Pesticide residue import tolerance MRLs explained

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Pesticide import tolerance maximum residue levels explained

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

Overview of the process for applying for pesticide import tolerance maximum residue levels (MRLs) in accordance with Regulation 396/2005. For agri-food sectors in non-EU countries that want to establish an MRL which is needed for production and trade, this overview describes the procedures, the data required, and the practical steps that can be taken

Background

What are import tolerances?

EU import tolerances are pesticide maximum residue levels (MRLs) set for agri-food products imported into the EU, to facilitate international trade.

An import tolerance may be set where:

- an active substance is not authorised in the EU (provided there are no public health concerns)
- a higher MRL than the one adopted in the EU is appropriate for a specific product, provided the EU has not set a lower MRL for public health reasons.

(Regulation 396/2005, Art. 3.2(g))

When is an import tolerance needed?

For food and feed produced outside the EU, “different agricultural practices as regards the use of plant protection products may be legally applied, sometimes resulting in pesticide residues differing from those resulting from uses legally applied in the Community” [Regulation 396/2005, recital (26)].

Import tolerances are needed, for example, where:

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- a crop produced outside the EU is not grown within the EU, so MRLs have not been requested
- a substance approved in the EU for certain crops is used on different crops in non-EU countries
- a crop outside the EU is grown under different climatic conditions, or faces pest or disease challenges that are not experienced by European farmers, so MRLs have not been requested
- a substance is essential to maintain production, and no alternatives are available.

Procedure

The same level of consumer protection must be assured for EU-produced and imported products, so an import tolerance is established in the same way as other MRLs, and requests for import tolerances follow the same procedure as MRL reviews.

The evaluation of each active substance is the responsibility of a nominated EU Member State (the "Rapporteur Member State", RMS). The relevant RMS for a particular substance can be found in the EU Pesticides Database (by searching for the substance of interest).

1. A party with a legitimate interest (including exporters, food processors, growers, importers and manufacturers of pesticides, and civil society organisations) can apply to the relevant RMS for an import tolerance. If a substance does not have a designated RMS, an application can be sent to the Commission to designate an RMS in consultation with the Member States.
2. The RMS drafts an Evaluation Report and submits it to the European Food Safety Authority (EFSA).
3. EFSA undertakes a risk assessment, which it publishes as a Reasoned Opinion.
4. The Commission evaluates the EFSA risk assessment and prepares a draft Regulation, which is discussed with, and finally approved by, Member States.

The EU regularly evaluates existing MRLs (Regulation 396/2005, Art. 12). During that re-evaluation process, the RMS gives the opportunity to interested parties to provide information on the substance under review. Since that review only considers existing MRLs, **an import tolerance request cannot be made through that review process**. A request for an import tolerance must be made using the steps described above.

Information and data requirements

An import tolerance request must include the following.

Information

- A copy of national legislation that includes the MRL requested (with a residue definition to facilitate enforcement), and the relevant good agricultural practice (GAP).

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- Evidence that use of the pesticide is authorised in the country where the MRL is set.

Requests for MRLs different from those established in an exporting country may require additional information (see Technical Guidelines: MRL Setting Procedure, 3.1).

Data

Data requirements depend on how well the active substance is known in the EU. If a substance has not been evaluated in the EU, a complete dataset could be required on toxicology, methods of analysis and residue behaviour. Specific data requirements can be requested from the relevant RMS. Data will include residue trials performed in a geographical region with comparable conditions to the country where the substance is authorised.

See Technical Guidelines on Data Requirements for Setting Maximum Residue Levels.

Which countries does an import tolerance cover?

A request for an import tolerance is likely to refer to agricultural practices in a single country. But once it is adopted, the import tolerance is applicable to that product from any origin.

When adopted, an import tolerance is included in the Annexes to Regulation 396/2005, and is visible on the EU Pesticide Residues database.

Recent examples

The European Commission has recently proposed or adopted import tolerances for a number of active substances, including:

- fenpropimorph
- flutriafol
- oxathiapiprolin

Recommended Actions

An MRL on a specific crop can be important for continued production and export of an agri-food product to the EU market. In such cases, producers and exporters should consider approaching the manufacturer of the active substance to explore the possibility of requesting an import tolerance.

The process for approving an import tolerance MRL in the EU can take time and can be costly. Suppliers should consider:

- if non-chemical solutions or effective alternative pesticides that already have EU MRLs are available in the exporting country

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- the reason why a pesticide is not approved in the EU – import tolerances will not be granted for substances that pose risks to consumer health. For many substances, the EU Pesticides Database includes reports that explain non-approval.

For information on the manufacturers of individual substances (and contact information where available), email network@colead.link.

A pesticide manufacturer's ability to support an import tolerance request will depend on the availability of relevant pesticide residue data, and the manufacturer's cost-benefit analysis of the import tolerance request process, among others. Making an application can be costly, so a manufacturer may decide that it is not commercially justified. This is particularly the case for generic (off-patent) active substances, which tend to have a lower selling price and to be more widely used in low- and middle-income countries.

It is possible to request an import tolerance without the support of the manufacturer of the substance, but data requirements are very difficult to meet without their involvement.

Resources

Online resources from the European Commission:

- Technical Guidelines: MRL Setting Procedure
- Technical Guidelines on Data Requirements for Setting Maximum Residue Levels, Comparability of Residue Trials and Extrapolation of Residue Data on Products from Plant And Animal Origin

Sources

Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin

Visit the AGRINFO website to view the latest AGRINFO Update newsletters and search the database.

Tables & Figures

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