for classifying a crop or a product as 'major' in the European Union:

 Daily intake contribution > 0.125 g/kg BW/day (mean daily consumption over the population) in GEMS Food Cluster Diet applicable to the concerned zone and relevant cultivation area (> 20 000 ha) and/or production (> 400 000 tonnes per year) in the zone

or

• Cultivation area > 20 000 ha and Production > 400 000 tonnes per year

For residues minor/major refers to <u>daily intake in combination with cultivation</u> <u>area/production</u>.

It must be emphasised that the two zones referred to in the residue guidelines (northern and southern) are not similar to the definition of zones for the authorisation of plant protection products (northern, central, southern). EPPO zones deviate from the previous two concepts.

This session discussed a concept and criteria to establish an EU-wide status of a crop.

Topics for discussion:

- 1. What are the benefits and drawbacks of a harmonized EU status of a crop?
- 2. How should a concept to establish an EU-wide uniform status of a crop in relation to the current definition of minor uses look like? And under which criteria?
- 3. How should such an EU-wide uniform status of a crop be established?

Summary of discussion:

The definition in Regulation (EC) No 1107/2009 of a 'minor use' ("... plants or plant products which are not widely grown ...") leaves it up to the individual Member States to define what is considered a 'minor use/crop' in their respective Member State. This is considered a problem for further harmonisation as it hampers the zonal procedure and mutual recognition. Different definitions from one Member State to another lead to huge delays in the registration process and increase of costs.

It should be kept in mind that a harmonised status of a crop does not preclude the importance and quality of that crop for the producing country.

For industry, the harmonisation of the definition would help to support minor uses with complete dossiers covering more crops in the zonal applications. A common definition will allow for more mutual recognitions for minor uses. A harmonized definition of minor uses is important and considered feasible at the zonal level. In this respect, a fixed acreage, at least per zone, to determine the status of a crop and as is done in other regions of the world, is strongly favoured.

In the REFIT it is concluded that the zonal system is not working as expected and if there is a common definition of minor uses there are more chances to make the system efficient. Besides, the PEST Committee of the European Parliament calls in a resolution for a harmonized definition of 'minor use' and recommends creating a single EU list of major crops.

The possible benefits and drawbacks of a harmonized status of a crop were discussed. A consequence of a harmonized status of a crop may be that crops that were previously 'minor' in a Member State, are now considered 'major' or *vice versa*.

<u>Benefits</u>: If there would be more major crops this would not lead to more risks as the uniform principles are equally valid and have to be met anyway. A harmonised status of a crop would in general lead to less residue data and no or less need of efficacy data.

To have a harmonised list with 'major crops' would also provide for more possibilities for minor pests/pathogens on major crops as now, not all Member States use the provision from Article 3(26) (b) "major crop with exceptional need".

A harmonised list of major crops would have the following advantages:

- It will facilitate the zonal process and mutual recognition as every crop has a similar status in each Member State.
- This approach will facilitate the work of industry (conventional and biological) in supporting a minor use.
- This approach may lead to a higher number of applications and authorisations for minor uses.
- This approach will contribute to a level playing field for EU growers of speciality crops.

 Eventually, a level playing field should result in a reduction of request for emergency authorisations according to Art. 53 of Regulation (EU) No 1107/2009.

<u>Drawbacks</u>: More data may be needed at the national level if your 'minor crop' becomes a 'major crop'. However, this might be overcome as there should already be authorisations on this crop in the 'major crop countries' so the Member States can apply Mutual Recognition. Prerequisite is that Mutual Recognition should work properly and there should be the willingness to share the data. The preference from a Member State that at a crop is called 'minor' or 'major' may just be a matter of perception/ terminology as a minor crop may still be of major economic importance in a Member State.

If the commodity is no longer considered as a minor use the competent authorities may no longer treat an application as an Article 51 applications and hence will require efficacy data or charge higher fees. This may ultimately lead to applicants/grower organisations not pursuing these types of applications.

A harmonised status of a crop and creating a single EU or zonal list of major crops was generally supported. As a first step, a discussion paper on this topic should be prepared, followed by a pilot project.

7.6 Session 4: Future organisation of minor uses work in Europe

This topic was discussed by all four BOGs.

Since April 2018, the MUCF is financially relying on voluntary contributions from the EU Member States, Norway and Switzerland. The governance and operational structure of the MUCF are organised as follows: the Annual General Meeting and Steering Group are responsible for the governance; the operational structure consists of eight Commodity Expert Groups (CEGs) and the HEG. Some CEGs are dealing with just one commodity whereas other CEGs are dealing with a group of commodities.

Many of the projects conducted in the framework of the CEGs are led by Central and Northern zone countries and France for the Southern zone.

Within the Member States the work on minor uses is organised differently. A majority of Member States can carry out efficacy/crop safety/residue trials.

Awareness should be raised on the importance of speciality crops, minor uses, minor uses' work and the work of the MUCF.

This session prepared recommendations on the future organisation of the work, including partnerships and groups as well as the MUCF structure itself.

Topics for discussion:

- 1. How to ensure sustainable functioning of the MUCF? What is the role herein of European bodies, National organisations, and other stakeholders?
- 2. What is the envisaged role and structure of the MUCF?
- 3. How to raise awareness of stakeholders on minor uses?
- 4. Is the current organisation of the minor use work with different Commodity Expert Groups (CEGs) and the HEG working satisfactorily?
- 5. Should needs and priorities be identified per commodity instead of per country? Which are the advantages/disadvantages of the different methods?
- 6. What are the possible obstacles preventing more active participation in (CEG) projects from some Member States and how can they be overcome?
- 7. How can the participation of growers' organisations and industry in (CEG) projects be increased?
- 8. Is trial capacity sufficient in all Member States and for all stakeholders?
- 9. What would be the benefits of increasing the collaboration with international partners for the minor uses work in Europe (e.g. harmonisation at a global level, participating in global projects etc.)?

Summary of discussion:

There are several ways in which sustainable funding can be secured: (i) create a budget line, linked to other policy incentives e.g. Green Deal, Farm to Fork Strategy, (ii) establish a positive incentive (e.g. information to projects) for countries that

contribute, (iii) improve the visibility of concrete results of the work on minor uses to the end-users (=farmers), (v) extend cooperation for the list of needs to research institutions.

Growers and Crop Protection Industry benefit from the work of the MUCF so why should contributions from these groups for the MUCF not be considered? Member States are reluctant to funding from third parties because of the perceived risk of conflict of interest. Co-funding by third parties for individual projects would be acceptable. However, this seems disputable as a horizontal/broad infrastructure financing has less risk for a conflict of interest.

The MUCF could be the "expert advisory group" for the solutions to phytosanitary needs, the anti-resistance strategy, the rotations strategy and IPM for groups of crops. MUCF should expand its activities and increase staff to become (more) involved in (i) projects for data generation, (ii) coordinate discussions on needs and solutions between local teams of farmers, industry and the Member States, (iii) enhance communication e.g. info on MUCF website on what to do if you have a minor use problem, including a link to Chairs and Co-chairs of CEGs and Q&A document, and (iv) put on the Commission website a link to the MUCF. Also, the MUCF should have a more steering role in the preparation of the agendas and work plans of CEGs.

The results of the MUCF work, leading to authorisations at the national level and bringing crop protection solutions to farmers, should become more visible. Realised solutions should be displayed in EUMUDA. EUMUDA could also list all Art 51 authorisations granted in the different Member States. This could facilitate mutual recognition.

The role of the MUCF can also be strengthened if companies accept that the MUCF should become the owner of the data of CEG projects. ECPA is currently developing an e-builder tool. This tool is aiming at supporting companies without a dedicated IT tool to build their submission dossiers. This will be open source and freely available and minor use applications from grower groups may be facilitated with such tool in the future.

The current operational structure works well. MUCF has a 'lighter' role in CEGs and focuses on horizontal and coordinating issues (Guidance Document, SCoPAFF meetings etc.). Face-to-face meetings of CEGs and HEG are organised once a year all back-to-back. Plenary sessions to discuss topics of common interest should be continued. Other meetings can be more targeted project meetings (remotely, video- or teleconferencing). Minor uses needs should be identified both per country and per commodity. CEG F&V is a very large group and although it has already been discussed that there should be one meeting but with two parts in the agenda, it is perceived that for some topics there is not enough time for a detailed discussion. Agendas for CEG and HEG meetings should be well known in advance so that potential participants can judge in advance the usefulness for them of the meeting.

More growers should be represented in CEG-meetings. This can be arranged with assistance from Copa-Cogeca. Copa-Cogeca is already present in the HEG. It is also suggested to organise Priority Setting Meetings (like IR4 in the USA and PMC in Canada) where the industry comes in and present what is in the pipeline and what active substances could be worked on.

Although it seems that the trial capacity to carry out efficacy/crop safety/residue trials is sufficient in the Member States a better overview is needed of what facilities and with what qualifications exist in the different Member States.

One of the benefits of increasing the collaboration with international partners for the minor uses work in Europe is harmonising of MRL setting, harmonisation of GAPs especially before launching field studies, building trust between European and international partners.

8. REFERENCES

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Report on the Questionnaire on Minor Uses work in EU Member States, Norway and Switzerland, MUCF, March 2018

Strategic Research Agenda for IPM in Europe, November 2016

Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005), 10 October 2018

Workshop on research in Integrated Pest Management, C-IPM projects funded under calls 1 & 2, 22-23 November 2018

9. ANNEXES

1	Members of the organizing Committee
2	List of workshop participants
3	Agenda for the Workshop
4a	Background document BOG 1 and 2
4b	Background document BOG 3 and 4
5	Presentations' slides (separate document).
6	BOGs' slides (separate document)

Annex 1: Members of the Organizing Committee

- Mr Jean-Claude Malet, France
- Ms Claudia Jilesen, the Netherlands
- Ms Sanja Manduric, Sweden
- Mr Donal Lynch, Ireland
- Ms Paula de Vera, Copa-Cogeca
- Ms Sheridawn Shoeman, European Crop Protection Organisation (ECPA)
- Mr Ulf Heilig, International Biocontrol Manufacturers Association (IBMA)
- Ms Flora Limache, EU Minor Uses Coordination Facility (EUMUCF)
- Mr Jeroen Meeussen, EU Minor Uses Coordination Facility (EUMUCF)

Annex 2: List of Workshop Participants

MUCF - Workshop on 'Minor uses and speciality crops: the way forward in Europe' French Ministry of Agriculture, Paris (FR),2020-02-18/20



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Annex 3: Agenda for the Workshop



EUROPEAN UNION MINOR USES COORDINATION FACILITY



Workshop on "Minor Uses and Speciality Crops: The way forward in Europe"

Programme

	Tuesda	ay 18 February 2020
09:30 - 10:00		Registration
09:30 - 10:00	Coffee/tea break	
10:00 - 11:00	Plenary session	Welcome and introduction (setting the scene) - Introduction (Ms Anne-Cécile Cotillon,
	Room Gambetta	 Ministry of Agriculture and Food, France) Objectives of the Workshop (Mr Jeroen Meeussen and Ms Flora Limache, MUCF) Perspective on the production of speciality crops in Europe (Ms Paula de Vera, Copa-Cogeca) Introduction from European Commission (Ms Desislava Ivanova, DG SANTE; Mr Aymeric Berling, DG AGRI)
Experience an	d expectations of stak	seholders
11:00 - 11:40	Plenary session Room Gambetta	 Experience and expectations from a Northern grower organisation (Ms Agneta Sundgren Federation of Swedish Farmers) Experience and expectations from an Eastern European country from the Central Zone (Ms Malgorzata Flaszka, Ministry of Agriculture and Rural Development, Poland)
11:40 - 11:50	Health break	

Experience an	nd expectations of stak	seholders - continued
11:50 - 12:45	Plenary session Room Gambetta	 Experience and expectations from Ireland (Mr Donal Lynch, Ministry of Agriculture, Food and Fisheries, Ireland) Experience and expectations from CEG Fruits and Vegetables (Mr Jean-Claude Malet, Ministry of Agriculture and Food, France) Experience and expectations from CEG Hops (Ms Magda Rak Cizej, Slovenian Institute of Hop Research and Brewing, Slovenia) Experience and expectations from CEG Seeds (Ms Gea Bouwman, Plantum, Netherlands)
12:45 - 14:00	Lunch	
Experience an	d expectations of stak	keholders – continued
14:00 - 15:00	Plenary session Room Gambetta	 Experience and expectations from conventional/ biopesticide industry (Ms Sheridawn Shoeman, ECPA) Experience and expectations from biocontrol industry (Mr Ulf Heilig, IBMA) Experience and expectations from an individual company- registration department
		 (Ms Elisabeth Douce, UPL) Experience and expectations from IPM research network (Mr Johannes Fahrentrapp, C-IPM Eranet; Ms Rosemary Collier, EUVRIN)
Breakout Gro	ups	
15:00 – 15:15	Plenary session Room Gambetta	Explanation on Breakout Groups
15:25 – 16:50	Breakout group 1 Room BJ 213A	Session 1 Obstacles in minor uses work and possible ways forward
15:25 – 16:50	Breakout group 2 Room BJ 354	Session 1 Obstacles in minor uses work and possible ways forward
15:25 – 16:50	Breakout group 3 Room B001 Varenne	Session 1 Obstacles in minor uses work and possible ways forward
15:25 – 16:50	Breakout group 4 Room Gambetta	Session 1 Obstacles in minor uses work and possible ways forward
16:50 - 17:05	Coffee/tea break	

Break-out Groups		
17:05 – 18:15	Breakout group 1	Session 2
		IPM research and integration in minor uses work
	Room BJ 213A	
17:05 – 18:15	Breakout group 2	Session 2
		IPM research and integration in minor uses work
	Room BJ 354	
17:05 – 18:15	Breakout group 3	Session 2
		Regulatory procedures: how to facilitate
	Room B001	authorisations for minor uses
	Varenne	
17:05 – 18:15	Breakout group 4	Session 2
		Regulatory procedures: how to facilitate
	Room Gambetta	authorisations for minor uses
18:15 – 18:45		Preparation of BOG presentation (Chairs and
		Rapporteurs)
19:30		Workshop dinner

Wednesday 19 February 2020		
Breakout Gro	ups	
09:00 – 09:45	Plenary session Room Gambetta	BOG presentations Questions and clarifications
Understanding	g of minor uses work,	experience and expectations
09:45 - 10:30	Plenary session Room Gambetta	 Overview on how Member States organise minor uses work (Ms Flora Limache, MUCF) Experience and expectations of advisory services (Mr Niels Enggaard Klausen, Hortiadvice, Denmark) Experience of the minor uses work in North America (Mr Dan Kunkel, IR-4, USA)
10:30 – 10:50	Coffee/tea break	
Breakout Gro	ups	
11:00 – 12:30	Breakout group 1 Room BJ 213A	Session 3 IPM implementation and how to bring results of IPM research to growers
11:00 – 12:30	Breakout group 2 Room BJ 354	Session 3 IPM implementation and how to bring results of IPM research to growers
11:00 – 12:30	Breakout group 3 Room B001 Varenne	Session 3 Harmonized status of crops in relation to the definition of minor uses

11:00 – 12:30	Breakout group 4	Session 3
		Harmonized status of crops in relation to the
	Room Gambetta	definition of minor uses
12:30 - 14:00	Lunch	
Breakout Gro	ups	
14:00 - 16:00	Breakout group 1	Session 3- continued
		Session 4
	Room BJ 213A	Future organisation of minor uses work in Europe
14:00 - 16:00	Breakout group 2	Session 3- continued
		Session 4
	Room BJ 354	Future organisation of minor uses work in Europe
14:00 - 16:00	Breakout group 3	Session 3- continued
		Session 4
	Room B001	Future organisation of minor uses work in Europe
	Varenne	
14:00 - 16:00	Breakout group 4	Session 3-continued
		Session 4
	Room Gambetta	Future organisation of minor uses work in Europe
16:00 - 16:30	Coffee/tea break	
16:30 - 17:30	Breakout group 1	Session 4
		Future organisation of minor uses work in Europe
	Room BJ 213A	
16:30 - 17:30	Breakout group 2	Session 4
		Future organisation of minor uses work in Europe
	Room BJ 354	
16:30 - 17:30	Breakout group 3	Session 4
		Future organisation of minor uses work in Europe
	Room B001	
	Varenne	
16:30 - 17:30	Breakout group 4	Session 4
		Future organisation of minor uses work in Europe
	Room Gambetta	
17:30 – 18:00		Preparation of BOG presentation (Chairs and
		Rapporteurs)

Thursday 20 February 2020 Breakout Groups			
09:00 - 10:00	Plenary session	BOG presentations	
	Room Gambetta	- Questions and clarifications	
10:00 - 10:30	Coffee/tea break		
Conclusions and recommendations			
10:30 – 11:45	Plenary session	Presentation of draft conclusions and	
		recommendations	
	Room Gambetta	Summary and Conclusion	
11:45 - 12:00	Closing remarks	The way forward	
12:00		End of Workshop	

Annex 4a: Background document BOG 1 and 2







Workshop on "Minor Uses and Speciality Crops: the way forward in Europe"

Breakout groups 1 and 2

All Breakout groups (BOGs) will consist of a mix of different stakeholders.

The BOGS have common topics on obstacles related to minor uses work and organisational aspects. The BOGs have as well some specific topics for their consideration. The participants of BOGs 1 and 2 will discuss topics focusing on IPM research, IPM implementation and minor uses projects in the EU.

Each BOG has one Chair and one Rapporteur. The Chair and the Rapporteur are responsible for running the discussion in the BOG, for summarizing the results of the discussion and for presenting the results of their group in the plenary session. Discussion and brainstorming should be done by all participants!

Each BOG participant should bear in mind the objectives of the Workshop, relevant to BOGs 1 and 2:

- Exchange on experience and expectations on minor uses work and on the MUCF of stakeholders, with a focus on growers and Member States
- Prepare recommendations on how to integrate IPM research in minor uses' work and on how to incentivise bringing integrated solutions to growers.
- Raise awareness of research institutions and other stakeholders on minor uses work in Europe and on the work of the MUCF
- Increase the trust and collaboration between Member States and between stakeholders.
- Identify how to overcome obstacles in research and practical implementation of minor uses work in practice, and define the different roles of the MUCF, European Commission, Member States and other stakeholders in addressing these issues.

Day 1-18 February 2020

Session 1: Obstacles in minor uses work and possible ways forward

Introduction

Different stakeholders are involved in minor uses work: governments (representatives from Ministries and competent authorities), EU policy makers, growers' organisations, national minor uses experts, industry (conventional and biological), research centres, advisory services, and international partners.

Minor uses correspond to plant protection needs on speciality crops (fruits, vegetables, ornamentals, herbs, seeds and mother plants, hops, rice, tobacco) and can also concern some exceptional plant protection needs on major (arable) crops, for example flea beetle on oilseed rape.

Different groups of stakeholders face different obstacles in their day-to-day work on minor uses.

For the MUCF minor uses work comprises different steps (see Figure 1 in Annex 1): i) the identification of minor uses needs, ii) the search for possible solutions, iii) the generation of data (residue/efficacy/crop safety) in projects, iv) the application for authorisation/extension of use of plant protection products, followed by v) the bringing of integrated (building blocks) solutions under IPM strategies to the grower.

The OECD Thought starter paper (background document A) provides insight on general problems faced by growers. Growers play a key role in sustainable crop production as highlighted in Copa and Cogeca's position on sustainable crops protection (see box on the next page, background document B). Insight on regulatory incentives is provided in the OECD Guidance document (background document C).

Thought starter paper 'How Integrated Pest Management (IPM) tools can help fill in the gaps as regards minor uses'.

Understanding the minor use problems growers are trying to address

The minor use problems growers are trying to address are their limited pest management options exacerbated by development of resistance to pesticides, loss of pesticide products as a result of re-evaluation and de-registration processes, residue violations leading to loss in consumer and market confidence and limited options to address emerging pest/disease issues. The key issue for growers is to be able to produce a high yielding, marketable crop.

Copa and Cogeca position on sustainable crops protection, November 2019

As part of their job, farmers may have recourse to Plant Protection Products (PPPs) to grow healthy crops on competitive terms and ensure that consumer demands are met at the same time, irrespective of the production method. Their day-to-day work, from which they earn a living in a very competitive market, involves providing safe food, feed and non-food agricultural products and safeguarding the environment. Also, the proper use of PPPs is an important tool in maximising yields whereby resources are used in the best and most efficient possible way, hence a lower carbon footprint for each produced unit. Besides, these PPPs support high quality agricultural production.

The OECD Guidance Document on Regulatory Incentives for the Registration of Pesticide Minor Uses briefly discusses the different aspects of incentives that are typically utilised including;

Economic incentives (or increased "value") for registrants

- Data protection
- Expedited reviews
- Fee reductions or waivers

Technical arrangements based on sound science

- Extrapolation and mutually accepted data
- Number of trials

Authorisation process arrangements

- Third party registrations
- Temporary approvals (off-label & emergency schemes)

Research

• Data generation assisted schemes (dedicated minor use programmes that are specifically

designed to work with grower groups and registrants in undertaking the necessary

generation and making of regulatory submissions)

Promotion of safer alternatives

• Reduced risk incentives

Liability

• Liability waivers/disclaimers

Aim of the session

The aim of session 1 is to compile the views of the stakeholders on the obstacles they encounter and identify possible ways forward. This compilation can be done in the format of a table which can be used as a basis to prepare the list of concrete actions at the end of the workshop (roadmap).

In this session individual minor uses needs (combination of crop, pest and country) are out of scope and should as such not be considered. These needs are already available in EUMUDA. The process how to identify minor uses needs will be discussed in session 4.

To prepare session 1, participants are asked to take note of the obstacles (and possible ways forward) that are presented in the plenary session.

To illustrate obstacles and possible ways forward, participants are invited to use concrete examples e.g. from a crop sector.

Topics for discussion:

- 5. What are the obstacles faced by growers in relation to the protection of speciality crops and major (arable) crops?
- 6. What are the obstacles faced by EU and national (both Ministry and competent authorities) policy makers in relation to minor uses? Obstacles faced by regulators and evaluators are out of scope of this session and will be discussed in session 2 of BOG 3 and 4.
- 7. What are the minor uses obstacles faced by the other stakeholders, industry, research, advisory services?
- 8. How could these obstacles be overcome?

Background documents for session 1:

- Thought starter paper 'How Integrated Pest Management (IPM) tools can help fill in the gaps as regards minor uses', May 2016 (background document A)
- Copa and Cogeca position on sustainable crops protection, November 2019 (background document B)
- Guidance Document on Regulatory Incentives for the Registration of Pesticide Minor Uses; OECD Series on Pesticides No. 63,23-Jun-2011 (background document C)

Session 2: IPM research and integration in minor uses work

Introduction

In session 2, participants will focus on research in Integrated Pest Management (IPM) and projects to generate data on efficacy/crop safety (including under IPM) and residue under the supervision of the Commodity Expert Groups (CEGs).

A definition and general principles of IPM are provided in the Sustainable Use Directive 2009/128/EC (background document D). See boxes below. Art 55 of Regulation (EC) No 1107/2009 includes that the use of plant protection products shall comply with the provisions of the Sustainable Use Directive and in particular IPM.

Sustainable Use Directive 2009/128/EC

IPM means careful consideration of all available plant protection methods and subsequent integration of appropriate measures that discourage the development of populations of harmful organisms and keep the use of plant protection products and other forms of intervention to levels that are economically and ecologically justified and reduce or minimise risks to human health and the environment. IPM emphasises

the growth of a healthy crop with the least possible disruption to agro-ecosystems and encourages natural pest control mechanisms.

Sustainable Use Directive 2009/128/EC

General principles of IPM are: 1. prevention, 2. monitoring, 3. decision-making, 4. non-chemical methods, 5. use pesticides as specific as possible for the target, 6. limit the use of pesticides to levels that are necessary, 7. anti-resistance strategies, and 8. learn and optimise.

IPM research and the role of Minor Uses in it

A lot of research is ongoing on IPM, but minor uses and speciality crops are not always addressed sufficiently. This issue has been identified by the Eranet C-IPM (Coordination Integrated Pest Management), see Strategic Research Agenda (background document E).

Strategic Research Agenda for IPM in Europe (C-IPM, November 2016)

European agricultural research has mainly focused on the production of arable crops. Thus, the "small" productions, with very high added value, have been often sidelined. Hence, there is a need for a re-investment in research, in general, on minor crops. While the research gap in Europe is widening between major and minor crops, southern countries have continued to invest and consequently minor crops in these countries represent a very important component of their trade balance because of the added value of these productions, which are very often also a very important component of the diet in very well identified systems (e.g. household gardens).

Under the Eranet C-IPM, 16 projects for IPM and minor uses have been funded. Some of these projects are finalised, others are still ongoing (report of the Workshop on research in Integrated Pest Management, November 2018) (background document F).

In the OECD Thought starter paper 'How Integrated Pest Management (IPM) tools can help fill in the gaps as regards minor uses' (background document A) it is also recommended to specifically incorporate minor use needs as part of IPM research, development and implementation initiatives and programmes for IPM.

There is a need to make an inventory of IPM solutions that are available as a result of research programmes and assess how this inventory can be done. When discussing which IPM solutions are available, it is important to avoid only discussing generally

accepted methods. The focus should be more on inventive, newer, not yet widely used, methods.

There is a real need to integrate IPM research, as described in the Strategic Research Agenda of C-IPM (background document E), in minor uses work.

Strategic Research Agenda for IPM in Europe (C-IPM, November 2016)

Research needs in core theme C

- Put in place a European network to harmonise all ongoing activities related to minor uses;
- Create a European inventory of minor use problems and available solutions and rank

them in order of importance in collaboration with EUMUDA;

- Encourage knowledge-sharing with stakeholders on a selected number of topics;
- Develop alternative solutions based on inventory and interests of international stakeholders:
- Promote the development of alternative solutions to chemicals and their application;
- Liaise with non-European programmes on minor uses in order to share knowledge and solution-finding;
- Foster activities and initiatives related to breeding for resistance for minor crops;
- Re-investment in research for minor crops and knowledge-sharing between southern
 and
 northern countries.

CEG projects

The projects under the Commodity Expert Groups are run to generate data on efficacy/crop safety or residues for the purpose of authorisation of plant protection products on minor uses.

Projects in EUMUDA are on individual plant protection products, which can be conventional or biological products Other types of solutions may be incorporated in future projects. Data generated under CEGs is used for authorisation of plant protection products. This data is useful for building blocks in IPM strategies.

The EU Minor Uses Database (EUMUDA) is a central tool to solve minor uses issues in the EU. It supports the activities of the Commodity Expert Groups (CEGs) and provides information on minor uses needs (crop/pest combinations) and their priorities, and CEG projects and crop areas in the EU.

www.eumuda.eu

Aim of the session

The aim of this session is to discuss and propose ways how to integrate research on Integrated Pest Management (IPM) and their results in minor uses work and into projects done under the supervision of the Commodity Expert Groups (CEGs).

Topics for discussion:

- 5. How to make an inventory of existing solutions and/or new solutions coming from IPM research for minor uses?
- 6. How to increase collaboration with IPM research networks?
- 7. How to integrate IPM research in minor uses work?
- 8. How can researchers in IPM benefit from the work of the Commodity Expert Groups?

Background documents for session 2:

- Sustainable Use Directive 2009/128/EC (background document D)
- Strategic Research Agenda for IPM in Europe, November 2016 (background document E)
- Workshop on research in Integrated Pest Management, C-IPM projects funded under calls 1 & 2, 22-23 November 2018 (background document F) https://www.youtube.com/watch?v=WE_ZznNc9NA
- Thought starter paper 'How Integrated Pest Management (IPM) tools can help fill in the gaps as regards minor uses', May 2016 (background document A)

Day 2-19 February 2020

Session 3: IPM implementation and how to bring results of IPM research to growers

Introduction

IPM implementation is mandatory in every Member State according to the Sustainable Use Directive (background document D), and Member States have to set up National Action Plans (NAPs) for this purpose. However, to date IPM implementation and reduction of the use of conventional (chemical) pesticides do not (yet) meet the expectations of the Sustainable Use Directive in all Member States².

It is needed to improve the link between results of IPM research and practical solutions available for growers. In that aspect advisory services play a key role.

Many advisers and growers are very active in the search for useful results coming out of research projects. They participate in research experiments, conferences, subscribe to journals, newsletters etc.

Research results can quickly be translated into practice if they are efficient, economically viable and if they have passed the regulatory process for authorisation (where relevant). To achieve that, closer collaboration between growers, industry and researchers should be established to identify the needs in the field and translate them into feasible solutions to be developed in the laboratories. The transition to alternative methods and practical adjustments at farm level may affect the competitiveness of the market. In addition, environmental effects of alternative methods are generally not as well studied as the effects of chemical pesticides, such as mechanical weed control instead of herbicides.

These questions on the economical viability and environmental effects of alternative methods are broader than only for minor uses but may be more crucial for speciality farms.

The OECD Thought starter paper 'How Integrated Pest Management (IPM) tools (background document A) can help fill in the gaps as regards minor uses' also provides useful information on this topic.

Thought starter paper 'How Integrated Pest Management (IPM) tools can help fill in the gaps as regards minor uses'

What are the gaps and barriers that prevent adoption of IPM tools and technologies?

The barriers that prevent adoption of IPM tools and technologies are the limited number of tools and lack of information and knowledge to help growers implement IPM. Traditionally the main focus for crop protection has been the development of conventional chemicals; IPM is seen as complex and generally growers see access to

² REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL On Member State National Action Plans and on progress in the implementation of Directive 2009/128/EC on the sustainable use of pesticides (2017)

chemicals as the solution to minor use problems. Other gaps include flexibility in legislative frameworks and regulatory processes to facilitate the registration of biological control agents and IPM-compatible pesticide products.

Thought starter paper 'How Integrated Pest Management (IPM) tools can help fill in the gaps as regards minor uses'

What should be done to help growers take better IPM measures?

A broader approach should be taken to managing crop production and the options available to manage the risks of loss of productivity and marketability through pests and diseases. Research and development and implementation of IPM tools and technologies should be done through a coordinated, participatory and cooperative approach across all sectors of research and development, education and awareness and implementation.

Crop profiles

Crop profiles are documents that provide baseline information e.g. per zone on crop production and IPM practices and record the pest management needs and issues faced by growers. The Canadian minor uses programme PMC prepares and publishes such documents. A Crop Profile for Raspberry (background document G) is added as an example (see box on the next page). Similar initiatives are taken in European countries.

Canadian Crop Profiles

The current process in Canada involves a contract between the Pest Management Centre (PMC) with the Canadian Horticultural Council (CHC) and is paid through Canadian Agriculture Partnership funding and all work done by PMC staff is compensated via salary dollars.

CHC is responsible for identifying a crop representative for each reporting province. Reporting provinces are determined by Canadian acreage. PMC provide data collection forms, which list the pests/diseases/weeds/IPM practices for which data should be collected. This data is then sent back to CHC for quality control and then forwarded on to PMC for finalisation. The responses provided should cover the three most recent growing seasons.

In addition to the data collection forms, CHC will ask the crop representative to review the crop production practices text section and provide updates with any new practices and key issues.

Pests/practices to be included are based on what's been in previous crop profile versions, review of priority lists from the Canadian National Minor Use Workshops, review of provincial ag websites, grower newsletters, and any updates added during

the key issues document. PMC will then send these lists to Provincial Crop Specialists (before we circulate the data collection forms) to review and add input.

PMC will pull production statistics from Statistics Canada, build the pesticide tables, update the pest/disease/weed text, and update key issues.

For publication, PMC prepares the report in-house and it is only published as an electronic publication on our government website.

Crop Profile for Raspberry

The Crop Profile for Raspberry in Canada, 2016 provides an overview of production and pest management practices for raspberry in Canada. Information is provided on abiotic factors affecting its growth. The biology of key disease, insect and mite and weed problems is presented as well as cultural and chemical methods of control. Detailed information is provided in tabular form on pest occurrence, integrated pest management options, as well as registered pesticides available to growers, current as of December, 2018.

Aim of the session

The aim of this session is to discuss and propose ways to improve the link between results of IPM research, CEG projects and how practical solutions can be made available for growers. Participants should discuss the role of advisory services in this respect. Participants should discuss and propose ways to disseminate information on the IPM research programmes, their progress and their results to relevant stakeholders. In this session also the usefulness and feasibility of crop profiles should be discussed.

Topics for discussion:

- 12. What is the experience of stakeholders (growers, advisory services) in the implementation of IPM in general?
- 13. How to translate the work from IPM research and CEG projects into practical solutions for growers?
- 14. How can data obtained through CEGs (projects) be used for setting IPM strategies for growers?
- 15. How to disseminate results from IPM research programmes and their progress to relevant stakeholders?
- 16. How to increase the collaboration of stakeholders (research institutes, Ministries, MUCF) with advisory services?
- 17. Are there alternative approaches to 'crop profiles'?
- 18. Are crop profiles or similar approaches useful for finding solutions for minor uses?
- 19. What would be the benefits of preparing 'crop profiles' or similar approaches?

- 20. What would be the drawbacks of preparing 'crop profiles' or similar approaches?
- 21. How can the work on crop profiles or similar approaches be supported and developed?
- 22. Who should be the actors involved in the development of crop profiles or similar approaches?

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Background documents for session 3:

- Sustainable Use Directive 2009/128/EC (background document D)
- Thought starter paper 'How Integrated Pest Management (IPM) tools can help fill in the gaps as regards minor uses', May 2016 (background document A)
- Crop profile for Raspberry in Canada, 2016 (background document G)

Session 4: Future organisation of minor uses work in Europe

Introduction

Firstly, a short description of the current organisation of the minor uses work is provided.

The EU Minor Uses Facility was initially funded by the European Commission (DG SANTE), France, the Netherlands and Germany. In April 2018, after three years, the grant agreement with the EU Commission expired. Since then, the MUCF is financially relying on voluntary contributions from EU Member States, Norway and Switzerland. The MUCF is hosted by the European and Mediterranean Plant Protection Organization (EPPO), in Paris, France.

Governance and operational structure of the MUCF (Figure 2, Annex 1)

Annual General Meeting

All countries that commit to regular funding of the Coordination Facility are 'members' and are entitled to be represented in the Annual General Meeting (AGM). DG SANTE and Director-General EPPO attend the AGM as observers. The Coordination Facility is also present. The role of the Annual General Meeting is to approve the annual report, financial overview, workplan and budget and appoint the Steering Group.

Steering Group

The Minor Uses Steering Group comprises representatives from Germany, Italy, Netherlands, Sweden and Switzerland. DG SANTE and Director-General EPPO attend the meetings as observers. The Coordination Facility is also present. The Steering Group supervises and supports the work of the Coordination Facility.

Commodity Expert Groups

The Commodity Expert Groups work to close minor use gaps at EU level by finding chemical or non-chemical solutions within an Integrated Pest Management (IPM) framework. The Commodity Expert Group consists of national minor use experts and representatives of the respective growers' associations or grower groups.

Horizontal Expert Group

The Horizontal Expert Group discusses general issues related to minor uses, as identified by the Commodity Expert Groups, the Steering Group or its members, aiming for the establishment of harmonised procedures and at creating a level playing field among Member States.

The Horizontal Expert Groups comprises national minor uses contact points (Ministries and competent authorities, CEG Chairs and Co-Chairs).

The main groups and partners involved in minor uses work are displayed in Figures 2 and 3 in Annex 1.

There are eight Commodity Expert Groups operated by the MUCF: Fruits and Vegetables, Herbs, Hops, Mushrooms, Ornamentals, Rice (but dormant), Seeds, Tobacco.

Some CEGs are dealing with just one commodity whereas other CEGs are dealing with a group of commodities.

Many of the projects conducted in the framework of the Commodity Expert Groups (CEGs) are led by Central and Northern zone countries, and France for the Southern zone. Hence, there is a need to increase participation of countries and project leaders, particularly from the Southern zone. Also, participation of more growers' organisations and industry is needed in this framework.

The MUCF minor uses work comprises different steps (see Figure 1 in Annex 1): (i) the identification of minor uses needs, (ii) the search for possible solutions, (iii) the generation of data (residue/efficacy/crop safety) in projects, (iv) the application for authorisation/extension of use of plant protection products, followed by (v) the bringing of integrated solutions (building blocks) under IPM strategies to the grower.

Information related to these different steps (minor uses needs, database searches, CEG projects) is available on the Minor Uses Database EUMUDA: publicly available (minor uses needs) or with restricted access (for database searches and projects). Searches for possible solutions have been performed using Homologa database. Information on PPP authorisations will in the (near) future also be available on the database PPPAMS.

Within Member States the work on minor uses is organised differently.

According to the survey conducted to Member States, Norway and Switzerland (Report March 2018, background document H) overall 34% of Member States have set up a group specific to minor uses. Almost 60% of the Member States do not have a specific group but stakeholders have activities on minor uses and meetings are held. The groups are considered specific to minor uses when the name of the group indicates this, e.g. 'orphan uses committee' in France or 'Minor uses Working group' in Germany, or when it is coordinated by the organisation specific to minor uses, e.g. the Expert Centre for Speciality Crops in the Netherlands (see the box below).

Most of the Member States do not have a specific group but organise cooperation between stakeholders (e.g. authorisation holders, professional organisations and users, research organisations). Often the competent authority organises these meetings, such as in the United Kingdom and Estonia.

An example of how the work is organised in the Netherlands is provided in the OECD thought starter paper (background document A).

Thought starter paper 'How Integrated Pest Management (IPM) tools can help fill in the gaps as regards minor uses'

In the Netherlands an Expert Centre for Speciality Crops (ECSC) was established in 2010 as a knowledge network focussed on speciality crops and minor uses. The main role for ECSC is to facilitate processes that support speciality crops including tools and technologies required to enable their production to be viable not only in the Netherlands but also more widely in Europe (see www.specialitycrops.eu). When seeking to fill minor use gaps, ECSC relies on its multi-disciplinary network to look at a broad range of tools and to focus on addressing minor use gaps in an IPM context.

According to the survey that was conducted in 2017 by the MUCF on how Member States organise minor uses work (background document H), one of the results indicated that a majority of Member States have the capacity to carry out efficacy/crop safety/residue trials, with a variety of experimental facilities among Member States. These facilities are often Good Laboratory Practice/Good Experimental Practice (GLP/GEP) certified or accredited.

Awareness raising on minor uses work and the MUCF to stakeholders is important. In this respect, the EPPO Standard on Raising public awareness of Quarantine and Emerging Pests provides useful information (background document I).

Aim of the session

The aim of the session is to make recommendations on the future organisation of the work. The discussion could take place by considering the partnership and groups and considering the above-mentioned steps on minor uses work. It should also consider the MUCF structure itself.

To facilitate the discussions, it is proposed to consider also by whom and how the work can be performed and with which funding.

A list of concrete actions for the future organisation of minor uses work in Europe should be prepared.

Participants should discuss how awareness can be raised on the importance of speciality crops, minor uses, minor uses work and the MUCF to stakeholders and to disseminate 'success stories'. A list of actions could be prepared.

Topics for discussion:

- 10. How to ensure sustainable functioning of the MUCF? What is the role herein of European bodies, National organisations, and other stakeholders?
- 11. What is the envisaged role and structure of the MUCF?
- 12. How to raise awareness of stakeholders on minor uses?

- 13. Is the current organisation of the minor use work with different Commodity Expert Groups (CEGs) and the HEG working satisfactorily?
- 14. Should needs and priorities be identified per commodity instead of per country? Which are the advantages/disadvantages of the different methods?
- 15. What are the possible obstacles preventing more active participation in (CEG) projects from certain Member States and how can they be overcome?
- 16. How can the participation of growers' organisations and industry in (CEG) projects be increased?
- 17. Is trial capacity sufficient in all Member States and for all stakeholders?
- 18. What would be the benefits of increasing the collaboration with international partners for the minor uses work in Europe (e.g. harmonisation at global level, participating in global projects etc.)?

Background documents for session 4:

- Report on the Questionnaire on Minor Uses work in EU Member States, Norway and Switzerland, MUCF, March 2018 (background document H)
- Thought starter paper 'How Integrated Pest Management (IPM) tools can help fill in the gaps as regards minor uses', May 2016 (background document A)
- EPPO Standard PM 3/86 (1) Raising public awareness of Quarantine and Emerging Pests, September 2019 (background document I)

Annex 1

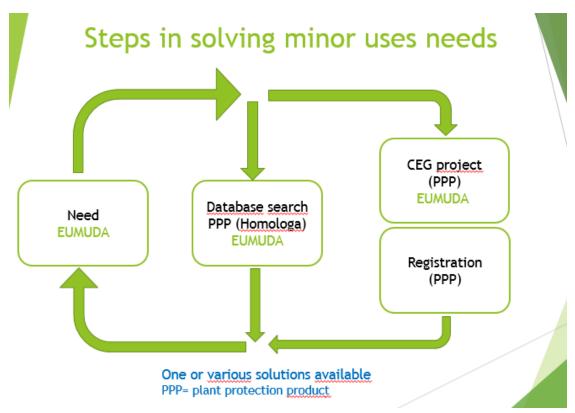


Figure 1: MUCF steps in solving minor uses needs

Diagram of relationship

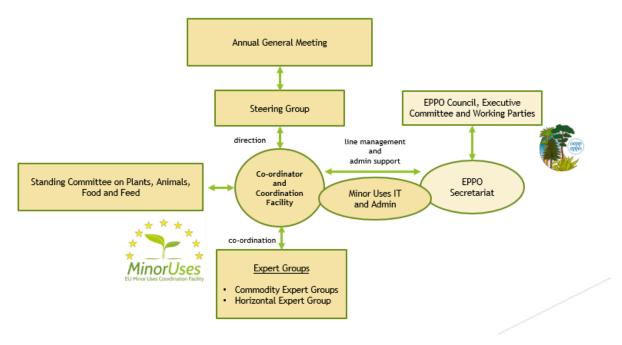


Figure 2: Diagram of relationship of Minor Uses groups and EPPO with the MUCF

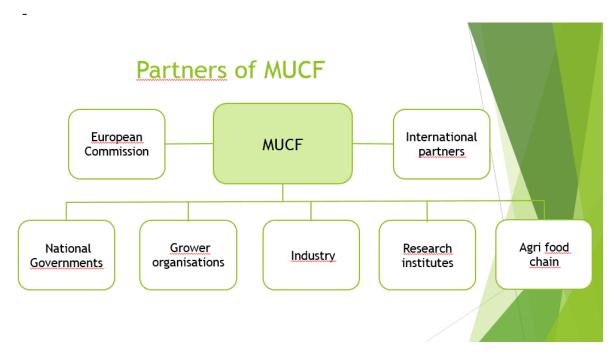


Figure 3: European and international partners of the MUCF

Annex 2

Background documents

A	Thought starter paper 'How Integrated Pest Management (IPM) tools can help fill in the gaps as regards minor uses', May 2016
В	Copa and Cogeca position on sustainable crops protection, November 2019
С	Guidance Document on Regulatory Incentives for the Registration of Pesticide Minor Uses; OECD Series on Pesticides No. 63, 23-Jun-2011
D	Sustainable Use Directive 2009/128/EC
Е	Strategic Research Agenda for IPM in Europe, November 2016
F	Workshop on research in Integrated Pest Management, C-IPM projects funded under calls 1 & 2, 22-23 November 2018
G	Crop profile for Raspberry in Canada, 2016
Н	Report on the Questionnaire on Minor Uses work in EU Member States, Norway and Switzerland, MUCF, March 2018
I	EPPO Standard PM 3/86 (1) Raising public awareness of Quarantine and Emerging Pests, September 2019

Annex 4b: Background document BOG 3 and 4







Workshop on "Minor Uses and Speciality Crops: the way forward in Europe"

Breakout groups 3 and 4

All Breakout groups (BOGs) will consist of a mix of different stakeholders.

The BOGS have common topics on obstacles related to minor uses work and organisational aspects. The BOGs have as well some specific topics for their consideration. The participants of BOGs 3 and 4 will discuss topics focusing on regulatory aspects in the EU.

Each BOG has one Chair and one Rapporteur. The Chair and the Rapporteur are responsible for running the discussion in the BOG, for summarizing the results of the discussion and for presenting the results of their group in the plenary session. Discussion and brainstorming should be done by all participants!

Each BOG participant should bear in mind the objectives of the Workshop, relevant to BOGs 3 and 4:

- Raise awareness of EU institutions and other stakeholders on minor uses work in Europe and on the work of the MUCF.
- Prepare recommendations on the future organisation of the minor uses work in Europe at regulatory and institutional level.
- Identify how to overcome obstacles including regulatory hurdles related to minor uses work, and define the different roles of the MUCF, European Commission and other EU institutions in addressing these issues.
- Discuss benefits and drawbacks, as well as develop a concept, criteria and a way forward to establish an EU-wide (or zonal) uniform status of a crop in relation to the current definition of a minor use.

A list of background documents relevant for sessions 1 to 4 is provided in Annex 2.

Day 1-18 February 2020

Session 1: Obstacles in minor uses work and possible ways forward

Introduction

Different stakeholders are involved in minor uses work: governments (representatives from Ministries and competent authorities), EU policy makers, growers' organisations, national minor uses experts, industry (conventional and biological), research centres, advisory services, and international partners.

Minor uses correspond to plant protection needs on speciality crops (fruits, vegetables, ornamentals, herbs, seeds and mother plants, hops, rice, tobacco) and can also concern some exceptional plant protection needs on major (arable) crops, for example flea beetle on oilseed rape.

Different groups of stakeholders face different obstacles in their day-to-day work on minor uses.

For the MUCF minor uses work comprises different steps (see Figure 1 in Annex 1): i) the identification of minor uses needs, ii) the search for possible solutions, iii) the generation of data (residue/efficacy/crop safety) in projects, iv) the application for authorisation/extension of use of plant protection products, followed by v) the bringing of integrated (building blocks) solutions under IPM strategies to the grower.

The OECD Thought starter paper (background document A) provides insight on general problems faced by growers. Growers play a key role in sustainable crop production as highlighted in Copa and Cogeca's position on sustainable crops protection (see box on the next page, background document B). Insight on regulatory incentives is provided in the OECD Guidance document (background document C).

Thought starter paper 'How Integrated Pest Management (IPM) tools can help fill in the gaps as regards minor uses'.

Understanding the minor use problems growers are trying to address

The minor use problems growers are trying to address are their limited pest management options exacerbated by development of resistance to pesticides, loss of pesticide products as a result of re-evaluation and de-registration processes, residue violations leading to loss in consumer and market confidence and limited options to address emerging pest/disease issues. The key issue for growers is to be able to produce a high yielding, marketable crop.

Copa and Cogeca position on sustainable crops protection, November 2019

As part of their job, farmers may have recourse to Plant Protection Products (PPPs) to grow healthy crops on competitive terms and ensure that consumer demands are met at the same time, irrespective of the production method. Their day-to-day work, from which they earn a living in a very competitive market, involves providing safe food, feed and non-food agricultural products and safeguarding the environment. Also, the proper use of PPPs is an important tool in maximising yields whereby resources are used in the best and most efficient possible way, hence a lower carbon footprint for each produced unit. Besides, these PPPs support high quality agricultural production.

The OECD Guidance Document on Regulatory Incentives for the Registration of Pesticide Minor Uses briefly discusses the different aspects of incentives that are typically utilised including;

Economic incentives (or increased "value") for registrants

- Data protection
- Expedited reviews
- Fee reductions or waivers

Technical arrangements based on sound science

- Extrapolation and mutually accepted data
- Number of trials

Authorisation process arrangements

- Third party registrations
- Temporary approvals (off-label & emergency schemes)

Research

• Data generation assisted schemes (dedicated minor use programmes that are specifically

designed to work with grower groups and registrants in undertaking the necessary data

generation and making of regulatory submissions)

Promotion of safer alternatives

• Reduced risk incentives

Liability

• Liability waivers/disclaimers

Aim of the session

The aim of session 1 is to compile the views of the stakeholders on the obstacles they encounter and identify possible ways forward. This compilation can be done in the format of a table which can be used as a basis to prepare the list of concrete actions at the end of the workshop (roadmap).

In this session individual minor uses needs (combination of crop, pest and country) are out of scope and should as such not be considered. These needs are already available in EUMUDA. The process how to identify minor uses needs will be discussed in session 4.

To prepare session 1, participants are asked to take note of the obstacles (and possible ways forward) that are presented in the plenary session.

To illustrate obstacles and possible ways forward, participants are invited to use concrete examples e.g. from a crop sector.

Topics for discussion:

- 9. What are the obstacles faced by growers in relation to the protection of speciality crops and major (arable) crops?
- 10. What are the obstacles faced by EU and national (both Ministry and competent authorities) policy makers in relation to minor uses? Obstacles faced by regulators and evaluators are out of scope of this session and will be discussed in session 2 of BOG 3 and 4.
- 11. What are the minor uses obstacles faced by the other stakeholders, industry, research, advisory services?
- 12. How could these obstacles be overcome?

Background documents for session 1:

- Thought starter paper 'How Integrated Pest Management (IPM) tools can help fill in the gaps as regards minor uses', May 2016 (background document A)
- Copa and Cogeca position on sustainable crops protection, November 2019 (background document B)
- Guidance Document on Regulatory Incentives for the Registration of Pesticide Minor Uses; OECD Series on Pesticides No. 63,23-Jun-2011 (background document C)

Session 2: Regulatory procedures: how to facilitate authorisations for minor uses

Introduction

In session 2, participants will focus on regulatory procedures for minor uses under the framework of Regulation (EC) No 1107/2009 (background document J).

An applicant can apply for an authorisation for a minor use according to Article 33, Article 40 or Article 51. The general principles of the zonal system, mutual recognition and applications for extension of authorisations for minor uses are described in the 'Draft Guidance Document on Minor Uses according to Regulation (EC) No 1107/2009, rev. 6.3, May 2019' (background document K).

Although in general the application for an extension for minor uses according to Article 51 follows the same (zonal) procedure as other applications, there are currently differences in the situation of implementation of the minor use provisions of Regulation (EC) No 1107/2009 and this creates uncertainty and divergence between Member States. Whilst different approaches may be consistent with the Regulation, greater harmonisation would support the authorisation of minor uses on a national and zonal level.

One of the outcomes of the consultation performed as part of the REFIT process (background document L) is, that the availability of plant protection products for minor uses is negatively affected by a lack of clarity regarding the rules for authorisation and of harmonisation between Member States.

The REFIT programme (Regulatory Fitness and Performance Programme) is organised by the European Commission to see if existing legislation is (still) fit for purpose, and to improve existing EU legislation.

Extract from the REFIT Evaluation (p. 116)

The lack of harmonisation between MSs in the process of minor use authorisation (as well as in the definition) was indicated during the interviews and the focus groups as a factor hindering the effectiveness of the procedure. MS tend to establish their own procedures and do not seek synergies between each other, not even within the same zonal system. Therefore, for instance, an applicant is not incentivised to apply for uses that could be relevant for minor crops in other countries. Lack of clarity and delays in the process lead, instead, in some cases, to the use of emergency authorisations (under Art. 53).

According to Regulation (EC) No. 1107/2009, Article 51, paragraph 1, several categories of applicants may apply for a minor use extension. However, the 'Report on the Questionnaire on Minor Uses Work' (background document H) shows that not all the possible categories of applicants actually ask for an authorisation in all Member States, while in principle all the categories as listed in Article 51 may apply for a minor use extension.

Regulation (EC) No. 1107/2009, Article 51, paragraph 1

The authorisation holder, official or scientific bodies involved in agricultural activities, professional agricultural organisations or professional users may ask for the authorisation of a plant protection product already authorised in the Member State concerned to be extended to minor uses not yet covered by that authorisation.

The Agri-Food Chain Round Table for Plant Protection³ favours an 'EU-wide authorisation' for Speciality Crops and minor uses (as explained in the box on the next page, see background document M). Whilst the current legislation neither requires nor prescribes such an 'EU level authorisation', there is scope for the

³ The 'Agri-Food Chain Round Table for Plant Protection' is a consortium of the following organizations: AAF, AREFLH, CELCAA, Coceral, Copa-Cogeca, ECPA, ELC, ESA, Fediol, FEFAC, FoodDrinkEurope, Freshfel, Frucom, IBMA, Profel and Union Fleurs.

Member States to make better use of the zonal and mutual recognition system to ensure that minor use authorisations are granted throughout the EU.

Agri-Food Chain Round Table for Plant Protection

<u>Proposal for a Pan-European authorisation of Plant Protection Products for Speciality Crops</u>

While major improvements are possible in the national application of the zonal process and mutual recognition, further improvements can also be achieved by making changes in the legislation. The application of a 'one zone concept' – and not just for evaluation but also for authorisation - would be helpful for minor uses. The provision for a one zone evaluation already exists within Regulation 1107/2009 for plant protection products used in greenhouses (protected crops), in storage or as a seed treatment. Through this provision an evaluation by one Member State enables an authorisation throughout the EU, through zonal application or mutual recognition (art. 33.2(b). The application of such provision to Specialty Crops and other minor uses should provide benefits, if accompanied by the political motivation to apply the legislation correctly.

A next step, which would require legislative change, would be a true one zone concept, i.e. including one zone authorisation, where the result of the evaluation of a minor use, would be an European authorization for this use. This would save time and money consuming procedures for zonal application and mutual recognition, and would be justified, as all risks would already be evaluated, and be minor in nature, since it concerns minor uses.

Data access and sharing

When data (studies) are shared, duplication of the work can be avoided, and costs saved. In principle in projects run under Commodity Expert Groups data generated can be used to support authorisations in Member States; other parties should ask permission to use the data.

However, data is not always shared due to data protection rules. When Member States do not own data, support from authorisations' holders and authorities is needed. More information is provided in the report on minor uses work (background document H).

Aim of the session

The discussion will cover zonal evaluation and mutual recognition. The aim is to exchange on the way Member States deal with minor uses applications and find solutions to facilitate authorisations of minor uses in the current regulatory framework. Solutions that require pragmatic legislative changes can also be discussed in the light of a 'vision for the future'. The group will also discuss on ways to improve data access and sharing.

Topics for discussion:

- 6. How do Member States and applicants (industry and third parties) deal with minor uses applications? What are the obstacles they encounter in the zonal procedure?
- 7. What is the view of the other stakeholders on the procedures to get plant protection products registered for minor uses?
- 8. How to improve procedures and practices to authorise minor uses? What options can be identified, within the existing legal framework, by a better implementation of existing rules? As part of a 'vision for the future' explore the benefits/drawbacks of a Pan-European authorisation for minor uses (Article 51) applications.
- 9. Authorisation of plant protection products-how to stimulate applications by industry and by third parties?
- 10. How can data sharing be increased especially for efficacy/crop safety and residue trials?

Background documents for session 2:

- Regulation (EC) No 1107/2009 (background document J)
- Draft Guidance Document on Minor Uses according to Regulation (EC) No 1107/2009, rev. 6.3, May 2019 (background document K)
- Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005), 10 October 2018(background document L)
- Report on the Questionnaire on Minor Uses work in EU Member States, Norway and Switzerland, MUCF, March 2018 (background document H)
- Agri-Food Chain Round Table for Plant Protection Proposal for a Pan-European authorisation of Plant Protection Products for Speciality Crops (background document M)

Day 2-19 February 2020

Session 3: Harmonized status of crops in relation to the definition of minor uses

Introduction

In session 3, participants will focus on the definition of 'minor' and 'major' and what the advantages and disadvantages are of a harmonized status of a crop in the EU.

Different definitions of 'minor/major' are used in different regulatory structures. Sometimes 'minor/major' refers to the use of a plant protection product, but it can also be used to characterize the status of a crop.

The following definition of a 'minor use' is provided in Article 3(26) of Regulation (EC) 1107/2009:

A '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.

However, that leaves it up to individual Member States to define what is considered a 'minor use/crop' in their respective Member State. This is considered a problem for further harmonisation as it hampers the zonal procedure and mutual recognition.

As it is stated in the final report of the REFIT consultant (background document L), the definition of minor uses is not sufficiently clear and procedures are often not clearly established. In addition, the PEST Committee of the European Parliament calls in a resolution for a harmonized definition of 'minor use' and recommends creating a single EU list of major crops.

In this respect, the MUCF report on how Member States organise minor uses work (background document H) contains very useful information.

Extract from Report on the Questionnaire on Minor Uses work in EU Member States, Norway and Switzerland, March 2018

Overall the criteria given by the Member States are very diverse, and of quantitative and/ or qualitative nature. To qualify a use as minor, Member States use primarily criteria linked to the crop: surface, production volume, type of crop (speciality) or dietary intake. Some Member States also consider the pest occurrence. One Member State referred to the type of agriculture (organic/ecological farming).

Different definitions of 'minor/major' are used in different regulatory documents. Regulation (EC) No 1107/2009, EPPO Standards and the 'Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs' are using different criteria to distinguish between 'major' and 'minor'.

Extract from different regulatory documents (regulations and guidance documents)

The definition in Regulation (EC) No 1107/2009 refers clearly to the <u>cultivation area</u> (".... plants or plant products which are not widely grown").

In EPPO standard PP 1/224(2) on the 'Principles of efficacy evaluation for minor use' it is indicated that "Minor uses are those uses of PPPs in which either the crop is considered to be of low economic importance at national level (minor crop), or the pest (minor pest) is not important on a major crop". In this case minor/major refers to economic importance.

In the Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs, SANCO 7525/VI/95, Rev. 10.3, 13 June 2017 the following criteria are used for classifying a crop or a product as 'major' in the European Union:

 Daily intake contribution > 0.125 g/kg bw/day (mean daily consumption over the population) in GEMS Food Cluster Diet applicable to the concerned zone and relevant

cultivation area (> 20 000 ha) and/or production (> 400 000 tonnes per year) in the zone

or

- Cultivation area > 20 000 ha and Production > 400 000 tonnes per year

For residues minor/major refers to <u>daily intake in combination with cultivation</u> <u>area/production</u>.

It must be emphasised that the two zones referred to in the residue guidelines (northern and southern) are not similar to definition of zones for the authorisation of plant protection products (northern, central, southern). EPPO zones deviate from the previous two concepts.

Aim of the session

The aim of this session is to discuss and propose a concept and criteria to establish an EU-wide status of a crop. Firstly, the possible benefits and drawbacks of a harmonized status of a crop should be discussed. It should be kept in mind that a harmonized status of a crop does not preclude the importance and quality of that crop for the producing country. A consequence of a harmonized status of a crop may be that crops that were previously 'minor' in a Member State, are now considered 'major' or *vice versa*.

It should also be recognized that the importance of crop is not only linked to its production in a country but also its processing and/or consumption, which can be different in many European countries, should be considered. Hops can be used as an example. Hop production is restricted to a limited number of Member States, but the consumption of beer is widespread over Europe.

Topics for discussion:

- 4. What are the benefits and drawbacks of a harmonized EU status of a crop?
- 5. How should a concept to establish an EU-wide uniform status of a crop in relation to the current definition of minor uses look like? And under which criteria?
- 6. How should such an EU-wide uniform status of a crop be established?

Background documents for session 3:

- Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005), 10 October 2018 (background document L)
- Report on the Questionnaire on Minor Uses work in EU Member States, Norway and Switzerland, MUCF, March 2018 (background document H)

Session 4: Future organisation of minor uses work in Europe

Introduction

Firstly, a short description of the current organisation of the minor uses work is provided.

The EU Minor Uses Facility was initially funded by the European Commission (DG SANTE), France, the Netherlands and Germany. In April 2018, after three years, the grant agreement with the EU Commission expired. Since then, the MUCF is financially relying on voluntary contributions from EU Member States, Norway and Switzerland. The MUCF is hosted by the European and Mediterranean Plant Protection Organization (EPPO), in Paris, France.

Governance and operational structure of the MUCF (Figure 2, Annex 1)

Annual General Meeting

All countries that commit to regular funding of the Coordination Facility are 'members' and are entitled to be represented in the Annual General Meeting (AGM). DG SANTE and Director-General EPPO attend the AGM as observers. The Coordination Facility is also present. The role of the Annual General Meeting is to approve the annual report, financial overview, workplan and budget and appoint the Steering Group.

Steering Group

The Minor Uses Steering Group comprises representatives from Germany, Italy, Netherlands, Sweden and Switzerland. DG SANTE and Director-General EPPO attend the meetings as observers. The Coordination Facility is also present. The Steering Group supervises and supports the work of the Coordination Facility.

Commodity Expert Groups

The Commodity Expert Groups work to close minor use gaps at EU level by finding chemical or non-chemical solutions within an Integrated Pest Management (IPM) framework. The Commodity Expert Group consists of national minor use experts and representatives of the respective growers' associations or grower groups.

Horizontal Expert Group

The Horizontal Expert Group discusses general issues related to minor uses, as identified by the Commodity Expert Groups, the Steering Group or its members, aiming for the establishment of harmonised procedures and at creating a level playing field among Member States.

The Horizontal Expert Groups comprises national minor uses contact points (Ministries and competent authorities, CEG Chairs and Co-Chairs).

The main groups and partners involved in minor uses work are displayed in Figures 2 and 3 in Annex 1.

There are eight Commodity Expert Groups operated by the MUCF: Fruits and Vegetables, Herbs, Hops, Mushrooms, Ornamentals, Rice (but dormant), Seeds, Tobacco.

Some CEGs are dealing with just one commodity whereas other CEGs are dealing with a group of commodities.

Many of the projects conducted in the framework of the Commodity Expert Groups (CEGs) are led by Central and Northern zone countries, and France for the Southern zone. Hence, there is a need to increase participation of countries and project leaders, particularly from the Southern zone. Also, participation of more growers' organisations and industry is needed in this framework.

The MUCF minor uses work comprises different steps (see Figure 1 in Annex 1): (i) the identification of minor uses needs, (ii) the search for possible solutions, (iii) the generation of data (residue/efficacy/crop safety) in projects, (iv) the application for authorisation/extension of use of plant protection products, followed by (v) the bringing of integrated solutions (building blocks) under IPM strategies to the grower.

Information related to these different steps (minor uses needs, database searches, CEG projects) is available on the Minor Uses Database EUMUDA: publicly available (minor uses needs) or with restricted access (for database searches and projects). Searches for possible solutions have been performed using Homologa database. Information on PPP authorisations will in the (near) future also be available on the database PPPAMS.

Within Member States the work on minor uses is organised differently.

According to the survey conducted to Member States, Norway and Switzerland (Report March 2018, background document H) overall 34% of Member States have set up a group specific to minor uses. Almost 60% of the Member States do not have a specific group but stakeholders have activities on minor uses and meetings are held. The groups are considered specific to minor uses when the name of the group indicates this, e.g. 'orphan uses committee' in France or 'Minor uses Working group' in Germany, or when it is coordinated by the organisation specific to minor uses, e.g. the Expert Centre for Speciality Crops in the Netherlands (see the box below).

Most of the Member States do not have a specific group but organise cooperation between stakeholders (e.g. authorisation holders, professional organisations and users, research organisations). Often the competent authority organises these meetings, such as in the United Kingdom and Estonia.

An example of how the work is organised in the Netherlands is provided in the OECD thought starter paper (background document A).

Thought starter paper 'How Integrated Pest Management (IPM) tools can help fill in the gaps as regards minor uses'

In the Netherlands an Expert Centre for Speciality Crops (ECSC) was established in 2010 as a knowledge network focussed on speciality crops and minor uses. The main role for ECSC is to facilitate processes that support speciality crops including tools and technologies required to enable their production to be viable not only in the Netherlands but also more widely in Europe (see www.specialitycrops.eu). When seeking to fill minor use gaps, ECSC relies on its multi-disciplinary network to look at a broad range of tools and to focus on addressing minor use gaps in an IPM context.

According to the survey that was conducted in 2017 by the MUCF on how Member States organise minor uses work (background document H), one of the results indicated that a majority of Member States have the capacity to carry out efficacy/crop safety/residue trials, with a variety of experimental facilities among Member States. These facilities are often Good Laboratory Practice/Good Experimental Practice (GLP/GEP) certified or accredited.

Awareness raising on minor uses work and the MUCF to stakeholders is important. In this respect, the EPPO Standard on Raising public awareness of Quarantine and Emerging Pests provides useful information (background document I).

Aim of the session

The aim of the session is to make recommendations on the future organisation of the work. The discussion could take place by considering the partnership and groups and considering the above-mentioned steps on minor uses work. It should also consider the MUCF structure itself.

To facilitate the discussions, it is proposed to consider also by whom and how the work can be performed and with which funding.

A list of concrete actions for the future organisation of minor uses work in Europe should be prepared.

Participants should discuss how awareness can be raised on the importance of speciality crops, minor uses, minor uses work and the MUCF to stakeholders and to disseminate 'success stories'. A list of actions could be prepared.

Topics for discussion:

- 19. How to ensure sustainable functioning of the MUCF? What is the role herein of European bodies, National organisations, and other stakeholders?
- 20. What is the envisaged role and structure of the MUCF?
- 21. How to raise awareness of stakeholders on minor uses?

- 22. Is the current organisation of the minor use work with different Commodity Expert Groups (CEGs) and the HEG working satisfactorily?
- 23. Should needs and priorities be identified per commodity instead of per country? Which are the advantages/disadvantages of the different methods?
- 24. What are the possible obstacles preventing more active participation in (CEG) projects from certain Member States and how can they be overcome?
- 25. How can the participation of growers' organisations and industry in (CEG) projects be increased?
- 26. Is trial capacity sufficient in all Member States and for all stakeholders?
- 27. What would be the benefits of increasing the collaboration with international partners for the minor uses work in Europe (e.g. harmonisation at global level, participating in global projects etc.)?

Background documents for session 4:

- Report on the Questionnaire on Minor Uses work in EU Member States, Norway and Switzerland, MUCF, March 2018 (background document H)
- Thought starter paper 'How Integrated Pest Management (IPM) tools can help fill in the gaps as regards minor uses', May 2016 (background document A)
- EPPO Standard PM 3/86 (1) Raising public awareness of Quarantine and Emerging Pests, September 2019 (background document I)

Annex 1

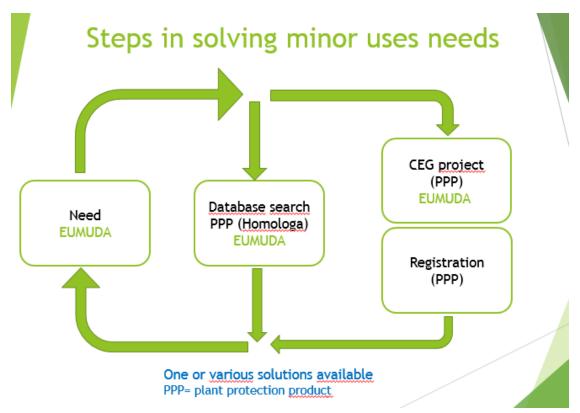


Figure 1: MUCF steps in solving minor uses needs

Diagram of relationship

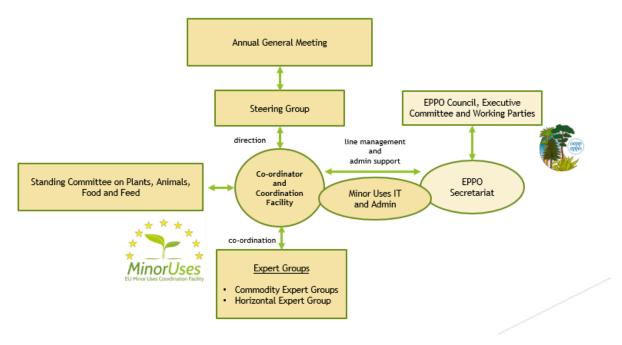


Figure 2: Diagram of relationship of Minor Uses groups and EPPO with the MUCF

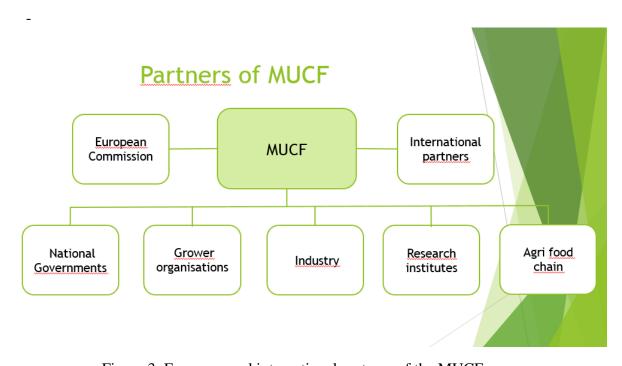


Figure 3: European and international partners of the MUCF

Annex 2

Background documents

A	Thought starter paper 'How Integrated Pest Management (IPM) tools can help fill in the gaps as regards minor uses', May 2016
В	Copa and Cogeca position on sustainable crops protection, November 2019
С	Guidance Document on Regulatory Incentives for the Registration of Pesticide Minor Uses; OECD Series on Pesticides No. 63, 23-Jun-2011
Н	Report on the Questionnaire on Minor Uses work in EU Member States, Norway and Switzerland, MUCF, March 2018
I	EPPO Standard PM 3/86 (1) Raising public awareness of Quarantine and Emerging Pests, September 2019
J	Regulation (EC) No 1107/2009
K	Draft Guidance Document on Minor Uses according to Regulation (EC) No 1107/2009, rev. 6.3, May 2019
L	Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005), 10 October 2018
M	Agri-Food Chain Round Table for Plant Protection - Proposal for a Pan- European authorisation of Plant Protection Products for Speciality Crops