Position Paper

Position Paper on the Implementing Regulation on the Identification of Unacceptable Co-formulants of pesticides

PAN Europe considers that the Commission's proposal for a new implementing regulation on co-formulants used in pesticides[1] fails to ensure compliance with Reg. (EU) 1107/2009, i.e that co-formulants used in pesticide products cause no harm to human health or have no unacceptable effect on the environment. Instead of implementing a harmonised approach through an EU-centralised assessment based on mandatory data requirements like for pesticide active substances, the European Commission asks the 27 Member States to carry out the work themselves, without providing them with the needed data.

After years of delays, the European Commission published a proposal for an implementing regulation concerning pesticide co-formulants, supplementing Regulation(EU)1107/2009 (hereafter "the pesticide regulation"), with regards to "unacceptable co-formulants", as prescribed in article 27. The pesticide regulation suggests that article 27 should have been already implemented by 14 June 2016 (article 81). Yet, only in 2021 a first ad-hoc implementing act listing "unacceptable co-formulants" was adopted. The new implementing regulation proposal sets out "detailed rules for the identification of unacceptable co-formulants" on a continuous basis.

Background: Co-formulants

"Co-formulants" are part of the mixtures contained in pesticide products, serving to enhance product efficiency and usability. These are for instance surfactants, anti-foaming agents, solvents or wetting agents. The regulatory framework considers co-formulants as "biologically inactive" components of pesticide products against the targeted 'harmful' organisms, in contrast to the declared "active ingredients" i.e., the component that is declared as acting against the targeted 'harmful' organism. For instance, glyphosate kills weeds while imidacloprid kills insects but in order to be effective, they need co-formulants to be added to the product. Added co-formulants can make up to more than 50% of a product formulation.

A large number of co-formulants used in pesticide products were confirmed as being harmful to health and the environment, by public authorities and researchers. In 2021, a first list of "unacceptable co-formulants" was adopted by the EU Commission, containing 144 substances to be banned due to their inherent hazardous properties[2].

[1] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13416-Plant-protection-products-pesticides-identification-of-unacceptable-co-formulants_en

[2] Regulation (EC) 2021/383 amending Annex III to Regulation (EC) No 1107/2009

For instance, while they were considered "safe" for decades, POE-tallowamines were banned as co-formulants, now confirmed as highly toxic and having powerful effects against plants[3], just like an active substance[4]. According to the pesticide regulation, it is up to the pesticide producers to disclose if a component of a pesticide is an active substance or a co-formulant. The misclassification of POE-tallowamines by the pesticide industry did not lead to any kind of legal redress on behalf of Member States or the European Commission. This example highlights the necessity to assess in a stricter way the environmental and health risks posed by these substances the moment they are sprayed into our environment.

Still, which co-formulants are used in pesticides and the composition of the products are not publicly available. Furthermore, and contrary to claims by the Directorate General for Health from the European Commission (DG Sante), a significant proportion of the co-formulants are currently not assessed under REACH. For those that are assessed, the risk assessment is highly superficial, especially with regards to environmental toxicity. Many independent studies found clear evidence where co-formulants pose grave risks to human health, the environment and/or non-target organisms[5].

Regulatory state of play: Context of the implementing regulation

Regulation (EU) 1107/2009 sets out the underlying approval criteria for pesticides: they cannot have a harmful effect on human or animal health or an unacceptable effect on the environment. This wording is the same for all components of pesticide products: active substances (Art. 4), co-formulants (Art. 27), safeners and synergists (Art. 25 & 26), as well as full pesticide products (Art. 29(1)(e)).

Art. 27 requires the establishment of a negative list of “unacceptable co-formulants” to be banned from use in pesticide products at EU level. A first list was adopted by the Commission in an non-transparent ad-hoc process based on proposals from the Member States, as co-formulants are currently only ‘authorised’ as part of the product authorisation at Member State levels.

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[3] Defarge, N., Spiroux de Vendômois, J., & Séralini, G. E. (2018). Toxicity of formulants and heavy metals in glyphosate-based herbicides and other pesticides. Toxicology Reports, 5, 156–163. https://doi.org/10.1016/j.toxrep.2017.12.025

[4] Mesnage, R., Benbrook, C., & Antoniou, M. N. (2019). Insight into the confusion over surfactant co-formulants in glyphosate-based herbicides. Food and Chemical Toxicology, 128, 137–145. https://doi.org/10.1016/j.fct.2019.03.053

[5] Mesnage, R., & Antoniou, M. N. (2018). Ignoring Adjuvant Toxicity Falsifies the Safety Profile of Commercial Pesticides. Frontiers in Public Health, 5. https://www.frontiersin.org/article/10.3389/fpubh.2017.00361; A., & Brown, M. J. F. (2021). Co-formulant in a commercial fungicide product causes lethal and sub-lethal effects in bumble bees. Scientific Reports, 11(1), 21653. https://doi.org/10.1038/s41598-021-00919-x; Mullin, C. A. (2015). Effects of ‘inactive’ ingredients on bees. Current Opinion in Insect Science, 10, 194–200. https://doi.org/10.1016/j.cois.2015.05.006; Mesnage, R., Bernay, B., & Séralini, G.-E. (2013). Ethoxylated adjuvants of glyphosate-based herbicides are active principles of human cell toxicity. Toxicology, 313(2), 122–128. https://doi.org/10.1016/j.tox.2012.09.006; Straw, E. A., & Brown, M. J. F. (2021). Co-formulant in a commercial fungicide product causes lethal and sub-lethal effects in bumble bees. Scientific Reports, 11(1), 21653. https://doi.org/10.1038/s41598-021-00919-x; Straw, E. A., Thompson, L. J., Leadbeater, E., & Brown, M. J. F. (2022). ‘Inert’ ingredients are understudied, potentially dangerous to bees and deserve more research attention. Proceedings of the Royal Society B: Biological Sciences, 289(1970), 20212353. https://doi.org/10.1098/rspb.2021.2353

The now proposed implementing act spells out the procedures for the ongoing identification of unacceptable co-formulants. The implementing act foresees that it will be the task of the Member States to identify potential unacceptable co-formulants “on the basis of the information submitted in an application dossier” and to submit these 'candidates' to the Commission. Contrary to active substances, Member States will not automatically receive detailed and harmonised information on the toxicity of co-formulants, as the Commission is not proposing to implement mandatory data requirements other than their name and function in the application dossier. In some cases, when co-formulants are registered under REACH, the Member States will receive some information on their toxicity, but it will not ensure the high level of protection as foreseen in the pesticide legislation. A Member State shall notify the Commission and the other Member States if it considers a co-formulant non-compliant with regards to the exclusion criteria listed in the Annex. Depending on which criterion is concerned, the Member State must then first notify their concerns as foreseen under the REACH regulatory framework, e.g. submit reports to propose a new hazard classification. The Commission then awaits a respective decision by ECHA or EFSA to subsequently propose to the SCOPAFF Committee to list a substance as unacceptable.

PAN Europe’s Position on the proposed Implementing Regulation

PAN Europe considers that the proposed implementing act is not in line with the pesticide regulation as it fails to ensure that all co-formulants used in pesticide products do not cause a harmful effect on human or animal health, as well as an unacceptable effect on the environment. As co-formulants are equally sprayed onto our food and in the environment, we demand the same standard of risk assessment and the same safety criteria as for active substances in pesticide products. Crucially, four problematic core necessities lacking in the implementing regulation have been identified:

1. **Insufficient toxicity endpoints addressed**

As mentioned previously, the pesticide regulation requires the same level of protection of human health and the environment for co-formulants as for active substances. Weirdly enough, even though this implementing regulation proposal derives from the pesticide regulation, the Commission proposal refers in priority to other pieces of legislation (for instance REACH or the CLP regulation). Only at the very last stage does it refes to annex II from the pesticide regulation, but as a secondary resort.

For active substances, a series of more detailed and specific toxicity endpoints have been developed in Regulation(EU)283/2013 on data requirements for active substances. These endpoints are meant to enable a risk assessment for human health as well as the environment, that enables to ensure the absence of harm to human health and the absence of unacceptable harm to the environment, in compliance with the prescriptions of the pesticide regulation.

In order to comply with these prescriptions and align the level of safety of used co-formulants with that from active substances, the Commission proposal should also refer to the toxicity endpoints established in regulation 283/2013/EC.

2. No harmonised approach to assess the risk posed by co-formulants and no standardised data requirements to assess co-formulants

It establishes procedural rules and some unacceptable toxicity criteria but it fails to provide regulators with the needed data to assess the toxicity of co-formulants. The proposed regulation foresees that Member States will receive, 'where appropriate, the information submitted in accordance with Title II of Regulation No 1907/2006'. This corresponds to the information available under REACH for the chemicals that reach a certain sales tonnage in the EU. For many co-formulants, there is no REACH dossier, meaning no data. Furthermore, REACH data are limited regarding human toxicity and extremely limited regarding environmental toxicity. The proposed process thus remains fundamentally flawed as there are no underlying detailed EU-harmonised data requirements defined that will allow a proper risk assessment. Member States are thus required to carry out a risk assessment without the needed data.

Furthermore, the pesticide regulation obliges the Commission to establish data requirements for active substances, safeners, synergists and adjuvants. There is no reason to treat co-formulants in a different way. Weirdly enough, according to the pesticide regulation, for adjuvants, which are co-formulants, the Commission needs to establish data requirements as well[6]. There is no scientific or legal reason to treat 'non-adjuvant co-formulants' in a different way. The Commission should thus add to this implementing act proposal the establishment of data requirements applicable to co-formulants. Only such an approach consequently follows the rationale of the pesticide regulation, which demands that the EU Commission also adopts data requirements for all other parts of pesticide products: active substances, safeners and synergists, and adjuvants (which are co-formulants).

A second incoherence from the proposal lies in the fact that the European Commission proposes to leave it up to the 27 Member States to carry out 27 different risk assessments for the same co-formulants. Article 27, defining the regulation of co-formulants is part of Chapter II of the pesticide regulation 1107/2009/EC, dealing with active substances, safeners, synergists and co-formulants. On the other hand, pesticide formulations are dealt with by another chapter, Chapter III (Plant Protection Products). Article 27(3) claims that 'The Commission may review co-formulants at any time. It may take into account relevant information provided by Member States.' It thus seems that the Commission is responsible for the classification of co-formulants in the unacceptable list, while Member States should play a secondary role. Nowhere is it written that it is the responsibility of Member States to assess the risk posed by co-formulants and that they should be the trigger of the setting of co-formulants in the negative list. Furthermore, it does not make sense to have 27 different risk

[6] "Adjuvants" are defined as "consisting of [...] one or more co-formulants" but are separately marketed products to be mixed with pesticide products by the end-user. Art. 58, Reg. 1107/2009, requires the Commission to adopt detailed rules for the authorisation of adjuvants at Member State level, including data requirements.

assessments for identical substances. Apart from the waste of public money, this situation will lead to diverging conclusions in the Member States, inducing regulatory uncertainty and chaotic situations.

These 2 major incoherences will lead to regulatory uncertainty for Member States and EU citizens and the environment will not be protected in the same way across the EU. PAN Europe considers that co-formulants should be assessed based on the same data requirements as those from Regulation(EU)283/2013, and that the risk assessment should be carried out by EFSA in a transparent way, for all co-formulants used in the EU.

3. No concern for the mixing of dangerous substances

The current proposal maintains that co-formulants can be used in pesticide products when they are classified as confirmed likely carcinogens, toxic to reproduction or mutagens (C2, R2, or M2 classification). These substances can then be mixed with active substances or other co-formulants equally classified as C2, R2 or M2. The impact of such mixtures is unknown. We request that rules must be established to prohibit the mixing of various of these dangerous substances. This is even more indispensable as there is currently no long-term toxicity studies on formulations carried out in the frame of the national pesticide approvals. Otherwise, the risks to bystanders, the presence of residues in food and the risks of additive or synergistic effects would potentially significantly increase.

On top of that, there is currently no risk assessment on the cumulative or synergistic effect of co-formulants. The EU Chemical Strategy for Sustainability foresees that such potential effect is assessed. In order to do this, it is thus more than time that data on their toxicity is collected.

4. Non-respect of EU case law

In the Blaise ruling (case C616-17), the General Court of the EU ruled very clearly that it is the obligation of Member States to carry out long-term toxicity assessment of the formulations[7]. At present, to our knowledge, no long-term toxicity study is carried out on pesticide formulations. Member States thus still do not comply with the ruling of the Court. Member States do not have knowledge on the long-term toxicity of an important proportion of the used co-formulants. Member States thus do not comply with the obligation to make sure they have sufficient material "to exclude, in the light of current scientific and technical knowledge, the risk that that product exhibits such carcinogenicity or toxicity".
Therefore, the least that must be done to respect the ruling on a short-term basis, is to apply the ruling to pesticide's co-formulants, safeners and synergists.

[7] §116: It is therefore the task of the competent authorities, when examining an application for the authorisation of a plant protection product, to verify that the material submitted by the applicant, and primarily the tests, analyses and studies of the product, is sufficient to exclude, in the light of current scientific and technical knowledge, the risk that that product exhibits such carcinogenicity or toxicity. In that context, the 'cursory tests' mentioned by the referring court would not suffice to perform that verification properly.

Not doing so would expose Member States to legal procedures. As an example, last year, a French appeal court confirmed a ban from a French administrative tribunal on a herbicide (Roundup 360), among others for non-respect of article 29(6) which states that "interaction between the active substance, safeners, synergists and co-formulants shall be taken into account in the evaluation of plant protection products." The tribunal confirmed that risk assessors and risk managers (French ANSES in this case) must take into account the toxicity of co-formulants, and make sure they have sufficient information.

Conclusion: PAN Europe's demands

Co-formulants are sprayed onto our food and in the environment in the same way as active substances, safeners and synergists. The pesticide regulation explicitly states that the same basic principle applies: no harm to human health, no unacceptable harm to the environment. Independent research has repeatedly shown that these substances are not harmless 'inert' additives, but they can also have biological activity and pose grave dangers - in the same way as active substances. There is thus no reason that the European Commission proposes less strict rules on these chemicals. To ensure compliance, the Commission implementing regulation proposal needs to:

1. **Set the same safety criteria and toxicity endpoints as for active substances;**
2. **Adopt similar data requirements as for active substances - assess the data the same way as active substances;**
3. **Prohibit the mixing of substances of concern (C2, M2, R2, aquatic toxicity category 2) in the same product.**
4. **Carry out an EU risk assessment by the EFSA, rather than national risk assessments**

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