

TECHNICAL WORKSHOP ON RISK ASSESSMENT OF
THE PLANT PROTECTION PRODUCTS

TOPIC 1:
TRANSPARENCY AND
IDENTIFICATION, DATA AND
HAZARD ASSESSMENT

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ITEM 1: INFORMATION ABOUT THE IDENTIFICATION, CONCENTRATION AND FUNCTION OF THE CO-FORMULANT IN THE PPP

1.1. What information is needed to fully identify the co-formulants (including mixture), their range of concentration and their function.

Background

Substance identification: Data requirements under Regulation (EU) No 284/2013

Functions: Data requirements under Regulation (EU) No 284/2013: list of 22 functions

Definition of the functions for co-formulants used in biocidal products ([ECHA, 2021](#))

Concentration levels: provided in the SDS.

DEPA* approach – Substances and mixtures

- Name of all ingredients, including impurities (e.g., residual monomers in polymer co-formulants), additives etc. This includes ingredients present at concentrations below 0.1 % (in case they would contribute to the toxicity of the product).
- Content of all ingredients in weight % accounting for 100 %. For intervals, only very narrow ranges are accepted.
- Minimum: a descriptive name
- Preferably: a detailed name, structure, polydispersity index, Mn, Mw, degree of polymerisation



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DEPA approach – Substances of Unknown or Variable composition, Complex reaction products, and Biological materials (UVCBs)

The following is required to properly identify the content of a UVCB:

- Irrespective of concentration, all known components should be specified by their IUPAC name and CAS number
- All components present in a concentration >10 % in the UVCB should be specified with IUPAC name and preferably CAS number
- All components present in a concentration <10 % in the UVCB should be identified by a generic description of their chemical nature
- All components contributing to the classification of the UVCB should be specified
- Some UVCBs are so-called performance chemicals.
- A performance specification may supplement the compositional specification when a UVCB has a high batch variability regarding composition.



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Discussion

Proposed solutions	Proposed follow-up actions
<p><u>Example of data on identification of co-formulants to be requested:</u></p> <ul style="list-style-type: none">• Data requirements as defined in Regulation (EU) No 284/2013• Full composition of co-formulant mixture with the relative and absolute concentration of each component (up to 100%)• Information on impurities contained in each co-formulant although it was acknowledged that this may be problematic for certain co-formulants• Other physical chemical data (e.g., data on viscosity) <p>Detailed information on co-formulants to be shared between Member States (MSs), particularly if there are co-formulants considered to be equivalent (see point 2.4).</p>	<ul style="list-style-type: none">✓ Checklist of data to fully identify co-formulants to be included in the application dossiers, draft registration reports (dRR) and assessment reports.✓ List of working definitions (glossary) for the assessment of PPP and co-formulants to be drafted. <p>The checklist and the glossary could be inserted in the Guidance document on significant and non-significant changes to co-formulants (under revision). If this is not possible, a guidance document could be drafted specifically for the chemistry aspects of the formulation and co-formulants.</p> <ul style="list-style-type: none">✓ Revision of application dossiers, dRR, Volume 4 templates: proposal to have separate document for each co-formulant rather than a document for the PPP. This means that once a document on a co-formulant is drafted, it can be used each time a PPP has that co-formulant



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1.2. How to access the confidential data not owned by the applicant? Special considerations for when a co-formulant is a mixture.

Background: In most cases, the SDS contains only substances with hazardous data. The complete composition is Confidential Business Information (CBI) from the supplier: in general, the applicant does not have this information and MSs have to liaise with the manufacturers of the co-formulants.

Discussion

Proposed solutions	Proposed follow-up actions
<ul style="list-style-type: none"> ✓ <u>Short-term solution:</u> <ul style="list-style-type: none"> • Confidential information to be shared among MSs in a dedicated platform, such as existing databases (see point 2.4). • Data on the complete composition of co-formulant mixtures from the suppliers to be shared among MSs. <u>Long-term solution:</u> creation of an EU common database. ✓ The composition of coformulants which are mixtures can change over time. In the new database, the date of information update should be reported due to regular changes in co-formulants composition. ✓ In the draft registration report template/Volume 4, it is proposed to include the possibility of having several confidential parts with appendices, to differentiate the information from the applicant(s) and the rationale from MSs and other data (e.g., from the supplier), not available to the applicant(s). In addition, instructions on the content to be reported for each section may be indicated in the template. 	<ul style="list-style-type: none"> ✓ Existing databases containing confidential data to be shared among MSs in a platform ✓ Creation of an EU database to collect and regularly update the composition of all co-formulant mixtures, by using existing MSs/ECHA databases as a starting point. ✓ The EC and EFSA to check the feasibility of sharing confidential data between MSs (legal perspective). National legislation may need to be harmonized among MSs. ✓ Revision of application dossiers, dRR, Volume 4 templates



ITEM 1: INFORMATION ABOUT THE IDENTIFICATION, CONCENTRATION AND FUNCTION OF THE CO-FORMULANT IN THE PPP

1.3. Definition of relevant co-formulant and co-formulant of concern

Background

Difference between co-formulants of concern and relevant co-formulants
 Article 3 - Regulation (EC) 1107/2009: definition of 'substance of concern'

Discussion

Proposed solutions	Proposed follow-up actions
<p><u>Co-formulants of concern</u>: Criteria to be defined in a guidance document, relevant for risk managers decision-making:</p> <ul style="list-style-type: none"> The new CLP hazard classes could be taken into account in identifying co-formulants of concern Criteria for defining the notion of "concern": e.g., CLP Regulation (use of the CLP criteria for human health; tbc if relevant for environmental classifications); the definition of 'substance of concern' from the guidance documents on BPR; if the co-formulant is reactive; if it is a surfactant; the most frequently used ones according to the national market; etc. <p><u>Relevant co-formulants</u>: Criteria and analytical methods to be defined in a guidance document:</p> <ul style="list-style-type: none"> Data to be requested: <ul style="list-style-type: none"> - an analytical method to monitor relevant co-formulants. - a stability study after use: information on breakdown products of co-formulant, if components of concern are formed following the application of the PPP. Use of the definition of 'relevant metabolite' as used in the Guidance document on the assessment of the relevance of metabolites in groundwater metabolites, 2003. 	<ul style="list-style-type: none"> ✓ Drafting of a guidance document with the inclusion of a list of non-exhaustive criteria for defining co-formulants of concern and relevant co-formulants. ✓ Use of 1S1A approach to harmonize definitions between MSs.



ITEM 2: HAZARD EVALUATION OF PPP/CO-FORMULANTS

2.1 What data should be available to assess the hazard effects; In which circumstances would it be acceptable not to require data for substances presumed to be of no concern; How to identify which data are missing; In what circumstances should Member States request additional information to identify the hazards; And if data are needed, for which endpoint and what type of data/information.

Background

- Points 1.1 to 1.3 and point 1.11 of Regulation (EU) No 284/2013
- Judgment of the Court of 1 October 2019 ([C-616/17 - Blaise and Others](#)): conclusion on the safe use of the PPP (including long-term toxicity and carcinogenicity).

Discussion

Proposed solutions	Proposed follow-up actions
Genotoxicity: Screening of genotoxicity potential of co-formulants: to be performed as described in the Guidance document on the relevance of metabolites in groundwater metabolites, 2003	Genotoxicity ✓ Drafting of a guidance
Acute toxicity (ecotoxicity): <ul style="list-style-type: none">• Acute data on the PPP (non-vertebrate species) are available in most of the cases pending on exposure.• Lack of acute data for aquatics when PPP applied as seed treatments or other application methods that do not lead to direct contamination of surface water.	Acute toxicity (ecotoxicity and mammalian toxicity): ✓ See slide 8.



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Discussion

Proposed solutions	Proposed follow-up actions
<p>Acute toxicity (mammalian toxicity):</p> <ul style="list-style-type: none">• For the majority of PPP, acute toxicity is addressed according to the data requirements set in Regulation (EU) No 284/2013.• For 'older' PPP, studies with the formulation are often available, while for 'newer' PPP, alternative methods (e.g., bridging to other formulations or calculation of toxicity based on information on the individual ingredients) are more often used since vertebrate studies are only accepted as a last resort.• The assessment of applications for newer products can be complex and there is a need for harmonisation between MSs, since currently the approaches taken by the MSs differ greatly.• For co-formulants, acute data are available in most of the cases from SDS or other legal framework than pesticide. No data on polymers as exempted from REACH (see point 4.2), the consequence being that for many PPPs the calculation method cannot be used to fulfill the data requirement since there is not information on all of the ingredients in the PPP.• Finally, there is a need for harmonisation among MSs in which cases in vivo data are requested.	<p>Acute toxicity (ecotoxicity and mammalian toxicity):</p> <ul style="list-style-type: none">✓ Dedicated discussion to be organised with experts (e.g., general pesticide peer review experts' meetings, workshop or in a working group).



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Proposed solutions	Proposed follow-up actions
<p>Long-term toxicity (ecotoxicity) <u>For PPP:</u></p> <ul style="list-style-type: none"> For birds and mammals: based on data from the mammalian toxicity section. For aquatic organisms: the criteria to request data on chronic toxicity if the formulation is 10 times more acutely toxic than the a.s., could be further discussed. For all groups of NTOs: data only to be requested when there is exposure (see topic 2). <p>Proposed tiered approach:</p> <ol style="list-style-type: none"> To check the physical chemical properties and the environmental fate and behaviour data of the PPP/co-formulants . Current approach is to compare the toxicity of the PPP versus the active substance. If the PPP is more toxic, it would be due to toxicity of the co-formulants (or synergistic effect). In the case of higher toxicity an exposure assessment is needed in order for the risk to be assessed. <p><u>For co-formulants:</u> The proposed tiered approach as proposed for the mammalian toxicity section could be used. The exposure should be considered before requesting long term toxicity data.</p>	<p>Long term risk assessment (ecotoxicity)</p> <ul style="list-style-type: none"> ✓ Topic to be discussed at general pesticide peer review experts' meetings with experts. The outcome of the discussion will be communicated to stakeholders through the meeting reports.



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Proposed solutions	Proposed follow-up actions
<p>Long-term toxicity (mammalian toxicity) <u>Suggestions:</u> Only co-formulants for which all data sets are available (including long-term toxicity) would be acceptable, unless the applicant wishes to generate data. <u>Proposed approach:</u></p> <ul style="list-style-type: none"> ✓ (problem: applicant is usually not the manufacturer of the co-formulants). ✓ The applicant would need to provide access to data to MSs (at national level) or to peer reviewers (at EU level). ✓ Co-formulants which are considered not to be of concern and/or where some data are not necessary can be included in a positive list (based on the endpoint). ✓ Tiered approach: to screen critical co-formulants, those with data or not: <ol style="list-style-type: none"> 1. Screening of data: from other legal frameworks other than pesticide; literature data; to check the positive list on co-formulants; <i>in vitro</i>, <i>in silico</i> toolbox, etc., read across, etc. 2. If no data: it is proposed to request data by following the Annexes VIII, IX and X of REACH data requirements for all co-formulants. 3. Prioritisation exercise: grouping, comparative assessment 	<p>Long-term toxicity (mammalian toxicity)</p> <ul style="list-style-type: none"> ✓ Proposal to create a working group to draft a joint ECHA/EFSA guidance with biocide/pesticide (1S1A approach), including the proposal to follow a tiered approach. ✓ EFSA/ECHA to check the accessibility to raw data from ECHA REACH Registration dossiers. ✓ Creation of a positive list, i.e., co-formulants which are considered not to be of concern and/or where certain data are not required (see also point 1.3)



ITEM 2: HAZARD EVALUATION OF PPP/CO-FORMULANTS

2.2 On which basis could a justification for waiving considered valid and which approach or considerations to apply if no data is available.

Background

- Point 1.5 of Regulation (EU) No 284/2013: waiving data to be scientifically justified.
- Non exhaustive references: US EPA [Guidance Documents](#) for inert ingredients; US EPA [Inert Ingredients Overview and Guidance](#); [OECD Guidance Document](#) on Considerations for Waiving or Bridging of Mammalian Acute Toxicity Tests.

Discussion

Proposed solutions	Proposed follow-up actions
Waiving data should be specific to endpoints and to use/exposure. <u>Proposed approach:</u> <ul style="list-style-type: none">• Case-case justification• based on expert judgment	✓ To collect examples from MSs on which basis a justification for waiving is considered acceptable in the EU database . Examples should be reported by endpoint and by use/exposure.



ITEM 2: HAZARD EVALUATION OF PPP/CO-FORMULANTS

2.3 Source and hierarchy of data required: which sources of data can be used for the hazard identification and which type of data should be considered.

Background

Non exhaustive list of relevant sources the [EFSA technical report on co-formulants \(EFSA, 2022\)](#).

- From EU agencies: ECHA (REACH, biocide, CLP, Poison Centres DB), EMA (excipients, pharmaceuticals), EFSA (food/feed additive, food contact material), etc.
- For the European Commission: cosmetic ingredients, Annex III, etc.
- Other sources from non-EU/international agencies: JMPR, Canada and Australian national agencies, US EPA.

Discussion

Proposed solutions	Proposed follow-up actions
<p><u>Proposed approach</u>: Applicant(s) to collect regulatory status and data from other EU/non-EU sources, provided that the applicant specifies why the extracted information is relevant to the risk assessment (e.g., a non-approved cosmetic ingredient could be relevant information if there is a risk of dermal exposure to the PPP).</p>	<p>✓ Revision of application dossiers, draft registration reports/Volume 4 template to include instructions on the content to be reported for each section may be indicated in the template, minimum level of data relevant for the risk assessment to be requested to the applicant(s).</p>



ITEM 2: HAZARD EVALUATION OF PPP/CO-FORMULANTS

2.4 How to share (if co-formulants list available at MS level) and harmonise information and evaluation of co-formulants (e.g., establishing an EU database).

Background

Existing databases at MSs level based on the EU survey (November 2022-January 2023) collecting the composition of co-formulants, no data on hazard but potentially data whether listed in Annex III.

ECHA biocide database on co-formulants.

Use of non-EU databases (e.g., US EPA)

Discussion

Proposed solutions	Proposed follow-up actions
<ul style="list-style-type: none">✓ Long-term solution: creation of an EU harmonised database available to MSs, the EC and EU agencies: public and confidential versions.✓ Interim solution: to share existing databases among MSs on CIRCABC / DMS, feasibility to be checked by the EC and EFSA.✓ Due to possible legal barriers, the EC and EFSA to check the feasibility of sharing confidential data between Member States (legal perspective). It would be beneficial if national legislation is further harmonised between MSs: COM/EFSA will check how they can assist.	<ul style="list-style-type: none">✓ Creation of an EU database✓ Existing databases to be shared among MSs in a dedicated platform✓ The EC and EFSA to check the feasibility of sharing confidential data between Member States (legal perspective).



ITEM 2: HAZARD EVALUATION OF PPP/CO-FORMULANTS

2.5 Bridging assessment of PPPs, alternative co-formulants and equivalence assessment.

Background

Non exhaustive references: [Guidance document on significant and non-significant changes to co-formulants](#) (under revision) ; [EFSA Guidance Document on dermal absorption](#) (EFSA, 2017).

Discussion

Proposed solutions	Proposed follow-up actions
<p>Bridging PPP</p> <p>✓ One MS is working on an internal guidance to better defined criteria (e.g., structure, type of changes, CLP/CLH data, stepwise approach).</p> <p><u>Current approach:</u></p> <ul style="list-style-type: none">• Comparison of toxicity data of PPPs and the formulation type• If there is no toxicity data, comparison of the composition and physical chemical properties, dermal absorption values of PPPs• In ecotox, some bridging principles are followed but no harmonized criteria are available. <p>Bridging co-formulants</p> <p>✓ In theory, for co-formulants the CLP approach could be used by applying the read across approach.</p> <p>✓ In the ecotoxicity section, bridging of co-formulant data may be needed in the case there is no direct exposure to the PPP.</p>	<p>Bridging PPP (ecotoxicity):</p> <p>✓ Drafting a guidance document</p> <p>Bridging co-formulants (ecotoxicity)</p> <p>✓ Aquatic organism: the CLP approach.</p> <p>✓ Birds and mammals: to be aligned to toxicology approach</p> <p>Bridging co-formulants (mammalian toxicity)</p> <p>✓ Drafting a guidance document, including use of CLP and REACH requirement (read across, grouping)</p>



ITEM 3: STRATEGY TO IDENTIFY COMBINED EFFECTS AND LEVEL OF DATA

3.1. How to identify potentially combined effects (e.g., additive, or synergistic effects)

Background

Regulation (EC) No 1107/2009 and Regulation (EU) No 284/2013: 'no immediate or delayed harmful effect through other indirect effects taking into account known cumulative and synergistic effects'

Non exhaustive list of existing predictive tools that take into account potential interactions between substances:

- TEST (Toxicity Estimation Software Tool) by US EPA: to estimate the mixtures toxicity of components.
- QSAR Toolbox: by ECHA: to predict the toxicity of chemicals and mixtures.
- BPR documents - substances of concern

Discussion

Proposed solutions	Proposed follow-up actions
<p>✓ <u>Ecotoxicology</u>: The available guidance documents already provide recommendations on how to determine synergism when data are available for the mixture/PPP. MS already assess combined exposure to several active substances in the case they are included in a single PPP. The methodology can be applied also to co-formulants if toxicity data are available.</p> <p>✓ <u>Toxicology</u>: In case of several active substances or presence of safeners in the PPP: a methodology for combined assessment is currently used by some MSs to compare the metabolic pathway and toxicity, but also target organs.</p> <p>✓ <u>Toxicology, proposed approach</u>: to use the CLP calculation to conduct additive assessment. To use data from the literature search to check whether there are indications on synergistic effects.</p>	<p>✓ Data collection on synergistic effects by conducting a systematic literature search.</p>



ITEM 4: SPECIFIC CO-FORMULANTS

4.1. Co-formulants that are approved/no more approved/not approved as pesticide a.s.

Background

As defined in the Regulation (EC) 1107/2009: 'co-formulants are substances or preparations which are used or intended to be used in a PPP or adjuvant but are neither active substances nor safeners or synergists.'

Which approach to apply when a co-formulant is also approved as a pesticide active substance?

In particular, when the content on co-formulant is above the content on the active substance in the formulation?

Discussion

Proposed solutions	Proposed follow-up actions
<p><u>Proposed approach:</u></p> <ul style="list-style-type: none">✓ Physical chemical experts to communicate to the efficacy experts the need to check if a co-formulant functions as a pesticidal active substance.✓ If a co-formulant has a proven pesticidal activity in the PPP, it should be declared as a second active substance.✓ The PPP composition to be reviewed accordingly by the physical chemical experts.	<ul style="list-style-type: none">✓ To be discussed at the the Post Approval Issue Working Group (PAI) of the Section Phytopharmaceuticals meeting in September



ITEM 4: SPECIFIC CO-FORMULANTS

4.2. Co-formulants that are polymers in PPPs

Background

- Concerns to human health: no toxicity data on co-formulants that are polymers (as currently exempt from REACH registration). Usually, the monomers of the polymers are toxicologically relevant.
- Concerns to environment: the issue of polymers used as microcapsule technology in PPPs and the possibility of accumulation of (micro) plastics in nature.

DEPA approach (1/2)

- Complex:
 - Identity – often composed of molecules of various lengths
 - REACH exemption – limited data on identity, phys/chem and tox
 - ECHA guidance on polymers and monomers
 - Current work under REACH – polymers of low concern and polymers requiring registration
- DEPA focus for the past 3 years
 - Requested guidance for applicants and MS – document shared at PAFF meeting May 2021 and updated in July 2022 – EU phys-chem WS September 2022 (BE), written replies from some MS



ITEM 4: SPECIFIC CO-FORMULANTS

4.2. Co-formulants that are polymers in PPPs

DEPA approach (2/2)

Initial concerns: stability; toxicologically relevant residual monomers; lack of data on toxicity

Current concerns: information on identity; assessment of alternatives; lack of data on toxicity

Discussion

Proposed solutions	Proposed follow-up actions
<p>Proposed approach:</p> <ul style="list-style-type: none">✓ Use of the ECHA definition of polymer (ECHA, 2017)✓ Acceptable PPP storage stability data to indicate the stability of polymer co-formulants.✓ Specifications of the co-formulant should be requested to demonstrate the concentration and identity of unreacted monomers present in the polymer co-formulant.✓ In the draft guidance, the section on polymers should include a summary table of type of studies to be requested depending on the nature of the polymer and its function.	<ul style="list-style-type: none">✓ Specific data on polymers to add in the checklist of data to fully identify co-formulants (see point 1.1). This checklist may be inserted in the Guidance document on significant and non-significant changes to co-formulants (under revision). If this is not possible, a guidance document could be drafted specifically for the chemistry aspects of the PPP and co-formulants.



ITEM 4: SPECIFIC CO-FORMULANTS

4.3. Co-formulants that are UVCBs (substances of Unknown or Variable composition, Complex reaction products, and Biological materials)

Background

- UVCBs: complex mixtures, some of which may be hazardous to human health or the environment.
- Exact composition and toxicity profile often unknown / difficult to determine potential risks associated with UVCBs.
- Difficulties to generalize their risk profiles or establish standard test protocols for their evaluation.
- Often used in large quantities with a wide range of uses

DEPA approach

- Commonly used in PPPs – petroleum distillates, polymers (e.g., alcohol ethoxylates or ethoxylated fatty acids), some of them are already identified in Annex III to Regulation (EC) No 1107/2009
- How to best identify? – Specification, Performance specification?
- Assessment of alternatives

Discussion

Proposed solutions	Proposed follow-up actions
<p><u>Proposed approach:</u></p> <ul style="list-style-type: none">✓ Physical chemical colleagues should use the ECHA definition on UVCB✓ Performance specification and composition specification to be requested.	<ul style="list-style-type: none">✓ Specific data on UVCBs to add in the checklist of data to fully identify co-formulants (see point 1.1). This checklist may be inserted in the Guidance document on significant and non-significant changes to co-formulants (under revision). If this is not possible, a guidance document could be drafted specifically for the chemistry aspects of the PPP and co-formulants.



ITEM 4: SPECIFIC CO-FORMULANTS

4.4. Co-formulants that are PFAS

Background

PFAS restriction proposals – [on the ECHA website](#): proposed restriction of around 10 000 per- and polyfluoroalkyl substances (PFASs) prepared by authorities in Denmark, Germany, the Netherlands, Norway and Sweden.

A list of PFAS also identified as active substances is annexed.

DEPA approach

- Preservatives, function to release formaldehyde
- Discussion: ES presentation WS1, issue discussed at EU and NZ level
- For the Annex III process for the products authorised in DK, authorisation holders informed – reference to the ECHA investigation report ‘formaldehyde and formaldehyde releasers’- 15 March 2017
- Focus on preservatives in PPP and co-formulants
- Identified a number of products with formaldehyde releasers
- Option to request formulation change due to formaldehyde releasers

Discussion

Proposed solutions	Proposed follow-up actions
<p><u>Proposed approach</u>:</p> <ul style="list-style-type: none">✓ Physical chemical colleagues should use both the OECD definition of PFAS and ECHA definition.✓ If there is a co-formulant meeting the PFAS definition, this information may need to be notified to colleagues in mammalian toxicity and ecotoxicity sections and to communicate it to risk managers	<ul style="list-style-type: none">✓ Ongoing discussion at European Commission and ECHA level, pending the public consultation on REACH restrictions at ECHA level.



ITEM 4: SPECIFIC CO-FORMULANTS

4.5. Co-formulants that are formaldehyde releasers

Background

Formaldehyde is listed in Annex III and thus cannot be used as a co-formulant with exceedance of 0.1% as an impurity in a PPP. However, there are intentional and unintentional release of formaldehyde as impurities from co-formulants used in PPP.

Several discussions on going at PAFF level also raised by stakeholders, different positions from MSs: analytical proof needed, intentional and unintentional release, concentration level (0.1 %).

Discussion

Proposed solutions	Proposed follow-up actions
<p><u>Proposed approach:</u></p> <ul style="list-style-type: none">✓ Physical chemical colleagues to check if formaldehyde release co-formulants are present in the PPP based on the ECHA investigation report 2017: list of formaldehyde releasers.✓ Physical chemical colleagues to notify this information to colleagues in mammalian toxicity and ecotoxicity sections and to communicate it to risk managers	<ul style="list-style-type: none">✓ Ongoing discussion at European Commission level





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