EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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Report on the Workshop on guidance document and database for the assessment of PPP including co-formulants (20 June 2024, online)

Executive summary

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) organised a workshop on 20 June 2024 to discuss the improvement of guidance for the assessment of plant protection products (PPPs) including co-formulants and the setting up of a database for co-formulants.

A total of 127 participants from Member States, Norway, the European Chemicals Agency (ECHA), the European Food Safety Agency (EFSA) and DG SANTE attended the workshop (see Agenda as Annex 1 and participation as Annex 2).

Following presentations by ECHA, EFSA, DG SANTE and some Member States (see presentations as Annex 3), discussions on topics raised during the feedback from the Member States and Norway on a first outline of the guidance and on options to share data on co-formulants continued in break-out groups.

As a next step, DG SANTE will revise the draft guidance and further consult with Member States and stakeholders. DG SANTE will also continue to work to enable data sharing on co-formulants among the Member States (on a short- and longer-term basis).

Contents

1. Introduction

Plant Protection Products (PPPs) are mixtures composed of one or more active substance(s) - intended to repel, control or kill pests - and co-formulants that enhance product efficacy, facilitate handling/application, and improve storage and product/user safety.

The Commission, in collaboration with EFSA and Member States' competent authorities, is working towards improving transparency and efficiency of the assessment of PPPs – particularly regarding co-formulants.

During discussions with Member States[1] over the past 2 years, two concrete needs have been identified:

1. to develop a guidance document to increase harmonisation in the assessment of PPPs and to address perceived gaps in the assessments

2. to develop a database on co-formulants and PPPs so that workload is reduced for Member States by sharing data

An outline document with a workflow to assess PPP including co-formulants was made available to Member States in January 2024. Member States commented via the Standing Committee on Plants, Animals, Food and Feed and its Post Approval Issues Working Group and agreed to the principles of the outline document.

On 20 June 2024, a virtual workshop on the assessment of plant protection products and co-formulants was organised, in view of further discussing the draft guidance and of identifying short- and long-term possible solutions to share data on co-formulants among the Member States.

A total of 127 participants attended the workshop. The affiliations of the participants were: 104 experts from 24 Member States, 3 experts from Norway. In addition, 3 experts from ECHA, 6 experts from EFSA and 11 policy officers from DG SANTE participated.

Annex 2 lists the participating Member States and EEA-States and organisations.

Experts nominated by Member States and Norway, from ECHA and EFSA attended the presentations while the participation in the break-out groups were limited to a maximum of 4 experts per country to ensure manageable and meaningful discussions.

2. Outline of the Workshop

Prior to the workshop, DG SANTE shared with the participants the first draft of the guidance on the assessment of PPPs and the visual of the flowchart developed by DG SANTE based on the outline document previously agreed in principle with Member States and Norway.

The agenda of the workshop is contained in Annex 1. The morning of the workshop consisted of the welcome and the overview, followed by presentations on existing sources of information, databases on co-formulants: ECHA presented the new chemicals database 'ECHA CHEM' and the future EU Common Data platform on Chemicals, EFSA and DG SANTE gave an overview on sources of information other than

[1] See the related events on website: The Assessment of Plant Protection Products (PPPs) - European Commission (europa.eu), in particular the report of the Workshop on the assessment of plant protection products and co-formulants (scene setting and identification of possible ways forward) – 23 May 2023 and the report of the Technical workshop organised by EFSA - 21 and 22 June 2023

REACH and EFSA explained a new repository on co-formulants under development. Next, DG SANTE presented the first draft of guidance on the safety assessment of PPPs, including the flowchart and Denmark elaborated a case study where the outline/flowchart was applied. The presentations are annexed (Annex 3).

After the presentations, the experts from the Member States (max. 4 per MS), ECHA, EFSA and DG SANTE discussed a series of topics that DG SANTE identified following the consultation of the Member States on the outline/flowchart document.

List of topics
Composition See our proposal in the draft Guidance on the level to report on composition.
Concepts Our proposal is that the concept of unacceptable co-formulants covers the concept of substance 'of concern', therefore there is no need to refer to 'of concern' in the flowchart.
Unacceptable co-formulants Does the flowchart ensure that unacceptable co-formulants cannot be part of PPP? Where does the step on criterium 10 fit? Do we need to include criterium 10 in step 3b ii and in step 6a i?
Interplay In order to implement the concept of 1S1A and use the data and assessment from other regulations as far as possible, is there a need to add anything to the flowchart?
Food stuff, regulated as food/feed additives or food contact material Step 4b: What would be the situations 'for doubts'? what type of data would be expected, what kind of endpoints are relevant in this kind of situations?
REACH **Exemptions:** REACH sets different requirements, and there are several guidance documents on the exemptions. Situation 'unless if specifically justified' in Step 6c are there for future cases that the existing guidance documents do not cover. **WoE:** See our proposal in the Guidance, are there elements missing on how to apply WoE? **Additional information in** Step 6d ii: our view is that this is case by case
Other relevant guidance documents, templates Existing, relevant guidance documents need to be linked to the flowchart to ensure coherence, and some templates need to be revised (e.g. data templates, assessment templates). Proposals is to take into account - Guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products(SANCO/12638/2011) – under revision - EU Guidance Document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No. 1107/2009 (SANCO/10597/2003) - Guidance document for the generation and evaluation of data on the physical, chemical and technical properties of plant protection products under Regulation (EC) No. 1107/2009 (SANCO/10473/2003) – under revision
Environment The draft Guidance sets out that the ERA is based on PPP testing and that, therefore, there is long-term formulation data available. Therefore – a priori - specific data on ecotoxicology for all co-formulants would not be required. Existing GDs on aquatic and terrestrial organisms and problem formulation guide the RA of PPP.
Database and confidentiality Legal and technical guidance Short term and long-term solutions that will facilitate the assessment and ensure harmonisation Identification of actors; tools and systems

Experts who indicated interest in the database topic were part of the group 3, other experts were allocated to group 1 and 2 that discussed the same topics randomly. DG SANTE chaired the group discussions.

DG SANTE concluded the workshop that the report would be available at the dedicated website of DG SANTE[2], the presentations would be shared with the participants and a revised version of the guidance would be drafted for further consultation.

3. Feedback to the plenary on the group discussions

The note takers from each group reported back to the plenary.

Groups 1 and 2 discussed the same questions (see the outcome in the table below), while group 3 discussed on Database and confidentiality.

List of topics	Group 1	Group 2
Composition See our proposal in the draft Guidance on the level to report on composition.	General agreement, however, some further clarification is needed on: additive affects (scope, e.g. applicable only for certain endpoints?), reference and applicability to CLP principles (0.1% thresholds, specific thresholds), and that full composition is also needed for co-formulants (CF) which are mixtures.	The group agreed. It was noted that the guidance has to make it clear who supposed to provide the information on composition.
Concepts Our proposal is that the concept of unacceptable co-formulants covers the concept of substance 'of concern', therefore there is no need to refer to 'of concern' in the flowchart.	It needs to be clarified that a CF that is not on Annex III (unacceptable CF) may also pose a risk under certain conditions. Also general remark that CF should have as less hazards as possible (target: no contribution to systemic hazards) Definition of "of concern" in biocides seems to be broader than the criteria for listing Annex III. Possibility to refer to EU occupational limits – however these apply usually indoors. If a CF contributes to CLP classification of the PPP, this should trigger RA (in particular for systemic effects) To clarify which data could be considered for the assessment: only PPP dossier, other PPP dossiers, other legislation? To clarify how to proceed if there are more data for one endpoint available for the same CF (worst case, mean?). How to consider reliability of the source?	No comment

[2] The Assessment of Plant Protection Products (PPPs) - European Commission (europa.eu)

Unacceptable co-formulants Does the flowchart ensure that unacceptable co-formulants cannot be part of PPP? Where does the step on criterium 10 fit? Do we need to include criterium 10 in step 3b ii and in step 6a i?	Agreement that criterion 10 does not make to the step concerning AS,S,S. As regards CF which are also AS, check the approach followed for BPs. It is important to get access to information also from other sources (beyond PPP dossier). To be clarified which information/ Regulations can be referred to. Also clarify if information from other jurisdictions (US EPA/Canada) can be referred to. It should be stressed that the onus is on the applicant.	It was agreed that the step on criterion 10 can be only at the end of the flowchart and it is also relevant for environment.
Interplay In order to implement the concept of 1S1A and use the data and assessment from other regulations as far as possible, is there a need to add anything to the flowchart?	Not discussed due to time constraints	The water framework directive (environmental quality standards) was suggested to be added as alternative source. The group discussed that exposure routes that are relevant under 1107 but differ from other EU legislation needs to be taken into account, in the flowchart and thus the assessment of a co-formulant can result in different outcome.
Food stuff, regulated as food/feed additives or food contact material Step 4b: What would be the situations 'for doubts'? what type of data would be expected, what kind of endpoints are relevant in this kind of situations?	It needs to be clearly indicated which Regulations can be referred to (food, food additives, FCM, pharmaceuticals, REACH, excipients?) For environmental data, REACH data are more reliable than anything from food legislation. Take out reference to env for food data?	If no longer term data under food related regulations are available, WoE can be used.
REACH **Exemptions:** REACH sets different requirements, and there are several guidance documents on the exemptions. Situation 'unless if specifically justified' in Step 6c are there for future cases that the existing guidance documents do not cover. **WoE:** See our proposal in the Guidance, are there elements missing on how to apply WoE? **Additional information in**	Is there any way to check justifications provided in SDS? The "unless" clause needs to be better specified, in order to reduce its scope. For instance "... if there is any indication of persistency, if it is a PFAS..."	Regarding if no information available on polymers as they are exempted, it does not mean that there is no concern, it was mentioned that polymers will be added as a special case in the guidance and existing and future guidance under REACH will be considered. During assessment, REACH experts in the MS may need to be involved.

Step 6d ii: our view is that this is case by case		
Other relevant guidance documents, templates Existing, relevant guidance documents need to be linked to the flowchart to ensure coherence, and some templates need to be revised (e.g. data templates, assessment templates).[1]	Templates would be useful. Invitation to share existing templates used in Member States, to see if there could be a more general agreement.	Guidance on the Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (SANTE/2020/12830) and on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 of the EU Parliament and Council on placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (SANCO/12638/2011) and Part C of the DAR need also to be considered.
Environment The draft Guidance sets out that the ERA is based on PPP testing and that, therefore, there is long-term formulation data available. Therefore – a priori - specific data on ecotoxicology for all co-formulants would not be required. Existing GDs on aquatic and terrestrial organisms and problem formulation guide the RA of PPP.	Fate data are not covered in REACH, also in some dossiers there are no PPP data available for ecotox (extrapolations to other data), how to bridge there.	There are rarely product data on birds and mammals. Proposals of the group were to include additional assessment factor (extrapolation from other species in which cases studies show more toxicity than the active substance); to cover with mammal tox data. Also fate data are not covered by product data, and it was suggested using other sources such as REACH data in this case. EFSA repository collects data on behaviour of component in the environment, in particular on persistence.

Group 3: Confidentiality and database

1. Confidentiality

DG SANTE confirmed to see no problems with Member States sharing data on co-formulants since this action is for regulatory purposes and, therefore, no commercial applicants' interests are endangered.

It was suggested that the Authorities should reassure the manufacturers that the data will not be shared with third parties and to explain them exactly how it will be transferred, stored and shared, and that further discussion on options is needed to reach a written agreement. To this end, DG SANTE proposed to prepare an information sheet for manufacturers and to share a legal analysis to be commented and agreed by Member States.

2. Database

A discussion on short term and long-term solutions that will facilitate the assessment and ensure harmonisation was tabled during the workshop.

Short-term solutions

Objective: Create a basic, non-technical platform for sharing information

Key Features:

- Simple platform for information exchange among formulators.

- Communication tool for query and response visible to all participants to avoid repetition.

- Temporary measures until a more sophisticated solution is developed post-2028.

- Example:

3. EFSA's existing Excel database on co-formulants can be used as a starting point to be integrated later with data from authorisation of plant protection product dossiers.
4. A dedicated excel file to be filled in by Authorities and to be shared on CIRCABC.
5. Temporary read-only access to existing databases.

Long-term solution

Objective: Develop a comprehensive and detailed data management system for co-formulants

Key Features for a database:

- Ensuring accurate composition information, especially for substances with multiple constituents.

- Addressing confidentiality concerns while sharing data across nations.

- Possibly using systems like IUCLID but making them more user-friendly and specific to co-formulant needs.

- Recognizing the evolving nature of products and mixtures and allowing for updates.

- Proposals for improved codification and submission systems.

- Not necessarily linked to the PPP authorisation submission.

- Being able to avoid errors and duplicates.

Challenges and considerations:

- Confidentiality: Balancing data sharing with the need for confidentiality.

- Complexity of Information: Managing complex compositions and diverse manufacturers.

- Standardisation: Creating standardized templates and endpoints for data.

- Platform Choice: CIRCABC was deemed inadequate for long -term solutions; a dedicated document management system is preferred.

- Linking Data: Importance of linking co-formulant data with the products they are used in for better traceability and understanding.

- The creation of a positive list of co-formulant was discussed but soon deemed too cumbersome to achieve and use due to the diverse uses, concentrations, and formulation types.

Conclusion

The group was aligned on the need for both short- and long-term solutions to enhance data sharing on co-formulants. The short-term solution should be simple and facilitate immediate information exchange, while the long-term solution requires a more robust system addressing detailed data management, confidentiality, and standardization.

Annexes

Annex 1: Agenda of the Workshop

9:30-9:40	Welcome	Karin Nienstedt (DG SANTE)
Presentations on existing sources of information, databases on co-formulants:		
9:40-9:50	New chemicals database ECHA CHEM and the future EU Common Data platform on Chemicals	Annika Malkia (ECHA)
9:50-10:10	Other sources of information	Mathilde Colas, Chloé De Lentdecker (EFSA) Maristella Rubbiani (DG SANTE)
10:10-10:20	EFSA repository on co-formulants	Mathilde Colas, Chloé De Lentdecker (EFSA)
10:20-10:30	**Break**	
10:30-11:50	National databases- Germany	Mareike Bolten (BVL) René Schreiber (BfR) Marcus Hillebrand (UBA)
11:50-12:05	Q&A (clarification on the previous presentations)	All
Presentation of draft guidance		
12:05-12:30	First draft of guidance on the safety assessment of PPPs, including the flowchart	Maristella Rubbiani, Mark Williams, Zsuzsanna Konig, (DG SANTE)
12:30-13.30	**Lunch**	
13.30-14.30	Case study	Mads Holmgaard Kaspersen, Danish Ministry of Environment
Discussion on draft guidance and database (break-out groups)		
14:30-16:00	3 break-out groups - group 1 and 2; both covering identity, human health, environment - group 3 covering database and confidentiality	All experts participating to break-out groups
16:00-16:15	**Break**	
16:15-16:45	Reporting from groups	Group note-takers
16:45-17:00	Closing and next steps	DG SANTE

Annex 2: List of Member States, EEA-States and organisations participating to the workshop

Austria
Belgium
Bulgaria
Croatia
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Ireland
Italy

Latvia
Lithuania
Netherlands
Norway
Poland
Portugal
Slovakia
Slovenia
Spain
Sweden

the European Food Safety Agency (EFSA)

the European Chemicals Agency (ECHA)

the European Commission's Directorate-General for Health and Food Safety (DG SANTE)

Annex 3: Presentations

- **Presentations by EFSA, ECHA and the European Commission**
- **Presentations by Member States**