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Factsheet

Patterns of systematic and unlawful prolongation of toxic pesticide approvals by the European Commission

The EU Commission systematically prolongs the approval of toxic pesticides, including the most dangerous substances, so-called 'Candidates for Substitution'. While these substances should be approved for a maximum of 7 years, their re-assessments are notoriously delayed. The Commission condones this by systematically granting consecutive, 1-year approval extensions - keeping the most dangerous substances on the market without any re-evaluation.

Data on Prolongations: a Systematic Pattern

Delayed re-assessments and approval prolongations for pesticides at the EU level are a standard pattern. Alone in 2021, 136 substance approvals have been prolonged under Article 17, Reg. (EU) 1107/2009, which accounts for almost 30% of all currently EU-approved pesticide substances. In the same year, only 10 decisions regarding the (non-)renewal of active substances were adopted. Overall, extension decisions based on Article 17 far outnumber actual approval decisions.

Background information: Regulatory Framework of Approval and Renewal Timeframes

Pesticide 'active substances' are approved at EU level under Reg. (EU) 1107/2009. The rules provide that first-time approval is limited to a maximum of 10 years, and renewals can be granted for up to 15 years. For substances categorised as especially hazardous, so-called 'Candidates for Substitution', (re-) approval must be limited to a period not exceeding 7 years[1].

Re-approval applications must be submitted 3 years before approval expiry, to provide sufficient time for the review assessment. Under the applicable regulations[2], strict deadlines for the re-evaluation process for Member States, and the European Food Safety Authority (EFSA) are set to amount to a maximum of two and half years. As a result, the Commission and the Member States have more than six months before the approval period's expiry to decide whether or not to renew that approval.

In this context, an extension of the approval - possible under Article 17 Reg. (EU) 1107/2009 - should only be applied in exceptional circumstances, for a few months. Article 17 provides specifically that such an extension must be limited and based on *'the time needed to complete the procedure*'.

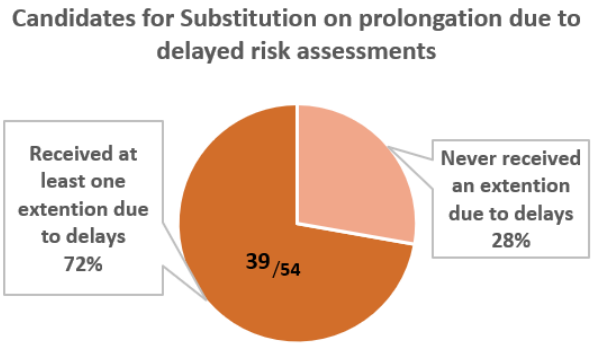
Data on prolongations: Candidates for Substitution

PAN Europe further investigated this pattern by looking at the most hazardous pesticides, so-called Candidates for Substitution (CfS). The first list of CfS was established in 2015 based on substances already approved in the EU. EU-level approval for these substances can only be granted for a period not exceeding 7 years[3], instead of 10 years for other pesticide substances. This has been decided by the legislator in order to re-evaluate more regularly the toxicity of these most harmful substances, in the light of

[1] Learn more on Candidates for Substitution here.
[2] Regulation (EC) 1107/2009 & Implementing Regulation (EU) 844/2021.
[3] See Article 24 of Reg. (EU) 1107/2009.

the most recent scientific information.

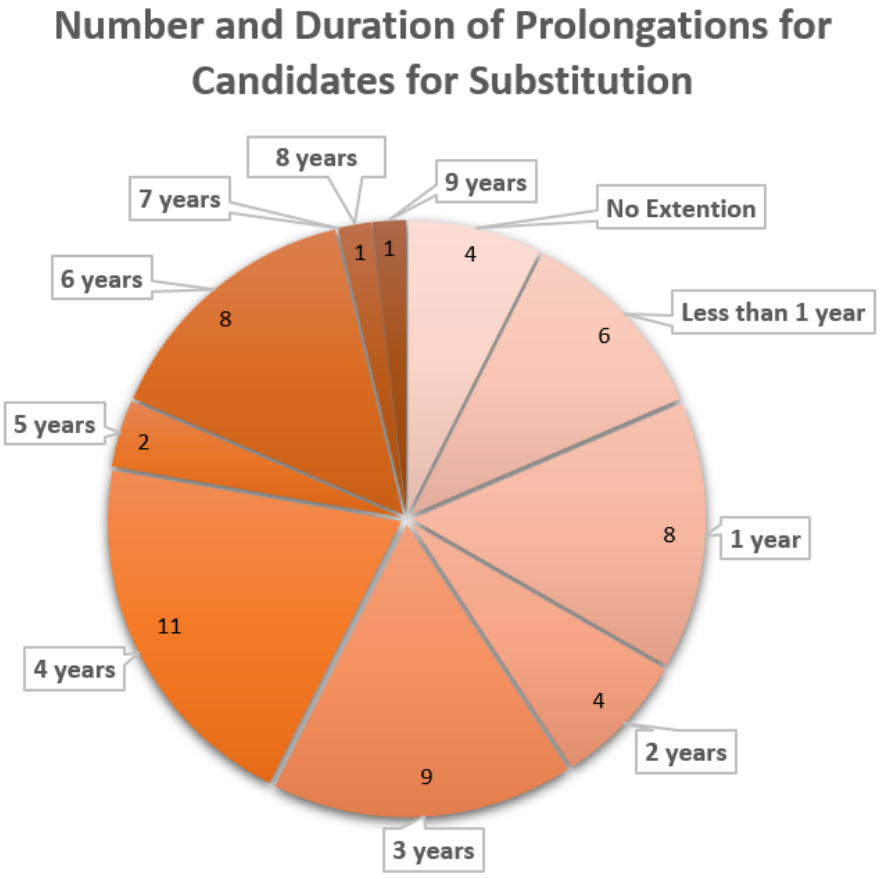
The current practice shows that even these substances categorised as the most dangerous are routinely and systematically granted successive 1-year extensions, without any limitations in sight. The longest extension granted so far is for 9 years.



Out of the 54 CfS approved today, 50 (93%) have received at least one extension. 39 (72%) of them received extensions solely based on delayed risk assessments, i.e. due to non-compliance with legal deadlines by the Member States, the European Commission and the European Food Safety Authority (EFSA).

As a result, although a maximum of 3 years is legally foreseen for the renewal process, renewal assessments are actually notoriously delayed:

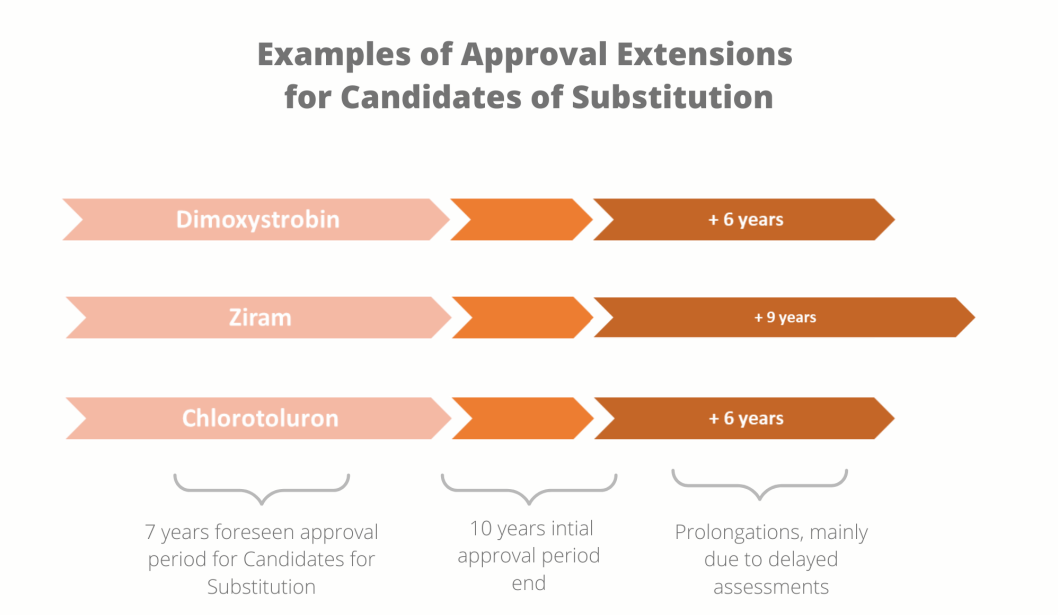
- 17 CfS were prolonged for more than 4 years solely due to delayed assessment.
- 10 CfS were prolonged for more than 5 years solely due to delayed assessment.



Massively Exceeding the Approval Timeframes

- 21 CfS are (or were) on the market for more than 14 years before renewal (4 of them are by now reapproved)
- 10 of these CfS are (or were) even on the market for more than 16 years before renewal (2 of them now re-approved)

Thus, these substances were already approved for more than twice the amount of time as foreseen for a Candidate of Substitution.



- *Extended for 9 years: Ziram*

According to independent literature, Ziram is an endocrine disruptor (sperm disruption) and was added to the SIN list[4]. The substance is also neurotoxic and associated with Parkinson's disease. It is on PAN Europe's list of the Toxic 12 pesticides that should be banned immediately.

- *Extended for more than 6 years: Chlorotoluron*

Chlorotoluron is classified as a suspected carcinogen and reprotoxic. The observed adverse effects in regulatory studies range from kidney adenomas and fetotoxicity to skeletal malformations and decreased foetal weight. Independent literature also reports on testicular toxicity, as well as degradation of the substance into metabolites in surface- and groundwater above concentration limits and persistence in soil. It is on PAN Europe's list of the Toxic 12 pesticides that should be banned immediately but the Commission is currently proposing a 7th extension of the approval of Chlorotoluron.

[4] The SIN (Substitute It Now) list is a list of widely used chemicals which should be removed as soon as possible as they pose a high threat to human health and the environment. The SIN List is developed by the non-profit ChemSec in close collaboration with scientists and technical experts; and based on credible, publicly available information from existing databases and scientific studies.

- *Extended for more than 6 years: Dimoxystrobin*

Dimoxystrobin is classified as suspected carcinogenic and toxic for reproduction. Namely, regulatory studies showed adenoma, adenoma-carcinoma and thyroid tumours, as well as endocrine-disrupting properties and developmental toxicity. In addition, Dimoxystrobin poses high risks for birds, mammals, aquatic invertebrates and algae and a very high risk for fish, according to EFSA, as well as to earthworms. It is on PAN Europe's list of the Toxic 12 pesticides that should be banned immediately.

Extensions: a Tactic for Keeping Cut-off Substances on the Market?

Article 17 is also misused by the European Commission to extend the approval of substances which do not meet the renewal criteria. In the past, Thiacloprid, classified as toxic for reproduction category 1B in 2015 by the European Chemicals Agency (ECHA), has for example been prolonged for more than 5 years before being withdrawn from the EU market in 2020.Article 4 of the Pesticide Regulation and point 3.6.4 of its Annex II which states that substances classified as Cat 1B reprotoxic may not be approved in the EU. The Commission thus deliberately maintains such pesticides in our environment.
Likewise, 8-hydroxyquinoline has been classified as a category 1B reprotoxicant since 2016, thereby meeting the cut-off criteria. Yet, the European Commission is currently proposing to extend its approval for a second time. The only outcome is therefore the removal of 8-hydroxyquinoline.

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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.