Comparative Assessment and Substitution

Position Paper

Brussels, 16 November 2022

Background

Under Regulation (EU) 1107/2009, active substances that are the most hazardous to human health or the environment[1] are approved as candidates for substitution. In addition to being approved for a maximum period of seven years, these substances can only be authorised in pesticide products by Member States when a comparative assessment has shown that they cannot be substituted with safer alternatives. Comparative assessment, in line with Article 50, is a legal requirement for all Member States since 1 August 2015[2].

Yet, none of the candidates for substitution have been substituted with a non-chemical alternative since 2015. Instead, recent studies showed that European citizens, including the most vulnerable groups, remain significantly exposed to the EU's most hazardous pesticides, whether through their food or in their environment. In 2020, as part of its Farm to Fork Strategy, the Commission has proposed to cut by 50% the use of the most dangerous pesticides containing candidates for substitution by 2030.

In this context, our organisation Pesticide Action Network (PAN) Europe has undertaken long-term research on the drivers of the persistent presence of candidates for substitution on the European market. In this context, we have analysed how comparative evaluation was carried out by different Member States, and the materials on which they rely. Many of our findings were published in a report in September this year. This position paper reiterates and complements them. These recommendations are intended to help the Commission to finally live up to its REFIT commitment to improve the efficiency of comparative assessment procedures; ensuring thereby that the substitution principle delivers its full potential, in terms of risk reduction for human health and the environment and sustainable crop protection's promotion, in the implementation of the Farm to Fork strategy.

1. *Modus operandi* recommended to improve the implementation of article 50

As a general recommendation, we consider the Commission does not need to use its delegation powers i.e. to amend Annex IV of Regulation (EU) 1107/2009 to improve the efficiency of comparative assessment, as mentioned in its REFIT report. According to our analysis, the origin of the current failure of the comparative assessment does not lie in a problematic Annex IV or in the absence of alternatives but in the operational implementation of Article 50 and Annex IV by Member States. This implementation is based on an EPPO standard on comparative assessment, a European guidance document and national guidance documents which all fail to comply with Article 50. Annex IV reflects the conditions of substitution set out in Article 50(1) in a compliant way. Although it does not provide much precision on how to apply these conditions, it does not pose a significant obstacle to the implementation of comparative assessment either. Thus, PAN Europe is in the view

[1] See Point 4 of Annex II of Regulation (EU) 1107/2009.
[2] See Article 2 of Commission Implementing Regulation (EU) 2015/408.

that further clarification on how to implement comparative assessment and when to substitute can be provided though European guidelines, without the need for the Commission to engage also in a delegation procedure.
A revision of Annex IV itself would be relevant if the Commission intended to modify the comparative assessment conditions themselves, but this could not be done without deviating from Article 50(1). Hence, to ensure a compliant and harmonised implementation of comparative assessment among Member States, the priority of the Commission should be the revision of its European guidance document. In addition to bringing practice into line with Regulation (EU) 1107/2009, this revision of the guidance document may enable substitution to occur at last.

PAN Europe's recommendations:

- ➢ The Commission should revise its European guidance document adopted in 2014 to provide any clarifications and guidance on any aspects of comparative assessment that are currently not covered by European guidance (starting with the aspects of comparative assessment covered by the EPPO standard).
- ➢ The European Commission should ensure that this review is carried out in an independent, transparent and participatory manner.
- ➢ The European Commission should establish a timetable and commit to delivering as soon as possible this revised guidance document, to ensure that Article 50 of Regulation (EC) 1107/2009 contributes to significant national reduction of the use of the most hazardous pesticides by 2030.

2. Further clarify the circumstances in which Member States *shall* perform a comparative assessment.

In accordance with Article 50(1), all applications for authorisation of products containing a candidate for substitution shall be subject to a comparative assessment. This legal obligation applies to all Member States and to all applications since 1st August 2015 pursuant to Article 2 of Commission Implementing Regulation (EU) No. 2015/408. The only circumstances in which Member States shall derogate from this general rule is "w*here it is necessary to acquire experience first through using that product in practice*" in accordance with Article 50(3).
Although paragraphs 1 and 3 of Article 50 are well reaffirmed and further detailed in the 2014 Guidance Document prepared by DG SANTE, Member States have interpreted them differently. Indeed, around half of Member States have adopted a national guidance document on comparative assessment in which they, in our view, illegally list further reasons for derogating to Article 50(1). The most significant additions are the following:

- Some Member States (e.g. Belgium) consider that their competent authorities are not required to perform a comparative assessment before granting a parallel trade permit, whereas neither Article 50 nor Article 52 indicates anything to this effect. This runs against the fact that comparative assessment is

a Member State's responsibility, depending on national alternatives, for which the zonal approach cannot be considered appropriate[3].

- With regard to mutual recognition, some Member States conduct a comparative assessment as indicated in their national guidance document (France), while others indicate in their guidance document that this is required prior to grant an authorisation but do not do so in practice (Belgium, Spain).
- A final prominent example is the handling of authorisations that contain at least one minor use. In Belgium, for example, it is considered that as soon as an application for authorisation contains a minor crop, the competent authorities are not required to conduct a comparative assessment[4]. This is clearly contrary to Article 50(1) and Annex IV, which make it clear that the consequence(s) of substitution on minor crops should be taken *into account,* and not that the risk of consequences for minor crops is a sufficient reason to exclude the very idea of substitution.

These additional derogations are a serious matter to urgently address. By further restricting the conditions under which a comparative assessment shall be conducted by their competent authorities, Member States deviate from Article 50(1) and undermine its compliant and harmonised implementation.

PAN Europe's recommendations:

- ➢ To address these enforcement issues, the new guidance document should expressly and strongly underline that in no other circumstances than those mentioned in Article 50(3) shall Member States derogate from their legal obligation to carry out a comparative assessment.
- ➢ Pending adoption of the revised guidance document, the European Commission, as guardian of the Treaties, should already alert Member States to the non-compliance of these practices, and remind them of its own obligations under the EU infringement procedure.

3. Further clarify how *regularly* Member States shall review authorisations of products containing a candidate for substitution.

While authorisations issued before 1 August 2015 are also exempt from this obligation, Member States are required under Article 50(4) to review *regularly* the authorisations granted and a*t the latest* at the time of renewal. In practice, it is important that the Commission defines what *regularly* means due to the (sometimes significantly) delays in reassessment procedures[5]. Indeed, at present, Member States are simply waiting for the renewal to perform such revision, even if reassessment procedures are unfortunately delayed by several years. However, in 2009, the legislators did not anticipate these reassessment delays when they adopted Article 50(4). Hence, Article 50(4) cannot be understood as covering authorisation periods that go far beyond the expected

[3] See page 4 of the European guidance document on Comparative Assessment.
[4] See point 9 of the Belgium guidance document.
[5] PAN Europe, Factsheet, Patterns of systematic and unlawful prolongation of toxic pesticide approvals, July 2022.

7-year period. The spirit of this article is that authorisations shall regularly be questioned and updated based on the latest technical advancement, but the practice is entirely different. Most of the product authorisations issued before 1 August 2015 have never been reviewed because of delays. These authorisations were not questioned for at least seven years.

PAN Europe's recommendation:

- ➢ To address these enforcement issues of Article 50(4), the Commission should define what *regularly* means by setting a time limit of maximum 5 years after which Member States shall (again) carry out a comparative assessment.

4. Development of EU guidance on the efficacy aspects of comparative assessment.

At present, the efficacy aspects of comparative assessment are assessed by Member States in accordance with the EPPO 271/3 standards on comparative assessment, as recommended by DG SANTE in its Guidance Document[6]. This EPPO standard and its proposed "stepwise" scheme to carry out comparative assessment are implemented by Member States. Those which adopted a national guidance document directly referring to it.

However, in several respects this standard gives an interpretation of Article 50 and Annex IV that is not compliant with Regulation (EU) 1107/2009:

- Minor use: as mentioned above, some Member States do not perform a comparative assessment for authorisation applications which cover at least one minor use. This incorrect interpretation of Article 50(1) is encouraged by the EPPO standard, which suggests that Member States are free to choose whether they consider it appropriate to perform a comparative assessment for minor uses. The EPPO decision scheme states the following: "*Are minor uses sufficient to stop CA, according to the available national CA procedure? If yes, stop CA*" (page 4). However, it is clear in both Article 50 and Annex IV that a comparative assessment must be performed, even in the presence of minor uses, and that the consequences on minor uses must be *taken into account* in the comparative analysis. However, Article 50 and Annex IV do not state that these consequences alone shall stop the comparative assessment.

- Resistance Risk Management:

- Article 50(1) requires Member States to assess whether "t*he 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*". Likewise, regarding alternatives, Annex IV mentions "*other methods or the chemical diversity of the active substances*". According to Regulation (EU) 1107/2009, it is therefore clear that both non- chemical and chemical alternatives must be considered, and that chemical diversity is not necessarily, i.e. not in all circumstances, required for

[6] See pages 3 and 11 of the European guidance document on Comparative Assessment.

substitution to apply. Yet, as demonstrated in our latest report, the scheme proposed by the EPPO standard, which is implemented by all Member States, runs against these two elements of the Regulation. Indeed, the standard recommends Member States to stop comparative assessment, in all circumstances, when the chemical diversity is considered insufficient to manage the resistance risk, disregarding the availability of non-chemical alternatives and their role in the fight against pest resistance. This approach does not comply with Article 50 and Annex IV and dismisses *de facto* the efficiency of non-chemical alternatives. A compliant interpretation of this provision of Article 50(1) would be that:

- Non-chemical alternatives' role in the fight against pest resistance is assessed in priority in line with the Integrated Pest management (IPM) principles[7] and scientific demonstration that these are the best mean to fight resistance;
- Chemical biodiversity should be assessed as a second step, when non-chemical alternatives are not available and the resistance risk in the target organism is demonstrated.

- Further, EPPO standard recommends assessing the chemical diversity in the light of the available chemical modes of actions, rather than of the available chemical active substances[8]. Apart from a few industry-funded scientific publications, this approach is not underpinned by science. This is a restrictive interpretation of the notion of chemical diversity which has no legal ground. Regulation (EC) 1107/2009 does not provide a definition of the "*chemical diversity"*, neither in Article 3 nor in Article 50. However, modes of action are not mentioned anywhere in the text of the Regulation and its Annex IV refers explicitly to "*the chemical diversity of the active substances"*. This shift towards the notion of chemical mode of action is therefore not legal based, but neither is it scientifically based (see box below). In practice, the consequences are significant as it makes it way more difficult to apply substitution.
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Modes of action: why this classification cannot be used for regulatory purpose

The mode of action of a pesticide refers to the way in which it causes physiological disruption in the target organism (nerve disruption, growth impairment, etc.). The pesticide industry, through various Resistance Action Committees, has established this classification for different classes of synthetic pesticides including fungicides, herbicides and insecticides. This classification system has never been approved by the EU or been used for regulatory purposes in the context of Regulation (EU) No. 1107/2009. This latter requires by contrast a substance-by-substance approach, which implies that such a classification cannot prejudge the conclusions of the risk assessment.

[7] IPM has been mandatory since 2014, under Directive (EU) 128/2009.

[8] *Based on expert judgement it is recommended that in a low resistance risk situation a sustainable resistance management strategy includes at least two MoAs. However, in the case where there is evidence of a medium risk of resistance to one or more of these PPPs or a medium risk of resistance in the target organism, at least three MoA are recommended. In the case where there is evidence of a high risk of resistance to one or more of these PPPs or a high risk of resistance in the target organism, at least 4 modes of action are recommended"*

According to these Resistance Action Committees, target organisms that develop resistance against a synthetic pesticide operating according to a particular mode of action develop systematic cross-resistance to pesticides that share that same mode of action. Thus, having chemical diversity, in the sense of a diversity of synthetic pesticides, would be insufficient to counter the emergence of (cross-)resistance in the target organism. To guard against such a risk, it would be crucial to have a diversity of chemical modes of action, i.e. a diversity of families of synthetic pesticides, as defined and classified by the above-mentioned Committees. These assumptions have been taken up by the EPPO standard which further defines the degree of diversity of chemical modes of action required to counteract cross-resistance. This ranges from two modes of action in case of low risk of resistance to at least four in case of high risk of resistance.

From a scientific point of view, the assumptions that 1) the development of cross-resistance in the target organism is systematic and 2) only the use of a diversity of modes of action as extrapolated by EPPO can counteract this cross-resistance are incorrect.

- Firstly, cross-resistance (within the same family of pesticides sharing the same mode of action) is not a widespread and systematic process. Such resistance may indeed develop, but this process is variable depending on the substance and the pest concerned, and therefore remains to be demonstrated on a case-by-case basis during the comparative assessment, using national field data. In the absence of such empirical evidence, competent authorities should not be able to reject substitution on the basis of theoretical possibility or uncertainty about the existence of cross-resistance.
- Secondly, it has been established by the scientific community[9] that the use of chemical diversity tends in the end to increase the resistance of target organisms rather than to counter it, especially when the approach consists of focusing on a diversity of modes of action and not on synthetic pesticides. On the contrary, the use of non-chemical alternatives, in line with the principle of integrated pest management established by Directive (EU) 128/2009, can overcome such resistance. In other words, the use of the concept of diversity of chemical modes of action and the obstruction of substitution does not guarantee better resistance management in target organisms.
- Thirdly, the EPPO standard is not based on any publication apart from the article 'Rotteveel et al., 2011' which itself only relies on industry work to justify this need for x chemical modes of action. In our view, this article lacks a scientific basis and the number of modes of action required is set too arbitrarily.

[9] 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: 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: 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

Based on the few information publicly available[10], it appears that these two efficacy-related conditions[11], wrongly interpreted by EPPO are the reason Member States stop comparative assessment.

- Practical and economic disadvantages:

- Point 3 of Annex IV is providing a definition, listing a series of significant practical disadvantages but also establishing their scope: "*Significant practical or economic disadvantage to the user is defined as a major quantifiable impairment of working practices or business activity leading to inability to maintain sufficient control of the target organism. Such a major impairment might be, for example, where no technical facilities for the use of the alternative are available or economically feasible*". In contrast, the stage D of EPPO's standard recommends Member States to stop comparative assessment when there are "*wider consequences for maintaining effective crop protection, including e.g. the security of future pest control, that might influence the decision of making a substitution and/or adverse impacts for non-crop uses*". This is beyond what is required from Annex IV.
- Further, EPPO's standard is not providing guidance on how this practical or economic disadvantage "*situation shall be substantiated*", nor does the European guidance document.

The fact that Member States rely closely on this EPPO standard is therefore problematic in many respects resulting from its lack of compliance with Article 50 and Annex IV. In our last report published in September 2022 we evidenced that the setting conditions of this standard by EPPO did not meet the current independence, transparency and participation requirements of the EU. More concretely, EPPO did not check whether the experts involved in the process had any interest in the matter discussed, i.e. the marketing of candidates for substitution.

General recommendations:

- ➢ As a general recommendation, we ask the Commission to stop recommending Member States to build their comparative assessment procedures on this EPPO's standard and to instead develop European guidance on how to interpret the efficiency-related aspect of comparative assessment. Any entity involved in the process shall this time meet the independence standards of the EU, in line with Article 17(1), (3) of the consolidated version of the Treaty on European Union and the judgement of the EU Court of Justice of 21 November 1991.
- ➢ Article 50(1) states that comparative is intended to "*weigh[ing] up the risks and benefits*". The Commission should explain how Member States should balance this with the cumulative nature of the comparative assessment conditions laid down later in the same Article 50(1) and Annex IV, and further investigate the compatibility of the current stepwise approach with this weighing objective.

[10] See REFIT supporting study, feedback of Member States to EPPO and PAN Europe's report.
[11] In particular management of the risk of resistance and consequences on minor uses.

Specific recommendations:

- Minor use: The commission should explain how Member States shall interpret the formulation *"taken into account"* of Article 50(1). It should also specify the nature of the consequences to be considered and propose criteria for determining the seriousness

- Resistance risk management:
  - Chemical diversity should be defined and assessed in the light of available active substances, in accordance with the principle of proportionality, in line with the formulation *"where relevant"* of Article 50(1).
  - To reflect the "*or*" conjunction of Article 50(1), it should be very clear that this chemical diversity is not necessary in all circumstances.
  - In line with IPM principles laid down in Annex III of Directive (EU) 128/2009, the guidance document should recommend Member States to evaluate non-chemical alternatives first and stop the comparative risk assessment when non-chemical alternatives meet the conditions laid down in Article 50(1).

5. Reversing the burden of proof

Both Article 50 and Annex IV remain silent on who bears the responsibility to provide data on the different aspects of comparative assessment. However, the Guidance Document adopted by DG Sante stressed the following: "*The information provided by authorisation holders can be helpful, but should always be analysed and supplemented by the Member State".*

Hence, it seems like a significant part of the work is currently in the hands of the national competent authorities. These latter have however in practice limited capacities to proceed with extensive research and analysis. On top of that, the EPPO standard states that "*where expert judgement would not be sufficient to address significant information gaps, the CA may not be meaningfully performed and completed. In this event, substitution of the candidate for that use is (provisionally) not possible*". This way, the EPPO standard takes advantage of the lack of resources in Member States to encourage Member States not to carry out a comparative assessment, although this is mandatory under Article 50(1).

PAN Europe's recommendation:

- The burden of proving that a product containing a candidate for substitution cannot be substituted should be the responsibility of the applicant for the authorisation of this product.
- The data provided should be robust, relevant and specific enough for comparative assessment purposes.
- When these points are insufficiently demonstrated, the authorisation should not be granted and substitution should occur. In other words, the benefit of the doubt should stop benefitting the applicant for the authorisation of a product containing a candidate for substitution.

In practice, this would mean the following for instance:

- ➢ When one non-chemical alternative exists, the competent authorities should reject the authorisation application, unless the applicant is able to demonstrate that xxx condition laid down in Article 50(1) is not met;
- ➢ When a diversity of xxx substances is available, competent authorities should stop the comparative assessment and reject the authorisation application unless the applicant is able to demonstrate, with national data, that xxx organisms are resistant to xxx substances etc.

6. Voluntary substitution (article 50(2)) should be covered by the new EU Guidance Document.

In accordance with Article 50(2), *"Member States may in exceptional cases also apply the provisions of paragraph 1 of this Article when evaluating an application for authorisation of a plant protection product not containing a candidate for substitution or a low-risk active substance, if a non-chemical control or prevention method exists for the same use and it is in general use in that Member State."*.

The actual Guidance Document of DG SANTE does not provide guidance on Article 50(2). As a result, some Member States make it a general policy to exclude the possibility to perform voluntary substitutions[12]. As the EU is now committed to moving towards a non-toxic environment and sustainable food system, a provision like Article 50(2) that supports such transitions should not be left unimplemented. In practice, the conditions of comparative assessment applying to Article 50(2) are the same as for Article 50(1). The Commission's role would be limited to defining the conditions in which such voluntary substitution may take place.

PAN Europe's recommendation:

- ➢ The new Guidance Document should provide guidance on how to interpret Article 50(2). Namely, the Commission should explain what being *"in general use"* means and list examples of exceptional cases.

7. National alignment with the updated European Guidance Document

As highlighted earlier in this document, on several aspects, the current national guidance documents run against the provisions of Article 50 and Annex IV, and against their implementation.

[12] Cf. National Guidance Documents: Spain page 19: "Spain will not be undertaking any of the optional comparative assessments allowed for by Article 50(2)" or Belgium page 7: "SPF will as a matter of principle not be undertaking any of the optional comparative assessments allowed for by Article 50(2).

PAN Europe's recommendation:

- The revision of the EU Guidance Document should be followed up by an alignment of all national practices. The Commission should encourage Member States to act in that sense in the shortest delay.

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Pesticide Action Network (PANEurope) 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.