



## Negligible risk amendment

### BRIEFING

Amending first paragraph points 3.6.5 and 3.8.2 of Annex II from negligible exposure to negligible risk.

Highlights:

- Increases permitted pesticide residues in food by hundreds even thousand times
- Assumes “safe” levels of exposure to EDCs exist, which is scientifically unfound
- Assumes that we have adequate testing to identify all ED-effects, which we don't
- Drastically changes the effectiveness of the scientific criteria on EDCs to protect human and environmental health from exposure to EDCs.
- It is done undemocratically as it will not be done in co-decision with the Parliament
- It contradicts the provisions of the regulation 1107/2009 which is based on the precautionary principle and aims to provide a high level of protection for humans, animals and the environment
- ED pesticides will be used in open fields and end up as residue in our food, putting humans, animal and the environment at unknown risk

## Background

### The Regulation

Regulation 1107/2009 concerning the placing of plant protection products on the market, requires that a substance shall only be approved if it meets certain approval criteria (Article 4) and apply the precautionary principle to ensure that the active substance shall not have any harmful impact on human and animal health, and no unacceptable effect on the environment.

The Pesticide Regulation 1107/2009 was a mutual trialogue agreement among European Parliament, European Council and European Commission, and is called hazard-based. This means that pesticides that are considered hazards for humans and the environment, shall not be authorised for use in the production of our food and the management of green areas.

The assessment of the active substance shall first establish that the criteria are satisfied set out in points 3.6.2 to 3.6.5 and 3.7 of Annex II. The first (3.6.2 to 3.6.5) refer to the impact on human health:

The pesticide active substance shall only be approved if it is not a mutagen (Category 1A & 1B), carcinogen (Category 1A & 1B), toxic to reproduction (Category 1A & 1B) or considered as having endocrine disrupting properties that may cause adverse effect in humans.

However, for substances that are carcinogens, toxic to reproduction and endocrine disruptors the legal text has a derogation, the **negligible exposure**:

*“...unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005<sup>1</sup>”.*

The derogation of negligible exposure also appears in the assessment of the ecotoxicity of active substances (Annex II, 3.8.2), in which case an active substance shall only be approved if:

*“it is not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use is negligible”.*

### The expansion of the definition of ‘negligible exposure’

Even though the definition of what is a negligible exposure seems clear (i.e. used in closed systems or conditions excluding contact with humans, residue levels below the default value of 0.01 mg/kg), in 2014, DG SANTE started working on a guidance document on the assessment of negligible exposure. PAN Europe called this work an “[escape route](#)”. Sweden also expressed its concerns on the guidance in a written letter sent to DG SANTE’s head of pesticide unit in 2014:

*“From a legal point of view, and bearing in mind the main objectives of the Regulation, we believe it is of utmost importance to maintain the initial purpose of the hazard-based cut-off criteria as well as the concept of the ‘negligible exposure’. We would therefore urge the Commission to safeguard and retain these principles, when developing the guidance on the definition of negligible exposure.”*

In a different communication the Swedish Chemical Agency writes to the Commission:

*“We now have the impression that there is a discussion on negligible exposure as a way to derogate from the hazard-based procedure, by introducing a more risk based one. In practice, such an approach would hollow out the cut-off criteria as such and ultimately*

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<sup>1</sup> According to Reg 396/2005 on maximum residue levels of pesticides in food, the default value is 0.01 mg/kg or lower in cases of toxicological concern.

*jeopardize the high level of protection of human health and the environment stipulated by the regulation”.*

In the draft guidance<sup>2</sup>, the Commission was already expanding the derogation by widening the meaning of “closed systems”, “excluding contact with humans” and “negligible”, and consequently introducing risk-estimation elements to estimate a safe dose of exposure. Although the guidance remains incomplete, it was clear that closed systems and excluding contact with humans did not refer just to greenhouses, but could also be achieved with the use of mitigation measures in farming and protection equipment. Similarly, negligible exposure would not be close to zero but equal to just 10 times or so the ‘safe’ exposure level. No scientific investigation was carried out to establish these definitions; they are purely hypothetical. Civil Society organisations, including PAN Europe, provided [comments](#) on the guidance.

### Amendment in the Regulatory Text: negligible exposure to negligible risk

In 2016, after a 2,5 years delay, the Commission presented the first draft of the scientific criteria to define endocrine disruptors. However, together with the criteria, the Commission also presented a proposal for an amendment in the legal text of the Regulation (reg. 1107/2009/EC, Annex II 3.6.5. and 3.8.2), which was not foreseen in its mandate: to change the “negligible exposure” derogation for endocrine disruptors to “negligible risk”. If the risk is negligible, the substance may be approved, even if it’s an endocrine disruptor and even if the exposure is not negligible but hundreds or thousand times higher.

Such an amendment was not presented for carcinogens or substances toxic to reproduction; the proposal will result in both ‘negligible exposure’ and ‘negligible risk’ in the text.

The proposal was criticised by [civil society organisations](#), including PAN Europe, endocrinology experts from [the endocrine society](#), as well as Member States.

Not only the Commission went beyond it’s legal mandate but the proposal itself was widening the derogation as if to fit to the draft guidance document on ‘negligible exposure’:

*“...unless the risk to humans from exposure ... is negligible, in particular where the product is used in closed systems or in other conditions which aim at excluding contact with humans, and where maximum residue levels of the active substance, safener or synergist concerned in or on food and feed can, taking account of the latest opinion of the Authority with respect to that active substance, synergist, safener, be set in accordance with Regulation (EC) No 396/2005, which ensure a high level of consumer protection”.*

i.e. farming conditions which aim at excluding contact with humans may be considered a close system and residue levels are defined simply by maximum residue limits regulations, as with any other authorised pesticide active substance, which may be hundreds or thousands of times more than negligible exposure (close to detection limit).

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<sup>2</sup> [https://ec.europa.eu/food/sites/food/files/safety/docs/adv-grp\\_wg\\_20150625\\_tech-guidance.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/adv-grp_wg_20150625_tech-guidance.pdf)

The Commission justifies the inclusion of “risk-based” elements in endocrine disruptors using article Article 78 (1)(a), based on EFSA’s 2013 opinion, as new scientific and technical knowledge. EFSA’s opinion says that endocrine disruptors may be assessed like most other substances of concern for human health and the environment, that is to say may also be subject to risk assessment, instead of hazard assessment. The Commission also refers to The Scientific Committee on Consumer Safety (SCCS) Memorandum issued in 2014, who in fact also refer to the work of EFSA. DG SANTE overlooked other scientific evidence, from Commission’s Joint Research Centre, revealing a high level of uncertainty over “safe levels of exposure for EDCs”<sup>3</sup>. Furthermore, the decision that the Pesticide Regulation will be hazard based has already been taken, and neither the Commission nor the Member States have the legal power to change this decision alone.

Since the ED criteria are hazard-based and the amendment in the derogation concerns the decision-making process, the Commission decided to retract temporarily the amendment proposal but promised to the Member States to present the proposal again when the process on the ED criteria has been completed.

### The new amendment on risk management

Keeping its word, the Commission is presenting again the proposal for amendment of the ‘negligible exposure’ derogation to ‘negligible risk’ for endocrine disrupting substances to the Member States and increase the limits of exposure to these chemicals by hundreds or thousand times. As before, the Commission is proposing to Member States to modify the negligible exposure to negligible risk only for endocrine disrupting substances as follows:

*“An active substance, safener or synergist shall only be approved if, ... , it is not considered, ..., to have endocrine disrupting properties that may cause adverse effect in humans, unless **the risk to humans from exposure** to that active substance, safener or synergist in a plant protection product, under realistic worst case proposed conditions of use, **is negligible**, in particular where the product is used in closed systems or in other conditions which **aim at excluding contact with humans**, and where maximum residue levels of the active substance, safener or synergist concerned in or on food and feed can, taking account of the latest opinion of the Authority with respect to that active substance, synergist, safener, be set in accordance with Regulation (EC) No 396/2005, which ensure a high level of consumer protection.*

Once again, the Commission uses article Article 78 (1)(a), based the EFSA’s 2013 opinion, as new scientific knowledge according to which endocrine disruptors may be assessed like most other substances of concern for human health and the environment, that is to say may also be subject to risk assessment, instead of hazard assessment.

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<sup>3</sup> <http://publications.jrc.ec.europa.eu/repository/bitstream/JRC83204/lb-na-26-068-en-n.pdf>

## The problem

### A vague definition

The definition of negligible risk, unlike the previous definition on exposure, is unacceptably vague in the proposal. With this element, the Commission gives the green light for applicants to establish a safe-exposure level for EDCs, based on models that probably consider the use of mitigation measures and high-tech equipment for farmer (to aim to exclude contact with humans), which doesn't correspond to real-life situations.

As a result, such pesticides will still be used in the field as long as exposure levels are below the non-observed adverse effects level (this is much higher than 'negligible' exposure) in animal models, which is exactly what the law mandates for every other non-hazardous pesticides.

### Raising exposure levels

Under negligible exposure residues in food and feed had to be below the default value, which in most cases is also the limit of detection for most pesticide substance. However, with the negligible risk amendment the exposure levels can be equal to the current Maximum Residue Limits as with non-hazardous pesticides. This change is a tremendous increase in the permitted exposure levels. Humans and animals will be exposed hundreds or even thousand times more to these hazardous pesticides (see Table 1).

*Table 1. Selection of pesticide active substances that are endocrine disruptors for humans that remain to be classified and comparison of the default value of negligible exposure to the proposed current MRLs.*

Endocrine Disrupting Pesticide (active ingredient)	Current Maximum Residue Limits (mg/kg)	Estimated increase in exposure (times) compared to default 0.01 mg/kg
mancozeb	5.0 (apples) - 10.0 (strawberries)	500 - 1000
thiram	5.0 (apples) - 10.0 (strawberries)	500 - 1000
tebuconazole	1.0 (cherries) – 5.0 (mandarins)	100 - 500
cypermethrin	1.0 (apples) – 2.0 (peaches)	100 - 200
2,4- D	0.1 (grapes) – 2.0 (wheat)	10 - 200

### Triggering Article 78 (1)(a) is unjustified

#### The Commission is not authorised to change the hazard-based criteria

The Pesticide Regulation 1107/2009, in contrary with the previous Directive 91/414/EEC, contains "cut-off" criteria for the approval of substances based on hazard properties of the substance (mutagen, carcinogen, toxic to reproduction and endocrine disruptor). This was

done to speed up the authorization process to avoid the extensive delays in decision-making and ensure a high level of protection of humans, animals and the environment.

Carcinogens and toxic to reproduction may also go through risk assessment but in other European regulations, not in Pesticide Regulation which refers to substances that are used in open fields, contaminate the surrounding environment -putting residents, bystanders, animals and ecosystems at risk- and end up as residues in our food. Therefore, there is a direct exposure with humans, and nature.

Using EFSA's argument that risk assessment can be done on EDs as with other chemicals, should not be treated as new information, since risk assessment can be done with other hazardous substances as well but in other sectors of the European Regulation, not within pesticide regulation. The decision to set cut-off criteria for all hazardous pesticides has already been taken.

Amending negligible exposure to negligible risk, cancels the cut-off criteria for ED pesticides and requests instead a risk assessment procedure to establish a 'hypothetical' safe level of exposure, which will inevitably result in extensive delays in decision making and therefore goes against the intention of the regulation to speed up the process and provide a high level of protection.

A Joint Research Centre report, also from 2013, reveals that there is no scientific consensus that safe levels of exposure for endocrine disrupting substances even exist, particularly during the early life stages when the organism is still under development and sensitive to alterations in hormone levels.

The Commission also misses to refer to much more recent and up-to-date scientific evidence from the Commission itself demonstrating that current testing protocols have major data gaps to identify efficiently endocrine disruptors ([JRC expert survey](#)), and that low dose effect during prenatal periods are not adequately addressed ([European Commission](#)).

Introducing such a major change in the legal text of the European Law should not lie in the hands of the Commission nor to the Member State delegates of SCoPAFF. Such an attempt is in fact unlawful and a similar process was previously objected by the European Parliament<sup>4</sup>.

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<sup>4</sup> <https://www.pan-europe.info/press-releases/2017/10/commissions-endocrine-criteria-proposal-beyond-legal-mandate-eu-parliament-0>