EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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Report on the workshop on the assessment of plant protection products and co-formulants (scene setting and identification of possible ways forward) (23 May 2023, Brussels)

Executive summary

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) organised a workshop on the assessment of plant protection products (PPPs) and co-formulants on 23 May 2023 in view of improving the harmonisation of the assessment of PPPs in Europe and increase the transparency of the assessments carried out.

128 participants attended the workshop (31 in presence and 97 online), namely experts from Member States, Norway, stakeholder organisations, the European Chemicals Agency (ECHA), the European Food Safety Agency (EFSA) and DG SANTE.

The presentations of the morning session (points of view and experience from stakeholders, ECHA, EFSA and some Member States related to the assessment of PPPs and/or co-formulants) are annexed to this report. In the afternoon, discussions on the challenges and possible ways forward took place in smaller groups of experts from Member States, Norway, EFSA and DG SANTE. The experts discussed the challenges concerning the assessment of PPPs, including co-formulants, and the possible actions that are needed to address them. The key challenges that were identified by the different breakout groups were: availability, quality and accessibility of data on co-formulants to Member States to carry out the assessment of the PPPs; need for a harmonised, transparent and resource-efficient risk assessment; and some additional specific topics.

Contents

1. Introduction

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 plant protection products – particularly regarding co-formulants.

A workshop on the assessment of plant protection products and co-formulants was organised on 23 May 2023 in a hybrid format, in view of improving the harmonisation of the assessment of PPPs in Europe and increase the transparency of the assessments carried out. The workshop aimed at 1) setting the scene (morning session) and 2) discussing the challenges needs, and possible actions to take (afternoon session).

2. Who Participated in the Workshop?

The morning session was attended by stakeholders' representatives, experts from Member States and Norway, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA) while the afternoon session was attended by experts from Member States, Norway and EFSA.

A total of 128 participants attended the workshop (31 in presence and 97 online). The affiliations of the participants were: 92 experts from 24 Member States, 3 experts from Norway, 8 participants representing 5 different stakeholder organisations. In addition, 14 policy officers from DG Health and Food Safety (SANTE) and DG Environment, 2 experts from ECHA and 9 experts from EFSA participated.

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

3. Outline of the Workshop

The agenda of the workshop is contained in Annex 1. The morning of the workshop consisted of the welcome and the overview of the situation by DG SANTE, followed by presentations from stakeholders, an overview of REACH requirements[1] (by ECHA) and an overview of mixtures classification according to Classification, Labelling and Packaging (CLP) Regulation (EC) No 1272/2008)[2] (by ECHA). EFSA explained their experience, and three Member States from the different regulatory zones (Northern, central and Southern) presented their current practices. Three Q&A sessions took place where questions for clarifications were answered. The presentations are annexed (Annex 3).

The afternoon session was organised in 13 breakout groups in three topics (human health, environment and procedural and other regulatory aspects. Two rounds of the breakout groups took place; first the experts discussed in the groups based on their own choice and then in a second group where they were assigned to randomly. All break-out groups got the same task, i.e. to answer the question "Based on your experience and on what you heard this morning, what are the challenges, what are the actions to solve them and what are the expected results?". The discussions were reflected in a feedback form filled by the moderators with help of

[1] https://echa.europa.eu/regulations/reach/understanding-reach
[2] https://echa.europa.eu/regulations/clp/legislation

the experts, recording all points raised without assigning them to individual experts. Highlights of the discussions of each break-out group were presented in the plenary before concluding the workshop.

4. Feedback to the plenary and the feedback forms of the breakout group discussions

The moderators of each group reported back to the plenary. In some groups, the three top challenges were listed, while in others the prioritisation could not be finalised due to time constraints.

The feedback forms from the various groups in Annex 4 list and explain the challenges and include the possible associated actions to address the identified challenges. It is important to note that the forms are a collection of the individual inputs and do not necessarily represent the consolidated view of the group. Furthermore, the information presented in the feedback forms cannot be considered as providing any official position and/or commitment to any future actions.

The main challenges presented by the moderators were:

- Data accessibility and confidentiality
- Data availability
- Resources Member States need to conduct assessment
- Composition of co-formulants, identity
- Grouping co-formulants e.g. those of no concern
- Combined effects (e.g. additive, or synergistic effects)
- Equivalence check
- Component based approach
- Communication

Annexes

Annex 1: Agenda of the Workshop

Time	Title	Presenter
I. Scene setting		
8.30-9.00	registration	
9.00-9.15	Welcome and objective of the workshop	Mr. Klaus Berend, DG SANTE
9.15-9.30	NGO point of view	Mr. Andy Battentier, Secrets toxiques
9.30-9.45	NGO point of view	Mr. Martin Dermine, PAN Europe
9.45-10.00	NGO point of view	Ms. Tess Renahan, PETA
10.00-10.15	Applicants' point of view	Mr. Kevin Heylen, Mr. Laurent Oger CropLife Europe
10.15-10.30	Q&A	
10.30-10.45	Coffee break	
10.45-11.00	Information requirements for co-formulants under REACH	Mr. Sampo Karkola, ECHA
11.00-11.15	CLP: methodology for classification of mixtures	Mr. Ari Karjalainen, ECHA
11.15-11.30	EFSA experience	Ms. Manuela Tiramani, EFSA
11.30-11.45	Q&A	
11.45-12.00	MS point of view	Ms. Claudia Grosskopf, Germany
12.00-12.15	MS point of view	Ms. Louise Lundberg, Denmark
12.15-12.30	MS point of view	Mr. Manuel Sanz, Spain
12.30-12.45	Q&A	
12.45-13.00	Closing	Mr. Klaus Berend, DG SANTE
II. Discussion on challenges and possible ways forward (closed meeting with Member States, Commission, EFSA, ECHA)		
14.00-14.30	registration	
14.30-17.00	Active discussion on challenges, needs, and possible actions to take (break-out groups and plenary) Closing (plenary)	All participants, discussion led by DG SANTE

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

Member States and EEA-States
Austria
Belgium
Bulgaria
Croatia
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Ireland
Italy
Latvia
Lithuania
Netherlands
Norway
Poland
Portugal
Romania
Slovakia
Slovenia
Spain
Sweden

Apologies:
Luxemburg

Stakeholder organisations
Secrets toxiques
Pesticide Action Network Europe (PAN EUROPE)
People for the Ethical Treatment of Animals (PETA)
CropLife Europe
International Biocontrol Manufacturers Association (IBMA)

Annex 3: Presentations

Presentations by EFSA, ECHA and the European Commission
Presentations by Member States
Presentations by Stakeholders

Annex 4: Feedback forms from the break-out groups

Breakout Group 1

Challenges	Actions needed and expected outcome
3 main challenges	
1- Problem to know the full composition of the co-formulant that can be a mixture in case the applicant is not the owner of the co-formulant. Lack of harmonisation among Member States (MSs) on the way to tackle this issue. In general, supplier is to be contacted. Related sub-issue: In case data are needed, would it be the supplier or the applicant to carry out the studies?	Agreement for asking for the complete (100% of the composition) composition of the formulation. Database to be built to avoid requesting the same information to the suppliers and to share the information among MSs.
2- Equivalence assessment not harmonised among MSs i.e. definition not clear enough and interpretation of equivalent/alternative co-formulant may be different depending on the country. Related sub-issues: - Co-formulants that are mixtures/ Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials (UVCB)/polymers. - Impurities of co-formulant e.g. co-formulants may contain the same main compounds but not the same impurities – could be considered alternative? are they equivalent?	Current SANCO Guidance document to be updated
3- How to anticipate the combined toxicity e.g. additive, synergistic or antagonistic effects. Related sub-issue: How to perform the risk assessment for the product (not with the active substance as it is currently done).	Proposal for a screening approach comparing the toxicity of the active substance alone and formulated. Create a database to share information on individual co-formulant i.e. identity, tox and ecotox data.
Other challenges mentioned	
Lack of harmonisation regarding data to be requested for co-formulants and lack of available data for co-formulants.	- Guidance Document describing the data to be requested could be drafted (e.g. tiered approach at least on hazard aspects; if hazard raised then risk assessment to be performed). -Create a database to share information on individual co-formulants. - Build a positive list of co-formulants that are fully tested.
Lack of harmonisation regarding the acute toxicity data for the formulation to be (or not) requested by MSs. Different interpretation among MSs i.e. studies to be requested, or based on CLP rule? However, acute tox data are not used for performing a risk assessment, therefore how could the risk assessment for the product be performed.	Proposal for a screening approach comparing the toxicity of the active substance alone and formulated.
Lack of alternative methods to replace *in vivo* studies.	Development of alternative methods.

Lack of long-term toxicity data.	- Provide long-term data on each single component. - Build a positive list of co-formulants that are fully tested to be used in PPP.

Breakout Group 2

Challenges	Actions needed and expected outcome
1. Incomplete data for the complete co-formulants identification (e.g., polymers, co-formulants without CAS number, UVCB) and breakdown products of co-formulants. This point also covers the problem of confidentiality in accessing the composition of co-formulants mixture (confidential business information for the supplier). Challenge to be addressed at EU and Member States level.	Requirement for the supplier to submit to the Rapporteur Member State (RMS) the complete composition of co-formulants that are mixtures. Proposal to revise the draft review Report template to include two different parts C: one for the RMS only and one for the applicant(s). Proposal to draft a Guidance document.
2. Problem of accessibility of information on the toxicological hazard on co-formulants. In the absence of data, which studies should be requested? Challenge to be addressed at EU and Member States level.	Proposal to update the EU regulation to define additional data requirement on co-formulants. Proposal to request all available data; at least the classification, QSAR and data from REACH registration dossier. Proposal to organise regular meetings between Member States to share experience and harmonise the approach among Member States. Proposal to draft a Guidance document.
3. Lack of data sharing between Member States when a co-formulant is present in different PPP. Challenge to be addressed at EU and Member States level.	Proposal to create an EU database to collect and share data on co-formulants between Member States. NB: one Member State questioned the feasibility of this solution due to legal barriers. Indeed, this Member State cannot share this information with other Member States in accordance with the agreement concluded with suppliers.
4. Lack of guidance in assessing alternative co-formulants. Challenge to be addressed at MS level only.	Proposal to draft a Guidance document.
5. Lack of guidance in assessing possible interactions between components (active substance, co-formulants, etc.) present in the PPP (e.g. synergist effects, metabolic activity of co-formulant versus the active substance in the PPP, etc.). Challenge to be addressed at EU and MS level	Proposal to give priority to the use of new approach methods (NAMs). Proposal to apply a safety factor when interactions between components are demonstrated.
6. Should risk assessments be performed for all or certain co-formulants of concern? (e.g., should we set reference values for all co-formulants?) It is acknowledged that it may be too challenging to perform a risk assessment for all co-formulants.	Proposal to perform the risk assessment for certain co-formulants. Proposal to always set reference values for the PPP in order to conclude on the safe use of the PPP.

7. Classification: Difficulty in assessing co-formulants when no ECHA harmonised classification (CLH) is available on the ECHA website, or, when several divergent notified classifications are established by the applicant(s) in different Safety Data Sheet (SDS). (For instance, diverging CLP classification in different SDS for a same co-formulant (e.g., kaolin clay)) Note: ECHA clarified that the Member States can send a CLH dossier linked to a co-formulant based on their evaluation. Member States can also consult the ECHA registry of intention (i.e., Member States' intention to prepare a CLH dossier), that is publicly available on the ECHA website.	Divergent opinions from Member State experts: One Member State proposed to disregard the notified classifications from companies and to consider only the CLH classification if available. Several Member States still take the self-classifications into account for their evaluation in addition to the ECHA harmonised classification. In addition, when assessing co-formulants, other data are also taken into account.

Breakout Group 3

Challenges	Actions needed and expected outcome
Unclear data requirements and assessment needs - Missing criteria on when to ask for more data on co-formulants. - When information is available in the dossier e.g. LD50 or other values for the co-formulants, the sources of this information or the underlying studies are often not reported or cannot be verified. - Available data e.g. from other regulatory frameworks are not fully exploited – not easy to retrieve them. - However, requirements in other frameworks might be also different and not fully applicable to the PPP use (food vs. non-food e.g. cosmetics, biocides). What can be used when?	Develop a tiered approach to determine what data are needed and how they can be efficiently assessed; use non-animal test methods, predictions such as QSAR, and a combination of data and computer models to generate new information where needed. Give guidance to navigate the different regulatory frameworks, data requirements, dossiers and databases. Create better tools to identify co-formulants that are not considered of concern because used in other regulatory frameworks e.g. for cosmetics or as food additives. Start with the information in REACH dossiers and determine additional specific requirements for the PPP uses. Develop a harmonised guidance in cooperation between MS/EFSA/ECHA.
High workload - Assessing the wealth of data will cause a big amount of work.	Prioritising. Stepwise assessment (tiered approach), starting with hazard assessment. Identify what else might be missing after the hazard assessment. Define criteria when we need a risk assessment – not to carry out a full risk assessment every time by default. Harmonise how we consider co-formulants to avoid parallel assessments with divergent outcomes at different authorities. EU wide shared database to collect not only data but also assessments, so that not everyone has to repeat the data collection and assessment over and over again. An easy overview is needed why and how something was evaluated (context) and if this evaluation is relevant for PPPs. Cross reference existing databases or assessments. Establish lists of co-formulants with issues and without issues to simplify the assessment process.
Taking into account possible changes of the composition due to degradation of the different components in the products. - Assessing mixtures of changing composition can be challenging, certainly testing everything for every scenario is not an option. - Other routes also exist how co-formulants are introduced into the	Get more information but avoid further testing. Use structural information to predict the behaviour of co-formulants.

environment and food chain which must be taken into account in the assessment.	Apply in silico methods to understand the degradation and formation of products of different toxicity. Use in vitro tests. Establish monitoring for problematic co-formulants.
Assessing every aspect of toxicity - Reference values valid for active substance may not be applicable to the whole product as a mixture (mixture toxicity). - Not all studies conducted for the active substance can also be conducted for co-formulants. - Long term toxicity assessment / setting reference values for co-formulants is difficult to be addressed by alternative methods.	Apply a screening approach. Use the methods that are currently available. Development of NAMs for long term toxicity. Validation of the new methods. Broad data collection on co-formulant long-term toxicity data, consider similarities between compounds.

Breakout Group 4

Challenges	Actions needed and expected outcome
Obtaining full and accurate composition of the PPP – recipe of PPP and of the individual co-formulants (i.e. those that are themselves mixtures). Applicant is sometimes not the owner of the data on some co-formulants. Need consistent and unambiguous naming to avoid misunderstandings. Need for harmonisation on the standard information to be accepted.	Register full composition of PPPs and components in a common EU database More detailed composition in Part C of the draft Renewal Report (dRR) Additional section in Part C of the dRR to include full composition details? Tougher decision-making
How to evaluate each combination of active substances + co-formulants? Too many combinations. Extrapolation rules needed. (Not such a problem at EU level as only 1-2 representative PPPs)	Database of combinations assessed Rules/guidance for extrapolation
Alternative co-formulants How to evaluate and decide if acceptable alternative/equivalent? Obtaining access to the detailed composition? (see also first challenge) When to ask for additional data?	Request quality control data (e.g. UVCB, polymers) Use of the Guidance document (GD) on significant and non-significant changes? (starting point) Streamlined approach – some experience already in some MS Look at previous GD on comparability of formulations (stricter approach) - more power for MS to make decisions Register full composition of PPPs and components in a common EU database More detailed composition in Part C of dRR Additional section in Part C of the dRR to include full composition detail? Tougher decision-making e.g. reject applications if robust data is not provided.
Resources – need to avoid excessive burden and redundancy One substance one assessment approach – need for a list of acceptable co-formulants (assessed) to avoid resource duplication. Need to be able to identify when a change of formulation needs assessment Avoiding duplication of work – need to avoid Member States asking for the same information multiple times. MS need access to same information. Mutual Recognition to be accepted without reopening. Harmonisation is key.	Common EU database and possibly a positive list Divide work between MS to use resources more efficiently Increase inter-zonal cooperation
How to decide which type of applications need full assessment – to avoid unnecessary work e.g. not for Mutual Recognition procedure. Need to avoid setting up a process that discourages necessary applications e.g. for minor uses.	Guidance

Analytical methods – what kind of methods are needed with respect to co-formulants/PPPs? Need to harmonise this (not possible for have methods for all co-formulants – only relevant ones – how to identify them as relevant). May be important for quality control – but can come from different PPPs or other products (e.g. biocides, detergents) so is very challenging.	Guidance document
Identification of co-formulants that need further attention – due to concerns for health or the environment	Guidance
Transparency and data access: Data on co-formulant is often owned by third parties who refuse disclosure, even to other Member State competent authorities	Guidance
Moving towards positive list – Regulation (EC) No 1107/2009 requires a negative list. Legal challenges in setting up a positive list?	
Efficacy: some changes to co-formulants (alternatives) may hinder efficacy. Need to avoid impacts on efficacy.	
Different regulatory frameworks – what to do if no data is available e.g. under REACH? E.g. EFSA Technical Report shows some are not registered. How to respect timeline of application process?	REACH amendment – to capture all substances?
SDS – quality issues	
Robust system of enforcement (e.g. checking authorised PPPs) is needed	
Access to quality data and information to perform assessments (available to all MS and agencies) - identifying and finding the right data – all relevant info to characterise the co-formulant e.g. also exposure	Guidance document Better tools to enable gathering of relevant technical information (not only studies) Positive list of co-formulants

Breakout Group 5

Challenges	Actions needed and expected outcome
1. Technical challenges (e.g. confidentiality makes sharing data difficult)	Part C of registration report for PPPs and volume 4 of the Draft Assessment Report (DAR) or Renewal Assessment Report (RAR) for active substances to be processed separately (not to share confidential data) Common database for all Member States. The legal aspects need to be clarified. Could EFSA/COM set up such a central database (avoid duplication of work)? The database would need to include info on different trade names for the same co-formulants.
2. We often do not have sufficient information on co-formulants so we need to request it	Harmonisation regarding what info to require (including what to be required on composition) Clarification of what can legally been required
How to use the data we have?	Harmonisation/guidance needed
High demands from NGOs. This might stem from NGOs not having access to all information.	Step-wise approach. In conclusions/documents, include clear statements on what was concluded regarding co-formulants.
Applicants may not have the data on the co-formulants (especially if the co-formulant is a mixture). The data owner may refuse to provide the information.	It is the responsibility of the applicant to provide the data.
One substance, one assessment – Difficult to achieve fluent communication between authorities on biocides, PPPs, cosmetics.	Separate process to assess the co-formulant, with a consultation with the member states
Safety Data Sheet (SDS) – how old can the info be to be acceptable? When information is missing, e.g. on unacceptable co-formulants in polymers, a harmonised approach is needed for what action the member state should take.	Harmonisation between Member States. ECHA could have a role (as SDS).
3. Already now a very high workload for the Member States. Difficult to take on new tasks.	Check only list of unacceptable co-formulants
Testing on vertebrate animals, how to handle it when performed for third countries, consider or not?	Start with non-animal studies, only if necessary testing on vertebrate animals. Have an approach at the EU level (for testing performed for third countries).

Breakout Group 6

Challenges	Actions needed and expected outcome
It is challenging to perform a complete identification of co formulants. Member States (MS) find quality of composition statements on co formulants quite low. Another MS agreed that composition statements gives issue (e.g., sometimes applicants do not provide such composition statements, or are not in line with safety data sheet). In some cases, for the same co formulant different composition statements are submitted to different MSs. MS authority needs to go back to applicants several time to retrieve missing information, which slows down the process.	Some MS have their own database (northern zone), maybe MS can share it, or an EU or a zonal database can be build. This would reduce delays and support harmonisation, and avoid situation in which applicant state different compositions for the same co formulants in different MS.
It is challenging to perform equivalence among different co-formulants because there is lack of possibility to verify equivalence claims. Sometimes the applicant claim equivalence between different co-formulants, but such equivalence cannot be verified either because not even the applicant knows the composition of the co formulant (e.g. co formulants belongs to other companies), or because such composition is confidential. In these cases, MS ask applicants to retrieve this information (e.g., by the co-formulants' manufacturers), which slows down the process.	The part C (the confidential Part of dossiers for the PPP) can be separated in 2 parts: 1. To be visible only for MS 2. To be visible only for applicant Same approach can be applied for Volume 4 of RAR/DAR at active substance level.
It is challenging to face the absence of guidance documents on how performing equivalence among different co-formulants. Even in case all needed data would be available, equivalence assessment among co-formulants there is a lack of guidelines (which increases workloads as we need to agree on approaches). A guidance document would support harmonisation and speed of the assessment.	MS suggested that, to obtain a Guidance Document (GD) on this topic, we do not need to start from scratch, as existing SANTE GD documents (or draft which already exist) can be used as a starting point. The GD should also address possible formulation changes: "what is an acceptable formulation change to be used as read across?"
It is challenging to face lack of harmonisation among MS as concern request for additional information concerning incomplete safety data sheet. If applicant send incomplete composition information in the safety data sheet, it is important to MS to know what to do and to which extent they can/should go back to the applicant asking for more information. There is need for harmonisation across MS. Another MS however argued that safety data sheet can be included in intervals of %, so applicant are legally entitled to not to give complete info (according to REACH only hazardous substances need to be notified).	It is important to have an EU regulation where it is reported which data the applicant must provide. This would enforce harmonisation and reduce missing information in this case. However, a MS highlighted that care is needed on consistency with REACH (i.e., according to REACH only hazardous substances need to be notified).
It is challenging checking if non-acceptable co formulants are present. As quantitative info on co formulants is not always disclosed, identifying non-acceptable co formulants is time consuming, and MS need to ask applicants to provide specific statements.	A GD may be needed aimed at fostering the provision of this sort of data can accelerate this process. The target of this GD should be the applicants and the suppliers of the co-formulants, or the applicant only, encouraging them to ask this info to suppliers.
It is challenging to understand possible effects on terrestrial non target organisms. Environmental endpoints were not really reflected in this morning presentations, which was too much focus human health. In particular, there is a lack of focus especially for terrestrial toxicity. The gap in terrestrial toxicity is also reflected in policy available	Enforce cooperation with NGOs to gather more information (e.g., practical experience on protection targets, or data gap that needs to be fixed with higher priority).

(Regulations). REACH asks data on terrestrial to be assessed, but this is often missing in dossier for co-formulants. This is the point of view at MS level, not sure what happens at zonal level. Other MS agreed that terrestrial toxicity is not well picked up by the Regulation, which is more focused on aquatic toxicity. With the new hazards identification in CLP this may improve.	

Breakout Group 7

Challenges	Actions needed and expected outcome
- Co formulants go beyond 1107/2009. Another legal framework (REACH) establishes different criteria. Different actors producing data. - Accessibility and lack of data (in particular for the co formulants that are produced in less quantities). - REACH is not sufficiently demanding on the amount of data requested. - Data provided in the Safety Data Sheet (SDS) by manufactures is getting more and more scarce. Same SDS in different languages does not contain the same information + different CAS number sometimes for the same "substance". - Reliable information in the SDS is needed. Part C needs to be better developed. - Applicants do not produce the co formulants. Problem of getting this info from procedures. Not willingness to share. - Tedious to get the composition of the co formulants that are mixtures. Challenge to ask the producers. - Clearer picture of what are these compounds, and their properties is needed. - Trust from the authorities on the "quality" of data provided by the applicants. Time consuming to contact the applicants to get this information! - Equivalence of co-formulants at Zonal level - Effective and robust analytical control for co formulants is needed. - Not sufficient data to assess the co formulant presence in the formulation. - General problem, not only for co-formulants: Lack of other testing methods (not animal options)	1) European Database with the identity of the co formulants and comparability between them. Following one substance one assessment → objective: to avoid duplication at MS level! ✓ Accessible to all the competent authorities and EFSA. ✓ Prioritize the most common/used co-formulants. ✓ Possible challenges: legal challenge of data protection, measure of equivalence, trade names?). ✓ Two possibilities: Only with information (then it would be up to each MS to decide in the "safety" or not of each co-formulant") or also with a positive list of co-formulants (ready to be accepted and used in all the assessments by MS – better for harmonisation). ✓ It should include robust product code name for co-formulants as it exists for other components. ✓ If there is information that is not in the database, a clear indication of where other data might be available. 2) Guidance document on the evaluation the co-formulants (including the comparability) 3) Establish some rules/guidance/on the responsibility of MS in the assessment of specific products (in particular for the existing ones) → e.g. what to do in case of mutual recognition? Who is responsible for the assessment of co-formulants? Expected outcome: less and shared/needed/transparent/ workload.

Breakout Group 8

Challenges	Actions needed and expected outcome
There seems to be a communication issue with the external stakeholders not fully understanding what is done already for the assessment of PPP in the MS. In some Member States (MS) the draft Renewal Report (dRR) is not available to the public or even the applicants. The EU level public consultations for Draft Assessment Reports (DAR) or Renewal Assessment Reports (RAR) are useful but it seems that the public still do not fully understand the amount of work and level of assessments performed (as evident from the presentations this morning).	The applicants should be given the dRR that is written by the regulatory authority. Promote other ways to communicate and raise awareness of the assessments that are already performed. IUCLID could be used for PPP at national assessments. This could then be made available (at least a summary outcome) to the public to demonstrate the data used and the risk assessments performed. Ensure better communication with NGOs. For example, when they advertise publications perhaps a response can be given to ensure that a complete picture is given (i.e., single high impact news stories do not give the context to the assessment already done).
The speed of assessments at EU level is slow and therefore any changes will take time to take effect.	
Data on co-formulants alone is scarce. Some data is included for aquatic organisms but not for other non-target organisms (NTO).	
Co-formulants that are mixtures themselves. It is difficult to know the composition. In some cases, the applicant for the PPP may not have the details of the composition of the co-formulant.	
The solution for the database was suggested without a specific challenge	The data base from a MS was extremely appreciated. It would be useful to have a similar EU level data base where all information can be accessed. The challenge would be to ensure that the information is organised in a good way but maintain confidentiality. Expected outcome – the MS and applicants would have better and harmonised knowledge of all the available data for co-formulants. This would allow the workload to be shared. If it was centralised at EU level would be useful. Also, it would have the benefit of ensuring that all data are considered in a comprehensive way (i.e. in the case of multiple applicants with different data packages) TOP PRIORITY
It is sometimes the case that an applicant may include several optional co-formulants for a specific purpose (i.e., it is just listed as "surfactant – e.g. surfactant XYZ, or surfactant ABC or surfactant X"). These are meant to be equivalent, but this is what the applicant believes is equivalent. How can the co-formulants be decided to be equivalent – how would this be done? What is	Perhaps the data base mentioned above could be a step forward.

Challenges	Actions needed and expected outcome
equivalent?	
As a similar issue to the one above – when an applicant proposes a change in the formulation composition, it is difficult to know whether the formulation change has an impact on the risk assessment/toxicity.	Suggested action – develop guidance on when it is possible to extrapolate from one formulation to another (bridging statements). This was acknowledged that it would be a challenge. A data collection could be done to identify which formulation types are more commonly showing higher toxicity relative to the active substance (e.g. EC formulations are more frequently showing higher toxicity to NTOs). It may also help better use literature data performed on non-representative formulations. Expected outcome – harmonisation of assessments in MS, communication to outside world of how assessments are performed and better use of literature data. TOP PRIORITY – both for chemists and risk assessors. It was acknowledged that there is already a GD for minor formulation changes. It does not consider the impact on the risk assessment for NTO. This could be further developed and updated. This could be done for all sections of the RAR.
For the risk assessment for aquatic organisms – there is a rule for when chronic toxicity data are required (it is in the data requirements) – based on the acute toxicity data. This seems not to be understood by the stakeholders. There is also a method for combi-toxicity for multiple active substances. The challenge of needing a proper exposure assessment for the active substance together with the co-formulants in order to complete the chronic risk assessment.	
Long-term toxicity data for products – it was questioned whether this is even meaningful? After application of a PPP the fate and behaviour of substances and co-formulants will mean that the exposure to the NTO will not be to the same mixture as the one in the PPP (i.e., different ratio). The challenge to ensure that the PPP and co-formulants pose a low risk to mixtures which are different to the PPP composition.	Suggested solution – develop a guidance document for a stepwise approach and deciding when data should be requested. Before starting the above. It is suggested that a detailed survey is undertaken to understand what assessments MS are already doing. For example, MS already ask chronic formulation data for bees.
Some cases co-formulants are known to be toxic (and classified as such). The PPP itself may not result in the need for classification. However, considering the risk to the environment – the high application rate of the co-formulants may mean that it poses a high risk.	
Cumulative exposure to co-formulants considering that they are used in multiple PPPs and also biocide products, other chemical products etc.	More data could be requested for common co-formulants. Prioritisation for highly used co-formulants. Very complex issue. Will depend on the chemistry, fate and behaviour of the co-formulants.

Challenges	Actions needed and expected outcome
	For a meaningful assessment we need to be able to assess the exposure to co-formulants and this would be logical to do with a cumulative approach. Suggestion action: Develop an approach for the assessment of for cumulative exposure of co-formulants. This would need exposure data on the individual co-formulants and then a prioritisation of those where there is highest exposure. TOP PRIORITY Considering the views of the NGOs it was considered a top priority.
Bioaccumulation of co-formulants in the environment including cumulative exposure from several co-formulants.	New CLP Regulation could provide data for assessments.

Breakout Group 9

Challenges	Actions needed and expected outcome
When to look at co-formulants alone and when to the formulation: • Advantage of co-formulants alone: can be present in different formulations but there are many sources of entry in the environment. • Advantage of the formulation is that it will cover synergistic effects.	

• Formulations: when is the formulation different from another formulation for which we already have data. Boundaries to be set.
• Bridging principles between similar formulations:
  o Formulations: threshold of 5% as suggested by a NGO
  o Chain effect can be tricky: Formulation A differs 5% from formulation B which differs 5% from formulation C which means that it is likely that A differs more than 5% of C.
• Lead formulation is not always used.
• Also qualitative challenge: what if heptanol and octanol? Chemical expert knowledge needed.
• Transparency
	• The comparison of PPPs is already used under ecotox based on tests, so the effects of co-formulants are already covered. At least in terms of acute aquatic toxicity. There is a lack of data for all the other organisms.
	• Harmonised way to interpret data requirements on extrapolation regarding data waiving for PPP assessment.

• Co-formulants: is prioritisation possible? Not all co-formulants are as relevant…. • Definition needed on what is a relevant co-formulant. • More focussed approach is needed. • Very important topic to avoid dramatic increase of work.	• Need for a Guidance Document with a decision tree to decide which co-formulant needs to go the risk assessment fase. • Biocides look at all classified co-formulants. For these reference values are derived. • For the prioritising of co-formulants: maybe an approach of a phys-chem evaluation and prediction on fate and only then evaluate ecotoxicology if relevant. • Can the work done for the annex 3 negative list be used as a basis for a prioritisation exercise? Maybe not if only cut-off criteria were used. • One substance one assessment principle
• Risk mitigation measures: should they be based on the active substance or on the formulation? This depends on what you are protecting/the way of entry. Eg drift (formulation) versus run-off (active substance). • Should run-off in future also be considered for co-formulants? Maybe only for the most hazardous.	
• Not all necessary information is available in the Material Safety Data Sheet (MSDS). The quality of MSDS is very heterogeneous. Often a lot of data is lacking, especially for ecotoxicology and fate (fate is worst). • Only 53% of co-formulants in RE registration? Can be an issue. • Not enough information about co-formulants, substances and/or mixtures. Confidential issues can appear.	
If fate and ecotox aspects for co-formulants needs to be evaluated exactly as for active substances or PPP (point 10 of the Annex of Regulation 574/2023), much more time will be needed to finish the evaluation.	

• Part C of the dossier submitted by the applicant has to be changed in order to include the information needed to be able to follow the criteria in the Annex of Regulation 574/2023. • A complete composition of the PPP has to be provided, including for the co-formulants that are mixtures on their own. • Transparency issue.	• Confidentiality issue needs to be solved. At least the data for classification and labelling should not be confidential. • To include any fate and ecotox information without exposing the composition of each co-formulant. • Creating a Member States only database of co-formulants so there is no longer a need to look into different sources.
it is not clear how the combined (eco)toxicity of the PPP should be addressed. Until now, the combined effect of the active substances was taken in consideration. Now, we will/should take in consideration also the co-formulants?	Model deviation ratio in aquatic Guidance Document and Bee Guidance Document to assess synergistic effects for active substances => principle can also be relevant for co-formulants.

Breakout Group 10

Challenges	Actions needed and expected outcome
Safety Data Sheet (SDS) are the basis of the assessment – and information on SDS is limited some times to acute data only SDS sheets are sometimes not very complete (fate and ecotox often limited information)	More cooperation with ECHA is needed for better SDS sheets
Limited time and resources Time which would be needed to assess studies for co-formulants, if they would be requested, is limited	Evaluation of studies on co-formulants to be done by ECHA (?) How can this ECHA assessment been seen by MS and can it be use for other purposes (PPP assessments) than those for which ECHA was mandated?
How can we better organise the work considering the high number of co-formulants, that they are appearing in different products, and considering that some data are confidential to the single PPP authorisation dossier	ECHA approach interesting: screening – considering the amount of number of co-formulants Ask more data from applicant (e.g. information for CLP calculations, but the applicant need the access to the info on the co-formulants it uses which is sometime an issue) Make more use of databases available – a common EU database would be a helpful and easy solution (but it might be no problem to have also national databases) EU work ongoing under one substance – one assessment, I particular activities regarding "data lake" PPPAMS development might be a solution
When is the best place for a screening of co-formulants and when is the best place to look at more details, including formulations? Do we need to look at formulations? Is it feasible to work with formulations? Do we look at every single co-formulant?	In fate we assume that the formulation breaks down when it the PPP is brought out, in fate we would be looking at single components once the PPP is brought into the environment (may be not in this extent for encapsulated formulations) ECHA approach interesting: screening – considering the amount of number of co-formulants
No detailed assessment on fate and residues is done on a standard basis (no data available), because the evaluation is focused on tox and ecotox of co-formulants: it is based on SDS and ECHA and REACH data, national database with info on particular substances (co-formulants) which also has info on companies (confidentiality issues).	
Status quo (not challenge): ecotox studies are available on acute effects for most species (not birds). We rely on these studies and consider that co-formulants are covered. Questions as regards long term ecotox: CLP classification is considered for ecotox, but it only considers aquatic	Existence (Norther Zone) / creation of a WG for discussing issues – also at EU level Working group (phys-chem) for cooperation, to discuss for instance to

ecotox classification for PPP: the complete composition including co-formulants is considered. studies are available for representative formulation, may be not for all PPPs but then it is extrapolated. Challenge: If co-formulant is mixture detailed information is asked to the respective company (no problem for zonal assessment, but so far difficult for implementation of Annex III co-formulants (information provided is not clear and should have been already reported in SDS sheets), replies from companies are difficult to get, replies are not harmonised.	change of composition of PPP
Should we treat co-formulants as we treat metabolites, coming with different "categories" in terms of relevance for the environment? If yes, the RA for co-formulants would be needed only if relevant. Co-formulants are expected not to be biologically active (as metabolites)	Categorisation of co-formulants for being able to focus the assessments "Positive list" of co-formulants (e.g. good data package and risk assessment data package or non-toxic substances), which could be safely used. Such a positive list may need to be linked to AS with certain properties. Use EFSA report as starting point and check how many more (and which) co-formulants are used in PPPs in the MS and that do not have the maximum data requirements according to the REACH regulation because they are in the lower tonnage band
Screening method or prioritisation method to identify co-formulants which need more attention and are more relevant based on their use or characteristics, introduce a "categorisation" for co-formulants	E.g. phys-chem. properties, enzyme induction properties, persistency, etc… could be used as criteria for such a categorisation. Prioritisation should also consider the volume of the co-formulants or those more widely used (broader scale) or prioritise on co-formulants in higher proportion in the PPP (within the PPP), and how is it formulated (e.g. spraying vs. bait formulation)
Every MS works on its own – different national databases available which may not be harmonsied –	More cost effective if workload and data would be shared and databases would be harmonised and pooled into one EU database
How to include relevant literature data and share it	

Breakout Group 11

Challenges	Actions needed and expected outcome
Harmonisation	Legislation EU database Zonal databases EFSA data collection One Substance One Assessment
General pressure of chemicals on the environment: these might be the co-formulants to start from	
Data accessibility	Single repository Short, medium and LT strategy Legally protective
Nice to know/need to know; sufficient vs insufficient data; is testing everything really leading to more protection?	Define what needs to be tested Follow the developments on NAMs
MS workload (but also applicants, contract research organisations -CROs, agencies)	EU database EFSA data collection One Substance One Assessment Grouping strategies Priority setting Short, medium and LT strategy Legally protective
Pesticides: double standard (if co-formulants are in PPPs or not)	
Hazard and/or risk assessment, and impact on the data needed	Workshop in June

Breakout Group 12

Challenges	Actions needed and expected outcome
Quality of the co-formulant (purity/impurities according to the different manufacturers; Changing of the co-formulant composition along the time; Safety Data Sheet (SDS) quality: SDS sheets are the basis of the assessment – and information on SDS is limited some times to acute data only.	Responsibility of MSs to enforce, also for changing of the co-formulants according to a different manufacturer. Push applicants to provide the right and updated info, not limited to a SDS if there are concerns (long term properties to be checked carefully).
First screening of co-formulants in the formulation, check concentration first and harmonised classification and labelling (C&L). Make use of the 6-package info first. Use first a component based approach. Use of a tiered approach in data evaluation for co-formulants. Clear data requirements for co-formulant should be provided. Consider the intrinsic properties of the co-formulant. Consider if the function and the concentration of the co-formulant can modify/alter hazard/risk.	Update data requirements; Update of OPEX guideline; Define more precise information to elaborate data and rules for the use of data; Implement the methodology; Set a specific WG.
Changing of composition : major and minor changes. Generic products have no info on co-formulants.	Focus on products at authorization level Clarify the limited importance of the representative formulation
Some MSs have their national list of authorized and unacceptable. Different approaches in MSs (one based on hazard and considering unacceptable also Cat 2 and STOT). To amend part C of dRR, splitting into part for concerned MS and notifier.	Harmonise the procedure among MSs; Provide asap notification according to the new Reg. Create a EU database based on the MSs list Mandate EFSA to do it, improving their technical report. EFSA/ECHA (?) to group chemicals according to their hazard, C&L, identity, functions, etc. Amend Annex III in order to include new hazard classes cut-off for CLP. Sharing of information not only at zonal level, even if confidential; Request a complete risk assessment for Ct2 or for substance with long term properties. Make use of the One substance-one assessment approach; Make use of the exempted substances identified by Reach to exclude non-hazardous co-formulants.
Test on formulation: not considering over exposure and cumulative exposure; not considering tank dilution and tank final mixture (more than one product mixed together).	No need to test formulation
EFSA to move to risk assessment for those co-formulants which have peculiar intrinsic properties. Ecotox studies are available on acute effects for most species (not birds). We rely on these studies and consider that co-formulants are covered. CLP classification is considered for ecotox, but it only considers aquatic ecotox.	Improve the submission of data for environment but make use of CLP data for aquatic.
Co-formulants for biopesticides/PPP micro-based should be considered	Consider the representative use formulation, check products at authorization stage like any other chemical-based ones.

Breakout Group 13

Challenges	Actions needed and expected outcome
Access to information/quality - Problem with getting information - Very often long-term tox data are not available, especially limited information on co-formulants	- Applicants role should be more proactive to provide data on co-formulants - A possible solution would be clearer data requirements
Resources/workload regarding time and people - Not duplicate work /double assessment, if it can be under REACH then enough - Administrative burden	- Prioritization what should be known - Nice to know vs need to know - Balance between quality and flexibility - Attempting a system that does not duplicate the work - Give political priority to the matter - Substance of concern (SoC approach) = substance of concern approach (biocides) →Narrow down to have a look only at the most problematic substances
Harmonization at EU level and national level - Interpretation of legislation - Asking for information – how much?	- EU co-formulant database (possibly provided by EFSA) - Guidance document: how to assess co-formulants? - SoC approach - EU guidance on tiered co-formulants evaluation - Have a look at active substance approval and on PPP authorization: different processes
- Growing awareness by society and expectations for quick actions - Complexity of pesticide topic is increasing: scientific, legislative and geographic - Reputation of pesticide topic	- Engage - Engage with stakeholders
REACH - quality of data (every study peer reviewed?) - exemptions - REACH data requirements not sufficient to fulfil PPP data requirements	- Take into account different legislations - Cooperation between different areas/legislation
Communication	Provide clarity in the assessment of PPP what has been done
Lack of data, especially long-term	- Generate data for PPPs themselves, NAMs (new approach methodologies) where possible e.g. genotox-test as required for glyphosate PPPs
active substance authorized with limited data on co-formulants in representative formulation	EFSA technical report can be the basis