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**NOTE**

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From: Presidency  
To: Delegations

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Subject: Acceleration of Sustainable Plant Production  
- *Outcome of the work carried out by the expert group*

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Delegations will find in Annex a document supplementing the note from the Netherlands Presidency on the above mentioned subject to be dealt with at the meeting of the Council (Agriculture and Fisheries) on 27-28 June 2016.

**Implementation Plan**

**on increasing low-risk plant protection product availability and accelerating integrated pest management implementation in Member States**

**by the**

**Expert Group on Sustainable Plant Protection**

**10<sup>th</sup> of June, 2016**

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## 1. Introduction

According to FAO a 70% increase in global agricultural production is necessary relative to 2005 to feed a global population projected for over 9 billion by the year 2050<sup>1</sup>. Even if taking into account that a third of all food produced globally for human consumption is wasted<sup>2</sup> it remains a challenge to be met in the context of increasing resource scarcities while minimising food safety risks and reducing environmental impact: to develop a sustainable agriculture.

A sustainable agriculture includes a sustainable way of protecting plants and using plant protection products in an approach of integrated pest management (IPM) that favours prevention, non-chemical methods, biological controls and low-risk products where they provide satisfactory pest control and are economically feasible.

Farmers need sufficient plant protection options to ensure a reliable supply of affordable and healthy agricultural products of high quality and to safeguard the competitiveness of European agriculture, allowing farmers to earn an income. Plant protection products constitute a potential risk and are therefore strictly regulated to make sure they have no harmful effect on human and animal health or any unacceptable effects on the environment. Increasing the availability of alternatives, such as low-risk plant protection products, contributes at the same time to a sustainable agriculture and to expanding the farmer's toolbox by increasing plant protection options.

In the AGRIFISH Council of 13 July and 22 October 2015 a large number of Member States agreed that while good progress has been made in the area of sustainability of plant protection by all Member States and the Commission, further steps are needed to accelerate the promotion of IPM and more emphasis should be placed on the promotion of plant protection alternatives, while also considering the competitiveness of European agriculture.

The Member States supported an initiative from the Netherlands, which aims at promoting a broader, greener range of measures and authorised substances, including alternative lower-risk plant protection methods and techniques, as well as basic substances and low-risk products. They agreed to participate in an expert group with interested Member States to explore short-term and long-term actions that could contribute to the "greening" of farmers' plant protection toolbox.

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<sup>1</sup> How to feed the world in 2050 – FAO

<sup>2</sup> Global Food losses and food waste 2011 - FAO

## **Mandate of the Expert Group on Sustainable Plant Protection**

The Expert Group consisting of representatives of 19 Member States, the Commission and EFSA was established in December 2015 for a period of six months. The objective of the group was to identify short and long-term actions to increase the availability of low-risk plant protection products and speed up the application of IPM in Member States. The Expert Group was to deliver an implementation plan that presents an overview of actions, a timeline, actors and the leading organisation for implementation. It was agreed that the Expert Group should look for actions within the scope of the current legislation and make recommendations for the future review of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market.

Non-governmental stakeholders were not part of the Expert Group, but a group of stakeholders representing industry, farmers and NGO's were consulted on their views during the process. Their positions are summarised in Annex II of this document.

### **2. State of play: progress already made**

Following the communication "A Thematic Strategy on the sustainable use of pesticides"<sup>3</sup>, a new legislative framework was adopted in 2009 for plant protection products and their use. Relevant to the Expert Group are:

- Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.<sup>4</sup>
- Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides<sup>5</sup>.

Regulation (EC) No 1107/2009 that became fully applicable in 2011 regulates the placing on the market of plant protection products.

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<sup>3</sup> COM(2006) 372 final

<sup>4</sup> OJ L 309, 24.11.2009, p. 1–50

<sup>5</sup> OJ L 309, 24.11.2009, p. 71–86

Objective of this Regulation is to ensure a high level of protection for both human and animal health and the environment and at the same time safeguard the competitiveness of European agriculture. The Regulation contains harmonised rules to achieve the same level of protection in Member States and to increase the free movement and availability of plant protection products in the EU.

The use of plant protection products is regulated by Directive 2009/128/EC. The main objectives of the Directive are reducing risks and impacts of pesticide use on human and animal health and the environment and promoting the uptake of IPM thus promoting alternative approaches or techniques such as non-chemical alternatives to pesticides.

### **Low-risk plant protection substances and products**

Regulation (EC) No 1107/2009 allows active substances to be approved as low-risk substances when they meet the general approval criteria and the specific low-risk criteria. Subsequently, plant protection products that contain only these low-risk active substances, contain no other substances of concern and require no specific risk mitigation measures can be authorised as low-risk plant protection products.

The Regulation offers several incentives for the development and placing on the market of low-risk substances and products. The period of first approval for low-risk substances is 15 years, instead of 10, and data protection on the studies used for the approval and subsequent authorisation are lengthened from 10 to 13 years. Moreover, the authorisation procedure for low-risk products must be completed within 120 days, instead of one year, provided no additional information is required. The low-risk status can be used for advertising.

In 2015 the first five substances were approved as low-risk products with more in the pipeline for approval in 2016 and beyond. On the basis of a preliminary analysis, the Commission identified several already approved active substances that may potentially be low risk, such as certain micro-organisms, botanicals and semiochemicals (e.g. pheromones), but were approved in the past under the previous legislation (Directive 91/414/EEC<sup>6</sup>) and thus were not legally designated as low-risk.

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<sup>6</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19/08/1991 P. 0001 – 0032)

In December 2015 the Standing Committee on Plant, Animals, Food and Feed agreed to prioritise the renewal of the approval of these potentially low-risk substances, to make sure they are designated officially as low-risk as soon as possible.

After Regulation (EC) No 1107/2009 came into force, it was recognised that the criteria for low-risk substances needed to be elaborated and clarified. The Commission, Member States and stakeholders are working together to deliver a proposal to amend the low-risk criteria.

Some substances that may be low-risk, such as micro-organisms, botanicals and semiochemicals (e.g. pheromones), also proved to have different characteristics than conventional chemical active substances used for plant protection. The working group on Biopesticides, consisting of the Commission and governmental experts, actively delivers guidance documents to ensure a consistent approach between Member States and facilitate and speed up the risk assessment and the approval and authorisation procedures for these types of substances. In 2016 the working group, with the help of experts from the private sector, delivered a guidance document on semiochemicals and took action to ensure efficient cooperation in the upcoming renewal process with regard to micro-organisms.

### **Minor uses**

Minor uses are uses of plant protection products on not widely grown crops with a high economic value for farmers, but often of low economic interest for the agro-pesticide industry resulting in a low number of applications for authorisation of such uses. Regulation (EC) No 1107/2009 contains specific rules for the extension of authorisation to minor uses, including low-risk products.

In September 2015, the EU Minor Uses Coordination Facility (co-funded by the Commission, France, Germany and the Netherlands) started with a mission "to enable farmers in the EU to produce high quality crops by filling minor uses gaps through efficient collaboration to improve availability of chemical and non-chemical tools within an IPM framework".

## **Basic substances**

Regulation (EC) No 1107/2009 also provides for the approval of basic substances. Basic substances are substances that are not of concern and are not predominantly used for plant protection purposes but may be useful in plant protection. Some of these substances are traditionally used by farmers and may include foodstuffs. Examples are vinegar, sucrose or calcium hydroxide. While approval legalises their use in plant protection, basic substances cannot be placed on the market as a plant protection product. Currently, eleven substances have been approved as basic substances and ten others are pending.

To facilitate the application and the assessment of such substances a working group on basic substances met in 2013 to progress with a working document to provide guidance on the application procedure. A few Member States have actively supported the application of basic substances for use in agricultural production. The Commission intends to follow up on basic substances by using the experiences gained with the first set of applications to revise the existing guidance document.

## **Integrated pest management**

Directive 2009/128/EC that came into force in 2009 sets rules for the sustainable use of plant protection products. According to the Directive, Member States shall take all necessary measures to promote low pesticide-input pest management, giving where possible priority to non-chemical methods, so that professional users switch to practices and products with the lowest risk to human health and the environment among those available for the same pest problem. Low pesticide-input pest management includes IPM as well as organic farming. Since the 1<sup>st</sup> of January 2014 professional users of plant protection products have to apply the general principles of IPM as defined in 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. It emphasises the growth of a healthy crop with the least possible disruption to agro-ecosystems and encourages natural pest control mechanisms.



From 2012 onwards Member States delivered and implemented National Action Plans (NAPs) to set up their quantitative objectives, targets, measures and timetables to reduce risks and impacts of pesticide use on human health and the environment, and to encourage the development and introduction of IPM and of alternative approaches or techniques in order to reduce dependency on the use of pesticides. Member States have established the conditions and are progressing in the implementation of IPM ensuring the availability of information and tools for pest monitoring and decision making as well as advisory services on IPM for professional users. NAPs and IPM Reports are all available in the DG SANTE webpage<sup>7</sup>. The Commission has funded two training programs under the Better Training for Safer Food program. One focused on training for the delivery of subsequent training courses to professional users, retailers and distributors, as required by Directive 2009/128/EC. The other focused on the inspection of spraying equipment for plant protection products.

The Commission is currently preparing a report to the European Parliament and the Council on these NAPs, and in parallel will publish an analysis of the Health and Food Audits and Analysis Directorate (formerly Food and Veterinary Office) on the NAPs which identifies good practices and areas of possible improvement.

## **Research and innovation**

Over the years, Member States and the Commission invested in research and innovation in the field of agriculture through the Framework Programs. In Framework Program 7 over € 100M was invested by the European Union in cooperative research projects and coordination support actions in the area of plant protection, plant health, IPM, risk assessment and diagnostics. Several projects were focused on the development and marketing of non-chemical methods or low-risk plant protection options. Of specific interest is the C-IPM Eranet, a coordination support action to coordinate collaborative research on IPM<sup>8</sup>. C-IPM Eranet identified knowledge gaps and needs on IPM research in Member States and delivered a (draft) strategic research agenda in 2015.

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<sup>7</sup> [http://ec.europa.eu/dgs/health\\_food-safety/](http://ec.europa.eu/dgs/health_food-safety/)

<sup>8</sup> <http://c-ipm.org/>

In the Horizon 2020 programme the Commission identified food security and sustainable agriculture and forestry as one of the societal challenges for the future which require solutions based on research and innovation. At the conference “Designing the path: a strategic approach to EU agricultural research and innovation” in January 2016, the Commission presented a draft paper<sup>9</sup> on the strategic approach to agriculture research and innovation. In this paper it was identified that further research is needed to provide farmers with alternative approaches (enabling them to reduce the use of plant protection products) and to support the implementation of Directive 2009/128/EC, including IPM. The strategy described in the draft paper is meant to be an input in programming the remaining three years (2018 to 2020) of Horizon 2020 and in guiding agricultural and forestry research and innovation activities after 2020.

## **Conclusion**

Considering the above, the Expert Group recognises that the Member States and the Commission have to date invested time and resources to move towards a more sustainable use of plant protection products. Good progress has been made both in the legislative framework, the assessment of low-risk products, stimulating IPM practices in Member States and in supporting and conducting research and innovation in these areas.

The Commission and the Member States can build upon the progress already made to further increase the availability of low-risk products and accelerate the implementation of IPM in Member States. The Expert Group has identified several key areas of action to further pursue this aim.

### **3. Key areas of action identified**

The Expert Group identified key areas of action to increase the availability of low-risk products, to accelerate the implementation of IPM, to support the research and development of alternative methods and explored recommendations for the future review of Regulation (EC) No 1107/2009.

#### **3.1 Increasing the availability of low-risk products**

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<sup>9</sup> <https://ec.europa.eu/programmes/horizon2020/en/news/designing-path-strategic-approach-eu-agricultural-research-and-innovation>

## **Accelerating approval and authorisation procedures in general**

Active substances and their products require rigorous risk assessments to ensure they have no adverse effects on human and animal health and pose no unacceptable risk to the environment before they are allowed to be placed on the market. This results in high standards of health and environment protection.

The time it takes to complete the approval process for active substances is a function of the regulatory requirements, the quality of the applicant's dossier, the applicant's responsiveness to requests for further information and the available resources and expertise of the rapporteur Member State, EFSA and the Commission. The time it takes for product authorisation is dependent on the same factors, but also heavily dependent on the functioning of the system of zonal evaluation and mutual recognition and a harmonised and consistent approach by Member States with consideration of their differences in climatic conditions and agricultural practice. The system of zonal evaluation allows for work-sharing between Member States and for a more efficient authorisation process. Since low-risk substances and products undergo the same rigorous assessment, the performance of these systems in general also influences the time-to-market and thus the availability of low-risk plant protection products in the EU.

While great progress has been made and the implementation of Regulation (EC) No 1107/2009 is still to be evaluated, the Expert Group currently recognises that there is a shared view among Member States, the Commission and stakeholders that the current implementation has not yet reached the level of harmonisation, work sharing and reduction of administrative burden that was originally envisaged when Regulation (EC) No 1107/2009 came into force. In their Overview Report published in 2015<sup>10</sup> on "Controls of plant protection products in Member States", the Health and Food Audits and Analysis Directorate (formerly Food and Veterinary Office) of the Commission identified delays and problems with the zonal authorisation system. There were delays for different reasons, including the limited capacity of the competent authorities involved in expert evaluations, organisational problems and the high number of applications.

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<sup>10</sup> Controls of Plant Protection Products in Member States - Overview Report, (former) Food and Veterinary Office, European Commission, 2015.

The former Food and Veterinary Office also identified shortcomings regarding mutual recognition of authorisations related to delays in the evaluation, but also to the non-acceptance or lack of trust in the assessments of reference Member States.

The upcoming expiry of the approval of a large number of active substances in the years 2018-2019 and the subsequent applications for the renewal of their approval will increase the workload of the Member States, EFSA and the Commission, risking a further delay in new products entering the EU market. An increase in timelines will particularly affect the development and availability of low-risk products, because it will erode the incentives provided for those products in the Regulation, such as the longer first approval period and the 120-day authorisation procedure.

The Expert Group therefore recognises that the availability of low risk plant protection products can be increased by tackling the current general issues regarding the implementation of Regulation (EC) No 1107/2009. The Expert Group therefore recommends:

- the Commission to continue their work to evaluate the implementation of Regulation (EC) No 1107/2009 and together with the Member States to stimulate the optimal functioning of the zonal system by identifying good practices in Member States and support their wider implementation;
- the Member States to reflect on how to remove impediments to harmonisation through the zonal system and to ensure sufficient resources are available to comply with the timelines set in Regulation (EC) No 1107/2009.

### **Accelerating procedures for low-risk active substances and products**

#### *- Expediting the approval of new potentially low-risk substances*

Following Regulation (EC) No 1107/2009 active substances are classified as low-risk by Commission and Member States at the end of the approval procedure on the basis of the complete evaluation performed by the rapporteur Member State and EFSA. Only after the approval as low-risk will the regulatory incentives for low-risk substances apply. To accelerate the availability of low-risk products it is necessary to explore how to expedite the approval process for potentially low-risk substances, within legal limits and without lowering the standards of the risk assessment.

The Expert Group proposes that Member States identify potentially low-risk active substances early in the approval process so that Member States, EFSA and the Commission can seek ways to expedite the procedure for their approval. This way of work can already be implemented on a voluntary basis within the scope of the current legislative framework.

- The Expert Group calls upon the Member States, EFSA and the Commission to expedite where possible the approval process of substances identified as potentially low-risk.

*- Expediting the renewal of low-risk substances*

The approval of active substances expires after 5, 7, 10 or 15 years according to the type of substance unless it is renewed after an assessment (renewal procedure). Substances are clustered into different renewal work programmes based on their expiry date. In December 2015 the Standing Committee on Plant, Animals, Food and Feed agreed to prioritise the renewal of the approval of a group of potentially low-risk substances in the upcoming renewal programme consisting of substances whose approval will expire in 2019-2021 (the 4<sup>th</sup> renewal programme). This way these substances can be assessed for low-risk status as soon as possible and, if low-risk, can benefit from the incentives in the Regulation. The Commission has prepared a decision establishing the legal framework for this renewal program.

- The Expert Group calls upon the Member States, EFSA and the Commission to expedite where possible the renewal of potentially low-risk substances in the 4<sup>th</sup> renewal programme.

*- Exploring ways to assign low-risk status to already approved substances*

Several substances that were approved under Directive 91/414/EC could potentially be of low-risk but are not designated as such because they can be assigned a low-risk status only as an outcome of the procedure for the renewal of their approval. The Expert Group explored whether there are other, quicker procedural paths to assess and assign the low-risk status to these substances and consulted internally including the Commission's Legal Service. Main options explored were:

1. The adoption of a specific implementing act containing a list of low-risk substances (based on Article 78(2)).
2. The procedure for the amendment of conditions of approval of an active substance (Article 7),
3. The procedure for the review of conditions of approval of an active substance (Article 21)

It was confirmed that Regulation (EC) No 1107/2009 does not contain any explicit legal basis allowing the Commission to anticipate the attribution of low-risk status to active substances already approved under Directive 91/414/EC. Before a substance can be approved as being of low-risk, it must be established that the safety criteria for approval under Article 4 and the low-risk criteria in Regulation (EC) No 1107/2009 are met. The legislator has not envisaged that this could be performed outside the framework of the procedure of approval or renewal of the approval of active substances. Hence, option 1 could not be pursued. Option 2 is not technically diverging from a renewal assessment, which is upcoming and will be carried out for all substances approved under Directive 91/414/EEC in the near future. For potentially low-risk substances whose renewal assessment is not planned in the current renewal programmes, applicants may consider to apply for the renewal earlier than three years before the expiry of their approval.

With respect to option 3, the Commission's Legal Service indicated that the procedure for the review of an active substance under Article 21 is not apt for low risk criteria as the Article is clearly focused on potential concern. Finally, it was suggested to explore the benefits of preparing a non-binding list of active substances that would qualify as probable low-risk.

The Expert Group considers option 2 to be not of practical benefit to applicants, because the requirements for the amendment procedure would not be less demanding than those of the renewal procedure and it would not bestow the same extension of the approval period as the renewal procedure would.

The Expert Group recognises in conclusion that there is no explicit legal base to grant a low-risk status to already approved substances and although some Member States regard the outcome of the legal consultation on some of the options as unsatisfactory, the Expert Group recognizes that the renewal procedure is the only realistic procedure that can result in a low-risk status of an already approved active substance.

The Expert Group considered the usefulness of a non-binding list of low risk substances to be identified among those already approved under Directive 91/414/EEC. It takes note that such list would not imply any legal obligation for Member States to regard substances on the list as low-risk substances in the sense of Regulation (EC) No 1107/2009 and to apply the incentive provisions.

Moreover, the list would be without prejudice to the outcome of the risk assessment under the renewal procedure for these substances. However, the Expert Group considers that the advantage of such a list is that it may aid users and advisers in selecting products, it may encourage their use in the context of the objectives of Directive 2009/128/EC and IPM and it may be used by Member States on a voluntary basis to expedite where possible the authorisation of products containing such substances.

To strengthen the usefulness of such a list, it is important that Commission and Member States both agree on its definition and that stakeholders are consulted in the process. The Expert Group therefore calls upon the Commission to explore further the legal and practical implications of such a list and to plan the process to produce it.

*- Meeting the 120-day legal time line for authorising a low-risk product*

Regulation (EC) No 1107/2009 sets the period for Member States to decide on low-risk product authorisation to 120 days. The thought behind this is that their low-risk nature allows a quicker evaluation of the product. This fast-track registration for products is an important incentive for industry to commit in the placing on the market of low-risk plant protection products, and must therefore not be compromised. The Expert Group recognises also that authorising a low-risk product in 120 days is not self-evident in the light of the set data requirements that are equal for all plant protection products. In order to ensure that this fast track authorisation procedure can be achieved, procedures must be streamlined and consistency between Member States should be granted, especially with regard to the zonal evaluation of these products. It also requires applicants to submit complete and high quality applications and related legal procedures to be completed in time.

Based on experiences of some Member States that authorised low-risk and potential low-risk products recently, the Expert Group identified several good practices. The Expert Group calls upon the Member States to consider the following recommendations to meet the 120-day legal timeline:

- Anticipate applications for the authorisation of low-risk products (e.g. based on earlier pre-submission meetings) and ensure that resources are available so that legal timelines can be met.

- Explore on a case-by-case basis the possibility to carry out preparatory work for the authorisation, such as the national evaluation and/or the zonal peer review, before the formal decision for the approval of the low-risk active substance is published.
- Advise the applicant to pick whenever possible as zonal rapporteur Member State the same Member State that was involved as rapporteur or (co-)rapporteur Member State for the approval of the active substance, so that the knowledge and experience gained in the approval process is immediately available in the zonal evaluation of the plant protection product.
- Make use of the flexibility in EPPO guidelines on efficacy to take a pragmatic stance to the efficacy requirement of low-risk products, taking into consideration their other benefits (see also below).
- Considering the properties of low-risk substances and products and to prevent duplication of work, Member States are encouraged to explore possibilities to refrain from opening the active substance dossier for re-assessment and from applying additional national requirements in the product authorisation procedure for low-risk products.

The Expert Group also invites all Member States to share knowledge and experiences with the 120-day authorisation process for low-risk products.

The Expert Group encourages the Commission to consider exploring possibilities to optimise the procedures with regard to Regulation (EC) No 396/2005 on maximum residue levels (MRL)<sup>11</sup> for low-risk substances so as to expedite the authorisation of low-risk products.

The Expert Group calls upon applicants to:

- Submit high quality and complete dossiers from the beginning of the process

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<sup>11</sup> Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1–16)



- To consider the use of the so-called "risk-envelope approach"<sup>12</sup> in the dossier for the approval of the active substance. In this approach the worst exposure cases are covered (the envelope), so that the evaluation of different product formulations with lower exposures within this envelope could be accelerated.

## **Measures to support businesses to apply for low-risk approval and authorisation**

### *- Reducing fees for low-risk products*

Regulation (EC) No 1107/2009 provides for fees to be established in a transparent manner and to correspond to the actual cost of the work involved except if it is in public interest to lower them. Several Member States have introduced reduced fees for the approval or authorisation of low-risk substances and products. Experiences vary regarding the effectiveness of this measure. Other cost factors, such as the cost to carry out the required studies, and market demand seem to have a greater effect on a company's decision to apply for approval and authorisation for low-risk products. Nevertheless, the Expert Group invites Member States to consider whether reduced fees have a role to play to increase the number of applications for low-risk substances and products in their country.

### *- Providing guidance to applicants*

Many applicants producing low-risk products are SME's with limited experience with approval and authorisation procedures and "dossier building". Experiences in several Member States show that good communication between registration authorities and applicants before and during the approval and authorisation process greatly helps the submission of good dossiers by the applicant and a rapid assessment by the Member State. Pre-submission meetings between applicant and the registration authority are especially useful to clarify possibilities and difficulties in the assessment procedure and to enhance completeness and quality of the dossiers submitted. In this pre-submission process, the possibilities of taking up minor uses in the application can be addressed as well, in order to contribute to the availability of low-risk options for minor uses. Other options to provide guidance to applicants could be a specialised helpdesk, or general and specialised workshops.

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<sup>12</sup> See Guidance document SANCO/11244/2011 rev. 5, 14 March 2011.

While some Member States already organise pre-submission meetings or other ways to provide guidance to applicants, and may have reduced fees for such meetings, others may have different requirements.

The Expert Group calls upon the Member States to:

- Consider providing pre-submission meetings or other options to inform applicants and consider exploring whether reduced fees for such meetings would have a role to play to increase the use of such meetings by applicants.
- Consider exploring whether appointing (specialised) dedicated experts for the intake and assessment of low risk substances and products would contribute to the acceleration of procedures in their country.

The Expert Group calls upon applicants to:

- Make use of pre-submission meetings provided by Member States.

### **Clarification and guidance on regulatory requirements**

#### *- Amendment of low-risk criteria*

In 2012 it was recognised that the criteria for low-risk substances as defined in Regulation (EC) No 1107/2009 needed further specification and clarification to increase transparency and grant consistency in decision-making. The Commission, Member States and stakeholders are working together to deliver a proposal to amend the low-risk criteria. The Commission expects the proposal to be put forward in the second half of 2016.

- The Expert Group calls upon the Commission to put forward the proposal for the amendment of the low-risk criteria to the Standing Committee for Plants, Animals, Food and Feed, aiming for its adoption as soon as possible.

#### *- Guidance on the zonal evaluation and mutual recognition of low-risk products*

The Commission provides guidance on the zonal evaluation and mutual recognition of plant protection products in a specific guidance document<sup>13</sup>.

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<sup>13</sup> Guidance document on zonal evaluation and mutual recognition (SANCO/13169/2010 rev. 9)

This guidance document can be updated in the future, based on upcoming experience with the 120-day product authorisation procedure for low-risk products in Member States.

- The Expert Group calls upon the Commission to update the guidance document on zonal evaluation of plant protection products as soon as sufficient experience in Member States is available.

*- Guidance on the efficacy assessment of low-risk products*

According to Regulation (EC) No 1107/2009 plant protection products shall be sufficiently effective. To date the efficacy assessment of low-risk products is often conducted in the same manner as for regular products. Low-risk plant protection products however often have lower efficacy or a different mode of action compared to their conventional counterparts, but have other benefits, including their low-risk properties. It is important that these benefits are taken into account. Regulation (EC) No 1107/2009 and the referred to EPPO guidelines on efficacy allow these other benefits to be taken into account when efficacy is assessed. In the Workshop on Efficacy Requirements in the Authorisation of Low-risk Products held on 6-7 April 2016<sup>14</sup>, it was concluded that further harmonisation between Member States is needed and that it is helpful to have further guidance on efficacy evaluation for low-risk products. EPPO will start an ad-hoc Expert Panel to produce a guideline on this topic, planned to be completed after summer 2017. The Expert Group recognises the need for such a guidance and calls upon the Member States to work together with EPPO on this guideline.

### **Recommendations regarding basic substances**

*- Supporting applications for approval of basic substances*

Basic substances are substances that are useful for plant protection purposes, but cannot be marketed as a plant protection product. It is therefore often unattractive for businesses to apply for approval. Moreover, when an application is made the quality of the dossier is often lacking sufficient information to allow a rapid evaluation.

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<sup>14</sup> [http://archives.eppo.int/MEETINGS/2016\\_conferences/low\\_risk\\_substances.htm](http://archives.eppo.int/MEETINGS/2016_conferences/low_risk_substances.htm)

For these reasons, several Member States have submitted applications for basic substances themselves or have supported applications by other parties.

To increase the number of successful approved basic substances available to farmers and other users, the Expert Group calls upon the Commission to:

- Reconvene the experts working group on basic substances which can share experience, keep an overview on pending applications and discuss possibilities for future work sharing;
- Simplify the working document on basic substances with constructive suggestions to improve the quality of applications and submitted dossiers, on the basis of experience gained in these last years with the approval process
- Explore with the Member States how uses of basic substances not initially supported by the applicant, but that are valuable for plant protection purposes, could be taken into account in the approval process.

The Expert Group calls upon the Member States to:

- Reflect on possible measures to assist stakeholders in the applications for approval of basic substances.

### **3.2 Accelerating the implementation of Integrated Pest Management (IPM) in Member States**

The availability of IPM practices, including methods and low-risk plant protection products, are important conditions for the further implementation of IPM. The actual uptake of IPM practices is not a trivial matter, especially because this may entail a change or modification of cropping systems, plant protection methods and practices by farmers and other professional users.

Notions of, and approaches to, IPM are continually evolving. Member States should ensure that professional users and their advisers have access to up-to-date information. They should also ensure that appropriate incentive systems exist, where they are necessary to encourage the uptake of IPM methodologies.

Within the overall context of IPM and especially to enhance its uptake by users, the Expert Group recognizes several specific areas, which should be supported and further developed:

### **On-Farm or experimental station research**

On-Farm-Research is an important instrument for the development and testing of new IPM methodologies in the field. If this kind of research succeeds, new methodologies could be brought to demonstration farms.

The Expert Group recommends Member States to:

- Reflect on the advantages of focussed applied research to reduce the impediments for the on-field use of IPM methodologies, including testing and validating the adaptation of cropping systems and plant protection measures to bring it as close to the end-user's practice as possible;
- Promote cooperation with stakeholders and farmers or other professional end-users, to propose pilot projects to implement IPM methodologies.
- Support Public-Private-Partnerships for research, training and knowledge exchange.

### **Demonstration farms and advice on IPM**

Advisory services and applied research in IPM (including On-Farm-Research) are fundamental to ensure resilience in plant protection and to adapt to changing conditions, including new pests and changes in the authorisation of plant protection products, in a sustainable way. Demonstration farms can play an important role in the divulgation of new IPM methodologies to farmers and advisors. They can facilitate the introduction and adaptation of IPM to local conditions, they help to identify research needs and ensure a timely uptake of research results. Demonstration farms can solicit a peer to peer communication with effective dissemination of best practices. An intensive linkage between research, advisory services and demonstration farms is important. The set-up of demonstration farms and their readiness to test and validate new farming methods is important to facilitate progress, as well as to enable the integration of lower risk plant protection methods and techniques (e.g. biological control), basic substances and low risk products in IPM approaches more widely in Member States.

In the workshop on Demonstration Farms for IPM held in Bonn on 24 and 25 May 2016, the above-mentioned functions of demonstration farms have been discussed and it was concluded that demonstration farms networks can be an effective tool to boost IPM implementation and dissemination while adapting IPM to local conditions. The demonstration farms are and can also become a suitable instrument to increase the visibility of sustainable agriculture practices – in particular IPM- to the general public.

The Expert Group recommends Member States and the European Commission to:

- Reflect on the advantages to support or initiate demonstration farm activities to present the benefits and efficacy of IPM including the use of low risk products on-farm, analyse the necessary modifications and the impacts for broad uptake by end-users.
- Consider appropriate funding schemes for demonstration farms, including public-private partnerships and appropriately co-financed systems.
- Ensure that professionally qualified advisory services are available to provide advice on IPM to end-users and to consider whether to support such services as part of the Farmer Advisory System (as defined in Regulation (EC) No 1305/2013<sup>15</sup>).

### **Facilitating information sharing on IPM between Member States**

A lot of information about the implementation of IPM in different Member States is available on the internet, but it is due to the national languages not always easily accessible. The Expert Group recognises the need to share information and experiences within and between Member States and considers a webportal to be a useful tool to facilitate access to the already available information. Translated national guidances on the implementation of the general principles of IPM could be uploaded to this website as well, to facilitate information sharing between Member States and stakeholders. Also, the Commission's training initiative Better Training for Safer Food (BTFS) can be a useful way for the exchange of knowledge to move forward the implementation of IPM.

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<sup>15</sup> Regulation (EC) No 1305/2013 of the European Parliament and of the Council of 17 December 2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and repealing Council Regulation (EC) No 1698/2005 (OJ L 347, 20.12.2013, p. 487–548)

- The Expert Group calls upon the Commission to evolve the existing website on Directive 2009/128/EC into a webportal linking to the currently available relevant information on IPM on OECD, EU and Member State level.
- The Expert Group calls upon the Member States and the Commission to share information on the implementation of general principles of IPM in Member States.
- The Expert Group calls upon the Commission to develop a course under the BTSF umbrella to give opportunity for officials and advisors to meet and discuss how to implement IPM in Member States. Preferably, these courses could be given on experimental farms within the EU.

### **Further development of indicators to monitor IPM**

To monitor the uptake of IPM by end-users in Member States harmonised indicators would be needed. The Expert Group calls upon the Commission and the Member States to exchange information on the existing national indicators set under Directive 2009/128/EC and move forward in the development of harmonised indicators, taking into account the existing work of the OECD.

### **3.3 Supporting the research and development of alternative methods**

The Horizon 2020 program recognises that Member States and EU policies seek to reduce reliance on pesticides for plant protection through the design and implementation of integrated approaches. The escalation of evolved resistance is putting further strains on the availability and use of plant protection products. Research and innovation is needed to develop alternatives to protect against current and future pests, which reduce reliance on pesticides and/or provide plant protection options with a lower risk profile or new modes of action.

The Expert Group calls upon Member States to:

- Continue cooperating to identify the needs of farmers and translating these needs into proposals for research projects in the area of IPM to be incorporated under research programmes at EU level such as Horizon 2020.

- Actively promote applications to Horizon 2020 calls in the area of sustainable food security, particularly the call for projects under "Innovation in Plant Protection" and those boosting cooperation and networking between IPM demonstration farms, and support the C-IPM Eragnet future initiatives related to IPM.

The Expert Group calls upon the Commission to:

- Continue considering the development and implementation of IPM techniques and low-risk substances and products to be important areas of research for the transition to sustainable agriculture and to continue prioritising these areas in current and future research programs at EU level.

### **3.4 Recommendations for the future review of Reg. (EC) No 1107/2009**

The Commission plans to launch the review of the implementation of Regulation (EC) No 1107/2009 under the REFIT program in 2016. The Expert Group calls upon the Commission to consider the following recommendations with regard to low-risk substances and products and basic substances in the review process.

#### **Increasing regulatory incentives for low-risk substances and products**

Regulation (EC) No 1107/2009 specifically states that incentives should be given for the placing on the market of low-risk plant protection products. The Expert Group recognises that expanding existing regulatory incentives and introducing new ones would encourage businesses, especially SME's, to develop low-risk substances and products and get them to the market more quickly.

One of the incentives already in place is a five-year longer approval period for low-risk active substances (15 years instead of 10 years). After that period, the approval can be renewed, but the renewed approval period for low-risk active substances is the same as that of other active substances. The Expert Group recognises that incentives for low-risk active substances should not be limited to the first approval period only, but should also extend to renewed approval periods. Such a regulatory change will reduce the regulatory cost for producers and the authorities.



This allows businesses to invest the saved resources in the development of new low-risk products instead and the authorities to focus their resources on the risk assessment of substances that have higher risk profiles.

The Expert Group recommends that in the future review of Regulation (EC) No 1107/2009 options are explored to extend the current incentive. One possible option would be to have a five-year longer renewed approval period for low-risk active substances (20 years instead of 15 years).

Considering their low-risk properties another option would be to remove the periodic renewal requirement for low-risk substances, provided there is a mechanism in place to allow their review when new information or scientific insights on risks become available.

### **Fast track provisional authorisation procedure for low-risk products**

The Expert Group explored possible alternative procedures under a revised Regulation (EC) No 1107/2009 that would reduce the time-to-market for low-risk products while keeping the authorisation subject to a full risk assessment and a peer review under the zonal arrangements. The Expert Group considers the following procedure suitable for further exploration and calls upon the Commission to take it into account in the future review of Regulation (EC) No 1107/2009:

- A revised procedure where potential low-risk substances (submitted with a full dossier according to the data requirements) will be subject to a complete risk assessment including an assessment of low-risk status. This will be followed by the publication of the Draft Assessment Report (DAR) of the proposed low-risk substance by the rapporteur Member State (RMS) with a recommendation for low-risk status;
- Applicants in favour of a provisional authorisation may decide to submit the request for authorisation of the plant protection product (based on the proposed low-risk substance) to the zonal RMS as soon as the DAR has been published;
- While EFSA starts the peer review of the substance, the zonal RMS simultaneously carries out the assessment of the application for product authorisation including the zonal commenting round on the product evaluation;
- The RMS may also evaluate provisional authorisations simultaneously with the substance, and issue their assessment for zonal commenting when the DAR is published;

- Member States may decide, in light of the RMS's assessment, to grant a provisional authorisation of the product containing the proposed low-risk substance before the final approval of the substance. Provisional authorisation of following zonal and mutual recognition applications may be on a voluntary basis.
- The EFSA peer review may lead to possibly additional dossier/information requirements, and possibly a withdrawal of low-risk classification to a normal substance classification, should the substance be re-classified during the approval process. The provisional authorisation should then be amended accordingly.

A provisional authorization for low-risk products containing new active substances by Member States can only be based on a solid assessment of the low-risk status of the substances in question. This fast track therefore would give Member States greater responsibility in the evaluation of new active substances as low-risk.

Maximum residue levels need to be established before the provisional authorisation of a low risk PP would be granted. For this fast-track procedure to work in an optimal way, it needs to be explored in the upcoming review process of Regulation (EC) No 396/2005 concerning the maximum residue levels (MRLs) whether there is a possibility to revise the procedure for MRL setting for low-risk substances in the future to better match the timelines of both procedures.

### **Other recommendations for the review process**

The Expert Group also identified several other ideas to be examined in the future review process, which would facilitate sustainable plant protection. The Expert Group calls upon the Commission to consider the following ideas and explore their advantages and disadvantages in the review process of Regulation (EC) No 1107/2009:

- Explore advantages and disadvantages of a renewed zonal or Union authorisation procedure for low-risk products, which provides simultaneous single application for the same zone (directly applicable with no mutual recognition needed) or even for all EU countries in the same time (similar to the EU authorisation procedure for biocides), taking into account the different agricultural practices and environmental conditions in Member States. This would reduce the regulatory cost for producers and reduce administrative burden for Member States. It would help getting low-risk products to the market quicker.

- Explore possibilities to allow the marketing of basic substances for plant protection in ways practical to farmers, including information on the use described in the review report. Currently approved basic substances can be used for plant protection purposes, but cannot be marketed as a plant protection product. Allowing the marketing of such products would be an incentive for companies to apply for basic substance approval, increasing the number of basic substances in the farmer's toolbox.
- Explore possibilities to promote the availability and use of substances with no direct biocidal or toxic mode of action acting solely on their repelling, attracting or confusing properties (e.g. pheromones and kairomones) by excluding them from the scope of the Regulation or the requirement of approval, provided the level of protection for human health and the environment will not be lowered.
- Explore ways to clarify the definition of active substance for plant protection to clearly exclude substances acting solely by physical means (physical barriers), provided the level of protection for human health and the environment will not be lowered.
- Explore the possibility of allowing the designation of a product as low-risk to be indicated on the label, so that it is clear to users when selecting a product.

#### **4. Coordination of future work to implement the plan**

The Expert Group has identified key areas of action on different levels for the Member States, the Commission and other players. These actions and their timelines are summarised in the overview table in Annex I.

To ensure the actions in this implementation plan are followed-up on, the Expert Group recommends the Member States and the Commission to monitor the implementation and progress on EU level until the end of 2017 and to report on its progress to the Standing Committee on Plants, Animals, Feed and Food and to the Council. For this purpose, the Expert Group –facilitated by the Commission– can play a role in supporting and monitoring the progress and prepare reports to the Standing Committee and to the Council.

## Annex I: Overview of actions, actors, timelines

Key areas and actions identified		Main actor	Others involved	Timeline
<b>Increasing availability of low-risk products</b>				
1.	Reflect on how to remove impediments to harmonisation through the zonal system and to ensure sufficient resources are available to comply with the timelines set in Regulation (EC) No 1107/2009	MS		Continuous
2.	Expedite where possible the approval process of substances identified as potentially low-risk	(R)MS, EFSA, COM	Applicants	Continuous
3.	Expedite where possible the renewal of potentially low-risk substances in the 4 <sup>th</sup> renewal programme	(R)MS, EFSA, COM	Applicants	Continuous
4.	Anticipate applications for the authorisation of low-risk products (e.g. based on earlier pre-submission meeting) and ensure that resources are available so that legal timelines can be met.	MS	Applicants	Continuous
5.	Explore on a case-by-case basis the possibility to carry out preparatory work for the authorisation, such as the national evaluation and/or the zonal peer review, before the formal decision for the approval of the low-risk active substance is published.	MS		Continuous
6.	Advise the applicant to pick whenever possible as zonal rapporteur Member State the same Member State that was involved as rapporteur or (co-)rapporteur Member State for the approval of the active substance, so that the knowledge and experience gained in the approval process is immediately available in the zonal evaluation of the plant protection product.	MS	Applicants	Continuous
7.	Make use of the flexibility in EPPO guidelines on efficacy to take a pragmatic stance to the efficacy requirement of low-risk products, taking into consideration their other benefits.	MS	Applicants	Continuous

8.	Explore possibilities to refrain from opening the active substance dossier for re-assessment and from applying additional national requirements in the product authorisation procedure for low-risk products.	MS		2016-2017
9.	Share knowledge and experiences with the 120-day authorisation process for low-risk products	MS		Continuous
10.	Consider whether reduced fees have a role to play to increase the number of applications for low-risk substances and products in their country	MS	Applicants	2016-2017
11.	Consider providing pre-submission meetings or other options to inform applicants and consider exploring whether reduced fees for such meetings would have a role to play to increase the use of such meetings by applicants.	MS	Applicants	2016-2017
12.	Consider exploring whether appointing (specialised) dedicated experts for the intake and assessment of low risk substances and products would contribute to the acceleration of procedures in their country.	MS	Applicants	2016-2017
13.	Reflect on possible measures to assist stakeholders in the applications for approval of basic substances.	MS		2016-2017
14.	Explore further the legal and practical implications of a non-binding list of low-risk substances and to plan the process to produce it.	COM	MS, stakeholders	2016-2017
15.	Continue their work to evaluate the implementation of Regulation (EC) No 1107/2009 and together with the Member States to stimulate the optimal functioning of the zonal system by identifying good practices in Member States and support their wider implementation	COM	MS, stakeholders	Continuous
16.	Consider exploring possibilities to optimise the procedures with regard to Regulation (EC) No 396/2005 on maximum residue levels (MRL) for low-risk substances so as to expedite the authorisation of low-risk products.	COM		2016-2017

17.	Put forward the proposal for the amendment of the low-risk criteria to the Standing Committee for Plants, Animals, Food and Feed, aiming for its adoption as soon as possible.	COM		Ongoing, 2 <sup>nd</sup> half of 2016
18.	Update the guidance document on zonal evaluation of plant protection products as soon as sufficient experience in Member States is available.	COM	MS	2017
19.	Reconvene the experts working group on basic substances which can share experience, keep an overview on pending applications and discuss possibilities for future work sharing;	COM	MS	2 <sup>nd</sup> half of 2016
20.	Simplify the working document on basic substances with constructive suggestions to improve the quality of applications and submitted dossiers, on the basis of experience gained in these last years with the approval process	COM	MS	2 <sup>nd</sup> half of 2016
21.	Explore with the Member States how uses of basic substances not initially supported by the applicant, but that are valuable for plant protection purposes, could be taken into account in the approval process.	COM	MS	2 <sup>nd</sup> half of 2016
22.	Submit high quality and complete dossiers from the beginning of the process	Applicants	MS	Continuous
23.	To consider the use of the so-called "risk-envelope approach" in the dossier for the approval of the active substance. In this approach the worst exposure cases are covered (the envelope), so that the evaluation of different product formulations with lower exposures within this envelope could be accelerated.	Applicants	MS	Continuous
24.	Make use of pre-submission meetings provided by Member States.	Applicants	MS	Continuous
25.	Deliver an EPPO Guideline on efficacy evaluation of low-risk products	EPPO	MS, COM	2017

<b>Accelerating the implementation of Integrated Pest Management (IPM) in Member States</b>				
26.	Reflect on the advantages of focussed applied research to reduce the impediments for the on-field use of IPM methodologies, including testing and validating the adaptation of cropping systems and plant protection measures to bring it as close to the end-user's practice as possible.	MS	Stakeholders	Continuous
27.	Promote cooperation with stakeholders and farmers or other professional end-users, to propose pilot projects to implement IPM methodologies.	MS	Stakeholders	Continuous
28.	Support Public-Private-Partnerships for research, training and knowledge exchange.	MS	Stakeholders	Continuous
29.	Reflect on the advantages to support or initiate demonstration farm activities to present the benefits and efficacy of IPM including the use of low risk products on-farm, analyse the necessary modifications and the impacts for broad uptake by end-users.	MS	Stakeholders	Continuous
30.	Consider appropriate funding schemes for demonstration farms, including public-private partnerships and appropriately co-financed systems.	MS, COM	Stakeholders	Continuous
31.	Share information on the implementation of general principles of IPM in Member States	MS, COM		2016-2017
32.	Ensure that professionally qualified advisory services are available to provide advice on IPM to end-users and to consider whether to support such services as part of the Farmer Advisory System (as defined in Regulation (EC) No 1305/2013).	MS	Stakeholders	Continuous
33.	Evolve the existing website on Directive 2009/128/EC into a webportal linking to the currently available relevant information on IPM on EU and Member State level.	COM	MS	2016-2017
34.	Develop a course under the BTSF umbrella to give opportunity for officials and advisors to meet and discuss how to implement IPM in Member States. Preferably, these courses could be given on experimental farms within the EU.	COM	MS	2017

35.	Exchange information on the existing national indicators set under Directive 2009/128/EC and move forward in the development of harmonised indicators, taking into account the existing work of the OECD.	COM	MS	2016-2017
<b>Supporting the research and development of alternative methods</b>				
36.	Continue cooperating to identify the needs of farmers and translating these needs into proposals for research projects in the area of IPM to be incorporated under research programmes at EU level such as Horizon 2020.	MS	Stakeholders	Continuous
37.	Actively promote applications to Horizon 2020 calls in the area of sustainable food security, particularly the call for projects under "Innovation in Plant Protection" and those boosting cooperation and networking between IPM demonstration farms, and support the C-IPM Eranet future initiatives related to IPM.	MS	Stakeholders	Continuous
38.	Continue considering the development and implementation of IPM techniques and low-risk substances and products to be important areas of research for the transition to sustainable agriculture and to continue prioritising these areas in current and future research programs at EU level.	COM		Continuous
<b>Recommendations for the future review of Reg. (EC) No 1107/2009</b>				
39.	Take into account the proposals and ideas of the Expert Group with regard to low-risk substances and products and basic substances in the review process of Regulation (EC) No 1107/2009	COM	MS, stakeholders	In review process of Regulation (EC) No 1107/2009
<b>Coordination of future work to implement the plan</b>				
40.	Monitor the implementation and progress on EU level	MS, COM		2016-2017



## **Annex II. Stakeholder's views**

In a special session the main concerned stakeholders were asked to give their views on the actions needed to increase the availability of low-risk products and accelerate the implementation of integrated pest management (IPM) in Member States. Where possible and relevant these views were taken into account in the plan. The stakeholder's views are summarised below.

### **4.1 IBMA**

IBMA maintain the position that the current incentives for low-risk active substances and plant protection products are inadequate. There is a need for a fast-track provisional approval system for active substances. This procedure can be introduced at the completeness check stage or at an existing timeline, the publication of the Draft Assessment Report (DAR). Data requirements would be unchanged with the exception of a lighter efficacy package. IBMA propose retaining the 120-day authorisation timeline for low-risk plant protection products containing only low-risk active substances and fitting representative use and product envelopes established during the approval process of the low-risk active substance. Approvals and authorisations for low-risk active substances and products should be time unlimited. Mechanisms and obligations for data call-in in the event of new or further scientific knowledge exist and provide a suitable safety net for circumstances unforeseen at the time of evaluation of low-risk active substances and plant protection products. IBMA call for consideration by Member State competent authorities when setting fees to fully utilise the provisions available in Regulation (EC) No 1107/2009 Art. 74 2(b) to charge lower fees when in the public interest. IBMA support activities to encourage and facilitate the full and true use of IPM. More IPM tools should be made available. Farmers and advisors should have access, training and be encouraged and facilitated to integrate them. Systems sharing risk of crop damage or failure should be investigated and evaluated. Access enhancing uptake of IPM, including advice, equipment and expertise should be facilitated. Non-use of IPM systems is counter to Directive 2009/128/EC and should not be possible.

## 4.2 ECPA

ECPA welcomes the Dutch initiative, which can help to further promote sustainable plant protection practices and support the work of the Expert Group on low-risk products and IPM. ECPA supports innovation and extension of the plant protection toolbox with new low risk products which can be biocontrols or chemicals. ECPA supports the efforts to reduce the burden in the registration process for low risk products and the development of proper incentives to foster innovation in this area. Reducing the burden in the regulatory process would help free-up scarce resources. We believe that such a review should consider the wider context and not only look to exempt some products from an unnecessarily burdensome regulatory process. There is therefore an opportunity to streamline the current regulatory framework to support the placing on the market of solutions. As an example, an evaluation of the efficacy criterion to ensure a better functioning of the zonal system would benefit all types of products while guaranteeing a sufficient level of efficacy for every component of any IPM strategy. We strongly believe that knowledge-sharing on IPM is the key step to make further progress – ensuring that farmers have the most up-to-date information to support efficient decision-making. IPM research has been ongoing for decades and results are available but often are not properly transferred to the end users, or may not even be practically applicable. Further development and uptake of IPM measures requires education, acceptance and implementation by farmers. Their involvement right from the start is a must! Our Industry is committed to progress and implement realistic and practical measures for sustainable agriculture, and we will continue to support the process of making plant protection more sustainable.

## 4.3 Pan Europe

PAN Europe is happy to hear that demonstration farms are one of the areas the Expert Group looks into. Demonstration farms can help develop and disseminate agronomic practices and have a wider scope than only the use of products to protect plants. According to PAN Europe low-risk products should not be used for preventative measures or as a broad-spectrum measure, since this does not fit IPM. Also low-risk products should be subject to the full risk assessment and not approved while awaiting confirmatory data.

PAN Europe would not be in favour of an open-ended approval concerning all low-risk substances. Nevertheless, would it be possible, PAN Europe would strongly support a proposal providing biocontrol products such open-ended approval, having thus a different regime, compared to synthetic low-risk substances.

#### **4.4. Copa Cogeca**

Copa Cogeca supports the view that procedures for low-risk substances and products should be accelerated. There are now only 5 low-risk actives and the approval process take up more than 2,5 years. Copa Cogeca supports the IPM concept and states that this is an integration of all means available to the farmer to protect his crops. According to Copa Cogeca the demonstration farms are an important way to transfer knowledge on IPM to farmers: showing how things work in the field is a very effective way to transfer knowledge and have others adopt new methods. Regarding research Copa Cogeca is of the opinion that available funds should be used for real research instead of “inventories of inventories” and that research projects should be brought to the farm level to identify the needs of farmers. Copa Cogeca supports the view that proper implementation of the current Regulation is required, especially the provisions on mutual recognition. Copa Cogeca also stresses that many farmers already use IPM methods in practice and that it is not needed to reinvent the wheel. Involve the end users when identifying next steps. When farmers have to decide how to protect their crops they look at the effect on their cost and production. They will resist changes that raise their cost and/or lower their production when they do not gain something in return. Farming is a commercial practice after all.

#### **4.5 IFOAM EU**

Organic farmers can use only substances that are naturally present for plant protection purposes. A lot of pioneering work has been done by organic farmers for the development of strategies for low-risk plant protection products based on naturally occurring substances and of “indirect methods” for plant health care to really practicable solutions. Spraying in the organic community is often limited to specialty crops. According to IFOAM organic farmers in these crops also need new solutions. This is important for the still existing gaps in strategies for more resilient systems (e.g. selective products for a specific pest or disease) and for upcoming problems, like new pests that spread because of climate change.

In IFOAM's view, products based on naturally occurring substances where the effect often depends on many factors should be developed in a participatory process in collaboration with farmers and especially tested in a strategy where agronomic practices, measures and biocontrol agents are combined. The organic farming sector has been pioneer and frontrunner in this area and could be in the future. IFOAM states that for substances that have an existing natural background where risks can be considered rather low after the first evaluation of a dossier the permission of the test use of the substance on a large number of farms should be possible. The availability of basic substances and traditional uses should be improved. More governments should support the application for the approval of a basic substance. IFOAM supports the concept of participatory research in close collaboration with farmers where research and farming is brought together. These concepts are particularly important for organic farming concepts. Since gaps of availability in organic farming are different from those in IPM, IFOAM wants a special compartment in the minor use concept for organic farming. Furthermore, it wants organic farming to be assigned the “minor use” status in general.

### **Annex III. Composition of the Expert Group**

The Expert Group on Sustainable Plant Protection consisted of representatives from:

- Austria
  - Belgium
  - Croatia
  - Denmark
  - Estonia
  - France
  - Germany
  - Greece
  - Ireland
  - Italy
  - Latvia
  - Lithuania
  - Malta
  - The Netherlands
  - Poland
  - Slovakia
  - Spain
  - Sweden
  - United Kingdom
  - Norway
  - European Commission
  - EFSA
-