

"Man is a part of nature, and his war against nature is inevitably a war against himself"

"By their very nature chemical controls are self-defeating, for they have been devised and applied without taking into account the complex biological systems against which they have been blindly hurled."

Tribute to Rachel Carson, whose words continue to resound with greater force on the 60th anniversary of her groundbreaking book Silent Spring.

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





Executive summary

This report shows that fruit contamination by the most harmful category of pesticides has grown worse and worse over the last 10 years. In some cases contamination has increased dramatically.

The category of pesticides examined here, labelled by regulators as Candidates for Substitution, are linked to increased risk of cancer, birth deformities, heart disease and other crippling health conditions. Most are also very harmful to biodiversity to the environment. It is therefore easy to understand why legislators decided to phase them out as long ago as 2009 in favour of safer alternatives. This report reveals for the first time precisely how this law has failed on every single occasion, spanning at least 278 cases.

We will show that the cause of this regulatory failure is twofold. Firstly, this report reveals for the first time that the European Commission and member governments overturned the objective of the Regulation on the approval of Pesticides by adopting guidelines that contradict it. These guidelines were written by an obscure external body, the European and Mediterranean Plant Protection Organisation or EPPO, that follows none of the transparency requirements that bind officials and is deeply compromised by industry representatives. Unsurprisingly then, the guidelines direct regulators to approve the most harmful chemicals and dismiss safer alternatives by insisting on principles and priorities that are missing from or contradict the law the text claims to reflect. So corporate interests, among them BASF, DuPont and Syngenta, wrote their own rules in their own interest and officials approved them. Officials are responsible for the second cause of failure; rejecting perfectly viable non-chemical pest controls that scientists say can cut pesticide use. They did that in opposition to the law and with the full knowledge of the European Commission that is supposed to uphold it.

This report is published on the 60th anniversary of Silent Spring, the seminal book that first alerted the world to the terrible price that pesticide poisons have on our environment and health. Its author, Rachel Carson, warned of a toxic relationship that formed in the US between officials and the agrochemical industry. We show just such a relationship in Europe 60 years later. She also warned of the futility of using ever more chemicals, writing that a war against nature is, ultimately, a wrongheaded war against ourselves. This report notes that all these years later, diligent scientists in the footsteps of Carson are still warning that the ever greater use of chemicals is almost certain to fail because it makes worse the very problem it is designed to solve. The era of pesticides may well be coming to an end, they say. But before it does, we need to decide if we want to live with this rising tide of chemical pollution that industry is producing and officials are sanctioning.

Many non-industry experts now agree that the far wiser option is to switch to sustainable farming methods. This report notes a host of ways policymakers can correct course, not least by rewriting the standards that have led to this shameful regulatory failure.

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Résumé exécutif

La catégorie de pesticides examinée ici, identifiée par les législateurs comme « Candidats à la substitution », est liée à un risque accru de cancer, de malformations congénitales, de maladies cardiaques et d'autres problèmes de santé invalidants. La plupart sont également très nocifs pour la biodiversité et l'environnement. Il est donc facile de comprendre pourquoi les législateurs ont décidé en 2009 de les éliminer progressivement au profit d'alternatives plus sûres. Ce rapport révèle pour la première fois comment cette loi a échoué, à chaque occasion depuis son adoption, dans au moins 278 cas.

Nous montrerons que la cause de cet échec réglementaire est double. Tout d'abord, ce rapport révèle que la Commission européenne et les gouvernements des Etats membres ont contourné l'objectif de la réglementation Pesticides en vigueur en s'appuyant sur un document de guidance qui la contredit. Ce document a été rédigé par un obscur organisme externe, l'Organisation européenne et méditerranéenne pour la protection des plantes ou OEPP, qui ne respecte aucune des exigences de transparence et d'indépendance qui s'imposent aux fonctionnaires européens, et qui est profondément compromis par les représentants de l'industrie. Il n'est donc pas surprenant que ce document de guidance incite les régulateurs à approuver les produits chimiques les plus nocifs et à rejeter les alternatives plus sûres en insistant sur des principes et des priorités qui sont absents ou en contradiction avec la loi que le document prétend refléter. Les entreprises, parmi lesquelles BASF, DuPont et Syngenta, ont donc rédigé leurs propres règles dans leur propre intérêt et les fonctionnaires les ont approuvées. Les fonctionnaires sont responsables de la deuxième cause de cet échec, à savoir le rejet de méthodes non chimiques de contrôle des parasites parfaitement viables qui, selon les scientifiques, peuvent réduire

l'utilisation des pesticides. Ils l'ont fait en opposition totale avec la loi en vigueur et au vu et au su de la Commission européenne qui est censée la faire respecter.

Ce rapport est publié à l'occasion du 60ème anniversaire de «Printemps silencieux» («Silent spring»), le livre référence qui a été le premier à alerter le monde sur le prix terrible que des pesticides a sur notre environnement et notre santé. Son auteur, Rachel Carson, a mis en garde contre la relation toxique qui s'est formée aux États-Unis entre les fonctionnaires et l'industrie agrochimique. 60 ans plus tard, nous constatons le même type de liens en Europe. Elle mettait également en garde contre le caractère vain d'une utilisation toujours plus accru de pesticides chimiques, soulignant qu'une guerre contre la nature est, en fin de compte, une querre malavisée contre nous-mêmes. Le présent rapport note que, toutes ces années plus tard, des scientifiques diligents, sur les traces de Carson, continuent d'avertir qu'une utilisation croissante de produits chimiques est très certainement une voie sans issue, car elle aggrave le problème qu'elle est censée résoudre. L'ère des pesticides pourrait bien toucher à sa fin, disent-ils. Mais avant toute chose, nous devons décider : souhaitons-nous vivre avec cette marée montante de pollution chimique que l'industrie produit et que les autorités entérinent ?

De nombreux d'experts n'appartenant pas à l'industrie s'accordent aujourd'hui pour dire que l'option la plus sage est de passer à des méthodes agricoles durables. Le présent rapport propose une multitude de pistes à suivre aux responsables politiques pour rectifier le tir, notamment en réécrivant le document de guidance ayant conduit à cet échec réglementaire honteux.

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Kurzfassung

Der Berichtzeigt, dass sich die Rückstandssituation bei den gefährlichsten Pestiziden im europäischen Obst in den letzten 10 Jahren deutlich verschlechtert hat. In einigen Fällen haben die Belastungen sogar dramatisch zugenommen.

Diese besonders gefährlichen Pestizide nach werden Europäischen Pestizidder "Substitutionskandidaten" Verordnung als klassifiziert. Ihre gefährlichen Eigenschaften werden mit Krebs, Fortpflanzungsschäden und anderen gesundheitlichen Beeinträchtigungen in Verbindung gebracht. Ebenso sind die meisten Substitutionskandidaten für die biologische Vielfalt und die Umwelt gefährlich. Es ist daher leicht nachvollziehbar, warum die Gesetzgeber 2009 beschlossen haben, sie zugunsten von weniger gefährlichen Alternativen aus dem Verkehr zu ziehen. In diesem Bericht wird erstmals genau dargelegt, wie diese Regelung in jedem einzelnen von mindestens 278 Fällen gescheitert ist.

Die Ursachen für dieses regulatorische Versagen liegt aus Sicht von PAN Europe in zwei Bereichen. Erstens enthüllt der Bericht, dass die Europäische Kommission und die Regierungen der Mitgliedstaatendas Ziel der EU-Pestizid-Verordnung durch die Verabschiedung von Standards konterkariert haben, weil sie das Ziel der EU-Verordnung aushebeln. Diese Standards wurden von einem externen Gremium erarbeitet, der Europäischen und Mediterranen Pflanzenschutzorganisation (EPPO), welche keiner der für Beamte verbindlichen Transparenzanforderungen folgen muss und die von Vertreter*innen der Industrie stark beeinflusst wird.

Es überrascht daher nicht, dass der von der EU erstellte Leitfaden für die Regulierungsbehörden der Mitgliedsstaaten so ausgestaltet ist, dass Mittel mit Substitutionskandidaten eher weiter zuzulassen werden als deren weitere Nutzung zu verweigern, da weniger gefährliche Alternativen zur Verfügung stehen. Die Möglichkeit der Substitution unterliegt in der EU-Leitlinie hohen Hürden an Grundsätzen und Prioritäten, die sich in der EU Pestizidverordnung nicht wiederspiegeln bzw. dem Verordnungsziel widersprechen. Als Grundlage der verabschiedeten EU-Leitlinie dient das EPPO Dokument, an deren Erstellung Unternehmen wie BASF, DuPont und Syngenta beteiligt waren und eine interessensgeleitete Einflussnahme darauf nahelegt.

Für die zweite Ursache des Scheiterns sind die offiziellen Stellen in den Mitgliedsstaaten verantwortlich. Sie lehnen durchaus praktikable, nicht-chemische Pflanzenschutzmaßnahmen als Ersatzverfahren ab, die laut der Forschung den Einsatz von Pestiziden verringern können. Der PAN-Bericht kritisiert, dass das Festhalten an besonders gefährlichen Pestiziden mit dem Argument, dass keine Alternativen verfügbar seien, das Pestizidrecht unter den Augen der Europäischen Kommission aushebelt.

Dieser Bericht wird am 60. Jahrestag von Silent Spring veröffentlicht, dem bahnbrechenden Buch, das die Welt erstmals auf den schrecklichen Preis aufmerksam machte, den chemisch-synthetische Pestizide für unsere Umwelt und Gesundheit haben. Seine Autorin, Rachel Carson, warnte vor einer toxischen Beziehung, die sich in den USA zwischen den Behörden und der agrochemischen Industrie entwickelte. 60 Jahre später zeigt der Bericht von PAN Europe eine solche Verflechtung in der Europäischen Union

Carson warnte auch vor der Sinnlosigkeit des Einsatzes von immer mehr Chemikalien und schrieb, dass ein Krieg gegen die Natur letztlich ein unvernünftiger Krieg gegen uns selbst sei.

Der Bericht verdeutlicht, dass viele Jahre später noch immer Wissenschaftler*innen wie damals Rachel Carson vor dem immer intensiveren Einsatz von Agrochemikalien warnen und darauf hinweisen, dass sie die Probleme verschlimmern, die sie eigentlich lösen sollten. Die Ära der chemischen Pestizide könnte bald zu Ende gehen, sagen sie. Doch es braucht einer gesellschaftspolitischen Entscheidung gegen ein Weiter so, gegen die zunehmende Flut an chemischer Verschmutzung, die von der Industrie produziert und von den Behörden gebilligt wird.

Viele industrieunabhängige Expertinnen und Experten sind sich inzwischen einig, dass die Umstellung auf nachhaltige Anbaumethoden die weitaus klügere Lösung darstellt. Der Bericht stellt eine Vielzahl von Möglichkeiten vor, wie die politischen Entscheidungsträger den Kurs korrigieren können, nicht zuletzt durch eine Neufassung der Leitlinien, die zu diesem regulatorischen Versagen beim Umgang mit den gefährlichsten Pestiziden geführt haben.



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Acronyms

CA: Comparative Assessment

CfS: Candidate for Substitution

DG SANTE: Directorate-General for Health and Food Safety

ECHA: European Chemical

Agency

EFSA: European Food Safety

Agency

EPPO: European and

Mediterranean Plant Protection Organisation

EU: European Union

FRAC: Fungicide Resistance

Action Committee

HRAC: Herbicide Resistance

Action Committee

IPM: Integrated Pest

Management

RAC: Insecticide Resistance

Action Committee

MoA: Mode of Action

PAFF: Standing Committee on

Plants, Animals, Food

and Feed

PPP: Plant Protection Product

RACs: Resistance Action

Committees

REFIT: Regulatory Fitness and

Performance Programme

SUR: Sustainable Use of

Pesticides Regulation

TUE: Treaty on European

Union



Glossary

Candidate product: an authorised pesticide product containing one or more Candidates for Substitution.

Comparative Assessment: assessment designed to compare the different parameters of a chemical against its alternative. In the specific context, it is a comparison of the agronomic efficiency, the economic impact and the impact on human health and the environment of a candidate product and all its chemical and non-chemical alternatives. Comparative assessment is regulated by Article 50 and Annex IV of the Regulation (EC) No. 1107/2009 (Pesticide Regulation).

Candidate for Substitution: active substance approved at EU-level for a period of 7 years that can only be authorised at national level if a comparative assessment has failed to identify safer alternatives. These are more dangerous substances for human health and/or the environment, as set out in point 4 of Annex II of the Pesticide Regulation.

Chemical diversity: the availability of different types of synthetic pesticides with different modes of action on their targeted organism.

Cross resistance: resistance to a particular pesticide that results in resistance to other pesticides through a common resistance mechanism.

Guidance Document: any document developed by a public authority that provides practical interpretation and information on a technical aspect of a regulation to ensure its operationality. A Guidance Document cannot deviate from the regulation itself.

Integrated Pest Management (IPM): as a cornerstone of EU agriculture, IPM aims "to keep the use of pesticide and other forms of intervention only to levels that are economically and ecologically justified" to ensure "the prevention and/or the suppression of organisms harm to plan". 'Sustainable biological, physical and other non-chemical methods must be preferred to chemical methods if they provide satisfactory pest control".

Pesticide Treadmill: the tendency of pests to become resistant to the deadly effects of particular pesticides, through the normal evolutionary process. New and more toxic pesticides then have to be used, to which pests may eventually become resistant, and the spiral continues (Oxford English definition). In 1962, Rachel Carson was one of the first to sound the alarm on this vicious circle, which is constantly fuelled in an agricultural system that relies mainly on chemical treatments.

Pesticide: a chemical formulation created to prevent, destroy or control organisms or disease against plants.



Mode of Action: the action of a pesticide at its target site, **i.e.** the way in which it causes physiological disruption in its target site. Example: a pesticide can affect nerves, growth or respiration.

Non-chemical alternatives: Varied panel of preventive and corrective methods to protect crops by means other than synthetic pesticides. This ranges from crop rotation to monitoring, mechanical weeding and biocontrol. In accordance with the IPM triangle, synthetic pesticides can only be considered as a last resort, when all these alternatives have failed to protect a crop.

Substitution: the replacement of hazardous chemical substances and products with less hazardous alternatives, either a non-chemical agricultural method or a chemical.

Pest Resistance: the genetically acquired ability of an organism to survive a pesticide application at doses that once killed most individuals of the same species. Read more here.

Integrated resistance management: integrated strategy designed to minimise or neutralise pest resistance.

Resistance Action Committees: committees administered by CropLife Europe proposing classifications of pesticide modes of action and promoting resistance management strategies based on chemical diversity.





Introduction

Since 2011, the contamination of European fruit and vegetables with many of the pesticides identified by the EU has the most harmful has steadily increased. This fact makes a mockery of official guidance to consumers to do the right thing for the environment and their health by buying fresh produce. According to the latest analysis¹ of official residue data by PAN Europe, the year 2020 marked by the publication of the European Green Deal has confirmed the trends previously observed in 5 season products:

- 1. Apple contamination has increased from 17% in 2011 to 34% in 2020 (+111%),
- 2. Pears contamination has increased from 26% in 2011 to 49% in 2020 (+107%),
- 3. Plum contamination has increased from 21% in 2011 to 26% in 2020 (+81%),
- 4. Table grape contamination has increased from 31% in 2011 to 46% in 2020 (+33%),
- 5. Raspberry contamination has remained relatively stable (23% in 2011; 25% in 2020).

These rising trends in contamination by the most dangerous pesticides are concerning for several reasons. Firstly, it runs counter to the expectations of <u>citizens</u>, who have repeatedly made it clear that reducing the use of pesticides is a priority, and that

the presence of these toxic residues in their food concerns them. Secondly, these results clash with the political commitment made in 2020 to halt the use of these most toxic pesticides in the EU by 2030, and the official statements that this is the route taken since 2019.

The increasing exposure of citizens and the environment is the consequence of a complete failure by Member States and the European Commission to implement an important principle of the EU's cornerstone pesticide legislation: the substitution principle. Introduced into the EU pesticide legislation in 2009, this principle requires that all substances identified as Candidates for Substitution (CfS) shall be replaced as soon as possible by safer (non-chemical or chemical) alternatives. Candidates are identified at the EUlevel on the basis of intrinsic harmful properties, while Member States are required to ensure that national authorisations are strictly limited to cases where no suitable alternatives are available. To this end, Member States must systematically conduct a comparative assessment of a candidate pesticide product and its alternatives prior to any national authorisation or decision to reject the application for authorisation. When authorisation is granted, it must be regularly reviewed to reflect existing practice.

Please refer to Annex I of the report.



There are currently 53 pesticide substances on the European market that have been classified by the Commission as "more dangerous pesticides" to human health and/or the environment based on a group of criteria² determined by the authorities in the approval process. This includes substances having carcinogenic, reprotoxic, endocrine disrupting effects, meeting two out of the three «persistence, bioaccumulative and toxic (PBT)» criteria. The substitution principle is one of the key drivers of the EU chemical framework to achieve a transition toward a toxic-free agricultural system. When it was introduced, it was seen as a tool that would support continuous improvement in the sustainability of agricultural practices, incentivise pioneers in the transition and ensure that the best possible protection would be provided to farmers and consumers. None of this has been achieved in practice. To PAN Europe's knowledge, not a single candidate product has been substituted for a nonchemical alternative since the introduction of the legal obligation to conduct a comparative assessment on Member States - never and nowhere in Europe. This total failure was documented for the first time in 2018 and led the Commission to conclude that the substitution framework failed to achieve its primary objective. This remains fully valid today, as no substitution with non-chemical alternatives seems to have occurred since 2018, although hundreds of comparative assessments were performed, resulting in hundreds of authorisations of these most toxic pesticides. Meanwhile, at the EU level, the approval periods of these substances are regularly extended beyond the standard seven years. All in all, it is hard to think of substitution as anything other than a scam. Candidate substances are authorised as easily as other pesticide substances³ and sometimes (EU) approved for as long - no matter what the regulation says. The only difference is that they are more toxic.

According to officials and industry, this failure is the result of a systematic lack of viable alternatives to candidate products. It is widely <u>demonstrated</u> that the implementation of Integrated Pest Management

(IPM) unlock significant reductions in pesticide use without significantly affecting yields. Yet, the Commission uncritically took the Member States' argumentation at face value when it decided to revise the substitution rules at the end of 2020 to increase efficiency. Until today, these rules have not yet been revised and no significant progress seems to have been made to identify the existing barriers to substitution or how to remove them. With regulators asleep on the job, PAN Europe has decided to investigate by itself. Why is CfS substitution failing? Why are non-chemical alternatives rejected on every occasion? What are the changes needed to ensure that substitution can drive the EU towards a sustainable agriculture and toxic-free food system sooner rather than later?

This report aims at stimulating an EU-wide reflection following some concrete conclusions: the main reason why substitution is not implemented is not the lack of alternatives, as claimed by industry and the authorities, but a guidance document that allows no passage for non-chemical alternatives, immediately dismissing them as unviable. Instead of substitution, the guidance document encourages the authorisation of more and more toxic pesticide products on the grounds that this is the right path to fight pesticide resistance. This document, written by an obscure organisation outside the EU (EPPO) with clear links to industry, establishes a deliberately flawed interpretation of the EU pesticide Regulation (EC) No 1107/2009. It faithfully mirrors the position of the chemical industry - that helped write it - keeping toxic products for sale on the EU market (part 1 of the report). While EU officials should have rejected this guidance document, the EU has instead embraced it as part of its corpus of pesticide soft law. All Member States follow this guidance and refrain from substitution due to the 'agronomic considerations' developed by the industry-packed European and Mediterranean Plant Protection Organisation (EPPO) (part 2). This crooked text is the key obstacle to substitution and a chief roadblock to the transition to sustainable agriculture.

² cf. 7 criteria listed at point 4 of Annex II of Regulation (EC) No. (EC) 1107/09.

³ Other pesticide substances can be approved for up to 15 years.



Substitution is key to ensure an actual use reduction of the most toxic pesticides

In 2020, the EU Commission committed to an EU-wide pesticide use reduction policy as part of its Farm to Fork Strategy and its Biodiversity Strategy toward 2030. The Sustainable Use of Pesticides (SUR) proposal will now turn this political commitment into a legal requirement for Member States to cut by 50% the use and risk of all pesticides by 2030, and by 50% the use of CfS pesticides. While most observers focus their attention on the means to achieve the first target, we concentrate in this report on the latter.

As the legal requirements from the pesticide legislation on substitution remain unimplemented to date, the EU political impulse is a step in the right direction. However, the target 50% target is too limited compared to the Pesticide Regulation itself, which makes substitution the norm and use (authorisation) the exception. A second weakness lies in the indicators chosen to monitor progress, which would only artificially reflect a reduction in use. Indeed, so far officials celebrate progress towards the pesticide reduction target based on sales statistics since 2019. However, these data clash with residue analysis of EFSA data. As clearly demonstrated by PAN Europe's last report, a decrease in sales of CfS pesticides is in no way reflecting an actual reduction of the presence of these substances in fruit and vegetables - which result from their use. Likewise, the decrease in the number of EU-wide approved Candidates for Substitution in no way guarantees that farmers on the ground actually reduce their overall use. Indeed, between 2015 and 2022, the number of Candidates for Substitution dropped from 77 to 53, but the detection of these remaining 53 Candidates for Substitution in fruits continued to increase until 2020 (most recent data). Their detection in apples and pears had nearly doubled to reach respectively 34% and 49% in 2020 for instance (more data in Annex I). As things stand, there is therefore a risk that Member States claim success while citizens' exposure actually increases.

In these circumstances, the effective implementation of the substitution principle becomes vital. By the means of substitution, Member States effectively facilitate a use reduction of the most toxic pesticides at their national level. This principle perfectly reflects Commissioner Kyriakides' recent <u>statement</u> that "we are not banning pesticides. We seek to replace them with safe and sustainable alternatives". We agree. It is thus crucial that this substitution principle becomes effective to achieve the agreed political goals. In other words, making substitution work must become a priority and be considered together with the SUR to increase legislative synergies.



Background: The substitution principle, one step closer to a toxic-free agriculture

Substitution as a guiding principle of the EU chemical framework

The road to embedding substitution principles into EU legislation stretches back almost two decades. At the turn of the century, the Commission of the European Communities engaged in long, principled debates preparing for a new EU chemical framework. In 2001, substitution was presented as one of the "key elements" of the "Strategy for a future Chemicals Policy" (2001). As a generic principle, 'substitution' is defined as the replacement of hazardous chemical substances and products with less hazardous alternatives. Pushes toward establishing legallybinding substitution obligations, however, were heavily disputed. To nobody's surprise, stark opposition came from industry actors, arguing that risk management measures suffice to ensure the safe use of hazardous substances, making substitution an unnecessary bureaucratic burden.

In 2006, substitution-geared provisions were first enshrined in EU legislation, as part of the new chemicals' framework <u>REACH</u>. Substitution-feasibility assessments became mandatory for a newly denoted category of 'substances of very high concern' (SVHC). In 2009, substitution principles were added in

the revision of the pesticide regulation, targeting the newly denoted category of 'Candidates for Substitution". In 2012, substitution provisions also were integrated into the new biocide regulation. For all three regulations, substitution assessments are foreseen as part of the authorisation procedures for chemicals categorised as the most hazardous. Under each regulation, these substances are identified based on their hazard properties. Policymakers consider that these hazard properties are not yet reason enough to prohibit a substance, but there is sufficient reason for concern to prescribe a 'comparative assessment' to screen for safer alternatives.

In 2020, the EU Commission presented its 'Chemical Strategy for Sustainability: Towards a Toxic-Free Environment'. The <u>strategy</u> anchors and mainstreams the substitution principle as a cornerstone of EU chemicals policy. It reaffirms the key role of substitution to foster a non-toxic environment. Substitution is promoted for all hazardous chemicals, including active substances, by safe and sustainable alternatives.



Anchoring substitution in the pesticide regulation: setbacks and high hopes

The path to adopting substitution principles in the pesticide regulation and a list of Candidates for Substitution is marked by political struggles and delays. During the drafting process, the Council significantly watered down the substitution parameters, against the will of the European Parliament.

As early as 2002, the Parliament expressly supported substitution provisions and comparative assessments for pesticides. Anchoring substitution principles in the new pesticide regulation became one of the Parliament's key demands to improve the pesticide framework compared to the previous directive. In 2006, a Commission draft proposal introduced the concept of "Candidates for Substitution" as a way to operationalise substitution. According to the first draft, the approval period for CfS should be 7 years.

In the first reading, the European Parliament tried to strengthen the substitution provisions. Parliamentarians <u>called</u> for a clarification that approval of CfS pesticides should only be granted once and only for 5 years. These suggestions had to be abandoned under pressure from the <u>Council</u>. The Council instead added an amendment ensuring that CfS approval can be granted more than once⁴. **This amendment foreshadows an apparent lack of political will by Member States to advance the phase-out of Candidate for Substitution substances.**

Following the adoption of the new pesticide regulation in 2009, it took more than half a decade to establish the first list of Candidates for Substitution. This broke the set deadline⁵ in the regulation and greatly delayed any potential substitution. A Commission-backed <u>study</u> presented options for the operationalisation of substitution criteria and developed an initial list of substances. The study was

presented in July 2013, following which, debates and negotiations between the Commission and Member States protracted the final <u>adoption</u> of the first list of 77 Candidates for Substitution in January 2015.

High hopes for the outcome

Nevertheless, high hopes were expressed for the positive impact that substitution would bring. The Commission announced the clear expectation that "comparative assessment and substitution by Member States should contribute to the use of plant protection products that require less risk mitigation and of non-chemical control or prevention methods" and would "encourage more sustainable crop protection".

While these 77 Candidates for Substitution represented around 15% of all approved active substances, they were nationally authorised on around 50% of all uses. Hence, substitution could bring about significant reductions in consumer exposure and protect the environment, especially the latter, as most Candidates pose high risks. Officials impose less strict approval requirements for pesticides that impact the environment than for human health. A pesticide shall have no unacceptable effects on the environment, while it shall have no harmful effects on human health⁷. As a result, environmentally hazardous substances are regularly approved with national mitigation 'measures' and as Candidates for Substitution⁸ as both are due to limit exposure and risks. Thus, it was expected that, through substitution, these highrisk substances could be taken off the market. After all, the comparative assessment should provide incentives for further reducing risks and "supports a process of continuous improvement" by encouraging "more sustainable crop protection".

⁴ Article 24 (1): "An active substance complying with the criteria provided for in Article 4 shall be approved, for a period not exceeding seven years. By way of derogation from article 14(2), the approval may be renewed once or more for periods not exceeding seven years"

Article 80 (7) Reg. (EC) 1107/2009 required the EU Commission to review all approved pesticide active substances under the predecessor directive and screen those that fulfilled the criteria for Candidates for Substitution until 31 December 2013.

⁶ Most Candidates for Substitution meet 2 or the criteria of Persistent, Bioaccumulative and Toxic (PBT). Today, 39 out of the 53 approved Candidates meet two of the PBT criteria.

⁷ Article 4 Reg. (EC) 1107/2009

⁸ Learn more <u>here</u> about Cypermethrin's renewal as Candidate for Substitution.

Comparative Assessment of CfS: scope and conditions

The substitution mechanism under the pesticide regulation (EC) No 1107/2009, requires that Member State authorities systematically perform a 'comparative assessment' when evaluating for authorisation a pesticide product that contains a Candidate for Substitution (Art. 50 (1)). Authorisations shall not be granted, or restrictions should be put in place, when the comparative assessment shows that safer alternatives exist, weighing up several listed criteria (Art. 50 & elaborated in Annex IV):

- (a) for the specific foreseen uses of the product, alternative pesticide products or nonchemical control or prevention methods already exist, which are significantly safer for human or animal health or the environment.
- (b) the substitution would not present significant economic or practical disadvantages.
- (c) The chemical diversity of the active substances, where relevant, or methods and practices of crop management and pest prevention are adequate to minimise the occurrence of resistance in the target organism.
- (d) The consequences on minor use authorisations are taken into account.

The only permissible exemption for Member States from this legal requirement is when it is considered necessary to acquire experience first through using the candidate product in practice (Article 50(3)). In that specific case, the product can be authorised for a maximum of 5 years.

In all other circumstances, Member states must perform comparative assessment "regularly", at the latest at renewal or amendment of the authorisation, so as to withdraw or amend product authorisations as soon as an alternative is identified.

According to PAN Europe, in line with recital 35 of Regulation (EC) No 1107/2009, comparative assessment should be understood in the light of the Integrated Pest Management (IPM) principles enshrined in Article 14 and Annex III of Directive (EC) No. 128/2009. In other words, the comparative assessment should have "regard to the principles of integrated pest management and giving priority to non-chemical and natural alternatives wherever possible", so as to "ensure a high level of protection of human and animal health and the environment".

This type of procedure was new for all Member States, apart from the Scandinavian countries which had adopted the substitution principle in the 1990s. Hence, it was crucial that the EU translate the conditions set out in Annex IV into concrete and operational criteria for national authorities to perform comparative assessments. And that's when everything started to go wrong. Rather than completely drawing up its own guidance document, or asking an agency to do so, as is the norm, the Commission and the Member States chose to partly rely on a standard developed by the European and Mediterranean Plant Protection Organisation (EPPO), which proposed an interpretation of all aspects of comparative assessment related to efficiency. To supplement this standard, the Commission provided guidance on how to compare the health and environmental benefits from alternatives. This report reveals that the EPPO's guidance document has thoroughly watered down the pesticide regulation and has blocked all substitution.



industry's trojan horse to avert substitution

I. EPPO standard on comparative assessment: a flawed interpretation of EU regulation driving the pesticide treadmill

The original EPPO standard was approved in September 2011, just two months after the entry into force of Regulation (EC)1107/2009, and revised twice since then. It offers a roadmap for officials to perform 'comparative assessment', a requirement defined in Annex IV of the regulation, which obliges administrations to compare the efficacy of a pesticide with available alternatives. It considers factors such as the development of crop pest resistance against pesticides, potential economic and practical disadvantages and impact on minor uses. The standard intends to "provide guidance and a decision support scheme to determine whether the substitution of a [Pesticide] is appropriate in view of agronomic considerations".

The standard operates in a "stepwise" manner, where pesticide applications "may be terminated at any stage" if one of the conditions set out is not met. The authors of this document pretend that these conditions faithfully reflect Annex IV, while they actually diverge in critical ways. In its first and second versions, the standard was based on 15 questions in a specified order. Once the uses of the candidate

product had been defined and the corresponding alternatives identified, the authorities had to compare (1) the effectiveness of these alternatives with the candidate product, (2) the risk of resistance, (3) the preventive and economic disadvantages as well as the effects on minor uses which could arise from substitution. A revised version published in 2019 bunched the process into 4 blocks of questions (A to D), covering the same decision scheme, but leaving the possibility for authorities to start the assessment at whatever stage they feel is most likely to terminate the comparative assessment early, saving them time and resources. Besides this innovation, the main change is that minor uses are dealt with in a separate section (proposed stage A). For each of these steps, the decision to proceed or halt the comparative assessment must be based on "expert judgement". EPPO assumed the responsibility of offering such judgement.

In substance, the flawed way in which each of these conditions¹⁰ is interpreted considerably restricts the possibilities of substitution.

⁹ European Commission, Guidance Document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 107/2009, SANCO/11507/2013 rev. 12 - 10 October 2014. URL link.

¹⁰ Effectiveness, resistance management, practical and economical disadvantage and impact on minor use autorisations.



Preliminary steps to comparative assessment: first obstacles to the assessment of non-chemical alternatives

Although the EPPO standard claims to consider chemical and non-chemical alternatives equally, it does not. In fact, the questions and flawed criteria developed by EPPO lead to a rejection of non-chemical methods (such as biological and mechanical technologies) as viable alternatives.

After starting by pointing out that "alternatives may be another (authorised) PPP, non-chemical alternative(s), measure(s) to prevent the occurrence of the pest, or combination of two or more methods", the EPPO standard is constantly undermining these non-chemical alternatives to marginalise what is the heart of IPM.

• Stepwise approach: synthetic alternatives first, non chemical alternatives last

If a non-chemical alternative is identified, EPPO still recommends assessing first chemical alternatives, and only then, «where appropriate», non-chemical alternatives. It is not adequately explained what this «where appropriate» wording means, but it seems to refer to the circumstances where comparative assessment had to be stopped for the chemical alternatives. According to PAN Europe, that comparative assessment must be driven by the general principles of Integrated Pest Management, as highlighted in recital 35 of Regulation (EC) No 1107/2009. This principle, laid down in Article 14 and Annex III of Directive (EC) No 128/2009, is that pesticides should always be considered a last resort when all non-chemical preventive and remedial alternatives have been used and the pest problem remains. The IPM principles are not only relevant at farm level, but must transcend all relevant public

policies and procedures, including comparative assessment.

Moreover, it is reasonable to assume that non-chemical alternatives, having passed the selective identification stage mentioned above¹¹, will be significantly safer for human health and the environment than the candidate chemical product, meaning that the chances of successful comparative assessment are a priori greater than when considering a chemical alternative. There is therefore no regulatory or practical justification for the counterproductive sequencing established by EPPO. It simply betrays an inclination to prioritise chemical solutions.

• Who benefits from the information gap?

Furthermore, the standard states that "where expert judgement would not be sufficient to address significant information gaps, the CA may not be meaningfully performed and completed. In this event, substitution of the candidate for that use is (provisionally) not possible". In other words, the lack of evidence on alternatives should put an end to comparative assessment, even though the burden of proving the existence of alternatives to a candidate product partly lies with the industry when applying for authorisation of a candidate product. According to the Commission, this information "should always be analysed and supplemented by the Member State". However, limited national resources or unwillingness are likely to undermine this public control on industry's statement, as regularly observed in pesticide risk assessment according to PAN Europe.

If non-chemical alternatives somehow manage to pass these first stages, the comparative assessment can start. And this is where the chances of substitution are dashed.

11

Long-term research available.





Chemical diversity: a pro-chemical response to pest resistance

Resistance <u>refers</u> to the genetically acquired ability of a pest (weed, fungi, insect) to survive a pesticide application at doses that once killed most individuals of the same species. It is a genetic evolutionary process, whereby the number of organisms able to resist a pesticide increases over time, while the ability of that pesticide to control the pest decreases. Growing pesticide resistance is a <u>well-established</u> phenomenon, which threatens crop yields. It requires integrated resistance strategies, which aim at minimising both the survival and the reproduction of resistant individuals.

In the context of comparative assessment, preventing the occurrence of resistance stands as one of the conditions an alternative must meet for substitution to occur:

"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, Regulation (EC) No 1107/2009). As one of the agronomic considerations of comparative assessment, this resistance-related condition is covered by stage B of the EPPO's standard which builds on another resistance-specific standard of the organisation, whose role is key in preventing substitution. Indeed, it is on the basis of this second standard that EPPO has established the existing chemical diversity as the sole criterion for assessing the risk of resistance arising from substitution, taking for granted that resistance can/should only be controlled by chemical means. This is a biassed interpretation of the Annex IV, which clearly refers to "other methods or the chemical diversity" with significant impact on the effective implementation of the substitution's scheme. PAN Europe claims that this biassed and flawed approach leads to the near complete prevention of opportunities for substitution, no matter that perfectly effective alternatives are available. This is demonstrated below.



Stage B is presented as follow:

Extract from the EPPO standard

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 authorised for use against the target pest(s)?

Yes Go to B5

No Go to B3

B3. Are there products with another MoA authorised 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

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)*

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

See details in EPPO Standard PP 1/213 on Risk Resistance Analysis



As demonstrated above, the key factor in that scheme is "whether there is sufficient chemical diversity in terms of the number of alternative modes of action against pests. If there is not, then CA will be completed at that point". The higher the risk of resistance is considered to be, the greater the chemical diversity (number of MoAs) should remain. In practice, it should be noted that there are very few low risk resistance situations or for which sufficient information is available. The most common practice is therefore to require a minimum of 3 or 4 MoAs¹², i.e. the availability of at least 3 or 4 synthetic pesticides with different MoAs in any given pest scenario.

This approach severely hinders substitution:

- Even though synthetic pesticides with the same MoA as the candidate product (yes to B2) as well as other synthetic pesticides with other MoAs (yes to B3) would still remain in case of substitution (no matter with what), this substitution should not take place if there is already less than 3 or MoAs left for the target pests and others in the crop (B5).
- If the candidate product is the only one with this chemical mode of action (no to B2), and the risk of resistance exists, again, substitution will not take place without 3 or 4 alternative chemical MoAs available and will necessarily lead to the loss of one of these modes of action, i.e. will reduce chemical diversity (even in case of substitution by another synthetic pesticide).
- Substitution should never be possible if the candidate product is the last synthetic pesticide available for the target pest and that the risk of resistance is present (yes to B1, no to B2 and no to B3) no matter what non-chemical alternatives exist and in general use.
- Substitution with a non-chemical alternative should only be possible if after that there are at least 3 or 4 synthetic pesticides with different MoAs to control the pests.

Inaddition, the EPPO standard recommends considering "whether the CfS active substance is contributing to the overall resistance management strategy and lowering the risk of resistance development by the target by being combined in a mixture with other active substances". Additionally, "other wider resistance considerations at a national level (occurrence, level, known cross-resistance) that may form part of the assessment on the implications for resistance if the CfS is removed."

What is striking in all these options is that the actual effect of the non-chemical alternative under comparative assessment for the specific use on the target pest is assigned little importance. All that matters for the EPPO is: will chemical diversity remain broad enough after substitution? This is what will determine whether or not it meets this agronomic condition, regardless that fact that:

- 1. The key role that non-chemical alternatives play in resistance management and control is ignored, although it is required by Annex IV of Regulation (EC) No 1107/2009.
- 2. That such broad chemical diversity (3/4 MoAs) is by no means required by the EU Regulation but has been promoted by EPPO.
- 3. That the systematic overuse of pesticides is the root cause of pesticide resistance and one of the reasons why IPM was established as a guiding principle for European agriculture under Directive (EC) No 128/2009. Would IPM be properly implemented, with all non-chemical methods being rightfully prioritised, pest resistance would not be an issue.

In addition to being contrary to European pesticide regulations, this promotion of chemical diversity encourages the use of more and more pesticides, while its effectiveness on resistance is clearly disputed.

¹² Cf. page 19, EPPO workshop on comparative assessment of plant protection products, URL link.



EPPO standard: driving the pesticide treadmill?

Reading the EPPO standard, it is as if an organism's resistance to a pesticide could only be countered by alternating or combining several pesticides (with different MoAs). This approach is locking farmers in a chemical system, while it is both **theoretically and empirically challenged**.

Since 1980, the field of 'resistance management' is very documented and counts more than 3 000 publications. Theories that recommend rotation of chemical MoAs, as embedded in the EPPO standards on resistance and on comparative assessment, are based on the assumption that resistance to each mode of action results from mutations at specific loci (target site resistance). However, this approach does not hold up to reality, which is that resistance is driven by more general, non-specific non-target site resistance. It means that organisms resist even in case of combination (different MoAs applied together on the same date) or of temporal cycling (different MoA applied on different dates within a year). This genetic ability to tolerate and resist chemical toxins from a new source, known as cross-resistance, results from the adaptation to another source (MoA). The EPPO standard pays little attention to the existing cross-resistance phenomenon that a target develops resistance to several MoAs - and against which chemical diversity has therefore little or no effect.

Thus, maintaining chemical diversity is proving increasingly pointless as nature continues to adapt and resist. This only contributes to reinforcing the pesticide treadmill for farmers, while the advantages in terms of yields and profits are decreasing. This is increasingly confirmed empirically as a growing body of research reports that resistance also develops in the presence of multiple modes of action and causes significant costs for farmers. In parallel, the quantity of available and marketed modes of action is no longer increasing, both because the industry is not capable of proposing new substances that meet the safety criteria and because a certain

number of pesticides are withdrawn from the market because they do not meet the safety criteria to be approved in the EU. The EU regulatory framework, when not re-approving a pesticide because of its excessive toxicity, does not take into account the number of MoAs, as invented by EPPO. In the long term, it is therefore not unreasonable to expect that this widespread resistance to several MoAs will make pesticides obsolete on more and more cropping systems. Without a paradigm shift, this will leave farmers in a dead end and totally dependent on chemicals, which are less and less effective, but whose impact on biodiversity and human health is becoming increasingly clear.

Therefore, it appears quite counterproductive from an agronomic perspective to limit valid resistance strategies to chemical diversity, unless the objective is precisely to encourage the use of pesticides rather than their substitution. To be in line with empirical agronomic reality and European pesticide regulations, the standard should have considered the wide range of non-chemical alternatives in the fight against resistance, and should even have made them the priority.





Integrated Pest Management: the cornerstone of resistance management

"Although there is high uncertainty regarding many resistance management choices, under almost all circumstances entomologists agree that using an integrated pest management, that results in few pesticides applications, should decrease the rate of resistance evolution". 13

Under Directive (EC) No 128/2009, IPM is defined as follow: "Integrated pest management means careful consideration of all available plant protection methods and subsequent integration of appropriate measures that discourage the development of populations of harmful organisms and keep the use of plant protection products and other forms of intervention to levels that are economically and ecologically justified and reduce or minimise risks to human health and the environment". Identified as the cornerstone of agriculture in the EU, it should be mainstreamed and implemented across regulations (substitution included), policies and agricultural practices to reduce the EU dependency to synthetic pesticides. This report is the latest evidence that the practice has been different and that the tendency is to blindly over rely on synthetic pesticide to prevent or control 'pests'.

Yet, practice shows that when the IPM principles are implemented, the need to use synthetic pesticides is greatly reduced, without farmers suffering a significant drop in their profits (cf. here and here). This reduction could reach 95% for insecticides. Such reductions in pesticide use help to control resistance, without farmers needing many chemical MoAs. Therefore, once IPM is taken into consideration during comparative assessment as required by Annex IV of Regulation (EC) No 1107/2009, the 3/4-modes of action requirement promoted by EPPO can no longer be justified (provided that it was ever relevant). Substitution becomes possible and constitutes the way to get farmers to tame the pesticide treadmill of which they are slaves, and thereby better control the resistance.

This pro-chemical diversity standard taken by EPPO in its standard on comparative assessment runs against substitution and it makes the support on a range of different types of pesticides (MoAs) the prerequisite to consider substitution. In practice, this range is large enough (3/4MoAs) to hinder substitution, it is thus opposed to pesticide regulation 1107/2009/EC and it clashes with the EU's ambition to reduce its dependence on synthetic pesticides. EPPO's standard fully reflects the pesticide industry's standard and there is no coincidence there, quite the contrary. The organisation has been completely infiltrated by the industry, which uses it as its puppet to weaken the substitution framework that goes against its commercial and financial interests.



Gould F, Brown ZS, Kuzma J. Wicked evolution: Can we address the sociobiological dilemma of pesticide resistance? Science. 2018 May 18;360(6390):728-732. URL link.



II. Behind the scene: when industry is both judge and jury

Background: presentation of EPPO

In view of the essential impact of the EPPO standard on the European pesticide substitution framework, it seems essential to examine this organisation, whose acronym must be quite mysterious to readers. EPPO stands for the European and Mediterranean Plant Protection Organisation, which defines itself as "an intergovernmental organisation responsible for cooperation in plant health within the Euro-Mediterranean region". This organisation was founded in 1951 by 15 European member countries but in 2022 has 52 members. All EU Member States are members as well as countries of the Mediterranean region.

Its objectives¹⁴ are as follows: "to support the Member Governments in their aim of assuring plant health, while preserving human and animal health and the environment;", "to develop internationally harmonised phytosanitary and other official plant protection measures and, as appropriate, to elaborate standards to that effect". It is thus a "standard-setting" organisation" whose standards are recommendations to the National Plant Protection Organisations of EPPO member countries. According to Article III of the EPPO Convention, only nation states can be members of the organisation and the organisation presents itself as an independent body providing technical expertise, in this case on comparative evaluation and resistance management. However, the organisation structurally collaborates with a number of 'experts', of which industry is consistently well represented, as detailed below. No proactive policy of independence has been established.

The structural involvement of the agrochemical industry in EPPO's work

EPPO management is organised around a Council and an Executive Committee, both of which are solely composed of high-level representatives of EPPO member countries. However, when it comes to the development of standards, i.e. the core role of the organisation, its structure is divided into working groups, including one on Plant Protection Products. The European Crop Protection Association (ECPA, now CropLife Europe) has permanent observer status in this working group. As regards the eligibility conditions and rights of observers, Article XII of the Convention only states the following: "With the consent of the Council, any non-member Government and any intergovernmental body whose responsibilities are related to those of the Organisation may be represented at any session of the Council by one or more observers without the right to vote". Crop Life Europe is neither a government nor an intergovernmental structure, but a federation representing the interests of agrochemical companies whose core business is the marketing of pesticides. This permanent observer status, which allows it to be informed of the strategic decisions of the council, position of member countries and work in progress¹⁵ in all areas is therefore surprising to say the least.

At no point does the Convention mention an independence policy to avoid conflicts of interest unlike EU bodies. Similarly there is no transparency policy, and therefore no mechanism for actors like PAN Europe to access documents similar to what the <u>Aarhus Regulation</u> permits in the EU. Last but not least, it is simply stated that the budget of the

¹⁴ Article VII of the Convention.

¹⁵ Article XIII of the EPPO convention on the functions of the Council.

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organisation depends on member governments and on "such other receipts as may be approved by the Council or the Executive Committee", without further information being given on this subject.

Then, the working group on Plant Protection Product is itself subdivided into different panels of "experts". The membership rules to join these panels, as approved by its executive committee in 2017, state that "suitable expertise is the main criterion for membership". Additionally, "nominations for Panel membership may be made by anyone, incl. permanent observers. Members may come from research institutions, universities, industry". That means that as a permanent member, CropLife Europe can nominate experts of its choice, without this being questioned. Indeed, membership rules do not require experts to declare their interests, nor other preventive actions to ensure that the appointed "experts" on these panels do not have an interest in the subject they are asked to address. Within EPPO, there is simply no distinction between stakeholders and experts.

As a result, the agrochemical industry, which is very directly concerned and impacted by the standards set by EPPO, is well represented on panels. Focusing on the working group on Resistance to Plant Protection Products, i.e. the one which wrote the two above-mentioned standards making chemical diversity the cure-all of resistance¹⁶, one can read that industry accounts for a quarter of the experts. It has two representatives from Syngenta and two representatives from DuPont and the other works for Corteva Agriscience. In addition, the different RACs are invited to share with the panel an update on their work at each meeting (cf. here).

This setting reveals a very clear conflict of interest, on the subject of pesticide resistance in general and substitution in particular, as these companies market products based on Candidates for Substitution. Syngenta markets the fungicide <u>Celest</u>®, which is a product based on the Candidate for Substitution Pirimicarb. It is <u>classified</u> as carcinogen category 2. The firm also markets several fungicide products

based on Fludioxonil, including Geoxe®. Fludioxonil is the most found candidate for substitution in fresh fruits and vegetables grown in the EU. Corteva markets in several Member States a nematicide based on Oxamyl, which is classified as very toxic for aquatic life, with long term effects. A complete list is impossible to compile as these companies market so many products based on candidate substitutes.

What stands out is that it is highly probable that the industry is not providing EPPO with an expertise but with an opinion coloured by their professional interest throughout EPPO discussions. They are in fact stakeholders helping to write their own rules.

EPPO's current activities are therefore structurally riddled with conflicts of interest that undermine the reliability of its work, including on comparative assessment. What possible interest could a firm see having its product substituted (i.e. in having its application for authorisation rejected by a Member State)? None, unless it is by another of the pesticides they market - which is precisely the sole option the chemical diversity stage of comparative assessment (according to EPPO) leaves open.

This is all the more scandalous as no other stakeholder is present to balance the discussion by bringing a different opinion. That could be representatives of civil society or representatives of agriculture based on the application of IPM and agroeconomic methods. In theory, "there is no limitation on the institutions for which (members) work", but as "the travel expenses of Panel members are not paid by EPPO", stakeholders' participation depends on the financial and human capacities of each organisation. As always, without a proactive policy of engaging a diverse and balanced range of stakeholders, it is the industry that always ends up represented.

This configuration has severe consequences on the impartiality and reliability of EPPO's work on comparative assessment. Unsurprisingly, EPPO's approach to combating resistance is the same as that promoted by the industry.

Together with the panel on General Standards on Efficacy Evaluation.



EPPO on resistance: a mirror of industry's stance

Since the 1980s, the strongest advocates of chemical diversity have been the agrochemical industry itself, which has dedicated considerable resources to elaborating this concept. Progressively, several topical resistance action committees (RACs, including the FRAC, HRAC, IRAC) have been created between industry associations to contribute to the research field of resistance management. These 'technical' committees are administered by CropLife International and staffed by members of the agrochemical industry¹⁷. They are represented among the working group on Resistance to Plant Protection Products by the chairs of the IRAC and of HRAC and they are regularly invited to present their latest work.

The <u>official</u> aim of these committees is to "provide a coordinated response by the crop protection industry to the problem of [pesticide] resistance". This includes monitoring the evolution of resistance and developing methods to combat it in reality, this is just a way for the industry to dress up its position in a scientific way: promoting the wider chemical diversity as a possibility to continue marketing as many products, including the most toxic ones which are threatened by substitution today, and by a withdrawal of the EU market tomorrow¹⁸.

"The availability of a number of different types of fungicides for the control of each major crop disease is highly beneficial to both the environment and to mitigate resistance problems. (...). Thus, it is crucial that chemical invention and new product development are sustained. (...) ideally there should be more than one site of action to decrease the risk of evolution of resistance to the new fungicide" (FRAC, i.e. BASF, Bayer, Corteva AgriScience, FMC, Sumitomo Chemical and Syngenta)

To assess and maintain this chemical diversity, these committees (RAC) have developed and keep updated detailed classifications of pesticides per mode of action. This one is now used by EPPO and all European Member States when conducting comparative assessment and analysing how many MoA are available, and how many will remain if substitution takes place. In other words, the industry has created the solution to chemical resistance and the tools to assess it. Both perfectly suit the industry's interest.

Instead of taking a critical step back, EPPO but also Member States heavily rely on these inputs. EPPO even seems to be aware of this knowledge dependence on the industry¹⁹, yet nothing is done to move away from it. On the contrary, the RACs have consistently <u>contributed</u> to EPPO's work on the standard on resistance and then on comparative assessment. The result is as follows: EPPO's position on resistance management, specifically stage B5 identified earlier as the bottleneck to substitution, happens to be the same as the one recommended by the RACs!



¹⁷ Check the "who we are" webpage of the above-mentioned websites.

See for instance the recent <u>withdrawal</u> of Isopyrazam or Candidates for exclusion (active substances meeting one the cut off criteria set out in Annex II of Regulation (EC) 1107/2009), for which Article 50 and Annex IV also apply.

[&]quot;The Panel was concerned that it may end up with a very unbalanced situation where the only available information comes from industry". URL link.



EPPO's Standard on Comparative Assessment

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

Extract from EPPO's standard.

RACs' recommendation

"Sustainable resistance management strategy for any crop and pathogen/weed/pest situation, no less than three pesticidal modes of action should be considered for a particular crop and target pest in individual geographies, of which one should ideally be from an accepted low risk category.

Four or more modes of action are desirable."

Extract from a proposal on the Revision of EU Directive 91/414 (the predecessor of the current pesticide regulation (EC) No 1107/2009).

EPPO's involvement in substitution: a push from industry?

Finally, PAN Europe considers that it is the industry that has pushed for the establishment of a standard on comparative assessment and for making chemical diversity its predominant parameter. Indeed, it was well aware that the chemical diversity argument, if adopted by EPPO as essential when performing comparative assessment, would help prevent substitution. To that end, the industry acted both via the Panel on General Standards and via the working group on Plant Protection Products, which are both already vested in it.

First of all, it should be highlighted that discussions on the impact of the future Regulation (EC) No 1107/2009 and its substitution mechanism took place in the Resistance Working Group as early as 2007, while the regulation itself was adopted on 21 October 2009. From that year, "concerns" on the

impact of this draft EU regulation were expressed regularly from experts so that EPPO <u>decided</u> to start considering "the possibilities for developing further some (...) of these topics" (resistance management and minor use) - that is before the EU has even had time to consider how to provide guidance for an aspect of a regulation that was still under negotiation!

Then, during the <u>8th meeting</u> of the Panel on General Standards on Efficacy Evaluation which took place in March 2008, for the first time, a "long discussion about the impact of draft EU legislation concerning plant protection products took place. The focus of the debate surrounded the modification of the Directive 91/414 to accommodate comparative assessment and the use of hazard based cut-off criteria as proposed by the EU Parliament (...) The Panel supported in general the views expressed by the Resistance Action Committees in a document presented at the meeting (about **chemical diversity being a crucial element**



in effective resistance management". Later that year, it was also adopted that "resistance strategy aspects are likely to be the most important factor in comparative assessment", and EPPO would give guidance on these resistance issues, building on its previous and ongoing related-work.

In other words, even before the regulation was adopted, EPPO had already decided:

- 1. to give guidance when the EU had not asked for it,
- 2. to prioritise the resistance criterion in the context of comparative assessment,
- to rely on its own work on resistance which, as developed above, mirrors industry's position.

Later in May 2009, a workshop with external participants was held in Brussels. Its rationale was that as no "quidance on how to perform CA was available, it was expected that wide differences between MS would develop (...) These differences would disturb resistance management (pests do not recognise borders), would disturb the level EU economic playing field, and would increase illegal use". In response, EPPO was kindly offering to "define how to perform comparative assessment and substitution in practice". The organising committee of this workshop included both BASF and Syngenta. In total, it gathered 61 participants, including 18 representatives of Member States, the European Commission, EPPO and for the rest of the agrochemical industry or researchers taking up the work of the RACs. EFSA however was not present, whereas it is the EU agency competent on pesticide-related issues, which normally develops the guidance documents. Once again this lack of balance in the representation of interests is quite shocking, but at this stage, the game was up. Their infiltration of the working group had already led to an influence on the position of EPPO, it was just a matter of promoting and repeating this approach through numerous representatives. During this workshop, it was officially <u>decided</u> that EPPO would produce a standard covering the efficiency aspects of comparative assessment and proposing a "tiered schematic approach".

In light of all that has been demonstrated above, PAN argues that this standard was the industry's trojan horse to neutralise the impact of the substitution framework on its business and to keep the most toxic substances due to be substituted with safer alternatives on the market. In 2018, CropLife Europe stated the following about substitution: "EPPO stepwise approach is appreciated" and "industry experience to date has been positive". Further on, one can read the example given by the organisation to illustrate this statement: for the 101 submissions by one of their member firms, 12 comparative assessments had been performed and resulted in 0 product loss, i.e. 0 substitution. This shows the master stroke of the industry which took advantage of the leniency of EPPO, and of its much looser independence practices than those of European bodies. However, this industry's coup could not be successfully achieved without the consent of the Commission and the Member States, which have endorsed this EPPO standard as part of the EU soft law corpus.

28



EU endorsement of the EPPO standard: how the EU undermined its substitution principle

In light of this extremely industry-driven EPPO standard, it seems quite astonishing, both in terms of content and process, that the EU made such a standard part of its body of soft law. And yet, it did!

Those Member States (mostly with booming chemical industries) that had expressed great reservations against the substitution principle from the start, who had tried to push back against the

European Parliament in the trilogue, now jumped on the opportunity presented in the form of the EPPO standard to stifle any effects of the substitution framework. Instead of fulfilling its role as the guardian over the proper implementation of the pesticide regulation, the Commission turned a blind eye when the standard was adopted and has continued to do so ever since.

I. EPPO standard in practice: the bottleneck to national substitutions

National implementation of the EPPO standard

Member States implicitly supported the EPPO standard in October 2014 when adopting the Guidance Document on comparative assessment and substitution meant to supplement the EPPO standard. Since then, all Member States authorities have applied the decision scheme developed by EPPO²⁰, for those instances where a comparative assessment is conducted. According to EPPO, substitution requires the availability of a large

number of chemical MoAs to consider the 'resistance management' condition of any comparative assessment to be fulfilled. Most Member States require at least 4 MoAs to consider resistance management provided, for all circumstances (whether high risk or not). Where this level of chemical diversity is not given, the comparative assessment stops²¹. In some Member States, such as France and Germany, the number of MoAs required ranges from 2 to 4 depending on the resistance circumstances, based on the EPPO's graduation of resistance risk.

²⁰ Cf. page 9 and 22, EPPO workshop on comparative assessment of plant protection products, URL <u>link</u>

²¹ Cf. page 18 - EPPO workshop



Eight Member States (BE, DE, FR, IT, NL, PT, SI, SP)²² have translated the standard into a national guidance document. In some cases, these guidance documents are plain copies of the EPPO's wording:

Belgium	Step 4: "If there are four modes of action or fewer available , substitution will not be appropriate as the chemical diversity of the active substances is unlikely to be sufficient to minimise the occurrence of resistance. European Plant Protection Organisation (EPPO) guidance requires at least four modes of action to manage a high resistance risk"	
The Netherlands	Step 9: "Are there 5 or more modes of action available for use?" ²³	
Portugal	Step 5: "If there are four modes of action or fewer available substitution will not be appropriate as the chemical diversity of the active substances is unlikely to be sufficient to minimi the occurrence of resistance."	
Step 5: "If there are four modes of action or fewer available substitution will not be appropriate as the chemical diversity of the active substances is unlikely to be sufficient to minimis the occurrence of resistance. European Plant Protection Organisation (EPPO) guidance requires at least four modes of action to manage a high resistance risk."		

Although Member States are not legally bound by this document of soft law, in practice, they all adopted this easy-to-use scheme. As a result, this has entirely blocked the substitution of Candidates for Substitution with safer alternatives.

The United Kingdom also had one.

See step 9, Application Comparative Assessment. URL <u>link</u>.



Authorisation of Candidate Products: standard practice for Member States

First off, it must be noted that a complete lack of transparency in most Member States makes it extremely difficult to get a full picture of comparative assessment practices today. Trying to gather this information took tedious efforts and considerable time investments, all while the questions were simple: How many comparative assessments have been conducted by each Member state since August 2015? Why are the comparative assessments stopped? How many Candidate products are authorised in each Member State?²⁴ How many product authorisations were rejected based on comparative assessments? As this information is not readily available, it took several years to gain insights into Member States' practices. While a comprehensive overview of all 27 Member states could not be assembled, the gathered

information suffices to grasp that substitution was never truly implemented.

The first data on the matter was published in October 2018, in the final <u>report</u> of the study supporting the Regulatory Fitness and Perform Programme (REFIT) Evaluation of the EU legislation on pesticides. In 2018, i.e. three years after the entry into force of the obligation to conduct a comparative assessment, five Member States had not yet set up a corresponding procedure, thus completely failing to fulfil this legal obligation. As a result, only 280 comparative assessments were conducted for 530 authorisation applications for candidate products submitted in 2015 and 2016. However, in none of these assessments has a substitution ever taken place: "in none of these cases has a PPP containing a CfS been replaced by another product or method"!



The national pesticide databases do not permit an easy search of all authorised products containing candidates for substitution. This could easily be facilitated with a search filter that would greatly improve transparency.



Around the same time, EPPO published data on a few Member States which pointed towards the same failure to implement substitution:

Member State	Number of Comparative Assessment Performed	Number of Substitution cases
Denmark	16	0
France	151	0
Spain	23	0
Spain	36	0

Since then, PAN Europe and its member organisations have contacted the Ministries of Agriculture or the competent regulatory authorities in each Member State to gain further information. Where more information was obtained, the answers on the current state of play again confirm the trend of non-implementation of substitution:

Member State	Number of Comparative Assessment Performed	Number of Substitution cases
Croatia (2022)	23	1 (with another synthetic pesticide)
France (2020)	142	2 (with other synthetic pesticides)
Hungary (2022)	Unknown	0
Portugal (2022)	Unknown	0
Sweden (2022)	Unknown	0

These findings led to conclude that the implementation of substitution had failed terribly and that Candidate products are routinely authorised. Next, we turn to the reasons for this failure.



Substitution greatly hampered by "resistance considerations"

In the study supporting the REFIT evaluation, one can read the following: "MS provided several reasons why not a single substitution has yet been made. In particular, the smaller MS reported that there

are no viable authorised alternatives to which a PPP containing a CfS could be compared. Consequently, a substitution cannot take place. Another reason that was raised is that substitutions are not always possible due to efforts to manage potential resistance, because having more available PPPs for a given pest reduces the likelihood of diseases or weeds developing resistance."

Member State	Reasons for stopping comparative assessment	
Denmark (2018)	"So far, the CA has stopped at Q1 or Q2, i.e. we have not been forced to deal with the more complicated questions. Should we make it to Q6-Q10 we would have to deviate from the numbers of modes of actions mentioned in PP 1/213." Nb: Q1 (alternative identification; Q2: MoAs)	
	No. Q1 (alternative identification; Q2: MOAS)	
France (2018)	Only 2 reached step 3 (health and environmental assessment), others were stopped for agronomic considerations (not specified) but see below.	
Spain (2018)	Substitution was refused due to "resistance management - There is not enough chemical diversity, less than four mode of action available for each of the uses", substitution would lead to the "loss of specific pest control tools" and would have "negative impact on minor uses".	
Croatia (2022)	"Lack of plant protection products in the Republic of Croatia", "the impossibility of replacement due to the fight against the resistance of harmful organisms, as well as the requested exemptions"	
France (2020)	73% of the cases due resistance considerations and impact on minor use.	
Sweden (2022)	"Most CA have stopped in the first step, either due to that no or few alternatives exist or that minor uses will be affected"	



Although scattered, this information demonstrates that:

- 1. Member States are systematically restricted by the EPPO-driven chemical rationale, which pushes them to reject nonchemical alternatives as viable alternatives. Chemical diversity is considered the highest asset. Where the number of available MoAs available against a targeted pest is already limited, substitution is discarded on the grounds that it would jeopardise this diversity. Any positive impacts of non-chemical alternatives on integrated resistance-management strategies are apparently not taken into account, as suggested in the EPPO's standard.
- 2. Comparative assessments only exceptionally go beyond the agronomic considerations developed by the EPPO. The benefits of substitution with non-chemical alternatives to human health and the environment are completely disregarded.
- 3. When chemical alternatives are compared, a lack of benefits leads to no substitution. In the few cases where the comparative assessment reaches the step of comparing the effects on human health and the environment of the candidate product with alternatives, the alternatives considered are chemical alternatives (as they have successfully passed the chemical diversity stage). However, the assessment often concludes that the substitution with the alternative chemical would not bring considerable health or environmental benefits and therefore substitution does not take place; except in very rare cases (twice in France, once in Croatia).

This has been further demonstrated in the context of legal action in the Netherlands.

The "TAVAS" court case, PAN Europe vs. the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)

In October 2018, the Ctgb decided to authorise the product TAVAS, which contains the Candidates for Substitution Metribuzin and Diflufenican. Thanks to an objection from PAN Europe, the Dutch services were first mandated to perform a comparative assessment to comply with Article 50 of Regulation No 1107/2009, which otherwise would not even have been performed. And not surprisingly, substitution was dismissed based on the chemical diversity barrier. The rationale for rejecting substitution was the following: such a substitution would have left only 3 chemical MoAs available, while the Dutch protocol on comparative assessment requires the availability of 5 MoAs to deem substitution appropriate. On this basis, non-chemical alternative methods (harrow) are rejected as nonviable and the product 'TAVAS' should be authorised. Unfortunately, the Dutch Administrative Court (CBB) has come to endorse this reasoning on the basis that it was in line with the Dutch protocol - without obviously considering whether this protocol was in line with Regulation No 1107/2009 itself.

What is interesting about this particular case is that there was an effective alternative to 'TAVAS', which is mechanical weeding with a harrow. There is no resistance to the mechanical action of a harrow. Thus, without the chemical diversity criteria, substitution could have occurred. And indeed, in another case in Sweden, where authorities have moved away from this chemical diversity criterion, and instead also take into account the positive impacts of non-chemical alternatives on resistance, substitution has been possible.



(Voluntary) substitution is possible: the Swedish case

At this point, readers may begin to doubt whether it is possible to substitute pesticides with non-chemical alternatives, or whether they exist at all. Sweden has proven that these alternatives work. While no Member State ever completed a substitution of a candidate product with non-chemical alternatives, Sweden has managed to do so in the context of a "voluntary substitution", i.e. for a pesticide which did not contain a Candidate for Substitution. On top of introducing the legal obligation on Member States to conduct a comparative assessment for all candidate products, Article 50 point 2 also offers Member States the possibility to do the same for other substances. In these cases, the same conditions of comparative assessment as for Candidates for Substitution apply and, in addition, the alternatives must also be in general use and this voluntary substitution should only be implemented in exceptional cases. The prerequisites to a substitution of 'regular' pesticides with non-chemical alternatives are therefore more restrictive than for Candidates for Substitution. In the minds of the legislators, the substitution of Candidates for Substitution would be the norm, while voluntary substitution would be the exception. And yet that's where substitution happened!

Before looking at the Swedish case, it should be noted that, in their attempt to limit as much as possible the impact and workload generated by the implementation of article 50, most Member States make it a general policy to exclude this possibility to perform voluntary substitutions²⁵. Only a few, including France and Sweden, have tried to use this possibility so far, with success in the <u>case</u> of Sweden.

Case study: Swedish substitution of Acetamiprid

With the expiry date in sight, a firm has applied for a renewal of its insecticide 'Imprid Skog' based on the active substance acetamiprid, a neonicotinoid, for use in forest nurseries and on small forest plants against pine weevil (Hylobius abietis). Having in mind the adverse effects of this substance on bees

and other species, and the alternative practices in the field, the competent Swedish authority, KEMI decided to conduct a comparative assessment to examine the possibilities of substitution for this specific use, i.e. if it is possible to manage these pests without it.

KEMI explained that since 2010, non-chemical alternative methods had been developed and increasingly used by the Swedish forest industry. While in 2014 these non-chemical methods were used for 17% of the forest plants, it had reached 50% in 2020. During the same period, the proportion of plants treated with insecticides containing acetamiprid dropped from 28% to 3%. On this basis, KEMI concluded that: 1) most of the forest plants are treated with nonchemical methods or untreated (are in general use: 60%), 2) these alternative methods are safer, 3) have no significant economical and practical disadvantages 4) as well as no consequences on minor uses. In May 2019, the renewal application of 'Imprid Skog' was thus rejected on the basis of these conclusions. After being challenged in a court of law, this substitution decision was validated by the Swedish Supreme Court.

The decisive factors in that case have been that these alternatives were already in use and had proven their effectiveness, with little consideration for the impact of substitution on chemical diversity which was made obsolete by the use of non-chemical alternatives. In fact, the chemical diversity available does not seem to have been a matter of concern at all, contrary to the economic and practical impacts. On that matter, the Court stated that "The fact that (economical and practical) disadvantages cannot be ruled out is not sufficient for them to be taken into account in the decision making".

PAN Europe has not been able to find out whether Sweden also relies on the EPPO standard as part of the comparative assessments required for voluntary substitution, but Sweden has clearly moved away from its decision scheme in this specific case to focus on other much more important factors (4 points above).

²⁵ Cf. National Guidance Documents: <u>Spain</u> page 19: "Spain will not be undertaking any of the optional comparative assessments allowed for by Article 50(2)" or <u>Belgium</u> page 7: "SPF will as a matter of principle not be undertaking any of the optional comparative assessments allowed for by Article 50(2)".



II. Commission failure to protect the standards as Guardian of the Treaties

A neglect of EU independence and transparency standards

In light of what has been pointed out above, it seems quite astonishing, both in terms of content and process, that the Commission endorsed this industry-driven standard as part of its soft law framework. In accordance with Article 17 (1) of the Treaty on European Union (TUE), the Commission should "promote the general interest of the Union and take appropriate initiatives to that end". Dividing the work of preparation of a guidance document with an organisation that does not share any of the principles of independence and participation required of EU bodies falls short of this Treaty's requirement. Since EPPO does not meet these criteria to partake in EU decision-making, it should not have mattered that EPPO already started the work in advance or that the organisation claims to have technical expertise on certain aspects of the comparative assessment. With the EPPO's impartiality unshielded, clear conflicts of interest shaped the organisation's conduct. The Commission should not have blindly trusted its work nor supported it as an EU standard.

By comparison, if the task had been assigned to a European body, much stricter rules would have been applied. In general, guidance documents on pesticide regulation are prepared either by the Commission itself or by EFSA, or in rare cases by the European Chemical Agency (ECHA). Pursuant to Article 17(3) of the TEU, the Commission shall be "completely independent" in carrying out its responsibility, and shall "neither seek nor take instruments from any (...) entity". This has been confirmed by the EU Court of Justice. Likewise, EFSA must operate in an independent, objective and transparent manner, and on the basis of scientific information²⁶, so does ECHA. At the very least, one

would expect that any document produced by an external organisation would be scientifically reviewed by an independent European body, in this case EFSA. The Commission itself does not have the expertise to critically review this document.

There is no doubt that the Commission was aware of conflicts of interest, having itself participated in a number of workshops where the industry was represented. The Commission should have known that the very existence of these conflicts of interest calls into question the reliability and impartiality of EPPO. And yet, the Commission tasked this intergovernmental organisation, which openly collaborates with the pesticide industry, with the role of defining an indicative detailed framework for comparative assessment.

Complete negligence on the part of the EU Commission was further confirmed in an exchange with PAN Europe in 2021. PAN Europe wrote to the Commission to point out the, yet again, very unbalanced representation of interests during an EPPO workshop in 2018, which led to its latest update of the standard (current form). Out of 72 participants, 44 were "delegates from crop protection companies and consultancy firms". This is nearly double the number of representatives of the regulatory authorities who were 25. In our letter, we denounced such a predominance of industry and asked the Commission to move away from the EPPO standards. In its reply, the Commission never gave a concrete answer to this point. Yet, based on its previous collaboration with EPPO, the Commission is well aware that these standards do not live up to the EU pesticide framework and that supporting them has significant consequences.

Articles 21 to 49 of Regulation (EC) No 178/2002. URL link.

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EPPO standard waters down the EU pesticide regulation

Later still, when the EPPO approach was proposed, the Commission should have intervened to ensure the proper application of the EU (pesticide) legislation as required by Article 17(1) of the TEU. Without the need to gain experience of the implementation of the EPPO standard, it was already apparent at the time of its elaboration that it was proposing a deviant interpretation of Article 50 and Annex IV of Regulation (EC) No 1107/2009 by dismissing non-chemical alternatives. Thus, it would hinder the effective implementation of the substitution principle.

Yet again, it seems that no steps were undertaken by the Commission to review the EPPO standard or to ask EPPO to align its decision scheme of comparative assessment with the IPM practices. Nor did the Commission show any intent to create an EU guidance document in parallel to EPPO's one, building on the assistance of a number of European or national institutes²⁷. Instead, the Commission participated in a few EPPO workshops but did not step in, as if comparative assessment was a matter external to the EU.

Once the standard was adopted by EPPO itself, it was simply endorsed by the Commission to supplement its own Guidance Document on human and environmental aspects. This is explicitly declared in the introductory statement of the guidance document as follows, and without any further comment from the Commission: "This document is meant to supplement the EPPO standard, i.e. to give Member States guidance on how to perform the comparative assessment of risks to health and the environment, and to provide an overall framework for comparative assessment". This guidance document on comparative assessment was proposed for adoption

by the Commission and adopted by Member States in October 2014.

Past experience with EPPO: shielding notorious neonicotinoids

The Commission should have been especially mindful and acted with due diligence, considering previous instructive experiences - or mistakes - in the relation to EPPO's work. Indeed, this is the second time that the Commission built on an EPPO standard to provide EU guidance. The endorsement of an EPPO standard as soft law also happened in the context of the provisional Directive (EEC) No 91/414. The EU needed guidance on how to assess the risk that pesticides pose to honey bees and decided to rely on EPPO. In a previous report, PAN Europe highlighted the disastrous effects of this endorsement of an EPPO standard in 2002 and how much the industry had again contributed to the preparation of flawed guidelines. The outright failure to protect bees with this standard from 2002 was only acknowledged six years later, thanks to an EFSA investigation on the causes of bee mortality in Europe. It led to a restriction of the use of the notorious bee killers Imidacloprid, Thiamethoxam and Clothianidin. These neonicotinoids, as well as many other substances, have been approved building on this EPPO standard. It took until 2013 for EFSA to publish a guidance document to replace this EPPO standard²⁸.

For all these reasons, it was the Commission's responsibility to intervene even before the comparative assessment standard was implemented by Member States. This statement has since been vindicated by recent developments. The Commission is now well aware that substitution failed and that the EPPO standard blocks rather than facilitates the process for Member States. Yet substantial action by the Commission is still awaited.

²⁷ International Organisation for Biological Control (<u>IOBC</u>), or National Research Institute for Agriculture, Food and Environment (<u>INRAE</u>) for instance

In practice this new standard is still not implemented yet due to a massive lobbying from the same industries that contributed to produce the flawed EPPO bee guideline.



Commission's commitment to fix substitution in 2019: what since?

Due to Member States' complete lack of transparency vis-a-vis the implementation of Article 50, even the Commission had limited knowledge on that matter until 2018. Nevertheless, this has changed since it conducted a REFIT evaluation of the EU pesticide legislation to check whether the pesticide regulation was 'fit for purpose'. It is in this context that the first data were collected from each Member State by a consultancy firm commissioned by the Commission. These results, presented earlier in the report, underline that no substitution has taken place in the space of three years out of the nearly 300 comparative evaluations conducted. It led the Commission to conclude that: "The rules for active substances that are candidates for substitution are **both ineffective and inefficient**. Available evidence shows that the comparative assessments for products containing active substances that are candidates for substitution carried out by Member States is complex and requires resources but did not lead to any **substitution**, mainly due to the lack of alternatives with proven better risk profiles. Thus, the expected benefits for human health or the environment from substituting these more hazardous active substances have not materialised." Further down, one can read that "the introduction of CfS and comparative assessments has not led to any further improvements in the level of protection of human health beyond what is already achieved by the standard approval and authorisation process for active substances and PPP, respectively". The regulation's purpose had therefore not been achieved.

Based on this implementation failure, the Commission committed in the final report published in May 2020 to "simplify the comparative assessment of Candidates for Substitution". To that end, it would "by end 2020 make use of its delegation of power to amend Annex IV of the PPP Regulation to improve the effectiveness of comparative assessments of

products containing candidates for substitution". Such progress is still pending today in September 2022. Asked by PAN Europe about the progress made, the Commission stated that the last time it had discussed this with the Member States was in September 2021. Since then, "the Commission launched an ad-hoc survey of Member States, in order to obtain an updated picture of the situation in their performance of comparative assessment and to gather proposals to amend the relevant Guidance Document". Currently, the Commission would still be "analysing the responses to identify the most suitable way forward". We welcome the Commission's move to obtain a comprehensive overview that is much needed but should have come much sooner. For the rest "analysing the most suitable way forward" just means in political jargon that no progress has been made so far - and the Commission has 1) either no idea where to start or/and 2) no willingness to actually make substitution effective.

If it is the first option, to PAN Europe, it is clear that the first step is to stop relying on EPPO's standard and to issue, instead, a European guidance in line with IPM principles and whose criteria would give priority to non-chemical alternatives and drop the concept of pesticide diversity. If it is option 2, the Commission should be reminded that the purpose of substitution is fully in line with recent Commissioner Kyriakides' statement, that "we are not banning pesticides. We seek to replace them with safe and sustainable alternatives". This replacement will not occur spontaneously. It must be driven by the Member States through substitution to ensure a clear cut in the use of the most toxic pesticides by 2030.



Conclusions

More than 10 years later, it is clear that the substitution principle has neither brought the expected benefits in terms of protection of human health and the environment, nor supported farmers in their transition to more sustainable agricultural practices. On the contrary, the increasingly frequent detection of candidate pesticides in food products reveals their ever-increasing use at certain stages of production. It is as if, rather than taking a step towards a toxic-free agriculture, the EU was taking a step towards an all-toxic agriculture, regardless of it EU Farm to Fork Strategy.

Contrary to what is claimed by officials and the industry, this report reveals that the main obstacle to substitution is not the lack of alternatives. The problem is that this substitution principle has been neutralised by the pesticide industry which participated in the writing of its guidance document! To do this, the industry used the international organisation EPPO as a puppet, making it repeat its own position in an official document then endorsed unchanged by the EU. It is master stroke by the industry to preserve its interests under threat from protective pesticide regulations.

In its current form, the EPPO's guidance document encourages the maintenance of as many highly toxic pesticides as possible on the market to fight resistance, and thus runs counter to the substitution of candidate pesticides with non-chemical alternatives. It is a proven fact that non-chemical

alternatives reduce the need for pesticides and facilitate the fight against pest resistance. Therefore, it is scandalous that they are currently being rejected on this ground!

PAN Europe denounces this pro-chemical approach, which is neither in line with Regulation (EC) No 1107/2008 defining conditions for substitution, nor with Directive (EC) No. 128/2009 which mainstream the IPM principle. Further, this EPPO standard goes against and will hinder the European commitment to reduce dependency on these most toxic pesticides in the context of its EU Farm to Fork Strategy.

All this happened only because the Commission and the Member States gave their blessing to this flawed guidance document of EPPO, rather than rejecting it and treating it for what it is: an industry position paper watering down the pesticide regulation and hindering its implementation. The Commission and the Member States have failed in their responsibility to implement the substitution framework as intended by the legislators in 2009 and thereby to protect as best as possible human health and the environment.

Today, the power to finally make this substitution mechanism a useful tool in achieving the Farm to Fork targets is again in the hands of the European Commission and the Member States.



Demands

1. Make the substitution principle effective: immediate revision of the Guidance Document on comparative Assessment and substitution

In the context of the current discussion on how to improve the effectiveness of comparative assessment, it is vital that the EU moves away from the EPPO's standard. The Commission did it once in the past with the standard on bee toxicity, it can and must do it again. The guidance document must be revised and ready for implementation by the end of 2023. This time, it is crucial that this work is conducted independently, in full transparency and with a *balanced* representation of the opinion of *different* stakeholders. The new Guidance Document should reflect the intent of Article 50 and Annex IV of Regulation (EC) No 1107/2009 and be in line with the IPM principles.

2. Ensure proactive implementation of substitution: national plans to aim for a 100% phase out of the most toxic pesticides

Without this EPPO's standard, PAN Europe considers that substitution of pesticides Candidates for Substitution could have occurred in a countless number of situations. Thus, all Member States should prepare and adopt a national plan to review all authorisations of pesticides containing candidates for substitution so as to withdraw these authorisations whenever and wherever an alternative exists by the end of 2024. This demand is in line with Article 50 which provides that those national authorisations should be regularly reviewed.

Member States will build on the new GUidance Document. In the context of the Sustainable Use of Pesticides Regulation, Member States should report on these progress to the Commission.

This demand will also ensure that Member States really contribute to the use reduction of the most hazardous pesticides containing candidate substitutes from the Farm-to-Fork strategy. Indeed, at present it is likely that the 50% reduction will simply be achieved by the "natural" EU-wide withdrawal of candidates for substitution that would not meet the safety criteria for renewal, this without any effort being made by Member States to change agricultural practices or implement substitution. Having this in mind, Member States actually should aim at a full phase out of the most toxic pesticides. This recommendation is in line with the demands of the ECI Save Bees & Farmers.



3. Make up for 10 years of inaction: ban the Toxic 12 now!

In addition to the national review of all authorisations in the next few years, PAN Europe demands an immediate ban of the <u>Toxic 12</u>. These substances have been selected based on different criteria including their effects on human health and/ or the environment, the level of citizens' exposure and their regulatory state of play (expiration date and ongoing prolongation(s)).



4. Provide transparency to ensure public scrutiny

At present, there is no transparency on the part of Member States as to how they comply with Article 50 of Regulation (EC) No. 1107/2009. This lack of transparency is a major obstacle to civil society scrutiny of government action, which allows governments to avoid being held accountable for their actions.

We demand that Member States maintain a website providing an overview of the number of pesticides containing candidate substitutes authorised, with an access to comparative assessments conducted prior to their authorisation.

5. Protect consumers: no residues in food

Over the last years, the drop from 77 approved Candidates for Substitution to 53 today has in no way ensured that consumers would be less exposed to these most hazardous substances. On the contrary, the 53 remaining Candidates for Substitution are more and more frequently detected in fresh and seasonal fruits produced in the EU. This growth is increasing the risk of combined exposure to the residues of the most hazardous pesticides and those

of other pesticides, while cocktail effects remain unassed today. Additionally, lots of Candidates for Substitution are currently suspected of having endocrine disrupting properties, for which there is no safe level of exposure according to endocrinologists. Having these risks in mind, the Maximum Residues Limits to these substances must all be lowered to the default value of 0.01mg/kg.



Annex

Residues analysis of 5 seasonal fruits: steady growth of detection between 2011 and 2020

Objective:

PAN Europe sought to find out whether the detection of most toxic pesticides has kept rising in 2020, compared to 2019.

Scope:

This analysis focused on the 5 most seasonal fruits produced in the European Union.

Methodology:

In September 2022, 53 Candidates for Substitution were still approved. PAN Europe extracted this list from the EU Pesticides database, to investigate whether CfS were detected in season fruits sold in the European market and how their presence had evolved over the last decade. The food residue data were taken from the EU national official monitoring data (EU Multiannual Control Programme) used to produce the European Food Safety Authority's (EFSA) annual reports, for the years 2011 up until 2020. According to EFSA, data collected under the EU MACP are "statistically representative enough to estimate the exposure of EU consumers to these residues". To preserve this representativeness, any risk-based sampling methods (Multiannual National Control Programmes), which explicitly target the most at-risk products for pesticide contamination, were excluded. The trend analysis is based only on the data of five seasonal fruits: apples, pears, plums, raspberries and table grapes, focusing **only** on those produced in the EU. In this way it is possible to address consumer exposure resulting from European use of candidate or substitution. Only unprocessed (fresh) products are taken into account²⁹. It must be emphasised that only residues of CfS that were found with a concentration level above or equal to 0.01 mg/kg have been included, which is considered the default detection limit for pesticides in Regulation (EC) No 396/2005. This correction is due to the fact that, through the years, more sophisticated techniques have become available to detect residues at lower levels than 0.01 mg/kg and could have biassed the analysis (inflated the trends). This correction enables us to distinguish genuine growth trends, from trends reflecting improvements in residue detection.

Please note that the sampling and analysis of food samples may have been the object of some variations over the years. The number of samples collected is not equal among types of fruit or countries of origin, and not all CfS may have been screened in each sample. Any such loss of statistical certainty is the responsibility of the authorities collecting the samples and not the authors of this report. The amount of data analysed over the years makes the present assessment and its conclusions the most representative analysis possible of real-world contamination rates.

²⁹ Since 2019, the processing of products is no longer always provided in EFSA's public datasets and thus unknown. However, based on the processing classification of previous years, it can reasonably be assumed that a significant part of the products sampled remain unprocessed.



Results:

Apples



Trend: Between 2011 and 2020 in total 17,767 samples of apples were tested for pesticides. Starting in 2011, already 17% of the apples contained CfS residues, which increased steadily to 34% in 2020. According to this trend this is a doubling (+111%) of the level of contamination with CfS.

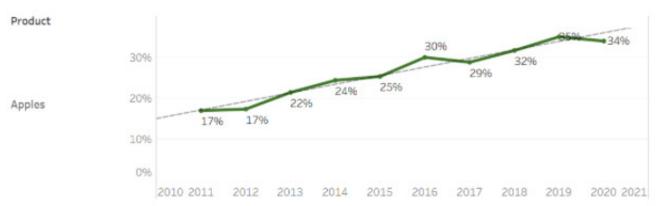


Figure 1. Increase of the % of apples contaminated with CfS.

Member States of origin: In 2020, member states producing apples with the highest level of CfS contamination were the Netherlands and Greece.

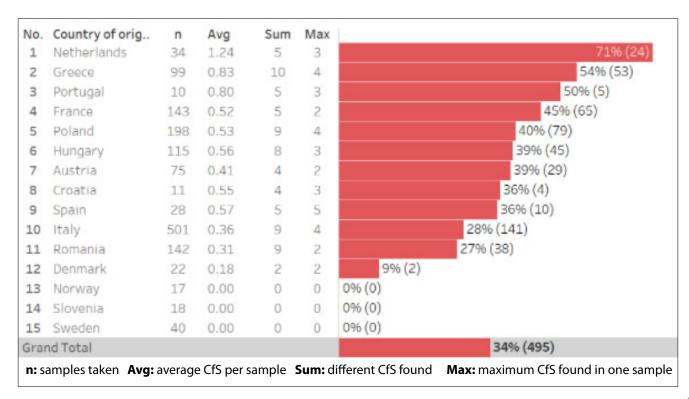


Figure 2. Countries of origin with the highest contamination of CfS in apples



Pears



Trend: Between 2011 and 2020 10,413 samples of pears have been tested for pesticides. In 2011, 26% of the pears were contaminated with one or more CfS. This contamination has increased to 49% in 2020. Based on the trendline, there is almost a doubling (+107%) of the contamination with CfS.

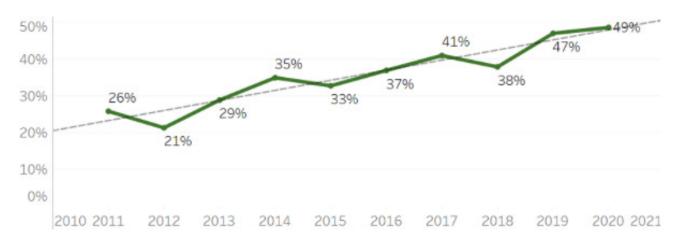


Figure 3. Increase of the % of pears contaminated with CfS.

Member States of origin: In 2020, member states which produced pears with the highest level of CfS contamination are Belgium, The Netherlands, Portugal, Spain and Greece.

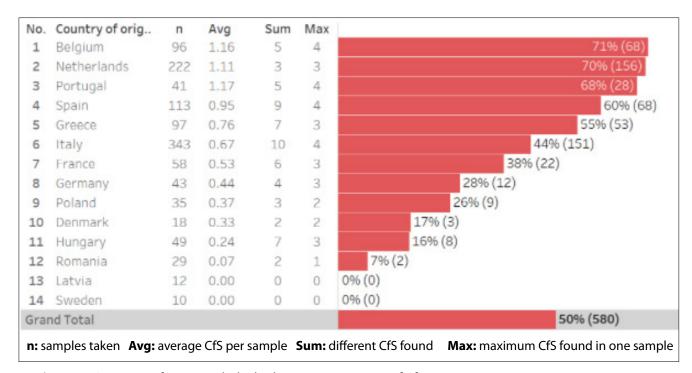


Figure 4. Countries of origin with the highest contamination of CfS in pears



Plums



Trend: 4,656 plum lots have been sampled between 2011 and 2020. In 2011 21% of the samples were contaminated with one or more CfS. In a period of ten years, this increased to 29% in 2020. The trendline shows an 81% increase of the contamination with CfS.

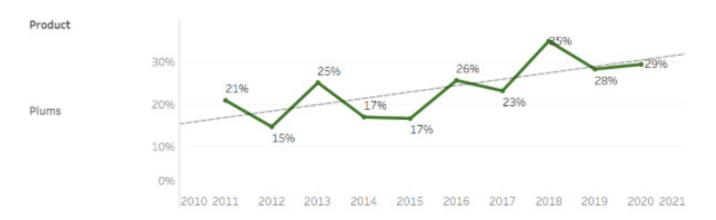


Figure 5. Increase in the % of plums contaminated with CfS.

Member States of origin: In 2020, member states which produced plums with the highest level of CfS contamination are Hungary, Greece, Poland, Italy and Spain.

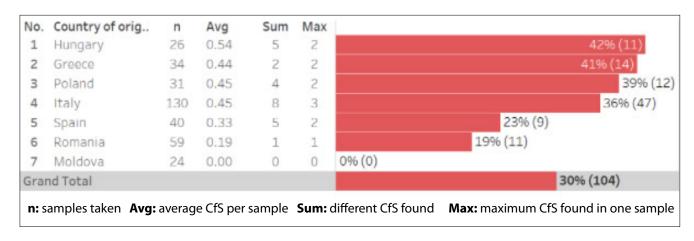


Figure 6. Countries of origin with the highest contamination of CfS in plums



Table grapes



Trend: 8,824 table grapes have been sampled between 2011 and 2020. In 2011 31% of the table grape samples were contaminated with one or more CfS. In the next ten years, the level of contamination increased to 44% in 2020. Mainly due to the large drop of contamination in 2019, there isn't an identifiable trend for table grapes.

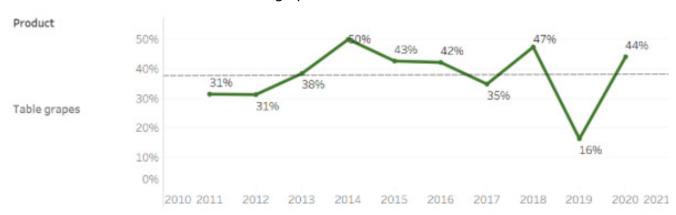


Figure 7. Increase of the % of table grapes contaminated with CfS.

Member States of origin: Member states which produced table grapes with the highest level of CfS contamination in 2020 were Greece, Italy, Romania, Hungary and Spain.

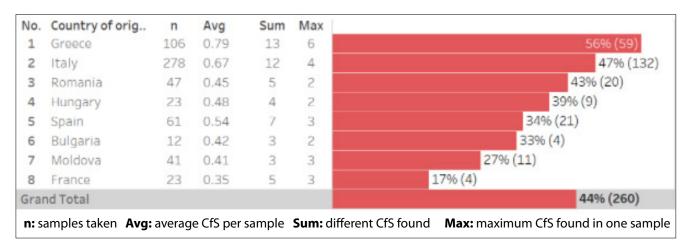


Figure 8. Countries of origin with the highest contamination of CfS in table grapes



Raspberries



Trend: Between 2011 and 2020 in total 1,497 samples of raspberries have been tested for pesticides. Starting in 2011, on 23% of raspberries, one or more CfS were found. This contamination has been stable, showing a contamination of 25% in 2020.

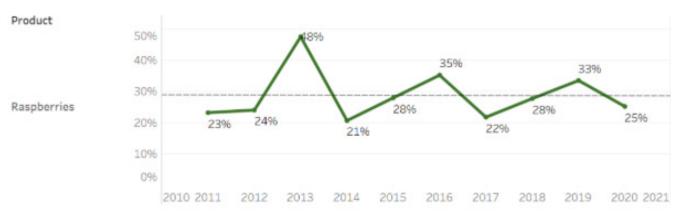


Figure 9. Increase in the % of raspberries contaminated with CfS.

Member States of origin: In 2020, Member States producing raspberries with the highest level of CfS contamination are Norway, Poland and Italy.

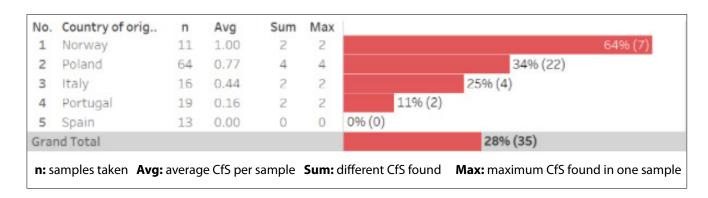


Figure 10. Countries of origin with the highest contamination of CfS in raspberries