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Introduction

In 2020, the EU <u>Farm to Fork Strategy</u> and the <u>Biodiversity Strategy towards 2030</u> introduced the first-ever EU pesticide use reduction policy. We welcomed this clear political acknowledgement that the EU cannot reshape its food system without eliminating its dependence on chemical pesticides, which represent a threat to people's health and biodiversity and cannot be part of the solution.

Both strategies call for a 50% reduction in the use and risk of chemical pesticides (target 1) and a 50% reduction in the use of more hazardous pesticides (target 2). These latter "more hazardous pesticides" are defined as "the plant protection products containing active substances that meet the cut-off criteria as set out in points 3.6.2. to 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009 or are identified as Candidates for Substitution in accordance with the criteria in point 4 of that Annex¹".

Under Regulation (EC) No 1107/2009, Member States and the European Commission have already had a legal obligation for 10 years to progressively eliminate all these particularly hazardous substances covered by target 2. Hence, the 50% reduction target in use by 2030 of these more hazardous substances is therefore both a recognition that the current pesticide framework has not been properly implemented by Member States and the European Commission and a limited and weak attempt to redeem. With this campaign, we claim that the still massive presence of candidates for substitution on the EU market is unlawful and call upon decision-makers to immediately take action to phase out all these most hazardous substances.

Regulatory background

In 2009, Regulation (EC) 1107/2009 on the placing of plant protection products on the market introduced a new category of active substances, the Candidates for Substitution, meant to identify the most dangerous substances approved on the European market. Their designation is based on the criteria set out in Annex II point 4 of the above-mentioned Regulation. This namely includes substances suspected of having carcinogenic, of being reprotoxic, of having endocrine-disrupting effects, and meeting two out the three persistence, bio accumulative and toxic (PBT) criteria². These all are a threat to human health, wildlife and/or to the environment.

According to Articles 24 and 50 of Regulation (EC) 1107/2009, these more dangerous substances have their approval more strictly controlled. Indeed, they can be approved for no more than 7 years, as opposed to 15 years for the other active substances. In addition, their use must be limited as much as possible through substitution by safer alternatives at national level. To this end, when an authorisation dossier for a pesticide contains a candidate for substitution, the Member State concerned is legally obliged to conduct a comparative assessment of this substance with existing alternatives. As soon as deemed possible in the light of the criteria set out in Annex IV of Regulation 1107/2009, substitution must take place, leading to a progressive loss of uses

² Cf. Annex II point 4 of Regulation (EC) No 1107/2009.













¹ Farm to Fork targets - Progress (europa.eu)



of these substances in different agricultural sectors.

Against this background, the number of authorised and approved Candidates for Substitution should have been progressively reduced until their full elimination today. This did not happen in any respect.

Why a campaign?

More than a decade after the entry into application of Regulation (EC) No 1107/2009 in 2011, whose major purpose is "to ensure a high level of protection of both human and animal health and the environment", we note that these core provisions have never been implemented and that no effort has been made in this direction. Candidates for Substitution are still massively approved and authorised in the Member States, and the specific (stricter) provisions coming with this category seem to have been completely ignored.

By their respective (in)action, the European Commission and the Member States are responsible for jeopardizing the objective of "protecting human and animal health and the environment" of Regulation (EC) 1107/2009 in different manners:

- Delays in implementation: While the criteria for identifying Candidates for Substitution came into force in 2011, a first <u>list</u> of 77 substances on the market meeting these criteria was only established in 2015³. For four years, the provisions overseeing substitution of candidates for substitution could simply not be implemented.
- No substitution: In 2019, the conclusions of <u>REFIT evaluation</u> revealed that out of 530 applications for national authorisations containing a Candidate for Substitution submitted between 2015-2018, none of them led to an authorisation with substitution. The REFIT further highlighted that comparative assessment was performed on only 50% (278) of these applications by Member States.
- Renewals of approvals: Between 2014 and 2021, 15 Candidates for Substitution were renewed under this qualification⁴, further feeding this failing substitution system. In addition, the Candidates for Substitution provisions were illegally lifted for Propoxycarbazone and Flumioxazin, which were both renewed as regular active substances (Part B).
- Extensions of approvals: Prior to a decision, approval period of Candidates for Substitution are abusively proposed for extension (e.g., for six years in the case of Ziram). These extensions are proposed by 'packages' with other active substances by the European Commission, limiting the scope for opposition from Member States. Of the 27 substances, whose approval was due to expire in 2021, 15 have had their approvals extended at least once in 2020 or in 2021⁵.

On these grounds, we claim that the presence of these 55 remaining Candidates for Substitution is unlawful. Would Regulation (EC) No 1107/2009 have been implemented correctly, all these substances would already be substituted by safer alternatives at national level, thus

⁴ ROBIN, D., & MARCHAND, P. (2021). The Slow Decrease of Active Substance Candidates for Substitution in the Framework of the European Pesticide Regulation (EC) No 1107/2009. *European Journal of Risk Regulation*, 1-22. doi:10.1017/err.2021.20 ⁵ *Ibid 4*.













³ Implementing Regulation (EU) No 2015/408 was in 2017 <u>amended</u> to include 8-hydroxyquinoline1 and 1-methylcyclopropene. A further <u>list</u> was published in 2020 adding seven other substances. Finally, <u>Flumetralin</u>, <u>Benzovindiflupyr</u> and <u>Cypermethrin</u> were approved or renewed as Candidates for Substitution.



reducing the volume of their (abusive) extensions and renewals of approvals at EU-level.

Instead, we witness a vicious circle that each actor in the chain maintains by not respecting its own obligations, building on a similar excuse: the alleged lack of viable alternatives. We clearly reject this claim that no viable alternatives exist. Alternatives, especially non-chemical ones, are broadly used by organic farmers, or farmers implementing real Integrated Pest Management, which grow the same cereals without candidates for substitution. The actual problem is that non-chemical alternatives are have constantly been dismissed, including in the <u>Guidance Document on comparative assessment and Substitution</u> from 2014 from the European Commission. We identify these Guidance Document as the major factor blocking substitution efforts and attempts to implement Integrated Pest Management. Indeed, this document uncritically endorses the <u>EPPO standard PP 1/271</u> entirely based on the narrative developed by the agri-chemical industry (for its own benefit), which is that chemical diversity is the right mean to counter fight the risk of pesticide resistance. We claim that this Guidance document is neither in line with Articles 50 and 55 of Regulation (EC) No 1107/2009, nor with its Annex IV.

High exposure in food: We also want to stress our concerns about the high levels of Candidates for Substitution residues in food allowed in the context of Regulation (EC) No 396/2005. Indeed, an analysis of the Maximum Levels of Residues established for these Candidates for Substitution revealed that more than 2,700 MRLs are set above the default value of 0.01mg/kg set in Article 18 of Regulation (EC) No 396/2005. Several of these MRLs concern the same food products⁶, which multiplies the likelihood that consumers will be exposed to more than one Candidate for Substitution at a time. In a regulatory system where the cumulative and synergistic effects of active substances are still not assessed (despite clear provisions to that effect⁷), we denounce a total lack of vigilance of regulators and political decision-makers. Consumers are exposed to explosive cocktail effects from the most toxic substances.

Key demands

At a time when the substitution of the most dangerous substances has become a guiding principle of the <u>EU Chemicals Strategy for Sustainability</u>, it is more unacceptable to see that it has remained an empty promise in the very regulation that was its precursor.

In the context of the Farm to Fork Strategy, the EU transition to a sustainable food system cannot be achieved until the more hazardous pesticides are fully eliminated from both its production and consumption system by 2030. To that end, Regulation (EC) No 1107/2009 already contains ambitious, strict, and clear provisions on these most hazardous substances, that only need to be implemented in the right way. Therefore, *Ban Toxic 12* calls upon European decision-makers and Member States to immediately address those implementation shortcomings.

Our key demands are the following:

⁷ Cf. Article 4(3)(b) of Regulation (EC) No 1107/2009 and Article 14 of Regulation (EC) No 396/2005.



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⁶ For pears for instance, 19 MRLs > 0.01mg/kg exist.



- Immediate ban of the 12 most toxic pesticides. These <u>Toxic Twelve</u> are among the most dangerous ones and exposure to them is the highest, due to their use in the fields and/or the important residues in food.
- Review of all national authorisations of pesticides containing a candidate for substitution.
 All Member States must ban these toxics whenever an alternative exists, which will lead to their phase-out by 2030 at the latest. Member States will have to report on their progress to the European Commission.
- Independent revision of the rules of substitution by the end of 2022: unlike the regulation itself, the Guidance Document from 2014 must be independently reviewed to incorporate non-chemical alternatives and to shift away from the current pesticide-intensive agricultural system. The ongoing work of the European Commission and the Post Approval Issue (PAI) working group in this respect must be accelerated and take place in full transparency.
- No more prolongation and renewal of these toxic substances from today. It is the responsibility of the European Commission to enforce the current rules (i. e. the approval for seven years), and to ensure that they are properly applied by Member States.
- No residues in food by 2035: Although not specified in Regulation (EC) No 1107/1009, we claim that the only acceptable level of exposure of consumers to these most toxic substances is a negligible one in the sense of points 3.6.3 to 3.6.5 of Annex II of (EC) No 396/2005 Regulation Regulation. In other words, all MRLs of Candidates for Substitution should all be lowered to 0.01mg/kg in anticipation of their withdrawal. This is justified both by the intrinsic properties of these most dangerous substances and by the lack of assessment of the cumulative and synergetic effects of exposure to several of them by regulators.



































