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Review

Beyond the urgency: pesticide Emergency Authorisations' exposure, toxicity, and risk for humans, bees, and the environment

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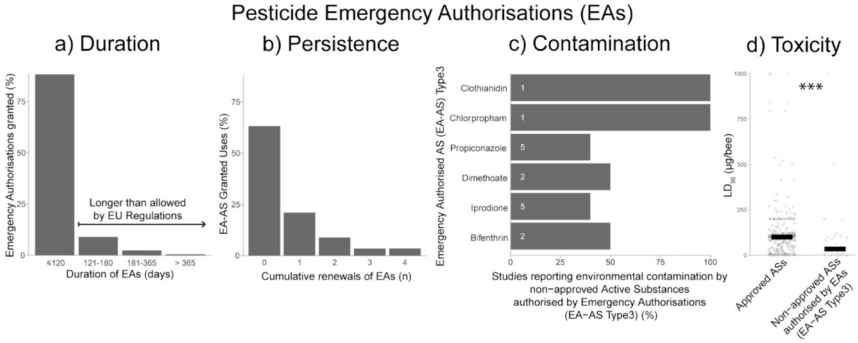
HIGHLIGHTS

- EU Member States (MSs) frequently grant pesticide Emergency Authorisations (EAs).
- 12 % of EAs ($n = 3173$) were granted for longer periods than prescribed by EU regulations.
- EAs were commonly renewed (37 %) over the years to control the same emergency.
- EAs allow highly toxic Active Substances to frequently contaminate the environment.
- We describe the most relevant agricultural emergencies and EA process challenges.

GRAPHICAL ABSTRACT



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ABSTRACT

The global challenge to increase agricultural production goes along with the need of decreasing pesticide risks. The European Union (EU) therefore evaluates and controls the risks posed by pesticides by regulating their authorisation through the science-based Risk Assessment process. Member States can however act in derogation to this process and grant the Emergency Authorisation (EA) of pesticides that are currently non-authorised. To protect the health of humans and the environment, Emergency Authorisations are only permitted in exceptional circumstances of agricultural emergency: their use should be limited (i.e., cannot exceed 120 days and one growing season) and concurrent research on alternative strategies must be enforced. Here, we assessed the impact of the Emergency Authorisations process to human and environmental health. Bees, bioindicators of

Abbreviations: AS, Active Substance contained in a Plant Protection Product; AS-DB, Database of active substance in European Union Member States; ADI, Acceptable Daily Intake; AOEL, Acceptable Operator Exposure Level; ARfD, Acute Reference Dose; CfS, Candidates for Substitution. Given their hazardous profile, Active Substance for which alternatives should be prioritised; EA, Emergency Authorisation; EA-AS, Emergency Authorised Active Substance: an active substance contained in an Emergency Authorised Plant Protection Product (EA-PPP); EA-DB, Database of Emergency Authorisation; EA-PPP, Emergency Authorised Plant Protection Product; EC, European Commission; EPPO, European and mediterranean Plant Protection Organization; EU, European Union; GU, Granted Use. The unique use profile of an Emergency Authorised Active Substance contained in an Emergency Authorised Plant Protection Product, taking in consideration the Member State, the pest, and the crop addressed by the Emergency Authorisation; FU, Fungicide; IN, Insecticide; MS, European Union Member State; PPP, Plant Protection Product; RA, Risk Assessment.

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environmental health, were used as model species. Our research demonstrates that i) Emergency Authorisations are widely used throughout EU Member States (annually granted Emergency Authorisations$_{\text{min-max, 2017–2021}}$ = 593–660); ii) 12 % of Emergency Authorisations granted the use of pesticides for longer than prescribed by EU regulations; iii) 37 % of Emergency Authorisations were repeatedly granted over time by the same Member State for the same agricultural purpose (i.e., to control the same pest on the same crop); iv) 21 % of Emergency Authorisations granted the use of Active Substances non-approved by risk assessment (EA-ASs Type3) which consequently contaminate the environment (44 % of environmental biomonitoring studies found EA-AS Type3) while being significantly more toxic to pollinators than regularly approved ASs. To facilitate the implementation of sustainable control strategies towards a safer environment for humans and other animals, we identified the most frequent agricultural emergencies and the key research needs. This first quantitative assessment of the Emergency Authorisation process unveils an enduring state of agricultural emergency that acts in derogation of the EU Regulation, leading to broad human, animal, and environmental implications.

1. Introduction

A major challenge for current global agricultural systems is to meet the growing food demand while reducing environmental impacts (Tilman et al., 2011). Pesticides' ubiquitous use have been increasing short-term agricultural production while causing negative impacts on the environment (Seibold et al., 2019) and a range of animals, including humans (Hernández et al., 2013), other mammals (Duzguner and Erdogan, 2010), birds (Mitra et al., 2021), and beneficial insects such as pollinators (Tosi et al., 2022). The adverse effects of pesticides can jeopardise essential ecosystem services such as pollination and biological pest control, thus putting at risk food security and biodiversity (Dainese et al., 2019; Pecenka et al., 2021).

Policy frameworks aimed at improving the sustainability of agricultural production, including pesticide use, are crucial to protect human and animal health, natural resources, and ecosystem services. The Green Deal was proposed by the European Commission to enhance the sustainability of multiple sectors, including agriculture (EC, 2019a). Key Green Deal targets, to be achieved by 2030, are detailed in specific Strategies and include recovering biodiversity through high-quality habitats for biodiversity (EC, 2020c), reaching up to 25 % of agricultural land under organic farming (EC, 2020d), better protecting citizens and the environment by banning most harmful chemicals, and reducing to 50 % the use and risk of chemicals and hazardous pesticides (EC, 2020f). To implement the Green Deal targets linked to pesticide risk, the European Commission proposed the Sustainable Use of Pesticides Regulation (EC, 2022a). This proposal was however withdrawn after negotiations with legislators (European Parliament, 2024). The EU objective of pesticide use reduction remains thus covered by the Sustainable Use of Pesticide Directive (2009/128/EC), which is however relatively outdated and considered insufficiently enforced by Member States to protect animal health and environmental sustainability (European Court of Auditors, 2020). Commission and Member States continue working on the improvement of the methodologies for the calculation of Harmonised Risk Indexes (HRIs) evaluating the compliance with the target ambitions. Novel pesticide regulations, aimed at specifying how Member States should achieve the targets, have not been proposed yet.

To ensure a high level of protection of humans, other animals, and the environment, the EU regulates the "authorisation" of Plant Protection Products (PPPs; pesticides formulations that protect crops or ornamental plants), the "approval" of Active Substances (ASs) contained in PPPs, and the Emergency Authorisation (EA) process (European Parliament and Council, 2009, Regulation (EU) 1107/2009, also called "PPP Regulation"). The PPP regulation builds on the precautionary principle and establishes that PPPs and ASs can be used when they are not expected to cause any harmful effects on human or animal health or any unacceptable effects on the environment (PPP regulation). A prerequisite for PPP authorisation is therefore to develop a Risk Assessment of the potential impacts caused by pesticides to human, animal, and environmental health.

When a danger to crops or the environment cannot be contained by authorised control measures, Member States may use the Emergency Authorisation process to protect agriculture and food production. Emergency Authorisations shall be granted, in the interest of agriculture and environmental protection, when "special circumstances" apply (EC, 2021; PPP regulation):

- no other reasonable means of control, including non-chemical ones, are available or affordable;
- a 120-day use period is not exceeded.

Each Emergency Authorisation should also be i) limited to one growing season, ii) limited to a specific area or territory, and iii) linked to a specific danger (e.g., caused by a defined pest species on one or multiple crops; EC, 2021). These and further appropriate risk mitigation measures should be reported and imposed, and applicants (e.g., grower's associations, agricultural cooperatives, regional administrations, and companies that are holders of PPP authorisations acting on behalf of growers) should demonstrate how the uses will be limited (EC, 2021). A renewal of the Emergency Authorisation of PPPs containing ASs that were non-approved by the standard Risk Assessment process may also be requested, when an agricultural emergency continues over time. In this case, applicants should additionally 1)"demonstrate that no other viable options exist […] and that temporary continuation […] is necessary to avoid unacceptable damage to plant production or ecosystems", 2) limit use "as much as possible", 3) "provide details of ongoing and future activities aimed at finding a long-term/permanent solution to eliminate the need for repeat applications for an Emergency Authorisation in the future", and 4) consider "the need for a programme of research that searches for alternative acceptable solutions" communicating to the European Commission and the Member States "the details on the objectives of the programme, a concrete time schedule and planned and taken efforts" (EC, 2021). There is however a wide qualitative and quantitative knowledge gap on the use of Emergency Authorisation renewals, their impact, and the most relevant crops and pests that require long-term alternative solutions and research.

The European Commission and the Member States have shown that the risks associated with the use of the Emergency Authorisation process have been increasing by 41 % in the last decade (EC, 2019b; EC, 2022b). The Harmonised Risk Index 2 (HRI 2) was used to estimate the risk posed by the granted authorisations (Directive (EU) 2019/782; EC, 2019b; EC, 2022b, consulted the 27/12/2022). The possible impacts of the Emergency Authorisation process thus raised concerns, also given that i) the number of Emergency Authorisations granted by Member States has tripled since 2011, ii) Member States provide repetitive renewals of the same Emergency Authorisation, and iii) only a few Member States communicate when and where emergency authorised pesticides are applied (EC, 2020e).

The Emergency Authorisation process has been described as a loophole allowing high-risk pesticides to remain in the market, overexploiting the concepts of "special circumstance" and "emergency" (Epstein et al., 2021, 2022). Recently, the renewal of Emergency Authorisations for the non-approved neonicotinoids was explicitly

prohibited by the European Commission after numerous renewals were granted by Lithuania and Romania (EC, 2020a; EC, 2020b). The EU Court of Justice further prohibited the Emergency Authorisations of PPPs containing banned neonicotinoid pesticides (ECJ, 2023; Council of State, Belgium, 2023). The use of non-approved or banned ASs authorised by Emergency Authorisations may lead to environmental contamination, since they have been previously found in the field (Bokšová et al., 2021; Calatayud-Vernich et al., 2019; Ligor et al., 2020; Tosi et al., 2018). Nonetheless, the environmental contamination caused by non-approved ASs authorised by Emergency Authorisations is still unknown and under investigated, and the public information on the extent of Emergency Authorisations' use and their related possible risks is limited.

Here, we qualitatively and quantitatively investigated the use of Emergency Authorisations, and assessed the environmental contamination and related risks to human, animal, and environmental health caused by emergency-authorised pesticides. We specifically examined 1) the extent of Emergency Authorisation uses across EU Member States, 2) the fulfilment of Emergency Authorisations' legal requirements, 3) the most relevant agricultural emergencies, 4) the link between emergency-authorised pesticides and their environmental contamination, and 5) the toxicity of emergency-authorised pesticides as compared to regulatory-authorised ones. We finally discuss the Emergency Authorisation process in the framework of the EU objectives of reducing pesticide risk and increasing agricultural sustainability, highlighting possible strategies towards a better protection of humans, animals, agriculture, and the environment.

2. Material and methods

2.1. The European pesticide regulatory framework

The risk assessment process ensure that pesticides do not cause harm to human or animal health and do not have unacceptable effects on the environment. The European Commission is the competent authority governing ASs approval, while Member States are the competent authority governing the authorisation of PPPs (PPP regulation; Fig. 1). This process establishes that either a) at least one PPP containing the target AS fulfils the approval criteria for at least one field use (e.g., control of a specific pest species in a specific crop), or b) the AS is not approved and its use is therefore forbidden in the EU market (PPP regulation; Fig. 1a). The most harmful approved ASs are included the list of "Candidates for Substitution" (CfS), aimed at enhancing their gradual removal from the market (PPP regulation).

Data on AS approval status are available in the open-access AS DataBase (AS-DB), formally named "European list" of "Active substances, safeners and synergists" (Fig. 1a,b, EC, 2022c, consulted the 20/04/2022). The AS-DB uses two categories of ASs, reflecting EU approval status: approved, or not approved (Fig. 1a). A not approved ASs may be banned, not renewed, pending, and not yet assessed. The AS-DB also contains the list of Member States that authorised PPPs containing the ASs (Fig. 1b). When the AS-DB does not specify the list of Member States, we considered that all Member States have at least one PPP containing the approved substance. ASs were classified by the target organisms they aim to control: fungicides, herbicides, insecticides, or acaricides.

2.2. The Emergency Authorisation process

In special circumstances, Member States can use the Emergency Authorisation process to grant the use of non-authorised PPPs and corresponding ASs contained (PPP regulation; Fig. 1c). Here, we defined as Emergency Authorised Active Substances (EA-AS) all AS ingredients of Emergency Authorised Plant Protection Products (EA-PPP, Fig. 1c). We categorized the EA-ASs in three types that reflect the regulation status of both the PPP and the AS contained (Fig. 1c):

1. EA-AS Type1: The Emergency Authorisation allows at least one non-authorised use of an authorised PPP containing one or more approved ASs;
2. EA-AS Type2: The Emergency Authorisation allows at least one non-authorised use(s) of a non-authorised PPP containing approved ASs;
3. EA-AS Type3: The Emergency Authorisation allows at least one non-authorised use(s) of a non-authorised PPP containing at least one non-approved AS.

Because EA-AS Type3 allow to use ASs that are not permitted at EU level, it is considered as the most potentially harmful category.

Data on Emergency Authorisations, EA-ASs, EA-PPPs, their uses, and

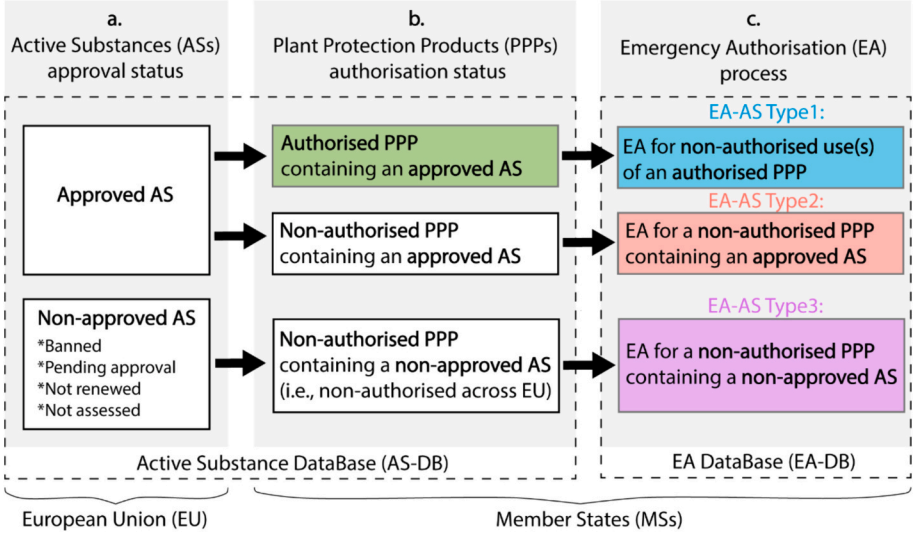

Fig. 1. Overview of the EU pesticide regulatory framework. Pesticide use may be granted via (a) the approval of Active Substances (ASs), (b) the authorisation of Plant Protection Products (PPPs), and (c) the Emergency Authorisation (EA) process. (a) ASs can be approved or non-approved at EU level, while (b) PPPs containing an approved AS can be authorised at Member State (MS) level and then placed on the Member States national market (green square). (c) Emergency Authorisations can be granted for either non-authorised use(s) of authorised PPPs (EA-AS Type1, blue square), non-authorised PPPs containing approved AS(s) (EA-AS Type2, red square), or non-authorised PPPs containing at least a non-approved AS (EA-AS Type3, violet square). Coloured squares correspond to pesticides that can be placed on the national market(s) and used. All data are available in the open-access AS-DB and EA-DB.

the Member States requesting the Emergency Authorisations are available in the open-access Emergency Authorisation DataBase (EA-DB; Fig. 1c; EC, 2022c, consulted the 20/04/2022). The EA-DB contains the notifications of the granted Emergency Authorisations for EA-PPPs (Fig. 1c) and EA-ASs across the 28 Member States. Member States are fully responsible for granting Emergency Authorisations and, thereby, for duly providing information about the Emergency Authorisations. The application and notification of an Emergency Authorisation is processed by the National Competent Authorities through the Plant Protection Products Application Management System. This ensures that detailed information about Emergency Authorisations is shared through the EA-DB to the other Member States, the European Commission, and the wider public. While the EA-DB has information on Emergency Authorisations since 2013, this data has been systematically uploaded by the National Competent Authorities since June 2016 (EC, 2022c; Fig. S1). We thus focused our analysis on the Emergency Authorisations occurring in the more comprehensive 2017–2021 period. The duration of each Emergency Authorisation was calculated as the number of days between the first authorised day of use and the day of its expiration.

2.2.1. Emergency Authorization granted uses

We developed the new category of Emergency Authorization Granted Use (GU). A GU corresponds to the unique combination of AS, Member State, crop, and pest. For example, a single GU consists of a single AS used in a specific Member State to control a single pest on a single crop (e.g., spinosad × Austria × pome fruits × *Drosophila suzukii*).

Crops and pests are defined in the EA-DB by taxonomic level according to European and mediterranean Plant Protection Organization (EPPO, https://www.eppo.int/) pest and crop identification codes (Table S1). EPPO's pest and crop identification codes can correspond to different group/taxonomic levels (e.g., pomaceous fruit plants and *Malus domestica*). Although one level can be a subgroup of another, we consider them as different crops or pests for accuracy and simplicity.

We counted the GU across years to define the number of times each Member State renewed EA-ASs use to address the same emergency, i.e., protect the same crop from the same pest in subsequent years. GUs renewed multiple times during the same year (same growing season) were not counted as renewals. GU counts higher than one corresponds to a repeated renewal of a unique EA-AS use.

We quantified the number of Emergency Authorisations for each identified pest-crops pair to identify the most common unique crop-pest combinations in the EA-DB. Because an Emergency Authorisation may include multiple pests and crops, those reporting multiple crop-pest pairs were considered as separated ones (e.g., the same Emergency Authorisation granted for treating Drosophila on *P. avium* and *P. cerasus* was counted as two Emergency Authorisations).

2.2.2. Emergency authorised active substance frequency

Because a harmonised database on the list of PPPs authorised across Member States is currently missing, we assessed the most frequent EA-AS Types by linking the AS-DB and the EA-DB using the EA-AS as unique reference (Fig. 1). The AS-DB includes the list of all approved ASs and the Member States that authorised them through at least one PPP. We thus used the AS-DB to define the number of Emergency Authorisations granting the use of EA-AS Type1 and Type2. EA-AS Type3 include ASs that are non-approved; since this decision is taken at EU level (Fig. 1), EA-AS Type3 do not change across Member States. As it was not possible to verify ASs approval status before 2021, we only used 2021 data to guarantee accuracy on the approval status results. When the AS-DB did not report an AS expiry date, we considered the same AS approval status throughout the assessment period.

2.3. Environmental contamination by emergency authorised active substances

We assessed the real-word contamination by non-approved ASs authorised by Emergency Authorisations (EA-ASs Type3, Fig. 1) in the EU. We focused on EA-AS Type3 contamination because, while Type1 and Type2 include authorised ASs (see Section 2.2) and thus their contamination cannot be distinguished between regulatory or emergency-authorised uses, EA-AS Type3 environmental contamination is necessarily related to either Emergency Authorisations or illegal applications.

We quantified the contamination of non-approved ASs in honey, bee, beebread, bee wax, pollen, propolis, nectar, and royal jelly. We used a systematic review process focusing on peer-reviewed scientific publications using biomonitoring with bees to retrieve environmental contamination data in EU Member States. We categorized ASs according to their approval status when the environmental contamination was found and thus verified that the sampling occurred when the ASs was not approved. We assessed the percentage of peer-reviewed scientific studies reporting non-approved AS contamination and the related number of Emergency Authorisations granting their use.

The detailed review process procedure – searching for articles and search string, article screening, selection criteria, and data extraction – is described in the Supplementary Materials text and in Tables S6-S7. This search was tailored to our scope and applied the Reporting standards for Systematic Evidence Syntheses in environmental research (ROSES, Table S6, James et al., 2016). The search was performed the on the 23rd of February 2024 using Web of Science (www.webofscience.com).

The 2087 unique articles retrieved by the search were screened against the selection criteria to define the included ones. Briefly, studies were included when they i) were written in English, ii) identified pesticide contamination in bees or samples collected by bees, and iii) were performed in field conditions within EU Member States between 2017 and 2021. We used the articles that met the inclusion criteria to extract data on pesticide contamination occurrence. Using this data on pesticide contamination, we were able to further select the articles that specifically screened EA-AS Type3 contamination.

2.4. Toxicity of emergency authorised active substances

We described the toxicity of EA-ASs to humans and honey bees. We used the honey bee (*Apis mellifera* L.) as model species due to its wide official use as surrogate of non-target organisms in Environmental Risk Assessment, its critical role as pollinator sustaining food production and biodiversity, and wide availability of pesticide toxicity information.

We used the information in the Draft Assessment Reports to highlight the risk caused by ASs to humans, including information on their carcinogenicity, genotoxicity, neurotoxicity, endocrine, reproductive, and developmental toxicity. To further evaluate the risks for human health, we identified EA-AS included in the list of Candidates for Substitution (CfS; PPP regulation; Regulation EU 540/2011). Given their hazardous profile, CfS ASs have an approval period of seven years rather than ten years (Regulation EU 540/2011). Human toxicity data were retrieved from the Pesticide Properties Database (Lewis et al., 2016).

We assessed whether approved ASs and non-approved ASs authorised by Emergency Authorisations (EA-ASs Type3) have different toxicity on beneficial organisms using the vast literature on honey bee toxicity. We focused on non-approved EA-AS Type3 because EA-AS Type1–2 include approved ASs. We used the median lethal dose (LD_{50}, i.e., dose causing the death of 50 % of the tested population; oral exposure) as lethal toxicity endpoint for honey bees. Lower LD_{50} indicates higher lethal toxicity. LD_{50} data were retrieved from a recently published database on pesticide toxicity (Tosi et al., 2022), further refined with EFSA OpenFoodTox data (https://www.efsa.europa.eu/en/data-report/chemical-hazards-database-openfoodtox). When multiple LD_{50} values for an AS were available, we selected the lowest value following a precautionary approach. Our LD_{50} database includes toxicity data of both regularly-approved AS and EA-AS. The approval status of each AS in 2021 was defined using the AS-DB.

2.5. Statistics

Data were organised and processed with R 4.1.2 (R core team, 2022). We used the tidyverse packages (Wickham et al., 2019) to generate a customised database for each study objective. The plots were built with the package ggplot2 (Wickham, 2016).

We used the Kruskal Wallis H test to test the impact of approval status (approved vs non-approved ASs authorised by Emergency Authorisations, EA-AS Type3) on bee toxicity, and the Wilcox test to verify the statistical difference among groups. The Kruskal Wallis H and Wilcoxon non-parametric tests are well suited to test differences between groups with non-normal distributions. We visualised whether the trend of the number of EA-ASs was increasing, decreasing, or stationary for each Member State by fitting a linear model using the number of EA-ASs as a response variable and year as a fixed effect. Because the analysis was performed on the overall EA-ASs population, we associated regression coefficients >1 or lower than −1 with an increasing or decreasing trend, respectively (Faraway, 2016).

3. Results

3.1. Standard risk assessment of active substances

The European list of "Active substances, safeners and synergists" (Active Substance DataBase, AS-DB) included 30 % of approved, 64 % of non-approved (banned or not renewed), 5 % of pending, and 1 % of not yet assessed ASs ($n = 1469$). Fifty-five ASs were ingredients of PPPs used in all 28 Member States (Table S2). Greece, Spain, France, and Austria were the Member States with the highest number of ASs in authorised PPPs, while Malta, Latvia, Lithuania, and Denmark were those with the lowest.

3.2. Emergency Authorised Active Substances (EA-ASs) across space and time

The Emergency Authorisation DataBase (EA-DB) listed 354 EA-ASs. These EA-ASs were used as ingredients of 1481 EA-PPPs. Between 2013 and 2016, the number of granted Emergency Authorisations was 220. Between 2017 and 2021, the number of granted Emergency Authorisations was 3173 (Fig. S1). The yearly number of EA-AS remained persistently over 200 between 2017 and 2021, with an annual average of 223 EA-ASs (Fig. 2a). Given the higher reliability of the EA-DB between 2017 and 2021, the analysis focused on this period.

The number of EA-ASs increased in 36 % of Member States ($n = 28$), remained stable in 46 %, and decreased in 18 % (Table S3, Fig. 2b, time period: 2017–2021).

While Cyprus, Romania, and Malta authorised the use of <10 EA-ASs (<3 % of all EU EA-ASs), Austria, France, Germany, Greece, Italy, and Spain authorised the use of >70 EA-ASs (>20 %, Fig. 3, S2).

In 2021, Emergency Authorisations were granted for PPPs containing EA-AS Type1, Type2, and Type3 in 62 %, 17 %, and 21 % of cases, respectively ($n = 765$). EA-AS Type1 was the most frequently granted, as compared to EA-AS Type2 and Type3, in 18 Member States. While Member States granted an average of 4 EA-ASs Type3, >5 were granted by Greece, Spain, Austria, France, Germany, Hungary, and Latvia (Fig. 4; time period : 2021).

3.3. Emergency Authorisations duration and cumulative renewals

Twelve percent of the 3173 Emergency Authorisations were granted for a longer period than the legal maximum of 120 days (Fig. 5a). Fourteen EA-PPPs were granted for more than one year. The longest Emergency Authorisation (forty months between 2016 and 2020) was granted in Spain to allow the use of fludioxonil, a fungicide applied through seed dressing.

Thirty-seven percent of the EA-AS GUs were renewed in subsequent years by the same Member State to tackle the same emergency. Three percent of the EA-AS GUs were renewed consistently throughout the whole duration of the screened period (four years, Fig. 5b). The number of times the same EA-AS GU was granted varied across Member States. More than half of the EA-AS GUs renewals occurred in Austria, Belgium, Hungary, Slovenia, and Lithuania (Fig. S3).

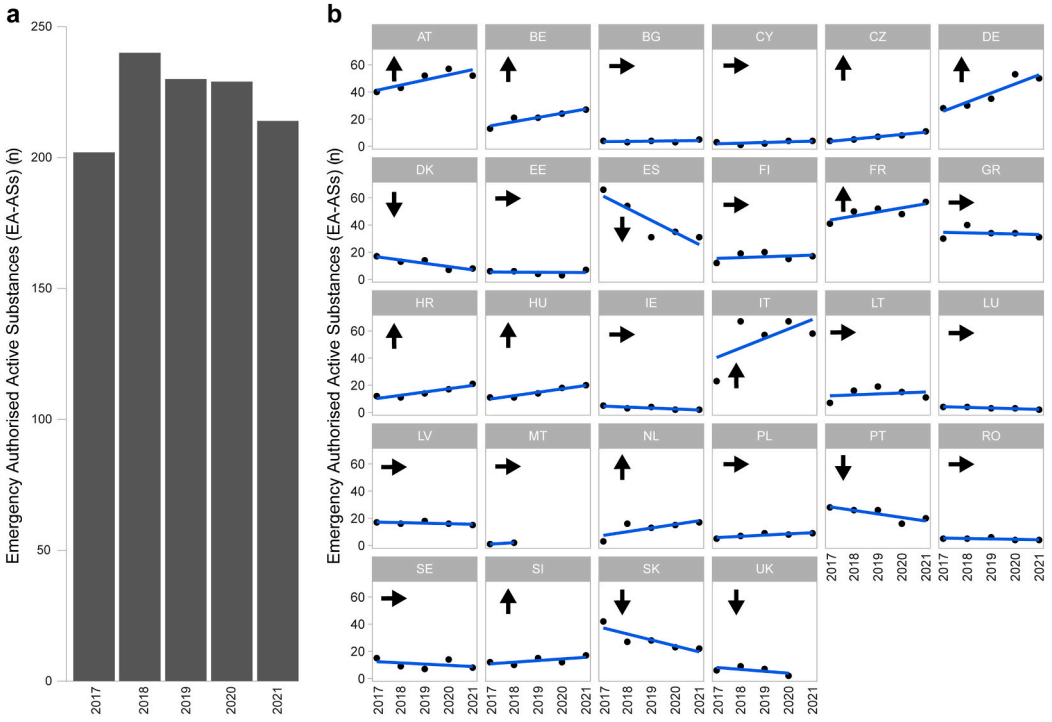

Fig. 2. Emergency Authorised Active Substances (EA-ASs) granted across time and space. We report the 2017–2021 results at (a) EU and (b) Member States (MSs) level ($n_{MS} = 28$, $n_{EA\text{-}ASs} = 342$). In b), we used a linear model to visualise increasing (upwards arrow), stable (horizontal arrow), or decreasing (downward arrow) trends across years per each Member State; black dots indicate the number of EA-ASs per year, and the blue line the estimated trend.

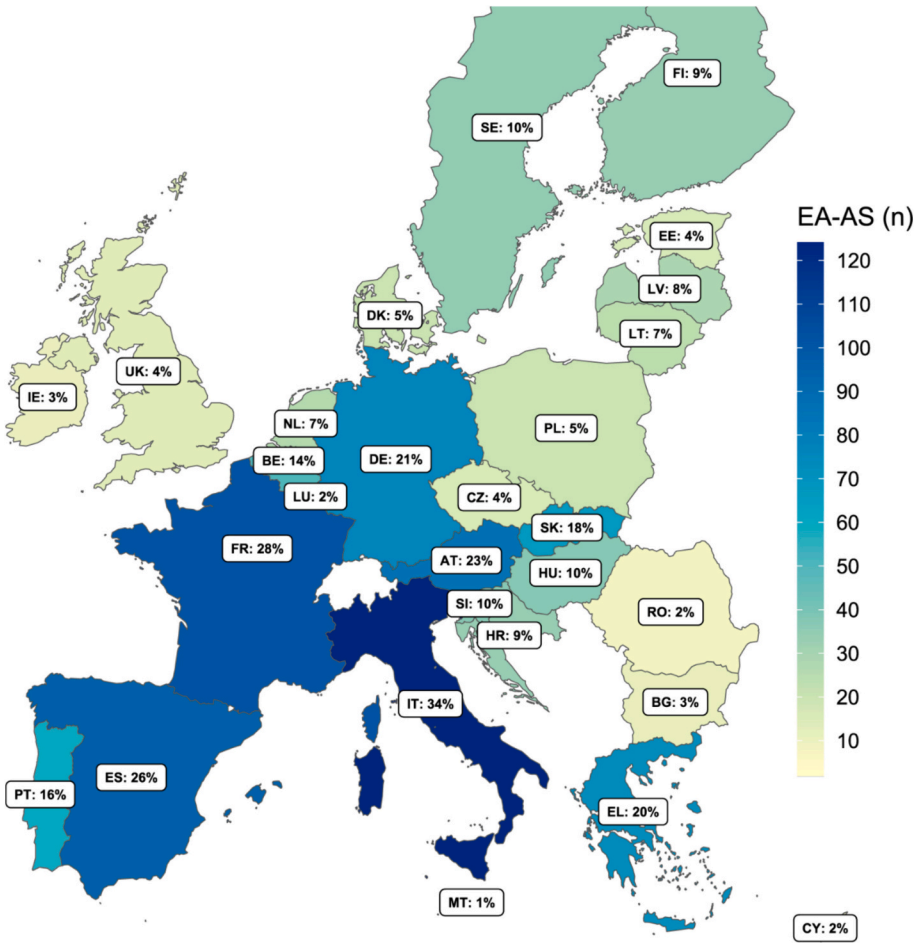

Fig. 3. Emergency Authorised Active Substances (EA-ASs) included in Plant Protection Products (PPPs) across the 28 European Member States. The darker the colour of the Member State, the greater the number EA-ASs granted nationally. We indicate the percentage of EA-ASs granted by each Member State as compared to the overall EU value (100 %, $n = 342$) within the black-outlined labels.

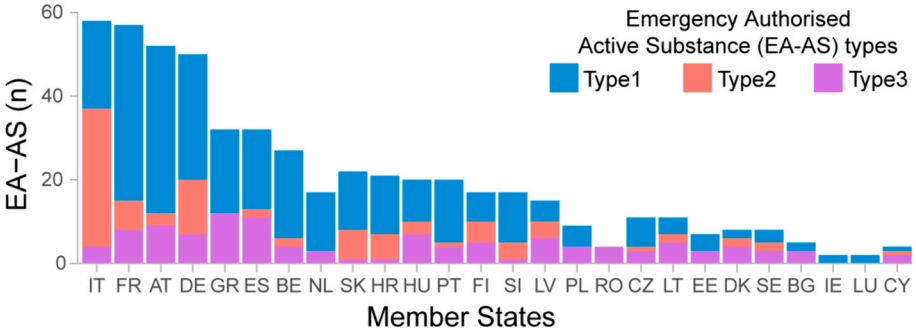

Fig. 4. Emergency Authorised Active Substances (EA-ASs) granted by each EU Member State according to their types. Emergency Authorisations can grant non-authorised use(s) of i) an authorised PPP containing an approved AS (EA-AS Type1), ii) a non-authorised PPP containing an approved AS (EA-AS Type2), and iii) a non-authorised PPP containing a non-approved AS (EA-AS Type3). The United Kingdom and Malta are missing since they did not grant any emergency authorisation in the considered period (2021; see Methods for details).

3.4. Key pests and crops targeted by Emergency Authorisations

We identified 12,260 unique pest-crop combinations controlled by Emergency Authorisations (Table S4). The most frequent pest species included a fungus (*Venturia inaequalis*) and four either native (*Pagomynia hyoscyami* and *Atomaria linearis*) or alien (*Drosophila suzuki* and *Agriotes* spp.) insect species (Fig. 6). *D. suzuki* was by far the most frequently controlled pest, typically through the EA-AS spinosad. The fruit crops *Malus domestica*, *Prunus avium*, *Prunus cerasus*, *Prunus domestica*, *Prunus persica*, *Rubus ideaus*, and *Vaccinium myrtillus* were the most common hosts for the most abundant pests.

3.5. Emergency Authorised Active Substances contaminate the environment

Out of the 2087 unique articles retrieved by the systematic literature review process, twenty-eight biomonitoring studies measured pesticide contamination of EU bee matrices between 2017 and 2021

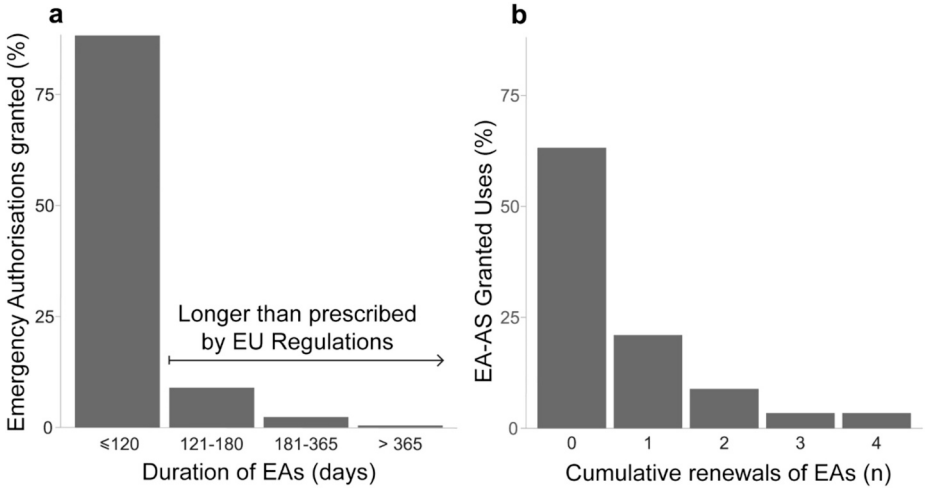

Fig. 5. Duration and persistence of Emergency Authorisations (EAs) and their Granted Uses (GUs). We show (a) the duration (number of days between the first authorised day of use and the day of its expiration) of each Emergency Authorisation. Emergency Authorisations longer than 120 days are not permitted according to EU Regulation 1107/2009. We report (b) the percentage of Emergency Authorised Active Substance (EA-AS) Granted Uses (GUs) that were cumulatively renewed in subsequent years. The number of cumulative renewals goes from 0 (no renewals) to up to four times (EA granted for 5 different years). A GU identifies a unique use of an EA-ASs: a cumulative renewal of a GU indicates that the AS is used by same Member State to protect the same crop from the same pest for at least two years.

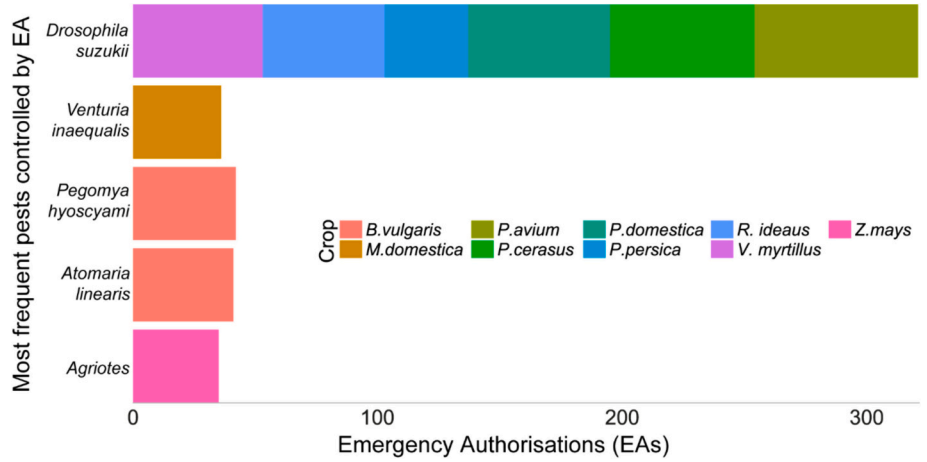

Fig. 6. Most frequent pests and crops controlled through Emergency Authorisations. We report the number of Emergency Authorisations granted to tackle the most frequent pest-crop combinations.

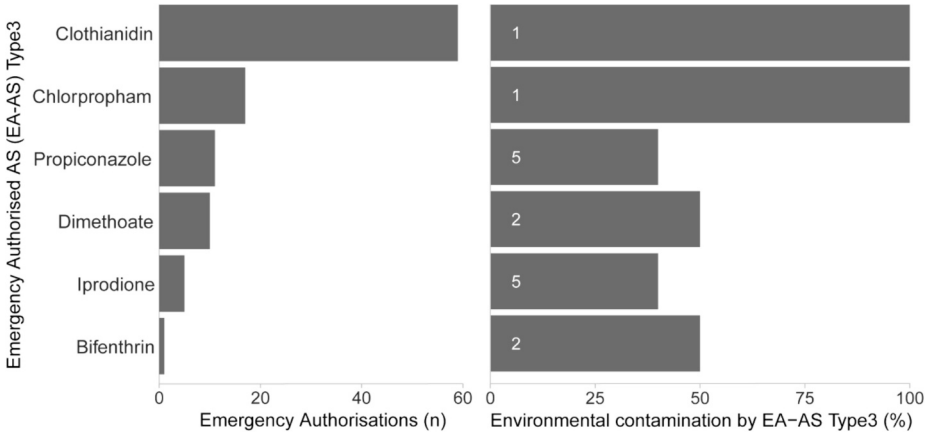

Fig. 7. Non-approved Active Substances authorised by Emergency Authorisations (EA-AS Type3) and their environmental contamination. For each EA-ASs Type3 found in a biomonitoring study, we report (a) the quantity of Emergency Authorisations granting its use, and (b) the percentage of biomonitoring studies reporting its real-world occurrence in the environment. To coherently link Emergency Authorisations and environmental contamination, all data refers to non-approved ASs (EA-AS Type3) within the 2017–2021 period. In b), white numbers inside the bars indicate the number of studies that monitored EA-AS Type3 ($n = 9$). A comprehensive range of environmental matrices was monitored: bees, honey, beebread, bee wax, pollen, propolis, nectar, and royal jelly (see Methods).

(Supplementary Materials, Table S7). Nine of these studies specifically searched for the contamination of EA-ASs Type3. The 44 % of these studies found EA-ASs Type3 in bee matrices. The biomonitoring studies recorded the presence of 6 environmental contaminants (clothianidin, chlorpropham, propiconazole, dimethoate, iprodione, and bifenthrin) which use, while being non-approved, was granted by Member States through the Emergency Authorisation process (EA-ASs Type 3; Fig. 7).

3.6. Emergency Authorised Active Substances are highly toxic

Non-approved ASs authorised by Emergency Authorisations (EA-ASs Type3) were significantly more toxic to honey bees as compared to regularly approved ASs (Fig. 8, Kruskal-Wallis H test: $X^2 = 10.54$, df = 1, $P = 0.001$).

The most toxic EA-ASs were the neonicotinoids clothianidin, imidacloprid, and thiamethoxam ($LD_{50} < 0.01$ μg/bee, Table S5). Twenty-four Member States granted Emergency Authorisations of at least one neonicotinoid each year between 2017 and 2021 (Fig. S4).

Neonicotinoids (clothianidin, imidacloprid, and thiamethoxam), beta-cyfluthrin, and spinosad are the EA-ASs that were both i) most frequently granted through Emergency Authorisations, and ii) highly toxic ($LD_{50} < 0.1$ μg/bee; Fig. 9, Table S5). All these EA-ASs, except spinosad, were EA-AS Type3.

EA-ASs Type3 (1,3-dichloropropene and beta-cyfluthrin) and Candidates for Substitution (CfS; Fludioxonil, and lambda-cyalothrin) were among the most frequent EA-ASs (Table 1, Table S5).

Many Emergency Authorisations were used to allow the use of EA-ASs across and within Member States. This resulted, for example, in 20 Member States granting the use of the same EA-AS (i.e., Fludioxonil; Table 1), and a single Member State to allow the use of the same EA-AS 36 times (spinosad in France).

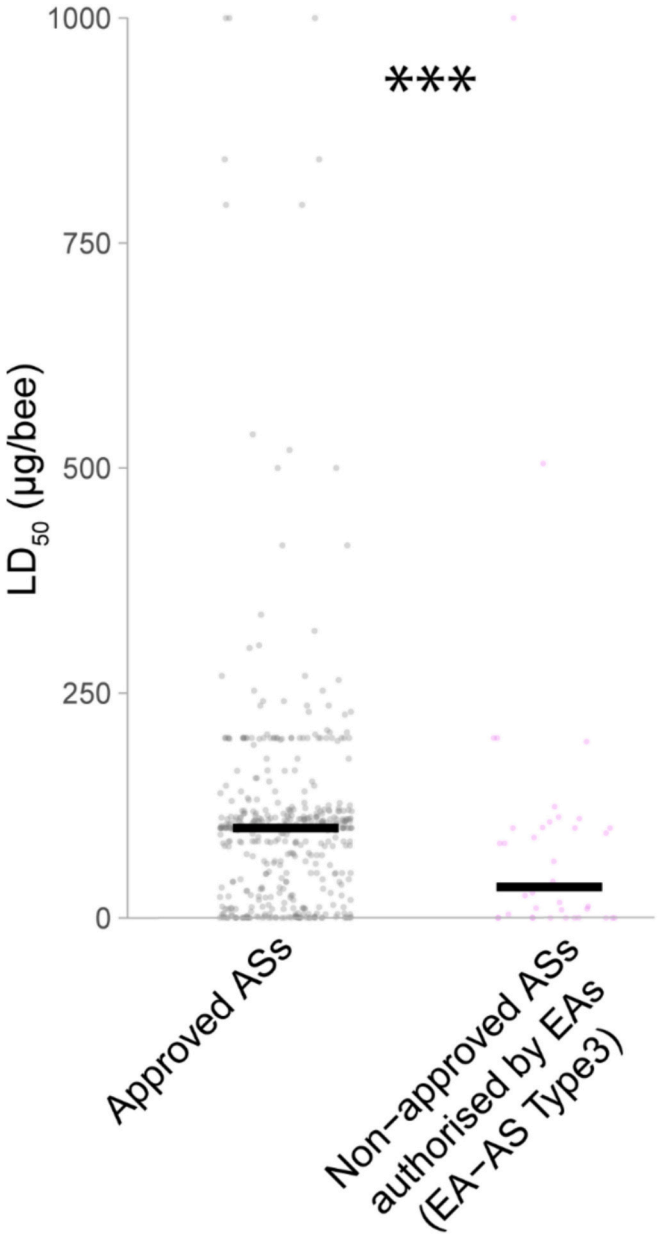

Fig. 8. Non-approved Active Substances authorised by Emergency Authorisations (EA-ASs Type3) are more toxic than regularly approved Active Substances (ASs). We used the median Lethal Dose ($LD_{50,\ oral}$) for honey bees, bioindicators of environmental health and surrogate of pollinators in Risk Assessments. The horizontal black line indicates the median value. The three asterisks (***) indicate a significant difference between the toxicity of EA-ASs and regularly approved ASs ($P = 0.001$, Wilcoxon test).

Fig. 9. Emergency Authorisations (EAs) granted for the most common and toxic Emergency Authorised Active Substances (EA-ASs), across EU Member States. Toxicity was quantified on honey bees (LD_{50} < 0.1 μg/bee), bioindicators of environmental health and surrogate of pollinators in Risk Assessments (see Methods). To ease display, we only show Member States that granted at least one Emergency Authorisation for these EA-AS within the target time range (2017–2021).

Table 1
The most frequently granted Emergency Authorised Active Substances (EA-ASs) and their toxicity to humans and honey bees. For each EA-AS, we report the list of EU Member States (MSs) that granted its use through Emergency Authorisations, the total number of granted Emergency Authorisations, the Member State that most frequently granted its use, its Type category (see Methods), its Mode of Action (IRAC or FRAC group classification), its toxicity to honey bees (medial lethal dose, $LD_{50, oral}$), and its toxicity and risk for humans (data collected in the Draft Assessment Reports). To facilitate display, we report the fifteen EA-ASs which use was most frequently granted by Emergency Authorisations (see Table S5 for a complete list). NA indicates that toxicity values are Not Available.

Emergency Authorised Active Substance	EU Member States	Total granted Emergency Authorisations (n)	Max Emergency Authorisations in a single Member State (n, MS)	EA-AS Type	Mode of Action (MoA)	Honey bee toxicity ($LD_{50, oral}$; μg/bee)	Human toxicity and risk
Cyantraniliprole	BE, BG, DE, EL, ES, FR, HR, HU, IE, IT, LV, NL, PL, PT, SI, SK, UK	170	35 (DE)	Type1, Type2	IN, IRAC 28	>0.1055	Moderate alert. Potential skin sensitizer. Risk for side-effects on thyroid. Possible liver toxicant.
Spinosad	AT, CZ, DE, DK, EL, ES, FR, NL, PT, SE, SI, SK, UK	96	36 (FR)	Type1	IN, IRAC 5	0.057	Moderate alert. Possible thyroid toxicant. May cause inflammation of various organs.
Metalaxyl-M	AT, BE, CZ, DE, EE, EL, ES, FI, FR, HR, HU, IT, LT, LV, PL, PT, SE, SI, SK	88	13 (FR)	Type1, Type2	FU, FRAC 4	>97.3	Moderate alert. Mammals' acute toxicity. Possible liver toxicant: moderate.
Pyrethrins	AT, DE, ES, FR, HR, HU, IT, LT, LU, NL, PT, SE, SI, SK	82	15 (DE)	Type1, Type2	IN, IRAC 3	0.95	Moderate alert. Mammals' acute toxicity: moderate; possible endocrine disruptor. Possible Reproduction/ Developmental (Rep/Dev) effects. May cause dermatitis,gastrointestinal problems. Possible thyroid and liver toxicant.
Thiamethoxam	AT, BE, BG, CZ, DE, DK, EE, ES, FI, FR, HR, HU, LT, LV, PL, RO, SK	81	15 (HU)	Type3	IN, IRAC 4	0.005	Moderate alert. Mammals' acute toxicity: moderate. Mammals' chronic toxicity. Increased incidence of liver cell adenoma and adenocarcinoma in mice: moderate.
Fludioxonil	AT, BE, CZ, DE, EE, EL, ES, FI, FR, HR, HU, IT, LT, LV, NL, PL, PT, RO, SI, SK	76	10 (IT)	Type1	FU, FRAC E	>100	CfS. Moderate alert. Possible Carcinogen. Possible Rep/Dev effects. Liver and kidney toxicant.

(*continued on next page*)

Table 1 (*continued*)

Emergency Authorised Active Substance	EU Member States	Total granted Emergency Authorisations (n)	Max Emergency Authorisations in a single Member State (n, MS)	EA-AS Type	Mode of Action (MoA)	Honey bee toxicity ($LD_{50,\ oral}$; μg/bee)	Human toxicity and risk
Lambda-cyhalothrin	AT, DE, EE, EL, ES, FI, FR, IT, PL, PT, SE, SK	73	29 (DE)	Type1, Type2	IN, IRAC 3	0.91	CfS. Low ADI/ARfD/AOEL; Persistent, Bioaccumulative, and Toxic. High alert: high Mammals' acute toxicity. Harmful if swallowed, inhaled or in contact with skin. Possible immune system and thyroid toxicant in susceptible individuals.
Spirotetramat	AT, BE, DE, EL, ES, FR, IT, LT, NL, PT, SI, SK, UK	69	22 (DE)	Type1, Type2	IN, IRAC 23	>107.3	High alert: Rep/Dev effects. Possible liver and kidney toxicant. May cause lung damage.
Clothianidin	AT, BE, BG, CZ, DK, EE, ES, FI, HU, LT, LV, PL, PT, RO	59	20 (HU)	Type3	IN, IRAC 4	0.004	High alert. Neurotoxicant. Effects consistent with endocrine disruption have been noted in rodents and dogs. May cause hypotension, hypothermia, and impaired pupillary function.
1,3-dichloropropene	CY, EL, ES, FR, IT, MT, PT	57	17 (PT)	Type3	IN, NA	NA	High alert. Rep/Dev effects. Highly toxic Mutagenic potential. Possible urinary, liver and kidney toxicant.
Zinc phosphide	AT, BG, CZ, DE, FR, HR, SK	56	24 (HR)	Type1	Rodenticide, NA	NA	Acute toxicity mammals. Rep/Dev effects. Highly toxic in phosphine form. May be fatal if swallowed.
Lime sulphur (calcium polysulphid)	AT, BE, CZ, DE, FR, LU, LV, NL, SI, SK	46	10 (DE)	Type1, Type2	FU, NA	>69.8	Rep/Dev effects. May cause stomach and oesophagus burns if ingested. May be fatal if ingested. Harmful to most body organs.
Beta-cyfluthrin	AT, BE, CZ, DK, EE, ES, FI, HU, LT, LV, PL, RO	43	10 (HU)	Type3	IN, NA	NA	Acute toxicity in mammals. Rep/Dev effects. May cause metabolic or neurological disturbances.
Imidacloprid	AT, BE, BG, DK, EL, FI, FR, HU, LT, LV, PL, RO	41	10 (BE)	Type3	IN, IRAC 4	0.004	High alert. Rep/dev effects. Moderately toxic. Potential liver, kidney, thyroid, heart, and spleen toxicants.
Azadirachtin (Margosa extract)	AT, CZ, DE, ES, FR, HR, IT, SK	39	13 (FR)	Type1	IN, IRAC UN*	8.1	Low alert. Possible liver and thyroid toxicant. Possible sensitising agent.

4. Discussion

Our research demonstrates that the Emergency Authorisation process is widely used across time and space in the EU. More than 200 Emergency Authorised Active Substances (EA-ASs) have been granted per year, through even long-lasting, recurring, and non-compliant Emergency Authorisations. We confirm that the Emergency Authorisation process has been widely exploited to grant the use of Active Substances (ASs) that were not approved through the standard regulatory process, with the percentage of non-approved ASs authorised by Emergency Authorisations (EA-AS Type3) rising from 10 % to 21 % between 2020 and 2021 (EC, 2020e). We reveal that the Emergency Authorisation process has had an extensive influence on the EU territory: the six Member States with the highest number of EA-ASs (Austria, France, Germany, Greece, Italy, and Spain) represent half of the European agricultural land (Pawlak et al., 2021). We finally highlight how the broad use of Emergency Authorisations could lead to the environmental contamination of highly toxic pesticides.

Surprisingly, Emergency Authorisations were frequently non-compliant with European Union (EU) regulations. Twelve percent of granted Emergency Authorisations were granted for longer periods than the legal maximum duration of 120 days (PPP regulation). This legal limit was set to comply with the concept of emergency, preventing EA-AS use for more than a single growing season before assessing both the persistence of the danger caused by the controlled pest and allowing the development alternative control measures (EC, 2021).

Emergency Authorisations were frequently (~1/3 of times) renewed in subsequent years to control the same emergency repetitively over time. Three percent of Emergency Authorisations were renewed consistently throughout the whole assessed period (2017–2021), and all Member States renewed at least one Emergency Authorisation to control the same emergency. Five Member States (Austria, Belgium, Hungary, Lithuania, and Slovenia) granted more than half of their national Emergency Authorisations through renewals. Nevertheless, national regulations are at times limiting Emergency Authorisations renewal: for instance, the United Kingdom allows a maximum of three Emergency Authorisations renewals (https://www.hse.gov.uk/pesticides/pesticides-registration/applicant-guide/the-applicant-guide-emergen.htm; consulted the 8/10/22).

Through Emergency Authorisation renewals and non-compliant durations, this research shows that this process is often used to recurringly control established pests over extended periods, rather than unexpected, short-term emergencies as expected. For instance, 7 % of Emergency Authorisations are used to control *Drosophila suzukii*, an insect (Diptera) that has been established in Europe since 2008 (Fig. 9, Cini et al., 2012). Emergency Authorisations were also used to control pests that have been established in Europe since the early twentieth century, such as *Pegomya hyoscyami* (Diptera) and *Atomaria linearis* (Coleoptera; Edwards and Thompson, 1934; Michelsen, 1980). Emergency Authorisations should only be used for emergencies, and more sustainable alternatives must be concurrently developed (EC, 2021). Our quantitative, detailed results further question the coherence between the Emergency Authorisation regulation and its implementation in the real world, the interpretation of the concept of emergency, and the ability in finding safer alternatives to typically harmful, non-approved ASs.

Non-approved ASs frequently contaminate the environment. This is likely caused by the common agricultural use of Emergency Authorised Plant Protection Products (EA-PPPs). Our results may underestimate the

actual environmental contamination caused by EA-ASs: just a few studies have measured the presence of non-approved ASs authorised by Emergency Authorisations (EA-ASs Type3) in the environment, still most of them recorded frequent contaminations (Fig. 7b). Because EA-ASs (Type3) contamination may also be linked with pesticide illegal uses and/or long-term persistency (Straw et al., 2023; Zioga et al., 2023), further research is needed to identify the causes of this extensive contamination and the consequent risks to humans, other animals, and the environment.

Neonicotinoids (clothianidin), organophosphates (dimethoate), and pyrethroids (bifenthrin) are among the most often granted EA-ASs Type3 found in the environment. Because non-approved neonicotinoids use was granted by 24 Member States through 239 Emergency Authorisations over time, our results confirm that the Emergency Authorisation process allowed neonicotinoids to remain on the market (Epstein et al., 2022). Our results further expand these concerns to other classes of highly toxic pesticides, drawing a broader, worrying scenario.

The toxicity of non-approved ASs authorised by Emergency Authorisations (EA-AS Type3) is higher as compared to regularly approved AS (Fig. 5). Beta-cyfluthrin, spinosad, and the neonicotinoids imidacloprid, clothianidin, and thiamethoxam were the most frequently used EA-AS that showed high toxicity to bee pollinators. Non-approved ASs commonly authorised by Emergency Authorisations (1,3-dichloropropene, beta-cyfluthrin, and various Candidates for Substitution such as fludioxonil and lambda-cyhalothrin) showed also concern in terms of human safety, e.g., because of their high persistency, bioaccumulation properties, and high risk posed to consumers and farmers.

Our work allows prioritising research and policies towards the implementation of safer alternatives to the pests and crops that required the most Emergency Authorisations. Among alternatives, agroecology and Integrated Pest Management approaches can improve the resilience of agricultural ecosystems (Garibaldi et al., 2023; Pecenka et al., 2021; Samnegård et al., 2019). Integrated Pest Management approaches, together with alternative ASs and pest control methods, were also specifically suggested to replace neonicotinoids (Furlan et al., 2018; Furlan and Kreutzweiser, 2015; Jactel et al., 2019; Pecenka et al., 2021).

While the EU pesticide databases (AS-DB, EA-DB) represent essential open-access resources, a better implementation of FAIR principles (Findability, Accessibility, Interoperability, and Reusability; Wilkinson et al., 2016) integrating a comprehensive metadata approach (e.g., format, record version) and interoperability between databases across European Union Member States (e.g., CAS number for active substances) would be crucial to better understand pesticide and Emergency Authorisations' uses.

Our results suggest that a more comprehensive, thorough assessment of the impacts of Emergency Authorisations should be included in ambitious and urgent-to-apply EU policies (i.e., Green Deal) towards a more sustainable environment. Their exposure, toxicity, and risk should be better investigated while alternatives and mitigation measures enhanced and implemented. A more systematic, accurate, and transparent monitoring and reporting of Emergency Authorisations use and compliance to regulations is urgent. Policy makers, researchers, and other key stakeholders should integrate their effort towards the crucial reduction of pesticide risks for humans, animals, and the environment.

5. Conclusions

This first detailed assessment of the impacts of pesticide Emergency Authorisations reveals that this common but understudied process leads to broad human, animal, and environmental implications, raising concern on the enduring state of emergency that acts in derogation of the EU Regulation.

Emergency Authorisations' wide use across time and space leads to the environmental contamination by numerous highly toxic, non-approved active substances. Emergency Authorisations were surprisingly non-compliant with EU regulations, as they were relatively frequently granted for longer periods than prescribed by the law and recurringly renewed to control the same emergency over time.

The prolonged, chronic use of Emergency Authorisations and the limited development of alternatives raise concerns about the sustainability of agricultural practices and their long-term health implications. Here, we provided new insights on the pests and crops that are most frequently addressed as agricultural emergencies and would thus require sustainable alternatives.

This research finally aims at contributing to the development of a more sustainable agriculture and a safer environment for humans and other animals.

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CRediT authorship contribution statement

Luca Carisio: Writing – review & editing, Writing – original draft, Visualization, Validation, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Noa Simon Delso:** Writing – review & editing, Writing – original draft, Validation, Methodology, Investigation, Formal analysis, Conceptualization. **Simone Tosi:** Writing – review & editing, Visualization, Validation, Supervision, Project administration, Methodology, Investigation, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

The raw data include the (1) "Carisio et al_2024_AS DataBase", providing data on active substances used as PPP active ingredients in Europe and their approval status, and the (2), "Carisio et al_2024_EA DataBase", providing data on the Emergency Authorisations granted by EU Member States between 2013 and 2022. The two open-access databases have been deposited online in the Open Science Framework (OSF) platform and is available at the link https://osf.io/ug384.

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