Pesticide Action Network Europe

Position Paper - Strengthening EU Guidance on negligible exposure to pesticides

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I. Background

Regulation 1107/2009 on the placing of plant protection products on the market establishes strict approval criteria for active substances, ensuring that pesticides do not pose harmful effects on human and animal health or cause unacceptable environmental impacts. The Regulation is rooted in the precautionary principle and introduced hazard-based 'cut-off' criteria, which prohibit the approval of substances with certain intrinsic hazardous properties. These include substances that are mutagenic, carcinogenic, toxic for reproduction (CMRs), endocrine disruptors (EDs), persistent organic pollutants (POPs), persistent, bioaccumulative, and toxic (PBT), or very persistent and very bioaccumulative (vPvB). The rationale behind these criteria is that any level of exposure to such substances presents an unacceptable risk, making their approval incompatible with the high legal standards of health and environmental protection. These criteria were also introduced to speed up the non-approval process for very hazardous substances by bypassing additional risk assessment steps to determine safe exposure levels and directly concluding their non-renewal.

However, the Regulation provides a theoretical exception, in that never applied, for certain hazardous substances (specifically, carcinogens, reprotoxic substances, and endocrine disruptors for humans or non-target organisms) to be approved only if exposure is 'negligible'. This means that the pesticide products are used in closed systems or in other conditions that lead to no human contact and non-detectable residues in food (i.e. below the default value of 0.01 mg/kg or the relevant Level of Quantification (LOQ)).

For years, the European Commission and Member States have struggled to establish a common understanding of how this strict regulatory provision should be applied in risk assessment; while companies were referring to this derogation to get their substances approved. These differences led to work being halted in 2015 before being relaunched in 2021. Despite this renewed effort, significant problems persist in the draft guidance document shared with select stakeholders at the end of 2024.

PAN Europe finds that **the draft guidance** -although improved- **still fails to uphold the hazard-based approach required by Regulation 1107/2009. While it clarifies that certain outdoor uses of such pesticides should not be considered to result in negligible exposure, it introduces loopholes that could allow hazardous substances to be approved under misleading assumptions of negligible exposure**. It also promotes an approach that assumes that there are safe levels of exposure for "cut-off" substances, including endocrine-disrupting chemicals. Therefore, PAN Europe calls for a thorough revision of the guidance to ensure full alignment with the precautionary principle and the strict cut-off criteria, effectively protecting both humans and non-target organisms from hazardous pesticides.

II. Key Concerns and Recommendations

- **Endocrine disruptors should be treated as non-threshold substances**

There is no scientific consensus that ED substances have safe exposure thresholds. Even at very low levels, these chemicals may interfere with the action of hormones and disrupt hormonal systems. When exposure takes place during early life stages, this may lead to permanent adverse effects. This was the conclusion of JRC's expert advisory group on endocrine disruptors[1], while experts of the endocrine society have advised against the use of so-called 'safe thresholds', as used in traditional toxicology, for endocrine disruptors[2]. Similarly, the Danish Centre on Endocrine Disrupters also recommends using a non-threshold approach as default for endocrine disruptors when deriving reference doses (e.g. derived no effect level)[3]. Thus the Commission's approach lacks scientific justification and support from experts in the field of endocrinology.

👉The precautionary principle requires EDs to be treated as non-threshold substances unless clear evidence proves otherwise.

- **Non-target organisms should not be discarded**

The guidance does not address the legal requirement regarding the assessment of negligible exposure to endocrine-disrupting substances for non-target organisms, suggesting that this should be carried out on a case-by-case basis. This decision is neither legally nor scientifically supported. It presents a clear 'legal gap', which will prevent a common understanding of negligible exposure by Member States and EFSA, and result in non-harmonised assessments and decision-making.

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[1] Munn S, Goumenou M. Key scientific issues relevant to the identification and characterisation of endocrine disrupting substances - Report of the Endocrine Disrupters Expert Advisory Group. EUR 25919. Luxembourg (Luxembourg): Publications Office of the European Union; 2013. JRC79981

[2] Demeneix B, Vandenberg LN, Ivell R, Zoeller RT. Thresholds and Endocrine Disruptors: An Endocrine Society Policy Perspective. J Endocr Soc. 2020 Jul 9;4(10):bvaa085. doi: 10.1210/jendso/bvaa085. PMID: 33834149

[3] https://www.cend.dk/files/ED_Risk_report-final-2019.pdf

👉The negligible exposure assessment for non-target organisms should be included in the scope of the guidance to prevent loopholes and inconsistencies among Member States.

- **Clarification of key definitions**

The definitions of *"closed systems"* and *"conditions excluding human contact"* must be revised to align with the Regulation's intent.

👉Closed systems should be defined as ensuring no human exposure and no environmental emissions, rather than simply minimising them *"as far as technically possible".* Vague language such as *"in view of preventing"* should be removed to prevent subjective interpretation by different Member States.

👉In concrete terms, open-field applications and non-sealed environments, including greenhouses, tunnels, and shelters, should be excluded from being considered closed systems. Moreover, permanent greenhouses should not be considered *per se* as closed spaces preventing emissions into the environment, as already demonstrated by EFSA[4], scientific studies[5] and PAN Europe's study[6]. Likewise, treated seeds may result in emissions into the environment and therefore negligible exposure should be demonstrated each time, based on official field data.

- **Protective equipment cannot guarantee negligible exposure**

Personal protective equipment (PPE) and other risk mitigation strategies should not be relied upon as proof of negligible exposure. Field studies indicate that PPE effectiveness is frequently overestimated, leading to higher-than-anticipated exposure levels, even following specific advice on the use of the equipment[7].

- **Only field data should inform assessment**

Negligible exposure should be demonstrated through real exposure/field studies rather than theoretical modeling. Moreover, the guidance refers to an EFSA Guidance for the calculation of exposure of operators, workers, bystanders and residents, which includes conventional uses,

[4] EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments, 20 March 2014.

[5] Boye K, Boström G, Jonsson O, Gönczi M, Löfkvist K, Kreuger J. Greenhouse production contributes to pesticide occurrences in Swedish streams. Sci Total Environ. 2022 Feb 25;809:152215. doi: 10.1016/j.scitotenv.2021.152215. Epub 2021 Dec 7. PMID: 34890678.
Kang G et al, Pesticides in Greenhouse Airborne Particulate Matter: Occurrence, Distribution, Transformation Products, and Potential Human Exposure Risks, 2024/01/23, doi: 10.1021/acs.est.3c06270, Environmental Science & Technology, https://doi.org/10.1021/acs.est.3c06270

[6] PAN Europe, Report on Permanent Greenhouses.

[7] Garrigou A, Laurent C, Berthet A, Colosio C, Jas N, et al.. Critical review of the role of PPE in the prevention of risks related to agricultural pesticide use. Safety Science, 2020, 123, pp.104527. https://doi.org/10.1016/j.ssci.2019.104527

none of which should be considered as negligible. There is no assessment of those scenarios that could be considered negligible according to the guidance document.

- **Stronger protection against water contamination**

The limit of 0.1µg/L is the standard value for pesticide residues in drinking water and groundwater. PAN Europe recommends a stricter safety factor of at least 10 (i.e., 0.01 µg/L) to consider negligible exposure.

- **Negligible exposure must not be confused with negligible risk**

Evidently, the guidance inappropriately equates negligible exposure with negligible risk, undermining the Regulation's hazard-based approach. It relies on a risk-based assessment that assumes a "safe" threshold can be established using standard risk-based tools such as the Acceptable Operator Exposure Level (AOEL) and the Margin of Exposure (MoE). As mentioned above this is particularly problematic for endocrine disruptors, for which there is no scientific consensus of a threshold. It also blocks the original intention of the EU law, to accelerate the non-renewal decisions regarding very hazardous pesticide active substances.

This is all the more problematic because the guidance fails to clearly define what a threshold of negligible exposure could be. Instead, it confusingly refers to the standard safety factor of 100 i.e., the same MoE value used for pesticide substances that do not fall under strict cut-off hazard criteria. It even suggests that any exposure below AOEL could qualify as negligible exposure. This would all depend on the Member States and EFSA which are left to decide on the level of exposure that can be considered negligible on a case-by-case basis.

👉To align with the Regulation's intent, negligible exposure must be strictly defined as no human contact (and no emissions into the environment). The guidance must provide a detailed methodology to ensure harmonised assessment of negligible exposure across the Member States. If a threshold for such substances were ever scientifically validated, which remains highly uncertain, a significantly higher safety factor (MoE) of at least 10,000 would be necessary.

III. Conclusion

The current guidance document does not adequately reflect the hazard-based approach required by the Regulation and instead introduces risk-assessment principles for highly hazardous substances that could allow dangerous substances to remain in use. PAN Europe urges the Commission to revise the guidance to:

- Ensure that negligible exposure is strictly interpreted as **no contact with humans and no emissions into the environment**.
- Recognise endocrine-disrupting substances as **non-threshold substances** by default.
- Provide guidance to establish negligible exposure to the environment.
- Base exposure assessments on **real-world field data**, not theoretical models.

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Pesticide Action Network (PAN Europe) is a network of NGOs working to reduce the use of hazardous pesticides and have them replaced with ecologically sound alternatives. We work to eliminate dependency on chemical pesticides and to support safe sustainable pest control methods. Our network brings together over 45 consumer, public health and environmental organisations and women's groups from across Europe.

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