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How pesticides are regulated in the European Union

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EFSA and the assessment of active substances

The trade and distribution of plant protection products (PPPs) are regulated by the legislation of the European Union (EU). PPPs may not be placed on the market or used without prior authorisation. The authorisation system includes: 1/ assessment of the active substances used in PPPs, carried out by the European Food Safety Authority **(EFSA**) and 2/ authorisation of the products by the Member States (MSs) at national level. PPPs are in principle regulated under Regulation (EC) No 1107/2009[1]. All issues related to the legal standards for pesticide residues in food and feed fall within the scope of Regulation (EC) No 396/2005[2].

Assessment of pesticide active substances

PPPs are chemical compounds used to protect crops by destroying or controlling pests or weeds. Active substances (a.s.) – chemicals or micro-organisms – are the main ingredients in the products that provide their effect. Active substances may be approved only if it has been demonstrated that they or their residues have the following characteristics: they do not have any immediate or delayed harmful effect on human or animal health, directly or via drinking water, food, feed or air, or through cumulative or synergistic effects; they do not create exposure in the workplace; they do not have an unacceptable effect on the environment, in particular with regard to non-target species and biodiversity.

How does the review process work?

In the EU, a.s. are assessed through a pesticide review system which includes the following steps: 1/ The manufacturer submits an application for approval of an a.s., which must be accompanied by a dossier with the relevant studies. In the dossier, the manufacturer must use harmonised guidance (mainly from the European Commission (EC) or EFSA), which specifies what information and studies must be included, and EFSA guidance is regularly updated; 2/ The appointed Rapporteur Member State (RMS) prepares an initial draft (or renewal) assessment report; 3/ The risk assessment carried out by the Rapporteur Member State is reviewed by EFSA, in cooperation with all MSs – this process includes public and expert consultations; 4/ EFSA prepares a draft conclusion on the a.s., and after its publication the EC decides whether to include it in the EU list of approved a.s. This determines whether the substance may be used in PPPs in the EU. The MSs assess or reassess the safety of PPPs containing a.s. that are sold on their territory; this process is followed by renewal of the approval of the a.s. – substances are approved for a period of 15 years and, before the expiry of this period, the applicant may apply for renewal. The application is submitted to the Rapporteur Member State, which prepares an updated assessment report that is reviewed by EFSA in cooperation with the MSs. The conclusions of the review and consultation process are presented in an EFSA technical report, and further information on the process of reviewing and authorising a.s. and PPPs in the EU is available on the EFSA website: http://www.efsa.europa.eu.

Roles and responsibilities

EFSA has overseen the review process for a.s. used in PPPs in the EU since 2003. This activity is carried out by the Pesticides Unit in EFSA, with the support of a network of experts from the MSs, following a legally established procedure and methodology approved by risk managers. Experts from EFSA's Panel on Plant Protection Products are not routinely involved in the review, but the Panel is sometimes requested to endorse

scientific conclusions. EFSA is also responsible for: proposing maximum residue levels (MRLs) for pesticides in products of plant and animal origin placed on the EU market; MRLs are the upper legal limit for pesticide residues, permitted and set on the basis of good agricultural practice, which ensures the lowest exposure of the consumer necessary to protect vulnerable consumers. Before an MRL is set or modified following a request from an applicant when a new product is placed on the market, EFSA assesses the behaviour of pesticide residues and the possible health risk to consumers from residues in food, after which the PPP may be authorised. In order to avoid unacceptable risk to consumers, harmonised MRLs have been established in the EU (an EU MRL database is available: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/). The compilation and publication of annual monitoring programmes, carried out by the EU MSs plus Norway and Iceland, aim to ensure that pesticide residues in food comply with legal standards, i.e. are in line with the MRLs. EFSA uses these data to assess the current risk from pesticide residues to European consumers.

Member States provide EFSA with a network of about 600 experts to conduct the review and consultation processes when working on active substances. Experts from the MSs contribute to the process in two ways: 1/ they submit written comments on the review of the draft assessment report prepared by the Rapporteur Member State; 2/ they participate in expert consultations (meetings and teleconferences) organised by EFSA in various scientific fields (e.g. toxicology, ecotoxicology). The experts form a collective scientific view or that of individual public bodies in the MSs before the consolidated comments on the review are submitted on behalf of the MSs. All contributions are published on the EFSA website in the main document accompanying the Authority's conclusion.

The European Commission takes the decision on the approval of a given active substance, in consultation with the MSs, following the scientific assessment of the a.s. by EFSA. This reflects the fundamental principles of the EU food safety system: the separation of the roles of risk assessors and risk managers. After the approval of an a.s., it may be used in PPPs.

Use of evidence in the risk assessment process

In the EU regulatory system for pesticides, the responsibility for demonstrating the safety of an a.s. lies with the companies that wish to place their products on the market. Regulation (EC) No 1107/2009 requires applicants to submit a dossier containing mandatory safety studies and to carry out a review of the scientific literature published over the previous 10 years, addressing side effects of the a.s. and its metabolites on health, the environment and non-target organisms. Third parties may also contribute by providing data, studies and information directly to the Rapporteur Member State and EFSA during the public consultation. Mandatory safety

studies cover areas such as the toxicology of the substances, their behaviour in the environment, or their effects on non-target organisms such as birds, fish or bees. The mandatory studies in support of a pesticide application must strictly follow guidance approved by experts at international level and the information must be used in accordance with the methodology endorsed by EU guidance documents; they may, for example, be conducted in compliance with good laboratory practice. The mandatory safety studies are funded by industry and conducted in specialised certified laboratories, which are regularly audited. As part of the application, each study is described in a detailed report that must include raw data. This process allows bodies such as EFSA to verify the reliability and quality of the results and to determine which aspects of the study must be included in the risk assessment. Additional information from the scientific literature is particularly important to ensure that risk assessors at national and European level have the necessary evidence on which to base the assessment of a given a.s. This usually includes: original studies on the hazard of the substance; original data and meta-analyses of epidemiological studies; a review report that summarises and aggregates the results of the original studies. Additional data from the scientific literature may be introduced by the Rapporteur Member State or by other parties during the public consultation or other phases of the review process. It is not uncommon for experts from the MSs and EFSA to disagree with industry on the interpretation of study data in the risk assessment. In such cases, the experts involved in the review process apply a different interpretation of the study results in their assessment and may reach their own conclusion.

The work of European and non-European scientific organisations on pesticides

While EFSA is responsible for the scientific risk assessment of pesticides in all areas (environment and workplace), the European Chemicals Agency (ECHA) is responsible for the harmonised classification of chemical pesticides requiring labelling as hazardous substances. Some pesticides have non-agricultural uses, which means that they must be registered as biocides or medicinal products. Sometimes ECHA carries out hazard and risk assessment for a compound that has been approved by EFSA for use as a pesticide.

Pesticides are strictly regulated in most regions of the world, and a number of international organisations, such as the World Health Organization (WHO) and the Organisation for Economic Co-operation and Development (OECD), regularly assess pesticides. EFSA and ECHA work in close cooperation in a number of areas, including the assessment of pesticides and substances used as pesticides and biocides. The cooperation includes exchange of work programmes and scientific information, mutual access to data submitted to each agency, and participation as observers and experts from the other agency. When different conclusions are reached, the agencies prepare a joint position containing the differing expert views. An important area of collaboration is the harmonised classification and labelling of pesticide active substances. EFSA uses in its assessment the

harmonised classification proposed by ECHA, which requires the MSs to submit a proposal for harmonised classification.

EFSA also cooperates with other international organisations and non-European countries on activities in the field of pesticides, such as those of the OECD. Cooperation in the assessment of specific pesticides is limited to the participation of experts as observers, and this is two-way. Experts from other regulatory authorities may be invited as observers in the review processes carried out by EFSA. Representatives of the Authority may also be invited to present their conclusions to other regulatory authorities. The two-way cooperation is also extended to international organisations such as WHO/FAO (Food and Agriculture Organization) and JMPR (Joint Meeting on Pesticide Residues), which are the responsible bodies for pesticide risk assessment. Where necessary, cooperation may also cover other institutions such as IARC (International Agency for Research on Cancer), which conducts hazard assessment of carcinogenic agents, including some pesticides, as well as programmes such as the International Programme on Chemical Safety. Where discrepancies are identified, EFSA requests an assessment by a third party and, if necessary, requests clarification.

Independence and transparency of the process

The EFSA team that conducts the review of active substances is subject to the same obligations as the staff of the European Parliament, the European Commission and the Council of the EU – the legislative teams. Pesticide experts from the national authorities in the MSs belong to organisations designated by their governments to participate in the review process. The review process is a joint activity that includes the contributions of authorised experts from the MSs, as well as scientists with the relevant expertise from other organisations. Alongside this process, consultations take place that may be public or targeted at specific groups.

The scientific decision-making process can be followed from beginning to end. The EFSA website is publicly accessible and anyone can see how the assessment proceeds throughout the process. All documents related to the review are published, which makes it possible to follow how experts from the MSs assess each study and how comments from public consultations are incorporated into the scientific information.

The published documents include: a summary of the dossier submitted by the applicant; the draft assessment report prepared by the Rapporteur Member State, which is republished at the end of the process, reflecting the changes introduced during the review by EFSA; the EFSA review report, containing the comments received during the various consultation phases and the conclusions of the experts' meeting; the final EFSA conclusion on the active substances.

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Source:

https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/Pesticides-ebook-180424.pdf.

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[1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

2 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. Text with EEA relevance.