

## Annex 2 – Background information (non-exhaustive)

[Crop Life Europe](#). E McMillan, C., Bonifay, S., Dobe, C., Fliege, R., Krass, J.D., Terry, A. and Wormuth, M. (2023), Environmental exposure assessment of co-formulants in plant protection products under REACH. Integr Environ Assess Manag. <https://doi.org/10.1002/ieam.4755>

[Crop Life Europe](#): CLE Tools for registrants of chemicals to aid them in the assessment of substances used as co-formulants in plant protection products in the context of REACH.

[ECHA, 2017a](#). Guidance on the Biocidal Products Regulation. Volume III Human Health -Assessment & Evaluation (Parts B+C) Version 4.0 December 2017. Please see Appendix A for guidance on the assessment of substances of concern, including co-formulants, in biocide products.

[ECHA, 2017b](#). Guidance on the Biocidal Products Regulation. Volume IV Environment-Assessment and Evaluation (Parts B + C) Version 2.0 October 2017.

[ECHA, 2017c](#). Guidance for Identification and Naming of Substances under REACH and CLP, rev. 2.1.

[ECHA, 2018](#). Guidance on the Biocidal Products Regulation Volume V, Guidance on applications for technical equivalence Version 2.0 July 2018.

[ECHA, 2020](#). Guidance on the compilation of safety data sheets. Version 4.0 December 2020.

[ECHA, 2021](#). The list of definition of the functions of co-formulants was endorsed by the CG during the CG-45 meeting. 17 February 2021.

[ECHA, 2022a](#). Guidance on the Biocidal Products Regulation. Volume II: Efficacy Part A: Information Requirements Version 2.1, March 2022

[ECHA, 2022b](#). Guidance on the Biocidal Products Regulation. Volume II: Efficacy Parts B+C: Assessment and Evaluation Version 5.0, November 2022.

[ECHA, 2023](#). Guidance for monomers and polymers. February 2023 Version 3.0 Guidance for the implementation of REACH.

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[EFSA Scientific Committee, 2021](#). Guidance Document on Scientific criteria for grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals. EFSA Journal 2021;19(12):7033, 37 pp. <https://doi.org/10.2903/j.efsa.2021.7033>

[EFSA, 2011](#). Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. OJ L 309, 24.11.2009, p. 1-50. EFSA Journal 2011;9(2):2092. [49 pp.]. [doi:10.2903/j.efsa.2011.2092](https://doi.org/10.2903/j.efsa.2011.2092).

[EFSA, 2013a](#). International Framework Dealing with Human Risk Assessment of Combined Exposure to Multiple Chemicals. EFSA Journal 2013;11(7):3313, 69 pp. [doi:10.2903/j.efsa.2013.3313](https://doi.org/10.2903/j.efsa.2013.3313).

[EFSA, 2013b](#). Aquatic Mixture Toxicity Tool and additional Information. This "AGD\_AquaMix\_v1.22" is a tool is for the calculation of Mixture Toxicity for the aquatic risk assessment of plant protection products containing a combination of active substances, as addressed in section 10.3 of the Guidance on tiered risk assessment for edge-of-field surface waters (EFSA Journal 2013;11(7):3290).

[EFSA, 2022](#). Chapter 12 of the updated EFSA bird and mammal guidance document provides a stepwise approach for assessment of the PPP. Section 12.2 describes the combi-TER approach mentioned in the bullet point above

[EFSA, 2023](#). EFSA calculator tool for birds and mammals is able to perform an additive risk assessment with a TER combi approach. It was developed for performing an assessment when there are multiple active substances in a formulation but, in principle, the approach could be used for any co-formulant if data are available to calculate a TER for the individual components (assuming that the default parameters developed for active substances are also applicable for the co-formulant). The TER combi is an approach to combine the level of risk rather than calculating an additive toxicity value and an additive exposure value.

[European Commission, 2008](#). Common guidelines for the sharing of scientific data between EU agencies and COM.

[European Commission, 2012](#). Guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 of the EU Parliament and Council on placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. SANCO/12638/2011. 20 November 2012 rev. 2.

[European Commission, 2019](#). Combined Template to be used for Assessment Reports according to Regulation (EC) No 1107/2009 and Proposals for Harmonised Classification and Labelling according to Regulation (EC) No 1272/2008 Agreed by Member States' Competent Authorities in the SCoPAFF: Phytopharmaceutical legislation section. SANCO/12592/2012 rev. 2, 22 March 2019

[Judgment of the Court \(Grand Chamber\) of 1 October 2019](#). Criminal proceedings against Mathieu Blaise and Others. Request for a preliminary ruling from the Tribunal correctionnel de Foix. Case C-616/17.

[US EPA, Inert Ingredients Overview and Guidance](#).