Opinion on the European Union's policy on pesticides containing active substances classified as "candidates for substitution": a system favorable to public health and the environment too rarely implemented

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Opinion deliberated in plenary session on September 21 and validated digitally on October 9, 2023

Summary

The cnDAspe was asked for an opinion on April 14, 2023 by a group of French parliamentarians (French Assemblies and European Parliament) due to "an incorrect application of the provisions of article 50 of regulation (EC)N°1107/2009" which stipulates that Member States (MS) must ensure that they do not authorize or reduce the use, for a given crop, of pesticide products containing "candidates for substitution" (CfS), i.e. products deemed most hazardous, when alternatives exist that are less hazardous for human health and the environment.

To produce its opinion, the cnDAspe set up a group of experts who conducted a series of hearings (15 of the twenty or so organizations and personalities invited responded favorably) within a tight timeframe. The collective opinion was submitted to three European reviewers, two internal reviewers and then to the cnDAspe plenary assembly for adoption.

Currently, 53 active substances are listed as candidates for substitution; however, according to a survey conducted by the European Commission in 2021, of the 3,100 cases of possible substitution, 32 resulted in actual substitution in three countries: Germany, Croatia and France. The commission recognized that "the rules on candidate active substances for substitution are both inefficient and ineffective".

In the **preamble** to this opinion, which sets out the framework for the referral, cnDAspe has endeavored to recall the European legal framework that determines the principles of substitution. This framework is underpinned by the provisions on "a high level of protection for human health and the environment" contained in the Treaties that make up the European Union, which also recognize the precautionary principle. In 2020, these protection objectives were taken up in the European "Farm to Fork" and Biodiversity strategies proposed by the European Commission, which set a target of a 50% reduction in the use of pesticides by 2030. The secondary legislation on pesticides consists of Regulation (EC) 1107/2009 and Directive 2009/128/EC. The substitution of CfS is based on the implementation of a comparative assessment provided for in Article 50 and Annex IV of Regulation 1107/2009, and based on a methodological guide derived from the work of the European and Mediterranean Plant Protection Organization (EPPO), considered as a de facto delegate. This inter-governmental

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organization (of which the European Union is not a member, but which sits as an observer) is not subject to the principles of impartiality and transparency prescribed by European regulations.

cnDAspe is aware that this opinion is delivered in the context of major public health issues, as highlighted by the report from the French compensation fund for victims of plant protection products, which notes that "the number of claims for compensation for illness following occupational exposure to pesticides has doubled in the space of a year", and of environmental impact, with a confirmed drop in insect biomass and diversity, and widespread contamination of all water compartments (including marine waters).

After recalling that the deontology of public expertise in public health and the environment are at the heart of the cnDAspe's missions, it produced an analysis of the deontological and scientific issues relating to the referral.

While the regulatory framework is unique in the world, its implementation by Member States (MS) is limited, given the difficult-to-document criteria defined by the steps described in the EPPO comparative assessment guide, which is de facto a reference text. These steps are imposed on alternative solutions - same efficacy (which is stated to prevail over others), absence of economic/practical disadvantages, minimization of resistance, preservation of minor uses. In fact, chemical solutions are favored, whereas alternatives generally involve a range of solutions. What's more, the negative externalities associated with the use of CfS (impact on health and the environment, clean-up costs, etc.) are not taken into account. Although compulsory, comparative assessment is not systematically implemented by the Member States. The comparative assessment system assumes that an equal and sufficient amount of knowledge is available concerning chemical and non-chemical solutions, which is not the case. MS have the option of modifying this guide, but no rules have been put in place to inform other competent authorities of the reasons for such modifications. Although this guide has been revised three times since 2011, it has been produced by working groups that meet the criteria of competence, but not the current requirements in terms of transparency and management of links of interest. Finally, this guide was adopted by SCOPAFF without any right of review by the European Parliament.

The document "Draft proposal for amendment of Regulation (EC) 1107/2009 - Annex IV on comparative assessment" of the EU Commission proposes substantial advances, notably by considering that "widely used" alternative methods and techniques can be deemed "safe" (for health and the environment) and "effective" (for pest control).

Substitution of the most hazardous pesticides is covered by the regulatory regime for pesticides - Article 50 of Regulation 1107/2009. It is very little influenced by the other strand of pesticide policy - Directive 2009/128 on the "sustainable use of pesticides". The provisions relating to the marketing authorization of pesticides are not designed as instruments for achieving the objectives that prevail on the other side of this policy.

Finally, cnDAspe highlights the significant advances shown by studies on Integrated Pest Management (IPM) strategies using low quantities of pesticides, on their feasibility and benefits for the protection of crops, soils and biodiversity, and on the adoption of these strategies through knowledge exchange and peer learning among farmers. The IPMWORKS project has now been launched, bringing together 31 partners in 16 European countries.

In concluding its analysis, cnDAspe formulated its **recommendations** grouped under 6 major headings, identifying responsibility for action:

- Increase monitoring of the application of the substitution procedure for the most hazardous pesticides by the competent authorities in the Member States, and reinforce their obligations.
- Revise the comparative assessment criteria set out in Annex IV of Regulation 1107/2009: under the responsibility of the European Commission.

- Promote research and the production of information on alternatives to candidate substances for substitution on a European scale: under the responsibility of the Member States, their agencies and the European Commission.
- Revise the EPPO guidance document for the examination by the competent authorities of the Member States of the possible substitution of "the most hazardous pesticides": under the scientific responsibility of EFSA.
- Review the conditions for the production of technical documents for the implementation of Community policies relating to the marketing of pesticides, and move towards a new form of governance: on the initiative of the European Commission.
- Reform the European regulatory framework for pesticides to ensure effective substitution of CfS substances, in line with the objective of protecting human health and the environment: on the initiative of the European Commission.

Summary

Preamble

The Commission nationale de déontologie et des alertes en matière de santé publique et d'environnement (cnDAspe) was referred to (see the text of the referral in Appendix A) by several Members of the European Parliament, the French National Assembly and Senate, on April 14, 2023, pursuant to Article 4 of Law no. 2013-316 of April 16, 2013 on the independence of expertise in health and environmental matters and the protection of whistleblowers, due to "an incorrect application of the provisions of Article 50 of Regulation (EC) n°1107/2009" (hereinafter referred to as "the Regulation"), which stipulates that Member States (MS) must ensure that they do not authorize or reduce the use, for a given crop, of pesticide products containing "candidates for substitution", i.e. pesticides deemed to be the most hazardous, when less hazardous alternatives for human health and biodiversity make this possible.

More specifically, the authors of the referral would like cnDAspe to examine "all the information needed to establish transparency with regard to compliance with the expected rules of independence[1], compliance with the principle of substitution and the procedures governing its implementation, and compliance with the health and environmental protection objectives set by the legislator".

- **The legal framework determining the principles of substitution**

Today, the European Union is the main regulator of the conditions under which pesticides are used. Under the provisions of its founding treaties, the Union is developing its policy in this field with the aim of "**a high level of protection of human health**[2]" and "**protection of the environment**[3]". Moreover, according to the Court of Justice of the European Union-Luxembourg, "among the goods or interests protected by Article 36 [TFEU], the health and life of humans rank first[4]", and this overriding public interest takes precedence over economic interests[5]. It should also be remembered that the **precautionary principle** is recognized by the Treaties. More specifically, Article 191 states that "Union policy on the environment shall aim at a high level of protection, taking into account the diversity of situations in the various regions of the Union. It is based on the principles of precaution and preventive action".

Secondary legislation, which implements EU policy (such as, in particular, that applicable to pesticides), must respect the objectives and principles set out here and deriving from primary legislation**. In this respect, the so-called "pesticides package" contains a reiteration of the objectives set out in primary law, which take precedence over all others. It is against this backdrop that all the texts in the package should be read.**

In particular, the package comprises **Regulation (EC) No 1107/2009** of the European Parliament and of the Council concerning the placing of plant protection products on the market. It came into force on June 14, 2011, and repealed Directive 91/414/EEC on the same subject. The choice of a regulation instead of a directive is significant: it simplifies the application of European law, as it does not require transposition by Member States (MS). Directly applicable, it reinforces the uniformity of marketing conditions between each of them. The second major text in the "package" is **Directive 2009/128/EC (SUD**), establishing a

[1] Note from cnDAspe: this refers to the expected independence of the procedure for drawing up the guidelines that determine the substitution criteria

[2] Art. 168 § 1 of TFEU

[3] Art. 191 TFEU. Furthermore, and more specifically, "a high level of environmental protection and the improvement of the quality of the environment must be integrated into the Union's policies and ensured in accordance with the principle of sustainable development", in accordance with Article 37 of the Charter of Fundamental Rights of the Union.

[4] EUCJ, 10 nov. 1994, aff. C-320/93, *Ortscheit*.

[5] EUGJ, 12 jul. 1996, aff. C-180/96, UK vs/ *Commission*.

framework for Community action to achieve a sustainable use of pesticides. It applies to plant protection products as well as biocides.

These texts pursue clear objectives, which are worth recalling in order to understand their purpose and best interpret the meaning of their provisions; provisions which the French National Assembly may, moreover, have considered "complex and insufficiently protective[6]".
In this respect, Article 1§4 of Regulation 1107/2009 states that "the provisions of this Regulation shall be based on the precautionary principle in order to prevent active substances or products placed on the market from adversely affecting human and animal health or the environment. In particular, Member States are not prevented from applying the precautionary principle where there is scientific uncertainty about the risks to human or animal health or the environment posed by plant protection products to be authorized on their territory.[7]"

Furthermore, Recital 8 of the Regulation recalls that the text "aims to ensure a high level of protection of human and animal health and the environment, and at the same time to preserve the competitiveness of Community agriculture (...). The precautionary principle should be applied and this Regulation should ensure that industry demonstrates that substances or products manufactured or placed on the market have *no harmful effects on human or animal health and no unacceptable effects on the environment*". Recital 10 goes on to state that "substances should only be included in plant protection products if it has been demonstrated that they are of *clear benefit to plant production and are not expected to have any harmful effects on human or animal health or any unacceptable effects on the environment*".

More specifically, on the question of products containing the most hazardous active substances, recital 19 of the same regulation states that "certain active substances with certain properties should be identified at Community level as substances to be considered for substitution. Member States should regularly review plant protection products containing such active substances with a view to replacing them by plant protection products containing active substances requiring less mitigation, or by non-chemical methods of prevention or control".

Completing the edifice of protective objectives, Recital 24 of the Regulation stipulates that "it should be demonstrated, before plant protection products are placed on the market, that they are of clear benefit to plant production and have no harmful effect on human or animal health, in particular that of vulnerable groups, or any unacceptable effect on the environment". These conditions are expressly set out in Article 4 of Regulation 1107/2009 on the criteria for approval of active substances.
Turning now to the SUD Directive, Article 1 is crystal clear on its objectives, stating that it "establishes a framework for achieving a use of pesticides compatible with sustainable development by reducing the risks and impacts of pesticides on human health and the environment, and by encouraging the use of integrated pest management and of alternative methods or techniques, such as non-chemical alternatives to pesticides".

[6] Rapp. AN n° 852, 4 avr. 2018: : https://www.assemblee-nationale.fr/dyn/15/rapports/micphyto/l15b0852_rapport-information.
[7] The precautionary principle is also referred to in article 13 in connection with the regulations governing the approval of active substances.

The vigour of these principles contrasts with the words of French parliamentarians on the "ineffectiveness of Article 50 of Regulation 1107/2009", in the words of the French parliamentarians[8].

- **The substitution of CfS is based on the implementation of a comparative assessment provided for in Article 50 and Annex IV of Regulation 1107/2009 and based on the work of EPPO.**

EU policy on the substitution of "more hazardous" pesticides, as set out in Regulation 1107/2009 (Article 50 and Annex IV), requires Member States to carry out a comparative assessment when examining an application for authorization of a plant protection product (PPP) containing a Candidate for Substitution (CfS) active substance. Member States shall not authorize or restrict the use of a product containing a CfS substance for a particular crop where the comparative assessment demonstrates that :

- a non-chemical product or method already exists that is significantly safer for human or animal health, or for the environment ;
- substitution does not present significant or major economic or practical disadvantages;
- the chemical diversity of available active substances is adequate to minimize resistance (i.e. the chemical substances offer different modes of action);
- the consequences for minor use authorizations are taken into account[9].

More recently (2020[10]), the European Commission's "Farm to Fork" and Biodiversity strategies set a target of reducing pesticide use by 50% by 2030. Either one aims for a 50% reduction by halving all pesticides while retaining the full range, or one aims for a 50% reduction by doing away with CfS, which must then be replaced by non-chemical levers. In this context, each approach mobilizes the regulatory framework differently, but products containing active substances classified as "candidates for substitution", as mentioned in recital 19 of the Regulation and defined in point 4 of its Annex II, can only be given priority for this purpose.

Despite this regulatory framework, data published by the European Commission based on a survey of the competent authorities in the various MS conducted in the autumn of 2021 reveals a very low number of cases of substitution or modification of the marketing authorization conditions for pesticides classified as "candidates for substitution"[11]. According to this survey, to which only 16 MS responded, only 32 cases of substitution were reported (including 27 cases of refusal of mutual recognition), and 6 cases of amendments to the marketing authorization previously granted. These cases of decided substitutions or amendments originate from a very small number of MS, which would tend to underline the gap in adoption of the regulation between MS and the very spirit of the common rules enacted. The situation in other MS is not known. In addition, some Member States grant derogations that go beyond the provisions of

[8] Rapp. AN n° 852, 4 avr. 2018 : https://www.assemblee-nationale.fr/dyn/15/rapports/micphyto/l15b0852_rapport-information

[9] Annex IV of the Regulations provides more detailed explanations on the conditions for substitution:
- a significant difference in risk is identified on a case-by-case basis. The properties of the active substance and the PPP, the possibility of exposure and other factors such as the severity of restrictions imposed must be taken into account;
- for the environment, a factor of at least 10 x the difference in risk is considered significant;
- significant practical or economic disadvantage is defined as a major qualifying alteration in working practices or business activity.

[10] https://food.ec.europa.eu/plants/pesticides/sustainable-use-pesticides/farm-fork-targets-progress/eu-trends_en

[11] Information provided in response to a question from Members of the European Parliament. See Appendix E for detailed data obtained by PAN-Europe on the results of the survey conducted in 2021 by the European Commission.

the Regulation (article 50(3)), sometimes leading to appeals to the courts. An initial list of "candidate active substances for substitution" was drawn up in 2015 on the basis of point 4 of Annex II of the Regulation (see Annex F1 of this document). This list currently comprises 53 substances and is regularly updated following the finalization of EFSA's conclusions and decisions to renew or approve these active substances taken by the Commission's Standing Committee on Plants, Animals, Food and Feed (SCoPAFF). France has drawn up a list of "**candidate for exclusion**" molecules, containing those that are really very harmful, and which pay the highest level of diffuse pollution tax. This list has no European equivalent[12].

Article 24 and Annex II of the Regulation define a "candidate for substitution" as an active substance that meets one or more of the criteria set out in point 4 of Annex II (see exhibit).

- its Acceptable Daily Intake (ADI), Acute Reference Dose (ARfD) or Acceptable Occupational Exposure Level (AOEL) is significantly lower than those of the majority of approved active substances within the substance groups/use categories,
- it meets at least two criteria to be considered a PBT (Persistent, Bioaccumulative and Toxic) substance,
- there are reasons for concern linked to the nature of the critical effects (such as neurotoxic or immunotoxic developmental effects) which, in combination with the use or exposure patterns, correspond to use situations that could be of concern, e.g. via groundwater, even with very restrictive risk management measures,
- it contains a significant proportion of non-active isomers,
- it is or will be classified as a category 1A or 1B carcinogen,
- it is or will be classified as a category 1A or 1B reproductive toxicant
- it is considered to have endocrine disrupting properties likely to cause adverse effects in humans.

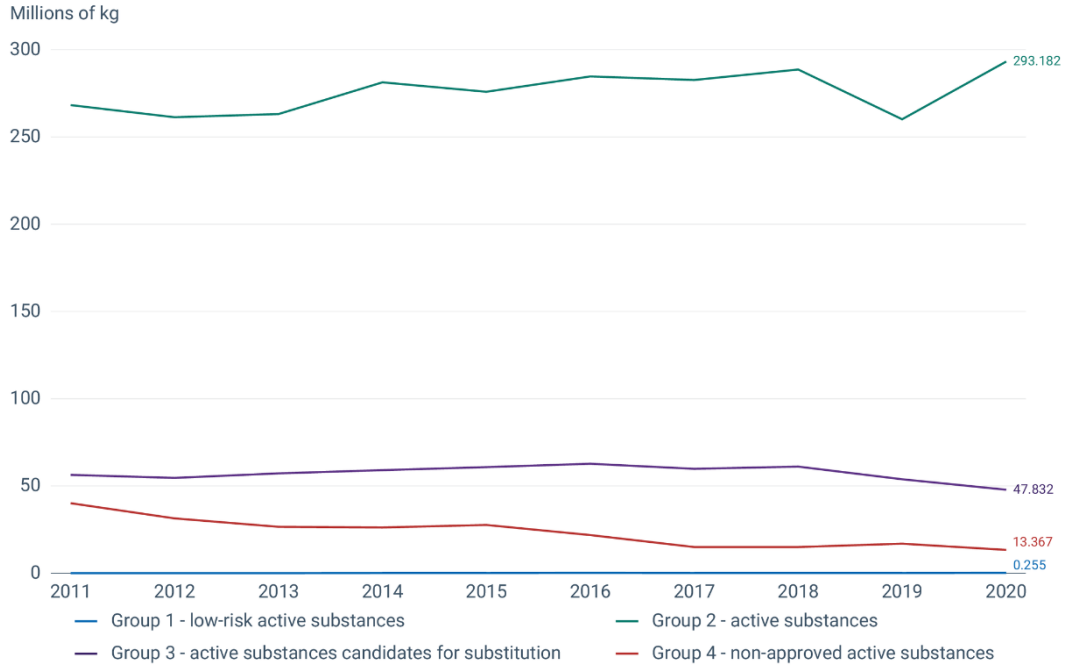
The reference document "*Guidance document on Comparative Assessment and Substitution of PPP* " published in 2014 - based on the protocol drafted in 2011 by the European and Mediterranean Plant Protection Organization (EPPO) - aimed to provide the various MS with a practical methodological framework for conducting the comparative analysis. The 16-page document details all the conditions to be met in order to select an alternative solution for a given use of a product containing a CfS substance. It also provides a few details on the state of mind in which this procedure should be implemented. Its objective is defined as follows: "*General objective: Comparative assessment and substitution aim to reduce risks by progressively replacing products containing substances that are candidates for substitution with methods and products of lesser concern, in the interests of protecting human or animal health and the environment*". It then goes on to set out a number of points which suggest that this system should be used sparingly. For example, the following elements support a dissuasive or restrictive connotation (relative to the ambitions later defended in the green deal): "*Substitution should be limited to cases where the benefit is obvious", "if an initial comparison of the risks posed by different products reveals that there is only a marginal difference in risk, further investigation could be avoided*", or "*Given the obvious advantages of a stepwise approach, it is suggested that where there is reason to believe, at the start of the comparative assessment, that there might be a problem in a certain area, for example the development of resistance, it may be useful to start the assessment in that particular area*".

[12] https://www.consultations-publiques.developpement-durable.gouv.fr/projet-d-arrete-rpd-pour-l-annee-2023-modifiant-l-a2765.html

The hearings held by the group of experts showed that there is a discrepancy between the spirit, which expresses a willingness to move, and its implementation, which forces immobilism, no doubt in equal measure for practical reasons and out of conservatism. For example, molecules known to be carcinogenic, mutagenic, reprotoxic or endocrine-disrupting are still on the market.

According to a report published in 2022 by the European Environment Agency, pesticide sales in the EU-27 remained relatively stable at around 350,000 tons per year between 2011 and 2020 (see figure 1). This stability, or here a very slow evolution, applies to pesticides containing Cfs active substances (group 3)[13].

Figure 1. Pesticide sales in the EU-27 by categorisation of active substances



Source : Eurostat, 2022b, 'Pesticide sales by categorisation of active substances', Eurostat Data Browser (https://ec.europa.eu/eurostat/databrowser/view/AEI_PESTSAL_RSK/default/table?lang=en&category=agr.aei.aei_pes) accessed 12 January 2023

The European Commission has recognized the need to change guidance on comparative assessment. The final report of the REFIT (regulatory fitness and performance programme) published in May 2020 acknowledged that "the rules on candidate active substances for substitution are both inefficient and ineffective"[14].

In 2018, the European and Mediterranean Plant Protection Organization (EPPO) workshop in Lisbon had already identified the knowledge gaps deemed most important based on responses from 19 EPPO member states, these gaps concerning: the availability and clarification of non-chemical alternative methods, particularly with regard to their efficacy, economy and resistance management; integrated pest management programs; the spectrum of target pests;

[13] The indicator used in this notice is the quantity of active substance (QSA). Other indicators exist at EU level. In France, the NODU (number of unit doses used) is used in addition to the IFT (index of treatment frequency). See the Inspectorate General's report on the financial assessment of the ECOPHYTO plan https://agriculture.gouv.fr/evaluation-des-actions-financieres-du-programme-ecophyto

[14] Report from the Commission to the European Parliament and to the Council. Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides https://eur- lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0208&from=EN

the comparison of single active substances with co-formulated products and tank mixes; the wider impact, anticipation of consequences.

These conclusions have also been highlighted during the Portuguese presidency of the EU in 2021. A revision of the EPPO guide has been proposed, not to change the substantive outcome, but to reorganize the order of assessment steps to potentially facilitate analysis, by clarifying missing steps in the decision tree, and moving towards a circular decision tree instead of a step-by-step approach.

Finally, up to the decision of the EUCJ of January the 29th 2023, MS could grant emergency authorizations for products that have been withdrawn from the market, for example because they did not meet all the criteria (e.g. CfS), or because they did not have adequate commercial potential for the applicants[15]. The Commission maintains a database of emergency authorizations granted by MS. It uses these data to calculate the Harmonized Risk Indicator 2 (HHR2).

The ineffectiveness of substitution raises questions about the modalities about the way in which the European Union has since 2014 adopted the protocol laying down the conditions to be met by alternative products or methods likely to replace the pesticide candidate for substitution, a protocol drawn up in 2011 by EPPO. This inter-governmental organization is part of the International Plant Protection Convention (IPPC), a treaty established under the auspices of the Food and Agriculture Organization of the United Nations (FAO). EPPO (of which the European Union is not a member, but which sits as an observer) is not subject to the principles of impartiality and transparency prescribed by European regulations. Impartiality and transparency are cardinal principles of the deontology of expertise in support of public policy[16], and make science-based choices possible. On this solid basis, duly informed decision-makers can then deliberate and arbitrate according to their own criteria.

This particular organization - the role assigned to EPPO in drafting normative texts - is specific to the plant sector. There are two opposing interpretations of EPPO's role and contribution to the process. For some, the fact that Europe adopts and relies on their 'guidance' gives EPPO a fairly direct (delegated) responsibility, which should lead it to respect the (same) deontological rules that apply to its standard-setting bodies. For others, EPPO's work constitutes the basis on which the MS (and other European authorities) have had the opportunity to express their views and assume full responsibility for their adoption. In this second configuration, EPPO cannot be held responsible or committed; it provides a framework for reflection which Europe is free to adopt or reject.

More generally, the production of standards is entrusted to standardization bodies: national (AFNOR in France), European (CEN) and international (ISO). In France, standardization is governed by decree no. 2009-697 of June 16, 2009. AFNOR is an association recognized as being in the public interest, whose "vocation is to bring together all private and public economic and social players interested in the development, promotion and dissemination of standardization. Its aim is to provide reference documents drawn up in a consensual manner by all interested parties". Its Board of Directors (BOD) includes representatives of companies, ministries and local authorities, social partners, consumer associations, non-governmental organizations (NGOs) and qualified personalities. The Board can call on the support of an Ethics Committee,

[15] Article 53.1 states: "By way of derogation from Article 28, in special circumstances, a Member State may authorize, for a period not exceeding 120 days, the placing on the market of plant protection products for limited and controlled use, where such a measure appears necessary because of a danger which cannot be contained by other reasonable means. The Member State concerned shall immediately inform the other Member States and the Commission of the measure taken, providing detailed information on the situation and any measures taken to ensure consumer safety."
[16] See Key elements of the deontology of public expertise underlying the cnDAspe's mission

which is responsible for overseeing collective and individual ethical provisions. The Interministerial Standards Delegate acts as a government commissioner.

Standardization committees are set up at the request of interested French parties, or in response to a request from CEN or ISO. They are representative of all categories of interest - suppliers - manufacturers - intermediaries - users - regulatory authorities - public policy-makers - beneficiaries. Standards development work is based on consensus. The texts thus drafted are the subject of a public inquiry; the response to all comments is public, and if any are rejected, the reasons are given. If the standards are intended to be mandatory and cited in a regulatory text, the relevant public authorities are also consulted. Once approved, standards are published. They are systematically re-examined at intervals defined by the standardization organization's procedures (5 years for Afnor).

In the regulatory field, the competent authorities rely either on standards drawn up by standards bodies, and these texts are made mandatory, or on texts produced by the official bodies they have designated as being in charge of scientific assessment.

This is why cnDAspe has been asked by members of parliament to conduct a critical analysis of this protocol, the conditions under which it was endorsed by the EU, and the conditions of its implementation by the competent authorities in the MS. It has also been asked to formulate recommendations based on this analysis, with a view to restoring this procedure for the substitution of "hazardous pesticides" to its original purpose of encouraging the use of other approaches to controlling "harmful organisms" than pesticides, in particular agronomic and biocontrol approaches.

This referral is part of the forthcoming revision of these provisions relating to the Substitution of "more hazardous" pesticides, with in particular, at the time of writing, a consultation organized by the European Commission on draft amendments to Annex IV of the Regulation called for by its Article 50.

- **The health and environmental challenges of substitution**

The cnDAspe points out that this referral is being made in the context whose impact on health and the environment is only beginning to be measured.

As far as France is concerned, data on the impact in terms of public health are available in the activity report of the pesticide victims' compensation fund[17]. The latest report, dated 2022 and based on 2021 data, lists 650 claims for compensation, 178 claims for recognition of occupational diseases and 8 claims for prenatal malformations. The list of occupational diseases includes hematological malignancies such as non-Hodgkin's lymphoma, Parkinson's disease and prostate cancer. The report highlights the "doubling in the space of one year of the number of claims for compensation for illnesses resulting from occupational exposure to pesticides", and points out that "the victims are mainly **agricultural workers aged over 50 in the mixed farming and livestock sectors**, cereal growing and viticulture ... **less than 8% of claims concern women**, and very few claims have yet been filed for children exposed during the prenatal period as a result of their parents' activity". In their report[18] prefiguring the creation of this fund, the Inspectorates General pointed out that, out of a potential 100,000 people in the agricultural sector, 10,000 were potentially concerned about developing a pathology linked to pesticide use, based in particular on figures from the Esteban cohort study. The difficulty of documenting the causal link between the declared pathology and exposure,

[17] https://fonds-indemnisation-pesticides.fr/actualites/rapport-dactivite-du-fonds-2022/

[18] Cgaaer_17069_2018_rapport.pdf (translation): "*if we retain the population exposed to chemical risks, and extrapolate the data concerning the two main occupational disease recognition tables, the population potentially suffering from diseases linked to plant protection products would be around 10,000 people*."

and the delay in declaring symptoms - between 10 and 40 years depending on the occupational disease - may explain this important under-reporting.

Due to the time constraint of this expertise, the expert group could not document the situation at European level.

As regards the endocrine disrupting effects[19] associated with usage of pesticide, the impact on human health has yet to be quantified. However, data from Santé Publique France show that impregnation of the population with pesticides can be significant. For example, "*in Esteban, pyrethroid concentrations in children were higher than those measured in adults. All metabolites except F-PBA were quantified at 99% or more in the adult and child populations*".

Numerous scientific studies and collective assessments have reported on the impact of pesticides on the environment, the coverage of its functionalities (including pollination) and the state of its biodiversity. We won't go into this in detail, as it's not the subject of the present referral, but let's recall the urgent nature of the situation as described by the scientific community:

- A confirmed decline in insect biomass and diversity[20].
- widespread contamination of all water compartments (including marine)[21].
- The omnipresence of polluted agricultural soils with levels frequently exceeding thresholds considered normal, which can only increase the risk of contaminating the food chain[22].

After recalling in this preamble the facts relating to the referral, cnDAspe undertakes a critical analysis of the conditions under which an international organization not subject to the rules of transparency and impartiality that apply to Community and Member State expertise bodies, has been delegated the task of defining the implementation of an important Community policy, and of analyzing possible biases in the construction of the protocol used by the competent authorities of the Member States to decide on the substitution or renewal of pesticides qualified as "more hazardous" on the EU market.

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[19] https://www.igas.gouv.fr/La-strategie-nationale-sur-les-perturbateurs-endocriniens-evaluation-de-la-mise.html : (translation): "*An endocrine disruptor is a chemical substance that alters the functioning of the hormonal system of living beings, leading to impacts on wildlife, with damage to biodiversity, and on human health, particularly during the foetal period. These substances are likely to increase the prevalence of a number of pathologies.*
They are found in a large number of everyday consumer products (cosmetics, food, plastics, etc.) and may be present in crop treatment products and certain medicines."

[20] Oosthoek S (2013). Pesticides spark broad biodiversity loss. Nature; Hallmann, C. A., Sorg, M., Jongejans, E., Siepel, H., Hofland, N., Schwan, H., ... & De Kroon, H. (2017). More than 75 percent decline over 27 years in total flying insect biomass in protected areas. *PloS one*, *12*(10), e0185809.

[21] Laure Mamy (coord.), Stéphane Pesce, (coord.) Wilfried Sanchez (coord.), et al. (Inrae and Ifremer, 2022). Impacts des produits phytopharmaceutiques sur la biodiversité et les services écosystémiques

[22] Silva, V., Mol, H. G., Zomer, P., Tienstra, M., Ritsema, C. J., & Geissen, V. (2019). Pesticide residues in European agricultural soils–A hidden reality unfolded. Science of the Total Environment, 653, 1532-1545.

I- Deontology of public expertise is at the heart of the competences and missions of the cnDAspe

The cnDAspe was established with the mission of "overseeing the deontology rules applying to scientific and technical expertise and the procedures for recording alerts in the fields of public health and the environment" (art. 2 of law no. 2013-316). To this end, it issues "general recommendations on the deontology principles specific to scientific and technical expertise in the fields of health and the environment and proceeds to their dissemination," as well as "recommendations concerning the mechanisms for dialogue between scientific bodies and civil society on scientific expertise procedures and the rules of deontology that relate to them." The annual report of the commission includes, as necessary, recommendations on the reforms that should be undertaken to improve the functioning of scientific and technical expertise.

The commission may refer matters to itself, or be referred to it by certain persons, in particular members of parliament (art. 4 of the law).

This mandate aims to ensure the quality and impartiality of the expertise produced in France in support of public policies in the fields of health and the environment, expertise that also informs citizens about the issues in these fields. However, in the fields of health and the environment, these public policies are largely set in the context of the European Union and are also informed by scientific and technical expertise conducted at the Community level. This expertise is supported by dedicated agencies and involves, to varying degrees, experts and competent authorities from the various MS.

This is particularly the case for agricultural policy and, within this framework, for the use of plant protection products, the approval of whose active substances is discussed at the community level and whose authorization to market the plant protection products derived from them is granted by the MS, according to three geoclimatic and agronomic zones[23], within a European regulatory framework.

The exercise of the mandate entrusted by law to the cnDAspe therefore legitimately leads it to take an interest in the deontology practices of the expertise conducted at the community level, as this is so decisive in shaping public policies as well as the practices of the different stakeholders at the national level.

In this context, cnDAspe is fully justified in conducting a critical analysis of the conditions under which an international organization not subject to the rules of transparency and impartiality that apply to Community and Member State expert bodies was able to receive a de facto delegation to define the modalities of implementation of an important Community policy, and to analyze possible biases in the construction of the protocol that is followed by the competent authorities of the MS to decide on the substitution or renewal of pesticides qualified as "more hazardous" on the EU market. The pre-existence of the EPPO has probably enabled it to be entrusted with this role, as indicated in the conclusions and recommendations of a 2009 workshop: "In terms of comparative assessment, issues relating to human health, the environment and the economy should be dealt with at Member State level, while three guiding tasks have been identified to be dealt with by the EPPO"[24] .

[23] North zone: Denmark, Estonia, Finland, Latvia, Lithuania, Sweden (Norway also participates in the expertise work for this zone); Central zone: Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia; South zone: Bulgaria, Cyprus, Greece, France, Italy, Malta, Portugal, Spain.

[24] Sunley, R. and Van Opstal, N. (2010), EPPO Workshop on Comparative Assessment in the framework of substitution: a summary of the conclusions and recommendations. EPPO Bulletin, 40: 101-104. https://doi.org/10.1111/j.1365-2338.2009.02359 : « *In terms of Comparative Assessment, human health,*

First, we will recall the deontological principles that prevail in the conduct of expert assessments.

Expertise is "*a set of activities whose purpose is to provide a client, in response to the question posed, with an interpretation, an opinion or a recommendation that is as objectively founded as possible, based on available knowledge and demonstrations, accompanied by a professional judgment*"[25].

Public entities whose mission is to carry out scientific or technical expertise in support of decision-making by risk management authorities must have the capacity to freely set their scientific objectives and choose the appropriate working methods. The relevance and quality of the support provided depend on **the impartiality and scientific excellence of their work**. This independence maintains a critical spirit that allows for the detection of problems at the stage of weak signals. **This independence must be consolidated by resolute action to prevent conflicts of interest**. Indeed, poorly managed links of interest can lead to conflicts of interest, affect the impartiality of the expertise, and therefore its quality and credibility.

Finally, in order to build and maintain society's trust in the reliability and impartiality of expertise, the requirement of **transparency aims to guarantee the public's right to reliable and understandable information**, and to give concrete expression to the mission of general interest that expertise represents.

The CNDAspe has published several opinions in this field, which can be consulted on its website[26].

Expertise in support of community policies is also governed by these principles (see further chapters III and IV).

environmental, and economic issues would need to be addressed at Member State level, while three guidance tasks were identified to be addressed by EPPO:"

[25] Norm NF X 50-110

[26] For example, the opinion on the deontology of expert appraisal procedures within European Union agencies (January 2019); the opinion on the conditions for public confidence in the process of evaluating the renewal of glyphosate authorization in Europe (January 2022); the opinion on the harmonization of systems for managing links of interest within the national expert appraisal authorities responsible for risk assessment and marketing authorization of pesticides within the European Union (June 2022).

II- Organization of the cnDAspe's work to respond to the referral

Within a tight timeframe, cnDAspe set up a group of experts, known as the "Formation Spéciale" by the French that established this Commission law, to lead the reflection and prepare its response in the form of an opinion (Appendix B, composition of the Expert group). To this end, it ensured that the members of this group had no conflict of interest with regard to the subject of the referral (see footnote of **appendix B-1** for access to the corresponding documents), in accordance with its own procedures[27].

cnDAspe has ensured that the composition of this expert group, and the invitation to external reviewers, allows for a multi-disciplinary view of the subject, and for the experience of other MS to be taken into account. These objectives also guided the choice of personalities and organizations invited to the hearings.

This group of experts defined the methodological framework and the questions that the expert appraisal would have to explore in order to respond to the referral, drawing on the regulatory references, standards and various sources of information set out in particular in point III.

This frame of reference was set out in the various questions put to the personalities and organizations invited to the hearings and sent to each of them with the invitation letters (Appendix C).

The personalities and bodies invited to be interviewed were chosen with a view to obtaining a variety of viewpoints on the subjects under consideration: farmers' organizations, representatives of industrial players in plant protection, public expert agencies in various MS, the competent authorities of the European Union, the French Ministry of Agriculture, European NGOs active in reducing the impact of pesticides, teachers and specialized researchers.

The agreement of the personalities interviewed was sought when it was deemed that all or part of their written contribution would constitute useful information to be published as an appendix to the Notice; the authors of these written contributions are then indicated. The members of the expert group are bound by a duty of confidentiality regarding the discussions and documents communicated to them by the persons interviewed, who are also asked to observe the same discretion.

Twenty personalities or entities were invited to hearings, of which 15 accepted the invitation, and were interviewed by videoconference between June 27 and September 5, 2023 (see list in Appendix D). Exchanges took place in English or French as appropriate, and were immediately translated if necessary, or immediately after the hearings, to facilitate exchanges within the expert group.

The group of experts produced a draft Opinion which was submitted to 3 independent external reviewers who, approached at the beginning of the summer, agreed to provide feedback within a very short timeframe, notably on the clarity of the argumentation, the relevance of the information used and any omissions (see Appendix B-2 for the list of external reviewers).

The draft opinion resulting from this process was then submitted to the cnDAspe, which deliberated on it at its regular session on September 21, leading to exchanges with a view to adoption of the final version by cnDAspe via digital transmission on the 8th October 2023.

[27] Procédure de prévention et de gestion des conflits d'intérêts de la cnDAspe (cnDAspe's procedure for preventing and managing conflicts of interest (in French only)

III- Information and documents that guided cnDAspe's analysis of the topic

This chapter briefly lists the sources of information gathered by the Specific Training program, which it deemed the most useful for its critical analysis.

- The essential elements of the deontology of public expertise on which the cnDAspe relies in the exercise of its mission[28].

- The report "Foresight: European Chemical Pesticide-Free Agriculture in 2050 » by Inrae and the European Research Alliance (20 countries), which elaborated 3 main scenarios of transformation of the present agriculture model in Europe, in the context of climate change, and evaluated their respective impacts on agriculture yields, greenhouse emissions and terrestrial biodiversity.

- The "Guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009" produced by the European Commission's DG Sanco in 2014 following its approval by MS.

- Le document "*Draft proposal for amendment of Regulation (EC) 1107/2009 - Annex IV on comparative assessment pursuant to Article 50*" élaboré by the Directorate Food Safety, Sustainability and Innovation of the General Directorate for Health and Food Safety, European Commission, submitted for consultation to the competent national authorities of the MS. This non-public document was requested by cnDAspe and was kindly provided in preparation for the hearing of representatives of this General Directorate.

- The European Commission's response to a request from PAN Europe, transmitted by the EU Ombudsman on the conditions under which it adopted the guidance document on comparative assessment in the context of the substitution of hazardous substances among pesticides (June 8, 2023).

- The « Document guide relatif à l'évaluation comparative des produits phytopharmaceutiques en France » (*'Guide to the comparative evaluation of plant protection products in France'*) produced by Anses (July 2015).
- The results of the survey carried out at the end of 2021 by the European Commission on the implementation within MS of comparative assessments when examining applications for renewal or new authorizations of products containing at least one active substance candidate for substitution (see section IV-1-a further).
- The results of the Dephy network : "On April 25, 2023, Dephy Ferme published an overall analysis of the figures for the entire network. Between their entry into a Dephy group and the 2018-2019-2020 average, the 774 cropping systems (1) in field crops/polyculture-livestock studied have reduced, on average, their treatment frequency indicator (IFT) by 26%, the latter dropping from 2.6 to 1.9".[29]

[28] Key elements of the deontology of public expertise underlying the cnDAspe's mission
[29] https://ecophytopic.fr/sites/default/files/2023-04/Synth%C3%A8se%20DEPHY%20FERME%202023_1.pdf. Quoted in the journal La France Agricole.

- Scientific work on the "*One health*" concept. Although the field is still to be explored, the need to cover the continuity between environmental compartments and living organisms in a decompartmentalized way is no longer open to debate. Animals are reservoirs of zoonoses for humans; veterinary or agricultural use of antibiotics weakens health systems; and an organism's health is the result of both specific causes of disease and of the good condition of its living environment. Current pesticide regulations treat each of these impacts separately. Specialists in the environmental fate of pesticides are still ill-equipped to assess their consequences, particularly on the ecosystem services that guarantee a sustainable environment[30].

- The impact study of different scenarios for regulating the marketing of chemical substances, carried out for the European Commission and made public by Corporate Europe Observatory (CEO) on July 11, 2023. European media[31] have reported estimates of avoided health costs, for different scenarios involving the withdrawal of certain chemical substances, of between 11 and 31 billion euros per year, in relation to illnesses resulting from exposure to these substances. Although this study concerns products subject to EU REACh regulations, and not specifically pesticides, it provides a measure of the cost of illnesses linked to hazardous substances released into the environment, consumer products and the workplace.

- Information provided by discussions with the personalities interviewed.

- Relevant general inspection reports:

    - Prefiguration of a compensation fund for victims of plant protection products: IGF - IGAS - CGAAER January 2018
    - National strategy on endocrine disruptors : CGEDD - IGAS - CGAAER December 2017

- The scientific literature on the topic. This Opinion does not aim to review this literature, but several relevant papers published in international journals are quoted as footnotes. Recent collective expertise reports on pesticides: in particular from Inserm, the joint report by Inrae and Ifremer and the Inrae report establishing the link between diversification and reduced pesticide use.

- The personal expertise of expert group members.

[30] How pesticides impact human health and ecosystems in Europe. EN HTML: TH-AM-23-007-EN-Q - ISBN: 978-92-9480-559-1 - ISSN: 2467-3196 - doi: 10.2800/760240 EN PDF: TH-AM-23-007-EN-N - ISBN: 978-92-9480-560-7 - ISSN: 2467-3196 - doi: 10.2800/98285

[31] Notably The Guardian and Le Monde

IV- Based on this information and its analysis of the deontological and scientific issues, the cnDAspe emphasizes that:

1. The number of substitutions decided by member states remains very limited

A survey was performed in 2021 by the European Commission (see Appendix E). A questionnaire was disseminated to the Member-states, resulting in the following assessment: 3,100 cases of possible substitution have been examined by Member-states. Around a third of these possible substitutions have led to the conduct of a formal comparative assessment being carried out. 1% only (32 out of 3100) resulted in an effective substitution decision. These 32 decisions were made by 3 countries: Germany, Croatia and France. Germany alone accounts for 27 substitution decisions, due to refusal by Germany of requests for mutual recognition. Decisions to amend the conditions of use of substances that are candidate for substitution are equally rare (6 cases: Germany, Austria, Greece). France stands out for the number of voluntary substitution decisions (21, in application of article 50-2 of the Regulation), with Sweden (1 case of voluntary substitution, the only 2 countries to have taken such steps.

According to a survey carried out in 2021 by the European Commission's DG Health[32], the main reasons given by MS to explain non-use of substitution are :

- Difficulties to compare risks, especially if the PPP contains more than one active substance.
- The need of chemical alternatives for the implementation of the Integrated Pest Management (IPM) principles. Quite often alternative methods are applied in combination with chemical methods, in order to increase their efficacy.
- The efficacy of the non-chemical alternatives is not established nor quantified and all the more so as they remain marginally practised (until they become a major lever in crop management under the impetus of the ban on other means of control).
- The low-risk active substances, biopesticides and commodity substances are often used in larger quantities (or have to be applied more frequently) to achieve the same level of efficacy as a curative chemical action, and are normally authorized for only a few specific uses. Often, the candidate product for substitution cannot be replaced in all the circumstances in which it is used; while alternatives may be available in only some circumstances, the candidate product for substitution is always necessary in the not covered situations (due, for example, to the lower reliability of the alternative in certain use patterns, to high pest pressure or to the development of resistance). The interest of certain non-chemical alternatives (including certain agronomic measures[33]) sometimes lies more in prevention than in curative action once an epidemic has been declared. Furthermore, it is clear that the use of alternatives is not without environmental consequences, and this is to be considered when analyzing the benefits and limitations of alternatives. Unlike pesticides, the assessment of the impact of alternatives on health and the environment is rarely substantiated.
- PPPs are authorized on the basis of a full risk assessment, whereas for non-chemical alternatives or prevention and cultivation methods, there are no data (not even statistics) and the assessment is therefore not as rigorous. This situation is all the less

[32] Summary document delivered to the experts for the hearing.
[33] In this respect, pruning perennial crops, for example, is a way of modifying air circulation through the plant, thereby reducing humidity conditions favorable to disease establishment. This is a preventive action with little curative effect, and should therefore not be evaluated on this basis alone.

likely to change if the alternatives are not used. Reasons must be given for any (partial) refusal of authorization.

- Insufficient information and guidance to assess whether a non-chemical control or prevention method is economically viable; it is often less straightforward to determine the costs and resulting pest control effect for a non-chemical control or prevention method than for the use of a conventional PPP. Furthermore, methods for the monetarization of external costs to the environment and the society are not well developed and are excluded from economic evaluations of alternatives.
- Lack of predictability about the resistance evolution, particularly with quarantine pests. Normally, the decisions are made on a case-by-case basis and on grounds of expertise considerations.
- Even if substitution is possible for the major uses of a PPP containing a candidate for substitution, if that PPP is authorised also for minor uses for which no alternatives are available, there is a risk that these minor uses would no longer be covered as industry can stop marketing the PPP due to limited profits if the major uses are not authorised anymore.

According to the European Commission's DG Health, these data show that the competent authorities in the MS accept the maintenance of active substances that are "candidates for substitution", mainly because of the lack of viable alternatives without significant practical or economic disadvantages. This is partly confirmed by the analysis of Faust et al.[34], who show that the sheer number of alternatives that are available, for a given use, is limited.

2. The Regulation has an impact on the limited number of substitution decisions

The limited number of substitutions is partly explained by the procedure and criteria designed to assess the value of alternatives and carry out a comparative evaluation. It is therefore worth examining the way in which Member States carry out comparative assessments.

a- The regulation's limited scope for reducing the use of the most hazardous pesticides.

The scope of the legal provisions organizing pesticide substitution can only be appreciated if we take into account the role played by Regulation 1107/2009 in the European regulatory regime for pesticides, which has a dual structure.

Issues relating to the marketing of pesticides are specified in Regulation 1107/2009. The aim of the latter is to ensure that pesticides are available to farmers to combat crop diseases. It replaces Directive 91/414, which aimed to harmonize access to pesticides throughout the European Union and ensure that all farmers in the various Member States have equal access to safe and effective "plant protection products". This was one of a series of legal texts contributing to the completion of the internal market, as established in the mid-1980s, through so-called "vertical" directives, laying down the standards that any product must meet in order to circulate freely within the internal market. From the 1960s to the 1980s, directives were drawn up for each of the key sectors of economic production in Europe (e.g. meat, pharmaceuticals, etc.), with directive 91/414 being the text concerning pesticides (then defined as plant protection products). Regulation 1107/2009 pursues this economic and market organization logic, as evidenced by Article 1.3, which states that the aim of the regulation is "to

[34] Faust, M., Vogs, C., Rotter, S. *et al.* Comparative assessment of plant protection products: how many cases will regulatory authorities have to answer?. *Environ Sci Eur* **26**, 11 (2014). https://doi.org/10.1186/s12302-014-0011-8

ensure a high level of protection of human and animal health and the environment, and to improve the functioning of the internal market by harmonizing the rules relating to the placing of plant protection products on the market, while improving agricultural production".

Issues relating to the sustainable use of pesticides are covered by Directive 2009/128 on the sustainable use of pesticides. This other facet of Europe's pesticide regulatory regime is very different in nature. Concern for the sustainable use of pesticides is linked to issues of habitat protection, water quality, risks to species as well as to farmers and any human population exposed to pesticides. Like the current political discussions around the Green Deal and the proactive reduction of pesticide use in Europe, this aspect of policy is driven, implicitly at least, by wider objectives concerning the evolution of agricultural production models in Europe. In other words, it is firmly rooted in the realm of environmental policy, an area which made punctual progress in the 1990s and beyond.

This aspect of pesticides policy has long been managed by the European Commission's Directorate-General for the Environment, whose influence varies according to the strategies adopted by the Commission presidency. Environmental policy on pesticides has developed more slowly than the other part of the policy (the first notable political initiative in this field was a Green Paper adopted in the early 2000s), and has generally relied on less binding instruments: agrochemical companies simply can't sell a product if the active substance on which it's based hasn't been approved, but the sustainability (and reduction) of pesticide use is supposed to be developed through national action plans which Member States have considerable autonomy to draw up, and through the production of quantitative information on pesticide use and risk across Europe (so-called information regulation)

The substitution of the most hazardous pesticides falls under the first part of the pesticide regulatory regime, as defined by Article 50 of Regulation 1107/2009. It is very little influenced by the other part of the pesticides policy, which concerns the risks and sustainability of pesticide use. The articulation of the two strands of policy is addressed in Article 55 of Regulation 1107/2009, which states that "plant protection products shall be used correctly" and refers to Directive 2009/128 as the reference text in this area. Given their wording, these articles compensate for the minimalist incorporation of the objectives of the environmental aspect of pesticides policy into the market organization aspect of the latter. In other words, the above-mentioned dichotomy remains a very strong and determining aspect of EU pesticide policy. Marketing authorization provisions are not conceived as instruments for achieving the objectives that prevail on the other side of this policy.

b- Content of article 50

The principles and objectives governing the interpretation of article 50 have been outlined above. They place the protection of human health and the environment above the interests of economic and agricultural development. In concrete terms, they must ensure that substances and products placed on the market have no harmful effects on human or animal health, and no unacceptable effects on the environment" (art.4).

As for the legal scope of this article, it should be remembered that its application is binding on member states, as indicated by the wording used in the French and English versions:

- "Member States shall carry out a comparative assessment (...)".
- "A comparative assessment shall be performed by Member States (...)".

This is not, therefore, an option left to the discretion of the Member States, but an obligation, non-compliance with which may, in principle, be subject to judicial review. As already emphasized, the transparency of the procedure could be improved, and in particular the information provided to member states, European institutions and the general public.

As for the conditions of application, Article 50 allows member states, for substances meeting the substitution criteria, to refuse, after evaluation, authorization or to restrict the use of a product. However, the conditions for substitution are cumulative and restrictive:

- existence of a non-chemical alternative or a chemical alternative with less impact ;
- substitution must not present any major economic or practical disadvantage;
- diversity of control methods to avoid resistance;
- withdrawal of the product for one use has no consequences for other minor uses.

Thus, it is sufficient to demonstrate that for a single specific use of a product, there is no alternative or that there is a "major economic disadvantage" to make the withdrawal of its marketing authorization unthinkable and render the article inoperative.

The European Commission's "Draft proposal for amendment of Regulation (EC) 1107/2009 - Annex IV on comparative assessment"of the EU Commission proposes substantial advances, notably (conditions 2 and 3) by considering that "widely used" alternative methods and techniques can be deemed "safe" (for health and the environment) and "effective" (for pest control), and by lowering to 5 (from 10) the environmental risk ratio required to consider the difference in risk between chemical solutions and alternative solutions as significant. This proposal is of major interest because it pragmatically recognizes that techniques that are "widely used" can a priori be deemed safe. It thus removes the frequent obstacle of the scarcity, or even absence, of scientific data on recognized methodologies to demonstrate this, leading to their elimination from the Comparative Analysis. However, the first paragraph of this proposal ("Comparative assessment procedure") introduces a major source of bias by placing the onus on the company applying for renewal of its authorization for a pesticide containing an active substance classified as CfS to make an inventory of alternative solutions and provide proof that these cannot satisfy conditions 2 to 4.

c- Member States rarely apply Article 50 without being subject to control

First of all, while the application of Article 50 is mandatory, it should be noted that some Member States choose not to undertake a comparative assessment, and enjoy a high degree of autonomy as regards substitution policy, which seems to be at odds with the importance, indeed the urgency, of replacing candidate substances for substitution, given their hazardous nature. In addition, Member States do not always respect the mandatory seven-year deadline for carrying out a comparative assessment, following the date of the last approval of the active substance on the list of substances being considered for substitution. There are several possible reasons for this failure to carry out a comparative assessment. The work program for risk assessments of alternative chemicals may not run in parallel with that of a particular candidate for substitution, so EFSA's conclusions on its alternatives are not available for comparison. PPP applications for "limited uses" are cited in the analysis provided by PAN Europe, but this explanation can be questioned, as comparative assessments are in all cases justified by the fact that the substance is included on the list of substances to be substituted. The fact that an application may or may not contain one or more minor uses should not hinder a comparative assessment. In any case, the monitoring of this deadline seems to be flawed. This is linked, moreover, to the absence of any obligation for MS to report on implementation (as illustrated by the fact that only 16 of the 27 MS responded to the October 2021 survey).

d- There is a lack of information on the implementation of Article 50 and on the alternatives considered by the Member States.

The imperfect implementation of Article 50 can also be seen in the lack of information sharing between the competent authorities of the MS, on the comparative assessments they have undertaken, the solutions compared, and the results of their assessments. Given the

importance of knowledge of alternatives in guaranteeing the possibility of substitution, the regulatory system in place should favor or encourage the production or circulation of information on these non-chemical alternatives, their use and their value. As it stands, the comparative assessment system assumes that an equal and sufficient amount of knowledge is available about chemical and non-chemical solutions. It would even be advisable to take into account the availability of the solutions envisaged, so that substitution does not subsequently come up against the withdrawal of the replacement molecule from the market.

Overall, one of the main limitations of the substitution system is that responsibility for producing information on non-chemical alternatives is not clearly defined. This results in a dearth of information on the subject. This is an important limitation of the substitution framework, as there is, on the whole, less research and knowledge available on non-chemical alternatives. Even where specific studies on alternatives and their efficacy are available, the results of these studies may not be fully usable in a substitution decision by Member States, as the efficacy, practicability and cost-effectiveness of non-chemical methods only appear at the level of the whole field ecosystem and its overall pest and disease load, rather than at the level of a specific pest, in the short term. There is a general lack of studies and information on the effectiveness and availability of alternative methods - with particular attention to how they work at farm or field level.

The implementation of this procedure in each country should be the subject of information to all MS, as well as information to the public in order to facilitate the sharing of information on non-chemical alternatives and agronomic practices. Guaranteeing the transparency of the procedure could make it easier for third parties to monitor and, potentially, have recourse to the courts.

Finally, the restrictive effect of the conditions of application of substitution is increased by the EPPO guide document, thus emptying article 50 of virtually all legal effect.

3. The EPPO guideline document and the conditions under which it was drawn up have an impact on substitution

a- The impact of the EPPO standard on substitution

The substantive content of the EPPO standard undoubtedly plays a role in substitution decisions[35]. The annex 4 of Regulation 1107/2009 provides a number of details for the conduct of the comparative assessments foreseen in article 50. Yet the annex leaves open a number of issues – notably the data and indicators to measure risks, benefits, disadvantages of various solutions. This void is filled by the EPPO standard, which was included by the European Commission in its own set of guidance (ref to document SANCO 2014), and endorsed by the Members-States in a meeting of SCOPAFF (add here date and reference of the decision). According to this guidance, comparative assessment should follow a step-wise approach, as visualized opposite:

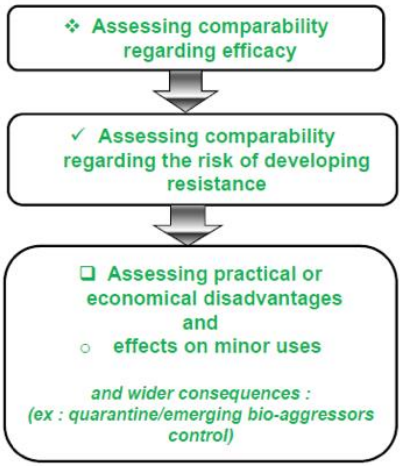

Figure 1 Flow chart for EPPO Standard PP 1/271

The effects of this stepwise approach on the recognition of the value of alternatives to chemical solutions should be considered. The guidance establishes that the criteria of efficacy prevail, or should be considered before, any other. This is in contradiction with the first paragraph of article 50 of Regulation 1107/2009, which establishes that risks and benefits of active

[35] https://www.eppo.int/MEETINGS/2018_meetings/wk_comparative_assessment

substances must be balanced. In a sense, the Regulation provides for the need to perform a global, integrated assessment of a substance under a series of dimensions. It does not establish, as the EPPO standard practically does, that efficacy is the primary criterion for the comparison between active substances and alternative solutions. Furthermore, the guidance gives a particular weight to chemical solutions, and effectively disfavours the replacement of chemical solutions by sets of chemical and non-chemical solutions, or IPM schemes, because it sets chemical solutions with 100% efficacy on the use in question, as the benchmark to be met. The guidance incorporates a preference for a one-to-one form of substitution, without taking into account, that chemical solutions are generally only replaced by sets of solutions, which demonstrate their value and effectiveness only over time.

Additionally, it should be noted that the guidance leaves little place for the consideration of the externalities of the general use of chemical solutions. The comparative assessment is made from the user's vantage point, with an emphasis on the limitations of alternatives (less effective, less reliable, less practical, more expensive) without taking into account the external, negative effects of the continuous, large-scale use of chemical solutions for the health of exposed populations, and for the environment. In this way, a herbicide molecule from a little-represented chemical family will be deemed necessary and unavoidable for resistance management where the cost to society of cleaning it up in water exceeds the benefits it brings to agriculture.

From a procedural point of view, two other limitations emerge. One relates to the adaptations of the EPPO standard by Member-States. Technical guidance cannot possibly define every aspect of a task or activity. As any other guideline, the standard by EPPO leaves open a number of aspects, or delegates them to the user of the guidance, who is left to make choices. What is more, the legal nature of the text (it is not a mandatory text) leaves open the possibility for Member-States to make use of other pieces of guidance, which she or he judges more appropriate. Indeed, it appears that national product-authorization bodies make use of different procedures when performing a comparative assessment, or adapt the initial EPPO guidance in their own way.

For its part, Anses is applying an amended version of the standard document which, unlike the approach developed by EPPO, does not initiate the comparison process by producing data on pest protection efficacy, data which are notoriously less available in the scientific literature for alternative plant protection methods, which from the outset makes it impossible to continue with the comparative analysis. The order of stages in this amended version also reduces the workload borne by the competent national authority[36].

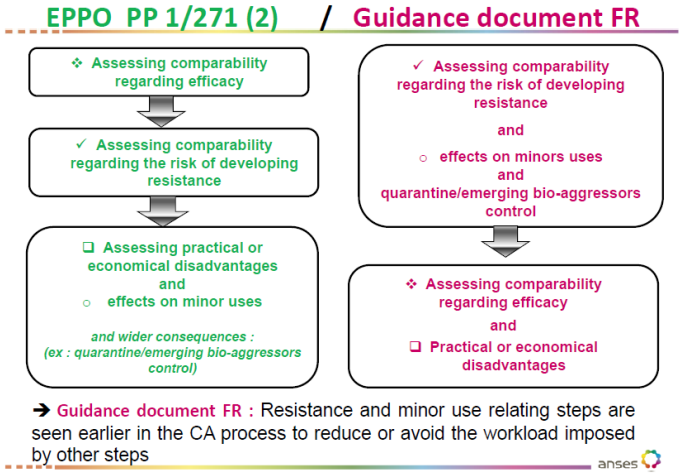

Figure 2 Adaptation of the EPPO Standard 1/271 by Anses (ref. 36)

This is not problematic as such, but a system of standard-setting such as this one should at least foresee mechanisms for sharing of experience between rule-users, and feedback from rule-

[36] Source : Comparative Assessment Feedback on Implementation in France.
EPPO Workshop on comparative Assessment of Plant protection Products Lisbon, 2018-10-24/25

users to rule-makers. Only in this manner can the initial rule be improved, and the substitution task, in all its complexity and sheer scale, hope to be carried out.

A second procedural limitation concerns the timing of the development of this guidance and the need to revise it, in light of the evolution of technical possibilities for crop protection. The current guidance system foresees no such revisions, even though the need to avail of non-chemical solutions is becoming more dire, with the decrease in the number of chemical solutions available for specific uses. It is worth pointing out here that the instruction framing the rule was issued at a time when innovation in new active ingredients was still flourishing. It therefore made sense to check that the previous solution was far less effective and more hazardous than the new one. As the rule has not evolved, it is now misaligned with the reality on the ground, as a result of two processes: each remaining molecule is increasingly becoming the sole representative of a broader chemical family, and is therefore more likely to be maintained because of its potential role in resistance management; the portfolio of directly similar alternatives for substitution has been exhausted, limiting the number of possible comparisons. A direct implication would have been to recognize the comparative validity of non-chemical alternatives (currently limited to the sole case of paragraph 2 of article 50).

Although this guide has been revised three times since 2011, it has been produced by working groups that meet the criteria of competence, but not the current requirements in terms of transparency and management of links of interest.

b- The EPPO guidance document is de facto a reference text

The above analysis of the EPPO standard suggests that the conditions under which they were developed and adopted into the EU regulatory framework should be re-examined. It appears that the elaboration of the guidelines was not mandated by the European Commission (the EU having only observer status within EPPO) to implement Article 50. There was no apparent political choice to use one particular technical organization rather than another to develop the required standard. It is also difficult to assess the policies and guidance given by the European Commission to EPPO to develop the standard. Instead, the EPPO guidance document became the default standard, due to the position EPPO had already acquired in the field of international harmonization of pesticides in use.

By 2009, when the need for a standard was becoming clear, EPPO was already established as the authoritative global organization for agronomic standard setting. In a manner reminiscent of the strategies used by international standards bodies to generate interest in their standards (e.g. ISO), EPPO presented itself as the organization of choice to bring together the experts needed to meet the need created by the forthcoming adoption of Regulation 1107/2009[37]. The workshop held in Brussels in 2009 attracted the main experts and stakeholders in this field, to reflect on the need for this guide and develop the document. A working group formed by EPPO

[37] https://www.eppo.int/MEETINGS/2009_meetings/wk_comparative_assessment: "The new EU regulations concerning the placing of plant protection products on the market will shortly come into force, repealing Council Directives 79/117/EEC and 91/414/EEC. From this point onwards, whenever a plant protection product contains an active substance that has been identified as a candidate for substitution, EU Member States will need to perform comparative assessment when evaluating an application for authorization. An EPPO Workshop was held in Brussels on 2009-05-06/07 in order to: define how to perform comparative assessment and substitution in practice, in relation to the new regulations; identify the areas where further guidance is needed for the implementation of the new regulations; determine how EPPO as a scientific and technical organization may assist its member countries in implementing the new regulations…"

then drafted the guide. The European Commission has confirmed that, ex-post facto, it has examined the guidelines proposed by EPPO and found them suitable for its needs.

In many respects, the EPPO guide document constitutes what might be termed a "de facto standard", as opposed to a "de jure standard", since it is the result of a long process of selecting a standards body which largely predates the adoption of Regulation 1107/2009. The guide seems appropriate because it was drawn up by experts who were familiar with the needs of the European Commission, rather than by the European Commission and a circle of representative stakeholders, who would have mandated a guide to meet particular political objectives. Finally, the guide was drawn up by a group of experts (academics, industry representatives, members of national authorities, European Commission officials) whose composition is not known. It may be noted that EPPO is an organization in which the presence of agrochemical companies is older and more established (for example, than that of biocontrol solution products), and it may be assumed that concerns (e.g. resistance, efficacy of substances) and expertise of these companies permeated the work of the comparative assessment body, more so than would have been the case had EPPO been explicitly chosen, and given a mandate, to develop a technical guide applying all the criteria and objectives of Regulation 1107/2009, including that of protecting human health and the environment and a more proactive substitution of CfS.

Finally, a formal mandate from the EPPO would have implied the application of the principles that were, at that precise moment, essential to the development of EFSA and, more generally, to European expertise: independence, transparency, excellence. There is no clear evidence that this was the case for this particular orientation. While there is a minimum amount of information on the skills and interests of some of the people who made up the working group responsible for issuing comparative assessment guidelines, it is clear that this minimal information no longer meets current requirements in terms of transparency and, consequently, the management of links of interest.

Finally, it could be argued that a technical standard such as this guidance document, which has a major bearing on the implementation of a European regulation, should be open to scrutiny by the European Parliament, in view of its role as co-legislator. Comparative assessment is likely to be one of the general measures designed to amend non-essential elements of Regulation 1107, as described in recital 55 of the regulation. In view of the importance of these measures, and as specified in the same recital of the Regulation, it can be assumed that the regulatory procedure with scrutiny (Decision 1999/468/EC) applies, so that the European Parliament has a right of scrutiny over the European Commission's proposal to the Member State Committee to adopt a guideline, and over the Member States' decisions to adopt that guideline. SCOPAFF's adoption of the EPPO comparative assessment guidelines was not subject to any particular scrutiny by the European Parliament. But given the potentially important implications of this guide for the achievement of the objectives of the legislation (in terms of protection of human health and the environment, substitution of hazardous substances, promotion of sustainable modes of agricultural production in Europe), it can be assumed that the European Parliament will be legitimately interested, in the future, in the adoption of a new guide on this subject.

A very significant antecedent: the "bee guideline"

The fact that EPPO adopts positions marked by strong conflicts of interest due to its composition has already placed the EU in an extremely delicate situation.

For example, EFSA's "bee" guideline (Guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees) has been blocked since 2013, as SCOPAFF members have never been able to agree to endorse it. These same members (at least the EU MS, who all sit on EPPO's governing bodies) had previously endorsed the guidance document "System for the environmental risk

assessment of plant protection products" (EPPO Bulletin, 2010), which, among other things, deemed it appropriate to consider "low risk to bees" a daily exposure of less than one tenth of the lethal dose, a very high value.

The experts commissioned by EFSA to draw up the guide document produced in 2013 were very severe, for their part, on the impasses in the EPPO documents on the subject.

EPPO's composition and governance mean that the government representatives on its decision-making bodies, who may not have the technical and scientific expertise to identify shortcomings or biases, endorse technical documents that are tainted by bias, under a technical and scientific guise.

When it comes to pesticides containing active substances classified as CfS, what is at stake is not only bees and biodiversity, but also the health of farmers, their families and employees, as well as people living near pesticide-applied areas.

It is therefore essential, as a general principle, that technical documents implementing operational choices resulting from EU policy deliberations and produced by EPPO or other external entities not subject to the stringent rules on conflict-of-interest management and transparency imposed on EU expert agencies, are subject to independent critical review and amendments deemed appropriate by the experts of its competent specialized agencies. Otherwise, the EU is committing an error of judgement which puts it in contradiction with its own principles of pesticide risk management.

4. Reducing pesticide use and combining crop, soil and biodiversity protection is an achievable goal.

This is shown by the IPMWORKS project that brought together 31 partners in 16 European countries (including ACTA, the network of French agricultural technical institutes, and APCA, the assembly of French chambers of agriculture), as well as by the experience of the French DEPHY farm network, whose objectives are to: (i) demonstrate the feasibility and benefits of Integrated Pest Management (IPM) strategies, which use low quantities of pesticides, and (ii) promote the adoption of these strategies through knowledge exchange and peer learning among farmers.

Reducing the use of pesticides by 50% by 2030 is the aim of the European Union's "Green Deal" and "Farm to Fork" strategies. Across Europe, agricultural policies have prioritized farmer involvement, which is essential in the quest to change farming practices. Projects and experiments launched with the support of farmers show that a reduction in the use of pesticides, while maintaining a high level of protection for crops, soils and biodiversity, is an achievable goal.

Before the advent of agriculture built around mechanization and supported by chemistry to cover plant protection and fertilization, agriculture was already making extensive use of disease and pest management levers through varietal choice and the mobilization of agronomic levers. These remain two major pillars of integrated crop management. Two other families of alternative practices have gradually been added with the rise of biocontrol and the generalization of mechanization, now assisted by on-board computers. As a result, four families of alternatives now account for the majority of actions taken to maintain crop health without resorting to chemicals[38].

[38] See appendix G

These non-chemical pest and disease management alternatives share a number of points in common, which are set out below:

- They frequently emphasize preventive rather than curative action. They aim to ensure that conditions are not ripe for the pest or disease to find a way to establish itself and multiply. Although they fall within the scope of IPM, they may have been deployed when, in retrospect, they were not useful, which can have a cost.
- They often give rise to complications: slower construction times, greater need for observation, or occasional need for manpower to install them. They therefore need to be anticipated.
- Finally, as they are not generalized or have to take account of local conditions, they concern smaller markets and are therefore often a little more expensive.

So, apart from the leverage of varietal choice, non-chemical alternatives will mostly be classified as more complicated, less reliable and less profitable than their chemical counterpart. At present, pesticide regulations do them no credit. Yet, pesticide marketing authorizations would benefit from supporting the spirit of Directive 2009/128, and only resorting to chemical treatment once preventive measures have been put in place and are proving outdated. As exposed in another chapter of this report, the mobilization of non-chemical alternatives is generally possible and can lead to substantial savings in pesticide use. For example, the network of volunteer farmers on Ecophyto Dephy farms has succeeded in reducing pesticide use by over 25% across all agricultural sectors[39]. Analyses of these results confirm that, in many cases, this has been achieved without any reduction in farm profitability. This is a good result, which would undoubtedly be further improved by the widespread use of the best practices employed.

We are therefore faced with a situation where, on the one hand, we can see that changes are possible and that alternative levers would undoubtedly be all the more reliable, numerous and effective the more frequently they are used and, on the other hand, that the regulatory framework does not favour them and even tends to discredit them in a fairly systematic way.

All non-chemical alternative levers can be the subject of experimentation to provide evidence of their effectiveness, make their use more reliable and clarify the conditions required for their recommendation. The scientific effort can also focus on highlighting the beneficial or problematic indirect effects of their use, which are not all trivial. For example, mechanized work increases trauma for machine operators, while biocontrol solutions can have an impact on non-target species. As these alternatives are not widely deployed, they are also the subject of little spontaneous interest on the part of the scientific community.

Recital 35 of Directive 1107/2009 says: "*To ensure a high level of protection of human and animal health and the environment, plant protection products should be used properly, in accordance with their authorisation, having regard to the principles of integrated pest management and giving priority to non-chemical and natural alternatives wherever possible*". [40]

The principles of IPM are given in Annex III of the directive 128/2009 (sustainable use of pesticides). If the new proposal of the Commission for the sustainable use of pesticides[41] was

[39] Analysis of results from Dephy farms in France shows a general decline in all sectors. Between the entry of the farms studied into the network and the average for 2018 to 2020, the treatment frequency indices (IFT) fell in all sectors: 33% in the vegetable sector, from 3.5 to 2.3 ; 35.3% in arboriculture, from 15.3 to 10 ; 24.4% in viticulture, from 10.4 to 7.9 ; 38% in the horticulture sector, from 6 to 3.7; 19% in tropical crops, from 4.7 to 3.8.

[40] The recital so follows: "The Council should include in the statutory management requirement referred to in Annex III to Council Regulation (EC) No 1782/2003 of 29 September 2003 establishing common rules for direct support schemes under the common agricultural policy and establishing certain support schemes for farmers, the principles of integrated pest management, including good plant protection practice and non-chemical methods of plant protection and pest and crop management."

[41] SUR Proposal R1 - version for RSC meeting clean LW (004) - additional changes from table (003)

agreed by the Council and the Parliament, the principles of IPM would become more stringent. However, this proposal is still under the scrutiny of the Council and the EU Parliament, so it is too early to predict, what will be its consequences to agronomic practices in the MS.

However, the EU biodiversity strategy (Biodiversity strategy for 2030 (europa.eu) calls for comprehensive, ambitious measures to protect nature and reverse the degradation of ecosystems. It will also include targets to reduce the pesticide use, and therefore system-based agroecological and preventive plant protection practices will most likely be the core of IPM methods instead of reliance on chemical PPPs in the coming years.

The focal agricultural research institutes all over the Europe (many of them created the alliance "Towards chemical pesticide-free agriculture in Europe in 2050") are currently conducting research to develop alternative methods to a range of plant protection problems to tackle this challenge, and these methods are implemented in the Member States. Also the EU directs significant amounts of research funding for such projects.

The alliance of research institutes "towards pesticide free agriculture" share the observation that the current trajectory of agriculture does not allow to meet the challenges of sustainability. Agriculture is directly responsible for exceeding several planetary limits[42]. Agriculture production, as a major driver of the Earth system exceeding planetary boundaries. Ecology and society, 22(4) ; other ?). Since it is also the biggest land user, it is in a position to be the leading provider of solutions. Two key areas of focus are limiting the effects of climate change and reversing the accelerating extinction of biodiversity. The alliance considers that aiming for a 50% reduction in the use and/or impact of pesticides by 2030 in the Green Pact does not allow to envision solutions commensurate with the stakes involved. As long as pesticides are still used, and as long as they are the benchmark for crop health protection, no non-chemical alternative will be worked on intensively enough to be mobilized within a reasonable timeframe. The levers used to reduce dependence (such as sprayer optimization, for example) differ from the levers to be used to do without pesticides altogether. Working on the former delays the need to work on the latter. The urgency of the situation rather calls for more radical change, based on the development and mobilization of major families of levers: digital technology via agricultural equipment, biocontrol including the mobilization of microbiota to do without chemical plant protection, varietal improvement, agronomic practices to cultivate plant associations that are less susceptible to disease, and so on. The contribution of international expertise has allowed to isolate three plausible scenarios that can be based on the current state of knowledge, in particular the implications in terms of yields, lower GHG emissions, hosted biodiversity, to serve as a reference framework. They can be used to pinpoint the major elements of innovation.

Among others, Anses points out that the scarcity of treatment solutions may lead to transferring the use of substituted products to others, and thus to a preponderance of a few active substances for certain uses, mechanically leading to an increase in their residues due to their omnipresence, and risks of lesser control of resistance in pest populations due to the unavailability of adequately wide range of modes of action. Therefore, applying substitution principle is not necessarily a straightforward means of reducing the risks to plant protection products.

[42] Campbell et al. (2017). Agriculture production, as a major driver of the Earth system exceeding planetary boundaries. Ecology and Society 22(4):8

V- Conclusion and recommendations

Stopping the use of the most hazardous substances relies in part on the substitution procedure as set out in Article 50 (and Annex IV) of Regulation 2009/197. This report establishes that the substitution system for the most hazardous substances is not effective.

The ineffectiveness of the European substitution system is problematic in two respects. Firstly, the risks to public health and the environment associated with the use of plant protection products are increasingly well documented. While it remains difficult to obtain an exhaustive overview at European level of the impact of pesticides on human health, and in particular on farmers and their employees - since the system for monitoring occupational illnesses is not harmonized, causal links are difficult to prove and the time taken for associated pathologies to appear is long - the hazards associated with candidate substances for substitution are recognized and should be reduced. On the other hand, other instruments aimed at reducing the use of pesticides, and hence their hazards, such as Directive 2009/128, are themselves ineffective. In France, the transposition of Directive 2009/128 has led to the adoption of successive ECOPHYTO plans to develop agricultural practices, boost research and training efforts, and assess, control and reduce risks and impacts on human health and the environment. It has to be said that the reduction targets have not been met.

The risk of legal recourse for member states, but also for European authorities, should be emphasized here. Indeed, the role of the courts is becoming increasingly important in today's major issues concerning the climate[43] and pesticides[44]. In other words, this is an area where public interests are represented by NGOs, citizens' groups and parliamentarians, and where recourse to the courts is aimed at forcing States and public authorities in general to simply apply the law, to respect their commitments or to adopt an interpretation of the rules in line with the principles, objectives and trajectories set out in the legal texts. In particular, this may involve checking the substitution procedure as implemented by a competent authority[45], or verifying the validity of the EPPO standard[46].

The cnDAspe therefore makes the following recommendations:

[43] CE, 6/5 CHR, 19 novembre 2020, *Commune de Grande-Synthe I*, n° 472301.

[44] TA Paris, 29 juin 2023, *Assoc. Notre affaire à tous et autres*, n° 2200534/4-1.

[45] Recourse may be based on the existence of alternative products and techniques that meet the conditions set out in article 50-1. The producer of the alternative product, collective groups of farmers committed to organic farming or other approaches who do not have products that meet their requirements, NGOs for the protection of public health, consumers and the environment are all persons with an interest in bringing this type of action.

[46] This control may be the subject of a preliminary question (in a main action challenging the authorization of a renewal of a marketing authorization for a product containing a candidate for substitution) referred to the CJEU in order to examine the conformity of the EPPO standard with the objectives of Regulation 110/2009, both in terms of substance and the procedure for their adoption.

1. Increase monitoring of the application of the substitution procedure for the most hazardous pesticides by the competent authorities in the Member States, and reinforce their obligations.

In view of the shortcomings in the implementation of Article 50 highlighted in this report, and in view of the loopholes in the implementation of substitution and the limits of the regulatory system that various parties could raise before the European courts, **the obligations incumbent on the competent authorities of the Member States and on petitioning companies need to be clarified**.

- A reminder that a full comparative assessment must be carried out at least every 7 years. The period of 7 years after the previous marketing authorization cannot be exceeded under any circumstances, even for minor uses. This evaluation is required each time the marketing authorization of a product containing an active substance classified as a "candidate for substitution" expires, or when the competent national authorities decide to initiate a voluntary substitution process (art. 50-2 of the Regulation). Moving progressively towards simultaneous renewal of authorizations in the various Member States will facilitate comparative analysis, as the different solutions will then be more often accessible in neighboring countries or at EU level.
- Set up an information system on the comparative assessment procedures undertaken by the competent authorities of the MS: each competent authority concerned implements a public information procedure by virtue of the right to information and public participation recognized by the Aarhus Convention and European Union law.
- Require MS to report in all cases on the implementation of substitution, or not, to the European Commission's DG Health. This feedback is necessary to enable steering and evaluation of the substitution policy for the most hazardous pesticides, as well as to inform the various stakeholders. This feedback will concern pesticides that have reached the end of their marketing authorization, as well as those whose marketing authorization has been withdrawn by the MS before its normal expiry date.
- Reinforce the obligations of competent authorities and petitioning companies to identify available alternative solutions. The burden of providing the information needed to conduct a high-quality comparative assessment, which must rest on all companies interested in seeing their solutions authorized, re-authorized or promoted, whether chemical or non-chemical, within a harmonized European framework open to all types of solution (chemical or alternative). A register of the most suitable alternatives for the use concerned can support this approach. EFSA will be entrusted with the task of determining the minimum information that companies must provide to the competent national authorities in order to have their solutions examined.
- Issuing public calls for tenders for solutions that are not only chemical, biological or mechanical, but also agronomic and cultural practices, which are not subject to authorization but to scientific and experience-based assessment of their relevance. National authorities must ensure that they have the skills and technical networks to evaluate these other elements of integrated pest management, in terms of their effectiveness, costs and possible practical drawbacks.
- At Member State level, increase the level of the fee for the examination of dossiers for products containing candidate substitution substances, so as to finance the additional burden of expertise that this updated comparative assessment will entail for the competent national authorities.

2. Revise the comparative assessment criteria set out in Annex IV of Regulation 1107/2009

In view of the weight given to the criteria of efficacy and practicability of alternatives to candidate substances for substitution in Annex IV of Regulation 1107/2009, one must :

- Promote rapidly some of the changes proposed in the document "Draft proposal for amendment of Regulation (EC) 1107/2009 - Annex IV on comparative assessment", in particular those which consider that "widely used" alternative methods and techniques can be deemed "safe" (for health and the environment) and "effective" (for pest control), and that which lowers to 5 (instead of 10) the environmental risk ratio required to consider as significant the difference in risk between chemical solutions and alternative solutions.
- Integrate the negative externalities of pesticide use into the comparative assessment of the most hazardous PPPs. Pesticide use is the source of external costs (e.g. for depollution, or for treating illnesses attributable to exposure to the most hazardous pesticides), which should be taken into account when calculating the comparative costs and benefits of the most hazardous substances and their alternatives. A harmonized framework for analyzing these negative externalities will be drawn up for this purpose and implemented in each Member State.

3. Promote research and the production of information on alternatives to candidate substances for substitution on a European scale

Correct comparative assessment requires risk assessors to have adequate knowledge and expertise of preventive and non-chemical agricultural practices, so as to be able to fully consider all alternatives, in a situation of rapid evolution of these solutions and knowledge of their advantages and disadvantages.

- To give risk assessors the opportunity to familiarize themselves with and learn from agricultural research into new technologies and viable non-chemical methods of plant protection currently being applied, for example in organic farming and biocontrol products. In particular, this involves documenting the value of alternative levers via R&D work, especially for levers with a preventive effect that are no longer of any use once an epidemic has been declared, and therefore cannot be assessed for their curative efficacy.
- Establish a shared resistance observatory for quarantine organisms, at least by zone: the fact that resistance to a particular mode of action has been declared should prompt caution, or ensure that non-chemical control methods enable populations to be properly managed.
- Pool existing expertise in the various member states across the 3 agro-climatic zones of the EU, and encourage the production and circulation of information on non-chemical alternatives, their use and their value.
- Promote the use by the competent authorities of the scientific and technical knowledge required for comparative assessment, and produced by European research and technical institutes, concerning integrated crop management (IPM) techniques, the development of new alternative techniques, their effectiveness, but also on the hazardousness of pesticides linked to chronic exposure, notably their impacts on pollinators, soil quality and fertility, indirect effects via microbiota and food.
- Develop forward-looking studies to analyze the consequences under the hypothesis of withdrawal, and experimentally test the best crop management methods to emerge, as

well as the incentive tools, including economical tools, to be mobilized to support change.

4. Revise the EPPO standard for consideration by MS competent authorities of the possible substitution of "the most hazardous pesticides"

In view of the criticisms levelled at the EPPO standard document for comparative assessment, it should be revised:

- Revise the current EPPO standard in such a way that the efficacy criterion does not take precedence over other comparative assessment criteria, notably the safety criterion vis-à-vis that of environmental and human health protection. Give priority to the full conclusions of health and environmental risk assessments, before assessing agricultural needs.
- In particular, the step-by-step approach proposed by EPPO should be modified, drawing on the experience of the national authorities that have carried out the largest number of substitutions since 2014;
- The EPPO standard should be revised to allow a more favorable assessment of alternative solutions whose effectiveness can be assessed systemically (in combination with other solutions), and whose effectiveness can be assessed over time.
- Clarify the differences and similarities between the comparative assessment approaches developed by member states' competent authorities, on the basis of the EPPO standard, and promote the harmonization of these approaches, taking as a reference those which seem to produce more favorable results in terms of substitution.

5. Review the conditions for the production of technical documents for the implementation of EU policies relating to the marketing of pesticides, and move towards a new form of governance

The standard developed by EPPO is, in fact, an instrument for implementing Regulation 1107/2009. Presented as guides resulting from an open procedure, supported by technical expertise and endorsed by SCOPAFF, they take on the force of de facto standards, which strongly influence the implementation of Article 50 and, ultimately, the way in which comparative assessments are carried out, and the possibility of making substitution decisions. It is therefore important to :

- Systematize scientific validation, by the competent EU expertise agency, of those technical documents concerning the operational implementation of EU legislative or regulatory measures concerning the control of the risk associated with pesticides, when the preparation of these documents has been entrusted to external entities not subject to the same rules on the management of links of interest and transparency as those applying to Union bodies.
- Introduce the same relative rules for the drafting of technical standards applied at EU level as those usually applied by standardization bodies: governance body representing the various interested parties, including management bodies, compliance with the rules inherent in conflicts of interest, expertise of the multidisciplinary working groups responsible for drafting texts, respect for

consensus, guaranteed transparency through systematic public inquiries, consultation of the competent authorities when application is provided for by regulation, periodic review and revision.
- Ultimately, entrust the drafting of these texts to the EU's competent expertise agency, which will proceed in accordance with its working procedures (consultation of competent authorities through its "Advisory Forum", consultation of stakeholders) and its rules on the quality of expertise. To this end, provide the competent agencies with the resources they need to carry out this task.

6. Reform the European regulatory framework for pesticides to ensure effective substitution of CfS substances, in accordance with the objective of protecting human health and the environment

Regulation 1107/2009 responds to issues of chemical product availability for farmers and the organization of the marketing of substances. However, the substitution procedure defined in Article 50 is also part of a policy to protect human health and the environment, and more far-reaching regulatory changes may be required in the medium term to ensure its effectiveness.

- Take into account the objective of promoting a sustainable, safe and reduced use of pesticides in Europe, as envisaged in the future SUR Regulation, in Regulation 1107/2009, and assess the contribution of the various provisions of this regulation to achieving these objectives (article 50, article 55...) in the context of a modification of this Regulation.
- Study the adoption of legal instruments to support innovation in the development of alternative chemical and non-chemical solutions, as substitution decisions are hampered by the limited availability of alternative solutions, in a context of pressure created by the gradual withdrawal of active substances from the market.
- Consider incentives for companies in the agrochemical and biocontrol sectors, such as the programmed withdrawal of hazardous substances ("phase-out") within 5 or 10 years, or the non-renewal of approvals for these substances more than two or three times, as well as incentives for research and innovation into alternative solutions.
- Use taxation at national level, and in particular the annual tax on sales of substances that are candidates for substitution, or pollution charges, to promote more rapid and effective substitution.

Appendices

Appendix A : Referral letter :

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

Annex B-1 : Composition of the expert group[47]

- Autio Sari, Senior Officer, PhD (environmental science), Tukes (Finnish Chemical Safety Agency), Helsinki (Finland)
- Brimo Sara, Junior Professor, Paris University-Panthéon-Assas, holder of the Chair "Observatory Health and Environment - Legal and Interdisciplinary Analysis" (OSE AJIR)
- Demortain David, Sociologist, DR Inrae, Interdisciplinaary Laboratory Sciences Innovations Societies (UMR CNRS, Inrae, Uni. Eiffel)
- Doussan Isabelle, Jurist, DR Inrae, Research group on Law, Economy, Management (GREDEG UMR CNRS 7321 Université Côte d'Azur)
- Reboud Xavier, DR Inrae, Dijon, Special advisor to the Scientific Director for agriculture of Inrae
- Moquay Viviane, Retired Inspector General of Veterinary Public Health, former chairwoman of the CGAAER "Food - Health" section (chair of the expert group, member of cnDAspe)

Appendix B-2 : External reviewers

- **Anna Berlin.** Agronomist and associate professor of plant pathology. Swedish University of Agricultural Sciences, Uppsala, Sweden.
- **Giovanni Dinelli** (https://www.unibo.it/sitoweb/giovanni.dinelli/en). Full Professor at the Department of Agricultural and Food Sciences of the University of Bologna (Italy), working in organic farming, agro-ecology, the effect of agricultural practices and environmental factors on the quality of agricultural production. Involved in various European projects of the 7th Framework Program, Horizon 2020, LIFE+ and EIT-FOOD.
- **Pavel Minar.** from 2005 Head of the Plant Protection Product Division in ÚKZÚZ (Central Institute for Supervision and Testing in Agriculture), Czech Republic. He is responsible for the system of plant protection products authorisation in the Czech Republic.

[47] Click **here** to see the Declarations of Interests (DoI) of the experts

Appendix C : Standard letter of invitation and questions to interviewees

Viviane Moquay

Chair of the expert group created by the cnDAspe in view to answer to the referral

Réf : CNDA/FH/2023-xx

Destinataire/Recipient

Subject : Hearing regarding the "Evaluation of the implementation of measures to replace "more hazardous pesticides" with products and methods that are safer for health and the environment in the EU"

M xxx

The French *Commission nationale de la déontologie et des alertes en santé publique et environnement* (cnDAspe) has been asked by members of the European Parliament, the French National Assembly and the French Senate to express its opinion on the factors that explain the failure of the EU policy on substitution of "more hazardous pesticides" (see attached the referral letter).

As it has done since its installation in 2017, the cnDAspe will investigate this matter with all the independence and impartiality required.

I have the honour of requesting that you be heard by the "Specific Committee" that the cnDAspe has set up for this purpose. The dates proposed for this audition are left to your choice, between xxxx and xxx in the slots indicated in appendix 1. Please let us know your preference as soon as possible.

You will find in appendix 2 the questions on which the working group would like to hear your point of view. To facilitate discussion at your hearing, please send us a note summarizing your answers to these questions 2 days beforehand. This note is for internal use only and is not intended for publication.

Thanking you in advance for your response to this invitation, I assure you, M xxx, of my highest consideration.

Viviane Moquay,

Chair of the expert group

PS: In order to guarantee the serenity and independence of the commission's work, any person interviewed or collaborating on the commission's work undertakes a general obligation of reserve and absolute confidentiality with regard to all facts of which he or she may become aware concerning the commission's work, composition and operation, until the commission's work is published.

This obligation of confidentiality applies not only to third parties, but also to members of the commission and its permanent secretariat.

Annex 1

Referral letter

Annex 2

Proposed dates

Annex 3

Questions on which the panel would like to have your views

The questions are specific to each invited personality/entity

(questions drawn from the following table, according to the entities or personalities invited)

General theme	Specific issues
1. Conditions for substitution and comparative assessment	1-a- It makes sense that pesticides identified as having a greater potential for risks to human health, soil quality and/or biodiversity be considered for replacement, for controlling pests, by lower impact products, alternative programs or methods. Based on you view and experience, do you consider that the four conditions set out in Art. 50 (1) and Annex IV of Regulation 1107/2009 constitute factors that might impede usage of pest control approaches other than pesticides PPP, such as agronomic and biocontrol methods? If yes, which in particular ? How then would you change the list and/or the label of these conditions to reduce or avoid this bias against control approaches other than pesticides PPP ?
	1-b According to your experience, does the procedure for classifying certain active substances as "candidates for substitution" really allow the most problematic pesticides to be subjected to a comparative analysis with a view to possible substitution ? Could other risk assessment criteria for active substances be added (for example their high volume of use)?

	1-c Do you share the view that the construction of the standard protocol elaborated by EPPO, that structures the rationale of the Guidance document on Comparative Assessment and Substitution of PPPs, is biased in favor of chemical pest control solutions ?
	1-d In coherence with the *Farm to Fork* strategy which aims to reduce by 50% the use of pesticides and by 20% the use of fertilizers by 2030, does it make sense to reverse the reasoning, i.e. to rely on a protocol that favors non-chemical solutions (eg biocontrol and/or agronomic methods), chemical solutions being retained if and only if the previous solutions prove unsatisfactory on explicit criteria ? If so, please state the steps and decision criteria of such a protocol that would lead to a preference for non-chemical solutions.
2- Delegation to external bodies	2-b The protocol that drives the Guidance document on Comparative Assessment and Substitution of PPPs, that is used to determine whether an active substance candidate for substitution is to be substituted was acted in October 2014 when DG SanCo adopted, this Guidance document. This protocol was builds on the standard EPPO protocol adopted in September 2011. Thank you for explaining how it was decided to delegate expertise to an entity such as EPPO, whose territory is not that of the European Union and whose principles of transparency and prevention of conflicts of interest do not meet EU rules.
	2-c Please expose your view on the steps that EFSA might take to regain control on the policy for substitution of more hazardous active substances. Is full control a reasonable objective ? Would you consider (an) alternative(s) ? Whether aiming at full control or any other transitory or intermediate option, do you think it would be necessary to revise some text governing the functioning of EFSA, or to update some articles of the 1107/2009 regulation on pesticides? If so, please state the essential points to be revised.
	2-d The elaboration of the OECD Test Guidelines pose a somehow similar question. Their hundreds of technical documents provide a detailed framework for health and environmental risk assessments that is used in the processes of registration of active substances (EFSA) and of the marketing authorization of PPPs (national competent authorities). Shouldn't EFSA regain the ability to establish its own *Test Guidelines* based on duly mandated internal and/or external experts selected according to its Independence principals and procedures ? Do you think this would require amending the 1981 OECD *Decision on Mutual Acceptance of Data in the Assessment of Chemicals* ? Would such major change be a reasonable objective ? Would you consider (an) alternative(s) ?
3- Voluntary substitution	Based on article 50, paragraph 2, or following other criteria, your agency has already voluntarily decided to substitute pesticides deemed hazardous, with other pest control methods or products. Have you encountered any difficulties in doing so because of the provisions of article 50, paragraphs 1 or 2 of the 1107/2009 regulation on pesticides ? What measures could you recommend to make it simpler and more effective to substitute hazardous pesticides with other products or methods ?

Appendix D : List of invited personalities and hearings dates

Invited personalities, Institution/organisms **(listed alphabetically by first name)**	**Date of hearing**
Anses, represented by Benoit Vallet, General Director, Charlotte Grastilleur Executive Vice-President, Regulated Products Division, Bertrand Bitaud, Marketing Authorization Department	5/9
Assemblée permanente des chambres d'agriculture	Did not respond to request for hearing
Bailleux Antoine Law Professor, Catholic University of Louvain, Brussels (see wrtitten contribution in appendix F-2-1)	27/6
Confédération Paysanne, represented by Sylvie Colas, national secretary in charge of pesticides and GMOs and Suzy Guichard, member of the confederation permanent team	6/7
CropLife Europe, represented by Olivier de Matos, General Director	11/7
Ctgb (Dutch Board for the Authorisation of Plant Protection Products and Biocides)	Did not respond to the request for hearing due to its parallel participation in the consultation on the draft revision of the substitution provisions.
Direction générale de l'alimentation, Ministère de l'Agriculture	Did not respond to request for hearing
DG SANTE, Commission Européenne, représentée par Klaus Berend, Head of Unit Pesticides and Biocides - Directorate-General Health and Food Safety	26/7
ECHA	Declined the invitation, considering that the agency was not concerned by the questions asked
EFSA, represented by Manuela Tiramani, Head of Pesticide Peer Review Unit, and Flavio Fergnani, External Relations Officer	26/7 (in conjunction with DG SANTE)
FNSEA	Did not respond to request for hearing
IBMA France represented by Céline Barthet (President) and Denis Longevialle (DG) and **IBMA Global** represented by Jennifer Lewis Executive Director and Jeroen Meeussen	10/7
Kemi (Swedish Chemicals Agency)	Has indicated not to be available
PAN Europe, represented by Salomé Roynel (see written contribution in appendix F-2-2)	29/6

Appendix E : Summary table of comparative assessment (CA) produced by PAN Europe.

Based on the information received from the Commission on its survey on comparative assessment conducted in autumn 2021 *

(extracts of a document provided by PAN Europe)

Member State	Total authorisation of PPP with CfS	Number of CA performed	Number of substitution (s)	Number of amendements of authorisation	Frequency	Voluntary CA
Spain	512	69	0	0		
Portugal	83	83	0	0		
Slovenia	119	21	0	0		
Germany	48 (incl. 4 mutual recognitions)	79 (incl 31 mutual recog.)	2 (renewals), 27 (rejection mutual recog.)	3	Each application	
Hungary	462	48	0	0	/	
France	396	260	2	0	Each application	21
Norway	?	5 (2 others for product application rejected)	0	0	Renewal applications	
Sweden	74	30	0	0	Renewal or amendment applications	1
Slovakia	368	72	0	0	Renewal or amendment applications	
Finland	80 (incl. identical or parallel products)	18 (1 other rejected but not because of substution)	0	0	Renewal or amendments No regular examination	
Austria	233	105	0	2	Applications	
Netherlands	179	36	0	0	Renewal or amendments	
Latvia	102	9	0	0	Renewal or amendments	
Greece	275	260	0	1	/	
Bulgaria	?	10	0	0	/	
Croatia	172	23	1	0	/	
Total	**3103 (+ ?)**	**1128**	**5 (+27 rejection mutual recognition)**	**6**		**22**

- Only 16 MS answered this survey. The situation in the other MS is unknown

Appendix F : Additional information

F-1 : Definition of active substances likely to be included in the list of candidates for substitution

Article 24 of the Regulation concerns active substances for which substitution is envisaged. It refers to point 4 of Annex II, which reads as follows:

An active substance shall be approved as a candidate for substitution pursuant to Article 24 where any of the following conditions are met:

—its ADI, ARfD or AOEL is significantly lower than those of the majority of the approved active substances within groups of substances/use categories,

— it meets two of the criteria to be considered as a PBT substance,

—there are reasons for concern linked to the nature of the critical effects (such as developmental neurotoxic or immunotoxic effects) which, in combination with the use/exposure patterns, amount to situations of use that could still cause concern, for example, high potential of risk to groundwater; even with very restrictive risk management measures (such as extensive personal protective equipment or very large buffer zones),

— it contains a significant proportion of non-active isomers,

—it is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B, if the substance has not been excluded in accordance with the criteria laid down in point 3.6.3,

—it is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B if the substance has not been excluded in accordance with the criteria laid down in point 3.6.4,

—if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, reviewed by the Authority, it is considered to have endocrine disrupting properties that may cause adverse effects in humans if the substance has not been excluded in accordance with the criteria laid down in point 3.6.5.

F-2 : Written contributions (published with the permission of the authors)

F-2-1- Antoine Bailleux

Professor of European Union law at UC Louvain (Saint-Louis - Brussels) Lawyer at the Brussels bar

(translation of the original contribution in French)

Question 2.c. On the appropriateness and implementation of EFSA monitoring of the policy of substitution of the most hazardous products

Given the current failures of comparative assessment at Member State level, it would certainly be appropriate to entrust EFSA with a certain role in the supervision and monitoring of the policy of substitution of the most hazardous products.

This role could be more or less important.

At the very least, it would certainly be desirable for EFSA to develop a comparative assessment protocol specific to the European Union, and therefore potentially different from that drawn up by EPPO. This would not pose any particular problem at international level, since, as far as I know, the category of "candidate substances for substitution" (and therefore the related comparative assessment method) is specific to the European Union. There is therefore no need to adopt an internationally standardized methodology in this respect.

In my opinion, this regulatory framework does not require any reform of Regulation 1107/2009 (which governs the marketing of pesticides) or Regulation 178/2002 (which establishes EFSA). In fact, according to Article 23 of the latter Regulation, EFSA is responsible for "promoting and coordinating the development of uniform risk assessment methods in the fields within its mission".

It is important to note, however, that such a protocol would only have added value for public health and the environment if it deviated on various points from the methodology currently recommended by EPPO. Without being an expert on the subject, it seems to me that, at the very least, the EFSA protocol should :

- Include a method for assessing non-chemical alternatives, in accordance with Directive 2009/128 ("SUD Directive") and Article 50 and Annex IV of Regulation 1107/2009;

- In accordance with Article 50 of Regulation 1107/2009, adopt a global approach to weighing up the risks and benefits of substitution, rather than an exclusionary approach which rules out any substitution as soon as one of the criteria set out in Annex IV of the Regulation - and particularly the first of them - is deemed to be met. This would also be more in line with the principle of primacy of health and environmental protection over the objective of improving production This primacy is set out in recital 24 of the preamble to Regulation 1107/2009 and was reiterated by the Court of Justice in several recent rulings[48].

A priori, one might have doubts about EFSA's ability or willingness to promote such a multifactorial and integrated assessment. Indeed, the protocol developed by EFSA for the approval of active substances "to control a serious plant health hazard that cannot be controlled by other available means, including non-chemical methods "[49] focuses almost exclusively on the issue of resistance to chemical alternatives.

However, the Commission's new objectives for reducing pesticide use seem to be prompting EFSA to pay greater attention to non-chemical alternatives. Its recent call for proposals to draw

[48] 1 Cf. e.g. judgment of May 5, 2022, R. en R. (Agricultural use of an unauthorized product), C-189/21, EU:C:2022:360, points 42 and 43; judgment of January 19, 2023, Pesticide Action Network Europe and others, C-162/21, EU:C:2023:30, point

[49] 2 Article 4, § 7, of Regulation 1107/2009. It should be noted that this protocol is currently also used by EFSA to monitor member states' compliance with the conditions laid down in Article 53 of the Regulation for the issue of emergency marketing authorizations for plant protection products.

up a protocol for the evaluation of emergency authorizations granted by Member States on the basis of Article 53 of Regulation 1107/2209 includes the question of non-chemical alternatives, including those used in organic farming.

EFSA could also be given a role in monitoring the application by member states of the provisions of Regulation 1107/2009 relating to the authorization of plant protection products. It would thus be perfectly conceivable that, in a similar way to what is provided for in Article 53 for emergency authorizations, Member States should be required to notify the Commission of all authorizations granted to plant protection products containing candidate substances for substitution. The Commission could entrust EFSA with the task of verifying that these authorizations comply with the regulatory framework, including, where applicable, the protocol developed at EU level.

This procedure is not currently provided for in Regulation 1107/2009. It could be incorporated into Article 50 of the Regulation. However, as the Regulation is a legislative act, amending it could prove cumbersome from a procedural point of view. An alternative might be to introduce this obligation via a Commission Implementing Regulation, for example (but not necessarily) as part of an amendment to Annex IV of the Regulation.

It should be pointed out, however, that while this option may look attractive on paper, in practice it is likely to run up against the very large number of authorizations currently granted on the basis of Article 50 of the Regulation. EFSA's limited resources mean that it cannot carry out a systematic assessment of these authorizations, so only a selective evaluation will be possible. The question of how and by whom such a selection will be made remains open. The evaluation of emergency authorizations granted by Member States on the basis of Article 53 gives little cause for optimism on this point. Only exceptionally, and under pressure from organized civil society, has the Commission asked EFSA to review such authorizations.

It would also be advisable to ensure that EFSA itself operates in a perfectly independent manner. There are still far too many conflicts of interest[50] , and the recent reform of the composition of its Management Board places EFSA under the control of the Member States. As amended by Regulation 2019/1381 of June 20, 2019, Article 25 of Regulation 178/2002 now stipulates that the Management Board shall comprise one representative of each Member State, two representatives of the European Parliament, two representatives of the Commission and four members from civil society. Governmental interests - which experience has shown are more often aligned with those of industry than those of health and the environment - therefore dominate the EFSA Board.

Finally, it should be noted that such a task of controlling comparative assessments, particularly if it includes a cost/benefit evaluation, requires specific skills, particularly in the agronomic field. I don't think that EFSA currently has such expertise.

2.d On the relevance, realism and reasonableness of EFSA establishing test guidelines independent of those prepared under the aegis of the OECD

In an ideal world, the European Union would succeed in getting the OECD to adopt strict rules on transparency, independence and avoidance of conflicts of interest with industry in the process of establishing guidelines. This would be in line with Article 13(e) of Regulation 178/2002, according to which the Union and the Member States "shall promote consistency between international technical standards and food legislation, while ensuring that the high level of protection adopted in the Community is not lowered". Unfortunately, although the EFSA and the Commission each have a seat, it seems that the European Union is often conspicuous by its absence at OECD meetings.

If this first option proves unrealistic, it can be argued that legally, the precautionary principle - which includes a requirement for objectivity and impartiality - requires an assessment, at EU

[50] https://corporateeurope.org/sites/default/files/attachments/recruitment_errors_-_june_19_update.pdf

level, of the appropriateness of each guideline emanating from the OECD. In the event of a negative conclusion, it would be up to EFSA, in an inclusive and transparent process, to develop guidelines specific to the European Union. This is perfectly compatible with Regulation 1107/2009, which refers to taking account of guidelines adopted at "Community or international" level. As for Implementing Regulations 283 and 284/2013 on data requirements, while they appear to give priority to international (or national) guidelines, these must be deemed "adequate", leaving the European Union a margin of discretion.

In the short term, this would have the effect of increasing the use of laboratory animals, which is contrary to one of the objectives of Regulation 1107/2009. However, it's a safe bet that, if the European guidelines reveal problems not revealed by the OECD guidelines, the latter will quickly be replaced by the former. The positive impact of the Brussels effect should not be overlooked either.

Such an approach would not, a priori, be compatible with the 1981 OECD decision on the mutual acceptance of data in the assessment of chemicals - even though this decision leaves the States Parties free to interpret the studies carried out on the basis of OECD guidelines. A superficial analysis suggests, however, that such a decision is not necessarily binding on the European Union. On the one hand, Article 6 § 3 of the OECD Convention states that "no decision shall be binding upon a Member unless and until it has complied with the requirements of its constitutional procedure". In that respect, I'm not sure (but this should be verified) that the 1981 decision was ever formally approved by the internal bodies of the European Union (which, incidentally, is not a full member of the OECD). In other words, it is not certain that the European Union could be held internationally liable in the event of non-compliance with this decision. On the other hand, and in any event, the Court of Justice is reluctant to give direct effect to the decisions of international bodies. Moreover, it has ruled that the European Union's international commitments cannot justify a departure from the general principles of European Union law[51] , which include the precautionary principle. In other words, it is not obvious either that failure to comply with the OECD decision would result in the European Union's responsibility under European law being called into question.

Brussels, June the 23rd, 2023

[51] Arrêt du 3 septembre 2008, Kadi et Al Barakaat International Foundation / Conseil et Commission, C-402 et C- 405/05 P, EU:C:2008:461

F-2-2- Salomé Roynel (PAN Europe, hearing 29/6/2023)

Comparative assessment and substitution of more hazardous pesticides

PAN's Europe hearing by the cnDAspe

Preparatory notes

June 2023

In June 2023, PAN Europe was invited to provide its view on comparative assessment and substitution of more hazardous pesticides by the experts group of the Commission nationale de la déontologie et des alertes en santé publique et environnement (cnDAspe). We welcome this opportunity to express our views and hope our contribution will serve the experts well in their work.

cnDAspe: Your report Pesticide Paradise showed that the construction of the standard protocol elaborated by EPPO that structures the rationale of the Guidance document on Comparative Assessment and Substitution of PPPs, is biassed in favour of chemical pest control solutions. Please elaborate on this key point and develop a structured demonstration of this "bias by design".

In September 2022, PAN Europe published a report entitled Pesticide Paradise, How industry and officials protected the most toxic pesticides from a policy push for sustainable farming. It followed up on a first report called Forbidden Fruit from May 2021. Forbidden Fruit highlighted the growing exposure of consumers to residues of candidates for substitution between 2011 and 2020 in fruit and vegetables grown in the EU (namely an increase in the frequency of contaminated products). Pesticide Paradise looked into the causes behind this persistent and growing presence of candidates for substitution in citizens' plates. The main finding of this report was that the strongest bottleneck to substitution, when Member States actually carry out a comparative assessment[52], is the way they assess pest resistance control building on the approach of the European and Mediterranean Plant Protection Organisation (EPPO).

Background

In September 2011, EPPO published a standard on comparative assessment to *"provide [Member States] guidance and a decision support scheme to determine whether the substitution of a [pesticide] is appropriate in view of agronomic considerations"*. In other words, this standard aims to interpret the conditions of comparative assessment covered in Article 50(1) from (b) to (d). The European Commission issued its own SANCO guidance document *"to supplement the EPPO standard"* and cover Article 50(1)(a) dealing with comparative assessment of health and environmental risks. It is clear from the SANCO document that the Commission encourages Member States to use the EPPO's standard, which they do. This SANCO Guidance Document was adopted by Member States in 2014.

In 2011, the EPPO's standard proposed a *"stepwise"* approach dividing the comparative assessment in 15 orderly questions. This assessment could *"be terminated at any stage"* when it appeared from the reply to one of these 15 successive questions that one of the conditions of comparative assessment was not met. A revised version of the protocol published in 2019

52 Some Member States are setting derogations to Article 50(1) other than the one foreseen in Article 50(3) of Regulation (EC) No 1107/2009, see Belgium example challenged in Court by PAN Europe.

bunched the process into 4 blocks (A to D), covering the same decision scheme, but leaving the possibility to national authorities to start the assessment at whatever stage they feel is most likely to terminate the comparative assessment early, saving them time and resources. Apart from a substantial change for minor uses[53], the 2019 version of EPPO's standard has remained content-wise identical to its original version from 2011. While pest resistance control was dealt by steps 6 to 10 in the 2011 protocol, it is now identically covered by 5 questions under stage B of the present EPPO's standard.

Article 50(1)(c) - Pest resistance management

In the context of comparative assessment, preventing the occurrence of pest resistance stands as one of the conditions an alternative must meet for substitution to occur (Article 50(1)(c) and Annex IV). Namely, "*Substitution shall be applied only where other methods or the chemical diversity of the active substances is sufficient to minimise the occurrence of resistance in the target organism*" (Annex IV). It appears clearly from this wording that both non-chemical practices and methods and the "chemical diversity" have to be considered.

This concept of "*chemical diversity*" was coined by the pesticide industry. Resistance to pesticides has been known for a long time. As early as in the 1970s, insects could no longer be controlled in tomatoes and cucumbers grown in greenhouses due to resistance. For a period of time, it even seemed like the greenhouse cultivation of these crops would have to stop. The introduction of biological control has saved greenhouse cultivation and is now used on almost all of tomato and cucumber crops by professional growers. This experience demonstrated that the only effective and sustainable response to resistance was to use non-chemical methods. However, this conclusion did not fit well with the profit-generating model of the pesticide industry. As early as 1984, an initiative (the Insecticide Resistance Action Committee, IRAC) was formed to provide a coordinated response by the pesticide industry to the problem of insecticide resistance which had become a serious threat, not only to pest control, but also to its profits. The solution was found in the multiple chemical strategy which claims that using many different pesticides (with different modes of action) is a prerequisite for "sustainable resistance management". This strategy was replicated for other families of pesticides (including herbicides and fungicides)[54]. This was a very clever strategy which invites the pesticide industry to continuously develop new (and expensive) pesticides to address ever growing resistance and averts the use of other plant protection methods.

This credo has been propagated since the 1980s with great success. The multiple chemical strategy has now been applied for more than 40 years by most farmers who rely on the guidance of advisors linked to the pesticide industry. The strategy was also uncritically endorsed by both EPPO and the European Food Safety Authority (EFSA)[55] in their respective methodologies to assess alternatives.

The concept of "*chemical diversity*" was also included in Annex IV of the EU Pesticides Regulation. However, Regulation (EC) 1107/2009 itself mentions the chemical diversity as one possibility among other methods to prevent resistance, the EPPO's standard makes it the *sine qua non* condition of resistance management. Furthermore, while Regulation (EC) 1107/2009 refers to the chemical diversity of the active substances, with no reference to modes of action, EPPO's standard reads as follows: "*The first consideration is whether there is sufficient chemical diversity in terms of the number of alternative modes of action against the target pest. If there is not, then CA will be completed at that point.*". **In other words, there are no legal requirements**

53 See Annex 1 - Minor uses in EPPO's standard on comparative assessment.
54 Herbicide Resistance Action Committee (HRAC), Fungicide Resistance Action Committee (FRAC).
55 See protocols on Articles 4(7) for herbicides, fungicides and insecticides used by EFSA to support the necessity to grant a derogation to active substances in the context of Article 4(7) as well as the need for Member States to grant emergency authorisations to products in the context of Article 50(3).

in Regulation (EC) 1107/2009 to rely on modes of action when assessing the chemical diversity of active substances and no support for ending comparative assessment solely on the basis of this analysis (i.e. without consideration of all non-chemical practices).

EPPO's standard is then taking the form of a multi-stage decision tree, ending inevitably with a final question B5 (if stage B1 to B4 did not stop comparative assessment) and the criteria for answering it in Note B(iii).

Assessing comparability regarding the risk of developing resistance (Stage B)	
B1. Does the target pest(s) have a high or medium inherent resistance risk (see Note B(i))?	
Yes	Go to B2
No	Go to B5
B2. Is there a product within the same mode of action (MoA) group authorized for use against the target pest(s)?	
Yes	Go to B5
No	Go to B3
B3. Are there products with another MoA authorized for use against the target pest(s)?	
Yes	Go to B4
No	Stop CA
B4. Does the candidate exhibit negative cross-resistance in the target pest(s) (see Note B(ii))?	
Yes	Stop CA
No	Go to B5

(continued)

B5. Given the available alternatives (chemical and non-chemical), is the candidate an important component (see Note B(iii)) of the resistance management strategy for the target pest and other pests in the crop not themselves subject to CA?	
Yes	Stop CA
No	Go to next appropriate stage (A, C or D)*

*If all other stages have already been considered without an indication that the CA should be stopped, substitution may be possible.

Explanatory notes

Note B(i)

The risk of resistance can be analysed based on PP 1/213 Resistance risk analysis. In CA the impact on a risk management strategy in the situation that a PPP is subject to substitution is assessed.

Note B(ii)

See detailed guidance provided in EPPO Standard PP1/213, section 5.3.5.

Note B(iii)

Based on expert judgment 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 (Rotteveel et al., 2011). The current resistance situation should be considered when evaluating the required number of mode of actions.

Source: Extract from EPPO's Standard on comparative assessment.

Note B(iii) defines when chemical diversity is "*sufficient*" according to EPPO based on modes of action. Depending on this ratio number of available modes of action/resistance risk, the comparative assessment can be ended before the national competent authority starts assessing the non-chemical methods for substitution of the product containing a candidate for substitution. As there are very few low risk resistance situations or for which sufficient information is available, one can reasonably assume that the availability of pesticides with at least 3 different modes of action will be examined for most of the examined crop/pest combinations. While this already constitutes a high threshold, some Member States have raised the hurdle a notch higher by making the availability of at least 4 modes of action a basic requirement, irrespective of the level of resistance risk (Spain, the Netherlands, Belgium and Portugal). In practice, it is very rare to have so many modes of action available on the EU market for each crop and pest, which makes substitution very unlikely to happen according to PAN Europe.

Reality check n°1: is this B stage obstructing substitution?

According to the most recent and comprehensive set of national data collected by the Commission in October/November 2021 and shared with PAN Europe following a request for access to documents[56], no more than 5 cases of substitution[57] occurred out of more than 1 000 comparative assessments since 2015. In other words, comparative assessment has resulted in a successful substitution in only 0,5% of the cases.

The role played by this mode of action's approach by EPPO in obstructing substitution is significant according to PAN Europe. The limited number of modes of action available clearly stands as the major bottleneck to substitution. This was clearly highlighted in the case of the TAVAS product brought before the Dutch court. This product contains two candidates for substitution (diflufenican and metribuzin). Following a first complaint by PAN Europe, the Dutch competent authorities were forced by an administrative court to comply with their obligation to carry out a comparative assessment of the product (i.e. to apply Article 50(1) of Regulation (EC) 1107). The product's application included an authorisation for potato crops against *dicotyledons (weed species)*. While 15 different herbicides had already been authorised for this crop/use combination and while 38% of the Dutch potato growers applied only mechanical weed control on this weed, substitution was found inappropriate, building on EPPO's rationale reinforced by the Dutch competent authority. Indeed, all together the 15 authorised products did not belong to 5 different modes of action, but only to 3, justifying the authorisation on the market of a 16th hazardous product. This case shows that the multiple chemical strategy is blocking substitution as well as promoting the "pesticide treadmill".

This example is not an isolated one. According to information collected and received by PAN Europe, in France, the majority of the comparative assessment performed for products containing one or several of the Toxic12 substances by PAN Europe, were stopped due to "*an insufficient number of modes of action*". This was also supported by the information submitted by Member States to the Commission[58]. The insufficient chemical diversity stands as the most common challenge raised, while the second most important one is the consequences on minor uses[59].

Another bottleneck raised by Member States in that context is the lack of data on the efficiency of non-chemical alternatives. Since in practice most of them do not look into them, this claim contains, at least partly, some intellectual dishonesty according to PAN Europe. Moreover, this raises the question of which side the burden of proof should fall on and who should benefit from the uncertainty. In this regard, the EPPO's standard in use reads as follows: "*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*". In the context of Regulation (EC) 1907/2006, which also foresees a substitution mechanism, the European Court considered that where there is insufficient evidence or uncertainty regarding the alternatives, this doubt must benefit to the substitution, not to the authorisation, in line with the precautionary principle.

Lessons learnt from voluntary substitution

On top of the mandatory comparative assessment of application for products containing candidates for substitution, Regulation 1107/2009 foresees a "voluntary substitution" mechanism in its Article 50(2): "*By way of derogation from Article 36(2) Member States may in*

[56] See Annex 3 - Summary table on comparative assessment by PAN Europe. Based on the requested information received from the Commission on its survey on comparative assessment conducted in Autumn 2021 (most recent collected data available).
[57] 1 in Croatia, 2 in France, 2 in Germany (mutual recognition excluded).
58 See Annex 3.
59 Also due to EPPO's standard. See Annex 1.

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". In this case, the conditions for substitution are not completely the same as for Article 50(1). Namely, these products containing substances other than candidates for substitution can only be replaced by non-chemical alternatives.

This **voluntary substitution is neither covered by the EPPO's standard on comparative assessment nor by SANCO guidance document**. Yet this voluntary mechanism has led to more successful cases of substitution than the implementation of Article 50(1) did:

- France: in 2018, France decided to perform a voluntary comparative assessment of glyphosate-based products. Substitution has been found feasible for 19 use/crop combinations. From the published comparative assessment's reports, it is clear that the approach adopted by the French regulatory agency to perform comparative assessment in this context has been different than the one used for Article 50(1), i.e. was not based on EPPO's standard. Although the comparative assessment was not totally aligned with IPM (alternatives were assessed individually), it shows that when properly assessed, non-chemical methods can be found as appropriate substitutes to the examined product.

- Sweden: in 2019, the Swedish regulatory agency also carried out a voluntary substitution of an acetamiprid-based product against pine weevil *(Hylobius abietis)* in forestry. One can reasonably wonder whether these cases of voluntary substitution would have been found possible if the EPPO's standard on comparative assessment, including its stage B, had been applied in these two successful cases. From the perspective of dedicated resources/benefits for human health and the environment, it would be interesting to know how many comparative assessments have been carried out under Article 50(2)[60], and in how many cases this has led to voluntary substitution. The success ratio would certainly be much higher than the 0.5% calculated by PAN Europe in the context of Article 50(1).

Reality check n°2: does the multiple resistance strategy bring any benefit in terms of pest resistance control?

Since the 1980s, resistance to pesticides has kept increasing for virtually all organisms (insects, fungi, plants). The pesticide industry itself admits: *"Resistance to conventional pesticides — among insects, weeds or microbial pathogens — is common on farms worldwide. CropLife International, an industry association based in Brussels, supports efforts that have counted 586 arthropod species, 235 fungi and 252 weeds with resistance to at least one synthetic pesticide"*[61]

60 If any other than those mentioned above.

61 With pesticide resistance rising, crop scientists look to CRISPR, bacteria for solutions - Genetic Literacy Project [11] Sowa G, Bednarska AJ, Ziółkowska E, Laskowski R. Homogeneity of agriculture landscape promotes insecticide resistance in the ground beetle Poecilus cupreus. PLoS One. 2022;17(4):e0266453. Published 2022 Apr 26. doi:10.1371/journal.pone.0266453.

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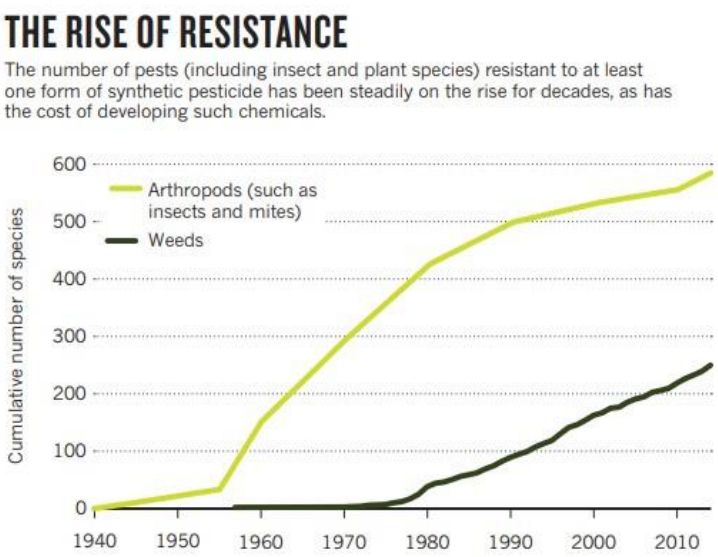

Independent scientists challenge the relevance of the multiple chemical strategy and acknowledge that integrated use of agronomic, mechanical, physical and biological alternatives is the most effective strategy to manage pest resistance and control[11]. According to Hicks and al.[62], the system of applying more and more pesticides is counterproductive: "*Resistance was correlated with the frequency of historical herbicide applications suggesting that evolution of resistance is primarily driven by intensity of exposure to herbicides but was unrelated directly to other cultural techniques*". Other resistance scientists including Gould and al[63] state that it is an illusion to consider that resistance can be tackled by synthetic pesticides: "*We mostly continue to use pesticides as if resistance is a temporary issue that will be addressed by commercialization of new pesticides with novel modes of action*". Likewise, Hoy[6465] stresses that *"resistance will remain an ongoing dilemma in pest management and we can only delay the onset of resistance to pesticides*". The solution *"involves employing effective agronomic practices to develop and maintain a healthy crop, monitoring pest densities, evaluating economic injury levels so that pesticides are applied only when necessary, deploying and conserving biological control agents, using host-plant resistance, cultural controls of the pest, biorational pest controls, and genetic control methods"*. Comont and al.[66] clearly question the effectiveness of the multiple chemical strategy: "*We contend that where specialist and generalist resistance mechanisms co-occur, similar trade-offs will be evident, calling into question the ubiquity of resistance management based on mixtures and combination therapies* ". Whelan and al.[6768] clearly point out the pesticide's industry responsibility: "T*he agriculture industry recognized the problem of pesticide resistance and responded by developing and enforcing guidelines on resistance management and prevention. These guidelines, (...) do not encourage eradication of pests but instead strive to maintain pests, even with the presence of resistant strains, at a level that does not cause economic damage to the crops.*".

cnDAspe: In line with the Farm to Fork strategy, which aims to reduce pesticide use by 50% and fertiliser use by 20% by 2030, do you think it would be appropriate to reverse the reasoning, i.e. to rely on a protocol that favours non-chemical solutions (e.g. biocontrol

62 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.
63 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.
64 Hoy MA. Myths, models and mitigation of resistance to pesticides. *Philos Trans R Soc Lond B Biol Sci.*
65 ;353(1376):1787-1795. doi:10.1098/rstb.1998.0331.
66 Comont, D., Lowe, C., Hull, R. and 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/s41467-020-16896-01.
67 Whelan CJ, Cunningham JJ. Resistance is not the end: lessons from pest management. Cancer Control.
68 ;27(1). doi:10.1177/1073274820922543

and/or agronomic methods), with chemical solutions being retained if and only if the previous solutions prove unsatisfactory on the basis of explicit criteria?

Yes, non-chemical alternatives must be assessed first and in an integrated manner. This is supported by what we underlined in the previous paragraph, i.e. that applying integrated pest management, giving priority to non-chemical methods first, is considered by independent resistance experts to be the most sustainable and effective method of managing resistance.

On top of being science-based, properly assessing non-chemical solutions and reversing the reasoning to give priority to these sustainable alternatives is a EU legal requirement for Member States, even if this is not explicitly stated in Article 50(1) and Annex IV of Regulation (EC) 1107/2009. These latter must indeed be read in the light of:

- Directive 128/2009/EC on the sustainable use of pesticides, and in particular Article 14(1), which states that "*Member States shall take all necessary measures to promote low pesticide-input pest control, giving priority to non-chemical methods wherever possible*".

- Recital 24 of Regulation (EC) 1107/2009, which states that "*when granting authorisations of plant protection products, the objective of protecting human and animal health and the environment should take priority over the objective of improving plant production*" (and thus related resistance/pest control challenges).

This has been largely confirmed by the Court of Justice of the EU in its preliminary ruling C-162/21 dated 19 January 2023. Although the case relates specifically to the interpretation to be given to article 53 of Regulation (EC) 1107/2009, the court drew several conclusions of principle, which support an interpretation of Regulation (EC) 1107/2009's provisions based on its primary objective of protecting and implementing and based on the basic principle of integrated pest management of Directive 2009/128/EC.

"44. In addition, it should be noted that the interpretation of Article 53(1) of Regulation No 1107/2009 in paragraph 39 above is supported by the obligation on the Member States, under Article 14(1) of Directive 2009/128, to take all necessary measures to promote low pesticide-input pest management, giving wherever possible priority to non-chemical methods, so that professional users of pesticides switch to practices and products with the lowest risk to human health and the environment among those available for the same pest problem. (...)

> ***46.*** *(...) the objective of Regulation No 1107/2009 which is, as stated in Article 1(3) and (4) of that regulation and reflected in recital 8 thereof, in particular to ensure a high level of protection of human and animal health and the environment.*

> ***47.*** *In that regard, it should be borne in mind that those provisions are based on the precautionary principle, which is one of the bases of the policy of a high level of protection pursued by the European Union in the field of the environment, in accordance with the first subparagraph of Article 191(2) TFEU, in order to prevent active substances or products placed on the market from harming human or animal health or the environment.*

Furthermore, it is clear, as stated in recital 24 of Regulation No 1107/2009, that the provisions governing authorisations must ensure a high standard of protection and that, in particular, when granting authorisations of plant protection products, the objective of protecting human and animal health and the environment should 'take priority' over the objective of improving plant production (...)

Appendix G : Main families of alternative methods - a summary

(Reboud Xavier, Inrae)

Article 50.2 allows the comparative analysis to be extended to non-chemical alternatives. Indeed, many agricultural innovations capable of supporting changes in farming models are working to improve crop protection without resorting to chemical protection. These practices and innovations have particularly benefited from the growth of organic farming over the last 40 years. Non-chemical alternatives can be classified into 4 main families, which can be further broken down into varietal genetics, agronomic practices, biocontrol solutions, and physical or mechanical actions.

Varietal genetics involves searching genetic resources for related species or variants with natural tolerance to the disease we are trying to avoid. For example, a pathogenic fungus may need to recognize a membrane receptor in order to enter the plant, and be unable to attack plants that do not have this receptor, or have a receptor that is too similar to be recognized. If, by cross-breeding and back-crossing, it is possible to switch a species of interest from a recognized receptor to one that is not, by making marginal changes to the genetic make-up, a more or less marked resistance trait will have been conferred on the plant. This has always been the practice in plant breeding, and has resulted in disease-resistant varieties. This approach is the subject of a great deal of research. It has the merit of offering a simple alternative to farmers who, by simply changing grape variety or varietal, no longer need to use pesticides to protect their fields. What's more, this field of innovation is fairly well marked out in terms of intellectual property management, and seed companies are investing in it. Two limitations: diseases evolve and may find a loophole that gives them back the ability to attack a plant despite its genetic baggage, so there is an arms race between varieties and diseases. In other words, the resistance trait erodes over time and needs to be renewed. The second limitation concerns the effect on yield potential of genetic changes made to reinforce resistance traits to a wider range of pests. It is potentially costly for the plant to invest part of its photosynthetic resources in protection against biotic stresses (viruses, bacterial diseases, fungi, weeds) or abiotic stresses (frost, drought). The aim of plant breeding has been to improve yield in terms of quantity and quality, in return for plant protection practices and the provision of optimal environmental conditions (frost protection, irrigation, etc.). Increasing the robustness or hardiness of varieties therefore means accepting a lower productivity potential, but this can generally be made up for in other ways. In other words, the most robust varieties that do not need to be protected by chemical treatment are generally not the most productive. This may have economic implications for farming systems aiming to maximize production per unit area, or in a collection basin close to the processing chain (like a sugar refinery). This can also lead to regulatory obstacles if, for example, a label restricts the choice of grape variety or varietal in order to maintain the desired typicity.

Agronomic practices cover a wide range of applications, from simply carrying out the actions required to manage a crop, such as ensuring its proper installation, fertilization or harvesting, to processes added explicitly to ensure a preventive or corrective measure, such as limiting competition with mechanical weeding or pruning branches to maintain good aeration, which will delay the development of certain diseases. What they have in common is that they identify growing conditions, and are generally carried out with the help of dedicated agri-equipment. Agronomic practices are often classed as part of integrated crop management. While this is fairly obvious when it comes to ploughing, which creates a bare, open space, it is a little less obvious when it comes to exporting chaff to avoid recharging the plot's weed seed bank with harvest residues, as this is a clean, dedicated action that has no immediate effect on the crop in place. Almost all farmers will say that they adopt good practices, and that they resort to pesticides precisely to cover the part of the risk they are unable to manage with simple measures. This is both true and false, insofar as agronomic practices are part of the anticipation process, do not generally have a total effect, are often costly and time-consuming. The use of

a mechanical weeding tool such as a rotary hoe or a weeder eliminates some weeds, but not all. Agronomic practices are rarely sufficient levers to guarantee crop protection. All avenues, including those recognized as effective, are only rarely mobilized. The question then becomes how much effort a farmer is prepared to make to mobilize this lever rather than curative chemistry. A similar limitation applies to the use of physical or mechanical alternatives. Apart from the fact that their mobilization can be technical, agronomic practices are carried out with equipment that is often expensive, even if shared purchases or implementation via the services of an agricultural contractor are generally a way of containing expenditure. This is a clear limitation when comparing chemical and mechanical alternatives: in one case, a solution involving a globally effective pesticide, relatively inexpensive, fairly easy to deploy and solving a well-defined problem with visible results; in the other, slower work times with expensive equipment, requiring anticipation and possibly favourable weather conditions to give full effect, which cannot easily be observed since the action may have been carried out without the need eventually being expressed (a favourable weather year, for example). Will the criteria of article 50 'economically viable and in common use' then be considered to have been met? Will the farmers directly concerned be inclined to align themselves with the interests of their territory, or of the society that will have to bear the health and pollution costs associated with pesticide use?

Biocontrol solutions bring together processes and products that can be used to protect crops, and which have in common that they are not derived from the chemical industry, or at least that they exist outside this perimeter. Regulations in the various countries are not yet fully standardized on the scope covered, and there is therefore a lack of clarity as to whether a given product, mechanism or approach should be classified as a biocontrol solution. The biocontrol sector has grown considerably over the last two decades, and has achieved some undeniable successes. We are all familiar with the use of pheromone diffusers to disrupt the reproduction of certain lepidopterans, the use of arthropods or nematode auxiliaries to manage pests in enclosed spaces, Bt toxin or carpovirusin, etc. Based on living organisms or products derived from living organisms, biocontrol solutions are often more delicate to use, more expensive to produce and to maintain in optimal condition than their chemical alternative for managing a particular pest. One exception is the release of a natural auxiliary to manage an invasive species, which can sometimes be sufficient to prevent any new epidemic phase of the pest. Farmers working under the organic farming label, who by definition do not allow themselves to use chemicals, have made a major contribution to the development of biocontrol solutions. The share taken by organic farming is generating market opportunities that are becoming attractive for generating investment, so there are a great many avenues under development. Biocontrol also benefits from a simplified and accelerated approval process for marketing. Without consumer recognition in the form of a willingness to pay a higher price for a food product, it remains rare for the biocontrol solution to be favored over its chemical alternative. In this way, the biocontrol solution remains in a niche market, and its cost remains higher. If, however, regulatory changes give a boost by removing all chemical products, then biocontrol solutions can take over. Such is the case with mint essential oils, used as an antigerminant to manage potato stocks. It's also the case with carpovirusin, which helps maintain the sanitary state of apples at the end of the season, while guaranteeing compliance with deadlines and low thresholds for residues of other pesticides on the fruit surface, as required by market standards. Likewise, sulfur is regularly used for its general antifungal activity as part of reasoned control programs designed to limit the risk of resistance to the main families of chemical molecules used. This is particularly the case in protection situations requiring a regular series of interventions throughout the growing season: potatoes, arboriculture, viticulture and certain horticultural sectors. Deploying biocontrol solutions may require dedicated equipment, which is still lacking (such as diffusers or, until recently, Trichogramma capsule dispensers) or is still very expensive (high-precision sprayers). It may also be incompatible with other phases of the crop management itinerary, such as the desire to co-exist with auxiliary releases and insecticide treatments in the same horticultural greenhouse, because there is not yet a complete panel of biocontrol solutions to manage all the main pests present on a crop. The sector can therefore evolve very quickly and benefit from scale effects making it more accessible, better informed

and more effective. For the time being, however, it remains a complementary, rather than the main, tool for all those who are not obliged by contract to use it.

Physical or mechanical actions include different ways of managing pests without resorting to chemical treatment. Insect-proof netting is one example, as is the destruction of certain weeds using a burner or any other lethal shock device (thermal, mechanical, light). In general, these solutions work quite well, and they can be made necessary and applied for other reasons, such as sanitary reasons, for example. Mulching will isolate fruit from the soil, but it will also act as a barrier to weeds or diseases of telluric origin. The underlying principles therefore combine the barrier action of an obstacle with direct physical effects on the organism, leading to its destruction or counteracting the combination of factors favorable to its establishment. Depending on the situation, the nature of the defect may be slightly different. They can make access to the crop more complicated for other actions to be carried out (as in the case of netting), or require considerable and tedious installation time (tarpaulin installation), which is not always mechanized, leading to significant manpower requirements, and are expensive, conveying a less-than-positive image of advanced artificialization, and corresponding to a multi-year investment (hot or cold greenhouse). The advent of digital technology and connected sensors may bring about changes: for example, umbrellas are being tested that unfold only if rain, frost or hail threaten, and which can keep bunches of grapes out of conditions conducive to the development of certain fungi. It remains to be seen whether these innovations will be considered compatible with the specifications of the labels that prevail in various sectors. Agro-equipment for installation or removal, or the infrastructures to be put in place, are all expensive and highly specific for markets that correspond to prototypes or small production runs. Some are obsolete, while others are self-built. There is undoubtedly room for improvement in this market, which often lacks the critical mass to ensure its maintenance and development.

To sum up, we can see from this description that there are a number of points in common which make comparison with a curative chemical solution difficult. You have to change many aspects, invest more, and accept the added constraints of slower or more labor-intensive worksites. What they all have in common is that they are initially more expensive, which is logical as long as they remain confined to specific situations. They are also less often 100% effective than their chemical alternatives. However, we have also seen that in cases where no chemical alternative is available, they can take over and provide satisfactory results. In the strict sense of the current wording of Article 50, non-chemical alternatives will only exceptionally be considered credible. Confined to niche markets, they also struggle to increase their reliability, lower their prices, benefit from technical support and regular networks of trials to which they can refer. Article 50 therefore appears too restrictive to give them a chance to establish themselves, which would allow them to evolve and improve. What's more, many of these alternatives can only be conceived as part of a system choice, with implications that go far beyond the simple substitution of one lever for another. Without doubt, the family of alternatives that comes out best concerns the genetic improvement route, since a farmer will always be required to choose what he grows and adapt the management itinerary to take advantage of it. Buying certain varietals or varieties is what he already does. It's easy to see why discussions on GMOs and NGTs have given rise to heated, contradictory debates.

As we know in other sectors affecting industry and society alike, prevention has a cost (avoiding accidents, delinquency, breakdowns). The cost can, moreover, be all the more difficult to assess as it translates into non-events if prevention has borne fruit. In fact, it needs to be translated into a saving on an expense that is not systematically accounted for, because it is difficult to identify and evaluate (who knows in advance the amount of the bill for repairing their car?). The same applies to agriculture: the desire to reduce dependence on curative chemical solutions by mobilizing other levers will primarily be achieved through a conscious choice to increase prevention. This is often referred to as IPM, as in the founding spirit of Directive 128/2009: "chemicals as a last resort". Experience shows that this is rarely applied in its entirety. A farmer will tell you "I know that the preventive measure will reduce the risk of

this or that disease by 50%, but as the solution is not totally effective, I'll still be forced to carry out a curative treatment with a pesticide that will solve the problem by almost 100%. In these circumstances, why should I have to carry out the action that is only 50% effective, for a total of 150%, if 100% is enough? In the absence of any incentive or constraint for the farmer, it's easy to understand why this line of reasoning is adopted. In its current configuration, Article 50 does not appear capable of changing the situation. At the very least, we could expect a translation into a re-evaluation of the conditions of use of the chemical solution and the doses to be used, so as to make up the missing 50%. Regulations apply an all-or-nothing approach where they should provide a framework for the slightest dependence. Thus, the framework for marketing authorizations should be something like "You can only buy and use this product if you are equipped to use it to the best of your ability, and if you have already put in place such and such a lever or such and such an action". It would be a very profitable outcome of the comparative analysis to define the framework of minimum preventive elements to be met in order to have the right to buy and apply this or that molecule, especially if it is recognized as not being harmless by being classified CfS? The majority of comparative analyses carried out on CfS molecules should leave a visible trace of the possible mobilization of non-chemical innovations to complement the limited use of chemicals. Part of the return on investment will come from the savings made by reducing pollution, lowering healthcare costs and making better use of the functionalities provided by the biodiversity present.