

Pesticide Co-formulants: Hidden Toxins Remain Under the Radar

What are Co-formulants, Synergists and Safeners in Pesticides?

Pesticide products usually contain one or more so-called “active substances” i.e., the component that is declared as acting against the targeted 'harmful' organism. For instance, glyphosate is an active substance that kills weeds while imidacloprid kills insects. Additionally, various substances are added to enhance the pesticides' toxicity and/or efficiency towards their target. Depending on their role, these substances are called, according to the Regulation (EC) 1107/2009, synergists (enhancing the toxicity of the declared active ingredient), safeners (increasing crop tolerance to the declared active substance), co-formulants (any other added substance, e.g., anti-foaming agents, solvents, surfactants), or adjuvants (separate products made up of co-formulants, that are mixed with a pesticide formulation just before use, to enhance its effectiveness or other pesticidal properties).¹

Depending on the added substances in each formulation, the pesticide products' toxicity and effects differ significantly.² Besides enhancing the effectiveness and toxicity of the active ingredient, the added substances are not “inert”, they can increase the product's toxicity and can also have their own intrinsic toxic properties³. In fact, some active substances are firmly reliant on added co-formulants to exercise their toxic action, e.g., surfactants are often a necessary ingredient of pesticide formulations. However, only the active substance goes through a harmonised risk assessment and approval procedure at EU level. **The risks and dangers of the additional substances are gravely overlooked.**⁴ If added co-formulants can increase the toxicity of a chemical on living organisms, it begs the question: what potential harm could they cause to humans and the environment?"?

A Danger for Human Health and the Environment

The dangers that added substances in pesticide products pose to human health and the environment have been downplayed by the EU Commission for years. Comprehensive information and risk assessments on co-formulants, safeners and synergists are blatantly lacking - while numerous **examples highlight the potential risks and dangers** that these substances pose to human health and the environment:

Surfactants in glyphosate-based herbicides: Adding to the risks of glyphosate

The declared active substance *glyphosate*, alone, is unable to break through the targeted plants' protective outer layer. Thus, glyphosate-based herbicides typically contain surfactant co-formulants,

¹ As defined in EU regulation 1107/2009 (Art. 2)

² Cox, C., & Sorgan, M. (2006). Unidentified Inert Ingredients in Pesticides: Implications for Human and Environmental Health. *Environmental Health Perspectives*, 114(12), 1803–1806. <https://doi.org/10.1289/ehp.9374>

³ 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>

⁴ 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>

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which are added to, enable the pesticide to penetrate through the plant's membrane and effectively exert its toxicity. These surfactants have been shown to facilitate faster absorption rates and increase exposure levels. This poses an increased risk of toxicity not only for the intended target organisms but also for non-targeted species that are exposed to the pesticide, including humans, amphibians, insects, etc.⁵ Moreover, various surfactants raise strong concerns for their intrinsically high toxicity.⁶

Example: Surfactant POE-tallowamine

Glyphosate-based herbicides in the EU frequently contained the co-formulant polyethoxylated (POE) tallowamine until it was banned for use in these products in 2018 due to its high toxicity. The European Food Safety Authority (EFSA) reported that the surfactant exhibits strong intrinsic toxicity, suggesting that the substance significantly increased the carcinogenicity of glyphosate-based herbicides.⁷ After decades of downplaying any risks associated with POE-tallowamine, the EU Commission finally decided to ban this substance, due to concerns for the environment, aquatic toxicity, and for human cell toxicity.⁸ Globally, this highly toxic substance, and variations of it, remain still commonly in use. Although POE-tallowamine has been replaced by other chemical surfactants in the EU, the 'efficacy' of glyphosate-based products has generally remained at the same level. Contrary to POE-tallowamine, the toxicity data for these new co-formulants are limited. This leaves us to wonder: What are the new substances being used, and why should we assume they are any less toxic?

Synergists and Safeners - NOT a priority to the EU Commission despite potential risks

The Commission repeatedly stated that the establishment of EU-level risk assessments for safeners and synergists is not a priority. In 2019, the Commission assessed that the "21 safeners and 13 synergists known"⁹ to them posed a "perceived low health risk"¹⁰ without providing any supporting evidence for this evaluation. This raises serious concerns, especially with regard to synergists: per definition, they serve to enhance pesticidal toxicity. In a response letter to PAN Europe's inquiry about these substances, the Commission then acknowledged knowing only about 7 safeners and 6 synergists. All questions concerning their risk evaluation were fully ignored.

Example: Synergist Piperonyl Butoxide (PBO)

This synergist is commonly used with insecticides and acts by decreasing insects' detoxification capacities. This endangers non-targeted species, e.g., bees.¹¹ The synergist leaves impacted insects in a hypersensitive state, destroying their ability to fight the insecticide. Research also indicates that PBO does not selectively affect only insects, but can also pose health risks to mammals, including humans.^{12 13}

⁵ 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>

⁶ 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>

⁷ EFSA [factsheet](#) on glyphosate risk assessment (2015)

⁸ Regulation (EC) 2021/383 amending Annex III to Regulation (EC) No 1107/2009

⁹ The Commission's response to text adopted in plenary [SP\(2019\)355](#) (2019)

¹⁰ [EC Working Document](#): Evaluation of Regulation (EC) No 1107/2009 (2020)

¹¹ Alptekin, S., Philippou, D., & Field, L. (2015). Insecticide Synergists: Good or Bad for Honey Bees? *Outlooks on Pest Management*, 26(2), 75–77. https://doi.org/10.1564/v26_apr_07

¹² Rivera-González, K. S., Beames, T. G., & Lipinski, R. J. (2021). Examining the developmental toxicity of piperonyl butoxide as a Sonic hedgehog pathway inhibitor. *Chemosphere*, 264(Pt 1), 128414. <https://doi.org/10.1016/j.chemosphere.2020.128414>

¹³ Murray, M. (2012). Toxicological Actions of Plant-Derived and Anthropogenic Methylendioxyphenyl-Substituted Chemicals in Mammals and Insects. *Journal of Toxicology and Environmental Health, Part B*, 15(6), 365–395. <https://doi.org/10.1080/10937404.2012.705105>

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Only in 2021, 12 years after the endorsement of Reg. (EC) 1107/2009, the Commission finally adopted the long overdue list of **“unacceptable co-formulants”** (Article 27), **containing 144 substances** to be banned due to their hazardous properties!¹⁴ Despite acknowledging the harmful impacts of these substances through this list, the Commission has yet **failed to adopt comprehensive and harmonised risk assessment procedures** to review and screen the added substances used in pesticides.

Moreover, the product formulations are not as thoroughly assessed as the active ingredients for their potential toxicity. Indeed, the data requirements for the whole products do not include, for example, in the toxicological studies section any chronic/long-term toxicity tests to address their potential human toxicity¹⁵. This information is simply extrapolated from the toxicity of the active substance, with the assumption that all ingredients are not toxic or that the combination of all the ingredients results in no additive or synergistic effects, which is not the case.

Massive Gaps in EU Risk Assessment: the European Commission Does Not Respect the Law

Regulation EC/1107/2009 obliges the EU Commission to adopt implementing acts concerning the approval of co-formulants, safeners, synergists and adjuvants. However, 12 years after the implementation of the regulation, the Commission has largely ignored these obligations:

Category	EU Obligations Reg. 1107/2009	Status quo?
Safeners and Synergists	Safeners and synergists should be approved according to the same approval criteria (in Art. 4) and procedure as ‘active ingredients’; data requirements should be defined (Art. 25&26).	Safeners and synergists are not approved at EU level ; data requirements were never defined. The Commission is working on a draft regulation, which was to be initially presented in the course of 2022. However, stakeholders have not been kept informed and the draft has yet to be released.
Co-formulants	<p>‘Exclusion’ criteria are applicable to co-formulants.</p> <p>A first negative list of unacceptable co-formulants was adopted at EU level.</p> <p>The Commission established detailed rules for the identification of unacceptable co-formulants¹⁶ (Art. 27). But the Implementing Regulation</p>	<p>Art. 27 was never fully implemented. The Commission suggests that currently applicable provisions under REACH and CLP regulations are sufficient. However, a large part of the co-formulants in use are not registered under REACH, and even if they are, only 1/3 of REACH files are complete in terms of toxicity studies. Moreover, the risk assessment requirements under REACH are significantly less stringent than those set out by Reg.1107/2009, particularly for chemicals produced at lower volumes (below 100 tonnes/year).</p> <p>In 2021,¹⁷ a first negative list of unacceptable co-</p>

¹⁴ Regulation (EC) 2021/383 amending Annex III to Regulation (EC) No 1107/2009

¹⁵ Regulation (EC) 284/2013 on data requirements for plant protection products; Section 7 Toxicological studies

¹⁶ Implementing Regulation (EU) 2023/574 in accordance with Regulation (EC) No 1107/2009

¹⁷ Regulation (EC) 2021/383 amending Annex III to Regulation (EC) No 1107/2009

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	<p>adopted is largely insufficient and fails to comply with Reg. (EU) 1107/2009.</p>	<p>formulants was adopted. The drafting process was untransparent and stakeholders were not involved.</p> <p>In March 2023, after years of delays, the European Commission adopted the Implementing Reg. 2023/574,¹⁸ supplementing Reg. 1107/2009, to set out “detailed rules for the identification of unacceptable co-formulants” on a continuous basis. The Implementing Regulation fails to establish the same safety criteria and standard of risk assessment as for active substances in pesticide products. It does not guarantee compliance with Reg.1107/2009, which requires that co-formulants used in pesticide products do not pose any risk to human health or the environment.</p>
Adjuvants	<p>Detailed rules for the authorisation of adjuvants at Member State level should be adopted (Art. 58).</p>	<p>No regulation was adopted and the Commission is not working on this issue. Member state provisions continue to apply.</p>

Lack of Transparency & Industry Oversight

The identity of co-formulants and full pesticide formulations are hidden from the public, justified by commercial confidentiality. This **lack of transparency is shocking**, considering the health and environmental risks at play. The Court of Justice of the EU¹⁹ had confirmed that information on emissions into the environment must be made publicly available, including the nature, and composition of these emissions as well as “information enabling the public to check” the authorisation assessment.

In light of **lacking oversight** mechanisms, **applicants can decide** which substance they “declare” as the ‘active substance’ and which ones are categorised as ‘inert’ co-formulants. While the Commission and the European Court of Justice²⁰ maintain that improper categorisation would be illegal, we argue that in practice, industry actors are the ones choosing which substances are more thoroughly assessed and which ones pass under the radar. Peer-reviewed research showed that added substances should arguably also be **considered as “active substances”**^{21,22} or found substances were even undeclared.²³

¹⁸ Implementing Regulation (EU) 2023/574 in accordance with Regulation (EC) No 1107/2009

¹⁹ Judgment Case C-673/13, 23.11.2016: <https://curia.europa.eu/jcms/upload/docs/application/pdf/2016-11/cp160128en.pdf>

²⁰ Ruling in the case C-616/17, Blaise and others, EU:C:2019:800

²¹ 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>

²² 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>

²³ Seralini, G.-E., & Jungers, G. (2020). Toxic compounds in herbicides without glyphosate. *Food and Chemical Toxicology*, 146, 111770. <https://doi.org/10.1016/j.fct.2020.111770>

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Glyphosate co-formulants are active substances too!

A separate analysis of glyphosate-based herbicides' co-formulants has revealed herbicidal activity, despite the absence of the "active substance" (glyphosate).²⁴ This demonstrates that the **current framework fails to ensure** that all active components in pesticide products are **appropriately declared** and therefore applicants can avoid control. The European Court of Justice²⁵ confirmed last year that the Commission and Member States have an obligation to ensure that all active ingredients are declared accordingly. Despite this evidence, the Commission does not see a need to act.

In numerous cases, the **presumably "inert" co-formulants significantly increase the toxicity** of the pesticide products, towards its target and/or non-targeted species, and the environment at large^{26 27}. The **EU so far fails to take these effects into account** in their pesticide risk assessments. The European Commission is turning a blind eye to this issue, despite the fact it is very well aware of the rules.

PAN Europe considers that the following aspects need to be urgently addressed:

1. **Transparency of pesticide formulations and co-formulants safeners, synergists and adjuvants:** information on the substances that are sprayed into their environment must be made publicly available.
2. The European Commission should rapidly set a plan to **fully implement regulation 1107/2009/EC** and put in place a system to thoroughly assess the toxicity of such substances, individually, and as a mixture.
3. Industry actors should not be allowed to determine which one is the active substance: this should be decided by scientific agencies. Furthermore, **co-formulants, adjuvants and synergists should all be assessed for the risk they pose to human health and the environment in the same way as active substances**, separately and jointly in the complete formulation. Differentiating active substances and other ingredients would thus make no more sense.

The sole responsibility of this publication lies with the author. The European Union is not responsible for any use that may be made of the information contained therein.

²⁴ 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>

²⁵ Ruling in the case C-616/17, Blaise and others, EU:C:2019:800

²⁶ 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>

²⁷ See also: 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> & 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>

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