Federal Office of Consumer Protection and Food Safety

ZAPID

Zonal Authorisation Procedure - Improvements and Developments

5-7 December 2023

Braunschweig, Germany

Final Workshop Report

This report compiles the output of an informal workshop with experts from Member States authorities and stakeholders. The document has not been adopted or endorsed by the European Commission and any views expressed may not in any circumstances be regarded as stating an official position of the Commission and/or commitment to any future action.

The report is not intended to create any legally binding effect, nor does it establish any binding interpretation of EU laws. Therefore, it shall not be relied upon for any legal purposes.

Hosted by:

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1 EXECUTIVE SUMMARY

Regulation (EC) No 1107/2009 lays down the rules and legal framework for a harmonised European assessment and decision-making process for plant protection products and their active substances, co-formulants, safeners and synergists. A zonal system of authorisation of PPPs was introduced by this Regulation. In view of its implementation, workshops had been organised:

- in January 2010 in Braunschweig (Germany): the *Guidance document on zonal evaluation and mutual recognition* and the *Guidance document on renewal, withdrawal and amendment* are the concrete outcome of this workshop.

- in June 2015, in Dublin (Ireland): concrete outcomes are the zonal and interzonal Steering Committees, the use of the PPP Application Management System ('Authorisation database') and the management of the re-authorisation process (Article 43). After the workshop, the dRR template had been revised, the minor use coordination facility has been founded and a zonal secretariat had been established in the Central Zone.

By 2022, it became increasingly clear that another workshop was needed and, therefore, the Zonal Authorisation Procedure - Improvements and Developments (ZAPID) Workshop took place in December 2023 in Braunschweig (Germany), which results are reported herewith.

The ZAPID workshop was organised by an organising committee established in March 2023 and made up of representatives of the Member States from all zones (DE, EL, ES, and SE), the European Commission and the chair of the Post Approval Issues WG. Member States, the European Commission and stakeholder organisations were invited to submit possible topics for the agenda. These topics have been grouped into five main categories which were discussed in breakout groups (BOG). The BOGs were also chaired by representatives from all regulatory zones (BE, ES, IE, NL, and SE). The chairs of the BOGs supported the organising committee in preparing the content of the discussions and preparing the final report.

The workshop was limited to the procedures related to the zonal evaluation, mutual recognition and re-authorisation according to Regulation (EC) No 1107/2009, including procedural guidance documents and the underlying IT structures supporting the competent authorities. The following topics were the focus of the breakout groups for which the respective chairs (participants from Member States) had prepared thought-starters:

- Meeting legal requirements – Tackling delays
    - Increasing complexity,
    - Insufficient staff,
    - Expanding frameworks,
    - Meeting policy objectives,
    - Possibility of central allocation of applications.

- Harmonising zonal decision making – Special focus on Mutual Recognition, minor uses, and assessment of co-formulants
    - Exhaustion of all possibilities for mutual recognition,
    - Common understanding of “minor use” or “minor crop”,
    - Co-formulants: Guidance document and database.

- Work sharing on digital platforms - The future of European IT-systems in PPP authorisation procedures
    - Exploration of existing databases,
    - IUCLID,
    - Co-formulants database.

- Implementation of new scientific and technical knowledge - Guidance Documents (e.g. GD SANCO 10328/2004)
    - New active substance data,
    - Current scientific and technological knowledge,
    - Data gaps in EFSA conclusion,
    - Delays in updating relevant Guidance documents.

- Authorisation of PPP in the light of the Green Deal - Low-risk, biocontrol and non-chemical PPP assessment
    - Definitions,
    - How to increase / make better use of existing capacity,
    - Harmonisation of risk assessment for natural substances and novel technologies,
    - New application technologies.

A total of 68 participants attended the workshop, representing Member States (45 participants), COM (3 participants), EFSA (4 participants), MUCF (1 participant), and applicant associations IBMA, CLE, ECCA (15 participants). The participants were invited based on their direct involvement and experience in PPP regulation laying the foundation for the technical and procedural nature of the discussion at the workshop. The European Commission covered the travel expenses of the national experts and the German competent authority, BVL, hosted the meeting in Braunschweig with funding from the respective Federal Ministry of Food and Agriculture.

This report summarises the outcome of the discussions, and collects the proposals and ideas mentioned during the discussions. Follow up discussions and actions would be needed to continue their implementation, where appropriate. In particular, all participants agreed that a follow-up workshop would be necessary.

2 BREAKOUT GROUP 1
Meeting legal requirements – Tackling delays

2.1 Thought starter

The following document has been prepared as a thought starter to initiate discussions in the Breakout Groups and should in no way be conceived as the official position of the European Commission or the Member States.

2.1.1 Background

Introduction

Across the EU MSs are not able to comply with the legal deadlines set out in the PPP Regulation. The main bottlenecks are the structurally increasing complexity and amount of work, insufficient staff to process the workload, and a slow decision-making process. The Commission took steps to aid Member States to increase their capacity and stimulated a movement towards full cost-recovery systems in Member States. This is very much welcomed.

However, it is recognised that the increase in capacity will not be sufficient to substantially reduce the delays, especially when at the same time the burden of technical and administrative requirements increases. Currently the workload still increases faster than the capacity. Hence, further measures are required, to mitigate the impact of the delays on the aims of the PPPR and for the achievement of the Farm-to-Fork and Chemical Strategies under the EU Green Deal.

We acknowledge the issue is complex and there is no simple solution. The delays can also be caused by internal factors at the competent authorities. These internal factors should be addressed by the competent authorities themselves. In this note, bottlenecks at European level are identified, and measures are proposed to achieve more balance between the human resources and the workload for the PPP Regulation. In this meeting we would like to share points of view on the urgency for additional measures, to discuss options to tackle the bottlenecks and specifically thinking together how to move forward in collaboration.

Bottlenecks at European level

The total backlog in the EU is too large to be processed with the available capacity within the legal timelines. Since no explicit priorities are set at the European level, this leads to delays for all types of applications.

Underlying this problem are two bottlenecks at European level other than limited resources:

1. The assessment framework, both technical and procedural, has expanded in recent years, greatly increasing the workload per application. As a result, the legal deadlines are no longer commensurate with the workload. With current practices, in other words, a number of legal deadlines are no longer realistic.
    - Procedurally, this situation primarily involves the introduced requirement for full reassessment of applications for substance and product renewals (eventually enacted in 2020/1740, Article 6(2)(m)), instead of only a review of new data and a new assessment framework (new/amended guidance documents) as referred to in Article 15 of the Regulation. And more recently the amendment of the General Food Law for the purpose of transparency, accompanied by additional workload (e.g. confidentiality check studies

for disclosure), also as a result of new administrative procedures and European IT systems (IUCLID). IUCLID and the one-substance-one-assessment approach are, however, expected to reduce the workload over time.

- Technically, this involved new components (such as endocrine disruption, unacceptable co-formulants) and revision of guidance documents, which consequently became more complex. The complexity is increasing not only due to recent scientific insights, but also by enabling ever-increasing refinements. Assessment of these higher tier refinements is time consuming.

The expansion of the framework will continue in the coming years (bees, birds & mammals, amphibians & reptiles, safeners & synergists, unacceptable co-formulants and cumulative risk assessment), thus entailing increased workload for each application.

2. Specifically, innovations, such as new "green" substances and products or innovative application technologies, should be allowed faster authorisation due to their often lower risk profiles. Given European and national policy goals, this is a priority, but has not been transposed into explicit policy at the EU level. The Regulation does not provide sufficient guidance for this, and if guidance is provided, it is not used quickly enough. Finally, the European Commission does not sufficiently direct the development of frameworks for certain innovations and leaves this too much to the Member States. Existing risk assessment frameworks do not leave enough room for expert judgement and continue approach things too often from a classical chemical perspective.

The delays caused by the bottlenecks mentioned above have the following undesirable effects, which are also receiving increasing political attention at the EU and national levels:

- Delayed availability of "green" and innovative products that are needed to make the agricultural transition and to achieve the EU goals in the Farm-to-Fork Strategy.
- Political and societal concerns that new scientific findings are being incorporated too slowly into the reassessment of certain chemical active substances and products. This manifests itself as increasing resistance to administrative renewals of the approval of certain chemical active substances at the EU level.

Proposed solutions

- There is no simple solution to the issues outlined above. Action must therefore be taken on multiple levels. The items below are relevant for this breakout group and are based on the input send by the participants for the workshop.

1. Set priorities at the European political-administrative level and on this basis make choices about what work can be taken out of "the system" or postponed.

Given Europe's persistent shortage of capacity in the coming years, priorities must be set and choices made. One obvious measure is to modify the legal timelines so they are more in line with practice. From the point of view of the competent authorities, this is obviously desirable. On the other hand, this in itself does not lead to acceleration, and the feasibility of such a proposal is estimated to be low, also given the EC's response on this point in the REFIT evaluation of the PPPR.

- As stated previously, the implementation burden is no longer commensurate with the legal timelines, which has consequences for the intended policy goals. This situation needs to be acknowledged at the political level of the EU. This necessitates setting priorities and making choices at the political level, while also acknowledging the consequences. After all, prioritising one thing leads to delaying something else.

- Given the policy goals, priority should obviously be given to:
    1. Applications for new substances and products that contribute to sustainable plant protection and the farm-to-fork goals, such as low-risk and "green" substances/products and innovative, dose-reducing application technologies, as well as the development of the necessary assessment framework for this purpose.
    2. The reassessment of chemicals with the highest risks.
- To make room for this, work must be taken out of the system. This can be done as follows:
    1. Delay the reassessment of non-priority substances by several years. The EC has the authority under Article 18 of the PPPR to establish a work programme for substance reassessments. Therefore, postpone the reassessment of products based on these active substances.
    2. Give low-risk substances an unlimited approval period (as with basic substances) and give "green" (bio-control) substances a much longer approval period, thus eliminating the need for capacity to reassess. Create a legal basis for this in Regulation (EC) No 1107/2009 through the SUR legislative proposal. Given the risk profile of such substances, this is justifiable. Should unforeseen risks become known in the future, it is always possible to withdraw or amend the substance approval or product authorisation when necessary.

2. Conduct EU-level discussions on the limit of complexity of assessment methodologies

It is questionable whether the growing complexity of the assessment framework *overall* leads to a higher level of protection. A discussion at EU level should be held on the need to limit the complexity of assessment methodologies in favour of increasing the feasibility.

The focus of the discussion on limits to complexity could be on restricting refinements to the methodology for existing documents, such as documents on bees, birds & mammals, and non-target arthropods. There should be explicit room to add new elements (e.g. neurodegenerative effects, amphibians and reptiles) to the risk assessment, as this will improve the protection of humans, animals and the environment. Relevant in this discussion will be the societal concerns, the increased transparency and engagement with the public.

3. Focus the effort of MS through centralised allocation of applications

Due to a lack of assessment capacity industry has trouble to find a zRMS for their applications. The actual submission of applications is irregular and difficult to predict. It is uncertain that dossiers will be submitted at a time that capacity is available. To focus the use of the available capacity on the prioritised applications and achieve a more balanced division of applications across all Member States there is much to be said for arranging the zRMS for product applications via a centrally organised allocation.

In Regulation (EC) No 1107/2009 this task (for product applications) was already foreseen for the Zonal Steering Committees. Applications can be submitted to the Steering Committee when the dossier is finalised. CA's can take them aboard when there is capacity to start the assessment.

Advantage of this method is a professionalised system with better regulated inflow and better insight into the capacity demand and supply. When allocating the available capacity of the individual CA's will be taken into account.

4. Improving the quality of the submitted dossier

A recent questionnaire among MS show that all MS provide information on their websites to help applicants to submit high quality dossiers, varying from explanations to checklists and manuals. Some

MS organise pre-submission meetings and strongly advice inexperienced applicants to hire a consultant.

Despite this, and earlier discussions on the quality of submitted dossiers and attempts to take measures for improvement, the MS are still confronted with (valid) dossiers of poor quality of the evaluation parts, and procedural mistakes in the PPP applications.

Dossiers of poor quality take more time (rough estimate approximately twice as much) to repair, evaluate and assess. Poor quality dossiers lead to a longer time to market for the applicant. They are also disadvantageous to other applicants that are waiting for their dossiers to be handled due to the delays caused by repairing the dossiers.

Poor quality dossiers are an unnecessary drain on the scarce assessment capacity of Member States and leads to delays. A discussion to address this issue is needed.

Background information relevant to this thought starter

Delays

Report on the compliance with the legal deadlines set out in the Regulation (EC) No 1107/2009 concerning the authorisation of plant protection products reported by Member States and Norway for the years 2017, 2018, 2019 and 2020 (EC Directorate-General for Health and Food Safety, September 2022).

Priority Work programme for AIR-4

Renewal of approval (europa.eu)

Commission Implementing Decision 2016/C 357/05

pesticides_ppp_app-proc_air-4_renewal-program.pdf (europa.eu)

Complexity

Workshop 'Reflecting on the increasing complexity in environmental risk assessment of Plant Protection Products' (Berlin, 12-13 November 2015). Poster on workshop

Allocation

The remit of the (Inter) Zonal Steering committees are included in Appendix 2 and 3 of GD on zonal evaluation and mutual recognition, withdrawal and amendment. These remits describe the roles of the Committees in allocation.

2.1.2 Discussion Points

Session 1: Workload in general

1. Do the participants recognise and acknowledge the problems and the identified bottlenecks?
2. What are the expectations towards setting realistic timelines?
3. Do the participants agree that more far-reaching measures are needed as previous attempts to address the delays were insufficient?
4. Do participants support the proposed measures?
5. Do participants see other measures with more impact that need to be discussed in these sessions?

Session 2/3: Measures

For each measure we need to discuss:

- -the scope of the measure
- -what is needed to implement the measures –which actor (COM, MS, EFSA, ECHA, industry) can contribute what?

Set priorities at the European political-administrative level and on this basis make choices about what work can be taken out of "the system" or postponed

6. What are the goals of this prioritisation?
7. Which application should be prioritised?
8. Which applications should be delayed and for how long?
9. What work can be taken out of "the system" or postponed?
10. Do we want to give low-risk substances an unlimited approval period (as with basic substances)?
11. What is an appropriate approval period for low-risk and "green" (bio-control) substances?
12. The priority of the new substances and products that contribute to sustainable plant protection and the farm-to-fork goals needs to be transposed into explicit policy at the EU level.
13. How to identify the new substances and products that contribute to the sustainable plant protection and the farm-to-fork goals?
14. What is needed to ensure that deadlines are met this time?
15. How to ensure that a possible next renewal of these substances do not coincide again?

Conduct EU-level discussions on the limit of complexity of assessment methodologies

16. Is there a need to limit the complexity of the assessment methodology, by means of restricting the refinements?
17. Methodology development is currently science driven. Is a new approach needed with more focus on feasibility?
18. What should be the conditions for methodology development?
19. What is the scope of the discussion on complexity: new to be developed methodology or also existing and under development methodology? How to move forward with the latter two?

Focus the effort of MSs through centralised allocation of applications

20. What are the benefits and disadvantages of centralised allocations?

21. Is there support to further elaborate centralised allocation?
22. What are the issues that need special attention when elaborating centralised allocation?

Improving the quality of the submitted dossier

23. Where lies the responsibility of the applicant and of the MS for the quality of the dossier?
24. What are possibilities for applicants to improve the quality of submitted dossiers?
25. What are possibilities for MS to support applicants to improve the quality of the dossier?
26. What are possibilities for MS to reject dossiers of poor quality (in evaluation parts or through procedural mistakes)?
27. What is needed to move forward?

2.2 Summary report

Background

Member States are not able to comply with the legal deadlines set out in the PPP Regulation for a variety of reasons including the rapidly increasing complexity of the evaluation work, the large number of evaluations to be carried out, insufficient staff to process the workload and a slow decision-making process. The workload will continue to expand in the coming years to take account of additional areas (e.g. bees, birds & mammals, amphibians & reptiles, safeners & synergists, co-formulants and cumulative risk assessment) thus resulting in even longer evaluation times.

The bottlenecks at European level are described in the Thought starter for BOG 1 and the participants of BOG 1 agree with the described bottlenecks.

The solutions proposed in the thought starter have been discussed, on the basis of the following subjects:

- Complexity of assessment methodologies
- Priority setting
- Centralised allocation for new applications
- Quality of submitted dossiers

2.2.1 Discussion on the complexity of assessment methodologies:

Guidance documents (GD)

GD tend to be conservative and their complexity has increased significantly over the years. Development of guidance documents is very science driven. As a result, it can lead to very conservative GD. Member States (MS) are encouraged to comment more on GD during the drafting and preparation phase, to ensure that they are more practical and more in line with reality. MS understand the practicalities of the implementation in a regulatory context. The regulatory deadlines for processing applications mean that the use of GD by the MS must be fully compatible with the time constraints. There is a need to go back and look at some GD to see if they are still fit for purpose. Do they really reflect reality and are they actually feasible feasibility checks during the development of guidance documents and before finalisation is needed to ensure that the guidance document produced is fit for purpose? Criteria for this feasibility check are needed.

Excellence network

A proposal was put forward to have a panel of MS experts which has the expertise in specific aspects of risk assessments that need specialised knowledge, e.g. specific high tier refinements in particular areas. The purpose is to ensure that the risk assessments and the use of the GD will be harmonised. This panel could be consulted by the MS if they run into a problem in a particular area or if they don't have the expertise in house to address the issue. The panels conclusion will then become the harmonised approach/position amongst the MS. The experts in the panel should work at a competent authority. Such a panel could also use their expertise to check on the feasibility of the GD in their area and to see if there are any ways to simplify the GD.

Risk assessment (RA)

Simple risk assessments over time started to expand in scope to reflect scientific advancement, scientific methodology and reality. If an assessment doesn't pass at Tier I then higher Tier refinements are required and this data need to be considered. This can be very time consuming but is a regulatory requirement and therefore needed.

Not every assessment will require the full higher Tier assessment as it may pass at Tier I. Risk assessment can be much simpler (and faster) for 'biocontrol' products but for a chemical product it can be much more complicated. Adding refinements doesn't necessarily make the product safer, but the risk assessment covers more realistic use scenarios, and the need for more specific risk mitigation measures is often identified after refinements. The practicality for the farmers of the risk mitigation measures proposed needs to be considered. It may be hard to reduce the complexity as there are so many new areas that are looked at now compared to 10 years ago.

Post-authorisation monitoring could be used to look at the actual residue levels found in the various compartments to see if the risk mitigation measures are working effectively under practical use conditions. And post-authorisation monitoring could be used for very complex issues that are difficult to assess a priori, e.g. effects on biodiversity and cumulative effects. A GD on monitoring is already available, and electronic record keeping by professional users will become mandatory in January 2026, making available use data on pesticides which would facilitate monitoring programmes and enforcement.

Training sessions for experts

Training is needed for experts, especially for new experts that don't have yet a lot of experience. Sometimes different MS accept/don't accept the same study because of a difference in their expertise and experience levels. EFSA could organise training workshops on the various new issues (bees, aquatics, genotoxicity, etc.) that would allow experts to get a better understanding of the various issues. It would also enable a more harmonised approach to evaluation work.

Risk mitigation

Risk mitigation is often needed to make sure that a product complies with the regulation and can be authorised (e.g. reduce the dose, reduce the number of treatments per year etc.). The competent authority then must re-calculate and this is time consuming. Harmonisation/agreement on risk mitigation measures across the EU is challenging as it varies from MS to MS. Setting Risk Mitigation Measures when granting authorisations is a national responsibility. The applicants may have different approaches to risk mitigation measures so this can add to the workload. Risk mitigation is often national specific, which can result in a mutual recognition application being rejected. Where possible, more harmonisation amongst MS is needed, e.g. with regard to the degree of risk reduction by often used mitigation measures (e.g. percentages of drift reduction of the different spray drift reducing

techniques (e.g. 50%, 75%, 90%)) for the approval of active substances (MAGPIE-approach) and the assessment of PPPs.

The record keeping of the farmers will be key to identifying if the risk mitigation measures are working. Farmers will have to keep their records in electronic format from 2026. EU level GD needed to ensure that the monitoring systems are fit for purpose. Monitoring is also important to look at resistance (for efficacy).

How the workload is shared between the MSs?

In the Southern Zone and Central Zone, the Article 43 product allocation is carried out centrally in order to share the workload evenly.

Overall wrap up

- A feasibility check is needed during the development of guidance documents and before finalisation to ensure that the guidance document produced is fit for purpose. More Member State input is required. Criteria are needed for the feasibility check.
- Guidance documents should be routinely evaluated to see if they remain fit for purpose and then should be amended as necessary. This could happen after a set number of years, after MS and EFSA have had a chance to work with the GD and have a better understanding of what may need to be changed/amended.
- Training sessions for experts, from MS and applicants, in the use of new/amended guidance documents (as has been organised by European Commission with EFSA and ECHA for the new endocrine disruption criteria).
- Set up a pilot “excellence network” with experts from the MS. The experts should have specialised knowledge/expertise in a specific area (e.g., on the use of a particular guidance document or ecotoxicology refinement etc.). They can then be consulted on their areas of expertise by experts in the other MS. The outcomes could then be catalogued so that all experts can learn the agreed approach to the various issues. This could be developed in combination with the EFSA training platform?
- CAs perform risk assessment before authorisation. For very complex issues, e.g. higher tier/refined risk assessment, cumulative effects, make more use of monitoring of effects in the environment in practice in order to implement an additional safety net for these complex issues (monitoring data could trigger regulatory action).

2.2.2 Prioritisation discussion

The workload both in terms of active substance and plant protection product evaluations has increased significantly over the last number of years. Unfortunately, capacity in the MS, COM and EFSA has not increased to reflect the increased workload. In addition, additional work has impacted on evaluation timelines at authorities for example briefing documents, policy advice, responding to media queries, disclosure requests etc. The generation of ED data and the ED evaluation itself has resulted not only in a backlog due to the ED-stop-the-clock (temporary situation), but in significant additional work for the MS. There is an urgent need to prioritise the workload to maximise output. Although the ZAPID workshop was supposed to focus exclusively on PPPs it was decided that it was necessary to look at the complete workload to come up with the most practical solutions.

Ideally, deadlines should be changed in Regulation (EC) No 1107/2009 to make them more realistic however this may not be possible as the legislation will not be reopened. In the legislation, the

maximum amount of time allowed for authorising an active substance is 15 years (maximum of 10 years for an active substance at first approval and a maximum of 15 years at renewal). The renewal of active substances takes up time from applicants and MS, as well as EFSA and COM. The peaks in PPP renewals are difficult to manage for MS. During the renewal process, industry loses the opportunity for label extensions as MS won't do a label extension until the end of the renewal. Where possible, giving active substances the full 15 years at renewal is necessary to help alleviate the pressure on MS.

COM used to extend approvals for 1 year (Article 17 of Regulation (EC) No 1107/2009), however, they now extend on a case-by-case basis based on realistic estimates, which allows them to prolong for longer periods of several years.

Delays in active substance renewals have a knock-on effect on the product authorisations. If the product has more than one active substance, if the active substances have an expiry date within one year, then MS wait until the second active substance is renewed before they carry out the evaluation. However, sometimes the second active substance gets extended, and MS would need to carry out two evaluations of the product. If there are three active substances in the product then the situation can become more complicated, and MS potentially can have 3 evaluations to perform. This is not feasible in terms of maximising MS resources. Should MS return to the 91/414 system and wait until the last active substance is renewed before carrying out the evaluation? However, as a consequence, it will take longer for new scientific data and new GDs to be taken into account. But in case new insights are more critical, it is at any time possible to perform a re-assessment in case needed, based on article 44 and/or 56 of Regulation (EC) No 1107/2009.

If the assessment of an active substance is delayed as a result of an open point (e.g. ED) then it should only be the open point that is looked at when the new data is submitted. The rest of the evaluation should not be re-opened. And in general, it saves time at PPP level if data gaps can be solved during the active substance evaluation as much as possible.

CAT 4 studies cause delays for the PPP renewals. EFSA conclusions have long list of data gaps. EFSA are now being asked to qualify the data gaps. Identifying if data gaps are 'nice to know' versus 'need to know', is an important improvement. The extension of timelines for the renewal of PPPs creates a problem for generic companies as they must wait longer to get their products on the market (increase in the frozen period).

Prioritisation of the active substance review program based on several factors was discussed, like for instance the risk profile of the active substance, the potential impact on biodiversity, low-risk active substances, and candidate for substitution (concept should be hazard based not high risk). Postponing some of the AIR 4 substances that are considered low-risk to make space for other work that the MS have would be an option. The possibility of granting low-risk substances unlimited approval was also mentioned as a possibility. This is probably unrealistic as Regulation (EC) No 1107/2009 would have to be re-opened. Also, not all participants were in favour of this approach.

The chair showed the group an excel tool developed in the Netherlands to estimate the EU workload over the coming years. The goal of this is to visualise the workload and the need to make deliberate choices instead of the situation that the day-to-day business rules.

At EU level, the prioritisation of active substance assessments was considered a good idea. However, it may not be feasible for MS to prioritise PPPs, as Regulation (EC) No 1107/2009 does not give MS a mechanism for prioritisation of plant protection products. Most MS have a first-in/first-start setup for the evaluation of PPPs. An EU GD for the prioritisation of evaluations would be helpful to address this problem. In addition, a GD may help MS prioritise their PPP workload without changing their

national legislation. One MS mentioned that they now have two lanes, a chemical lane with a first in first start system and a "green" lane with a first in first start system.

Overall wrap up

- Priority setting for the evaluations of active substances and PPPs is needed at EU level.
- Criteria should be laid down (in GD? Or explanatory notes? Or…?). Advice from BOG 1 is to prioritise
- new active substances
- renewal of potentially low-risk active substances (to get official low-risk status)
- new (innovative) products and new low-risk products
- label extensions for low-risk products and for PPP which add a new use/mode of action
- renewal of active substances that are candidates for substitution (CfS) and PPP based on CfS; all other renewals are deprioritised
- PPP applications that can prevent emergency authorisations
- PPP applications for minor uses
- For plant protection products where there is more than one active substance, the evaluation should be carried out after the last active substance is finalised i.e. only one product evaluation at renewal. Unless one of the active substances is a candidate for substitution. But in case new insights are more critical, it is at any time possible to perform a re-assessment in case needed, based on article 44 and/or 56 of Regulation (EC) No 1107/2009.

2.2.3 Centralised system for product allocation of new products (Article 33) with the aim of finding available MS capacity

The centralised zRMS allocation for new applications was discussed.

Advantages/Pros

- Identification of available capacities in alternative MSs – Some MSs would welcome additional zonal assessments.
- Identification of similar applications in more than one zone – possibility of the non-environmentally related assessment to be carried out in one zRMS and avoid duplication in the other zones.
- Possibility of clustering comparable applications in one MS to allow harmonisation and efficiency gains.
- Avoid the situation where an applicant submits the same application in more than one MS in the same zone or a subsequent application to a new zRMS following a negative decision.
- Increased transparency for MSs on new applications (ongoing and planned).

Disadvantages/Cons:

- Increased coordination costs at both national and zonal level – an additional layer of coordination leads to additional resource consumption for that task.
- MSs are avoiding applications due to existing workload and therefore might not easily volunteer for new incoming applications.
- Industry prefers to choose a zRMS and might not agree to a reallocation to another zRMS. There are several reasons for the applicants to prefer one zRMS over another one:
    - familiarity of communication with a particular authority or inexistence of language barriers that might exist elsewhere
    - timelines (and consequence on time to market),

- expertise in certain fields or type of PPP,
- level of national requirements and administrative documents,
- communication possibilities with the applicant (ex: pre-submission meetings),
- possibility for data call-in during the evaluation,
- different fees in place.

Overall, industry highlights this central allocation would jeopardise their regulatory (market) strategy

- Reallocation might be limited by legal issues – Legal advice is needed on the possibility of reallocation against the applicants' wishes.
- Distribution criteria will be needed (when the volunteering MSs available capacity is not enough for the demand).
- Removal of autonomy and control from the MSs on incoming workloads (black box for future applications).
- Allocation is different than application – allocation could be carried out centrally, but application must be made in the zRMS allocated.
- For Article 43 an application deadline is foreseen of 3 months after entry into force of active substance renewal. However, for Article 33 new applications are not subject to such strict deadlines. A deadline proposed or accepted by the applicant might not be met, leading to capacities left unused and to reshuffling of workloads, possibly with new reallocations to other MSs.
- Available capacity is at least two-fold: resources available in total numbers, but also resources available with the necessary knowledge set for specific applications (e.g. biopesticides) – resources available might not have the necessary skills/ knowledge for the next allocated application.
- Legal – in Regulation (EC) No 1107/2009 – the applicant should mention who they would prefer to carry out the evaluation – this gives an expectation that that MS should be the one to carry out the evaluation.

Overall wrap up

- Subject is about centralised notification of applications and subsequently a centrally organised allocation. The application itself is submitted to the zRMS.
- Aim of centralised notification is to use the available capacity at CAs in line with the EU priority setting for applications and achieve a more balanced division of applications across all CAs.
- The breakout group had discussed advantages and disadvantages. The overall opinion of the breakout group is that for now it is not useful to start centralised allocation of notifications of applications.

2.2.4 Quality of dossiers

Pre-submission meetings are very important to help improve the quality of dossiers (both for active substances and PPP) and the applicant has the right to ask for a pre-submission meeting under the transparency regulation. Industry finds pre-submission meetings helpful and argues that joint pre-submission meetings (across several Member States) could also be used to discuss and share work for common areas of the dossier or the evaluation of new active substance data (e.g. aquatic data) necessary to show a safe use. However, it should be noted that it's difficult for experts to give their opinions without looking at the dossier. Therefore, advice tends to be more general and based on issues that have arisen in the past. In some MS, sometimes the expert giving the opinion in the meeting is not the expert who does the evaluation, and they might have a different

opinion/interpretation, which can cause problems. In addition, it is important to communicate the agenda, presentation and related briefing documents, as well as the outcomes of pre-submission meetings effectively by applicants and by MSs, and also within the MS competent authority. Information given in pre-submission meetings on waivers has been very helpful in the past. France for example has general recommendations that they provide to each applicant once they accept an application. All the sections are covered in the document. A face-to-face meeting can only be held on specific issues.

MS inform applicants based on their experience but are of course no consultants. For other aspects/queries applicants with little experience of the process may find it helpful to go to a consultant.

MS, COM and EFSA published information on their websites about the different procedures and what is required to guide the applicant into providing a good-quality dossier.

The completeness check process is very important. MS should be very strict during the completeness check. If something is missing, the dossier should be sent back to the applicant to fix. Having the completeness check before the evaluation begins i.e. before the clock starts, is very helpful. This way MS can discuss problems with the applicant before the evaluation begins. In addition, a technical completeness check by the zRMS allows to identify possible data gaps and at the same time provides the applicant the opportunity to update the dRR accordingly. Some MS isolate the completeness check in this way from the timeline of the project so that doing a full completeness check doesn't impact on the timelines. The date of application is only when the completeness check has been finalised and the dossier has been deemed complete.

Quality of the dossier is often an issue for mutual recognition, specifically in case the original risk assessment is relatively old and based on a dossier of less quality.

Industry is sometimes confronted by different opinions which makes it harder to provide a quality dossier. Industry needs a better understanding of what the quality issues/problems are so that they can try to fix them for the future. Some frequent issues are:

- GAP tables can have a lot of uses which may impede the evaluation.
- The use of waivers can potentially be an issue. Waivers must be scientifically robust and provide a well-reasoned argument for non-submission of data.
- The use of endpoints deviating from the EU LoEP (List of Endpoints) by the applicant can result in the RMS having to re-do the risk assessment. EU endpoints should be used and there should be consistency in the use of endpoints for similar products. But applicants sometimes also face RMS deviating from EU agreed endpoints.
- Not following the correct methodology for the evaluation can cause problems for the evaluation and impact on timelines.
- Good communication between the applicant and the MS is very important to help alleviate some of these issues.

Overall wrap up

- All information needed to submit a complete and high-quality dossier is published on the websites of the competent authorities (CA), European Commission and EFSA.
- Due to the high complexity of the regulatory framework, it might be helpful if applicants with no or limited experience with Regulation (EC) No 1107/2009 seek the advice of a consultant.

- The completeness check and exchange with the applicant prior to evaluation concerning the completeness check is extremely important. CAs to reject an incomplete dossier to increase efficiency.
- Quality of dossiers is partly subjective, not everything is harmonised. CAs to communicate the main issues they face to applicants.
- The BOG shared best practices with respect to a pre-submission meeting (PSM) and suggests that CAs and applicants adhere to these best practices. Communicating on recurring main issues with the applicant and applicant organisations can result in higher quality dossiers.
- It is important that the applicant follows the applicable guidance documents and uses the EU agreed endpoints. Otherwise, a lot of recalculation is needed to complete the evaluations. CAs do not always act in a harmonised way about which GDs and EU agreed endpoints are applicable.
- A continuing issue is the mutual recognition dossier for a product that has been evaluated long time ago.
- It is not clear how to deal with new information/knowledge (court case ongoing at the European Court of Justice).

2.2.5 Industry presentation for tackling delays

A short presentation by CropLife Europe was provided to the breakout group, containing several proposals for efficiencies that will help with timelines.

- Joint pre-submission meetings (across several Member States) could also be used to discuss and share work for common areas of the dossier or the evaluation of new active substance data CLE would see a benefit in having Zonal guidance documents in each of the zones readily available with easy access and a transparent update schedule. Commenting period – applicant to help zRMS respond to cMS comments. This could have a positive impact on the zonal process, by reducing delays at cMS level or avoid refusal at that stage if for some reason cMS comments were not (fully) answered by the zRMS.
- Quality of the dossier – no clear criteria to define quality.
- CropLife Europe has position papers on all aspects of the zonal system which may help to identify efficiency gains (e.g. on Article 43 challenges – not discussed in ZAPID).

2.3 Summary table

Topic	ID	Summary of Discussion and conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
Complexity of assessment methodologies	1.1	A feasibility check is needed during the development of guidance documents and before finalisation to ensure that the guidance document produced is fit for purpose. More Member State input is required. Criteria are needed for the feasibility check.	Include feasibility check in the process of guidance development and set criteria for the feasibility check / EFSA Sub-action: Criteria for feasibility to be defined. Input collection for feasibility criteria by stakeholders in 3-month consultation, followed by endorsement and communication by COM and PAI	Short term (action was already agreed in HLM (High Level Meeting) of 2020 Short term
	1.2	Guidance documents should be routinely evaluated to see if they remain fit for purpose and then should be amended as necessary. This could happen after a set number of years, after MS and EFSA have had a chance to work with the GD and have a better understanding of what may need to be changed/amended.	Develop a process for evaluation of guidance documents / COM	Medium term
	1.3	Training sessions for experts (MS/applicants) in the use of new/amended guidance documents (as has been organised by European Commission with EFSA and ECHA for the new endocrine disruption criteria).	Organise training sessions for experts (MS/applicants) for new/amended guidance documents / EFSA	Short term
	1.4	Set up a pilot “excellence network” with experts from the MS. The experts should have specialised knowledge/expertise in a specific area (e.g., on the use of a particular	Set up a pilot “excellence network” with experts	Medium term

Topic	ID	Summary of Discussion and conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
		guidance document or ecotoxicology refinement etc.). They can then be consulted on their areas of expertise by experts in the other MS. The outcomes could then be catalogued so that all experts can learn the agreed approach to the various issues. This could be developed in combination with the EFSA training platform?	from the MS / PSN, in collaboration with EFSA	
	1.5	CAs perform risk assessment before authorisation. For very complex issues, e.g. higher tier/refined risk assessment, cumulative effects, make more use of monitoring of effects in the environment in practice in order to implement an additional safety net for these complex issues (monitoring data could trigger regulatory action).	Make more use of monitoring of effects in the environment in practice / PAI	Medium term
Prioritisation discussion	1.6	Priority setting for the evaluations of active substances and PPPs is needed at EU level.		
	1.7	Criteria should be laid down (in GD? Or explanatory notes? Or…?). Advice from BOG 1 is to prioritise: • new active substances • renewal of potentially low-risk active substances (to get official low-risk status) • new (innovative) products and new low-risk products • label extensions for low-risk products and for PPP which add a new use/mode of action • renewal of active substances that are candidates for substitution (CfS) and PPP based on CfS; all other renewals are deprioritised • PPP applications that can prevent emergency authorisations • PPP applications for minor uses	Lay down criteria for priority setting / COM	Short term
	1.8	For plant protection products where there is more than one active substance, the evaluation should be carried out after the last active substance is finalised i.e. only one product evaluation at renewal. Unless one of the active substances is a candidate for substitution. But in case new insights are more critical, it is at any time possible to perform a re-assessment in case needed, based on article 44 and/or 56 of Regulation (EC) No 1107/2009.	For PPPs with >1 active substance: perform 1 PPP renewal after finalisation of the last active substance, unless one of the active substances is a CfS / PAI	Medium term

Topic	ID	Summary of Discussion and conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
Centralised system for product allocation of new products (Article 33)	1.9	Subject is about centralised notification of applications and subsequently a centrally organised allocation. The application itself is submitted to the zRMS.		
	1.10	Aim of centralised notification is to use the available capacity at CAs in line with the EU priority setting for applications and achieve a more balanced division of applications across all CAs.		
	1.11	The breakout group had discussed advantages and disadvantages. The overall opinion of the breakout group is that for now it is not useful to start centralised allocation of notifications of applications.		
Quality of dossiers	1.12	All information needed to submit a complete and high-quality dossier is published on the websites of the competent authorities (CA), European Commission and EFSA.		
	1.13	Due to the high complexity of the regulatory framework, it might be helpful if applicants with no or limited experience with Regulation (EC) No 1107/2009 seek the advice of a consultant.	Due to the high complexity of the regulatory framework, it might be helpful if applicants with no or limited experience with Regulation (EC) No 1107/2009 seek the advice of a consultant. / applicants	Short term
	1.14	The completeness check and exchange with the applicant prior to evaluation concerning the completeness check is extremely important. CAs to reject an incomplete dossier to increase efficiency.	The completeness check and exchange with the applicant prior to evaluation concerning the	Short term

Topic	ID	Summary of Discussion and conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
			completeness check is extremely important. CAs to reject an incomplete dossier to increase efficiency. / CAs	
	1.15	Quality of dossiers is partly subjective, not everything is harmonised. CAs to communicate the main issues they face to applicants.	Communicate to applicants on recurring main issues with regard to quality of dossiers / PAI	Short term
	1.16	The BOG shared best practices with respect to a pre-submission meeting (PSM) and suggests that CAs and applicants adhere to these best practices.	Adhere to best practices for a pre-submission meeting (PSM) / CAs and applicants	Short term
	1.17	It is important that the applicant follows the applicable guidance documents and uses the EU agreed endpoints. Otherwise, a lot of recalculation is needed to complete the evaluations. CAs do not always act in a harmonised way about which GDs and EU agreed endpoints are applicable.	Follow applicable guidance documents and use EU agreed endpoints / applicants and CAs Make a clear overview of the available GDs and the into force date / COM CAs should adhere to the overview of available GDs and the into force date / CAs	Short term

Topic	ID	Summary of Discussion and conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
	1.18	A continuing issue is the mutual recognition dossier for a product that has been evaluated long time ago.	This will phase out in the future (quality of dossiers is improving due to increasing experience with Regulation (EC) No 1107/2009. Phasing out of mutual recognition based on dossiers under 91/414 will help). Also. COM could ask their legal service for a new evaluation of this problem / COM	Medium term
	1.19	It is not clear how to deal with new information/knowledge (court case ongoing at the European Court of Justice)		

3 BREAKOUT GROUP 2
Harmonising zonal decision making – Special focus on Mutual Recognition, minor uses, and assessment of co-formulants

3.1 Thought starter

The following document has been prepared as a thought starter to initiate discussions in the Breakout Groups and should in no way be conceived as the official position of the European Commission or the Member States.

3.1.1 Background

General

The objective of Regulation (EC) No 1107/2009 (hereafter referred to as "the Regulation") is to ensure a high level of protection for human and animal health, the environment, improve the functioning of the internal market through harmonisation whilst at the same time maintaining the competitiveness of EU agriculture and improving agricultural production. Furthermore, the regulation aims to increase the free movement of plant protection products (PPPs) and availability of those products in the Member States (MSs). There are numerous provisions within the regulation which aims to support these objectives, including an EU wide active substance approval procedure, zonal evaluation and mutual recognition systems and procedures for dealing with minor uses of PPPs.

Through this breakout group we will discuss the issues surrounding the interpretation and implementation of the provisions of mutual recognition, minor uses and the recently introduced concept of harmonised assessment of co-formulants.

Mutual Recognition

In the regulation the principle of mutual recognition is seen as one of the means of ensuring free movement of goods with the EU. Mutual recognition of product authorisations is built on the assumption that the assessment of a product dossier completed by one MS **shall** not be repeated by other MSs, except for clearly defined circumstances, thereby reducing administrative burdens for industry and MSs. It is based on a system of trust achieved through harmonised data requirements, harmonised product assessment parameters and harmonised guidance to facilitate that data generation and assessment.

The concept of mutual recognition of authorisations has been in place since the inception of Directive 91/414/EEC through Article 10 of that directive. However, this article was not widely used under the directive because applicants in a lot of cases were forced to provide significant data to prove that agricultural, environmental and climatic conditions between the 2 MSs were comparable. Furthermore, it was not always obvious where an authorisation was authorised in accordance with the uniform principles and in some instances it was easier to obtain a product authorisation through the national systems still operating in some of the MS. Some MSs did make use of this provision throughout the lifetime of the Directive, in particular as more substances were included in Annex I and product authorisations were authorised in accordance with agreed EU guidance and the uniform principles. With the introduction of Regulation (EC) No 1107/2009, the zonal system of authorisation was introduced with the intention of ensuring co-operation between MSs with comparable climatic conditions. The Regulation under Articles 40-42 also provides for the possibility of mutual recognition of product authorisations. Article 51.7 provides for the mutual recognition of

authorisations for minor uses and this topic will be discussed in more detail under the next subheading.

Minor Uses

Regulation (EC) No 1107/2009 defines minor use as follows:

"means use of a plant protection product in a particular Member State on plants or plant products which are:

a. not widely grown in that Member State; or
b. widely grown, to meet an exceptional plant protection need".

Use of the terms "minor use" or "minor crop" may infer that these are less important than other crops, but minor crops have a high economic value for farmers. Despite this, minor crops tend to be of low economic interest for authorisation holders and the crop protection industry due to the difficulties in getting a return on the significant investment required to gain authorisation.

It should be noted that various regulatory channels are open to applicants to apply for authorisation of and extension of authorisations for minor uses. These include applications through Article 33, Article 40 and Article 51. Whilst it is expected that applications through Article 33 are made by the authorisation holder themselves, applications under Article 40.2 and Article 51 can be made by those other than the authorisation holder such as official or scientific bodies, professional agricultural organisations or professional users where the intended use is in the public interest. Furthermore, Article 51.3 prescribes that MSs may take measures to encourage the submission of applications for extension to minor uses. Applications for an extension to minor uses of an already authorised product may also be made by those other than the authorisation holder in accordance with Article 40.1. Despite these possibilities, it is evident that these provisions are not widely availed off in all MSs.

The study published in 2018 as part of the REFIT process highlights some particular issues in relation to minor uses. These include; the lack of clarity around the rules for the minor use process, the lack of harmonisation between MSs in dealing with minor use authorisations, over reliance on the use of Article 53 emergency use authorisations and the costs relating to extensions of authorisations for minor use. Overall, the report highlighted that "The availability of PPPs for minor uses is being negatively affected by a lack of implementation of the Regulation".

The EU Minor Use Co-Ordination Facility (MUCF) established in 2015 with the financial support of the EU Commission and four MSs. The MUCF is comprised of a range of stakeholders including producer organisations, industry associations, research institutes, regulators, and government experts from EU and non-EU countries. By coordinating collaboration and exchange of data the MUCF aims to support the availability of crop protection solutions for minor uses and thereby making the growing of speciality crops in Europe sustainable and competitive. In 2021, an explanatory note on minor use procedures which was prepared and developed by expert members of the MUCF was endorsed by SCoPAFF (legislation). The document is aimed at providing guidance for applicants and authorities in applying for and assessing minor use applications.

Assessment of co-formulants

Co-formulants as defined under Regulation (EC) No 1107/2009 are substances or preparations which are intended to be used in a PPP or adjuvant but are neither active substances nor safeners nor synergists. Co-formulants contained in PPPs can take the form of very simple benign substances or of very complex preparations containing a multitude of substances. The vast majority of co-formulants are not used exclusively in PPPs can be regulated under various legislation including

REACH, biocides, cosmetic, food and feed additive legislation. Furthermore, hazardous substances placed on the market in the EU are subject to the rigours of CLP legislation.

Evaluation of co-formulants must be undertaken as part of both the representative product assessment for the EU approval of the active substance and as part of each individual PPP authorisation assessment.

Co-formulants which are not accepted for inclusion in a PPP (i.e. unacceptable co-formulants) must be listed in Annex III to Regulation (EC) No 1107/2009. In 2021 Commission Regulation (EU) 2021/383 amended Annex III and 144 unacceptable co-formulants were listed. However, a separate legislative process for the identification of unacceptable co-formulants was necessary and in March 2023 Commission Implementing Regulation (EU) 2023/574 laid down detailed rules for the identification of such co-formulants. Despite the provisions contained in this regulation it is evident that further guidance and resources are required so as to achieve a transparent, efficient and harmonised assessment process. Development of guidance on the assessment process and development of a database of co-formulants should take part in parallel. Workshops organised by the Commission and EFSA during 2023 identified some challenges that could impede the objectives mentioned above. Access to and availability of data on the co-formulants, resource requirements and non-duplication of work, equivalency checks and general communication were identified as some of the key challenges.

3.1.2 Discussion points

Mutual Recognition

The discussion should focus on the difficulties in implementing mutual recognition in the MSs, what obstacles are creating the difficulties and what measures can be used to ensure the correct implementation of all mutual recognition possibilities. Participants are invited to share best practices employed in the implementation of mutual recognition and the impediments that prevent its use. The following non-exhaustive list of discussion points and questions can be used by participants in developing the discussion:

- Are national requirements artificially creating obstacles especially where they may not be perceived to be scientifically justified?
- Can a common compendium of risk mitigation measures to be used in product evaluations allow for more consistency in outcomes /authorisations?
- Is there a balance to be struck in the application of “noted”/ “endorsed” guidance and the autonomy and subsidiarity principle for member states?
- Is there a need for or the legal possibility for a dispute settlement process similar to that used in biocides co-ordination group?

Minor Uses

The discussion should investigate the problems encountered by authorities and applicants when dealing with applications for minor uses. Considering the conclusion of the REFIT report that the availability of PPPs for minor use are been negatively affected by the lack of implementation of the legal parameters, participants should discuss all the avenues available for dealing with minor use authorisations considering the flexibilities provided for in Regulation (EC) No 1107/2009. The following non-exhaustive list of discussion points and questions can be used by participants in developing the discussion:

- Would a harmonised list of EU minor crops (or harmonised lists within the 3 regulatory zones) facilitate more availability of PPPs for minor uses?
- Is the lack of cohesion between Regulation (EC) No 1107/2009, Regulation (EC) No 396/2005 (and associated guidance documents) and EPPO requirements/guidance a hindrance to the minor use authorisation process?
- What role can the Minor Use Co-ordination Facility play in enabling harmonisation (e.g. development of guidance, development of databases etc.) in the minor use sphere.
- Is the risk envelope approach, zonal authorisation system and mutual recognition being used to the full extent and what is impeding the application of the full raft of possibilities by the member states?

Assessment of co-formulants

The discussions should focus on the policy of the implementation of assessment of co-formulants and identification of unacceptable co-formulants. Discussions on the development of a centralised databases and the maintenance of such a database will be discussed in detail in breakout group 3.

- Can the identification of unacceptable co-formulants be addressed by other regulatory regimes such as REACH, biocides or CLP or is a separate data evaluation by the PPP competent authority required in each and every case?
- Will the application of Regulation (EC) No 2023/574 slow down the already delayed PPP authorisation and renewal processes? Will a centralised repository of co-formulant assessments be fully used by member states given the historical reluctance for full trust in other member state evaluations?
- Does the current legal text provide applicants and member states with sufficient direction on the implementation of the requirements and if not how broad of a scope should a guidance document take?
- How will co-formulants where “sufficient” data is not already available be dealt with? Do the legal conditions exist to abstract this data from third parties and how will third party data be dealt with considering proprietary data issues and confidentiality?

Background Information

Guidance Document on Zonal Evaluation and Mutual Recognition

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

2014 Commission Report on Minor Uses

Explanatory Note on Minor Uses April 2022

EFSA technical report on data on co-formulants in products submitted for representative uses in the dossiers for active substances, including information from other EU legislation.

Report on the workshop on the assessment of plant protection products and co-formulants

Technical workshop on risk assessment for plant protection products | EFSA (europa.eu)

Link to EU Minor Uses Database website - EU Minor Uses EUMUDA Database - Home page

Link to MUCF website - EU Minor Uses Coordination Facility - Home page

3.2 Summary report

3.2.1 Background

Mutual Recognition

In the Regulation (EC) No 1107/2009 (hereafter referred to as “the Regulation”) the principle of mutual recognition is seen as one of the means of ensuring free movement of goods with the EU. Mutual recognition of product authorisations is built on the assumption that the assessment of a product dossier completed by one Member State (MS) shall not be repeated by other MSs, except for clearly defined circumstances, thereby reducing administrative burdens for industry and MSs. It is based on a system of trust achieved through harmonised data requirements, harmonised product assessment parameters and harmonised guidance to facilitate that data generation and assessment.

With the introduction of Regulation (EC) No 1107/2009, the zonal system of authorisation was introduced with the intention of ensuring co-operation between MSs with comparable climatic conditions. The Regulation under Articles 40-42 also provides for the possibility of mutual recognition of product authorisations. Despite the regulatory avenues and guidance available, it is obvious that there are difficulties for MSs and applicants alike in achieving an efficient and pragmatic approach to the implementation of mutual recognition.

Minor Uses

In general, minor crops and minor uses, despite having a high economic value for farmers, tend to be of low economic interest for authorisation holders and the crop protection industry due to the difficulties in getting a return on the significant investment required to gain authorisation.

Various regulatory channels are open to applicants to apply for authorisation of and extension of authorisations for minor uses. These include applications through Article 33, Article 40 and Article 51. According to articles 40.2 and 51.1, applications for authorisation of minor uses can be made by those other than the authorisation holder such as official or scientific bodies, professional agricultural organisations or professional users where the intended use is in the public interest. Furthermore, Article 51.3 prescribes that MSs may take measures to encourage the submission of applications for extension to minor uses. The EU Minor Use Co-Ordination Facility (MUCF) established in 2015 coordinates the collaboration and exchange of data to support the availability of crop protection solutions for minor uses and thereby making the growing of speciality crops in Europe sustainable and competitive. Despite all the regulatory possibilities and supports available, it is evident that these provisions are not widely availed off in all MSs. This was highlighted in the REFIT study published in 2018 were it reported that “The availability of PPPs for minor uses is being negatively affected by a lack of implementation of the Regulation”.

Assessment of co-formulants

Co-formulants as defined under Regulation (EC) No 1107/2009 are substances or preparations which are intended to be used in a PPP or adjuvant but are neither active substances nor safeners nor synergists. The vast majority of co-formulants are not used exclusively in PPPs can be regulated under various legislation including REACH, biocides, cosmetic, food and feed additive legislation. Furthermore, hazardous substances placed on the market in the EU are subject to the rigours of CLP legislation.

Evaluation of co-formulants must be undertaken as part of both the representative product assessment for the EU approval of the active substance and as part of each individual PPP authorisation assessment.

Co-formulants which are not accepted for inclusion in a PPP (i.e., unacceptable co-formulants) must be listed in Annex III to Regulation (EC) No 1107/2009. In 2021 Commission Regulation (EU) No 2021/383 amended Annex III and 144 unacceptable co-formulants were listed. However, a separate legislative process for the identification of unacceptable co-formulants was necessary and in March 2023 Commission Implementing Regulation (EU) No 2023/574 laid down detailed rules for the identification of such co-formulants. Despite the provisions contained in this regulation it is evident that further guidance and resources are required so as to achieve a transparent, efficient and harmonised assessment process. Development of guidance on the assessment process and development of a database of co-formulants should take part in parallel. Workshops organised by the Commission and EFSA during 2023 identified some challenges that could impede the objectives mentioned above. Access to and availability of data on the co-formulants, resource requirements and non-duplication of work, equivalency checks and general communication were identified as some of the key challenges.

3.2.2 Discussion

Mutual Recognition

At the start of the discussions a tour de table was held to identify what the participants considered the positives of mutual recognition and what was considered to be obstacles and problems with the mutual recognition procedure. The result of this was that the participants see that the non-duplication of work, a faster path to access to the market for PPPs, and that past experiences and developments have led somewhat towards more harmonisation across the wider PPP authorisation landscape. Despite these identified advantages it was obvious from the contributions that significant hurdles still exist in some areas which prevents the appropriate implementation of the provisions in all MSs.

National requirements in relation to specific environmental or agricultural conditions in a MS are permitted according to Article 36(3) of the regulation. These national specific requirements must be technically or scientifically justified. However, it was clear during the discussions that some national requirements are not always clearly justified and may not be in compliance with Article 36(3) in some circumstances. National specific requirements obviously slow down the authorisation process which in turn results in the 120-day timeframe for examination being exceeded. Because of this prescribed 120-day time period, some MSs are reluctant to assess additional national data under the mutual recognition procedure and will request that applications are submitted under the Article 33 procedure. It also became obvious during the discussions that it is not always possible for applicants to determine what the national requirements are in each MS and that this can lead to a hesitancy in applying for mutual recognition. It was also highlighted that despite different national requirements and extra assessments that the outcome doesn't change from the original MSs assessment.

A number of different aspects in relation to so called "old assessments" were brought up by the group as creating obstacles in certain circumstances. Discussions concentrated on the interpretation of guidance documents and agreements, the misconception that assessments need to be updated to today's requirements (i.e. Article 36(1)), lack of clarity in the original assessment process, old registration report formats and core dossier assessments.

A considerable length of time can pass between the original assessment and the request for mutual recognition in another MS. At the time of submission to the original MS an applicant may not have

considered applying elsewhere. When mutual recognition is then applied for in a new market, the original data and risk assessment may not have considered areas relevant in this new market. This is particularly pertinent in the area of the environmental assessment where all FOCUS scenarios are not considered in the original assessment. Older assessments which were evaluated prior to the agreement on the standardised dRR format can be difficult to interpret and can lack transparency. This creates the situation where some MSs refuse an application under Article 40 or insist on conducting a completely new risk assessment (which could then be evaluated using new endpoints and guidance). It should be noted that several MSs participating in the group stated that this is not the case in their countries and it is not legislated for in the current regulatory framework. Situations where new risk assessments under Article 40 are carried out can result in product authorisations for very similar products having different crops approved, different conditions of use and different risk mitigation measures. This leads to confusion for farmers and enforcement authorities alike.

The group briefly touched on the Article 40.2 provision whereby an application for authorisation could be made by an official or scientific entity in the absence of an application by the data holder. However, members of the group had very little experience in this situation although obstacles such as lack of access to the dossier, issues with the logistics of labelling and sourcing product and issues with liability and indemnity were considered as significant and a barrier to adoption of the provision. 1 MS indicated that they keep open lines of communication with applicants so that when the need for a product authorisation is brought to their attention by a grower organisation for example that they can encourage the data holder to make a regular mutual recognition application.

The last topic which arose in the group was the idea that an arbitration process (similar to that of the Biocides Co-ordination Group) be established that deals with disagreements in mutual recognitions and zonal assessments. The group was informed that this topic had been previously discussed in the Post Approval Issues Working Group and it was agreed in the Working Group that this wasn't feasible from a resource point of view with respect to what could be achieved from having such a process in place.

Minor Uses

The group discussed the various definitions of minor and major crops across the various linked legislations and guidance. It was highlighted that the definition in Regulation (EC) No 1107/2009 refers clearly to the cultivation area. In EPPO standard PP 1/224(2) on the 'Principles of efficacy evaluation for minor use,' minor/major refers to economic importance. In the Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs, SANCO 7525/VI/95, Rev. 10.3, 13 June 2017 daily intake in combination with cultivation area/production are the criteria used for classifying a crop or commodity as 'major' in the European Union. It was clear from the discussions that there is a reluctance amongst some MSs to change from their national criteria and this comes from different or even opposite perceptions. For example, some MSs are concerned that an EU wide definition would reclassify a current major crop to a minor crop and that this would somehow diminish the importance of the crop whilst others were concerned that minor crops would be reclassified as major and therefore take away some the regulatory provisions associated with minor crops/uses away from them.

The lack of availability of residue data to extend authorisations for minor uses was seen as an impediment and the different factors influencing this was discussed within the group. To have two residues' zones in EU is, especially for minor crops, an obstacle and it was discussed to revisit this concept. Because this concept is laid down in guidance and not in legislation an option would be to update the Guidance Document on residue extrapolations (SANCO 7525/VI/95). Besides, a wider use of residue data generated outside the EU, when scientifically valid, in granting minor uses extensions, should be considered. In this respect, the findings of the Global Residue Data Exchangeability project

(carried out by IR-4 in the USA) are very convincing in terms of data comparability as it is demonstrated by this study that it is not necessarily climatic circumstances, but the way PPPs are applied determine the residue level.

Several improvements of the regulatory system for minor uses were discussed and the possibilities to build on these foundations explored. The risk envelope approach, that considers that an assessment can cover a group of uses rather than individual uses, facilitates and supports the availability of products for minor uses. Not all MSs apply the risk envelope approach to its full extent and/or continue to ask for efficacy data for an Article 51 label extension. Sometimes label extensions for minor uses are not included in the GAP at the stage of renewal.

It was discussed by the group on how the establishment of the MUCF contributes considerably to awareness raising of the minor use issue and finding practical solutions for the betterment of EU agriculture. The Facility plays an important role in a better understanding how MSs organise minor uses work and address minor uses. In this respect, the MUCF is working on an update of the "Report on the Questionnaire on Minor Uses work in EU MSs, Norway and Switzerland (MUCF, 2017)". The MUCF is together with EPPO working on an Extrapolation Databases for efficacy crop safety and residue.

Assessment of co-formulants

The discussions in the group focused on the policy of the implementation of the assessment of co-formulants and the identification of unacceptable co-formulants. The development of a centralised database and the maintenance of such a database was a primary topic in breakout group 3.

The participants appreciated the efforts from EFSA and the European Commission initiating the discussions on the improvements for the assessment of co-formulants given the increased public interest and the current lack of a harmonised approach. The group further agreed that generally co-formulants are already covered by the established assessment methods, but a coordinated and consistent procedure needs to be developed taking into account Commission Implementing Regulation (EU) 2023/574, available databases (e.g. from the German authorities) and data produced for other regulations. It was clarified that the co-formulants topic comprises of both the identification of unacceptable co-formulants and the assessment of co-formulants as part of the evaluation of representative products for the approval of active ingredient and the national authorisation of plant protection products.

The group agreed with the proposals from the report on the Commission workshop held in May 2023 and subsequent EFSA led technical workshop held in June 2023 that a centralised database should be established with a focus on the identification and the composition of the co-formulants as a first step. This is with the intention to increase transparency, enable the sharing of data and thereby limiting the additional workload of the MSs and applicants. Given the reluctance by some MSs in currently accepting the assessments carried out by others, the possibility of some type of a peer review system was briefly discussed. It was noted that not only applicants for active substances and PPPs would need to be consulted and involved but also manufacturers and suppliers of co-formulants. It was mentioned that during recent Post Approval Issues (PAI) Working Group Meetings no MS volunteered to lead on the development. Therefore, it needs to be decided as to who is best placed to take the lead on the development.

In parallel to the development of a database, a guidance document needs to be developed with all stakeholders involved. The meeting further discussed if the same data as for actives substances are currently required for co-formulants based on the wording of criterion ten in the Annex of Regulation (EU) No 2023/574. However, the Commission official present indicated that this was not the

intention, and the point should be considered as a kind of safety net. It was mentioned among some of the participants that this had already been indicated by the Commission during the discussions on the regulation in the SCoPAFF legislation.

The participants further discussed the option of establishing a positive list for co-formulants once respective entries are available on the database, however this idea was not further elaborated as currently Regulation (EC) No 1107/2009 specifically only mentions identification of unacceptable co-formulants.

3.2.3 Conclusion

Mutual Recognition

In concluding on the discussions, members agreed that whilst national requirements are necessary in some very specific circumstances, that everyone needs to respect the legal provisions and limitations embodied in Article 36(3) and the limited scope to derogate under Article 41(2) of the regulation. Only national requirements that are linked to specific environmental and agricultural circumstances and which are technically and scientifically justifiable should be maintained. A periodic review which assesses the differences in assessment outcomes should be regularly carried out so that when it is obvious that national requirements are no longer required to demonstrate safe use that these can be relinquished by the authorities. Where the national requirements are justified then they need to be kept up to date and current and published in an open and transparent manner.

With regard to old assessments, it is acknowledged that what has already been assessed and finalised with an authorisation granted in accordance with Article 29 of the regulation it cannot be feasibly changed at this point. Furthermore, the guidance document on zonal assessment and mutual recognition (SANCO/13169/2010 rev. 11 of January 2021) interprets that products evaluated and authorised according to Directive 91/414/EEC fulfil the criteria in Article 29 of the regulation. However, to facilitate the smooth functioning of mutual recognition (and indeed zonal assessments), to bring about an increased level of harmonisation that all current and future evaluations conducted under the Article 36(1) procedure for Article 33 applications should respect guidance documents endorsed and noted by the Standing Committee, that expert agreements (e.g. as a result of zonal harmonisation workshops) are respected (insofar as they are compatible with Standing Committee decisions) and that the zRMS concludes on the full core dossier so as to minimise additional national assessments in future submissions. By applicants preparing and submitting high quality, clear, transparent data sets and dossiers, harmonisation and consistencies can be enhanced.

Use of the Article 40.2 provision is seen to be fraught with difficulties and uncertainties so MSs should encourage the use of mutual recognition by the data holders. MSs with experiences of the use of Article 40.2 process should be encouraged to disseminate their best practices in the appropriate forums.

This group also concluded that whilst biocides regulation legislates for an arbitration process to resolve disagreements through the Co-ordination Group, that under current PPP legislation no legal framework exists to establish such a procedure.

Minor Uses

The group agreed that the available provisions in the regulation and available Guidance Documents provide for a quicker way of evaluation for minor uses resulting in faster access to the EU market. The provisions give MSs sufficient flexibility to find solutions and to adapt to local/national circumstances. However, the lack of harmonisation in applying these provisions and conflicting definitions across the relevant legislation and guidelines are well known and can create obstacles and

uncertainty for all relevant stakeholders. Best practices on how minor use issues are dealt with across the different MSs should be shared and developed upon. By fully exploiting the "Risk Envelope" approach, MSs can address minor use needs without the need for substantial data sets or evaluation work. Furthermore, dissemination of completed minor use assessments should be made available on platforms such as CIRCABC or through the MUCF network. The development of a specific Part A template of the registration report specific for Article 51 minor use applications will further harmonise applications and assessments alike.

The group considered that a major obstacle to harmonisation was the lack of an EU wide definition of what constitutes a major and minor crop within the relevant legislative processes and the different criteria used across the MSs in defining minor crops. Work needs to be continued on the feasibility of developing a harmonised EU definition and examining the benefits of or disadvantages of such a harmonised list. In the meantime, MSs should make it publicly and readily available the lists of major and minor crops and uses in their countries. These should be centrally available through the MUCF or Commission websites.

The findings of the Global Residue Data Exchangeability project (carried out by IR-4 in the USA) can be used to explore if for minor uses, the EU can be considered as one zone for residues (and not two as it is currently: north and south).

As well as continuing with its existing activities (which benefit regulators and applicants alike), the MUCF can participate in the discussion on wider use of residue data generated outside the EU, to rethink the EPPO efficacy zones as well as the concept of two residue zones in the EU. The MUCF could coordinate the preparing of a discussion paper on an EU or zonal harmonised list of minor/major crops. Industry representatives present expressed their interest to contribute to such a paper. All MS should be encouraged to actively participate in all the ongoing activities of the MUCF.

It was considered that use of term "minor uses" doesn't accurately reflect the importance of the sector and that the term 'speciality crops' should preferably be used as this better reflects the status/value of these crops.

Assessment of co-formulants

Further discussions should take place in the PAI working group, other relevant working groups with the possibility of a specific workshop on database development and a follow-up scoping paper was considered reasonable to assist in extending the functionality and future proofing of the database. The German BFR database (or other databases already available) could be taken as starting point as to how to present and organise the hazard information of co-formulants including the ones consisting of a mixture of individual substances. Data already available so far from other regulations (e.g. REACH) should be used as far as possible and the "one substance one assessment" activities were mentioned to be beneficial on the long-term, but the group agreed not to wait for the announced common data-platform from ECHA. The Guidance Document should, among other things, specify the minimum set of requirements for co-formulants in terms of "need to know versus nice to know" based on Regulation (EU) No 284/2013, how to feed the database and how to perform the assessment for co-formulants to comply with all regulatory needs. All stakeholders, including association representatives of the PPP industry and representatives of co-formulants manufacturers and suppliers should be involved and consulted in these developments. MSs should share their respective assessments to improve harmonisation as early as possible taking into consideration the willingness of MSs to accept assessments conducted elsewhere.

3.3 Summary table

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium / Long term
Mutual Recognition and national requirements	2.1	National Requirements are legislated for in Regulation (EC) No 1107/2009 but are seen as an impediment to the smooth implementation of mutual recognition in many instances.	National requirements should be minimised but where required they must be legal with respect to Article 36(3) i.e. limited to specific environmental and agricultural circumstances and where technically and scientifically justified	All MSs publish up to date national requirements. Justify the requirements and specify implementation dates. A centralised repository of national requirements to be co-ordinated through the zonal steering committees and published in centralised location on the DG SANTE pesticides webpage. A periodic review which assesses the differences in assessment outcomes should be regularly carried out by the MSs so that when it is obvious that national requirements are no longer required to demonstrate safe use that these can be removed by the authorities.	Short and ongoing
Mutual recognition and transparent assessments	2.2	For some assessments it is not always obvious as to how a conclusion is reached. This can come about from using non-EU agreed endpoints, non-endorsed guidance documents and agreements. This results in extra evaluation work in the receiving MSs with differing outcomes in the assessment.	Transparent harmonised assessments result in less evaluation work in the MS dealing with mutual recognition applications and less 2.3ergences between MS2.4thorisations	EU agreed end points are used and in cases where they are not that this is clearly justified and identified in the registration report. Evaluators respect agreements made at zonal (and interzonal) insofar as they are compatible with SCoPAFF	Ongoing

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium / Long term
				decisions and respect Guidance Documents that have been endorsed/noted by the SCoPAFF. The zRMS must always conclude on full dossier submitted to them.	
Minor uses and definitions of major and minor crops	2.3	No EU wide definition of what constitutes a major or minor crop is available. This can create obstacles to addressing minor use needs as the uncertainties of the data requirements do not incentivise applicants to maximise labels in all MSs. Most MSs do have national lists but these are not always readily accessible.	An EU wide definition can be difficult to achieve due to diverging definitions between associated legislations, and guidance (e.g. Residue legislation, EPPO efficacy guidelines). Depending on the criteria used, different crops could have a change in categorisation in the MSs which could (depending on the change), help or hinder solving minor use needs in the MS.	All national lists that are currently available are published and maintained on the MUCF website and that a link to these lists be contained on the Commission PPP webpage. The MUCF (and its expert groups) scope the feasibility of developing harmonised EU wide lists of major and minor crops.	Short and medium
Minor Uses and the role of the MUCF	2.4	The MUCF is recognised as playing a hugely positive role in the area of minor uses. It has developed and brought together a network of experts from across the MSs and beyond since its inception. Development of guidance documents and databases is seen as an encouragement for	Co-ordinating projects on finding solutions for minor uses has contributed to the access to plant protection solutions for the speciality crop	MSs contribute financially to the running of the MUCF and actively participate in the expert groups. The facility should continue to develop databases in the areas of residue and efficacy	Short and medium

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium / Long term
		stakeholders to consider authorisations for minor uses and speciality	sector. The MUCF should continue to be used as a main driver in developing pragmatic and practical solutions for the speciality crop sector.	extrapolation. The MUCF alongside the SCoPAFF (residues) should be tasked with investigating the use of residue data from outside the EU and continuing with 2 separate EU residue zone policy with the aim to update and develop guidance in this area.	
Assessment of Co-formulants and database	2.5	It was acknowledged that assessment of co-formulants brings about extra workload for all stakeholders involved. Duplication of effort should be avoided relying on available data generated in the frame of other legislations, and the principle of work-sharing needs to be encouraged. Assessments already completed do not need to be replicated by each MS and that having a central repository would reduce workloads and increase efficiency in dealing with co-formulants	A centralised database should be established initially comprising of identity and composition of co-formulants. This should build on already available databases and data already available from other regulatory regimes.	A workshop should be convened by the Commission to scope out the development of the database with the contribution of all relevant stakeholders (including the co-formulant supplier industry). This should focus on what information the database should initially contain, possible future developments of the database and who should lead the development.	Short, medium and long
Assessment of Co-formulants and guidance documents	2.6	Co-formulants were already being assessed to differing degrees prior to the introduction of Regulation (EU) 2023/574. For a consistent and harmonised approach, guidance is needed to expand on the provisions of this recent implementing regulation. Complications can arise where co-formulants are mixtures in themselves where the supply chain is a few steps removed from the PPP applicant. Confidentiality issues and	Guidance is needed on both the data/assessment aspect and the use of the database. With full stakeholder participation, development of guidance on both	Guidance development will be initiated and developed by the PAI WG.	Short

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium / Long term
		extracting data from third party suppliers are likely to slow down or halt assessments.	aspects should go hand in hand because of the close interlinkages between the two.		

4 BREAKOUT GROUP 3
Work sharing on digital platforms - The future of European IT-systems in PPP authorisation procedures

4.1 Thought starter

The following document has been prepared as a thought starter to initiate discussions in the Breakout Groups and should in no way be conceived as the official position of the European Commission or the Member States.

4.1.1 Background

In the realm of Plant Protection Product (PPP) evaluations and authorisations, the zonal system has now been in use for well over a decade. This system introduced a new era of collaboration and efficiency. The regulatory process was harmonised and the workload was distributed among member states, leveraging their collective expertise and resources.

While the zonal system has undoubtedly brought forth numerous benefits, it was mostly not accompanied by centralised systems for data collection and communication. This necessitates a reliance on individual member states' own systems and procedures for the submission and retrieval of data, and has thereby generated certain inefficiencies and complexities.

The current regulatory landscape necessitates the exchange of large amounts of data through cumbersome channels, often requiring substantial manual intervention, both from a MS perspective but also from an industry perspective. Also communication between MS happens largely through an active process, of sending emails between the MS to indicate the state of dossiers. This reliance on manual data retrieval, transfer and processing, and manual communication poses challenges in terms of timeliness, accuracy, and overall workflow efficiency.

In 2021 an IT workshop was organised by the Netherlands in collaboration with Germany, titled “IT architecture for the European PPP Regulation”. Some exchanges on these subjects were already had there. The report of this meeting will be sent to the participants of this break out group as a background document.

At the same time, new challenges and sensitivities have cropped up since the introduction of the zonal system, with an ever-increasing public scrutiny of plant protection products. One of the more pressing areas of this scrutiny is the long-term safety of PPP, and an increasing focus on the safety of all of the co-formulants in PPP-formulations.

Recent discussions on this topic have shown a desire among member states to have a shared database that would allow them to more easily establish what is known about a certain co-formulant. Indeed, some countries already appear to have such databases, again at a national level, necessitating manual work to communicate between different countries if information from such databases would need to be exchanged.

Given that the evaluation of the formulation is an integral part of the overall PPP evaluation and the zonal evaluation procedure, it makes sense to have a communal database here. This could provide a more efficient and seamless collaboration between member states. Additionally, given that many co-formulants are used in multiple products, a communal database would make use of the work already performed on other formulations and possibly even in other regulatory frameworks.

To address these challenges and further enhance the effectiveness of the zonal system, this breakout group of the ZAPID workshop will explore the potential of various tools that could facilitate seamless collaboration among member states while minimising the need for “manual” data exchange. The group will delve into the realm of digital solutions, examining their potential to streamline data exchange, and foster a more integrated regulatory environment.

4.1.2 Discussion points

Use of IUCLID in PPP authorisations

IUCLID (International Uniform ChemicaL Information Database) has been mandatorily used for the submission of active substance dossiers for plant protection products for some time now. It effectively stores a wealth of data and can be configured to generate a variety of reports. While the evaluation process itself occurs outside of IUCLID, its role as a centralised repository of chemical substance data aligns well with its potential application in the context of PPPs.

However, over the past years several countries have developed their own software packages to manage various aspects of their national procedures for the submission and evaluation of PPPs. The development of these systems has often involved significant investments in terms of both financial resources and manpower. Understandably, member states that have developed such systems are reluctant or even unwilling to abandon them, as asides from the investment made, they have been tailored to meet their specific needs. Both MS and industry stakeholders’ express concerns about the potential for duplicating work, as requiring parallel entry in two separate systems could lead to discrepancies and increased workload rather than improved efficiency.

Drawing inspiration from the experiences within the framework of biocides, where a system was gradually developed and improved over time, we can explore how IUCLID could be effectively deployed within the framework of PPP’s.

Centralised Data Hub

IUCLID could serve as a central "hub" for data collection, facilitating frictionless data exchange and collaboration among MS and industry.

Complementing Existing Systems

Rather than requiring a complete overhaul of existing systems, IUCLID can be integrated as a complementary tool to streamline data submission and collection.

Other existing tools such as PPPAMS might be further employed to improve on communication between MS (see peer reviews, publication of final RR’s, status of dossiers…).

Identifying and addressing the specific requirements of MS and other stakeholders and illustrating the advantages of incorporating IUCLID to these parties is crucial for ensuring a smooth transition and maximising the benefits of IUCLID integration.

Discussion Points

You are invited to discuss the merits of utilising IUCLID in the framework of plant protection product dossier submissions. Please consider the following discussion points (of course additional points can be raised during the meeting):

- **Complementary Integration:** How can IUCLID be integrated as a complementary tool to existing systems without causing extensive duplication or disruptions for MS and stakeholders?

- **Data Collection Hub:** How could IUCLID effectively function as a centralised hub for PPP data collection.
    - Could this include means to deal with national addenda?
- **Streamlined Processes:** What steps can be taken to streamline data submission, collection, and communication through IUCLID integration, could PPPAMS be employed/improved upon as a better tool to improve communication between MS, possibly removing or greatly reducing the need for email communications?
- **Stakeholder Engagement:** How can MS, industry stakeholders, and other relevant parties be effectively engaged throughout the process of IUCLID integration for PPP authorisations?

Database on co-formulants

There is growing public scrutiny of pesticide use, and a demand for more transparency and accountability in the regulatory process. Co-formulants have come under increased scrutiny, resulting in multiple discussions on this subject over the course of this year. It has been established that a database would be desirable:

Co-formulants are non-active ingredients that are added to pesticides to improve their properties, such as stability, solubility, or application characteristics. There is currently no centralised database of information on co-formulants, which makes it difficult for regulators to assess their safety.

It now appears that EFSA would be willing to take upon itself the development of such a database, the initial form of the database might serve as a bridge to a more elaborate implementation under the "one substance -one assessment" (1S1A) framework, to be developed later.

This database would contain all required information on a co-formulant and would be accessible to Member States. The goal should be to enable MS who are evaluating a formulation to easily access available information, thereby ensuring efficient evaluations. Discussion in the contents of the database will take place in breakout group 2, we will focus more on the practical implementation of the database.

Discussion Points

You are invited to discuss the practicalities of developing and maintaining a communal database for co-formulants. Please consider the following discussion points (of course additional points can be raised during the meeting):

- **Data entry:** Should manufacturers be responsible for entering data on the identity of the co-formulants into the database, or should this be done by MS? If the manufacturer, what is required to make this possible for them?
    - How to ensure the information remains up to date?
    - Could data on previous “compositions” be maintained?
- **Access:** How should access to this DB work from an MS point of view. Different kinds of rights might exist (reading/writing)
- **Confidentiality:** How can the confidentiality of data in the database be protected, including the possible confidentiality of mixtures to the PPP manufacturer?
- **Communication:** Given that the need for this database springs from an increased public scrutiny on formulations, would MS want this database to also be able to be used for communication, and if so, what kind of communication?
- **MS involvement:** How can MS be kept involved during the development of this database?

4.2 Summary report

Use of IUCLID in PPP authorisations

An exploration was made of the use of IUCLID in the context of Plant Protection Products. For this a presentation on the R4BP3 system used by the biocide colleagues was given by ECHA. EFSA presented the IUCLID database in itself, and the members of the break out group discussed the use of IUCLID and the ESFC tool in PPP authorisations.

Database on co-formulants

Following previous discussions in other for the need for a database on co-formulants had been established. The group had a presentation of the German database, and discussed on what would be required for a common EU database on co-formulants, and how to best go about establishing such a database.

4.3 Summary table

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
Presentation by ECHA on R4BP3 System	3.1	An overview of biocidal product submission and evaluation procedures was presented by ECHA, including a walk-through example. The system is based on IUCLID, with administrative information provided via SPC summary documents. Communication with Competent Authorities is facilitated through the system, utilising R4BP3 as a central hub. ECHA is currently working on a project to reorganise REACH and BPR systems to ensure consistent design. The meeting provided an example of the submission workflow and the interfaces for various actors involved in the process. The current SPC system is scheduled to be migrated to IUCLID. The discussion then focused on the applicability of the R4BP3 system to PPP authorisations. While participants appreciated the workflow and the concept of a single system, they generally deemed it too simplistic for direct implementation in PPPs. They emphasised the need for a system that can accommodate the diverse submission types within the PPP system. A lengthy discussion ensued, leading to a consensus that the PPP system is complex, with varying national requirements and	• The R4BP3 system was deemed too simplistic for direct implementation in PPPs and emphasised the need for a more versatile system. • The PPP system is complex and has varying national requirements and potential for discrepancies in study interpretation. • It was understood that R4BP3 uses IUCLID as a common data platform, and that therefore using something similar for PPP is contingent on implementing IUCLID for PPP's • It was understood that the R4BP3	See proposed action for the point on IUCLID	

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
		potential for discrepancies in study interpretation based on the same dataset.	system is the result of a gradual development process, and that a similar approach could be used for PPP.		
Overview of current ESFC	3.2	A comprehensive overview and discussion of the ESFC system was presented. The system effectively replaces PPPAMS and plays a crucial role in emergency applications. A walk-through example of the application workflow for this system was provided, illustrating the various actors involved (across different sectors) and their corresponding access privileges within the platform. The system enables a complete history of the application and communication and the assignment of tasks	/	/	/
General Discussion – Day 1	3.3	The European Commission clarified that there is a desire to move towards a common data platform. IUCLID is specifically mentioned as the eventual solution, but its implementation is envisioned within a 5- to 10-year timeframe. The emphasis is on ensuring the reusability of chemical data across the platform.	• There are difficulties in using IUCLID for active substances, including access issues, increased administrative burden, and lack of	See proposed action for the point on IUCLID	

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
		A lengthy discussion ensued regarding the difficulties encountered by Member States and applicants in utilising IUCLID for active substances. These challenges encompass access issues and an increased administrative burden in reviewing dossiers compared to the previous document-centric approach. Industry participants highlighted the absence of adequate lifecycle management within the IUCLID system, leading to significant problems. They also expressed concern about the current practice of duplicating data rather than reusing it to maintain an audit history. With regard to a potential use of IUCLID for PPPs, participants discussed the need to address national requirements, particularly national administrative information. The possibility of splitting dossiers into core and national components was also explored as a potential solution.	lifecycle management. • There is a need to address national requirements, such as national administrative information, when using IUCLID for PPPs. This is a significant issue that adds complexity to the process. • Buy-in from national Competent Authorities is crucial for successful implementation. • There is a consensus that it would be detrimental to have to rush the implementation of such a system due to legislative pressure, as		

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
			happened for active substances.		
IUCLID	3.4	EFSA provided an in-depth presentation on IUCLID, covering its functionality and key terminology, including Endpoint Study Records, Endpoint summaries, dataset vs dossier distinctions. A discussion ensued on the differentiation between studies and assessments. Participants expressed the need for comprehensive oversight, enabling them to track what has been assessed, by whom, and the resulting outcomes. Member States (MS) outlined their requirements for the new database, emphasising user-friendliness and ease of access, management, and search compared to the current IUCLID system, which presents issues with Good Administrative Practice (GAP) information. One MS proposed the concept of separating studies from dossiers, suggesting the creation of distinct entities for each. It was acknowledged that any new system should be compatible with and complement existing national systems, while incorporating lessons learned from the implementation of IUCLID for active substances. The European Commission reiterated that the implementation of such a system is	• EFSA provided a detailed overview of IUCLID, including its key functionalities and terminology. • Participants discussed the need for a more user-friendly and accessible database that can effectively manage and search data. • The European Commission reiterated the timeline for implementing a new system, emphasising the need to start working on it promptly. • Participants discussed the limitations of the PPPAMS system	It was proposed during this workshop, that the current pace and way of discussing this subject should be intensified. A dedicated working group to explore this subject, to identify member State and relevant stakeholder desires, and to enable further work on this could be established. If such a working group were to be established, this would be to the commission. Ideally there is a requirement for both IT profiles and PPP dossier manager expertise to be consulted for this. This could be reinforced by identifying the current status of know-how by different types of users of the system. See also “recap” at the end of the document	Short/medium term

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
		envisioned within a 5- to 10-year timeframe, but work should commence promptly. Participants discussed the complexities and shortcomings of the PPPAMS system, acknowledging that it failed to fully achieve its original objectives. They emphasised that a plan to move towards an implementation of IUCLID for the PPP dossiers must demonstrate clear benefits to evaluators to secure buy-in from national MS management. One MS highlighted the frequent updates required for dossiers due to computational issues in IUCLID, stressing the need for a robust new system with dedicated support. A proposal was put forward to establish a working group with a structured approach to comprehending MS-level processes and assigning a diverse range of representatives from various sectors, including experts, regulators, IT professionals, and industry representatives.	and emphasised the need for a clear benefits plan to secure buy-in from national MS management. • A proposal was put forward to establish a working group to develop a structured approach to understanding MS-level processes. See also "recap" at the end of the document		
Co-formulant Database	3.5	BVL shared their workflow and processes for managing information on co-formulants under the data requirements of Regulation (EU) No 284/2013. They retrieve Part C, review compositional information for updates, obtain information from applicants if needed, and disseminate the composition data to relevant stakeholders.	• **Variation in data collection practices:** The discussion highlighted the variation in data collection practices among Member States, which could	The Commission will send the current list of items requested for the database back to the MS through the Post Annex I issues meeting. MS will be asked to highlight which items for them are essential, and to provide a motivation for this	Short term

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
		The discussion touched upon the concept of mixtures within mixtures, acknowledging the variation in data collection practices among Member States. The need for an easy-to-use system was emphasised. EFSA expressed their willingness to host and collaborate on a common database for co-formulants, providing they are mandated for this. However, EFSA indicated that their contribution would mainly be scientific, and that any IT architecture need would require further internal consideration in terms of feasibility. EFSA will also conduct an internal activity to extend the data collection tool to take stock of the work started in 2022 with the EFSA technical report. Industry representatives suggested reusing existing information on co-formulants from REACH and PCN notifications, rather than creating a new parallel platform. Participants agreed on the necessity of developing harmonised guidance on co-formulants before data could be standardised for inclusion in a database, although this guidance could also be developed in parallel. MS were tasked with examining their national legislation regarding data confidentiality on a common platform or requesting co-formulant information from BVL.	be addressed by a common database for co-formulants. • **Easy-to-use system:** A common database for co-formulants should be easy to use for all stakeholders. • **EFSA's willingness to collaborate:** EFSA expressed their willingness to host and collaborate on a common database for co-formulants, given a mandate from the Commission. • **Reusing existing information:** Industry representatives suggested reusing existing information on co-formulants from REACH and PCN notifications. Also the full re-use of	essentiality, so that we could start to build the database from that common ground	

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
		A potential benefit of a common database was recognised in the assessment of alternate co-formulants. During previous workshops a draft list of data which could be in this list was obtained from various experts. The group decides that this list will be sent back to the MS through the PAI group. The MS will then be asked to motivate these different data points which they ask for. This will be taken up by COM.	the existing German database is discussed • **Harmonised guidance:** Participants agreed on the need for harmonised guidance on co-formulants before data could be standardised for inclusion in a database. • **Benefits of a common database:** A common database for co-formulants could be beneficial for assessing alternate co-formulants. • **Start small:** The goal is to start with a small database that focuses on co-formulant-level information, rather than product-level information. Should only		

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
			contain that which is necessary.		
Recap	3.6		The meeting participants recommended establishing a dedicated working group to develop a common data system for Plant Protection Products. They suggested utilising and expanding the existing IUCLID PSN platform as a foundation. EFSA did not confirm whether the IUCLID PSN could be used to coordinate and discuss IUCLID issues for zonal PPP. Because the IUCLID PSN is yet dedicated to the current use of IUCLID for EU applications. Industry representatives expressed their desire to participate in this working group as a key stakeholder. One Member State (MS) raised concerns about the timeliness of such a move, advocating for a thorough analysis of requirements and further knowledge gained from the active		

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
			substance development process. All parties agreed that the system should undergo extensive development and testing prior to legislative implementation, preventing the software from being forced to "catch up" with the legislation. The meeting acknowledged the differences between PPP legislation and other regulatory frameworks, emphasising the need for a system that facilitates seamless evaluation for all stakeholders. Participants highlighted that the current legislation mandates a common data format, but not necessarily a common data system. Given the existence of IUCLID to display OHTs and its use for chemicals in other frameworks, acknowledging the COMM aims for a common database on chemicals, it is		

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
			probably easier to work with this as the basis for insertion of information into OECD/EU harmonised templates (common data format), rather than having to design some other tool from scratch. There is however acknowledgement that whilst IUCLID may be used as a basis, software functionality would need to be tailored to the relevant PPP legislation.		

5 BREAKOUT GROUP 4
Implementation of new scientific and technical knowledge - Guidance Documents (e.g. GD SANCO 10328/2004)

5.1 Thought starter

The following document has been prepared as a thought starter to initiate discussions in the Breakout Groups and should in no way be conceived as the official position of the European Commission or the Member States.

5.1.1 Background

New active substance data

Evaluation and (re-)authorisation of plant protection products should be based on endpoints established during the assessment of the active substance and listed in EFSA conclusions. Data on the active substance should primarily be evaluated within the EU review program by the designated RMS. This process guarantees that the data has been thoroughly evaluated and peer reviewed. However, there are several reasons as to why data on active substances can be submitted by applicants post annex inclusion:

- to address data gaps from EFSA conclusion. Which data gaps that should be addressed in product assessment was recently clarified by the IZSC[1],
- to support uses other than the representative uses in the review report; these data can be submitted both in an art 33/art 43 application, but also for label extension (art 45+33),
- to demonstrate acceptable use for the use of a product.

Regardless of why new data is submitted, evaluation of such in the product authorisation process will result in extra workload on an individual MS, leading to delays in product authorisations, and may cause differentiated conclusions, and hence end points, between MS and zones. Most MS have great difficulties keeping within the legal timeframes for evaluation of product authorisations, especially for applications according to article 43 where the is no stop-the-clock for request of supplementary documentation.

A guidance document (SANCO/10328/2004) was developed to establish a harmonised approach to evaluate new active substance data to avoid unnecessary duplication of work and to promote work-sharing between MS. This GD has then been revised at a number of occasions, last time in 2021.

The PAI group decided in September 2021 that the focus of the GD should be on human health issues and relevance of metabolites. However, issues regarding new active substance data relating to other parts of the evaluation has also been raised and need to be addressed. Often, these issues are concerning ecotoxicological studies which can be complex and time demanding to evaluate. SANCO/10328/2004 states that a final and peer reviewed assessment of new active substance data within product evaluation should be *made available within the timelines specified in Regulation (EC) No 1107/2009, Article 33 or 43 for the authorisation or renewal of the authorisation of the product,*

[1] https://circabc.europa.eu/ui/group/0b40948d-7247-4819-bbf9-ecca3250d893/library/05a3402f-54fd-496c-8fe2-435d2a8d75f7/details

respectively. However, the directions for when a common EU evaluation should be initiated and the procedure for this evaluation is not clear and raises several questions.

During the last few years, questions on submission and evaluation of new active substance data and how this should be processed has been raised numerous times in PAI and other forums. The circumstances during which new data has been submitted differs, hence the issues are similar but not identical. Even though a process for evaluation of new active substances is described in SANCO/10328/2004, this is not applicable in all situations. The process is also not described in detail and no information regarding how to facilitate work-sharing between MS is included. The SANCO GD states that *MS could request advice from the Commission and the other MS to identify the process to be followed through PAI meetings*. Even though these issues have been escalated to PAI meetings, no standard procedure for evaluation of new active substance data in product authorisation has been set.

To facilitate the evaluation of product authorisation in MS, there is a need for a harmonise view of:

- which new active substance data should be evaluated
- how we can promote work sharing and avoid duplication of work

Current scientific and technological knowledge

Regulation (EC) No 1107/2009 demands that "the Member State ... shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents available at the time of application" (Article 36.1). What this means in practice has not yet been clarified, hence there is a possibility for interpretation of what can be considered *current scientific and technical knowledge*. Interpretation of the wordings might be clarified in the case C-308/22 and the joint cases C-309/22 and C-310/22 in which the Advocate general Medina has made an opinion[2].

The delays in updating relevant Guidance documents (GD) results in product evaluations that does not always follow the latest scientific or technological knowledge since relevant GD have not been taken notes of or are not implemented yet. The delays also lead to unharmonised evaluations and unpredictable and different requests for the applicant in different MS, since there are different understandings to the phrase *using guidance documents available at the time of application* in Article 36.1 in Regulation (EC) No 1107/2009. Some MS requires that evaluations should follow GD that are available but not yet implemented, while other MS is of the opinion that the GD must have been take note of before is implemented in product evaluations. Ultimately this may result in products grants authorisations in some MS while rejected in other MS with similar prerequisites.

As a consequence of prolonged processes in updating existing and developing new GD, new scientific knowledge has developed during this time and there may be an immediate need for revision. Hence, the development of new scientific and technological knowledge may sometimes be faster that the revision and development of GD.

5.1.2 Discussion points

The discussion in this BOG should focus on suggestions for which new active substance data that should be evaluated in connection to product evaluation and which data that can be disregarded.

[2] eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:62022CC0308&qid=1699372355993 and eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:62022CC0309&qid=1699372976471

Suggestions for improvements and updates of SANCO/10328/2004 should be identified, as well as suggestions for the evaluation procedure in practice.

The question on how to handle disagreements and unharmonised approaches will be discussed in this BOG in connection to evaluation of new active substance data and endpoints used in product evaluations.

The following suggestion of questions for the discussion should be considered as starting points for the discussion sessions during the meeting.

- How do we define new active substance data?
    - Does it also include data for metabolites?
    - Public reports regarding active substances
    - Cat 4 studies
    - Article 56 or information regarding active substances from other MS

- What new data should be considered relevant and hence be further evaluated?
    - How do we categorise different data gaps and what does that mean for new active substance data and should that be considered in product evaluation?
    - Should only data that changes the final conclusion of the evaluation be considered or also data submitted to avoid risk mitigations?
    - In what scenarios can an expert judgement be used to determine whether a study is necessary or not? For e.g. ecotoxicological studies, it is not always easy to determine whether a new endpoint will change the outcome of the risk assessment.
    - Should data submitted to support a use on a new crop or against a new pest be considered?

- When does new active substance data result in new EU agreed endpoints and an update of LoEP?
    - In SANCO/10328/2004 it is specified that in particular new toxicological reference values and residue definitions may lead to an updated LoEP. Could this also be relevant for e.g. ecotoxicological endpoints?

- The process in practice
    - Who should evaluate the new data?

In which situations should RMS be responsible and in which situations should the evaluation be done by zRMS/cMS?
Who should take lead in the evaluation when data have been submitted simultaneously to more than one MS? How do we promote work-sharing between MS?

- How should the communication be handled?

What channels should we use? IUCLID, CIRCABC?

- How do we present the evaluated data and best share the conclusions? In a RR or as a separate document?
- How and where should the evaluations be handled when finalised? We need an agreed and standardised platform for saving the evaluations and conclusions. This is especially important when the evaluation do not result in an updated LoEP.
- What are reasonable timelines, both for evaluation and commenting of the evaluation? SANCO/10328/2004 states that an assessment of new active

substance data should be made available within the legal timelines in Regulation (EC) No 1107/2009, art 33 or 43. How can this be facilitated in practice?

- Definition of current scientific and technical knowledge
    - How do we interpret “current scientific and technical knowledge”?
    - Updates of GD is postponed or delayed – leading to that implemented GD to not necessarily consider the current scientific and technical knowledge. How do we handle disagreements between MS in regard to when a new/updated version of a GD should be implemented? How can we harmonise between MS?

- How do we deal with disagreements in product evaluations, both connected to new active substance data and to unharmonised interpretations of GD.
    - How can we deal with disagreements in evaluation of new active substance data?
    - Differences in interpretation regarding implementations of GD can lead to different evaluations and conclusions regarding new active substance endpoints.
    - Could something similar to what is used for biocides be used also for PPP? Is there a need for a new forum for these issues?

Documents for preparation of the discussion.

SANCO/10328/2004 – rev 9

5.2 Summary report

5.2.1 Background

Evaluation and (re-)authorisation of plant protection products (PPP) should generally be based on endpoints established during the assessment of the active substance (a.s) and listed in the European Food Safety Authority (EFSA) conclusion which forms the basis of a vote at the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF). Data on the active substance should primarily be evaluated within the EU review program by the designated Rapporteur Member State (RMS). This process guarantees that the data has been thoroughly evaluated and reviewed in a harmonised manner. However, there are several reasons why data on the active substance can be submitted by applicants post active substance approval/renewal of approval.

The Guidance Document SANCO 10328/2009 was originally drafted because more and more active substance data were being submitted to Member States (MSs) as part of product evaluations. When the requirement to submit confirmatory information was removed at the active substance review stage, unresolved issues moved to “MS must pay particular attention to” and the amount of active substance data submitted together with product applications increased.

A lot of questions regarding which data should be considered and how it should be evaluated have been raised by MSs. It is also clear that MSs handle this data in different ways and that the guidance document does not provide sufficient guidance for MSs to determine if the data should be further evaluated and how.

Regulation (EC) No 1107/2009 demands that “the Member State [...] shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using

guidance documents available at the time of application" (Article 36.1). However, there are different interpretations of this requirement regarding the current scientific and technical knowledge and the time of applicability of available GD. This results in MSs making their own and separate interpretation of this phrasing leading to disharmonisation in implementing GD's and data requirements among the MS.

Participants of BOG 4, comprised of representatives from 10 MS, 3 from industry associations representing applicants, and 1 observer from EFSA.

5.2.2 Discussion points

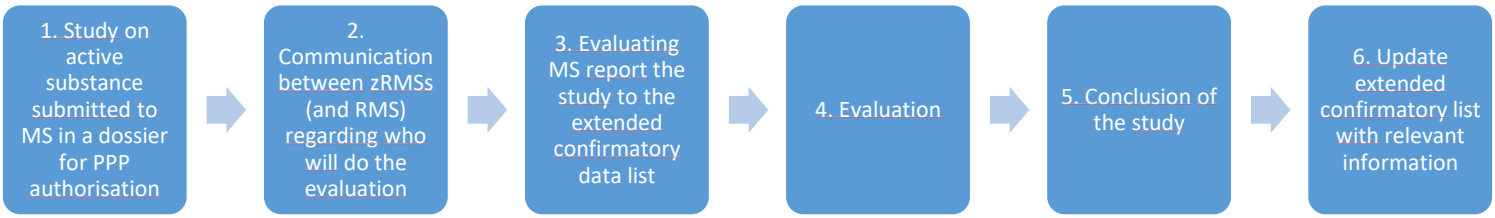
New active substance data and revision of SANCO 10328/2004

It was clear from the discussion in the BOG that it can be difficult for the MSs to determine when new active substance data submitted in an application for product authorisation should be evaluated and by whom and under which procedure. Since the available guidance for this data assessment is vague, MSs handle this data in different ways making it difficult for applicants to anticipate the requirements from each MS. The participants of the BOG agreed that there is a need for harmonisation and a clear process for handling new active substance data in PPP applications.

The discussion in the BOG focused initially on what can be considered new active substance data and in what situation new a.s data could be submitted to a MS during the product authorisation/product renewal assessment. There are situations that already have a specific procedure and those were not further discussed. Examples of cases that were deemed relevant for further discussions and for which a procedure must be clarified were:

- New active substance data needed to support uses that were not covered by the representative use(s) in the dossier supporting the EU approval/renewal.
- New active substance data to demonstrate safe use when risk mitigations are not enough to address the risk.
- New active substance data to address data gaps listed in EFSA Conclusion on Pesticides Peer review (EFSA conclusion) and reflected in the Review Report (RR) and listed in the approval regulation under the points "MS may particular attention to".

A suggested process for these cases that could be incorporated in an updated version of SANCO 10328/2004, was discussed and drafted at the workshop. Details of each step are described below.



1. An active substance study (that has not been part of the EU approval) is submitted to one or several MS as part of a dossier for product (re-)authorisation. It is suggested that when a study on an active substance is included in the dossier, justification for submission of the study together with information if the study has been previously evaluated by another EU MS is provided by the applicant. The applicant may also ask for a pre-submission meeting with zRMSs and then discuss

the process for the evaluation of new active substance studies and who should take the lead of the evaluation.

2. The suggestion is that there should be a communication between the zRMSs to agree on who is the most suitable zRMS to lead the evaluation of the study/studies. This can be based on who has come the furthest in evaluation of the PPP dossier and which MS has the capacity to evaluate the study within a reasonable time. This communication should be initiated by the MS who receives the data. In situations when it is not clear within which process the active substance study should be evaluated, this issue may be discussed between the different zRMS and raised at the Post approval issues working group (PAI) for support if necessary. For studies impacting toxicological reference values (TRV) and relevance of metabolites, RMS should carry out the evaluation according to the process already described in SANCO 10328/2004.
3. The evaluating MS (ideally the zRMS) should report the study and who will evaluate it via PAI meeting (to be included into an extended and repurposed confirmatory information list, which is already existing). It is suggested that this extended list should include information of which active substance studies that have been submitted in PPP dossiers and if they are necessary for the product evaluation. It should also be noted if the studies have been previously evaluated and what the conclusion of the evaluation was and where it can be found. By implementing this process, duplicated evaluations of the same study can be avoided.
4. The evaluation of the studies should be incorporated in the dRR of the product evaluation. The timelines for the evaluation and commenting of the evaluation of the new data are the same as for applications according to art 33 and art 43 in Regulation (EC) No 1107/2009. The dRR should be sent to all MS (all zones) for commenting and it should be clarified in the information submitted for commenting where the evaluation of the active substance study can be found in the dRR.
5. The final conclusion of the study should be included in the RR of the product and uploaded to CIRCABC. The link to CIRCABC and information that the evaluation has been finalised should be sent to all MS. The final RR should also be sent to the applicant.
6. At a PAI meeting, relevant information should be included to the extended confirmatory information list.

Issues for further discussion

- Data included in this process should in most cases not lead to an update of the EFSA conclusion on the active substance, as can be the case for studies related to hazard properties of the active substance. However, studies relating to TRV has a separate and already defined process. When and if EFSA should be involved in the above proposed process needs further discussions.
- What information is relevant to include in the extended confirmatory information list? Basic reference information to the study, where the evaluation can be found, which MS was responsible for the evaluation, the conclusion of the evaluation (a suggestion for this list has been submitted to PAI for further discussions).
- The information (or parts of the information) included in the extended confirmatory information list should be made available to the applicant, to facilitate that correct information is given to MS when applicants are submitting dossiers including such data.

Before an updated process is adopted and included in SANCO 10328/2004 it is recommended that a pilot case is conducted and evaluated to gain experience of the process.

There were cases that were brought up during the workshop for which it could not be concluded how to address them within the processes. These were:

- New active substance data to avoid risk mitigation when the risk mitigations are of such nature that they prevent any use of the product (e.g. insecticides that have limitations of not allowed to be used where pollinators exist);
- New active substance data to address a new product data requirement, in an application according to art 33, which was not a data requirement when the active substance dossier was submitted;
- Monitoring data for active substances.

New scientific and technological knowledge

It was obvious from the discussions in the BOG that MS have different views on which guidance document (GD) should be followed and what data to be used in a PPP application. It is also unclear if there is a common understanding of what "new" scientific knowledge means. This results in unpredictable requirements for the applicants and disharmony in approaches between MS in the zonal evaluation.

According to article 36(1) in Regulation No (EU) 1107/2009 the MS should use "guidance available at the time of application ". However, this is interpreted differently as some MS require applicants to follow GD that are available but have not been taken note of at the Standing Committee. There are also MS that require applicants to use endpoints that have been reviewed at EU level and included in the EFSA conclusion, but the decision at SCoPAFF has not yet been taken. In some MS there have been court cases in this regard and further rulings are awaited regarding what should be considered current scientific and technological knowledge for the evaluation of PPPs. The BOG did therefore not go into an extended discussion on a harmonised view or definition on this point. However, when the outcome of the pending court cases (C-308/22, C-309/22 and C-310/22), the Commission and PAI should provide clearer guidance on what GD and endpoints should be used to facilitate harmonisation during PPP assessment and limit discussions between MS.

5.3 Summary table

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
Data gaps in EFSA conclusion	4.1	Data gaps in EFSA conclusion: the BOG4 agree to make reference to 'Data gap in EFSA conclusion issued by izSC in March 2023 - version 43' as reference; Comment from EFSA: EFSA was not aware how MSs deal with data gaps in EFSA conclusion; EFSA will continue to set data gaps in section 10 and it is up to MSs and Commission to decide how to deal with those gaps.	The harmonised approach on how to handle data gaps in EFSA conclusion has not been adopted by all MS.	The harmonised approach should be further communicated to MS, EFSA and COM since a clear harmonised approach does provide MS and applicants with guidance on how to handle data gaps and applicants to know what data to submit with the product dossier. COM/EFSA/PAI	Short term
New data on active substance submitted in a dossier for product authorisation to zRMS in several zones	4.2	There might be several reasons why new active substance data, e.g. ecotox/efate, are submitted in the frame of product assessment; identified cases by BOG 4 have been discussed and categorised, to answer the question 'which data should be considered relevant and further evaluated and which should not be in the frame of PPP assessments"	Conclusion about data to be considered relevant: • Demonstrate safe uses for uses/GAPS not covered by representative uses/non representative formulations • New residue data: always at zonal level (consumer safety and refinement for the	It needs to be clarified in which cases new active substance data should be evaluated by MS and for which the GD is relevant. Cases that could not be categorised during the BOG4 discussion may need further clarifications regarding	Short-term

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
			ecotoxicological risk assessment) • New active substance needed to show (non) relevance of metabolites (due to e.g. national modelling requirements resulting in higher PECgw) • If new RAC opinion and relevance of metabolites needs to be demonstrated, art. 21 may be triggered if metabolite occurs > 0.1 µg/L for representative use. • 'MSs have to pay particular attention to', when part of the approval regulation: if new active substance data are relevant in this frame (i.e. relevance of metabolites, impacting ecotoxicology assessment.)	when evaluation by MS is relevant. PAI	

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
			Uncertain cases: • Data submitted according to guidance not yet endorsed. • Monitoring data and studies (likely they will be accepted by National authorities.) • Studies submitted to lower risk mitigations which can impact the product use. There may be other cases where it is necessary for MS to evaluate new as. data that have not been raised here.		
Who should take the lead of the evaluation?	4.3	It is clear in the current version of SANCO GD 10328/2004 that RMS is responsible for evaluating new toxicological data that may lead to new TRV. However, in the GD it is not clear who should be responsible for the evaluation of other active substance study.	Studies related to changes of TRV, residue definition and relevance of metabolites must be evaluated by RMS. For other studies necessary to demonstrate safe use, zRMS should assess those data in the dRR and all MS of all zones will be invited to comment.	Extend the list of Confirmatory information to include new active substance data that should be assessed with the product assessment. PAI	Medium term

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
			The information about the assessment of those active substance studies will be included in the confirmatory information list.		
Procedures	4.4	A new process for how new active substance data should be evaluated during a PPP assessment was discussed.	New active substance data submitted in a PPP dossier: • Applicant must provide the information to zRMSs and state which new active substance data are submitted for PPPs and why it is needed, to which MSs the new active substance studies are submitted and for which products (valid for art. 43 and art. 33). • Once it is agreed which MS will perform the assessment, the new active substance studies will be added to the extended 'confirmatory information table', proposed to be extended to new	Update SANCO GD 10328/2004 with the proposed procedure. PAI is responsible to form a small group of experts for this task.	Medium term

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
			active substance data post (renewal of) approval • The list is in the agenda of every PAI meeting; it will be proposed to PAI to open the access to applicants, unless a different communication process will be established • It will be necessary to decide which level of information will be included in the list, i.e. conclusion of assessment of the studies. • In case of adverse findings, art 21 procedure will be considered (involving EFSA) • As a matter of principle, the active substance data will be assessed in the dRR format		

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
			• During the commenting period, all MSs and the applicant will be given the opportunity to comment on the assessment which should be done according to the same timelines define by as Article 33/43 • Conclusion of the new active substance data assessment will be included in the final RR in CIRCA BC • In case of data triggering the change of TRV or changes to the residue definition or groundwater metabolites, the RMS will run the assessment, in line with the current SANCO 10328/2004. Next steps: start the revision of the SANCO GD 10328/2004 Rev.9, 2021, and meanwhile trying to apply this proposal in		

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
			a pragmatic way as pilot, while trying to gain experience before the adopting a new version of the GD, if there is an agreement at izSC/PAI among MSs.		
How should we deal with data that has been peer-reviewed but the EFSA conclusion is delayed due to e.g. ED data?	4.5	There are different views within MS on which data can be used to support product authorisations.	The legal opinion of the EU COM is that it is necessary to use EU existing endpoints, as agreed at the SCoPAFF during the approval/renewal of the active substance, i.e. after the endpoints are noted by SCoPAFF.	This should be further clarified when the outcome of the pending court cases in EU is known since this may affect this interpretation. COM	Short term
How do we interpret 'current scientific and technical knowledge'	4.6	The pending EU court cases might redefine what can be considered "current scientific and technological knowledge". Some MSs are flexible to allow applicants to use available but not yet noted/applicable GD if it allows to get registration; other MSs are in favour of using the new GD immediately when available (before being noted); other MSs will follow the GD once they have been noted by the SCoPAFF.	There is a common agreement in BOG4 that applicants must know what guidance need to be applied. Guiding principle: guidances used for PPPs assessment must be noted and applicable at the time of submission; Some MSs have different interpretation and consider that guidelines should be used already once published or when endorsed.	This should be further clarified when the outcome of the pending court cases is known since this may affect this interpretation. COM	Short term

6 BREAKOUT GROUP 5
Authorisation of PPP in the light of the Green Deal - Low-risk, biocontrol and non-chemical PPP assessment

6.1 Thought starter

The following document has been prepared as a thought starter to initiate discussions in the Breakout Groups and should in no way be conceived as the official position of the European Commission or the Member States.

6.1.1 Background

The "farm-to-fork" strategy will enable the transition to a sustainable food system that safeguards food security and ensures access to healthy diets from a healthy planet. It will reduce the environmental and climate footprint of the food system and strengthen its resilience, protect the health of citisens and guarantee the livelihood of economic operators. European Farm to Fork strategy has established very ambitious targets, two of them are related with the plant protection and plant protection products and have a clear impact in the market and availability of plant protection products at short term. These two targets are the following:

- ✓ Reduce by 50% the overall use and risk of chemical pesticides and reduce use by 50% of more hazardous pesticides.
- ✓ Achieve at least 25% of the EU's agricultural land under organic farming and a significant increase in organic aquaculture.

To achieve these objectives is necessary to enhance the availability of alternatives to chemical plant protection products and to promote and implement integrated pest management (IPM) strategies that includes all the potential and possible preventive and curative measures, including the use of new technologies as digital farming; drone application of plant protection products; local and spot application of plant protection products; new application techniques that reduce the rate of application…. Furthermore, IPM shall include the use of low-risk plant protection products; microorganisms based PPP; beneficial organisms…etc. One of the alternatives to chemical plant protection products is the low-risk plant protection products and biocontrol plant protection products.

Article 47 of the Regulation (EC) No 1107/2009 establishes provision for the authorisation of PPP as a low-risk PPP. As a first premise, all the active substances contained in the PPPs shall be approved as low-risk active substances and the PPPs shall be authorised as a low-risk PPPs provided no specific risk mitigation measures are needed following a risk assessment. In addition, the following premises must be met, among others, it does not contain a substance of concern; it is sufficiently effective; it complies with points (b), (c) and (f) to (i) of Article 29(1).

European Commission has been making important progress at the legislative level, thanks to the work carried out by the Biopesticide Working Group. In this way, a legislative package was published in September 2022 that contains specific criteria for the approval of active substances that are micro-organisms; data requirements for active substances and plant protection products based on microorganisms; specific uniform principles for evaluation and authorisation of plant protection products containing micro-organisms. Recently, the Standing Committee on Plants Animal, Food and Feed has endorsed the "Explanatory Notes for the implementation of the data requirements on micro-organisms and plant protection products containing them in the framework of the Regulation

(EC) No 1107/2009". This document gives additional information for the implementation and application of the data requirements related to microorganisms.

EU Commission organised a Workshop on "Possibilities to increase availability of PPPs" last 26 of October. In this workshop several MS expressed the problem of the lack of alternatives to chemical PPP and also the lack of substitution of those active substances that are not approved, and the reduced number of modes of action available to control some pests; diseases or weeds. Furthermore some ideas and possible solutions to increase the availability of plant protection products were showed and discussed, for example: increase EU & MS capacities for the assessment and approval of non-chemical solutions; prioritisation of biocontrol PPP applications; use of Article 40 and Article 51 in a more efficient way; use of the risk envelope approach for active substance and PPP assessment; explore the possibility of quick authorisation of the representative formulation and use of the approval of the active substance, reduce bureaucratic burden for biocontrol PPP applications. Outcome of this workshop has been summarised in a document in which different issues that difficult the availability of biocontrol PPP in the market and potential solutions have been identified. This document is included in the BOG 5 as a background document.

It is urgent to take measures at short and long term by all the actors involved in the process for the authorisation of plant protection products to increase the availability of alternative to chemical plant protection products in the market. These alternatives include, among others, low-risk plant protection products, microbial plant protection products, pheromones and semiochemical, plant extracts.

There are some proposed solutions to increase the availability of alternatives to chemical plant protection products in the market:

Measures to be taken by MS:

- Prioritise the assessment of non-chemical PPP (microorganisms; plant extracts; potential LOW-RISK PPP....)
- Maximise the use of Article 40 (Mutual Recognition)
- Maximise the use of Article 51 (extension of use for minor uses)
- Increase the use of the risk envelope assessment approach
- Increase capacities in particular multidisciplinary risk assessor team for the assessment of non-chemical PPP

Measure to be taken by applicants:

- Increase quality of dossier
- Unify applications in all MS
- Include as much as possible uses in one application, including major and minor uses to avoid extension of uses and duplication of assessments

Objectives of the Green Deal and in particular of the Farm to Fork strategy are not achieved only with measures that increase the availability of low-risk, biocontrol and non-chemical PPP, furthermore it is necessary to implement as much as possible all types of measure and techniques that allows the reduction of exposure to chemical PPP. The reduction of the overall use and risk of chemical pesticides can be achieved by the use of risk mitigation measures and new techniques and technologies for the application of PPP. In this sense EU Commission has developed a document "Compendium of conditions of use to reduce exposure and risk from plant protection product" that aims to be the starting point for further mapping and validation of the available conditions of use and specific technologies to reduce exposure from pesticides in the European Union. Furthermore, it is recognised that it is necessary to progress in the harmonisation on the decision taken by the

competent authorisation when granting authorisation of PPP with risk mitigation measures and/or restrictions on the use of PPP, the compendium document intend to contribute in this harmonisation. It is necessary to progress in this harmonisation, and this should be done at zonal and interzonal level.

6.1.2 Discussion points

BOG 5 has been identified for discussion of the measures to be taken in order to increase the authorisation of plant protection products that allow and contribute to achieve the objectives of the Green Deal and the Farm to Fork strategy.

Discussion shall be focused on authorisation of plant protection products, in particular low-risk, biocontrol and non-chemical PPP and not in the approval of active substances.

Organising committee has received several points for discussion, all these points have been grouped in two main groups and can serve to start the discussion in the BOG 5.

The discussion shall focus in identify the barriers and bottlenecks that do not allow to increase the availability of alternatives to chemical PPP in the market and identify potential solutions.

There are some questions that should be answered:

- ✓ Is it necessary to modify the legislative base, such as: approval/review deadlines, data requirements and criteria for approval and authorisations.
- ✓ Is it necessary to develop new guidance documents or to modify the existing guidance documents?
- ✓ Can we consider that the current zonal/interzonal PPP evaluation/authorisation system and procedure is sufficiently efficient for biocontrol PPP?
- ✓ Are we using efficiently all the provisions of Regulation (EC) No 1107/2009?

1. Procedure: How to accelerate the authorisation of “low-risk PPP”
    - ✓ Is it necessary to modify the legislative basis?
    - ✓ Reduction of fees
    - ✓ Reduction of bureaucratic burden
    - ✓ Prioritisation of applications - risk and benefits - Fast track procedure using the IZ procedure.
    - ✓ Reduce national DR
    - ✓ Increase the quality of dossiers
    - ✓ Green Team of Risk Assessors/risk managers with sufficient experience
    - ✓ Reduce commenting period
    - ✓ Common understanding of Article 47 (low-risk PPP)
    - ✓ Efficacy of low-risk PPP could be an issue that difficult the application of the harmonisation in the zone; MR...
    - ✓ Use of Mutual Recognition (Article 40.2)
2. New technologies:
    - ✓ How to include the Digital and Precision Agriculture (DPA) tools in the risk assessment?
    - ✓ Common understanding on the minimum requirements and necessary data basis for the acceptance of new application techniques between the MS.
    - ✓ How to implement the new application methods of PPP (drones/precision agriculture) in the zonal assessment of PPP; what is needed?

6.2 Summary report

Foreword

To achieve objectives of the Green Deal and the Farm to Fork strategy it is necessary to reduce the use of chemical plant protection products (PPP) and to enhance the use of alternatives to chemical plant protection products. Therefore, it is important to promote and implement integrated pest management (IPM) strategies that includes all the potential and possible preventive and curative measures, including the use of non-chemical ppp and new technologies as precision farming, new application techniques that reduce the rate of application. Furthermore, IPM shall include the use of biopesticides such as microorganisms, plant extracts, and semiochemicals and new technologies as dsRNA and peptides and low-risk plant protection products. One of the alternatives to regular chemical plant protection products is the low-risk plant protection products. We will focus particularly on biopesticides as the low-risk status can be granted as a result of the risk assessment. While beneficial are part of IPM measures they are subject to a separate regulatory process.

It is urgent to take measures at short and long term by all the actors involved in the process for the authorisation of plant protection products to increase the availability of alternatives to more hazardous chemical plant protection products. In the sense that not only they are available in the market, but also they are actually used by farmers within the IPM framework.

Participants of BOG5, who comprised representatives from 10 MS, 3 of industry, 1 of observers from EFSA.

6.2.1 Discussion points

The following questions were considered to identify the barriers and bottlenecks that hamper the availability of alternatives to chemical PPPs in the market and to propose actions and potential solutions:

- Is it necessary to modify the legislative base such as: approval/review deadlines; data requirements; criteria for approval and authorisations?
- Is it necessary to develop new guidance documents or to modify the existing guidance documents?
- Can we consider that the current zonal/interzonal PPP evaluation/authorisation system and procedure is sufficiently efficient for biocontrol PPP?
- Are we using efficiently all the provisions of Regulation (EC) No 1107/2009?

The main concerns regarding the authorisation of PPPs in the light of the Green Deal – Low-risk, biocontrol and non-chemical PPP assessment to ensure a sufficient availability of biopesticide solutions on the market were identified as follows by the participants of BOG 5:

- Definitions (Clarity of low-risk/low-hazard criteria – Guidance)
- Lack of resources/capacities
- Delays of authorisation of biopesticides
- Prioritisation of evaluation of biopesticides – How to prioritise and do national legal provisions allow it.
- Lack of expertise and knowledge (Green teams etc.)
- How to perform the risk assessment and DR
- How to integrate IPM and new technologies (precision and digital agriculture) in the risk assessment
- Procedures and harmonisation (mutual recognition etc.)

Definitions (Clarity of low-risk/low-hazard criteria – Guidance)

To achieve the objectives of the "farm-to-fork" strategy, a definition and common understanding on the term biopesticides is needed as a prerequisite for taking measures at member state level (prioritisation, fast track, lower fees) and to promote biopesticides as alternatives to chemical PPPs. The definition included in the proposal of the Sustainable Use Regulation (SUR) "plant protection products containing active substances that are plant products using natural means of biological origin or substances identical to them, such as micro-organisms, semiochemicals, extracts from plant products as defined in Article 3(6) of Regulation (EC) No 1107/2009" was identified as a potential definition as it has been discussed and can be included in a legislative act. Furthermore, it was identified as a necessity to have a list of active substances under the category of chemical and non-chemical, as there are different reduction goals for these groups of active substances.

The criteria for the approval of low-risk active substances was identified as a hazard criterion and not as a low-risk criteria, meanwhile the criterion for the authorisation of low-risk plant protection products is a criterion based on risk since risk mitigation measures are included in the criteria. However, it was identified as a necessity to harmonise the definition of generic and specific risk mitigation measure in this context.

Expertise and knowledge (Green teams etc.)

Participants of the BOG5 recognised the necessity to increase capacities for the assessment, and equally recognised it is also necessary to increase the knowledge in the area of biopesticides, such as microbiology, novel technologies, etc. In most of the MS that were participating in BOG 5 only one team of experts is available dealing with the assessment of all types (chemical and non-chemical) of PPPs. To facilitate the availability of biopesticides on the market the idea of so-called green teams (i.e. a team of experts dealing specifically/exclusively with biopesticides) was discussed as currently in place in the Netherlands. Alternatively, the collaboration between two MSs in a joint PPP assessment could be regarded as a way forward to compensate the lack of capacities and/ or specific expertise of individual Member States. It was further proposed to create an interzonal or zonal team of biopesticides experts in a joint review, although coordination of the team and harmonisation of the criteria for the assessment were identified as challenging. This solution would need to convince all MSs and it is very ambitious. According to Member States competent authorities, the current low number of applications for the assessment and registration of plant protection products based on biopesticides does not justify the necessity to increase capacities. However, it was observed that the Commission's reply to Council Decision (EU) 2022/2572 dated 19 December 2022 highlights the submission of 79 new applications for the approval of new biological control active substances (as outlined in the SUR proposal) and 54 extensions of uses scheduled for the period between 2023 and 2028 (IBMA pipeline survey). Deliberations ensued regarding the potential need or not for additional capacities from Member States to handle these new applications.

6.2.2 Conclusions

SUGGESTIONS TO REDUCE DELAYS OF AUTHORISATION OF BIOPESTICIDES

- Definition of biopesticides / list of substances that are considered biopesticides and needs to be promoted according to the challenges of the farm to fork strategy,
- MSs to explore possibility to implement fast track procedure and define relevant applicability criteria,

- Participants of BOG 5 took differing attitudes on provisional authorisations for biopesticides. Some alternative fast tracking options have been discussed (see table).

SUGGESTIONS TO ADRESS LACK OF CAPACITIES

- MSs recognise the necessity to increase capacities in number and knowledge,
- Implement systems at MS level to use the fees for hiring experts,
- Work sharing between MS: from bilateral collaboration to a Zonal/InterZonal Green Team. Use of CIRCABC as an exchange platform,
- Perpetual/longer approval period for low-risk active substance (and consequently modified authorisation of low-risk PPPs) as a way to reduce MSs workload. Preference across MSs for a longer approval period.

PROCEDURE AND HARMONISATION (mutual recognition etc.)

- Implementation of the low-risk criteria for active substance: low-hazard/low-risk, articulation between art.22/47. European Commission to finalise the low-risk Guidance Document,
- Interpretation of Article 47 (RMM): BPWG / PAI,
- Hazard criteria (classification) - hard cut off preventing some biopesticides categories (Natural substances, semiochemicals) to receive the low-risk status. Work around solution with consideration of the representative use (no specific RMM then low-risk): European Commission / PAI,
- Increased use of mutual recognition including interzonal mutual recognition to improve availability of sustainable alternatives,
- Interzonal procedure for low-risk products: proposal for a pilot project as a proof of concept.

HOW TO PERFORM THE RISK ASSESSMENT?

- Problem formulation approach for the new technologies of PPP
- Guidance for Microbial Consortia,
- Develop guidance for plant extracts,
- Develop guidance(s) for novel technologies,
- Better Training for Safer Food – advanced course (specific section/technology),
- Maintain calls for research projects on biopesticides including novel technologies [need to know vs nice to know - linked with the risk assessment],
- Increase expertise in presubmission advice to applicants as a way to improve quality of dossiers,
- Efficacy: proposal for a modification of the EPPO guidance (replace wording “low-risk products” by “low-risk active substances”).

NEW TECHNOLOGIES (PRECISION AND DIGITAL AGRICULTURE/IPM)

- It is recognised as an opportunity to reduce the volume of used PPP and to reduce exposure. New application technology can be used under the existing GAP in order to reduce the exposure and as a new application for registration. In both cases we need to characterise the exposure (environment/operator-bystander) and certify the machinery.

6.3 Summary table

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
Delays/Definitions	5.1	An EU wide legal definition is a prerequisite to take measures at MS level (prioritisation, fast track). Definition for chemical/non-chemical because different reduction goals.	EU Definition of biopesticides (basis: SUR definition). List from EU COM classifying substances (interim solution). Also definition for non-chemical (=biopesticide?)	Commission (consider the outcome if the SUR, and then replan of necessity)	Short term
Delays	5.2	Some national legal frameworks do not allow prioritisation. Do MSs comply with 120 days reduced timeline for low-risk PPPs? Belgium: separated pipeline (including fast track) for biopesticides PPPs. Bulgaria: administrative procedure for Mutual Recognition for low-risk PPPs + fast-track for low-risk PPPs. Most other MSs try to comply with 120 days for low-risk PPPs, with no specific fast track procedure. Malta: fast track (6 months) for all types of PPPs in exchange of higher fee, under request from the applicant (no stop the clock, needs a good dossier)-> first in first served, maximum number of applications per year Netherlands: Fast Track procedure: 1. It concerns an application for authorisation of a plant protection	Various situations in MSs as regards to fast track.	MSs to explore possibility to implement fast track procedure and define relevant applicability criteria (e.g. Malta, extra fee to open fast track, and or Belgium's biopesticides separate pipeline).	Short term

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
		product with at least 1 new use in the Netherlands, and 2. all active substances in the plant protection product in question belong to at least one of the following categories: a. (expected) low-risk substances; b. living micro-organisms (including viruses); c. non-chemical substances with non-toxic or selectively toxic effects, such as: - all semiochemicals (including pheromones); - plant extracts with non-toxic effects or selectively toxic effects; - nature-identical substances (such as dsRNA, antibodies, peptides) with selective-toxic effects National requirements for low-risk PPPs: (e.g. NL no groundwater DR for microorganisms)	For products based on low-risk active substances would general risk assessment as done in the core be enough?	Explore if there is a need for specific national risk assessment for products	

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
				based on low-risk active substances.	
Delays/Lack of capacity	5.3	How to increase/better use existing capacities of MS for the evaluation and registration of biopesticides (MO/botanicals/semiochemicals, novel technologies etc.)	Increase capacities – experts with sufficient knowledge in biopesticides PPPs. National green teams OR work-sharing – collaboration between MSs (co-RMS, expertise sharing) OR create Interzonal/zonal green team(s) (challenge: coordination, timeslot to perform work in coordination)? CIRCABC: exchange platform to define/identify potential solutions	Retained proposal: Increase of capacities + use the fee to hire people: Competent Authorities If not sufficient, consider the work-sharing proposal.	Short term
Delays/workload	5.4	Need to decrease the workload at MS level	Perpetual /longer approval period of the low-risk active substance), art. 56: applicant to inform about harmful effect. EU COM/MS could also do so to trigger a review	European Commission/MSs discussion (identified as an urgent discussion)	Medium term
Definition	5.5	Implementation of the low-risk criteria for active substance: low-hazard/low-risk, articulation between art.22/47.	Finalise the Guidance Document for low-risk Products. Interpretation of articulation of art.22/47 in the Guidance Document. Agreement between MSs of what a RMM by default (generic) is and what is a specific RMM by the risk assessment -> inclusion in the GD document.	European Commission to finalise the Guidance Document. Identify relevant forum (Biopesticides WG/PAI)	Short term

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
			Hazard criteria (classification) is a hard cut off preventing some biopesticides categories (Natural substances, semiochemicals) to receive the low-risk status. 2 step approach: 1. Hazard criteria 2. If for the representative use, use art. 47, if no specific RMM for the representative use RMS to include conclusion of the low-risk status of the representative PPP and use(s) in the DAR/RAR.	European Commission/PAI	
Harmonising Risk Assessment for natural substances and novel technologies (peptides, dsRNA, microbial consortia, bacteriophages etc.)	5.6	Develop an approach for performing problem formulation for natural substances and novel technologies (ask the right questions, see where the real concerns are, justification for waivers within the existing data requirements).	Survey from applicants to identify pipeline and define prioritisation (refers to CLE survey, focussing on DR-Part A related technologies) + IBMA Pipeline survey (peptides) Microbial consortia: guidance Take into account the problem formulation document discussed at SCoPAFF	-Problem formulation, prioritisation survey (CLE, IBMA) -Guidance for Microbial Consortia -Output from RATION project + results of the questionnaire to competent authorities -Output from EFSA Grant – "Develop a stepwise approach for a fit for purpose risk assessment, in particular for low-concern active substances and uses": 18 Months – 2025)	Short term (different deadlines)

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
				-maintain calls for research projects on biopesticides including novel technologies -Develop guidance for plant extracts -Develop guidance(s) for novel technologies -Better Training for Safer Food – advanced course (specific per section/technology)	
Encourage applications	5.7	Reduction of fees Reduction of bureaucratic burden	Reduced fees could encourage applications where needed (Northern Zone, less economic interest from applicant). Fees should maintain and increase capacities	Competent authorities to use the fees to <u>maintain</u> and increase capacities	Short term
Is it necessary to modify the legislative basis	5.8	Green deal objectives. We need to know clearly what has to be promoted. Clear distinction between chemical, non-chemical/biopesticides Would it help to have an interzonal procedure for low-risk Products (like seed coating and indoor uses)? It is likely that Member states would follow the procedure, while other will reopen the box.	General agreement on the need and benefits of a biopesticides definition. It is not necessary to modify the legislative basis, but can agree to targeted amendments for specific points **<u>Pilot project</u>:** Identify one example of low-risk active substance with field uses to perform the interzonal assessment by one ZRMS, one co-	Commission (consider the outcome if the SUR, and then replan of necessary)	Short term Short term

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
		Need to decrease the workload at MS level	ZRMS (applicant should prepare dossier accordingly) Perpetual /longer approval period of the low-risk active substances	Pilot project: Stakeholders to select one example and propose one zonal RMS and one co-ZRMS and to propose it to be agreed in the interzonal Steering Committee.	Short term
		Implementation of the low-risk criteria for active substance: low-hazard/low-risk, articulation between art.22/47.	Finalise the Guidance Document for low-risk Products. Interpretation of articulation of art.22/47 in the Guidance Document. Agreement between MSs of what a RMM by default (generic) is and what is a specific RMM by the risk assessment -> inclusion in the GD document. Hazard criteria (classification) is a hard cut off preventing some biopesticides categories (Natural substances, semiochemicals) to receive the low-risk status. 2 step approach: 1. Hazard criteria 2. If for the representative use, use art. 47, if no <u>specific</u> RMM for the representative use	European Commission/MSs discussion (identified as an urgent discussion) European Commission to finalise the Guidance Document. Identify relevant forum (Biopesticides WG/PAI)	Short term Short term Short term

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
		Provisional authorisation for biopesticides (3 years): Greece: does not see added value for the provision, double work. Different aspects must be considered. Germany: concern as regard of the current workload. Spain/NL: provisional authorisation is a way to promote the faster availability of biopesticides. Doesn't imply more work. Belgium: concern about efficacy data	RMS to include conclusion of the low-risk status of the representative PPP in the DAR/RAR. Different opinions among MSs on provisional authorisation and concerns. No consensus. Belgium noted the possibility to submit the dossier earlier in the procedure and use this possibility to reduce the timeline (an example was presented by Belgium). Authorisation of reference product at moment of finalising DAR (according to same logic as provisional authorisation Article 30 1c). EFSA proposal: align the peer review of a substances and the commenting period of the product. Have more experts from MSs in the peer review.	European Commission/PAI	
Encourage applications	5.9	how to decrease workload If applications are not of good quality -better use of zonal application and mutual recognition -increase expertise in pre-submission advise to applicants	Better quality of the dossiers Presubmission meetings are useful to prepare good quality dossiers	Applicants to increase the quality of the dossiers. Taking into consideration the conclusions of the	Short term

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
			Mutual Recognition has been identified as a possible solution when applications are not submitted	evaluation of the active substance at EU level It would be useful to have a series of examples, a document listing the type points that the applicant would need to pay attention to in order to increase the quality of the dossier. Also, pre-submission meetings are very useful for a preparation of a qualitative dossier Explanatory notes for the implementation of the data requirements on micro-organisms and plant protection products containing them shall be considered in the preparation of dossiers. Applicants & ZRMS to liaise presubmission meetings. EFSA has offered to be part of PSM meetings. Very useful especially to	

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
				discuss approach for innovative technologies.	
Lack of alternatives (problem of availability and variability)	5.10	Use of mutual recognition, including art. 40.2	Use of mutual recognition (including interzonal mutual recognition) - lack of alternatives and less economic interest for applicants	MS to explore the possibility to use the provisions of Article 40.2	Medium term
Efficacy	5.11	Efficacy: - Lower efficacy - Trials in Northern conditions often not available - EPPO zone differences within regulatory zone	Modify the EPPO guidance: replace wording “low-risk product” by “low-risk active substances” (see point above): Group agrees on the proposal	Proposal to EPPO	Short term
New application technologies	5.12	Flying drone technology for applying PPP is available in the market but cannot be used due to ban of aerial application (SUD). Considered as a method of application: Characterise the exposure generated by this new method of application (drift generated by the method, operator/bystander/resident exposure, etc.). Enable new application technologies under the current authorisations by certification of technologies that guarantee equivalence of new	Need new experimental data on exposure. Characterise exposure with models for this type of application. Make it possible to use these techniques for existing authorisations under the risk envelope. Bring the application method in the GAP table Take into account the compendium of conditions of use.	European Commission, EFSA, Member States, EUPAF (precision agriculture task force) A workshop is being help in April between the Member states, EFSA & the Task force. It would be worthwhile putting forward so that all relevant stakeholders are made aware of it and attend if necessary	Short term

Topic	ID	Summary of Discussion	Conclusion	Proposed action / Responsibility	Short/ Medium/ Long term
		technologies to existing ones (Drift, homogeneousness, GAP, max dose per cm^2) Need to have these new application techniques certified (machinery reg.)	More direction from COM in the development of a framework for innovative application technologies, including the assessment framework, but also the standardisation/normalisation and fulfilment of conditions under the Machinery Directive		

7 FINAL AGENDA

<table>
<tr><th colspan="3">Tuesday 5 December 2023</th></tr>
<tr><td>11.30-13.00</td><td></td><td>Registration – Welcome Coffee</td></tr>
<tr><td>13.00-13.30</td><td>Plenary session</td><td>Welcome and introductions (BVL and COM)

Housekeeping announcements</td></tr>
<tr><td>13.30-15.00</td><td>Plenary session</td><td>Setting the scene/Introduction to Breakout Groups
(Organising Committee/Chairs)
– Introduction and framework of the workshop
– Introduction to thought-starter for each BOG</td></tr>
<tr><td>15.00-15.30</td><td>Coffee break</td><td></td></tr>
<tr><td colspan="3">Breakout Groups (BOGs)</td></tr>
<tr><td>15.30-17.00</td><td>Break-out group session #1</td><td>1.5 hours for group to set out what they want to discuss and to allow group to reflect over night for work in day 2.

5 BOGs; chairs to lead discussions

<table><tr><th></th><th>Main topics</th></tr><tr><td>1</td><td>Meeting legal requirements – Tackling delays</td></tr><tr><td>2</td><td>Harmonising zonal decision making – Special focus on Mutual Recognition, minor uses, and assessment of co-formulants</td></tr><tr><td>3</td><td>Work sharing on digital platforms - The future of European IT-systems in PPP authorisation procedures</td></tr><tr><td>4</td><td>Implementation of new scientific and technical knowledge - Guidance Documents (e.g. GD SANCO 10328/2004)</td></tr><tr><td>5</td><td>Authorisation of PPP in the light of the Green Deal - Low-risk, biocontrol and non-chemical PPP assessment</td></tr></table>(Background paper and outline for each breakout group will be available prior to the workshop)</td></tr>
<tr><td>17.30-18.00</td><td>Plenary session</td><td>Stakeholder presentations (EFSA, MUCF)
(Moderation: BVL)</td></tr>
<tr><td>18.00-18.30</td><td>Plenary session</td><td>Closing remarks for day 1
(Organising committee/Chairs)</td></tr>
<tr><td>19.00</td><td>Get together</td><td>Meeting point at the Braunschweig Christmas Market</td></tr>
</table>

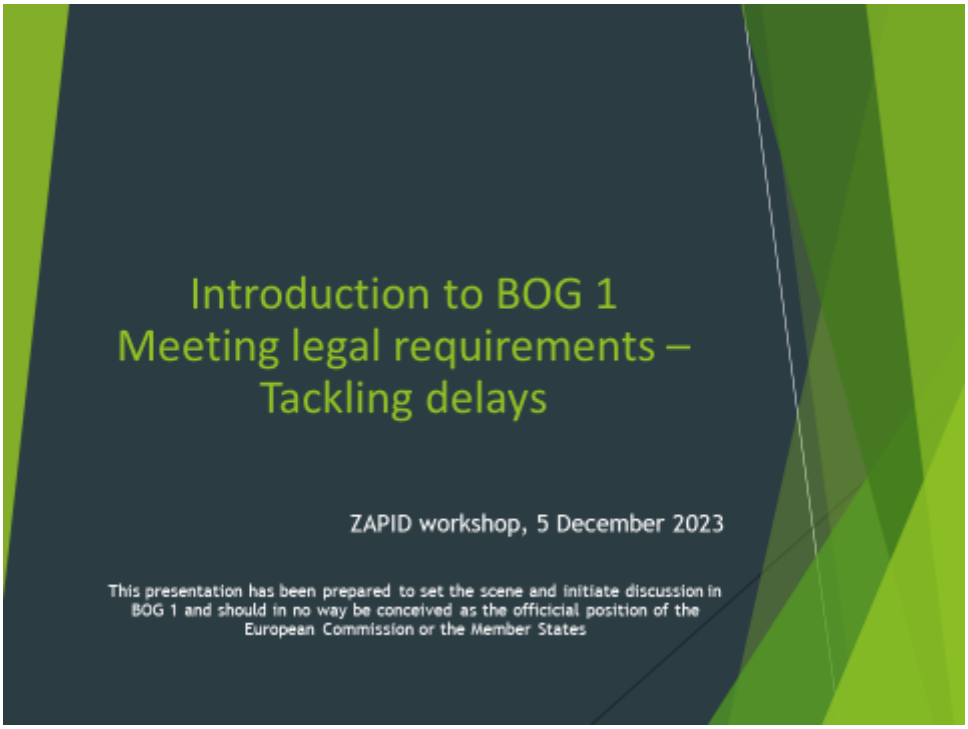
Wednesday 6 December 2023		
Breakout Groups (BOGs) – continued		
9.00-9.30	Plenary session	Stakeholder presentations (industry) (Moderation: BVL)
9.30-11.00	BOG session #2	Cont'd from previous day
11.00-11.30	Coffee break	
11.30-12.30	Plenary session	Initial feedback from BOGs (5 mins per BOGs + discussion) (Moderation: BVL)
12.30-14.00	Lunch	
Breakout Groups (BOGs) – continued		
14.00-16.00	BOG session #3	Cont'd from morning session
16.00-16.30	Coffee break	
16.30-18.00	Plenary session	Second feedback from BOGs (10 mins per BOGs + discussion) (Moderation: BVL)
19.00	Workshop Dinner	

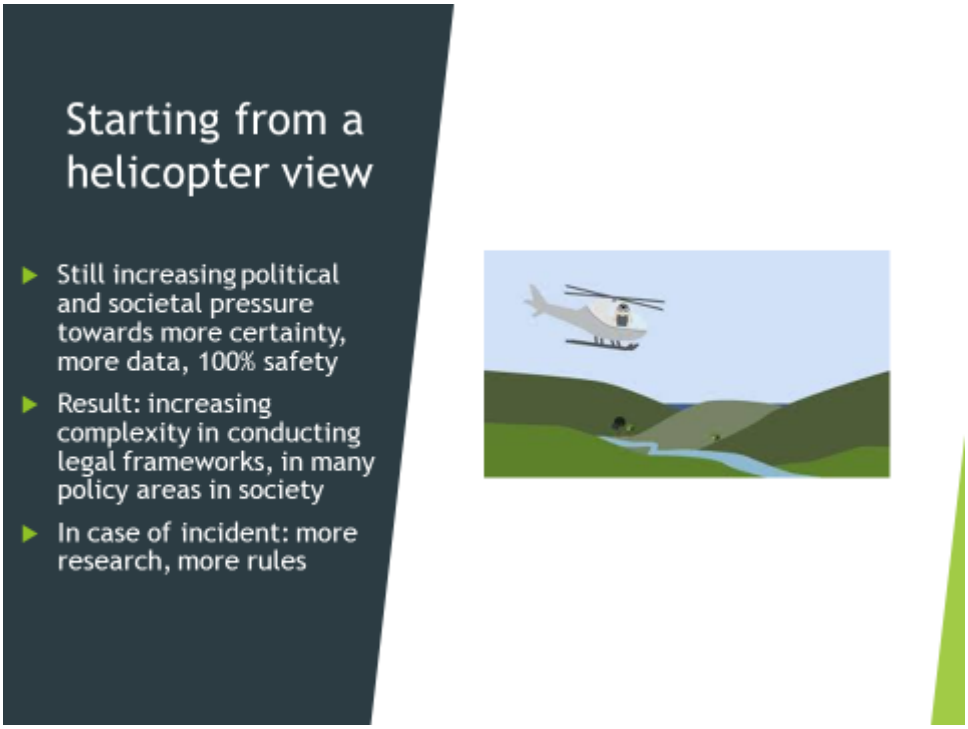
Thursday 7 December 2023		
Suggestions for improvements		
9.00-10.00	Plenary session	BOG presentations in plenary Questions and clarifications (Moderation: BVL)
10.00-10.45	Plenary session	Final plenary discussion
10.45-11.15	Coffee break	
Workshop summary and conclusions		
11.15-12.45	Plenary session	Summary and Conclusions – written draft document (Presented by each BOG) Proposals for recommendations and activities, and the way forward (Moderation: BVL)
12.45-13.00	Plenary session	Closing remarks for the workshop (Organising committee/COM)

8 Annex: Plenary presentations

8.1 Introduction to BOGs

8.1.1 BOG 1





Starting from a helicopter view

- More capacity needed to conduct legal frameworks in general
- Increasing workload; insuffient capacity
- Deliberate choices have to be made; otherwise, day-to-day business rules

PPP Regulation – main bottlenecks

- Structurally increasing complexity and amount of work
  - Assessment framework has expanded, technical, procedural and administrative, greatly increasing workload per application
  - Legal deadlines no longer commensurate with workload
  - Expansion of framework will continue

PPP Regulation – main bottlenecks

- Given European policy goals (EU green deal):
  - "green" substances and products should be prioritised
  - innovative application technologies should be stimulated
  - faster development of guidance for innovations is needed; also requires capacity
- Insufficient staff
- Slow decision-making process

Proposed solutions

- Set priorities
- ZAPID focuses on PPPs, but for setting priorities we must look at the complete workload; capacity can only be used once

Proposed solutions

- Limit complexity

- Increase feasibility

Proposed solutions

- Centralize allocation of applications

Proposed solutions

- Improve quality of submitted dossier

8.1.2 BOG 2

An Roinn Talmhaíochta,
Bia agus Mara
Department of Agriculture,
Food and the Marine

Workshop on Zonal Authorisation Procedure Improvements and Developments

5th-7th December 2023
Braunschweig, Germany

Pesticide Controls Division
Department of Agriculture, Food & the Marine
Ireland

BOG 2 - Harmonising zonal decision making – Special focus on Mutual Recognition, minor uses, and assessment of co-formulants

- Mutual Recognition
- Minor Uses
- Co-formulants

2 An Roinn Talmhaíochta, Bia agus Mara | Department of Agriculture, Food and the Marine

Mutual recognition

Reg. 1107 objectives

- Increase free movement of PPPs by laying down harmonised rules on the MR of authorisations
- Through the principle of MR
  - *Avoid any duplication of work*
  - *Reduce administrative burden for industry & MS*
  - *Provide more harmonised availability of PPPs*
  - *MS recognise or <u>amend</u> an authorisation…..*

Mutual recognition

Articles 40-42

- Procedures to be followed when application for MR is received
- Article 51 – minor use MR procedure described
- Guidance document on zonal evaluation & mutual recognition under Reg. 1107/2009

  SANCO/13169/2010 rev.11 (January 2021)

Minor Uses

- Encompasses minor crop not widely grown and also an exceptional need within a widely grown crop
- High economic value to growers but can be low economic interest for authorisation holders
- Can be dealt with under various regulatory channels (e.g. Art. 33, Art. 40, Art. 51)

Minor Uses

- 2014 COM report on minor uses established MUCF and concluded that correct implementation of Reg.1107/2009 would deal with minor use problems
- Specific mention in the REFIT Report of 2018
- Legal possibilities not been fully explored across all the member states
- Costs and lack of return on investment

Assessment of Co-formulants

- Blaise judgement (C-616/17) – co-formulants must be subject to assessment to determine any harmful effects
- Increased scrutiny from NGOs, politicians, civil society
- Art. 27 of 1107/2009 – Unacceptable co-formulants
- Annex III list – Reg. 2021/383. 144 substances
- Identification rules – Reg. 2023/574

Assessment of Co-formulants

- EFSA report on co-formulants contained in representative formulations
- EFSA and Commission workshops
- Data on the co-formulants
- Transparency and harmonisation
- Resources and efficiency of risk assessment

Assessment of Co-formulants

- Other regulatory frameworks and assessments
- Harmonised classification - CLP
- Need for guidance on implementation of Reg. 2023/574 (and updates to existing GDs)
- Need for a database of co-formulants contained in PPPs – sharing assessments etc.
- Repository for sharing assessments

Mutual recognition

Discussion Points

- Are national requirements artificially creating obstacles especially where they may not be perceived to be scientifically justified?
- Can a common compendium of risk mitigation measures to be used in product evaluations to allow for more consistency in outcomes /authorisations?
- Is there a balance to be struck in the application of “noted”/ “endorsed” guidance and the autonomy and subsidiarity principle for MSs?

Mutual recognition

Discussion Points

- Is there a need for or the legal possibility for an arbitration process similar to that used in biocides co-ordination group?
- What can be done to facilitate more use of the Article 40.2 process (whereby applications for MR are made by those other than the authorisation holder)?

Minor Uses

Discussion Points

- Would a harmonised list of EU minor crops (or harmonised lists within the 3 regulatory zones) facilitate more availability of PPPs for minor uses?
- Is the lack of cohesion between Regulation 1107/2009, Regulation 396/2005 (and associated guidance documents) and EPPO requirements/guidance a hindrance to the minor use authorisation process?

Minor Uses

Discussion Points

- What further role can the Minor Use Co-ordination Facility play in enabling harmonisation (e.g. development of guidance, development of databases etc.) in the minor use sphere.
- Is the risk envelope approach, zonal authorisation system and mutual recognition being used to the full extent and what is impeding the application of the full raft of possibilities by the member states?

Assessment of Co-formulants

Discussion Points

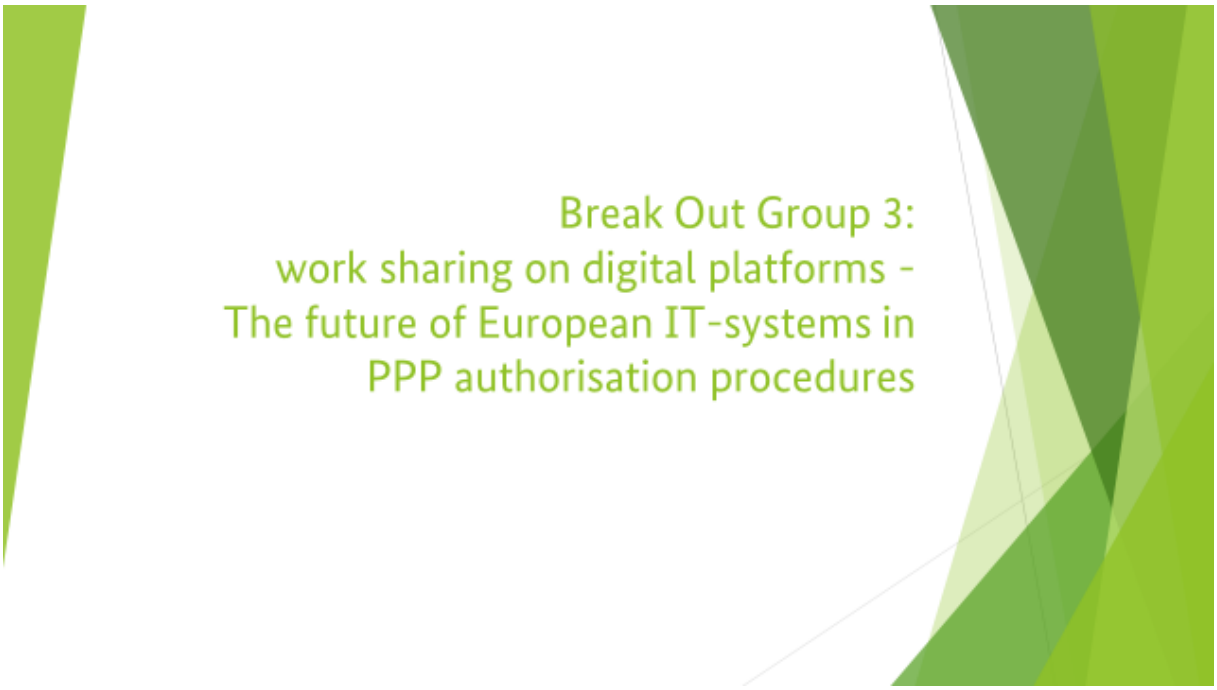
- Can the identification of unacceptable co-formulants be addressed by other regulatory regimes such as REACH, biocides or CLP or is a separate data evaluation by the PPP competent authority required in each and every case?
- Will the application of Regulation 2023/574 slow down the already delayed PPP authorisation and renewal processes? Will a centralised repository of co-formulant assessments be fully used by member states given the historical reluctance for full trust in other member state evaluations?

Assessment of Co-formulants

Discussion Points

- Does the current legal text provide applicants and member states with sufficient direction on the implementation of the requirements and if not how broad of a scope should a guidance document take?
- How will co-formulants where "sufficient" data is not already available be dealt with? Do the legal conditions exist to abstract this data from third parties and how will third party data be dealt with considering proprietary data issues and confidentiality?

8.1.3 BOG 3


Break Out Group 3:
work sharing on digital platforms -
The future of European IT-systems in
PPP authorisation procedures


Zonal system
Collaboration
Distribution of workload
Leveraging of collective expertise and resources
Harmonisation

Zonal system

- Collaboration
- Distribution of workload
- Leveraging of collective expertise and resources
- Harmonisation

But…

- Mostly not accompanied by centralised IT systems
- Relies on individual Member States systems and “manual” communication
- Poses a challenge for timeliness, accuracy and workload efficiency

Exploration of existing systems

- Different systems already exist at an EU level for use at active substance or PPP level
  - IUCLID
  - PPPAMS/ESFC
- Other systems exist within the biocide section, which could also serve as inspiration
  - R4BP3

MS concerns regarding these systems

- Compatibility with existing MS systems
- Avoidance of duplication of entry work
- Meeting MS requirements

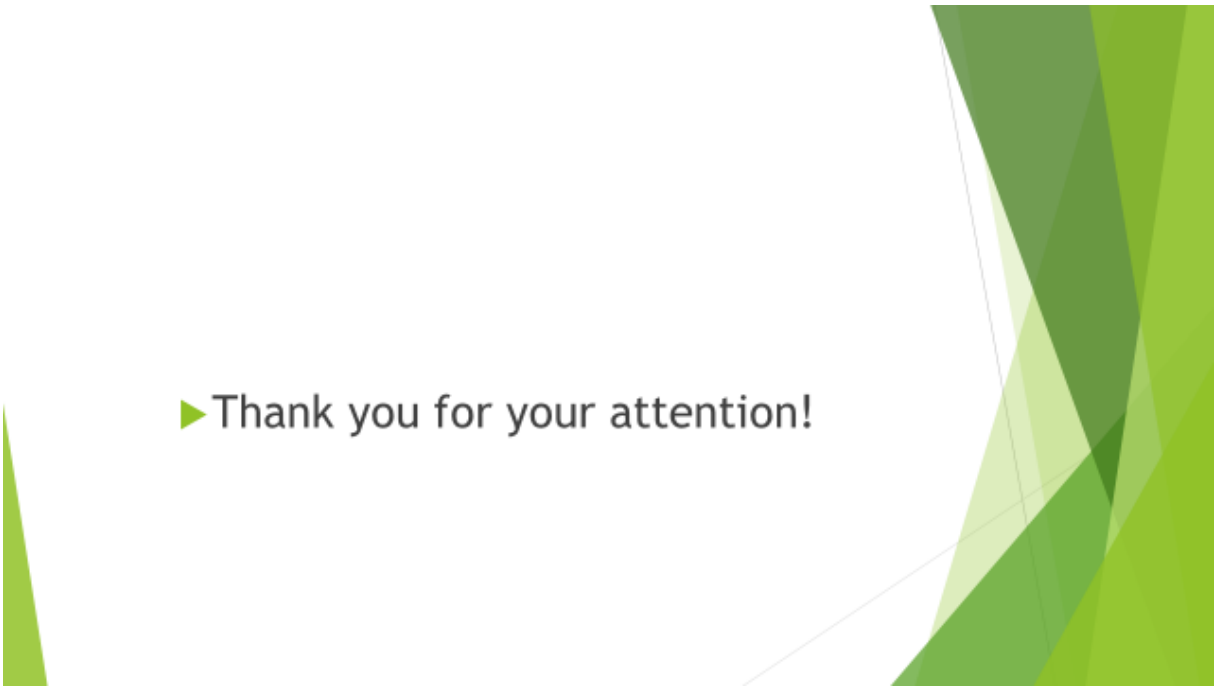
And also: co-formulants

- Increased scrutiny of the public to coformulants
- There have been multiple discussions on how to adress the public concern regarding this issue
- It has become apparent that there is desire amongst the MS for a database

EU database

- Different MS have different practices
- Some MS have already quite a database in place with information on conformulants
- Past discussions have shown that there is willingness at EFSA to develop a database on coformulants
- Discussion will focus mainly on the practical side

- Thank you for your attention!



BOG 4 - Implementation of new scientific and technical knowledge - Guidance Documents (e.g. GD SANCO 10328/2004)

ZAPID workshop

Braunschweig 5-7 December 2023

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Background

New active substance data

- There are several reasons why new a.s. data can be submitted post annex inclusion.
- A GD (SANCO/10328/2004) was developed to establish a harmonized approach to evaluate new a.s. data
- The focus of the GD is human health issues and relevance of metabolites
- GD do not give details regarding the process and refers to PAI for support
- Several issues has been raised to PAI concerning new a.s. data in the PPP evaluation process.
- There is a lack of standard procedures for handling new a.s. data in the PPP process and a need for updating SANCO/10328/2004 is evident

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Discussion points

New active substance data

- How do we define new active substance data?
- What new data should be considered relevant and further evaluated?
- How should the process work in practice?
  - Who takes the lead of the evaluation
  - How is information shared?
  - What is reasonable timelines for evaluations?
  - How should the evaluation and conclusion be archived and used in future evaluations?

Background

Current scientific and technical knowledge

- Regulation (EC) 1107/2009 demands that "*the Member State … shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents available at the time of application*"
- Unclear interpretation of *current scientific and technical knowledge*
- Delays in implementation and updating of GD hamper the use of new knowledge in PPP evaluations.
- It can also cause unharmonized evaluations since the phrase *using guidance documents available at the time of application* can be interpret differently by MS

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Discussion points

Current scientific and technical knowledge

- How do we interpret "*current scientific and technical knowledge*"?
- How do we deal with disagreements in product evaluations, both connected to new active substance data and to unharmonized interpretations of GD.

Output

- Suggestions for updates of SANCO/10328/2004
- Clarified process for new a.s. data post annex inclusion

- Suggestion of how to handle disagreements in evaluation of new a.s. substance data and intrepretation of *current scientific and technical knowledge*

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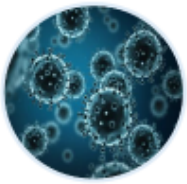
8.1.5 BOG 5

ZAPID WORKSHOP
BOG 5
Authorisation of PPP in the light of the Green Deal - Low risk, biocontrol and non-chemical ppp assessment

2030 FARM TO FORK TARGETS

Reduce by 50% the **overall use and risk of chemical pesticides** and reduce use by 50% **of more hazardous pesticides**

Reduce **nutrient losses** by at least **50%** while ensuring no deterioration in soil fertility; this will reduce use of **fertilisers** by at least **20 %**



Reduce sales of **antimicrobials** for farmed animals and in aquaculture by **50%**

Achieve at least 25% of the EU's agricultural land **under organic farming** and a significant increase in organic aquaculture

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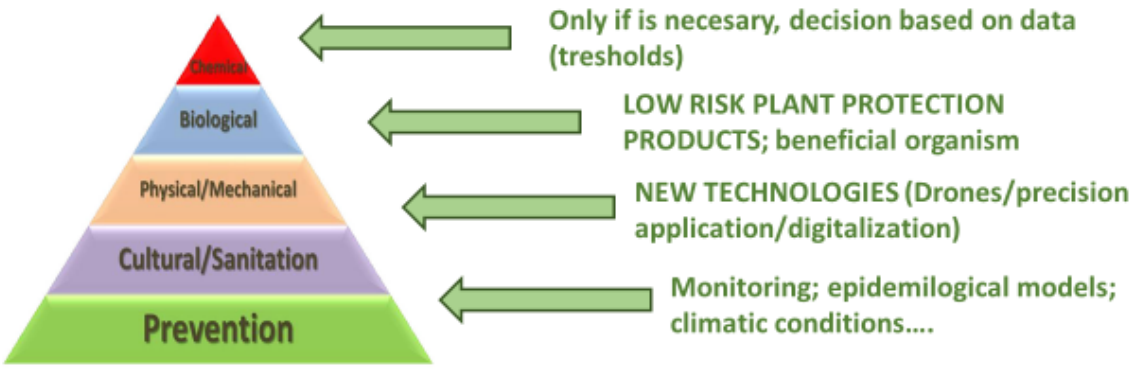
INTEGRATED PEST MANAGEMENT



ZAPID WS - BO5 - Authorisation of PPP in the light of the Green Deal

1. Feedback from DCG on "Best practices of how to accelerate low risk procedures":

1) Starting a discussion aimed to minimize zonal specific (mainly environmental) aspects for LR products, and to investigate the possibilities for an interzonal process for LR PPP.

2) Development of a guidance document for the harmonisation of authorisation criteria for LR PPP.

2. Outcome of the Workshop on Possibilities to increase availability of PPPs, 26 October 2023. Background document for the ZAPID (break out session 1, 2 and 5), 4-7 December 2023

3. 20 topics related with the Authorisation of PPP in the light of the Green Deal

4. SANTE document on Compendium of conditions of use to reduce exposure and risk_EU Commission

ZAPID WS - BO5 - Authorisation of PPP in the light of the Green Deal

- **Is it necessary to modify the legislation?, such as: approval/review deadlines; data requirements; criteria for approval and authorizations...**
- **Is it necessary to develop new guidance documents or to modify the existing guidance documents?**
- **Can we consider that the current zonal/interzonal PPP evaluation/authorization system and procedure is sufficiently efficient for biocontrol PPP?**
- **Are we using efficiently all the provisions of Reg 1107/2009?**

ZAPID WS - BO5 - Authorisation of PPP in the light of the Green Deal

1. Procedure: How to acelerate the authorization of "LR PPP"

- ✓ Reduction of fees
- ✓ Fast track procedure using the IZ procedure
- ✓ Reduce national DR
- ✓ Use of Mutual Recognition (Art 40.2)
- ✓ Green Team of Risk Asessors with sufficient experience
- ✓ Reduce commenting period
- ✓ Common understanding of Art 47 (LR PPP)

2. New technologies:

- ✓ How to include the Digital and Precision Agriculture (DPA) tools in the risk assessment
- ✓ Common understanding on the minimum requirements and necessary data basis for the acceptance of new application techniques between the MS.
- ✓ How to implement the new application methods of PPP (drones/precision agriculture) in the zonal assessment of PPP

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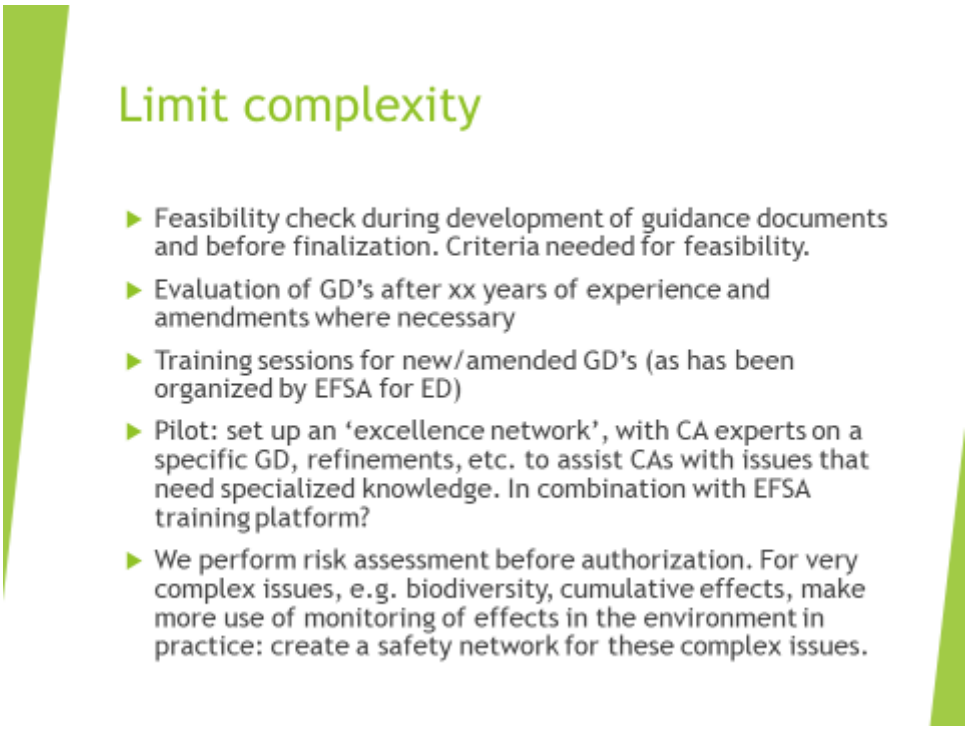
THANK YOU FOR YOUR ATTENTION

8.2 Final presentations BOGs

8.2.1 BOG 1



Prioritisation

- Priority setting is needed, at EU level
- Lay down (in GD?) with the criteria. Advise from BOG1:
  - All new a.s.
  - Renewal potentially low risk a.s. (to get official low risk status)
  - New (innovative) PPP and new low risk PPP
  - Label extensions for low risk PPP and for PPP which add a new use/mode of action
  - Renewal of a.s. that are CfS and PPP based on CfS; all other renewals are deprioritised
  - PPP applications that can prevent emergency authorisations
  - PPP applications for minor uses
- Renewal PPP based on >1 a.s.: do 1 renewal, after finalization of the last a.s., unless the PPP contains a CfS

Centralized allocation of applications

- Subject is about centralized *notification* of applications and subsequently a centrally organized allocation. The application itself is submitted to the zRMS.
- Aim of centralized notification is to use the available capacity at CAs in line with the EU priority setting for applications and achieve a more balanced division of applications across all CAs.
- The breakout group had discussed advantages and disadvantages.
- The disadvantages outweigh the advantages.
- The overall opinion of the breakout group is that for now it is not useful to start centralized allocation of notifications of applications.

Improving the quality of the dossier – 1

- All information needed to submit a complete and good dossier is published on the websites of the competent authorities (CA), European Commission and EFSA.
- It is important that the applicant follows the applicable guidance documents and uses the correct endpoints. Otherwise, a lot of recalculation is needed. CAs do not always act in a harmonized way with regard to which GDs are applicable
- Due to the high complexity of the regulatory framework CAs advise applicants with no or limited experience with 1107/2009 to seek advice of a consultant.
- The importance of the completeness check has been highlighted by the BOG: CAs to reject an incomplete dossier in order to increase efficiency.

Improving the quality of the dossier – 2

- Quality of dossiers is partly subjective, not everything is harmonized. CAs to communicate the main issues they face to applicants.
- One issue already mentioned: mutual recognition dossier for a product that has been evaluated long time ago.
- The group shared best practices with regard to a pre-submission meeting (PSM). Request to CAs and applicants to adhere to these best practices.
- It is not clear how to deal with new information/knowledge (court case ongoing at the European Court of Justice)

8.2.2 BOG 2

BOG 2 - Harmonising zonal decision making – Special focus on Mutual Recognition, minor uses, and assessment of co-formulants

- Mutual Recognition
- Minor Uses
- Co-formulants

Mutual recognition

Positives

- Avoid duplication of work
- Faster access to market for the PPPs
- Led to a drive for harmonisation

Challenges

- Older assessments - non alignment with current auths.
- Timelines
- Interpretation of guidance and expert judgement

Mutual recognition

Discussions

- National requirements need to be justified (Art 36.3)
  - *Keep them up to date and published*
- Expert agreements are followed E.g ecotox
- Court ruling could bring clarity on using older assessments or derail the process
- Core dossier assessments (or lack of full assessment)
- Art. 40.2 no real experiences in MS
- Use of arbitration process similar to biocides

Minor Uses

Positives

- Regulation allows flexibility
- Risk envelope approach
- MUCF

Challenges

- All minor uses not included in core dossiers (e.g. Art 43)
- Dealing with non ppp company applicants
- Fear of experts being undermined (e.g efficacy)

Minor Uses

Discussions

- Harmonised list of minor crops across the EU
- Better communication or dissemination of assessments
- Best practices across the MSs
- Consideration of non EU residue data (in context of IR4 study)
- Lot of tools available that should be used to their full potential
- Conflict between EPPO zones, residue zones, reg. zones

Co-Formulants

Positives

- Clarification of requirements
- Lead to increased safety
- Harmonisation if collaboration is done early

Challenges

- Overreaction - too complicated
- Workload - dealing with incomplete data and 3rd parties
- Buy in to a centralised database over already established national systems

Co-Formulants

Discussions

- Harmonisation needed - due to the complexity that could arise in some situations
- How to deal with equivalence
- Peer review system - acceptance of other assessments
- Negative lists Vs positive lists
- Development of guidance and database
- Stepwise approach needed without reinventing the wheel

Mutual recognition

Conclusion:

- More consistent dossiers and transparent assessments – should lead to less opening of the box, focus on the future
- Art 36.3 to be respected with regard to national requirements/assessments

Mutual recognition

Actions:

- Respect the agreements made in the past, guidances (e.g. outcome of ecotox harmonisation workshop)!
- Improve quality of the dossiers, facilitates work of experts and leads to less inconsistencies in outcomes
- Idea to have a centralised place (e.g COM website, at least with links to national websites) for all the national requirements, in best case with implementation dates for the different versions

Minor Uses

Conclusion:

- EU wide harmonised list of major and minor crops has both advantages and disadvantages.
- Linkages with definitions or criteria in sister legislation and guidelines need consideration and the role of outside actors
- Broadly the system works although maybe not in a fully harmonised fashion

Minor Uses

Actions:

- Publication of the national lists
- Discuss the criteria used to define major and minor
- Harmonised list of major and minor crops in the EU
- MUCF to act as coordinator and continue working on the topic
- MSs to upload assessments on CIRCABC and to increase dissemination of the information on completed projects (in context of Art. 51 EAMUs)

Minor Uses

Actions:

- Publication of the national lists
- Discuss the criteria used to define major and minor
- Harmonised list of major and minor crops in the EU
- MUCF to act as coordinator and continue working on the topic
- MSs to upload assessments on CIRCABC and to increase dissemination of the information on completed projects (in context of Art. 51 EAMUs)

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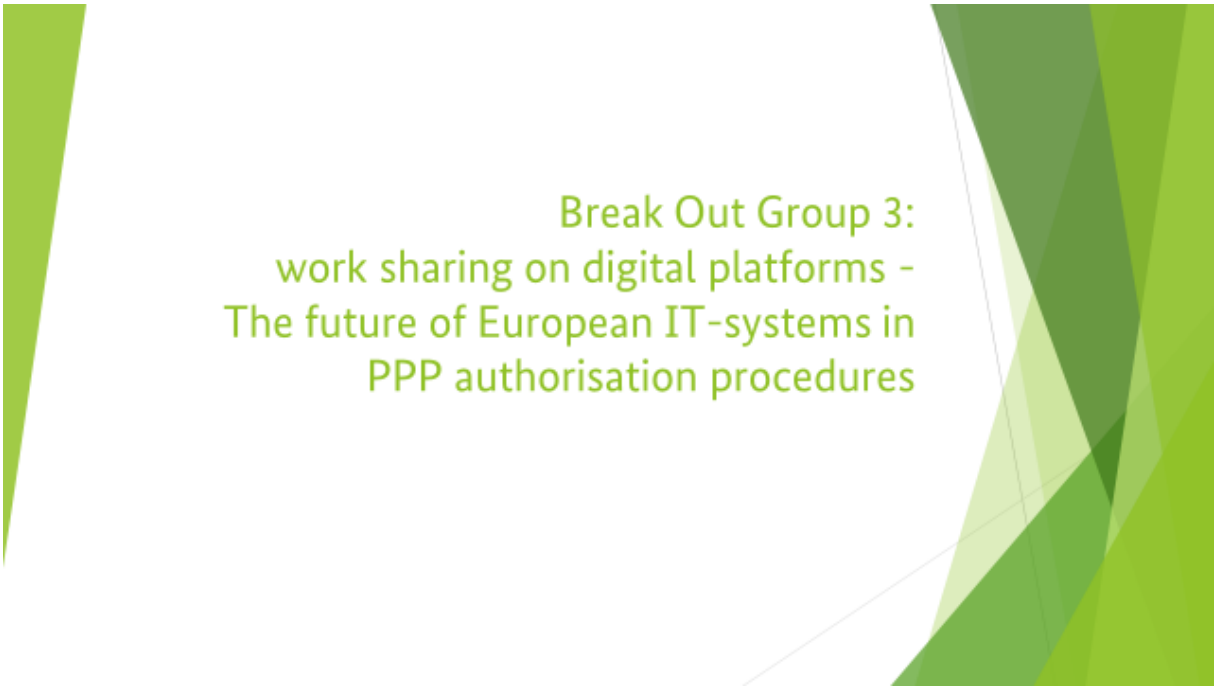
Co-Formulants

Proposed actions

- Stepwise approach
- Organise workshop on database
- Stakeholders will extend activities
- Development of guidance
- In PAI no volunteer - Decide on who should lead in development
- Keep information

8.2.3 BOG 3


Break Out Group 3:
work sharing on digital platforms -
The future of European IT-systems in
PPP authorisation procedures


Use of common platforms
Discussions where had on
ESFC
R4BP3
and IUCLID

- Main takeaways
  - Some countries flag problems in how dossiers are currently managed (contacting other countries,…)
  - Some improvements to the current way countries handle dossiers can also be identified (keeping track of status of studies etc,…)

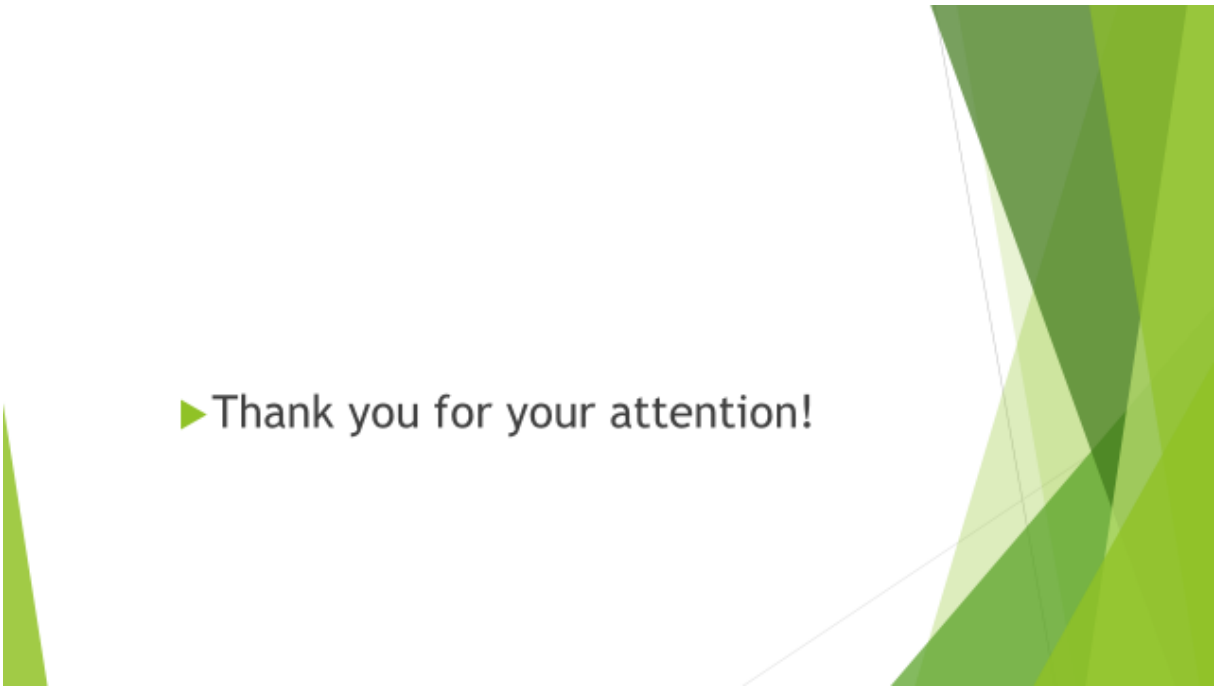
- An exploration of the needs of MS and what possible improvements could be made to the current system is a prerequisite before moving forwards
- From there, we could establish how a common platform could be used to improve the experience of the MS.
- This is a discussion which could be started right now, rather than wait for something to be decided for us, as was the case for IUCLID for a.s.
- An ongoing exchange would be ideally be started up, lessons of previous experiences need to be remembered

Co-formulants database

- Increased scrutiny on co-formulants
- Desire for a database was established prior to ZAPID
  - Not a positive list
  - Not an intention to request more data than what is currently requested
- Goal is harmonisation, transparency, and communication

- COM will do a consultation of the MS, based on the already existing list of desired data
  - Will establish what data is requested with a reasoning why it is required (from legislation, or from requirement to perform the evaluation)
  - Guidance might also follow from this
  - Would aid in the three main goals of harmonisation, transparency and communication.

- Thank you for your attention!



BOG 4 - Implementation of new scientific and technical knowledge - Guidance Documents (e.g. GD SANCO 10328/2004)

ZAPID workshop

Braunschweig 5-7 December 2023

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Summerizing

- How do we define new a.s. data?
- We decided not to focus on
  - Art 44
  - Art 56
  - MRL
  - CLP

- New a.s. data that is necessary for the approval of PPP need to be assessed.
  - To support a use that was not included in the EU approval
  - To demonstrate safe use
  - To address new requirements in an application accroding to art 33 that were not in place at the time of the AIR dossier submission
  - To address data gaps in EFSA conclusion

  Open point: Can we accept new studies to avoid very restrictive risk mitigations?

  Open point: How do we handle monitoring data?

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Suggestions for updated process in SANCO 10328/2004

Information regarding which MS the study has been submitted should be provided by the applicant	During this communication it can be clearer if the study is necessary or if it should follow an other process. The communication is initated by the MS.	This is done in PAI meeting.	The timelines for evaluation are the same as for art 33/43. The dRR is send for commenting to all MS and the applicant. It should be clarified where the study can be found in the dRR.	Final RR made available at CIRCABC and to the applicant	This is done in PAI meeting. Relevant information could be conclusion, EP, where to find it....

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Updated process in SANCO 10328/2004

- If the MS consider that an evaluation trigger art 21, this will be taken to SCoPAFF.
- Pilot study to gain experience before adoption.

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New scientific and technological data

- Data included in EFSA conclusion and accepted at SCoPAFF should be used in PPP applications.
- It must be clear for the applicant which GD should be used when preparing an application.
  - MS interpret *available at the time* differently. Some uses parts of a draft GD, some demand that applicant follow GD that has not been taken note of, some allow applicants to volountarly use not applicable GD, others use only applicable GD
- The current official interpretation is that GD taken note of should be applied by the MS
- Pending court case in EU that can change this interpretation.

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Ideas and suggestions

- **Suggestion to PAI to update SANCO 10328/2004**
- Should we have a central system to handle the issue of new a.s. data?
- Step wise publications of peer reviewed data
- List of all applicable GD at the time of an application

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QUESTIONS?

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8.2.5 BOG 5

ZAPID WORKSHOP
BOG 5
Authorisation of PPP in the light of the Green Deal - Low risk, biocontrol and non-chemical ppp assessment

- Definitions (biopesticide; Low risk vs Low Hazard)
- Resoruces ; time line expertise
- Prioritisation
- Procedures – MR ; Art 51; Art 47 interpretation
- Risk Assessment – Data Requirements – Harmonization
- IPM + New technologies

Definitions – We need definition of biopesticide at EU level – EU Comm list? in order to decide the prioritization of the app of PPP based on biopesticides. How to implement the definition of the SUR

Expertise and capacities – Green Team. All MS agree that is necesary to increase the capacities for this type of PPP. Diferent positions/ diferent posibilities zonal Green Team (coordination)

Interpretation of the Art 47: Specific vs generic RMM

Efficacy – Modify EPPO guidance on LR in order to relate with LR a.s. instead of L.R PPP. Facilitate the use of less number eficacy trails from different zones

ZAPID WS - BO5 - Authorisation of PPP in the light of the Green Deal

- **Is it necessary to modify the legislation?, such as: approval/review deadlines; data requirements; criteria for approval and authorizations...**
- **Is it necessary to develop new guidance documents or to modify the existing guidance documents?**
- **Can we consider that the current zonal/interzonal PPP evaluation/authorization system and procedure is sufficiently efficient for biocontrol PPP?**
- **Are we using efficiently all the provisions of Reg 1107/2009?**

Day 2 Morning Session

Delays/Definitions: A EU wide legal definition is a prerequisite to take measures at MS level (prioritization, fast track).

Delays/Lack of capacity: How to increase/better use existing capacities of MS for the evaluation and registration of biopesticides (MO/botanicals/semiochemicals, novel technologies etc.). Increase capacities by CA. Worksharing between MS at diferent levels

Delays/workload: Need to decrease the workload at MS level used for other type applications (Art 43) to prioritize. Perpetual authorisation/longer approval period of the LR AS, art. 56: applicant to inform about harmful effect. EU COM/MS could also do so to trigger a review Art 21

Lack of harmonization/Definition: Implementation of the LR criteria for AS: low-hazard/low-risk, articulation between art.22/47. Agreement between MSs of what is RMM by default (generic) and what is a specific RMM by the risk assessment -> inclusion in the GD document.

Day 2 Afternoon Session

Harmonising Risk Assessment for natural substances and novel technologies (peptides, dsRNA, microbial consortia, bacteriophages etc.): Try to avoid new DR. Instead of new DR develop an approach for performing **problem formulation** approach for natural substances and novel technologies (ask the right questions, see where the real concerns are, justification for waivers within the existing data requirements). Survey from applicants to identify pipeline and define prioritisation (refers to CLE survey, focussing on DR-Part A related technologies)

Delays (Prioritization/ Fast track) Some national legal frameworks do not allow prioritisation. MSs comply with the 120 days deadline established in the Reg. for LR PPP. There are diferent situations in MS (voluntary fast track assuming some conditions; separate pipeline for biopesticides; fast track for MR of LRPPP). MS to explore possibilities of prioritization and fast track

Day 2 Afternoon Session

Encourage submission of applications - Reduced fees : Reduce fee could be a motivation for the submission of applications , MS should take in mind to have sufficient economic resourses to maintain the human resources/capacities and expertise. Fees shall represent the real work

New Tecnologies /IPM: New technology can be used under the existing GAP in order to reduce the exposure and as a new application for registration. In both cases we need to characterize the exposure (environment/operator-bystander) and certify the machinery

BOG 5 –Authorisation of PPP in the light of the Green Deal - Low risk, biocontrol and non-chemical ppp assessment

DELAYS OF AUTHORIZATION OF BIOPESTICIDES:

- Definition of biopesticide / list of substances that needs to be promoted
- MSs to explore possibility to implement fast track procedure and define relevant applicability criteria

LACK CAPACITIES:

- MS recognise the necessity to increase capacities in number and knowledge
- Implement systems at MS level to use the fees for hiring experts
- Work sharing between MS: from Bilateral collaboration to a Zonal Green Team

BOG 5 –Authorisation of PPP in the light of the Green Deal - Low risk, biocontrol and non-chemical ppp assessment

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BOG 5 –Authorisation of PPP in the light of the Green Deal - Low risk, biocontrol and non-chemical ppp assessment

HARMONIZATION

- Implementation of the LR criteria for AS: low-hazard/low-risk, articulation between art.22/47. European Commission to finalize the LR Guidance Document.
- Interpretation of Art 47 (RMM): BPWG / PAI

RISK ASSESSMENT:

- Problem formulation approach for the new technologies of PPP
- Guidance for Microbial Consortia
- Develop guidance for plant extracts
- Develop guidance(s) for novel technologies
- Better Training for Safer Food – advanced course (specific section/technology)
- Maintain calls for research projects on biopesticides including novel technologies [need to know vs nice to know - linked with the risk assessment

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BOG 5 –Authorisation of PPP in the light of the Green Deal - Low risk, biocontrol and non-chemical ppp assessment

New Technologies (Precision and Digital Agriculture/IPM): It is recognized as an opportunity to reduce the volume of used PPP. New technology can be used under the existing GAP in order to reduce the exposure and as a new application for registration. In both cases **we need to characterize the exposure (environment/operator-bystander) and certify the machinery**

BOG 5 –Authorisation of PPP in the light of the Green Deal - Low risk, biocontrol and non-chemical ppp assessment

Change legislation:

- Definition of biopesticide
- IZ assessment of LR PPP – Different point of views, some difficulties are identified. Pilot project
- *Provisional approval of biopesticide* – Example BE & ES. Align EFSA Peer review encourage the participation of MS in Peer Review (zonal comenting period)

Efficacy of LRPPP – Modify EPPO guidance and to refere to the LR a.s.

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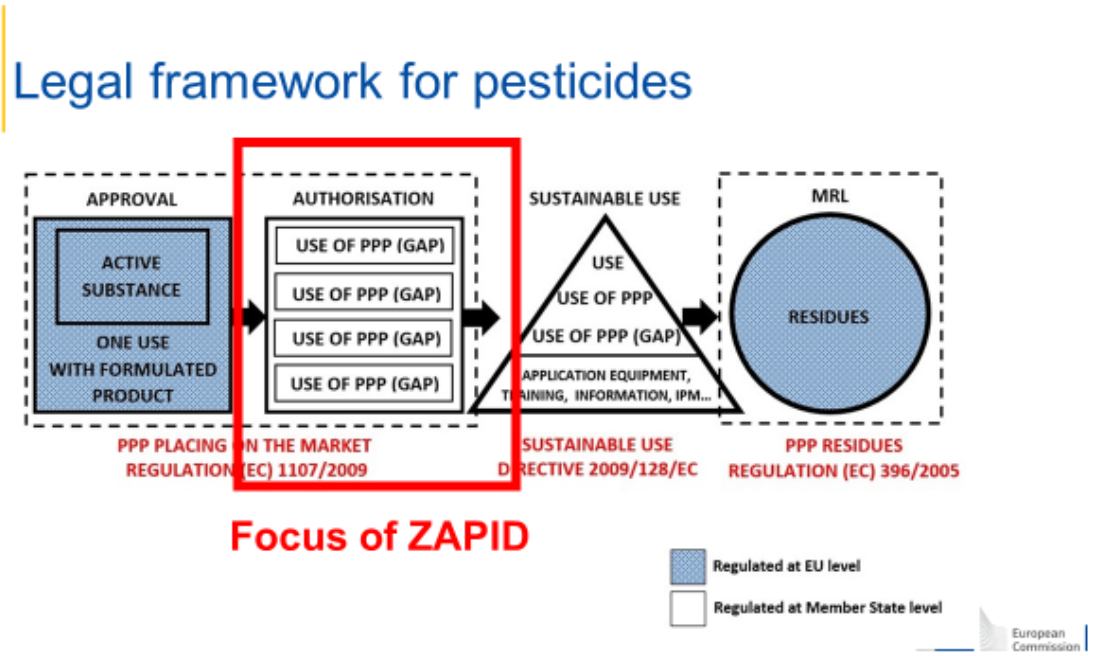
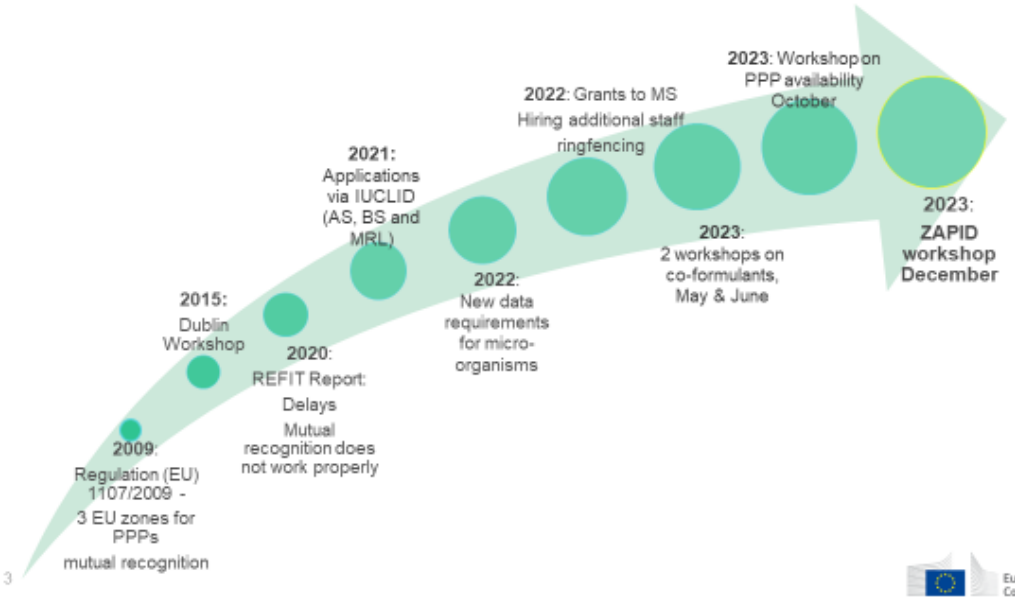
THANK YOU FOR YOUR ATTENTION

8.3 Keynote

8.3.1 European Commission





3

European Commission

The problems

Not keeping the **regulatory deadlines**

(UN)AVAILABILITY of Plant Protection Products at MS level

Slow **ACCESS** to the market and lack of (non-chemical) active substances **ALTERNATIVES**

Less PPPs - more **RESISTANCE**

PPPs for **MINOR USES**

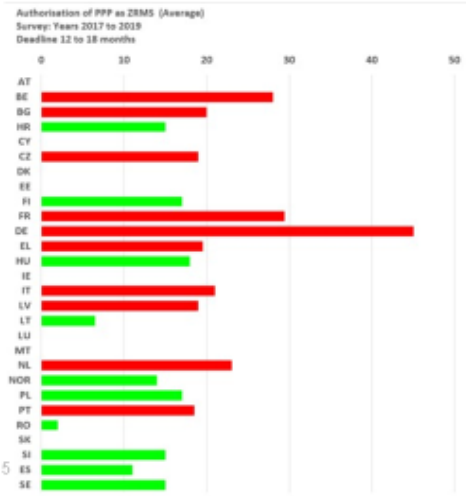
4

European Commission

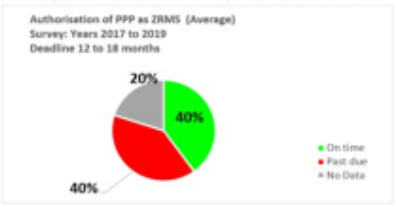
Authorisation of a plant protection product - (legal deadline 12-18 months) #1

(COM staff working document 2022 - 1st survey: from 1 January 2017 to 31 December 2019

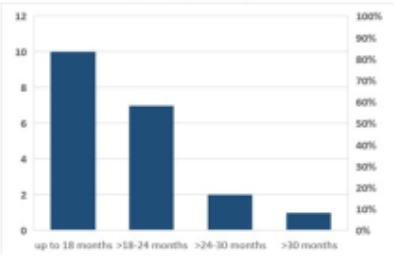
Average time per country to complete the procedure (months)



Percentage of countries within the legal deadline, exceeding the legal deadline and that did not provide information



Number of countries grouped by the average timing in months to complete the procedure

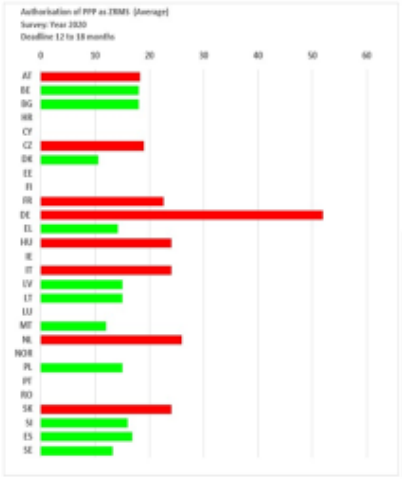


European Commission

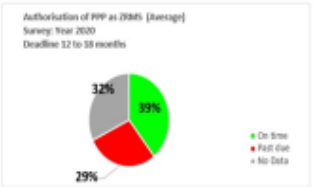
5

COM staff working document 2022 - 2nd survey: from 1 January 2020 to 31 December 2020

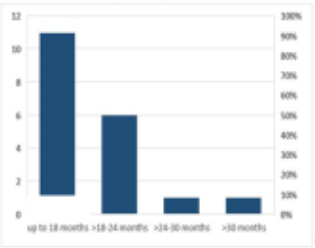
Average time in months per country to complete the procedure



Compliance with the legal deadline



Number of countries grouped by the average time in months to complete the procedure



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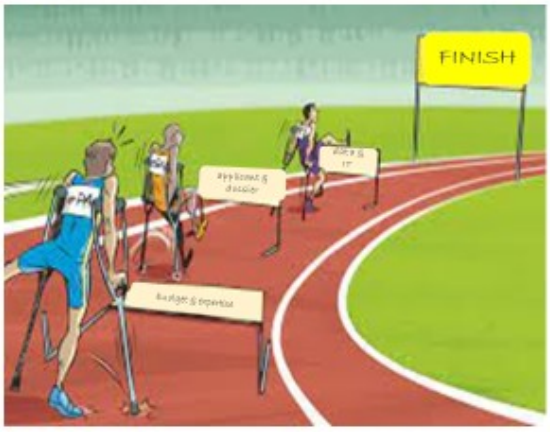
6

Authorisation of PPPs as ZRMS

EL	DE	FR	IT	PL	ES	AT	CZ	MT	NL	BE	SE	DK	LV	SI	LT	HR	HU	SK	BG	FI	IE	NO	PT	CY	EE	LU	RO
83	65	52	38	25	20	15	15	12	11	5	5	3	3	3	2	1	1	1	0	0	0	0	0	/	/	/	/

European Commission

Some Reasons/Hurdles



- **DELAYS** (lack of staff/expertise? Administrative red-tape? Not sharing workload?)
- **(IN)COMPLETNESS** of AS/PPP dossiers
- **FEES**
- **IT related** obstacles
- **INCREASING REQUIREMENTS** for the risk assessments
- **APPLICANTS** do not ask for authorisation in MS (cost, administration)
- Authorisation may be given but PPP is not placed on the market
- Actual **USE** by the farmers

7

European Commission

Some actions so far

- **COM grants** - only 6 MS applied
  - to hire new staff (microbiologists)
  - ringfence fees
- Support MS to **enhance the capacity** of MS authorities to **evaluate biopesticides**.
  - BTSF
- Draft Compendium on application techniques (risk mitigation measures)
- Draft Problem Formulation document (**need to know** vs. nice to know)
- Support MS to assess PPP formulations (Co-formulants)

8

European Commission

ZAPID will find viable and pragmatic solutions

- The main problems are known and we have the right experts in the room.
- Looking forward – what can be made better in the **authorisation process in the MS?**
- **lessons learned** from the past
- **pursue pragmatic solutions**
- **best practice examples** and what works
- **think out of the box**
- **WHAT ELSE?**

8.3.2 MUCF

PLENARY SESSION: ZONAL AUTHORISATION PROCEDURE IMPROVEMENTS & DEVELOPMENTS WORKSHOP

INTRODUCTION OF THE MINOR USES COORDINATION FACILITY AND OVERVIEW OF AVAILABLE INFORMATION ON MINOR USES WORK IN EUROPE.

MUCF TEAM
2023-12-5/7
BRAUNSCHWEIG, GERMANY

ABOUT THE EUROPEAN MINOR USES COORDINATION FACILITY (MUCF)

- Established in 2015, initially funded by the EU and the governments of FR, DE and the NL for 3 years. Funding dependent on voluntary contributions since 2019.

The MUCF's **Mission** is to support European stakeholders in closing crop protection gaps in minor uses:

- It coordinates **collaboration** and information exchange to improve the availability of sustainable crop protection solutions within an IPM framework.
- The objective is to enable farmers to produce high-quality crops and contribute to sustainable European agriculture.

MUCF MAIN FIELDS OF ACTIVITY & CORE COMPETENCIES

Meetings	Database EUMUDA https://www.eumuda.eu/	Information Exchange
+ Host & facilitate MUCF Commodity, Horizontal & Residue Expert meetings (2 x per year).	+ Host & further develop the European Minor Uses Database (EUMUDA).	+ Coordinate & support minor uses work among all European Member Countries and stakeholders.
+ Organise meetings between stakeholders to discuss possible solutions and approaches for identified minor uses needs.	+ Implement & collect minor use needs and priorities, minor uses, minor crops, and crop acreage data information.	+ Address regulatory hurdles & minor uses issues.
		+ MUCF newsletter, EUMUDA latest news e-letter.
		+ in #LetsTalkAboutMinorUses #MinorUsesMajorImportance

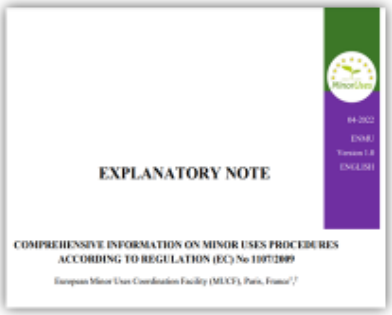
EXPLANATORY NOTE ON MINOR USES PROCEDURES ACCORDING TO REG. (EC) 1107/2009

- The Explanatory Note on Minor Uses has been developed and peer-reviewed in co-operation with experts from several EU Member States (Belgium, Germany, Denmark, France, Hungary, Italy, Ireland, Lithuania, the Netherlands, Spain, and Sweden), the United Kingdom, Norway, Switzerland, and with support of DG SANTE's Legal Service.
- This document has been presented to the Standing Committee on Plants, Animals, Food and Feed on 2022-03-30/31.
- **Endorsed** by SCoPAFF (section: Legislation) in **March 2022**.
- **Scope**: The Note has been developed to provide comprehensive information on minor uses procedures in the context of the implementation of Article 51 and other provisions related to minor uses for different parties such as authorisation holders, official or scientific bodies involved in agricultural activities, professional agricultural organisations, professional users and competent authorities, as well as for the MUCF Commodity Expert Groups (CEG) and Horizontal Expert Groups (HEG).
- Issues related to safeners and synergists (according to Article 25(3) of Regulation (EC) No 1107/2009) are not considered in this Note.

EXPLANATORY NOTE ON MINOR USES PROCEDURES ACCORDING TO REG. (EC) 1107/2009

Objectives:

- To encourage EU Member States, the United Kingdom, Norway and Switzerland to take a consistent approach:
  - in the evaluation of dossiers
  - the use of the risk envelope approach
  - in the use of relevant extrapolation tables and extrapolation possibilities for residues.
- To stimulate the practical implementation of Regulation (EC) No 1107/2009, reduce obstacles and other impediments for mutual recognition of minor uses between EU Member States, the United Kingdom, Norway, Switzerland and to encourage harmonisation.
- To explain the application procedures to professional users, agricultural organisations, official or scientific bodies involved in agricultural activities and other stakeholders.



4/17/2024 European Minor Uses Coordination Facility - MUCF

MUCF MINOR USES SURVEY 2022

- **Scope:** Provide an overview of updated information and compiled data on minor uses work and procedures in several European countries.
- Update of the 2017 survey.
- 60 questions divided into 7 chapters, sent to 30 countries:
  - Responsibilities, definitions, figures of minor uses and minor crops.
  - Trials
  - Article 51 (extension of authorisation for minor uses).
  - Risk assessment
  - **Mutual recognition**
  - Draft Registration Report
  - General topics
- 22 countries participated in the 2022 survey:

Austria, Belgium, Cyprus, Estonia, Finland, France, Greece, Germany, Hungary, Ireland, Latvia, Lithuania, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Spain, Sweden, Switzerland, the United Kingdom.

MUCF MINOR USES SURVEY 2022

- **Objective:** The 'Survey 2022 compiled data and information document' shall provide a foundation for future discourse and work actions related to minor uses and associated issues and raise discussion points for stakeholders (PPP authorisation holders, official or scientific bodies involved in agricultural activities, professional agricultural organisations, competent authorities, European Commission, etc.).
- MUCF Minor uses survey 2022 outcome does present:
  - Individual answers from the respondents.
  - When possible, a merge and summary of the individual answers.
  - Proposals and perspectives, as a discussion basis for future work.
- To be available by the end of 2023.
- Based on the provided answers, the **MUCF experts will explore in the coming year(s):**
  - The possibility to define criteria for a harmonised minor crop definition.
  - The possibility to elaborate a single European minor/major crop list per regulatory zone, or a single European minor/ major crop list.
  - To develop an abridged 'dRR (Part A) template' (to be used voluntarily).

EUMUDA DATABASES: AVAILABLE DATA AND FURTHER DEVELOPMENT

EUMUDA table of needs https://www.eumuda.eu/database/table_minor_uses

- The table of needs display minor uses gaps and information on the urgency and occurrence of needs in Europe, shared with the MUCF by the national MUCF contact points.
- The MUCF CEGs focus on closing these gaps by setting up projects (trial data generation and sharing).

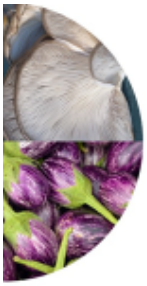
Ranked	Crop common name	Pest scientific name	Pest common name
No. 1	raspberry	*Drosophila suzukii*	spotted wing drosophila
No. 2	onion	*Peronospora destructor*	downy mildew
No. 3	white cabbage	*Delia radicum*	cabbage root fly

Residue/efficacy trials database

- Displaying information on efficacy and residue trial data availability from CEG projects and shared national trial data (i.e. German trial database).

Minor/major crops database

- Database of the crop status in the European countries, available by the end of 2023.
- 11 countries included for now: Austria, Finland, Portugal, Czech Republic, Germany, Switzerland, Denmark, Ireland, United Kingdom, Estonia, and Latvia, more countries to be included step by step.



THANK YOU FOR YOUR ATTENTION

Minor Uses Coordination Facility
21 Boulevard Richard Lenoir
750011 Paris
France

www.minoruses.eu

8.3.3 CropLife Europe

CropLife Europe – Key elements

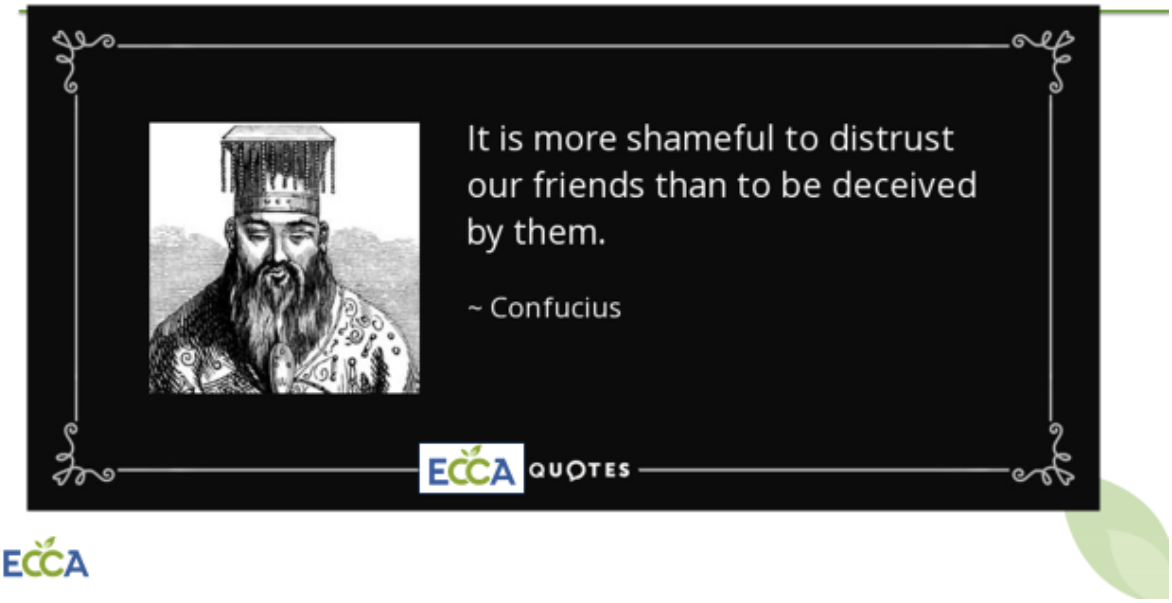
- Appreciation for the opportunity
- Harmonizing zonal decisions – Realization of effort and complexity
- Realize efficiency options + Zonal mindset of all stakeholders
- 8 years since previous zonal workshop
  - ❖ ZAPID workshop = Kickstart event
- Identification of actions triggering implementation discussions in different fora (Cfr. 2015 Dublin workshop / REFIT recommendations)
- Post-workshop follow-up and next steps (implementation)

8.3.4 ECCA

ECCA
european crop care association

ZAPID workshop

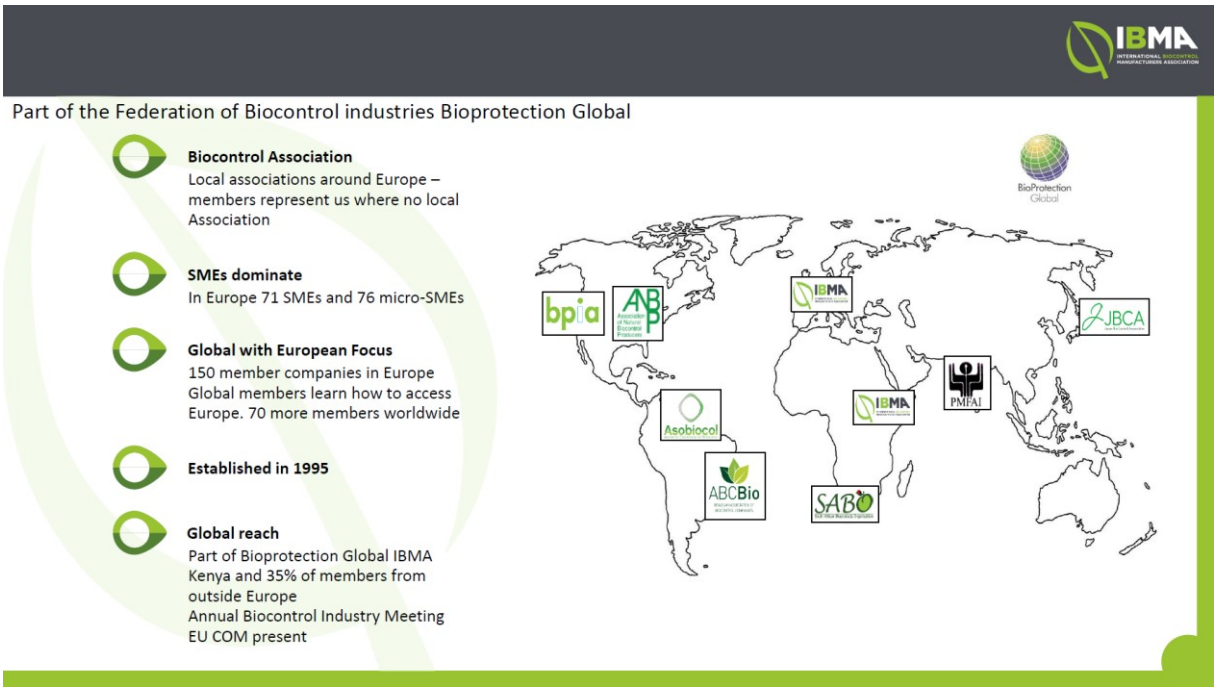
5 – 7 December 2023



ECCA

8.3.5 IBMA


Biological Control
ZAPID Workshop 5-7 December 2023
IBMA
INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION


IBMA
Part of the Federation of Biocontrol industries Bioprotection Global
Biocontrol Association
Local associations around Europe – members represent us where no local Association
SMEs dominate
In Europe 71 SMEs and 76 micro-SMEs
Global with European Focus
150 member companies in Europe
Global members learn how to access Europe. 70 more members worldwide
Established in 1995
Global reach
Part of Bioprotection Global IBMA
Kenya and 35% of members from outside Europe
Annual Biocontrol Industry Meeting
EU COM present
BioProtection Global
bpia
ABP
IBMA
JBCA
PMFAI
Asobiocol
ABCBio
SABO

How to accelerate authorisation of biocontrol ?

Existing 1107 Provisions – ZAPID talks

- Mutual Recognition
- Low Risk
- Minor Uses
- MS implementation of timelines

Possible future provisions- SUR ?

- Priority lane for Biocontrol
- Expert Teams
- Label Extensions
- Provisional Authorisation
- Extension to re-registration timeline

3

We need an EU Wide Definition of Biological Control

Invertebrates

Semiochemicals

Microbials

Natural substances

4

8.4 BOG 3 – German database on co-formulants

Federal Office of
Consumer Protection
and Food Safety

German database on co-formulants

Quite more information than only on co-formulants

INFOZUPF

- **Database was designed for the application process of PPP**

- **Registration of the complete information on the individual application**
  - Formulation of the PPP
    - Manufacturers of the formulation
  - Active substance
    - Manufacturers of active substance
  - Hazard information according to GHS
  - GAP
  - ...

German database on (not only) co-formulants 6/12/2023 Page 2

Federal Office of Consumer Protection and Food Safety

German database on co-formulants

Registration of the application as PPP	Registration of the formulation	Data transfer for risk assessment
Data requirements according to Reg. (EU) 1107/2009	Data requirements on composition of co-formulants according to Reg. (EU) 284/2013	BfR, UBA (and JKI)

Federal Office of Consumer Protection and Food Safety

German database on co-formulants

Identification of co-formulants

Start
- Draft Registration Report
- Part C

Step 1
- MSDS of co-formulants
- Request of composition statements by the manufacturers

Step 2
- Registration or modification of the registrated co-formulant in INFOZUPF

Data registration INFOZUPF

Formulation of PPP

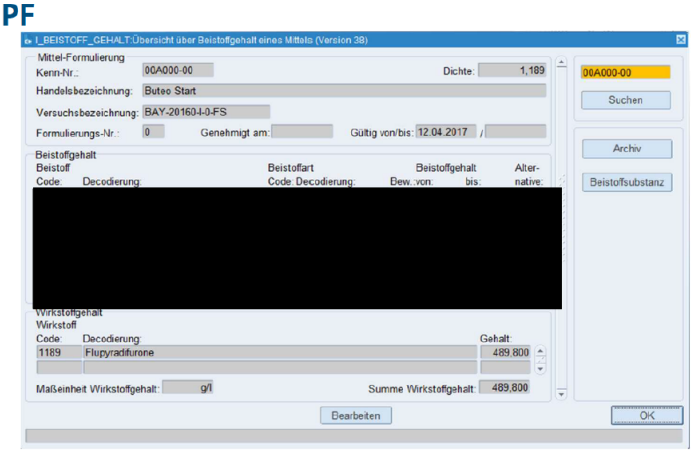
Co-formulants

- Content
- Function according to Reg. (EU) 284/2013

Active substance content

Registration of different versions of the formulation

- Change of formulation SANCO/12638/2011



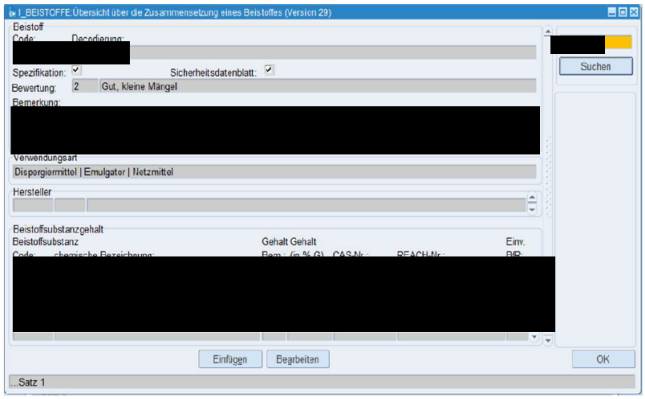
Data registration INFOZUPF

Co-formulants

- Single substances
- Mixtures

Individual identifiers for mixtures and substances

Content of individual substances in the mixture



BVL database INFOZUPF

Registration of co-formulants (mixtures and substances)

- **Co-formulants**
  - All co-formulants (mixture/substance) are assigned to a unique identifier
  - Check of the current registrated composition
  - Check on change of composition (MSDS, C&L)
  - Identifiers CAS nr., EC nr., REACH Registration nr.

- **Individual identifiers for mixtures and substances**
  - One co-formulant/substance - one identifier in all PPPs
  - Changes of CAS nr.
  - Changes in the composition occur more and more often
  - Markers for substances which are active substances and substances according to Annex III

Identification of co-formulants

- Distribution of the registered application data

BfR – ProSafe	UBA – ICS (Informationssystem Chemikaliensicherheit)	JKI - RIBEZUPF
• Risk assessment humantox	• Risk assesment ecotox	•Risk assessment efficacy

Federal Office of Consumer Protection and Food Safety

Further databases used

BfR

- **Document Management System**
- **Validation of data of tox studies**
- **Assessment tools**

Federal Office of Consumer Protection and Food Safety

Further databases used

UBA

- **Document Management System**
- **Validation of data of ecotox studies**
  - Registration of study data according to IUCLID 5 (OECD datapoints)
  - Research inside the registrated study data

- **Limitations**
  - Data on co-formulants are currently not evaluated individually, except the respective co-formulant has impact on the toxicity of the PPP
  - Applicant has to submit studies on the PPP

Federal Office of Consumer Protection and Food Safety

Further databases used

JKI

- **Document Management System**
- **No risk assesment of co-formulants**

Federal Office of Consumer Protection and Food Safety

Reqirements for the identity of co-formulants

Experts view

- Detailed composition is required → DE: substances > 0.1% w/w
- Composition should be provided in a machine-readable format (e.g. xml, Excel template)
- Versioning of the composition in the database is required (e.g. formulation changes)
- Referencing system is necessary for the traceability of the data
- Identification of co-formulants (mixtures and substances) by unique identifiers

Federal Office of Consumer Protection and Food Safety

Thank you for your attention!

Contact:

Dep. 2 Plant protection Products
Unit 213 - Evaluation Product Chemistry, Parallel Trade, Adjuvants

BfR
German Federal Institute for Risk Assessment

ProSafe-Pesticides

Database of the Pesticide Safety Department

30.10.2023, Berlin

Unit 64: Toxicology of Products and their Safe Use
Department Pesticides Safety

About ProSafe-Pesticides: Background

Programme requirements

Primary source of information for evaluation-relevant data for the PPP and biocide procedure at BfR

- General product information, information about application/authorisation, GAP lists, composition of mixture, substance & mixture properties and classification, etc..

Traceability of data using a referencing system

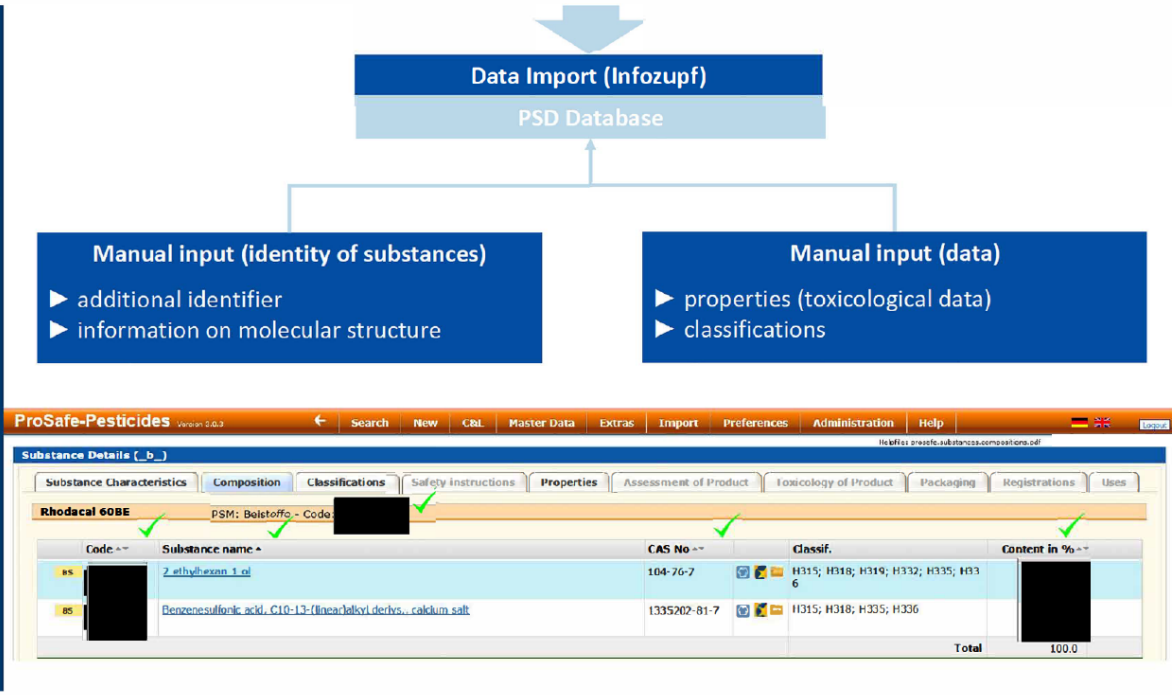
- Referencing the entries with the source or an evaluation

Support in the evaluation of products with regard to toxicological assessment

- Conventional assessment (`calculation method´) according to CLP Regulation

BfR

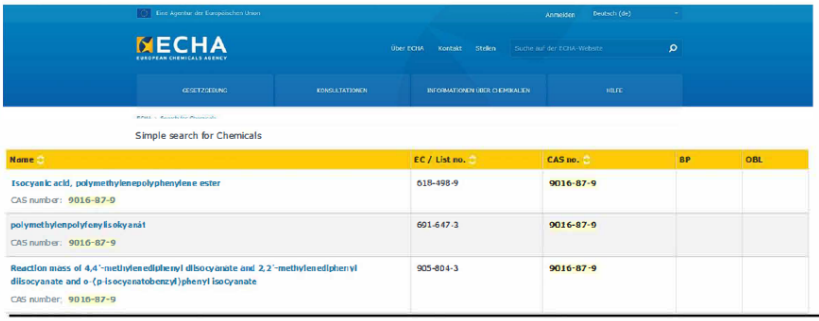
Data on co-formulants: Data collection procedure



Data on co-formulants: Data collection procedure

Identity of the co-formulants

- ▶ Identifier for co-formulant substances (relevant)
  - CAS No → Generally used identifier of substances in compositions
  - EC No → Occasionally used identifier of substances in compositions
  - ECHA ID → Unique identifier of a substance in the ECHA database
  - REACH Dossier ID → Unique identifier of a REACH registration dossier for a substance
  - Index No → Unique identifier for an entry in the ANNEX VI of the CLP regulation



→ ECHA ID: 100.112.554

→ ECHA ID: 100.219.407

→ ECHA ID: 100.136.923

BfR

Data on co-formulants: Data collection procedure

Identity of the co-formulants

- ▶ Identifier for co-formulant substances (relevant)
  - CAS No → Generally used identifier of substances in compositions
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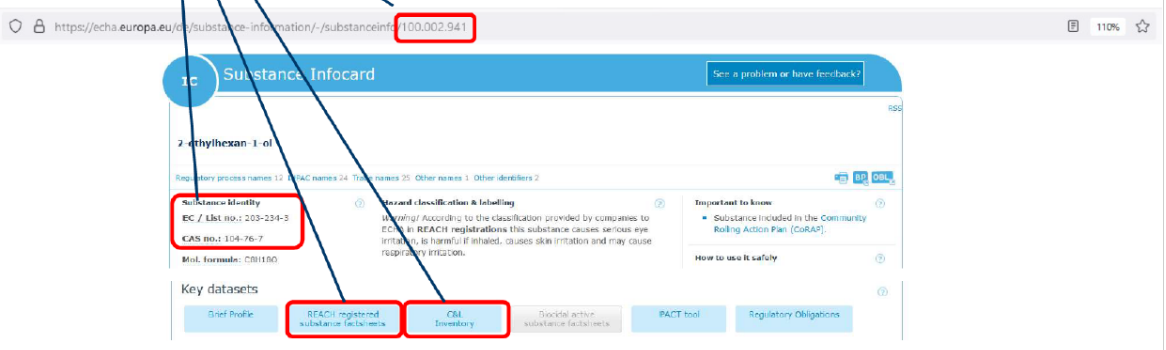


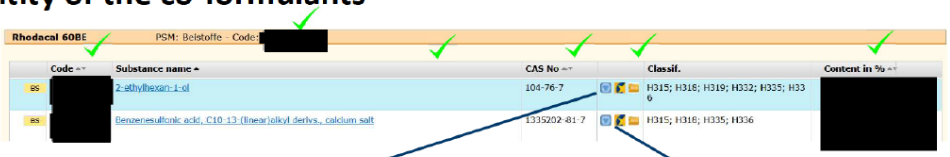
Data on co-formulants: Data collection procedure

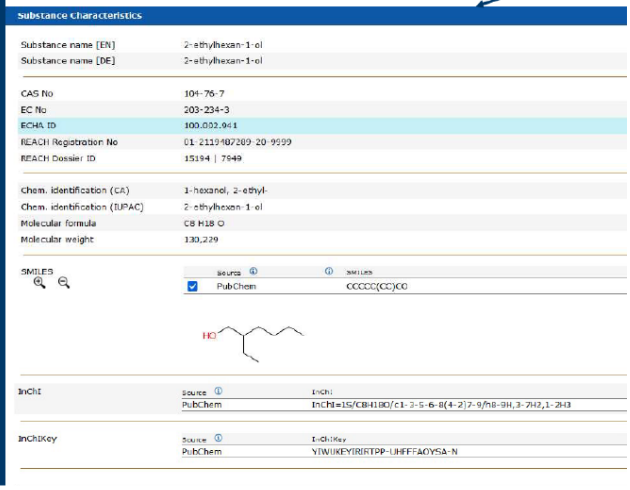
Identity of the co-formulants

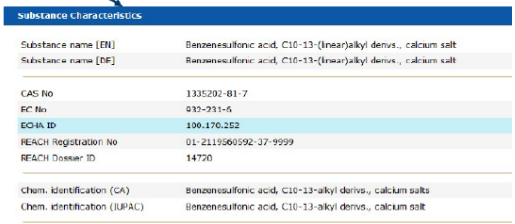
- Information on molecular structure for co-formulant substances
  - SMILES
  - InChI/InChIKey (IUPAC)
  - Molecular formula
  - Molecular weight
  - IUPAC name

Data on co-formulants: Data collection procedure

Identity of the co-formulants



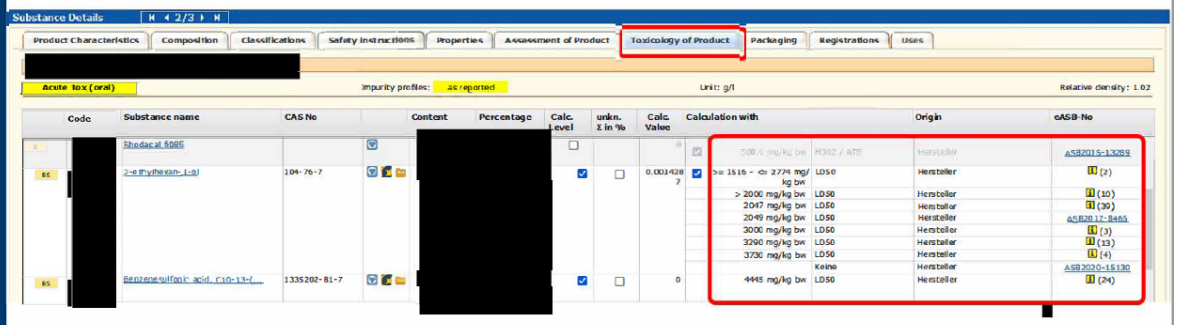




Data on co-formulants: Data collection procedure

Properties of the co-formulants: Toxicological data

- Toxicological data for co-formulants (substances/mixture)
  - Acute toxicity: oral, dermal & inhalation
  - Skin and eye irritation
  - Skin sensitization



BfR

Data on co-formulants: Data collection procedure

Properties of the co-formulants: Toxicological data

- Toxicological data for co-formulants (substances/mixture)
  - Acute toxicity: oral, dermal & inhalation
  - Skin and eye irritation
  - Skin sensitization

- Relevant data scources
  - Safety data sheet (substances/mixture)
    → Section 11: Toxicological information

Criteria for input into PSD Database

- Results from an toxicological study
- Study was performed with the co-formulant

SDS from the manufacturer (pdf)

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product:

Acute oral toxicity	:	Remarks: no data available
Acute inhalation toxicity	:	Acute toxicity estimate: 3.75 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	Remarks: no data available

Components:

2-Ethylhexanol:

Acute oral toxicity	:	LD50 (Rat, male): ca. 2,047 mg/kg Method: OECD Test Guideline 401
Acute inhalation toxicity	:	LC50 (Rat, male and female): 0.89 - 5.3 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Assessment: The component/mixture is moderately toxic after short term inhalation.
Acute dermal toxicity	:	LD0 (Rat, male and female): > 3,000 mg/kg Method: OECD Test Guideline 402

Data on co-formulants: Data collection procedure

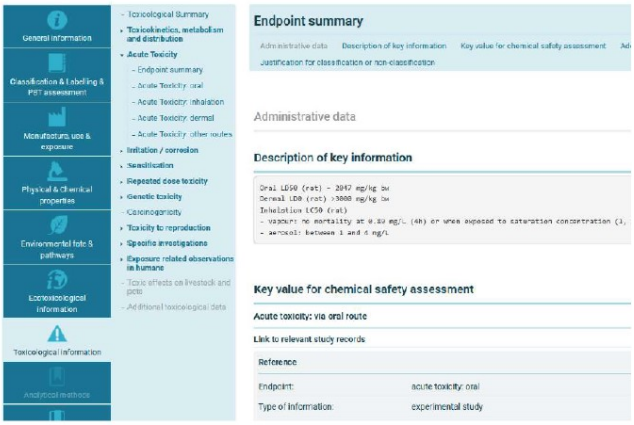
Properties of the co-formulants: Toxicological data

- ▶ Toxicological data for co-formulants (substances/mixture)
  - Acute toxicity: oral, dermal & inhalation
  - Skin and eye irritation
  - Skin sensitization
- ▶ Relevant data scources
  - Safety data sheet (substances/mixture)
    → Section 11: Toxicological information
  - REACH Registration dossier (substance)
    → Toxicological information

Criteria for input into PSD Database

- ▶ Results from an toxicological study
- ▶ Study was performed with the co-formulant

REACH Registration Dossier (HTML)



Data on co-formulants: Data collection procedure

Properties of the co-formulants: Toxicological data

- ▶ Toxicological data for co-formulants (substances/mixture)
  - Acute toxicity: oral, dermal & inhalation
  - Skin and eye irritation
  - Skin sensitization
- ▶ Relevant data scources
  - Safety data sheet (substances/mixture)
    → Section 11: Toxicological information
  - REACH Registration dossier (substance)
    → Toxicological information
  - RAC Opinion (substance)
  - CLP Regulation, ANNEX VI (substance)

Criteria for input into PSD Database

- ▶ Results from an toxicological study
- ▶ Study was performed with the co-formulant

RAC Opinion (pdf)

Classification		Labelling			Specific Conc. Limits, M-factors and ATE
Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	
Acute Tox. 2 Acute Tox. 4 Skin Irrit. 2 Eye Dam. 1 Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 1	H330 H302 H315 H318 H317 H400 H410	GHS06 GHS05 GHS09 Dgr	H330 H302 H315 H318 H317 H410		oral: ATE = 450 mg/kg bw inhalation: ATE = 0.21 mg/L (dusts or mists) Skin Sens. 1A; H317: C ≥ 0.036 % M = 1 M = 1

CLP Regulation - ANNEX VI (pdf)

Classification		Labelling			Specific Conc. Limits, M- factors and ATE	Notes
Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Repr. 2 Acute Tox. 3 Aquatic Chronic 1 Aquatic Acute 1	H361d H301 H410 H400	GHS08 GHS06 GHS09 Dgr	H361d H301 H410		oral: ATE = 140 mg/kg bw M = 10 M = 10'	

Data on co-formulants: Data collection procedure

Properties of the co-formulants: Toxicological data

- ▶ Toxicological data for co-formulants (substances/mixture)
  - Acute toxicity: oral, dermal & inhalation
  - Skin and eye irritation
  - Skin sensitization
- ▶ Relevant data scources
  - Safety data sheet (substances/mixture)
    → Section 11: Toxicological information
  - REACH Registration dossier (substance)
    → Toxicological information
  - RAC Opinion (substance)
  - CLP Regulation, ANNEX VI (substance)

Criteria for input into PSD Database

- ▶ Results from an toxicological study
- ▶ Study was performed with the co-formulant

RAC Opinion (pdf)

Classification		Labelling			Specific Conc. Limits, M-factors and ATE
Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	
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CLP Regulation - ANNEX VI (pdf)

Classification		Labelling			Specific Conc. Limits, M- factors and ATE	Notes
Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Repr. 2 Acute Tox. 3 Aquatic Chronic 1 Aquatic Acute 1	H361d H301 H410 H400	GHS08 GHS06 GHS09 Dgr	H361d H301 H410		oral: ATE = 140 mg/kg bw M = 10 M = 10	

Data on co-formulants: Data collection procedure

Classification acc. to CLP of the co-formulants

- ▶ Classification acc. to CLP (+EUH-Phrases) for co-formulants (substances/mixture)
  - Classifications related to human toxicology are entered (in general | e.g. H3xx)
  - Generic/specific concentration limit for each classification is provided
  - Additional derived classifications are marked [•]

#		Classification	Symbol	Category	Date	State	Concentration	Origin
CLP								
		H-Statements (Hazard statements)						
1	☐	H318	GHS05	Eye Dam. 1	2018-10-30	SDB	>= 3.0 - <= 100.0	Manufacturer
2	☐	H319 •		Eye Irrit. 2	2018-10-30	SDB	>= 1.0 - < 3.0	Manufacturer

Generic concentration limits of ingredients of a mixture classified as Skin corrosive Category 1 and/or eye Category 1 or 2 for effects on the eye that trigger classification of the mixture for effects on the eye (Category 1 or 2)

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Irreversible Eye Effects	Reversible Eye Effects
	Category 1	Category 2
Eye Effects Category 1 or Skin Corrosive Category 1A, 1B, 1C	≥ 3 %	≥ 1 % but < 3 %

Data on co-formulants: Data collection procedure

Classification acc. to CLP of the co-formulants

- ▶ Classification acc. to CLP (+EUH-Phrases) for co-formulants (substances/mixture)
  - Classifications related to human toxicology are entered (in general | e.g. H3xx)
  - Generic/specific concentration limit for each classification is provided
  - Additional derived classifications are marked [•]
- ▶ Relevant data scources
  - Safety data sheet (substances/mixture)
    - → Section 2: co-formulant (mixture)
    - → Section 3: co-formulant (substances)

Criteria for input into PSD Database

▶ Identity of the co-formulant is clearly stated

SDS from the manufacturer (pdf)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (Regulation (EC) No 1272/2008)

Acute toxicity, Category 4 Skin irritation, Category 2 Serious eye damage, Category 1 Specific target organ toxicity - single exposure, Category 3 Long-term (chronic) aquatic hazard, Category 3	H332: Harmful if inhaled. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. (Respiratory system) H412: Harmful to aquatic life with long lasting effects.

SECTION 3: Composition/information on ingredients

Chemical name	Identification number	Classification Regulation (EC) No 1272/2008	Concentration [%]
Benzenesulfonic acid, C10-13-(linear)alkyl derivs., calcium salt	List Number : 932-231-6	Skin irritation, Category 2 ; H315 Serious eye damage, Category 1 ; H318 Long-term (chronic) aquatic hazard, Category 3 ; H412	>= 60 - < 70
2-ethylhexan-1-ol	CAS-No. : 104-76-7 EINECS-No. : 203-234-3	Acute toxicity, Category 4 ; H332 Skin irritation, Category 2 ; H315 Eye irritation, Category 2 ; H319 Specific target organ toxicity - single exposure, Category 3 ; H335 (Respiratory system)	>= 40 - < 50

Data on co-formulants: Data collection procedure

Classification acc. to CLP of the co-formulants

- ▶ Classification acc. to CLP (+EUH-Phrases) for co-formulants (substances/mixture)
  - Classifications related to human toxicology are entered (in general | e.g. H3xx)
  - Generic/specific concentration limit for each classification is provided
  - Additional derived classifications are marked [•]
- ▶ Relevant data scources
  - Safety data sheet (substances/mixture)
    - → Section 2: co-formulant (mixture)
    - → Section 3: co-formulant (substances)
  - REACH Registration dossier (substance)
    - → Toxicological information

Criteria for input into PSD Database

▶ Identity of the co-formulant is clearly stated

REACH Registration Dossier (HTML)

2-ethylhexan-1-ol

EC number: 203-234-3 | CAS number: 104-76-7

General information
- GHS
- DSD - DPD
- PBT assessment

Classification & Labelling & PBT assessment

Manufacture, use & exposure

Physical & Chemical properties

Environmental fate & pathways

Ecotoxicological

Classification

+ Physical hazards

- Health hazards

Acute toxicity - oral

Reason for no classification:	data conclusive but not sufficient for classification

Acute toxicity - dermal

Reason for no classification:	data conclusive but not sufficient for classification

Acute toxicity - inhalation

Hazard category:	Acute Tox. 4
Hazard statement:	H332: Harmful if inhaled.

Skin corrosion / irritation

Hazard category:	Skin Irrit. 2
Hazard statement:	H315: Causes skin irritation.

Data on co-formulants: Data collection procedure

Classification acc. to CLP of the co-formulants

- ▶ Classification acc. to CLP (+EUH-Phrases) for co-formulants (substances/mixture)
  - Classifications related to human toxicology are entered (in general | e.g. H3xx)
  - Generic/specific concentration limit for each classification is provided
  - Additional derived classifications are marked [•]

- ▶ Relevant data scources
  - Safety data sheet (substances/mixture)
    - → Section 2: co-formulant (mixture)
    - → Section 3: co-formulant (substances)
  - REACH Registration dossier (substance)
    - → Toxicological information
  - RAC Opinion (substance)
  - CLP Regulation, ANNEX VI (substance)

Criteria for input into PSD Database

▶ Identity of the co-formulant is clearly stated

RAC Opinion (pdf)

Classification		Labelling			Specific Conc. Limits, M-factors and ATE
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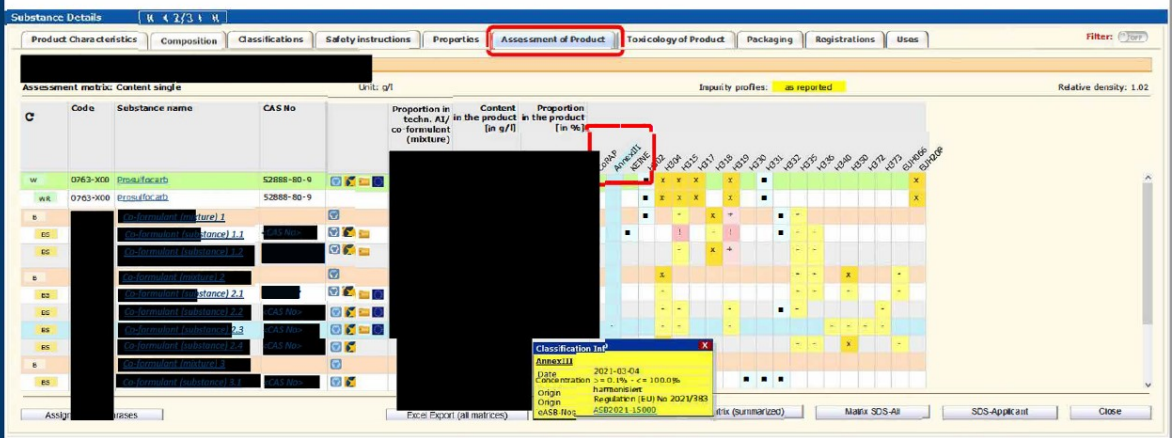
CLP Regulation - ANNEX VI (pdf)

Classification		Labelling			Specific Conc. Limits, M- factors and ATE
Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	
Resp. Sens. 1 Skin Sens. 1A	H334 H317	GHS08 Dgr	H334 H317		Skin Sens. 1A;H317:C ≥ 0,001 %'

Data on co-formulants: Data collection procedure

Further data considered for the co-formulants



BfR

Data on co-formulants: Data collection procedure

Further data considered for the co-formulants

- Regulation (EC) No 1107/2009 – ANNEX III
  - co-formulants which are not accepted for inclusion in plant protection products
  - Generic/specific concentration limit is provided
    → ANNEX III

- Community rolling action plan (CoRAP)
  [https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table]
    → CoRAP

- Endocrine disruptor assessment list
  [https://echa.europa.eu/de/ed-assessment]
    → ED

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Data on co-formulants: Data collection procedure

Further data considered for the co-formulants

- Candidate List of substances of very high concern for authorization
  [https://echa.europa.eu/candidate-list-table]
    → SoVHC [Source: ECHA (Candidate List)]

- List of substances included in Annex XIV of Regulation (EC) No 1907/2006
  [https://echa.europa.eu/authorisation-list]
    → SoVHC [Source: Legal act (Commission Regulation)]

- No classification with H3xx according to Regulation (EC) No 1272/2008 (CLP)
  - means of indicating that documents relating to a co-fomulant exist, but without classification for human health
    → none (*keine*)

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