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From: General Secretariat of the Council

To: Delegations

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Subject: Progress report on the implementation plan to increase the availability of low-risk plant protection products and accelerate implementation of integrated pest management in Member States
- Note from the Commission

Delegations will find in Annex a note from the Commission in relation to the subject mentioned above to be discussed at the Council (Agriculture and Fisheries) on 15-16 July 2019.

Progress report on the implementation plan to increase the availability of low-risk plant protection products and accelerate implementation of integrated pest management in Member States

The Agriculture and Fisheries Council took note in June 2016 of an implementation plan aiming at speeding-up the uptake of more sustainable plant protection products and practices across the EU. The plan comprised 40 actions concerning placing of low-risk plant protection substances and products on the market, as well as the implementation of integrated pest management (IPM) schemes which are compulsory since 2014 as provided by Directive 2009/128/EC on the sustainable use of pesticides.

The Expert Group on Sustainable Plant Protection and the Standing Committee on Plants, Animals, Food and Feed have monitored the progress achieved by the Member States, the Commission and external stakeholders, each of them sharing the responsibility for the specific actions.

The progress report presented to the Agriculture and Fisheries Council provides an overview of the status of the various actions.

As regards the **availability of low-risk substances and products**, the progress report notes that:

- The actions of the implementation plan which were addressed to the Commission by the Expert Group in 2016 have been achieved or are well on track.
- Revised low-risk criteria entered into force in August 2017 and guidance has been elaborated to facilitate their interpretation for the manufacturers of low-risk substances and products.
- A list of potentially low-risk active substances was published in July 2018 via a Commission Notice in order to support the Member States in their efforts to accelerate their assessments under the renewal programme of active substances and give priority to the authorisation of products containing such substances to stimulate the sector to use these low-risk products in line with the objectives of Directive 2009/128/EC.
- A fast-track procedure has been developed through an optimised internal work practice to facilitate the assessment of the need to set maximum residue limits for low-risk and basic substances. By exempting the low-risk substances from these obligations related to residues, the authorisation of low-risk products is very much expedited.

- An expert group on biopesticides (e.g. microorganisms and semiochemicals) and another one on basic substances have been discussing several guidance documents to develop common understanding of risk assessment approaches amongst applicants, competent authorities and the European Food Safety Authority (EFSA).
- Work has been initiated with Member States, EFSA and experts from the industry to update the data requirements and assessment methodologies for micro-organisms within the current regulatory framework.

All of these actions will probably take time to deliver results, but a positive trend towards more sustainable plant protection products is since a couple of years evidenced by the fact that a majority of applications for approval of new active substances concern substances or microorganisms that are potentially low-risk substances. However, it will take time before this translates into a significantly increasing number of authorisations of low-risk plant protection products in Member States.

Furthermore, all competent authorities in the Member States still have to gain experience and some of them need to step up their actions to reach the objectives of the implementation plan.

As regards the **support to further implementation of IPM and research and development for alternative methods**, the progress report notes that:

- All actions of the implementation plan to be initiated by the Commission were achieved.
- The awareness about IPM has increased through the compilation of all available guidelines, recommendations and advice through the web-portal of the Commission.
- Several training courses were set up by the Commission and eventually reached hundreds of professionals in all 28 Member States by ‘training the trainers’ of professional users, by training the controllers of the pesticides application equipment and by harmonising in a consistent way the implementation in each Member State of the IPM principles and farming schemes.
- On 15 May 2019 a first set of harmonised risk indicators was adopted under Directive 2009/128/EC. This will allow to measure progress towards more sustainable plant protection practices in the EU.

- Concerning the research and development of alternative techniques, the EU Framework Research Programme Horizon 2020 has funded more than 40 projects (i.e. more than EUR 200 million) and will continue to focus on non-chemical substitutes to plant protection products or less risky practices.

However, the progress report is also underlining that more action is still needed to fully develop the potential of IPM e.g. by disseminating the increasing knowledge obtained from research activities towards the farmers, among others via demonstration activities.

In conclusion:

Progress has been achieved since 2016 in transformation towards more sustainable plant protection practices by EU farmers.

However, there are significant divergences and some Member States need to do much more as regards prioritisation and promotion of low-risk active substances and products. All Member States should make serious efforts to meet the shorter deadlines for product authorisations foreseen in Regulation (EC) No 1107/2009.

Member States must deploy additional efforts to implement the principles of integrated pest management into concrete farming practices for many more crops than today. This is one of the key obligations of Directive 2009/128/EC on the sustainable use of pesticides.

Ministers can find the progress report in the annex to this note.

**Progress report on the implementation plan to increase the availability
of low-risk products and accelerate implementation of
integrated pest management in Member States**

March 2019

Executive summary

An implementation plan for low-risk plant protection products and integrated pest management aiming at accelerating the uptake of more sustainable plant protection products and practices across the EU was noted by the AGRIFISH Council in June 2016.

A set of forty actions were addressed to the Member States, the Commission and external stakeholders, each of them bearing a share of the responsibility for the success of this implementation plan.

The Standing Committee on Plants, Animals, Food and Feed via its Expert Group on Sustainable Plant Protection of the Section Phytopharmaceuticals - Plant Protection Products – Legislation monitored the planned actions and achievements over the last 3 years. Almost three years after the adoption of the implementation plan, this progress report gives an overview of the status of the realisation of the actions and contains recommendations for the future.

A trend towards more sustainable plant protection products is evidenced by the fact that a majority of applications for approval of new active substances nowadays concern substances or microorganisms that are potentially low-risk substances. Likewise, applications for the approval of basic substances are increasing. The recently published list of 58 candidate low-risk substances aims at stimulating Member States in prioritising the authorisation of products containing them. However, the positive trend observed for low-risk active substances does not yet fully translate into a significantly increasing number of authorisations of low-risk plant protection products in Member States. Several guidelines, which were recently adopted or are soon to be finalised, and the facilitation and incentivising efforts engaged by several Member States are expected to bear fruit in the mid-term. Nevertheless, all competent authorities in the Member States still have to gain experience and some of them need to engage more to reach the objectives of the implementation plan.

Similarly, the implementation plan has fostered many actions regarding integrated pest management (IPM) farming schemes, which are a requirement for all EU farmers according to the plant protection products legal framework adopted in 2009. More action to foster IPM practices, e.g. by disseminating the ever-rising set of knowledge obtained from research activities towards the farmers, among others via demonstration activities, are still needed to fully develop the potential of IPM.

1. Introduction

In June 2016 the AGRIFISH Council noted the Implementation Plan on increasing low-risk plant protection product availability and accelerating integrated pest management implementation in Member States. The plan was prepared by the Expert Group on Sustainable Plant Protection, a group proposed by the Netherlands and facilitated by the Commission after the AGRIFISH Council meeting on 22 October 2015. The Plan identified key areas of action to increase the availability of low-risk products, to accelerate the implementation of integrated pest management (IPM), to support the research and development of alternative methods.

The Expert Group was tasked to monitor and report on the progress of the implementation of the actions to the Council and the Standing Committee on Plants, Animals, Food and Feed. For this purpose, the Expert Group reconvened four times between October 2016 and November 2017. This report of the Expert Group presents the state of play of the implementation of the actions in the Plan and gives an outlook on the way forward. It is based on the input of Member States, the Commission and stakeholders, collected through a questionnaire, a stakeholder session and a final consultation of the Standing Committee (February 2019). In total 22 Member States and Norway provided information for this report.

For the progress on the actions in the implementation plan related to integrated pest management (IPM), reference is also made to the report from the Commission to the European Parliament and the Council on Member States National Action Plans and on progress in the implementation of Directive 2009/128/EC¹, hereinafter referred to as the Sustainable Use Directive (SUD). This report was published in October 2017 and covers also the implementation of Article 14 with regard to IPM. The Commission also published an Overview Report on Sustainable Use of Pesticides², which includes a more detailed analysis, including examples of good practice, as well as obstacles identified by Member States.

In February 2017 the European Parliament adopted a resolution³ on low-risk pesticides of biological origin calling on the Commission and the Member States to undertake several actions to increase the availability of such pesticides in the Union. In August 2017 the Commission's response⁴ to the Resolution was published.

The European Parliamentary Research Service published in 2018 a study⁵ which, among others, explained the limited use of low-risk PPPs by the low profits they generate (niche markets).

The report⁶ of the European Parliament's PEST Committee adopted on 16 January 2019 underlined the lack of availability of low-risk plant protection product "*caused by the lengthy evaluation, authorisation and registration process*" as hindering the implementation and development of integrated pest management.

1 https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_sup_report-overview_en.pdf

2 http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=114

3 European Parliament resolution of 15 February 2017 on low-risk pesticides of biological origin (2016/2903(RSP)) <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2017-0042+0+DOC+XML+V0//EN>

4 Follow-up to the European Parliament resolution of 15 February 2017 on low-risk pesticides of biological origin, 2016/2903 (RSP)

5 European Parliament Research Service (April 2018) European Implementation Assessment. Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market. ISBN: 978-92-846-2734-9.

6 Report on the Union's authorisation procedure for pesticides from the Special Committee on the Union's authorisation procedure for pesticides (A8-0475/2018 - (2018/2153(INI)) - PE627.625v02-00) – 18.12.2018

2. State of play actions related to increasing the availability of low-risk plant protection products

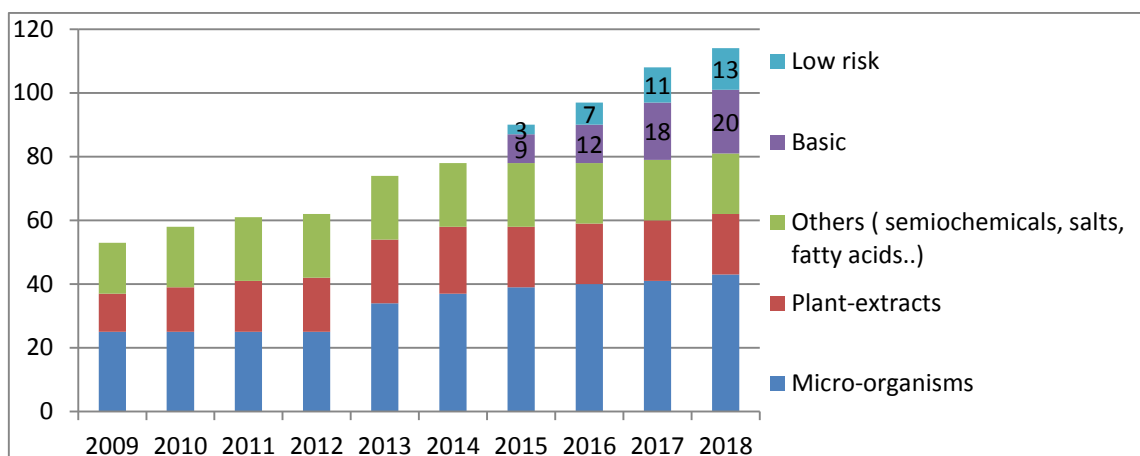
2.1 General summary

Plant protection products can be authorised as low-risk products when they contain only active substances that meet the low-risk criteria as specified in Regulation (EC) 1107/2009 on the placing on the market of plant protection products and do not contain other substances of concern. Moreover, Article 14 of the Sustainable Use Directive provides for Member States to take all necessary measures to induce professional users to switch to practices and products with the lowest risk to human health and the environment. Low-risk plant protection products often contain active substances of biological origin, but they can also be synthetic chemicals as long as they meet the low-risk criteria. Low-risk plant protection products provide a more sustainable option for farmers to protect their crops. The implementation plan therefore identified actions to increase the availability of such products.

Since the implementation plan's endorsement, the number of approved low-risk active substances has increased up to 13, by February 2019, of which 9 are new active substances and 4 renewal of approvals which were identified as low-risk substances. The number of low-risk substances is expected to further increase in the future, because about half of the new active substances currently under evaluation for approval are biopesticides (micro-organisms, plant extracts), the prime group of candidates for low-risk substances. There was an increase in these biopesticides in 2018 and a further increase is predicted in 2022⁷. In addition, among the 486 approved substances the Commission has identified 58 substances that are potentially low-risk based on current knowledge: this status shall be confirmed during the renewal of their approval.

Similarly, the number of approved basic substances – substances of no concern that are predominantly used for other purposes such as food but are useful for plant protection purposes, especially for organic farmers or amateur users – increased from 11 to 20. In total, around 23% of the substances currently approved are or are expected to be low-risk.

⁷ By end of 2022 the substances falling under part IV of the renewal programme (AIR IV substances) should be reviewed, a.o. to confirm the approvability and their low-risk status.



Due to the still low number of officially approved low-risk substances and their only recent approval as such, the number of plant protection products authorised as low-risk product is rather small. In the last three years, a total of 91 applications for low-risk product authorisations were received in the 22 Member States that provided data for this report⁸. A total of 75 low-risk authorisations (36 in 2018) were granted in the same period. The reported data indicate that the zonal rapporteur Member State that evaluates the product for one of the three zones within the EU usually is not able to complete the process within the fast-track procedure of 120 days, the legal timeline for low-risk products. After the zonal rapporteur Member State completes the process and grants authorisations, the other ("concerned") Member States in the zone grant authorisation within the legal timelines in only about half of the cases. Low-risk product authorisations through mutual recognition are also usually completed within the legal timelines in most Member States. No conclusions can be drawn on the effect of the implementation plan on these numbers, because the time period between the endorsement of the implementation plan and this report has been too short.

⁸ Counts of applications and authorisations may be for the same product in different Member States.

2.2 Member State actions

- *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*

Ensuring sufficient resources to comply with the timelines set in Regulation (EC) No 1107/2009 is an ongoing challenge for many Member States. Some Member States reported they are hiring additional staff or are investing in the professional development of existing staff. A number of Member States reported that resources are not available to increase the number of staff working on the approval of substances and authorisation of plant protection products in general and/or on low-risk product specifically.

With regard to harmonisation, Member States work together on zonal level in the zonal and inter-zonal steering groups. The Northern Zone for example produced a specific guidance document for the evaluation of products that is used by all Member States in that zone, ensuring a harmonised way of working. The Central Zone has collectively listed topics for further harmonisation and is addressing them in focused workshops. Specifically on low-risk products Member States have worked together with the Commission or EPPO in several working groups to produce guidance documents that are relevant for low-risk products, such as those on the implementation of the low-risk criteria, the low-risk product authorisation procedure and the evaluation of efficacy of low-risk products that have been completed or are currently in development (see also section 2.3 and 2.4). Such guidance documents will boost a harmonised and therefore more efficient approach.

EFSA has launched an online consultation space and forum through which risk assessors in Member States can share their knowledge on (the evaluation of) micro-organisms.

- *Expedite where possible the approval or renewal process of substances identified as potentially low-risk*

Twelve Member States reported they did not implement this recommendation. Many Member States reported that due to legal limitations they cannot prioritise potentially low-risk substances over other substances in the absence of prioritisation in the EU review programme. Some Member State reported that for new active substance it is difficult to identify the ones fulfilling the low-risk criteria before the evaluation is completed. On the other hand, many Member States offer pre-submission meetings to help applicants in submitting complete dossiers, which contributes to a smooth assessment process. In addition, six Member States reported to have taken specific measures to expedite the evaluation of potentially low-risk substances within the existing legal constraints. Three Member States reported they are prioritising the evaluation of potentially low-risk substances. One Member State reported they have a single contact point for such applications, anticipating upcoming applications and ensuring availability of resources to start immediately the evaluation after submission. Two Member States reported that the submissions are processed in a specific workflow for the intake, assessment and decision making, in one of these Member State with a specific team of experts handling such applications. Another Member State reported they offer applicants who have authorised products in the US a check of the US-EPA dossier as regards components that could be accepted in the EU dossier.

- *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.*

Five Member States reported to have taken specific measures to anticipate applications for the authorisations of low-risk products. Four Member States reported that they offer pre-submission meetings but did not undertake other specific measures to anticipate applications for low-risk products. To increase the quality of submitted dossiers, one Member State invested in informing applicants through workshops and in elaborating a specific biopesticides evaluation manual. Twelve Member States reported that they did not yet receive any application for the authorisation of a low-risk product, see only very few cases or do not treat low-risk products differently in terms of process or priority. Several Member States report that they have insufficient resources and do not expect to be able to meet the shorter legal timelines for the authorisation of low-risk products.

- *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.*

Two Member States reported they have a dedicated procedure for low-risk products. The action was not implemented by other Member States for a variety of reasons, such as legal limitations, legal certainty, lack of resources or because no applications for low-risk authorisations were received. Four Member States reported that they do accept pre-submission meetings in the period between publication of the EFSA conclusion on the peer review of the active substance and the entry into force of an approval decision but applicants are reluctant to submit application for low-risk products containing substances not yet cleared at EU level. One Member State suggests to start anticipating the preparation of authorisations for the products containing the potentially low-risk active substances identified in the Commission Notice mentioned under section 2.3. of this progress report (2018/C 265/02).

- *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.*

Almost all Member States reported that they advise the applicant in this sense when applicable, i.e. when the application for authorisation is done in the zone of the rapporteur. One Member State reported that it is important to recommend to applicants to select a zonal rapporteur that has sufficient resources available to process the application. It also reported positive experience with work sharing between Member States

- *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.*

Seventeen Member States reported that they take a pragmatic stance to the efficacy requirements of low-risk products and will apply the recently published EPPO standard (see section 2.4). Other Member States reported that they have not received any application for a low-risk product authorisation and, therefore, have no experience yet.

- *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.*

Ten Member States reported they do not have national requirements or they are not applicable to low-risk products. Four Member States reported they apply this principle wherever possible and one Member State reported that it performed a detailed review of the process and national requirements and made some adaptations.

- *Share knowledge and experiences with the 120-day authorisation process for low-risk products*

This action has not been implemented sufficiently yet, because there are still a low number of substances formally approved as low-risk and therefore the number of applications for low-risk products is limited and confined to only some Member States. Member States that have such experience shared it with other Member States in EU working groups or in the zonal steering committees. It is recommended to take initiatives for knowledge sharing on EU or zonal level in the future when more Member States receive applications for low-risk products.

- *Consider whether reduced fees have a role to play to increase the number of applications for low-risk substances and products in their country*

Seventeen Member States reported that they have reduced fees for low-risk substances (up to zero in one Member State) or products or for substances and products of biological origin. Other Member States reported that they do not have reduced fees because the fees are set to cover the costs of the competent authority. Some Member States reported that they calculate fees on an hourly basis and thus the costs for low-risk substances or products will be lower, because the procedure takes less time (or is supposed to). Several Member States pointed out that fees or a reduction of fees are not decisive for the applicant to decide on submitting the application. The main costs for the applicant are in performing the studies required for the application dossier. One Member State reported that in addition to reduced fees, they offer a grant to cover part of the costs for producing data for a low-risk application.

- *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.*

Seventeen Member states reported that they provide free pre-submission meetings for applicants. Two Member States reported that they are reviewing their fee structure and considering whether to implement free pre-submission meetings. Many Member States reported that communication with applicants before the submission of the application helps to improve the quality and completeness of applications and allows a better planning and allocation of resources to ensure a smooth evaluation process.

- *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.*

Seven Member States reported that they have dedicated experts for low-risk substances and products or for certain categories of substances, such as micro-organisms or substances of biological origin, both of which are major groups of candidates of low-risk substances. Some Member States have formed specific teams dealing with such substances. Fourteen Member States reported that they have no dedicated experts due to a limited number of applications or limited resources. Two Member States reported that they have appointed such experts and one reported that a single contact point was assigned specifically to this task.

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

Nine Member States reported that they provide support to stakeholders who want to submit applications for the approval of a basic substance. The type of support differs between Member States. It can be financial support through grants or providing knowledge or expertise or both. Three other Member States provide information on basic substance application through their websites, in conferences or provide consultation to answer questions.

2.3 Commission actions

- *Explore further the legal and practical implications of a non-binding list of low-risk substances and to plan the process to produce it.*

The Commission has published a Notice⁹ establishing a list of potentially low-risk active substances approved for use in plant protection. These potentially low-risk substances were approved under the previous Directive 91/414/EEC. The Notice is intended to support Member States in the implementation of the Sustainable Use Directive and to allow them to expedite on a voluntary basis the authorisation procedure for plant protection products containing such substances. The list is established for informative purpose and was compiled by screening all active substances approved under Directive 91/414/EEC using information available in the EFSA Conclusion and the Commission's review reports. Active substances are listed when they are expected to meet the low-risk criteria of Article 22 and Annex II point 5 of the Regulation. The list was verified by the Working Group on Low-risk substances and products and stakeholders were consulted in the process. The list is without prejudice to the outcome of any forthcoming evaluations performed in accordance with the provisions of Regulation (EC) No 1107/2009 for the purpose of the renewal, amendment or review of the approval of an active substance. Member States may use the list as considered appropriate to inform users and other stakeholders and to promote more effectively the use of plant protection products with substances of lower risk to contribute to the objectives of Directive 2009/128/EC.

- *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 REFIT evaluation of the pesticides legislation will soon be finalised. Provisions on low-risk substances and products are included in the evaluation. The report on the evaluation is expected in June 2019.

⁹ OJ C 265, 27.7.2018, p.8

- *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.*

Plant protection products can only be authorised if maximum residue limits (MRLs) have been set or when the substance is included in Annex IV of Regulation (EC) No 396/2005 when the setting of MRLs is not required. Low-risk substances are expected to not require MRLs and thus the majority of them will be included in Annex IV. To ensure that the inclusion in Annex IV is decided upon as soon as possible, the Commission implemented an internal work practice so that, as soon as the Standing Committee on Plants, Animals, Food and Feed – phytopharmaceuticals, section legislation, votes in favour of the approval of a substance as low-risk, the Commission tables a proposal for Annex IV inclusion in the next meeting of the residue section of the Standing Committee. The same work practice is applied to basic substances. The ongoing REFIT evaluation of the pesticides legislation is addressing also implementation of Regulation 396/2005 and the links and coherence with Regulation 1107/2009.

- *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.*

To facilitate the identification of low-risk substances while ensuring a high level of protection of human health and the environment, the Commission adopted Commission Regulation (EU) 2017/1432¹⁰ amending Regulation (EC) No 1107/2009 as regards the criteria for the approval of low-risk active substances. The amended low-risk criteria entered into force on 28 August 2017.

¹⁰ OJ L205, 8.8.2017, p. 59

- *Update the guidance document on zonal evaluation of plant protection products as soon as sufficient experience in Member States is available.*

The Regulation provides for an accelerated authorisation procedure for low-risk products, with a timeline of 120 days instead of one year. To provide for a harmonised authorisation procedure the Commission, with the help of the Member States, updated the guidance document on zonal evaluation and mutual recognition. The new revision of the guidance document was prepared in the Working Group for Post-Approval Issues and discussed in the Standing Committee. Stakeholders were consulted in the process. A revised version is intended to be presented for endorsement to the Standing Committee for Plants, Animals, Food and Feed in the near future.

- *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 an applicant, but that are valuable for plant protection purposes, could be taken into account in the approval process.*

Basic substances are substances that are predominantly used for other purposes (such as foodstuffs) but that may be useful for plant protection purposes. They are mainly used by organic farmers and amateur users, but may also be useful to conventional farmers. Because their safety is already assessed under other Union legislation or is based on historical use as a foodstuff, basic substances undergo a simplified evaluation procedure and are approved for an indefinite period at EU level. Their use does not require authorisation at Member State level.

The Working Group on Basic Substances reconvened on 11 October 2017, chaired by the Commission. Member States, EFSA and stakeholders (applicants) attended to share their experiences with the approval procedure, the risk assessment, the decision making process of basic substances and post-approval issues, such as enforcement.

The Commission proposed a revision of the working document on basic substances to make it more accessible and provide more guidance to applicants. It provides further clarification of the basic substance provisions and includes a simplified procedure for applications for extensions of use in the case where the EFSA technical report provides sufficient information for decision making. After consulting the Standing Committee, the new revision is expected to be published in the second half of 2019.

- *Additional actions not foreseen in the implementation plan*

Specifically for biopesticides, the major group of candidates for low-risk substances, a focused working group chaired by the Commission is currently elaborating technical guidance on topics regarding human toxicology, such as the evaluation of secondary metabolites produced by microorganisms, sensitisation and interpretation of clearance of microorganisms in test animals, as well as one dedicated to multiple antimicrobial resistance.

2.4 EPPO actions

- *Deliver a Guideline on efficacy evaluation of low-risk products*

Low-risk plant protection products have a different mode of action compared to their conventional counterparts, often very targeted or non directly toxic and their efficacy is very much dependent on the perfect timing with respect to the life-cycles of pest and crop and consequently more subject to environmental variability. It is important to take these considerations into account when evaluating their efficacy. The European and Mediterranean Plant Protection Organisation (EPPO) delivered an EPPO standard on the principles of efficacy evaluation of low-risk plant protection products. It was published on 13 October 2017¹¹. The standard will contribute to a more pragmatic efficacy evaluation of low-risk products and a harmonised approach within the Union.

¹¹ Bulletin OEPP/EPPO Bulletin (2017) 47 (3), p. 297–304

2.5 Stakeholder actions

The duration of the approval and authorisation processes depends largely on the quality and completeness of the dossiers submitted by the applicants. Incomplete dossiers will lead to requests for additional information which takes time. Therefore, the implementation plan identified several actions for stakeholders or applicants.

- *Submit high quality and complete dossiers from the beginning of the process*
- *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.*
- *Make use of pre-submission meetings provided by Member States.*

Stakeholders were asked on the progress made on behalf of their members. Industry associations advise new members about preparing dossiers for applications, for example by providing training sessions and provide opportunities to share knowledge between their members on this topic.

Industry associations have encouraged applicants to make use of the risk envelope approach where applicable and to think beyond the initial use and anticipate other uses in their active substance application, which is important for the feasibility of the 120-day low-risk product authorisation timeline.

Industry associations furthermore stressed the importance of a dialogue between the applicant and the evaluating body and encouraged applicants to make use of pre-submission meetings.

At the last general assembly of the biocontrol industry association, two Member States joined forces to provide a training to applicants for biopesticides and low-risk products to help improving applications.

3. State of play of actions related to the implementation of Integrated Pest Management (IPM) in Member States

3.1 General summary

Article 55 of Regulation 1107/2009 establishes that plant protection products shall be used properly in compliance with authorised conditions and also comply with the provisions of Directive 2009/128/EC and in particular the general principles of IPM as referred to in Article 14 and Annex III of the Directive. Moreover, in accordance with Article 4 of the same Directive Member States had to elaborate their national action plans which have among others the objective to encourage the development and introduction of IPM and alternative techniques to reduce dependency on the use of pesticides.

The above mentioned Commission report to the European Parliament and the Council states that the implementation of the Directive remains patchy. Member States have made progress and some areas are well implemented. Pest monitoring and warning systems are in place in almost all Member States as well as professional advisory services and training. Many Member States invest in IPM research and have general or crop-specific guidelines. A growing group of Member States has demonstration farms to develop and disseminate IPM practices. However, with regard to IPM, it was also found that Member States have not converted general principles into prescriptive and assessable criteria, and they see IPM mainly as an education tool for farmers. In addition, while Member States take a range of measures to promote the use of IPM and report positive outcomes with implementing educational tools to facilitate the adoption of IPM, this does not necessarily ensure that the relevant IPM techniques are actually implemented by pesticide professional users. Moreover, not every Member State incorporates IPM in their inspections on farm level.

3.2 Member State actions

- *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.*

Data collected for the Commission's report on the SUD for the period 2013 – 2015 shows that efforts and funds are invested in IPM related research projects in 23 out of the 28 Member States. Significant amounts (more than 1,2 Mio EUR/year) are allocated in research in eight Member States. In five of the above mentioned 23 Member States, the funding comes only from the national budget, and there is a combined financing (national and EU funds) in ten other Member States. In eight of the Member States, research projects are also financed or co-financed by the pesticide industry or other stakeholders.

Member States reported different ways of establishing partnerships between government, agencies, the research community and the private sector such as farmers, industry and NGO's. Some Member States organise regular, formal round-tables on pesticides or IPM or hold conferences on IPM. Several Member States reported to have established public-private research programmes or IPM demonstration centres. Such partnership projects aimed at showing farmers the opportunity to cultivate profitably while reducing the use of plant protection products in their crops thanks to integrated management methodologies, including non-chemical weeding such as robotic mechanical weeding.

Other Member States reported using the European Innovation Partnership programme on agricultural sustainability and productivity or have established national networks for agricultural research and experimentation. One Member State reviewed all recent IPM research projects to ascertain whether they contain information that could be transferred eventually into farming practice.

- *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.*

Data collected for the Commission's report on the SUD shows that IPM demonstration farm networks were established in twelve Member States to disseminate IPM techniques for the local climatic conditions and crops grown. The number of demonstration farms varies between Member States, from one to around 3,000. In some Member States these are fully publicly funded and in other Member States they are privately funded or mixed. Some Member States report that the setting up of demonstration farms is part of EU-funded rural development plans. The data collected for this report shows that nine Member States are currently considering setting up demonstration farms in their country in the future or expanding the scope of existing ones to include IPM. One Member State reported that a new demonstration farm specifically dedicated to agro-ecology has been set-up since autumn 2018. Another Member State set in place a swift recognition procedure for farms or pilot farms that can serve as reference for the implementation of IPM.

- *Share information on the implementation of general principles of IPM in Member States*

Member States regularly exchange knowledge on the implementation of IPM between each other through the Working Group set up under the Sustainable Use Directive and targeted workshops, such as the most recent demonstration farm workshop organised in Germany in spring 2016. Knowledge sharing on European level between Member States, farmers, researchers and other stakeholders took place through EU funded programmes such as the C-IPM Eranet network and specific operational groups under the European Innovation Partnership programme.

Although the C-IPM programme was completed in 2016, a workshop was organised and took place on 22 – 23 November 2018 in Paris. The C-IPM initiative promoted work sharing, to avoid duplication of research with regard to IPM. As part of this initiative, C-IPM launched two calls for projects in co-operation with several funders of research, who allocated a total of 12 million € to IPM research projects selected in 2015 (5 M€) and 2016 (7 M€). The workshop mentioned above aimed at presenting the state of play of the projects launched under the second call in 2016. More than 50 participants attended the event, mainly representatives from research institutions and universities, but also from MS competent authorities, growers associations and NGOs. The event was structured in five blocks:

- IPM and minor uses;
- Pest and disease monitoring for IPM;
- Sustainability and integrated biocontrol;
- Integrated weed management;
- Other issues.

Several of the projects listed above included as an objective the development of a decision support system, in order to facilitate PPP professional users in decision-making with regard to pest control methods and techniques.

IPM has been a topic included in SUD WG meeting agendas since November 2016. In May 2017 and March 2018, speakers from individual Member States and from research and advisory services, as well as farmers presented their practices and explained the challenges faced and the benefits from applying IPM general principles, including at farm level. An IPM workshop is planned by the Commission in May 2019.

To exchange knowledge on IPM within Member States, data collected for the Commission's report on the SUD shows that 23 Member States have crop or sector-specific IPM Guidelines available. The Guidelines have been drafted by official services in six of the Member States, by growers' associations in one Member State and by the involvement of both official services and relevant stakeholders in the other 16 Member States. The number of IPM Guidelines varies significantly between Member States, from 3 to more than 90. According to Member States' own estimates, more than 90 % of the utilisable agricultural area is covered by crop/sector-specific Guidelines in seven Member States, between 50 and 90 % in five Member States, between 10 and 30 % in two Member States and less than 10 % in two Member States. No numbers were provided in this regard by the remaining 12 Member States.

Apart from IPM guidelines, Member States report to use conferences, seminars and online platforms to spread knowledge on IPM within their country. Moreover the training requirements in the SUD require the subject of IPM to be part of training programmes to be delivered to users, distributors and advisors. Several Member States also report that dissemination activities from research projects in IPM play an important role in spreading knowledge about existing and new methodologies.

- *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 (EU) No 1305/2013).*

Data collected for the Commission's report on the SUD shows that advisory services are provided to pesticide professional users in all 28 Member States. In three Member States, advisors are representatives from designated competent authorities and in eight Member States advisory services are provided by the private sector (private bodies, freelance advisors or staff from other relevant stakeholders). In the remaining 17 Member States, there is a combination of both practices. Some Member States control that there is a clear separation of activities between the adviser training activities and the sales activities of sellers, so that farmers receive neutral and balanced information.

3.3 Commission actions

- *Evolve the existing website on Directive 2009/128/EC into a web-portal linking to the currently available relevant information on IPM on EU and Member State level.*

The Commission launched a SUD web-portal¹² on 10 October 2017, where links are provided to Member State authorities' websites and other relevant information sources. At present, one Member State has not yet provided any links. The web-portal has a search function, allowing a search by Member State or by topic. Eighteen Member States provided links to IPM related information, *i.e.* IPM related national legislation, IPM Guidelines, leaflets and brochures, recommendations and advice, awareness-raising campaigns etc.

- *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.*

In 2015 and 2016, the Commission organised twelve training sessions under the Better Training for Safer Food (BTSF) initiative for Member State experts, which covered all subjects to be included in Member States training programmes for PPP operators (professional users, distributors and advisors). The training programme was designed in a way as to provide a consistent and high-level understanding on how to implement training provisions and provided an opportunity to exchange good practices. All 28 Member States participated and some 338 staff were trained.

In addition, the Commission organised six Better Training for Safer Food (BTSF) courses in 2015 and 2016 on pesticide application equipment (PAE), with 102 participants from 25 Member States, and six more courses in the following two years, 2017 and 2018 with each of them gathering 115 participants. As there was a very positive feedback by participants, and a need was identified by the Commission, another BTSF project on PAE testing is under way (first training sessions expected to take place in the second half of 2019).

¹² https://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides_en

Following discussions with Member States and based on their proposals, the Commission launched another BTSF project, focusing on IPM implementation and its assessment at farm level by Member States authorities. Between December 2018 and June 2020, 14 sessions will be organised, with 30 participants each. The sessions are tailor made so that they cover a specific group of crops. Seven of these sessions are developed for Member States from the Central and Northern zone, and the other seven for Member States from the Southern zone. The target group of participants includes central and regional/local authorities and advisors from both private and governmental bodies. The first training session for Member States from the Southern zone for solanaceous vegetable production under protected cultivation (greenhouses) took place in December 2018. The first session for Member States from the Central and Northern zone (greenhouse production of cucurbitaceous vegetables) took place in February 2019. If considered necessary and depending on budget availability, this BTSF project can be extended for two more years. The main objective of the IPM training sessions is for Member States to provide their contribution towards assessment of IPM general principles implementation at farm level by Member State authorities, allowing for consistency and uniformity across the EU.

The Commission intends to establish another BTSF scheme dedicated to the risk assessment of microorganisms and biopesticides in the course of 2019-2020.

- *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.*

To measure the progress achieved in the reduction of risks and adverse impacts from pesticide use for human health and the environment, Directive 2009/128/EC requires harmonised risk indicators to be established. It also provides for Member States to continue to use existing national indicators or adopt additional ones as appropriate.

Following discussions with Member States, first within an Expert Group and then at the SUD Working Group meeting in March 2018 and consultations of stakeholders through its Feedback mechanism, the Commission drafted a Directive amending Directive 2009/128/EC to establish harmonised risk indicators (HRI). The Standing Committee on Plants, Animals, Food and Feed gave a favourable opinion on the draft Directive in January 2019, which at the time when this report was produced was under scrutiny of the Council and the European Parliament. At the same time, the range of indicators developed by Member States linked to their National Action Plans will remain in place. The current Indicators are intended to complement, rather than replace, these national indicators. The Commission is committed to work on the development of further harmonised risk indicators.

As HRI established are linked to statistics on plant protection products sales, DG Health and Food Safety will continue working in close co-operation with DG European Statistics and Member States on reaching a solution with regard to statistics on pesticide use. In November 2019, a joint meeting of the SUD Working Group and the Agro-Environmental Statistics WG will take place to discuss potential issues.

4. State of play of actions on supporting research and development of alternative methods

4.1 Member State actions

- *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.*

Seven Member States reported that they participate in EU funded research programmes under Framework Programme 7 or Horizon 2020 related to the area of sustainable plant protection. Seven Member States reported that they have regular exchanges with stakeholders, including researchers, to identify the needs for farmers and translating those needs into research projects. Two Member States were developing a consultation tool accessible to farmers to identify their specific interests and hence contribute to strategic plans for national or European Research programmes.

- *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.*

Thirteen Member States have actively promoted applications to Horizon 2020 calls in the area of sustainable food security or have parties in their Member States who submitted applications. One form of promotion reported was creating a central website in the language of the Member State with information on project calls and how to apply.

4.2 Commission actions

- *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 programmes at EU level.*

The funding of research and innovation in plant protection to identify new low-risk substances and other sustainable control methods such as biological techniques – in the FP 7 programme over 100 million EURO were invested in plant health, integrated pest management, risk assessment and diagnostics. Horizon 2020 further addresses this area of research with focused projects to identify alternative low impact sustainable techniques.

The Commission in coherence with pesticides policy and pursuing the sustainable development goals is continuing to support research for development of IPM and alternative techniques. In the most recent calls for 2018-2020 under Horizon 2020 27 million EURO have been allocated to the target calls on "Integrated health approaches and alternatives to pesticides use", "New and emerging risks to plant health" and "Stepping up Integrated pest management". Moreover, other recently closed or just opened calls are relevant for projects boosting sustainable crop protection such as those under the "Rural renaissance" section concerning "Thematic networks compiling knowledge ready for practice" and "Networking European Farms to boost thematic knowledge exchanges and close the innovation gap".

The Commission committed to provide support to Member States in developing a methodology and a range of criteria for the assessment of IPM implementation at farm level. A BTSF/IPM project was designed with this aim. The IPM workshop referred to above (May 2019) will be focusing on IPM assessment at farm level.

In addition, since January 2018 Commission services initiated a series of audits of the Member States' implementation of the Directive on Sustainable Use of Pesticides. Aspects related to IPM enforcement and assessment at farm level is part of these audits. Four Member States were already audited in 2018, and six further ones will be by mid April 2019. The main findings and conclusions will be summarised in the second report from the Commission to the European Parliament and the Council, which will be published in the second half of 2019.

5 Recommendations for the future review of Regulation (EC) No 1107/2009

- *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.*

The Expert Group on Sustainable Plant Protection (April 2017) set up a workshop to discuss how to amend Regulation (EC) No 1107/2009 to further increase the availability of low-risk products and basic substances. Fourteen Member States, EFSA and the Commission participated in the workshop. The report of the workshop has been made available to the Standing Committee and the Commission for future consideration after the completion of the REFIT evaluation of the pesticide legislation.

6. Conclusions and way forward

6.1 Conclusions

The implementation plan has increased awareness among Member States, the Commission and stakeholders for the low-risk concept and the need to take action to increase the availability of low-risk plant protection products. The actions completed have increased the legal comprehension on the identification and evaluation, both conceptual and procedural, of low-risk substances and products. It has also triggered various actions to develop in priority more sustainable ways of growing and protecting crops.

It is clear that the regulatory concept of low-risk substances is new and the renewal has not yet been concluded for all active substances on the market. The number of low-risk substances and products is still low and so far not many Member States have received applications for the authorisation of low-risk products. While the report shows that many Member States have set lower fees for low-risk products and provide free pre-submission meetings, so far only a small number of Member States have been in the position to actively prioritise low-risk products or to devote specific resources and expertise to them.

The number of low risk products needs to grow to enable farmers and other end-users to be able to choose low-risk options for their particular needs within the framework of integrated pest management, making the concept more meaningful in the everyday business of growing crops. This will be accomplished in part by the ongoing review of active substances for the renewal of their approval and by industry's increased focus on applications for the approval of biopesticides, as is evident from the current nature of substances under evaluation for first-time approval. However, continuous efforts by Member States, EFSA and the Commission are necessary to ensure that sufficient resources and expertise are available to be able to meet the timelines for the approval of potentially low-risk active substances and to expedite these procedures where possible. In particular, Member States should ensure sufficient resources to be able to meet the shorter legal timelines ("fast track") for the expected increase in the number of applications for authorisation of low-risk products in order to get them to the market as quickly as possible. Likewise, continuous effort of applicants is required to submit high quality and complete dossiers, in order to allow for swift evaluation and decision making.

The implementation plan also increased awareness on the actions needed to further extend the range of measures, which would ensure a better implementation of integrated pest management in Member States. It is clear that Member States in general undertook efforts and actions in this direction. The Commission stepped up the effort to monitor and support the implementation of the Sustainable Use Directive, including integrated pest management, in the Member States. The report to the European Parliament and the Council¹³ concludes that, while the SUD offers the potential to greatly reduce the risks from pesticide use, at the time the report was produced, improvements were limited and insufficient to achieve the environmental and health improvements the Directive was designed to achieve. Although Member States have taken a range of measures to promote IPM and educate farmers, they have not converted the IPM principles into prescriptive and assessable criteria, thus not necessarily ensuring that IPM principles are applied at farm level and IPM techniques available are actually implemented by users. Therefore, notwithstanding the progress made, further effort from Member States and the Commission is needed in this area.

It is recognised that the increasing awareness and political priority for sustainable plant protection continues to drive the funding for research in this area, on EU and Member State level. There is also an increased effort in taking actions to disseminate this knowledge to end-users, notably by using demonstration farm networks as locations where research and farming come together to develop and implement new and pragmatic IPM methods.

6.2 Recommendations on the way forward

With respect to the key areas for action identified in the implementation plan:

- Increasing the availability of low-risk products
- Further improving the implementation of Integrated Pest Management (IPM) in Member States
- Supporting the research and development of alternative methods
- Recommendations for the future review of Reg. (EC) No 1107/2009

the experts group on Sustainable Plant Protection recommends the following for the way forward.

¹³ https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_sup_report-overview_en.pdf

All relevant stakeholders should keep working on the key areas identified by the implementation plan, not only finalising those actions ongoing but making further progress to pursue the objectives of the plan on the basis of experience gained also through the renewal assessment process initiated in 2016 on several potentially low risk active substances approved under Directive 91/414/EEC. It can be envisaged that in the next three years, the outcomes of this renewal process will require stakeholders and Member States to focus on the application and re-assessment of several authorisations for potentially low risk plant protection products and the experience gained up to now and the actions already accomplished should permit to implement the process without delays.

All Member States should actively contribute to work-sharing practices at EU level to improve the efficiency of the zonal authorisation system and mutual recognition, especially when the number of applications for the authorisation of low-risk products continues to increase in the future. For this same objective to increase availability of low risk plant protection products, the Commission should continue to facilitate the development of technical guidance for the harmonisation of the evaluation process and the respect of implementing deadlines through the respective working groups on biopesticides, low-risk products and basic substances.

Moreover, with respect to accelerating the implementation of IPM, following the presentation of the Commission report on the SUD to the AGRIFISH Council of 6 November 2017, Agriculture Ministers indicated among the most important measures: improvement with regard to the use of low-risk plant protection products, establishing adequate pest monitoring systems, allocation of adequate financial support, increasing the use of alternative non-chemical methods, training of pesticide operators, strengthening official controls on the use of pesticides and development of harmonised risk indicators.

Hence, Member States should allocate resources to transfer into concrete actions the identified best practices and explore other incentives which could support users to switch to new sustainable techniques, taking into account the potential of other policy measures set under the Common Agriculture Policy (CAP).

On this basis, the Commission should continue to monitor and support implementation by the Member States to provide assurance that the objectives of the Directive are being achieved. With regard to IPM, the Commission should support the Member States in the development of methodologies to assess compliance with the eight IPM principles, taking into account the diversity of EU agriculture and the principle of subsidiarity. Finally, IPM training sessions under the Better Training for Safer Food should continue. In the development of new policies, the Commission should continue to take into account in the development of new policies the objectives of setting necessary conditions for the implementation of integrated pest management which do not only include the availability of alternative low risk products, but the existence of a comprehensive knowledge based system for prevention and reduction of pest risks with advisory services and informative tools built up for this purpose.

As regards supporting research, the Commission should continue to keep among the priorities the development of sustainable plant protection and identify further how complementary and synergic effects could be achieved e.g. soliciting the divulgation of innovative and useful results among stakeholders through an EU network of IPM demonstration-farms which could facilitate such exchanges.

Member States should ensure that the subject of sustainable use of pesticides and development of alternative methods is given due relevance within their national agricultural research programmes and participate in EU projects and explore how to benefit from other actions initiated by Horizon 2020 and its following framework programme (e.g. thematic networks) or by Rural Development programmes such as operational groups to transfer the research outcomes into real concrete developments within a multi-actors approach and adapt knowledge ready for the farmers.

Finally, following-up the REFIT evaluation the Commission should identify the most appropriate actions to foster the development of sustainable plant protection practices, including low-risk products and integrated pest management.
