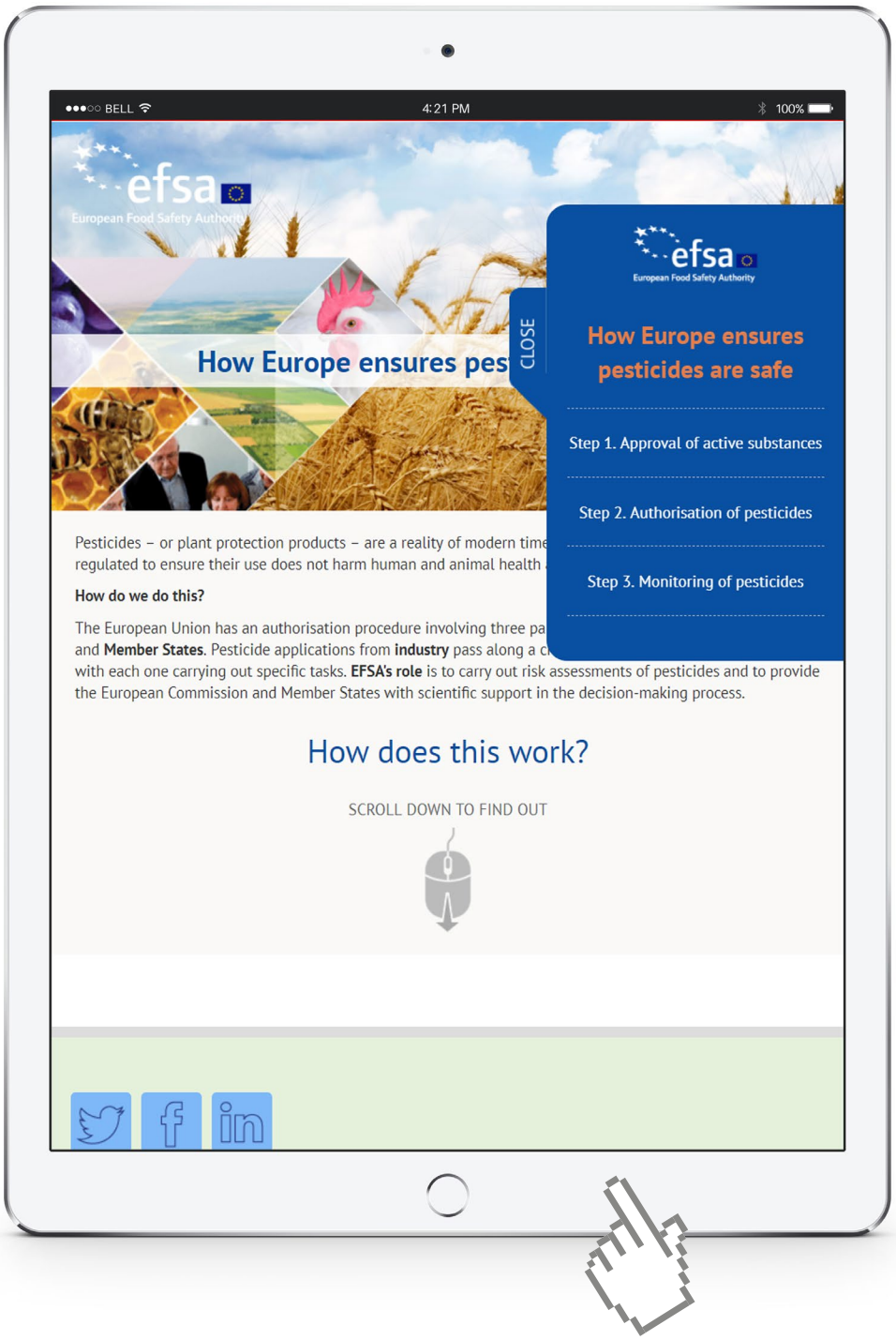
HOW **PESTICIDES** ARE REGULATED IN THE EU

EFSA and the assessment of active substances

efsa
European Food Safety Authority

Table of Contents

How Europe ensures pesticides are safe - Interactive infographic



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Legal framework

The marketing and use of plant protection products is regulated by a large body of EU legislation. Plant protection products cannot be placed on the market or used without prior authorisation. A dual system is in place, under which EFSA evaluates active substances used in plant protection products and Member States evaluate and authorise the products at national level. Plant protection products are principally regulated by framework Regulation (EC) No 1107/2009.

All matters related to legal limits for pesticide residues in food and feed are covered by Regulation (EC) No 396/2005. This regulation also contains provisions on official controls of pesticides residues in food of plant and animal origin that may arise from their use in plant protection.

Assessment of pesticide active substances

Plant protection products and active substances are different. Plant protection products are chemical compounds used to protect crops by killing or controlling pests or weeds. Active substances – such as chemicals or micro-organisms – are the essential ingredients in the products that enable them to do their job.

An active substance can be approved only if it is demonstrated that the substance and its residues:

- Do not have any immediate or delayed harmful effects on human or animal health, directly or through drinking water, food, feed or air, or exposure in the workplace or through cumulative and synergistic effects (where the scientific methods to assess such effects are available).
- Do not have unacceptable effects on the environment, particularly with regards to non-target species and biodiversity.

The peer review process: how it works

In the EU, active substances are assessed through the pesticides peer review system, which follows a phased approach:

1. A manufacturer submits an application for approval of an active substance. The application has to be supported by a dossier of relevant data and studies. In compiling its dossier, the manufacturer should use the agreed guidance (mostly from the Commission or EFSA), which details which information and studies to include and which complements the data requirements in the relevant Regulations. EFSA's guidance is updated regularly.
2. An initial draft assessment report (DAR) or a renewal assessment report (RAR) is produced by a designated rapporteur Member State (RMS).
3. The RMS's risk assessment is peer reviewed by EFSA in cooperation with all Member States. This stage includes public and expert consultations.
4. EFSA drafts a report ("Conclusion") on the active substance.

After EFSA has published its Conclusion, the European Commission decides whether or not to include the substance in the EU's list of approved active substances. This determines whether the substance can be used in plant protection products in the EU.

EU Member States assess or re-assess the safety of plant protection products containing the active substance that are sold in their territory.

The same process is followed for the renewal of the approval of active substances. Active substances are approved for a period of up to 15 years and before the expiry date the applicant may apply for renewal. The application is submitted to a RMS, which provides its initial evaluation in a renewal assessment report (RAR). EFSA then carries out a peer review of the RAR in collaboration with Member States.

The outcome of the peer review and/or other consultation processes is presented in EFSA's conclusions and technical reports.

Further information and multimedia content on the process for the peer review of active substances and the authorisation of plant protection products in the EU can be found on EFSA's website.

Roles and responsibilities

EFSA

Since 2003, EFSA has overseen the EU peer review of active substances used in plant protection products. This task is carried out by EFSA's Pesticides Unit, supported by a network of experts from Member States, following procedures set out in the legislation and internal EFSA decisions and applying the methodology endorsed by risk managers for regulatory assessments. Experts from EFSA's Scientific Panel on Plant Production Products are not regularly involved in the peer review process, although the Panel has been requested to endorse some scientifically complex conclusions in the past.

EFSA is also responsible for:

- Proposing the maximum residue levels (MRLs) of pesticides to be permitted in products of plant or animal origin marketed in the EU.

What are MRLs?

Maximum residue levels (MRLs) are the upper levels of pesticide residues that are legally permissible in or on food or animal feed, based on good agricultural practice and the lowest consumer exposure necessary to protect vulnerable consumers.

Before an MRL is set or amended – for example, because an applicant requests the authorisation of a new pesticide – EFSA assesses the residue behaviour of the pesticide and possible consumer health risks from residues in food. Provided that EFSA's risk assessment does not identify any unacceptable risks to consumers, EU-harmonised MRLs are set (Database of MRLs in the EU) and the plant protection product can be authorised.

- Compiling and publishing an annual monitoring programme carried out by all EU Member States, plus Norway and Iceland, the purpose of which is to ensure that pesticide residues in foods fall within legal limits i.e. they comply with MRLs. EFSA uses the results to assess the actual risk of pesticides residues to European consumers.

Member States

EFSA draws on a network of approximately 600 public sector experts from Member States to carry out the peer review and expert consultations for its work on active substances. Up to 100 of these experts may contribute to the peer review of a single active substance.

Experts from Member States may contribute to the process in two ways:

- Submitting written comments on behalf of their Member State to the peer review of the draft assessment report produced by the rapporteur member state.
- Taking part in expert consultations (meetings and teleconferences) organised by EFSA on different scientific areas (e.g. mammalian toxicology, ecotoxicology)

Experts represent the collective scientific views of the experts in the Member State and do not participate in a personal capacity. For example, one expert may be collecting input from two or three public organisations within their Member State before submitting consolidated comments on behalf of that Member State to the peer review.

All contributions are published on EFSA's website in the background documents that accompany the EFSA Conclusion.

European Commission

EFSA oversees the scientific risk assessments of active substances. The decision on whether to approve an active substance is taken by the European Commission in consultation with Member States. This reflects a fundamental principle of the food safety system that operates in the European Union: the separation of the roles of risk assessment and risk management. Once an active substance has been approved it can be used in a plant protection product. In the area of pesticides, the European Commission is also responsible for setting the methodology to be used in the regulatory assessments, including the scientific methodology.

Use of evidence in the risk assessment process

In the EU regulatory system for pesticides, the burden of proof of safety lies with the company that seeks to place its products on the market.

Regulation (EC) No 1107/2009 states that applicants are required to present a dossier containing a set of mandatory safety studies and to carry out a literature review of scientific studies published in the last 10 years that look at the side-effects of the active substance and its metabolites on health, the environment and non-target species .

Third parties may also contribute, by providing data, studies and information directly to the Rapporteur Member State and to EFSA during the public consultation.

Mandatory safety studies

These studies cover aspects such as the toxicology of the substance, its behaviour in the environment or the effects on non-target organisms such as birds, fish or bees. When a company submits mandatory studies to support an application for pesticides, it is required to follow the strict guidelines agreed by experts at international level and to use the information according to the methodology laid down in EU guidance documents. For example, they must be conducted under good laboratory practice (GLP), an OECD protocol designed to ensure consistency, reliability and integrity in chemical safety tests.

Mandatory safety studies are paid for by industry and carried out in specially certified laboratories that are subject to regular audits. When submitted by a company as part of an application, each study is described in a detailed study report that must include the raw data. This process allows authorities such as EFSA to check the reliability and quality of the results and decide which aspects of the study to use in the risk assessment.

Other scientific information from the open literature

Scientific information from the open literature is essential in ensuring risk assessors at a national and European level have all relevant evidence to hand about a given active substance on which to base their evaluation. Typically, it comprises::

- Original studies on the hazards or other properties of the substance that are relevant for the risk assessment, as well as original studies and meta-analyses of epidemiological evaluations.
- Review papers summarising and aggregating the results of original studies.

In addition to the studies included by the applicant in the dossier, other studies from the open literature can be incorporated by the RMS as well as by all involved parties during the public consultation and other commenting phases of the peer review.

It is not unusual for Member State and EFSA experts to disagree with industry on how the results of the studies that they submit in their dossiers should be interpreted for the risk assessment. For example, the peer reviewers may consider that a study is valid but that the conclusion proposed by the study authors – and supported by industry – is not substantiated by the findings. In such cases, the experts use a different interpretation of the study results in their assessment than that proposed by the authors. The experts involved in the peer review are able to draw their own conclusions because they have access to, and can check themselves, the raw data submitted for every study.

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

While EFSA is responsible for the scientific risk assessment of pesticides in all areas – from occupational exposure to the environment – the European Chemicals Agency (ECHA) is responsible for the harmonised classification of chemical pesticides requiring labelling as hazardous substances. In addition, several pesticides have non-agricultural uses, which means that under EU legislation they must be registered as biocides, medicines or assessed under other EU legislation. As a consequence it is not unusual for ECHA to carry out hazard and risk assessments for a molecule (or very similar molecule) that has also been assessed by EFSA for use as a pesticide.

Pesticides are heavily regulated in most regions of the world. In addition, international organisations, in particular the OECD and WHO regularly conduct assessments of pesticides. It is therefore common for assessments of the same pesticides to be conducted in different jurisdictions and/or by international organisations.

The interplay between EFSA and ECHA

EFSA and ECHA work closely together in several areas including the assessment of pesticides and substances used as both pesticide and biocides. The collaboration is covered by a memorandum of understanding, and includes the exchange of work plans, mutual access to data submitted to each agency, and the participation as observers of staff and experts from the other agency.

A process is also in place for dealing with scientific divergences between the two agencies. When a possible divergence is identified both agencies assess the case jointly e.g. to identify

if the different conclusions are explained by the submission of different data/information, or the application of different regulatory principles. When there is a real divergence, the agencies prepare a joint statement detailing the different expert views.

An important area of collaboration is the harmonised classification and labelling (CLH) of pesticide active substances.

Ideally, the EFSA and ECHA processes run in parallel and are based on the same information. In such cases, EFSA uses in its assessment the harmonised classification proposed by ECHA. The ECHA process requires a Member State to submit a proposal for harmonising the classification to ECHA. When a Member State has not submitted a proposal to ECHA, EFSA experts use ECHA guidance to develop an ad hoc classification. This is used in the EFSA assessment but does not have the status of a harmonised classification.

The interplay with international organisations

Bilateral cooperation between EFSA and non EU/EEA countries is common in the area of pesticides. Cooperation on methodological developments is usually handled through international organisations such as the OECD. Cooperation on the assessment of specific pesticides is limited to the participation of experts as observers and is bidirectional. Experts from other regulatory bodies can be invited as observers to EFSA peer-review meetings, e.g. in cases where assessments are being carried out in parallel, or upon request from the third party. EFSA may also be invited to present its conclusions to other regulatory bodies.

This bidirectional cooperation is also extended to international organisations, such as the WHO/FAO Joint Meeting on Pesticides Residues (JMPR) which is the WHO body responsible for the risk assessment of pesticides. If needed, it may also cover other institutions such as the International Agency for Research on Cancer (IARC), which carries out hazard assessments for carcinogenic agents including some pesticides, and programmes such as the International Programme on Chemical Safety (IPCS).

Unless a memorandum of understanding is in place, there are no procedures for covering possible divergences with non-EU and international assessments. When relevant divergences are identified, EFSA assesses the third-party assessment and if necessary requests clarifications.

An international assessment that indicates a concern not identified during the EU evaluation may trigger a new re-assessment, as happened with the reassessment of human health hazards for chlorpyrifos in 2014.

Independence, consultation and transparency in the process

The EFSA staff that carry out the peer review of active substances are bound by the same duties and obligations as staff in the European Parliament, European Commission, and Council: the EU Staff Regulations. This provides a stringent framework which regulates staff behaviour, independence, working conditions and rights.

In addition, EFSA staff complete an annual declaration of interest in which they stipulate their previous employment and any external activities.

Pesticide experts from national authorities in the Member States belong to organisations that are appointed by Member State governments to take part in the peer review process.

The peer review process is a collaborative endeavour that includes contributions from authorised Member State experts as well as scientists with relevant expertise from other bodies. Central to the process are consultations, which may be public or targeted at specific groups.

The scientific decision-making process can be traced from start to finish. Anyone can go to EFSA's website and review how the assessment evolved over time. All documents related to the peer review are published, so it is possible to see how experts from the EU Member States appraised each study and how comments from the public consultation were incorporated into the scientific thinking.

The published documents include:

- A summary of the dossier submitted by the applicants at the start of the peer review process
- The draft assessment report drawn up by the rapporteur Member State, and republished at the end of the process highlighting the changes introduced during the EFSA peer-review
- The EFSA peer review report, containing the comments received during the different consultation phases and the outcomes of the expert meetings.
- The final EFSA Conclusion on the safety of the active substance in question.