Alert regarding the obstruction of the principle of substitution of more dangerous pesticides in the EU

Alert brought to the attention of the National Commission on Ethics and Alerts in Public Health and Environment by the coalition of associations Secrets Toxiques and MPs

Eric Andrieu (Parlement européen – S&D), Michèle Rivasi (Parlement européen – Verts/ALE), Claude Gruffat (Parlement européen – Verts/ALE), Benoît Biteau (Verts/ALE),

Manon Aubry (Parlement européen, La Gauche-GUE/NGL)
Leila Chaibi (Parlement européen, La Gauche-GUE/NGL)
Aurore Lalucq (Parlement européen, S&D)
Pierre Larrouturou (Parlement européen, S&D)
Stéphane Delautrette (Assemblée nationale, SOC)
Pascal Durand (Parlement européen, S&D)
Raphaël Glucksman (Parlement européen, S&D)
Nora Mebarek (Parlement européen, S&D)
Marie Toussaint (Parlement européen, Verts/ALE)
Jean-Claude Tissot (Sénat, SER)
Nicolas Thierry (Assemblée nationale, ECO)
Joël Labbé (Sénat, ECO)
Chantal Jourdan (Assemblée nationale, SOC)
Sylvain Carrière (Assemblée nationale, ECO)
Sylvie Guillaume (Parlement européen, S&D)

Dear Mr. President,

We hereby wish, in our capacity as French and European parliamentarians, to refer to your Commission, in application of Article 4 of Law n°2013-316 of 16 April 2013 on the independence of expertise in health and environmental matters and the protection of whistleblowers, an incorrect application of the provisions of Article 50 of Regulation (EC) No 1107/2009 (hereinafter the "Regulation"). All Member States of the European Union (EU) rely on a recommendation of the European and Mediterranean Plant Protection Organization (EPPO) for their decisions on the marketing authorization of European pesticides, as the latter has the task of identifying candidates for substitution, i.e. the most dangerous pesticides that can be authorized in the EU, but whose authorization by Member States should be avoided when less dangerous alternatives for human health and biodiversity allow it. Considering the status and activity of EPPO, there is indeed reason to question the lack of independence and conflict of interest policy of this organization that is not one set up by the European Union (EU). An investigation conducted by the non-governmental organization Pesticide Action Network Europe (PAN Europe) revealed that certain representatives of the pesticide industry were able to influence the development of this "standard", which led to an incorrect interpretation of the Regulation allowing Member States to systematically authorize pesticides that have less dangerous alternatives. In the end, it is the general objective of protecting human and animal health and the environment that is undermined by what seems to be a deficiency in the marketing authorization procedure for pesticides. It seems necessary to us to draw the attention of your Commission to these shortcomings and to invite you to take action to identify them and to allow the actors concerned to find solutions to remedy them.

1. Background

1.1. The legal framework for the most hazardous pesticides in the EU

EPPO has defined the guidelines on which the comparative assessment of alternatives to the most hazardous pesticides in the EU is based in accordance with Article 50 and Annex IV of the Regulation. In order to ensure the high level of protection of human and animal health and the environment provided for in Article 1 of the Regulation, "certain active substances with certain properties should be identified at Community level as candidates for substitution. Member States should regularly review plant protection products containing such active substances with a view to replacing them with plant protection products containing active substances that present less risk to health and the environment" (recital 19 of the Regulation).

The properties mentioned in this recital of the Pesticides Regulation constitute criteria for identifying candidates for substitution, which are detailed in point 4 of Annex II. They include endocrine disrupting properties with negligible exposure, neurodevelopmental or immunotoxic effects, classification as category 1A or 1B carcinogenic or toxic for reproduction with negligible exposure substances, etc. When re-evaluated by the European Food Safety Agency (EFSA), a significant proportion of the substances identified in this category are not renewed or withdrawn during the approval period because they now fail to meet the approval criteria[1]. This highlights the concerning impacts these substances have on human health and biodiversity.

In the recent context of the EU's Farm to Fork and Biodiversity Strategies, the European Commission has explicitly identified pesticide products containing candidate substitutes as "more hazardous pesticides" and has specifically proposed a target to reduce their use by 50% by 2030.

As explained in Recital 19 of the Regulation, the obligation of Member States is to substitute safer alternatives for these more hazardous pesticides as soon as possible, in order to reduce exposure of citizens and the environment and to promote more sustainable crop protection. This "substitution principle" is made legally binding and more detailed in Article 50(1) of the Regulation.

The latter provides that Member States shall authorize the use on a given crop of products containing a substance for which substitution is envisaged only when a comparative assessment has been carried out and has shown that its replacement by a safer alternative is not possible, taking into account the specific conditions specified in Article 50(1) and in Annex IV. They shall thus grant authorizations only if:

"(a) for the uses specified in the application an authorised plant protection product, or a non-chemical control or prevention method, already exists which is significantly safer for human or animal health or the environment;

(b) the substitution by plant protection products or non-chemical control or prevention methods referred to in point (a) does not present significant economic or practical disadvantages;

[1] See for instance Isopyrazam, Dimoxystrobin, Oxamyl or Ipconazole

(c) the chemical diversity of the active substances, where relevant, or methods and practices of crop management and pest prevention are adequate to minimise the occurrence of resistance in the target organism; and

(d) the consequences on minor use authorisations are taken into account."

In addition, comparative assessments must be made in light of Recital 24, which clearly states that "when granting authorizations for plant protection products, the objective of protecting human and animal health and the environment should be given priority. Human and animal health and the environment must take precedence over the objective of improving plant protection." This was unequivocally confirmed by the Court of Justice of the EU in a recent preliminary ruling.

1.2 Background

The Pesticide Regulation came into force in 2011. That same year, EPPO published a document offering guidelines on comparative assessment to "provide guidance and a decision support tool for determining whether substitution of a [more hazardous pesticide] is appropriate." This standard proposes a "step-by-step decision process" for evaluating some of the above conditions in Section 50 and Schedule IV of the Regulations during a comparative assessment. It clearly refers to the Regulation and its Article 50(1), thus clearly emphasizing that these guidelines are intended for EU Member States in applying the Regulation. In 2014, the European Commission published a European guidance document on comparative assessment in which it explicitly tells Member States to use the EPPO guidelines as is, and gives additional guidance on how to assess differences in risks to human health, animal health and the environment (conditions for comparative assessment not covered by the EPPO document). It thus gives EPPO's work a certain normative value, by calling on national decision makers to implement its recommendations.

The EU guidance document was adopted by the Member States in October 2014, a few months before the entry into force of Article 50(1) (on 1 April 2015). Since that date, the EPPO recommendation has been used as a standard by all Member States in combination with the EU guidance document to decide on the substitution or authorization of more hazardous pesticides. It has subsequently been marginally revised twice by EPPO, most recently in 2018, without the Commission reviewing its decision to make it the core component of its guidance document. This standard thus appears to play a crucial role in the procedure under Article 50 of the Regulation, a role that is all the more important as this standard applies to substances of particular concern for human health, animal health and the environment.

1.3. State of play of substitution in Europe

It was only in the spring of 2020 that the first data on the application of the substitution principle was made public by the Commission. These data indicate that out of 530 applications for authorization of pesticides containing a candidate for substitution submitted in 2015 and 2016 in the different European Member States, no substitution was made. No more recent information was made public until December 2022, when new figures were published in a Commission response to a written parliamentary question. The answer states that only 11 cases of substitution (general refusal of authorization or refusal for certain uses/crops) of more dangerous pesticides are currently registered in the whole EU. This progress is minimal compared to the number of authorizations issued. Indeed, the results of a

study conducted by the European Commission among Member States, revealed in the context of a request for access to documents[2], support this statement: Spain (512 authorizations), Hungary (462), France (396) - data from October 2021. However, this study also shows that in some Member States, such as Germany (48), farmers do without these substances for which no application for authorization has been made. The data for France also reveal two recent cases of substitution, and 21 "voluntary substitutions"[3], without the substances concerned being mentioned. Overall, this does not seem to have advanced the protection of European citizens and the environment. Indeed, according to a recent report, consumer exposure to residues of candidates for substitution has continued to increase between 2011 and 2019, contrary to the objective stated by the European legislator in the Regulation.

It is in the light of all these elements, and in particular the identification of these massively authorized pesticides as more dangerous, that it is important for us to seize your Commission of the matter. We would like to see light shed on the role played by this EPPO standard and the way in which Member States respect their obligation to apply the substitution principle.

1.4. Urgency of the referral

The European Commission has recently communicated its intention to propose a revision of its guidelines on the substitution of more hazardous pesticides. The Commission's stated intention is to present a first working draft of this revision in May, for discussion with Member States in July, with the objective of concluding this revision by the end of 2023.

Although we do not know the nature of the revisions that the European Commission will propose, the central place that EPPO recommendations currently occupy in the current guidelines is a key point of our referral. We therefore also question the place they could continue to occupy in a revised version. In view of the revision timetable announced by the European Commission, and in order to ensure that an opinion given by your Commission is taken into account in this framework, we kindly ask you to consider our referral as requiring urgent consideration. We believe it is important to ask your Commission to issue an opinion by October 2023, so that the working group to which the proposed revision of the guidelines will be submitted can take note of it before the conclusion of its work and any final adoption.

2. Subjects of the alert

2.1. Lack of guarantee of independence of EPPO

EPPO defines itself as "an intergovernmental organization responsible for cooperation in plant health in the Euro-Mediterranean region". It has 52 members, including EU Member States. However, it is a non-EU organization. EU standards and practices to ensure the independence of expert, research and regulatory bodies do not apply. However, EPPO has not developed a similar policy internally to ensure that its activities are not influenced by actors whose interests could deviate from the general interest. On the contrary, the structure of the organization allows the pesticide industry to be represented and to influence the work of the organization at all relevant levels.

---

[2] Documents available on the European Commission's "EASE" data portal (reference 2023/0368): Electronic Access to Commission Documents (EASE) (europa.eu)

[3] See Article 50(2): Member States may also apply the substitution principle to other pesticides that do not contain candidates for substitution.

EPPO is thus divided into working groups, including one on plant protection products. The former European Crop Protection Association (ECPA, now CropLife Europe) has a permanent observer status in this working group.

This working group on plant protection products is itself subdivided into different panels or expert working groups. According to the membership rules, "appropriate expertise is the main criteria for membership" and "nominations for membership of a panel can be made by anyone, including permanent observers [and thus CropLife Europe]. Members can come from research institutions, universities, industry." No requirement for balance and transparency in the representation of interests is mentioned.

For example, one-fifth of the members of the working group on plant protection product resistance (i.e., the group responsible for drafting the contentious standard on comparative assessment) are representatives of the pesticide industry (4 out of 20). These include 2 representatives from Syngenta, although Syngenta markets a fungicide called "Celest®", a Pirimicarb-based product that is a candidate for substitution, as well as several fludioxonil-based fungicide products, the most common candidate for substitution in fresh fruit and vegetables grown in the EU, according to PAN Europe's "Forbidden Fruit" report. These representatives also belong to the Resistance Action Committees run by CropLife International (see below).

The working group organizes regular workshops where EPPO recommendations are discussed, drafted and revised. In this context, the pesticide industry is systematically invited to organize, chair or even intervene as a panelist. Two important workshops are worth mentioning:

- In Brussels in 2009, the BASF and Syngenta companies were on the organizing committee. 43 of the 61 participants were representatives of the agrochemical industry or researchers taking up the work of the "scientific committees" set up by CropLife International,

- In Lisbon, in 2018; 44 out of 72 participants were "delegates from crop protection companies and consultancies".

Thus, the two most fundamental workshops on comparative assessment of candidate products for substitution were organized by EPPO. The first one led to the drafting of the first version of the EPPO standard, while the second one led to its revision in 2018.

In our view, the central role played in EPPO's work by industry players and members recommended by them raises legitimate and serious doubts about the independence of this organization and the reliability of its recommendations. This independence and reliability are all the more important however, as practice has given EPPO recommendations a normative value having a concrete impact on the application of Article 50 of the Regulation.

It seems plausible to us, in view of the situation summarized above, that one may consider that the pesticide industry sets the rules of comparative assessments, which are then imposed on its own substances, and can therefore shape the rules to its benefit. This conflict of interest leads to a regulatory capture that was highlighted in the report "Pesticide Paradise"[4] by the NGO PAN Europe. It shows that the content of the EPPO standard actually reflects the

[4] See page 27 of the Paradis Pesticide report.

position on comparative assessments promoted by the pesticide industry in position papers dating back to the time of the legislative negotiations leading to the adoption of the Regulation in 2009.

There is a strong suspicion that such a regulatory capture would not have been possible had EPPO been subject to the European rules of transparency, independence and participation that apply, among others, to the European Food Safety Agency (EFSA), the agency in charge of drafting such guidelines and protocols when it comes to pesticide evaluation (cf. articles 21 to 49 of Regulation (EC) No 178/2002). Moreover, by not critically examining this standard before adopting it and by continuing to use it today, it seems to us that the European Commission and the Member States are also compromising their obligations (in particular those provided for in articles 17(1) and (3) of the Treaty on European Union and in article 11(2) of Regulation (EC) No 1107/2009).

2.2 Content of the EPPO Standard: promotion of the multiple chemical strategy defended by the pesticide industry

As explained above, the EPPO Standard claims to present an operational approach to comparative assessment in accordance with the criteria of Article 50(1) of the Regulation. However, it seems to us that it provides a reductive and erroneous reading of this provision, which systematically hinders the substitution principle.

This is evidenced in particular by the fact that the EPPO standard recommends to conduct assessments only in light of the available chemical diversity of modes of action (see below) to evaluate whether the risk of resistance is contained, rather than taking into account the chemical diversity of active substances as required by Article 50. The approach advocated by EPPO thus also ignores the need to take into account the efficacy of all non-chemical alternatives, as required by Article 50(1)(c) of the Regulation.

The mode of action of a pesticide refers to the way it causes physiological disturbances in the target organism (disturbance of nerves, nervous balance, physical activity, etc.). The pesticide industry, through various "Resistance Action Committees"[5] created by CropLife International, has itself established this classification from the 1980s onwards for different classes of synthetic pesticides (including fungicides, herbicides and insecticides), at a time when resistance to synthetic pesticides challenged its existing business model.

In response to this evolution of resistance to synthetic pesticides, the industry imposed through its "Committees" the idea that the answer to such evolution is to apply different pesticides sharing different modes of action. This strategy is known as the "multiple chemical strategy," and is based on the idea that the multiplication of pesticide types can counteract the adaptation and resistance capabilities of their targets. Although its effectiveness in combating resistance is widely questioned by independent resistance researchers[6], it is nevertheless included in the EPPO standard.

---

[5] FRAC, HRAC, IRAC.

[6] Comont, D., Lowe, C., Hull, R. et al. Evolution of generalist resistance to herbicide mixtures reveals a trade-off in resistance management. Nat Commun 11, 3086 (2020). doi: https://doi.org/10.1038/s41467-020-16896-0; Gould, F et al, Wicked evolution: Can we address the sociobiological dilemma of pesticide resistance?, Science 360 (6390), 728-732. doi: https://doi.org/10.1126/science.aar3780; Hicks, HL. et al. The factors driving evolved herbicide resistance at a national scale, Nat Ecol Evol. 2018 Mar;2(3):529-536. doi:

The latter requires the availability of several classes of synthetic pesticides (usually 3 or 4) in order to conclude that substitution is feasible for use on a particular crop, without requiring further evaluation of the actual efficacy of synthetic and non-synthetic alternatives. A product for which there is at least one more effective alternative may thus be maintained on the market and not be substituted in favor of that alternative, merely because an arbitrary threshold of products is not reached, and despite the fact that this threshold reflects only a vision of the response to the problem of resistance and not an undisputed scientific reality.

This normative shift is not consistent with the wording of paragraph (1)(c) of Article 50 of the Regulation, which clearly refers to "chemical diversity of active substances, where appropriate, or to methods and practices of crop management and pest prevention," nor is it based on scientific data, and appears to play a determining role in Member States' decisions to refuse substitution.

2.3 Resistance and lack of transparency by Member States

There is no European database listing the commercialization authorizations of pesticides containing substances eligible for substitution. The national databases do not use this classification as a search criterion for a clear identification. Furthermore, the publication by Member State of their conclusions on comparative assessments conducted before an authorization decision is the exception (NL, SE). This lack of transparency prevents any control over national practices.

In 2020, the European Commission pointed out that in 2018, five Member States had not yet adopted a national comparative assessment procedure and that out of the 530 dossiers submitted in 2015 and 2016 (which, it should be remembered, did not result in any substitution), only 280 comparative assessments had been carried out. These facts and figures contravene to the obligation Member States have to carry out a comparative assessment of all applications for authorization in accordance with Article 50(1) of the Regulation.

Among those Member States that, contrary to the illegal but dominant practice, respect their obligation to conduct a comparative assessment, the most frequent reason for accepting the commercialization of a more dangerous pesticide and refusing to make a substitution is not the absence of an alternative, but the risk of resistance that this would generate. This assessment by the Member States is made in light of the protocols they follow, and therefore in accordance with the conditions laid down by the EPPO standard. It seems to us however that it ignores the spirit and the letter of the Regulation.

Conclusion

By adopting Regulation (EC) No 1107/2009, the European legislator has clearly established a high level of requirement for the authorization regime of pesticides in Europe. It has given the Member States a key role in the examination of authorizations for the marketing and use of plant protection products. Above all, it set the objective of protecting human and animal health and limiting the environmental risks associated with the use of such products. The

---

https://doi.org/10.1038/s41559-018-0470- 1; Kang, SE et al, Evidence for the agricultural origin of resistance to multiple antimicrobials in Aspergillus fumigatus, a fungal pathogen of humans, G3 Genes|Genomes|Genetics, Volume 12, Issue 2, February 2022, jkab427, doi: https://doi.org/10.1093/g3journal/jkab427

impact of pesticides on life and on the environment is a known and recognized risk factor, as much by agricultural actors as by scientific research and political decision makers.

The identification of pesticides considered to be more dangerous, and the creation of a mechanism for monitoring and substituting these products with less dangerous alternatives, is an essential lever for action to reduce the risks they pose to human health and biodiversity and to encourage changes in use. It is an important tool for the Member States, in particular to enable them to achieve the objective of reducing the use of these pesticides by 50% by 2030. This risk mitigation, however, assumes that the procedures used in studying the relevant products, their impact, and their comparison with possible substitutes are sufficiently transparent and based on an effective expertise and methodology free of any suspicion. In this respect, it is regrettable that the European Commission has not kept its commitment, made in 2019, to review the rules of comparative assessment by 2021, thus maintaining the normative value of the EPPO recommendations. Finally, while it appears that the Commission has just recently announced to launch this review, we note that it is taking place well after the dates initially envisaged.

For all the reasons that we are presenting in this alert, it seems to us there are strong grounds for suspecting that these conditions have not been met.

The proven practice of Member States in applying the substitution principle shows that the guidelines they use are established by an organization that does not offer the minimum guarantees of independence an actor producing recommendations with normative value should present.

Beyond the lack of application of EU rules on independence, there is also a reasonable suspicion that the pesticide industry holds sway within EPPO itself and thus influences the setting of standards directly impacting their economic interests. Finally, the lack of transparency on the part of the Member States regarding the application of the substitution principle and the small number of comparative evaluations actually carried out make it difficult to effectively evaluate compliance with the law. The non-application or misapplication of this principle therefore logically leads us to fear the persistence of environmental and human risks that the legislator has clearly sought to identify and prevent.

It seems to us that the use of the EPPO standard by Member States is in fact not a facilitation but an obstacle to the principle of substitution established by law, that the causes of this situation can be attributed to a set of ethical failures, and that it creates or maintains negative consequences on human health and biodiversity.

On the basis of all these elements, we therefore call on your Commission to ask EPPO and all relevant actors and authorities to provide you with all the information required to establish transparency as to the respect of the expected rules of independence, the respect of the principle of substitution and of the procedures governing its implementation, and the respect of the objectives of protection of health and environment set by the legislator.

We also invite you to carry out your work, as far as possible and in view of your means and resources, within a short period of time, so that all the actors concerned, and in particular the Member States and the European Commission, can take note of your opinion and take into account your conclusions and recommendations in the framework of the procedure for the revision of the guidelines on the substitution of more dangerous pesticides recently announced

by the European Commission. As such, an opinion delivered in October 2023 could be effectively taken into account in this work.

We remain at your disposal to provide any additional information you may deem necessary for the proper conduct of your work.