



A NOT-FOR-PROFIT NGO REGISTERED UNDER FRENCH LAW, POLLINIS IS FUNDED EXCLUSIVELY BY DONATIONS FROM INDIVIDUALS TO PROTECT WILD AND HONEY BEES, AND TO PROMOTE SUSTAINABLE AGRICULTURE IN ORDER TO HELP PRESERVE POLLINATORS.

PESTICIDES : EU'S SYSTEM OF ENDLESS EXTENSIONS THREATENS BIODIVERSITY AND HUMAN HEALTH

Abstract : Currently, 453 active substances¹ used in fungicides, herbicides, insecticides and bactericides are registered in the European Union. Authorised for an initial period of 10 years, about a third of these substances are nevertheless commercialised for much longer periods, without any reassessment of their risks as provided for by European regulations.

POLLINIS has identified 119 synthetic pesticides – some of which pose significant risks to human health and the environment – that currently benefit from administrative extensions (without reassessment) of their approval. Since 2011, 35 substances that were ultimately banned in regard to their toxicity were also granted extensions lasting up to seven years.

These substances are thus maintained on the market despite the expiry of their initial approval and without any consideration of their sanitary and environmental risks. POLLINIS challenges the legality of the systematic and widespread extensions granted to pesticide manufacturers, particularly in light of the precautionary principle. The association has therefore filed an action before the European General Court in order to cancel the fifth consecutive approval extension for an SDHI fungicide, boscalid.

KEY FIGURES

453 active substances used in plant protection products are currently authorised in Europe.

119 of these are synthetic pesticides that currently benefit from automatic extensions, years after the expiry of their initial approval.

35 substances that benefited from successive extensions in the past – sometimes for up to seven years – were ultimately banned because of their toxicity.

¹ [EU Pesticide Database](#) - visited in February 2023

1. EUROPEAN REGULATION FLAWS: AUTOMATIC EXTENSIONS AND GRACE PERIODS

The European Union is one of the main markets for pesticides in the world: each year, around 350,000 tons are sold in the European Union, almost a quarter of global sales².

To be authorised in the EU, the active substances that make up pesticides³ must undergo a risk assessment to ensure that their use and residues do not have harmful effects on human and animal health, or unacceptable consequences for the environment – as required by the relevant regulation concerning the marketing of plant protection products⁴.

Their initial approval “shall be for a period not exceeding 10 years” (Art. 5) and may be renewed at the manufacturer’s request, at the latest three years before the expiry date. This period is necessary to reassess the potential risks of the substance to animal and human health, as well as the environment.

If the evaluation cannot be completed in time, Article 17 of the Regulation provides that the authorisation may be extended “for a period sufficient to examine the application” if the delay is due to “reasons beyond the control of the applicant”.

Once its extension periods end, a non-renewed substance is not immediately withdrawn from the market. To avoid penalising its manufacturers and users, the substance benefits from transitional measures and a “grace period” that allows it to remain on the market for up to six months, which may be followed by an additional maximum period of one year for storage and use.



² Eurostat - Agri-environmental indicator - consumption of pesticides. Avril 2022.

³ A pesticide formulation is composed of one or more active substances combined with co-formulants, adjuvants, safeners and synergists.

⁴ Règlement (CE) N° 1107/2009 of the European Parliament and of the Council of 21 October 2009.

2. AGROCHEMICAL COMPANIES THRIVE ON SYSTEMATIC EXTENSIONS

Whereas it is meant to be limited to rare cases, the use of the extensions provided for by European law has nevertheless become widespread and systematic, against a backdrop of chronic delays in the procedure for renewing approvals.

SYSTEMATIC DELAYS: THE EXAMPLE OF BOSCALID

Boscalid, an SDHI fungicide commercialised by BASF, was first approved in the EU in 2008 and is currently enjoying its fifth extension period since 2018. In its successive decisions, the European Commission has never clarified why it considered that the company could not be held accountable for the delay in the renewal procedure.

POLLINIS, having been granted access to documents from the European Food Safety Authority (EFSA) regarding boscalid's reassessment procedure*, revealed that EFSA had made 122 requests for additional information in the reassessment dossier. BASF had consequently submitted approximately 200 new files and studies covering five areas of major importance to the risk assessment of the substance.

Despite the numerous additional documents requested by EFSA to complete the reassessment, the Commission neglected to investigate whether the delay in the procedure could be attributable, even partially, to BASF.

* As provided for by Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents.

In its successive decisions to extend approval periods, the European Commission does not examine the reasons for non-compliance with the deadlines; furthermore, in the event of delays in the risk reassessment procedure, its granting of extensions appears automatic.

The European Parliament itself made this point in a 2020 resolution concerning the extensions granted to 26 active substances, including boscalid. Indeed, the MEPs considered that *"the Commission has failed to explain the reasons for the extension, other than saying: 'Due to the fact that the assessment of all those substances has been delayed for reasons beyond the control of the applicants, the approvals of those active substances are likely to expire before a decision has been taken on their renewal'"*⁵.

POLLINIS searched the EU legislation access platform EUR-Lex for the applicable regulations for the 453 active substances authorised in Europe, and identified **180 substances – including 119 synthetic pesticides** – whose approval periods have been extended to date⁶.

34 amongst these have had their approval extended multiple times and for durations of at least 5 years.

For some, like flufenacet and fosthiazate, the accumulated extensions add up to more than nine years beyond the official expiry of their approvals, with a total of 8 consecutive extensions⁷. First approved in the EU in January 2003, deltamethrin, an active substance that is highly toxic to bees⁸ and aquatic organisms⁹, is currently benefiting from an eighth extension that is due to expire in October 2023, to wit: a deferral of its renewal procedure for at least a decade.

⁵ [European Parliament resolution of 10 July 2020](#)

⁶ This figure does not include substances still authorised under their original approval, and which have already been granted an extension.

⁷ foodwatch - [Glyphosate, just the tip of the Iceberg](#) - December 2022

⁸ [Active ingredient fact sheet](#) from SAgE Pesticides, an information portal of Québec's ministries of Agriculture and Environment, and its Institute of Public Health.

⁹ [Deltamethrin toxicological data sheet](#) from the French National Research and Safety Institute for the Prevention of Occupational Accidents and Diseases (INRS).

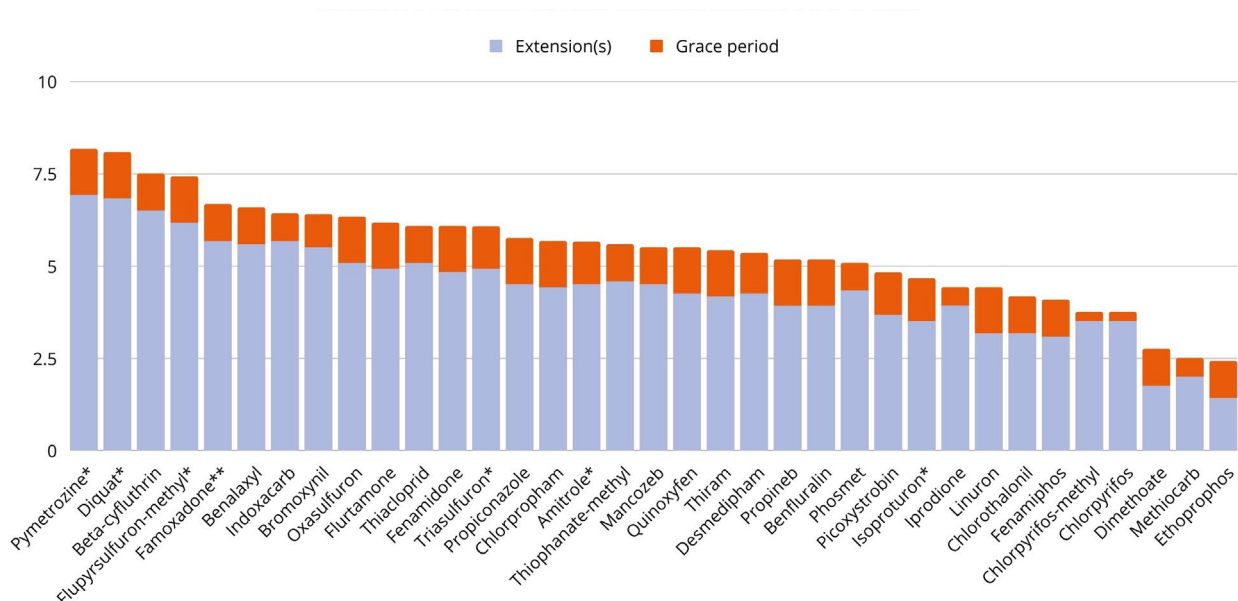
3. POTENTIALLY NOXIOUS PESTICIDES ARE MAINTAINED ON THE MARKET FOR AS LONG AS POSSIBLE

This system enables the extended use of substances without considering the risks to animal and human health or to the environment – **in violation of the precautionary principle provided for in Article 4 of the regulation¹⁰ and in European treaties.**

Indeed, several substances that have benefited from this systematic practice were later found to pose significant risks to health and/or the environment. **35 active substances authorised after 2001 and ultimately banned due to proven risks and/or lack of data in their evaluation had been granted extension(s) from one to seven years after the expiry of their initial approval.¹¹**

BANNED PESTICIDES: EXTENSIONS FROM 1 TO 8 YEARS

For each of the 35 active substances ultimately banned due to their toxicity, this graph compiles extensions and grace periods that they were granted.



*These substances were granted an extension by amending Directive N° 91/414/EEC, which governed the placing of plant protection products on the market in the EU before Regulation (EC) No 1007/2009.

** Famoxadone's initial approval lasted 13 years.

¹⁰ Consideration (24) of the Regulation also provides that “when granting authorisations of plant protection products, the objective of protecting human and animal health and the environment should take priority over the objective of improving plant production”.

¹¹ For 6 of these substances, extensions were granted by an amendment to Directive No 91/414/EEC, which governed the placing of plant protection products on the market in the EU before the entry into force and application by Member States of the Regulation (EC) No 1007/2009.

Beta-cyfluthrin, for instance, was used for 17 years, including more than 7 years comprising extensions followed by a grace period, before being banned¹² due to:

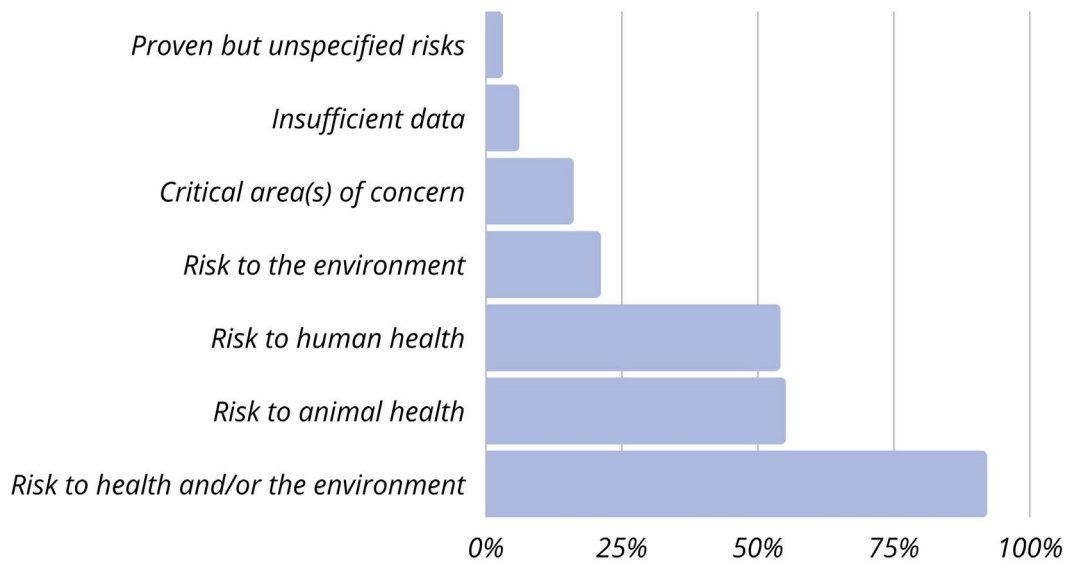
- Unacceptable risk to workers loading and sowing seeds treated with beta-cyfluthrin;
- High risk to residents, non-target arthropods and aquatic organisms for potato and wheat field applications;
- Unacceptable risk to operators, workers and non-target arthropods for use on tomatoes in greenhouses.

All grace periods and extensions combined, **the 35 substances that were ultimately banned were commercialised and used for an average of more than 5 years beyond the expiry of their approval.**

A total of 32 of these substances were ultimately banned for the risks they posed to health and/or the environment. For 19 of them (54%), the rejection of the renewal application was based on risks to human health, including three instances of unacceptable risks. Four substances are also classified as carcinogens, three as endocrine disrupters and six as reprotoxic.

ILLEGAL EXTENSIONS: REASONS FOR BANNING PESTICIDES

Reasons given for not renewing the approval of an active substance, out of the 35 active substances that were granted extensions before being banned. Several reasons can be given for the same rejection.¹³



¹² [Commission Implementing Regulation \(EU\) 2020/892 of 29 June 2020](#)

¹³ This graph was obtained by compiling the reasons given by the European Commission to justify the non-renewal of substance approvals. For animal health risks, they may refer to mammals, arthropods, birds, aquatic organisms, etc. Areas of critical concern may refer to human health, animal health and/or the environment.

INDOXACARB, HIGH RISK TO CONSUMERS: APPROVAL PERIOD EXTENDED FOR 5 YEARS AND 8 MONTHS¹⁴

Indoxacarb is used as an insecticide in various products against butterfly eggs and larvae. Approved in April 2006, it was subsequently withdrawn from the market in December 2021, **5 years and 8 months after the expiry of its approval**, for an effective end of use in September 2022.

Assessments carried out prior to the ban identified a high risk to consumers and workers when applied on lettuce, a high long-term risk to wild mammals, and a high risk to bees when used to produce seeds in maize, sweet corn and lettuce crops.

Between 2017 (the year after the end of its approval) and 2021, more than 32 tons of indoxacarb were sold in France¹⁵.

PHOSMET, RISK TO BEES: APPROVAL PERIOD EXTENDED FOR 4 YEARS AND 4 MONTHS¹⁶

Used on various crops – in particular, rapeseed oil in France –, phosmet is an insecticide that was approved by the EU in October 2007 and banned in February 2022, **4 years and 4 months after the expiry of its approval**, for an effective end of use in November 2022.

In its assessment, EFSA pointed out unacceptable levels of non-dietary exposure for operators and residents, a high risk to bees and non-target arthropods, as well as a reproductive risk to mammals and birds.

Due to a lack of information in the dossier submitted by the applicant, the consumer risk assessment could not be completed before the rejection of the renewal application, and the assessment of developmental neurotoxicity could not be finalised.

Between 2018 (the year after the end of its approval) and 2021, 1,385 tons of phosmet were sold in France, with record sales the year of its ban at 500 tons¹⁷.

BROMOXYNIL, RISK TO CHILDREN: APPROVAL PERIOD EXTENDED FOR 5 YEARS AND 6 MONTHS¹⁸

Approved in March 2005, this herbicide was ultimately banned in September 2020, **5 years and 6 months after the expiry of its approval**, for an effective end of use in September 2021.

¹⁴ [Commission Implementing Regulation \(EU\) 2021/2081 of 26 November 2021](#)

¹⁵ [BNV-D Tracabilité](#), database compiling the sales of phytopharmaceutical products.

¹⁶ [Commission Implementing Regulation \(EU\) 2022/94 of 24 January 2022](#)

¹⁷ [BNV-D Tracabilité](#), database compiling the sales of phytopharmaceutical products.

¹⁸ [Commission Implementing Regulation \(EU\) 2020/1276 of 11 September 2020](#)

Assessments prior to the ban highlighted a risk to child residents due to non-dietary exposure, and a high risk to wild mammals through dietary exposure. The risk assessment for consumers and aquatic organisms could not be finalised.

Between 2016 (the year after the end of its approval) and 2021, 283 tons of bromoxynil were sold in France¹⁹.

BENFLURALIN, RISK TO BIRDS: APPROVAL PERIOD EXTENDED FOR 3 YEARS AND 9 MONTHS²⁰

Used as an herbicide, especially in endive and chicory crops, benfluralin was approved in 2009 and banned in February 2023, **3 years and 9 months after the expiry of its approval**, for an effective end of use in May 2024.

EFSA's assessments pointed out a long-term risk to birds, mammals and aquatic organisms.

Between 2020 (the year after the end of its approval) and 2021, 62 tons of benfluralin were sold in France²¹.

S-METOLACHLOR, SOON BANNED IN FRANCE: AT LEAST 8 YEARS AND 4 MONTHS OF EXTENSIONS IN THE EUROPEAN UNION²²

This herbicide, used primarily for maize, soya and sunflower crops, was approved in 2005. In May 2022, its approval period was extended for the seventh time²³ by the European Commission, with a potential ban by July 2023 **at the earliest**, 8 years and 4 months after the expiry of its approval.

On February 15th, 2023, the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) announced the ban of its main uses in France due to the groundwater contamination caused by the substance. The concentrations of three of its metabolites were indeed *“higher than the quality limit set by the European legislation”*, the Agency stated²⁴.

Between 2015 (the year after the end of its approval) and 2021, 11,432 tons of S-metolachlor were sold in France²⁵.

¹⁹ [BNV-D Traçabilité](#), database compiling the sales of phytopharmaceutical products.

²⁰ [Commission Implementing Regulation \(EU\) 2023/149 of 20 January 2023](#)

²¹ [BNV-D Traçabilité](#), database compiling the sales of phytopharmaceutical products.

²² [Commission Implementing Regulation \(EU\) 2022/708 of 5 May 2022](#)

²³ foodwatch, [Glyphosate, just the tip of the Iceberg](#), December 2022

²⁴ « [S-métolachlore : vers l'interdiction des principaux usages pour préserver la qualité des eaux souterraines](#) », ANSES, 15/02/2023

²⁵ [BNV-D Traçabilité](#), database compiling the sales of phytopharmaceutical products.

A BAN ON AUTOMATIC EXTENSIONS: POLLINIS FILES A PLEA BEFORE THE ECJ AGAINST BOSCALID

BASF's boscalid²⁶ is one of the synthetic pesticides that currently benefits from this illegal system. By 31 July 2023²⁷, this SDHI fungicide will have enjoyed 5 years of undue commercialisation without reassessment of its risks.

And yet, since the initial approval of this substance, scientific research has emphasised the dangers associated with its use. In November 2018, the preliminary reevaluation report on boscalid identified, in particular, an area of critical concern regarding its risks to child residents in the vicinity of grape, pea and bean crops where it is applied, as well as a risk to the development of bees²⁸.

In light of these risks, and considering the mechanism by which SDHI pesticides block cell respiration, 450 scientists signed an appeal in *Le Monde* in January 2020 calling for an end to the outdoor use of boscalid²⁹.

The extensions systematically granted to boscalid run counter to the precautionary principle and directly threaten human health, animal health and the environment. For these reasons, after submitting a request for internal review, POLLINIS filed a plea before the General Court of the European Union against the Commission's refusal to review its extension of boscalid's approval period for the fifth time.

²⁶ Product fact sheets for BASF's "[Cantus](#)", "[Endura](#)", "[Emerald](#)"

²⁷ [Commission Implementing Regulation \(EU\) 2022/708 of 5 May 2022](#)

²⁸ Nov. 2018, [Draft Renewal Assessment Report prepared according to the Commission Regulation \(EU\) N° 1107/2009](#). BOSCALID Volume 1. RMS: Slovakia. Co-RMS: France.

²⁹ [Le Monde](#). Pesticides SDHI : 450 scientifiques appellent à appliquer le principe de précaution au plus vite. 21 janvier 2020.

NOTE MÉTHODOLOGIQUE

POLLINIS based its analysis on Regulation (EU) No 540/2011, which is available on the platform [EUR-Lex](#) to identify the substances benefitting from an extension as of 10 February 2023. The data was then cross-referenced with the extension decisions.

Out of the 180 substances thus identified – not taking into account those that have been granted extensions and whose renewal outcome has since been decided, nor those whose approvals have not yet expired but which have already been extended – POLLINIS distinguished active substances of natural origin, inorganic substances, and non-pesticidal active substances used as antifreeze or growth regulators. 119 synthetic pesticide active substances remained after this sorting.

Information regarding the origin of pesticides was extracted from the [Pesticide Properties Database](#), managed by the Environmental Research Unit at the University of Hertfordshire.

The list of active substances whose approvals were not renewed after one or more extensions was also compiled using the EUR-Lex platform, by identifying the non-renewal decisions taken under Article 20 of Regulation (EC) 1107/2009, before 10 February 2023.

ABOUT

APPENDIX

Contact POLLINIS at presse@pollinis.org to access the recap charts.

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Lars Neumeister, pesticide expert, author of the report

“[Locked-in Pesticides – Europe’s dependency on harmful pesticides and how to overcome it](#)” (foodwatch, 30/06/2022)

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