EU pesticide regulations (maximum residue levels) explained

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Explained: EU regulations governing pesticide maximum residue levels in food and feed and their implications for third countries

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

Update

This overview of Regulation (EC) No 396/2005, concerning EU pesticide maximum residue levels (MRLs) and the ongoing review process, provides background information explaining the frequent amendments to the associated secondary legislation and annexes, and their importance for third countries.

Background

EU pesticide legislation

There are two main areas of EU pesticide legislation:

- Regulation (EC) No 1107/2009 which lays down rules for the authorisation of pesticides in commercial form, and for their placing on the market, use and control within the EU
- Regulation (EC) No 396/2005 on maximum residue levels (MRLs) of pesticides in or on food and feed of plant and animal origin.

Pesticide MRLs are set to protect consumers from exposure to unacceptable levels of residues in food and feed. An MRL is the highest level of a pesticide residue that is legally tolerated in or on food or feed when pesticides are applied correctly (using good agricultural practices - GAP).

EU legislation on pesticide MRLs covers food and feed produced in the EU, as well as imports from third countries. MRLs for all crops and all pesticides can be found in the EU's Pesticide Residues database. If a pesticide is not specifically mentioned in the regulation or database, the MRL is automatically set at the default level of 0.01 mg/kg (generally the limit of determination, LOD).

Regulation (EC) No 396/2005 sets pesticide MRLs that are harmonised across all EU countries. Farmers, traders and importers are responsible for compliance with MRLs. Member State authorities are responsible for controlling and enforcing MRLs, including checks on imported produce.

EU MRL-setting and review process

MRLs are reviewed by EFSA on an ongoing basis, with a timetable that is updated each quarter (e.g. EFSA 2022).

For each pesticide active substance, an EU Member State is designated as the Rapporteur Member State. To set new MRLs, or to review existing MRLs, a consumer intake assessment is carried out by the Rapporteur Member State and submitted to the European Food Safety Authority (EFSA). This assessment is based on the properties of the pesticide, the maximum levels expected on food, and the different diets of European consumers, taking into consideration the safety of diverse consumer groups including babies and children.

EFSA provides a scientific opinion on the MRLs. Based on this, the Commission, in discussion with technical representatives from EU Member States, will determine the final MRLs and any other appropriate risk management measures needed, or they may issue a request for additional data.

The EU MRL-setting and review process takes into account Codex MRLs (CXLs). CXLs are the internationally agreed food standards covering pesticide residues in or on food and feed, set by the Joint Meeting on Pesticide Residues (JMPR) of the Food and Agriculture Organization (FAO) and World Health Organization (WHO).

The EU will not accept CXLs where:

- they would be an ineffective or inappropriate means of fulfilling the EU's objectives (e.g. consumer protection, environmental concerns)
- there is a scientific justification for not doing so (e.g. identified risks)
- they would result in a different level of protection from that determined as appropriate in the EU.

The Commission has calculated that the EU is aligned with more than 70% of the CXLs established between 2008 and 2018 (WTO 2021).

What are the major implications for exporting countries?

Action is required when MRLs change

When EU MRLs change for substances widely used on food or feed destined for export to the EU, there may be important implications, and timely action will be needed by both private sector operators and the national authorities.

Once an EU MRL change is proposed or under discussion, producer/exporter associations and national authorities are advised to start checking the good agricultural practices (GAPs) and availability of alternatives as soon as possible.

For each use of the active substance/s involved, the GAPs (dose rate, number of applications, application method or pre-harvest interval) must to be checked to ensure compliance. Before new MRLs are applied, product labels may need to be revised, and producers may need to adapt their practices or, if not possible, stop using the substance and look for an alternative.

Absence of an MRL and the minor crops issue

If there is no EU MRL for a given substance, the MRL is set at the limit of determination (LOD) relevant to the specific substance, or at the default of 0.01 mg/kg. In most cases this means that the substance cannot be used in third countries on food or feed destined for export to the EU.

In some circumstances it may still be possible to use the substance:

- If the residue levels do not exceed the LOD
- Where an import tolerance (IT) is authorised. An import tolerance is an MRL that is set when the use of an active substance is not authorised in the EU, but is authorised elsewhere in the world, provided it meets EU safety standards. In cases where there is no EU MRL, and where the residue exceeds the LOD, an application for an import tolerance can be submitted to the EU authorities. The dossier for this application must contain information on residues, toxicology and risks to consumers, as well as an approval for use of the substance in the producing country, and a proposed MRL. Applications submitted since 2009 are listed in the Commission's Overview Table.
- Where there is an approved extrapolation from an existing MRL on a representative crop in the same crop group (e.g. from French beans to snow peas).

A particular problem affecting low-volume crops (such as many fruit and vegetable crops), often referred to as "minor crops", is that they represent a small market for pesticide manufacturers. Generating the data needed to establish a new MRL is expensive, and for many minor crops in AGRINFO partner countries, it is not an attractive investment; the market is simply too small to cover the costs. The situation is exacerbated by the EU's pesticide reduction strategy and the ongoing MRL review process, which are leading to the reduction or loss of MRLs for many widely used substances. For a growing number of minor crops there are now few or no MRLs for

substances available to control important pests or diseases on crops for export. For some pests, the substances that are available represent a narrowing spectrum of biological activity, with associated risks of pest and disease resistance.

Controls and enforcement of EU MRLs

All food and feed supplied on the EU market must comply with EU MRLs. At EU Member State level, residue monitoring programmes must be in place**.** For food of animal origin, third countries exporting to the EU are also required to have in place and submit a pesticide residue monitoring plan.

In the case of imported produce, testing for pesticide residues is conducted during EU border controls. Checks on entry to the EU are implemented according to the Official Controls Regulation 2017/625, and are risk-based. In the case of products for which there is a known or emerging risk, or where there is evidence of widespread serious non-compliance, the frequency of official controls may be temporarily increased and certain emergency measures applied, according to Regulation (EU) 2019/1793).

If MRL monitoring and border controls identify an actual or potential risk to consumers' health, this will be communicated to the Rapid Alert System for Food and Feed (RASFF). RASFF enables EU food and feed control authorities to exchange information about any serious risks detected, and to act rapidly in a coordinated way. Depending on the seriousness of the risk, interceptions reported to RASFF can trigger a response ranging from simple information exchange to a border rejection, or an alert leading to withdrawal from the market.

Engaging in the EU MRL-setting and review process

MRLs are reviewed by EFSA on an ongoing basis. Under the EFSA MRL review process, if a third country has an interest or concern about the MRL review of a particular active substance, it can submit information to the Rapporteur Member State. This is done prior to the EFSA risk assessment, and in coordination with the substance manufacturer. Interested parties can request a subscription to an EFSA notification system that will alert them when the relevant review is launched (via pesticides.mrl@efsa.europa.eu). An overview of the MRL review process shows the status of ongoing and upcoming reviews (EFSA 2022).

Before the EU introduces or amends an MRL, the change must be notified in advance to the World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) or Technical Barriers to Trade (TBT) Committee. Once this notification is received by the WTO, the proposed change is announced, and a 60-day feedback period is triggered. If third countries have a concern about the potential impact on their production and export, they can submit feedback via their relevant WTO National Enquiry Points . Comments will then be considered by the Commission prior to adoption of the proposal.

Resources

Codex Pesticides Residues in Food Online Database.

EFSA (2022) Overview of the MRL review progress under Article 12 of Regulation (EC) No 396/2005.

WTO (2021) Ongoing Review of Maximum Residue Levels under Article 12 of Regulation (EC) No.306/2005: Communication from the European Union.

Sources

Regulation (EC) No 396/2005

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