7. Assessment of co-formulants: Data collection on co-formulants used in formulations for representative uses in the context of the EFSA peer review process

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PREV unit

Trusted science for safe food

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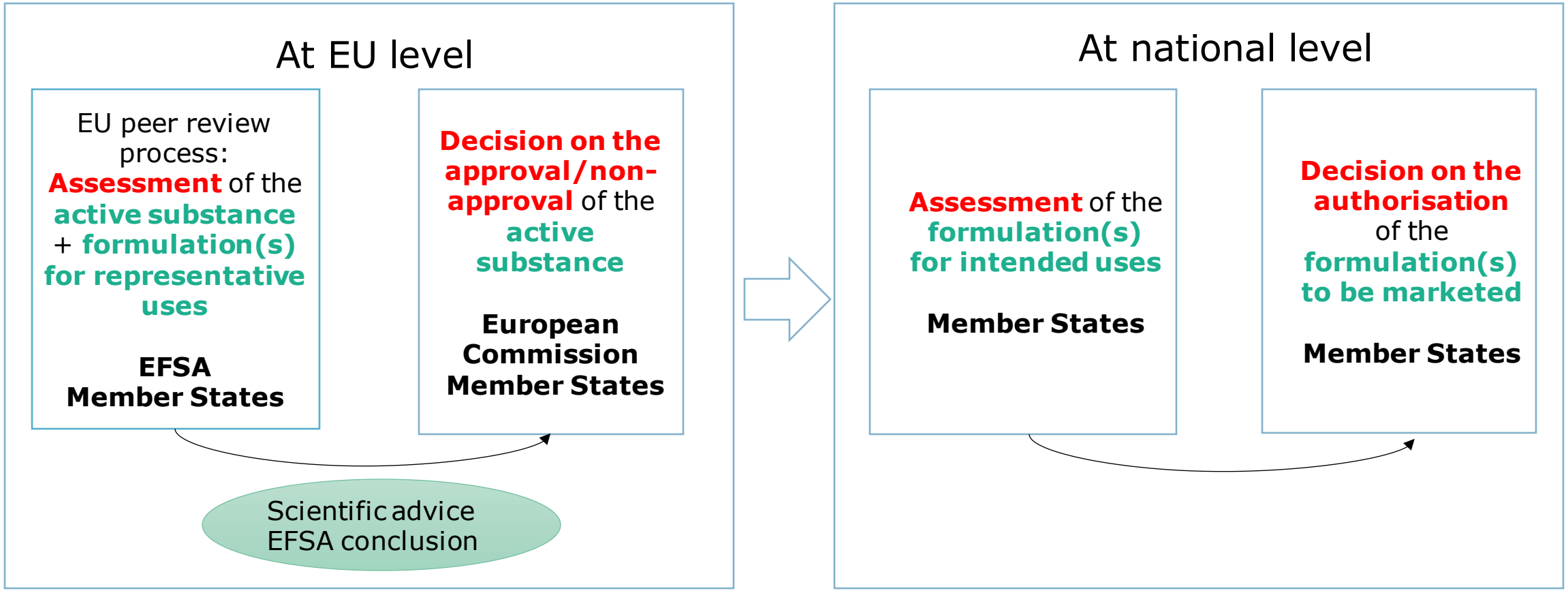
Overview of the regulation of PPPs in the EU

Two-step system:

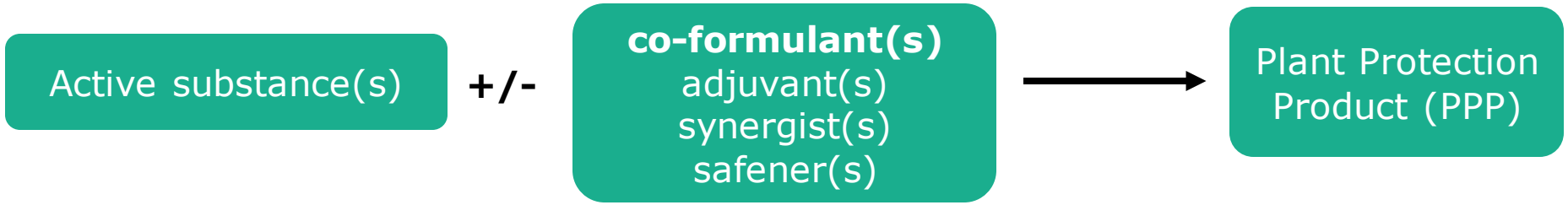


Composition of a PPP may change over time (Article 45 of Regulation (EC) No 1107/2009)

INTRODUCTION

Definition from Article 2(3)c of Regulation (EC) 1107/2009

Co-formulants: 'substances or preparations which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists.'



In the EU peer review framework

- Submission of data on declared co-formulants **by the applicant(s)**
- Assessments of co-formulants **by the RMS**
- Peer review of the RMS assessment of co-formulants **by Member States/EFSA/applicant(s)**

Data requirements from Regulation (EU) No 284/2013

Section 1 Identity of the PPP: contents, chemical names, CAS/EC numbers, functions, etc. **Section 5 Analytical methods:** methods for the determination of relevant co-formulants. **Section 7 Toxicological studies:** references to REACH registration dossiers, SDS.
Point 1.11 (introduction): possibility for MSs to require **further information** on co-formulants as required for the active substance in Reg. (EU) No 283/2013.

DATA COLLECTION ON CO-FORMULANTS

Context

- Increased interest in pesticide formulations and co-formulants in recent years
- March 2021: Regulation (EU) 2021/383[1] – list of unacceptable co-formulants

Terms of Reference

Overview of the data and considerations for the assessment on co-formulants:

- identification of the co-formulants declared in the PPP for representative uses
- collection of the main comments/aspects examined during the EFSA peer review process
- EU regulatory frameworks other than pesticides applicable to co-formulants

Data collection on co-formulants contained in all PPP for representative use(s)
Dossiers for which an EFSA output was finalised **between January 2019 and March 2022**

Methodology

- Collection of information from Volume 4 of the DAR/RAR and SDS
- Relevant data sources from other EU legal frameworks for the assessment of co-formulants

[1] Commission Regulation (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009

DATA COLLECTION ON CO-FORMULANTS
Results: overview of the data submitted

Key figures:

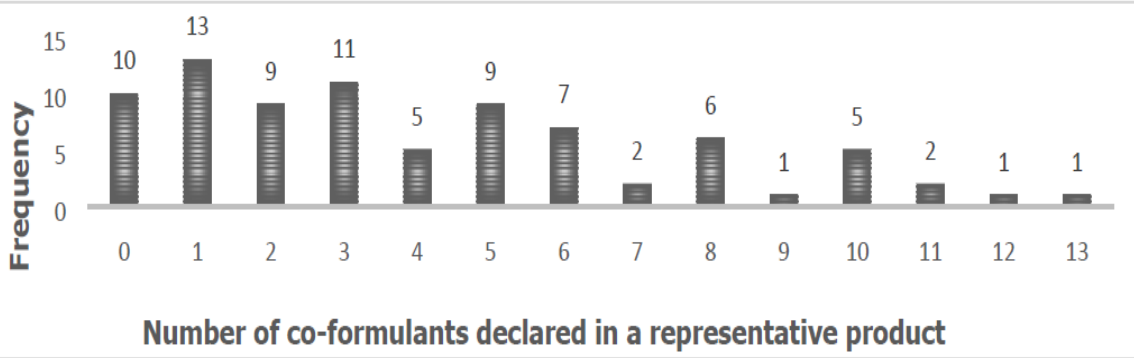
- 58 active substances
- 82 formulations for representative uses
- 182 co-formulants declared

Extract of the list of 182 co-formulants by frequency of indication as co-formulant:

Chemical name [a]	CAS number	EC number	Frequency of indication as a co-formulant
Aromatic hydrocarbon (solvent naphtha (petroleum), heavy aromatic)	64742-94-5	265-198-5	11
1,2-benzisothiazol-3(2H)-one	2634-33-5	220-120-9	10
1,2-propanediol (Propane-1,2-diol)	57-55-6	200-338-0	10
Xanthan gum	11138-66-2	234-394-2	9
Silicon dioxide	7631-86-9	231-545-4	8
Lignosulfonic acid, sodium salt	8061-51-6	617-124-1	7
Sodium hydroxide (sodium salt)	1310-73-2	215-185-5	7
Silicon dioxide	112926-00-8	601-214-2	7
Lignosulfonic acid, calcium salt	8061-52-7	617-125-7	6
Hydrated aluminium silicate: Kaolin clay	1332-58-7	310-194-1	6
Sorbitan monooleate	1338-43-8	215-665-4	5
2-ethylhexan-1-ol	104-76-7	203-234-3	5

[a] As distinct chemical names, CAS numbers and EC numbers can be linked to different substances, co-formulants were identified by the unique combination of CAS and EC numbers for accurate substance identification (SID). Finally, the most common chemical names have been reported.

Distribution of co-formulants per plant protection product:



5 most declared functions:

- Wetting agent
- Emulsifier
- Dispersing agent
- Solvent
- Preservative
- Carrier

Results: overview of the data submitted, and main comments/aspects raised during the PR process

Type of data reported in the pesticide assessment reports

- **Data on substance identity**
- **Physico-chemical data**
- **SDS data**, reference to **REACH registration dossier**
- **CLH** for the (eco)toxicological properties of the co-formulants
- Reference to **other EU regulatory status**
- No specific data on co-formulants generated for purposes of the PPP regulation

Main aspects raised by MSs/EFSA/Applicant(s) during the peer review process

- **Substance identification (SID)**: request for additional information
- **CLH:** if a co-formulant has a harmonised classification and its content triggers the classification of the PPP, the labelling requirement to be extended to the PPP.
- **Hazard assessment** (in some cases, exposure/risk assessment)

Results: Relevant data sources from other EU legal framework for the assessment of co-formulants

REACH Regulation

- **96 out of 182 co-formulants (circa 53 %)** have been registered under REACH

REACH registration dossiers	Number of co-formulants having a REACH registration dossier (/182)	% of the sub-set of co-formulants registered under REACH
Registration for 1000 tonnes or more a year	77	80.2
Registration for 100 to 1000 tonnes a year	10	10.4
Registration for 10-100 tonnes a year	5	5.2
Registration for 1-10 tonnes a year	1	1.0
Registration as cease manufacture	1	1.0
Registration as intermediate use only [a]	2	2.1
Total	96	53

- For **61 out of 96 co-formulants** linked to a REACH registration dossier, at least one compliance check or an examination of testing proposals was performed by ECHA on the REACH registration dossier

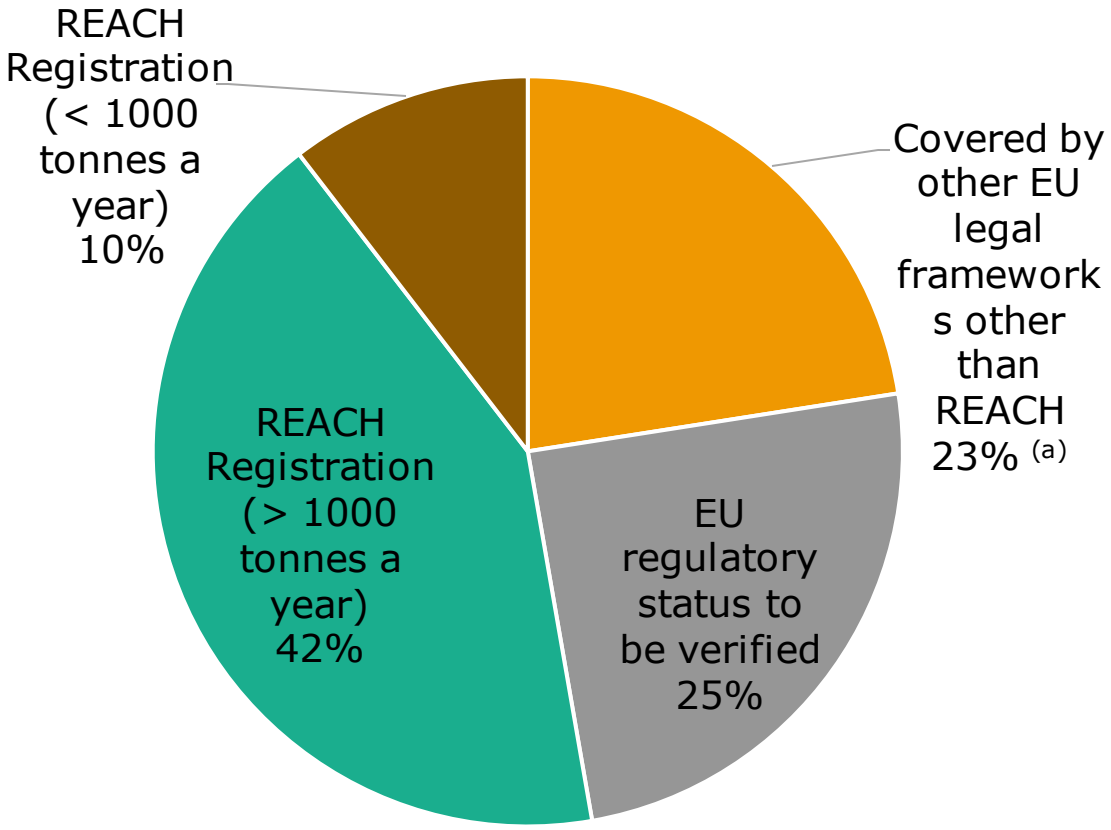
Results: Relevant data sources from other EU legal framework for the assessment of co-formulants

List of co-formulants declared in pesticide formulations for representative uses subject to various EU legal frameworks

N°	Chemical name (a)	CAS number	Approved as biocide	Approved as food additive	Approved as feed additive	Listed as food contact material	Listed as food contact material	Listed as cosmetic	Listed as excipient	Other status
			Regulation (EU) No 528/2012	Regulation (EC) 1333/2008 Regulation (EU) No 231/2012	Regulation (EC) No 1831/2003	Regulation (EU) 2011/10	Directive 2007/42/EC	Regulation (EC) No 1223/2009	Annex to the EC guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'	
1	Yeast	Not allocated			X					- food stuff
2	Dextrose (glucose)	50-99-7				X				- food stuff
3	Carboxymethyl cellulose (CMC) /Cellulose polymer	9004-32-4		X	X					
4	Xanthan gum	11138-66-2		X	X					

DATA COLLECTION ON CO-FORMULANTS
Conclusion

- **Descriptive analysis – state of the art**
- **Overview of co-formulants declared in pesticide formulations for representative uses regulated by EU legal frameworks**



Legal framework	% (/182 co-formulants)	Number of co-formulants
Registration under REACH	52.7	96
Approved as food contact material	30.2	55
Approved as food additive	21.4	39
Approved as feed additive	19.2	35
Listed as cosmetic	12.1	22
Approved as biocide	11.0	20
Listed as excipient with a known action or effect	8.2	15
EU regulatory status to be verified	24.7	45

(a) Regulations concerning biocides, food contact materials, feed additives, food additives, listed as ingredients in cosmetic products and/or listed as excipients with a known action or effect.

Co-formulants declared in pesticide formulations for representative uses – open discussion

From the outlined analysis, considering that:

- Co-formulants are covered by **different EU regulations**
- **Variable level of data**
- Evaluation performed **at EU and national level** (two-steps system)
- The **way of assessing** co-formulants varies between EU agencies and MSs
- Possible **change in composition** from a declared formulation for representative uses initially notified by an industry to the marketed product
- Different **roles and responsibilities** of the actors involved

How to improve and harmonise the assessment of co-formulants in the framework of pesticide Regulation?

Which way to explore?

Co-formulants declared in pesticide formulations for representative uses – open discussion

Potential ways forward:

✓ ~~Discussion at the PSN meeting~~

❑ Specific aspects to be subject to **further analysis** as not fully considered in the technical report :

- the concentration levels of co-formulants in the PPP for representative uses
- the outcome of the compliance check for those registered under REACH
- exemption from registration those not registered under REACH

❑ Improve **data sharing**

- principles of One Substance One Assessment (OSOA)
- existence of any data collection on co-formulants at national level? EU survey?

❑ Better definition of **roles and responsibilities** of each party (next slide)

Co-formulants declared in pesticide formulations for representative uses – open discussion

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❑ Better definition of **roles and responsibilities** of each party at EU level

Applicant(s)

Data submission and preparation of documents H and J of the application dossier

- **Checklist** of information on co-formulants to be submitted and reported in the application dossier?

RMS

Assessment of the data on co-formulants when preparing Volume 4 of the assessment report

All Member States, EFSA and the applicants

Peer review of the RMS assessment of the data on co-formulants

- Any missing information to be requested to the applicant
- RMS assessment and conclusion to be reported separately from the information submitted by the applicant
- Change in the composition of the PPP if a co-formulant is listed in Annex III to Regulation (EC) No 1107/2009
- How to consider a co-formulant that is also an approved pesticide active substance?
  - Justification to demonstrate the lack of pesticidal effect?
  - Change in composition of the formulation?

EFSA

EFSA conclusion and LoEP

- Outcome of the assessment of co-formulants to be reported **in the EFSA conclusion and the LoEP?**
- Lack of data may lead to issue that could not be finalized?

Anything else?

Useful links

EFSA Technical report on co-formulants published on 8 August 2022

Legislation

- **Chemicals** Regulation (EC) No 1907/2006 (REACH Regulation)
- **Biocides** Regulation (EU) No 528/2012 (BPR)
- **Cosmetic ingredients** Regulation (EC) No 1223/2009:
- **Feed additives** Regulation (EC) No 1831/2003
- **Food additives** Regulation (EC) No 1333/2008 (Annex II)
  Regulation (EU) No 231/2012
- **Food contact materials** Directive 2007/42/EC (Annex II)
  Regulation (EU) 2011/10 (Annex I)
- **Excipients with a known action or effect:** Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668)
- Classification under CLP regulation: ECHA website
- List of unacceptable co-formulants: Commission Regulation (EU) 2021/383

Thank you very much for your attention!

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