

Questions and Answers on Residues and Contaminants in Foodstuffs

What are residues?

Residues are substances that can occur in foodstuffs as a side effect of using veterinary medicines or phytosanitary products. They are unwanted traces of medicines or plant protection products or derivatives thereof which remain in the final product.

And contaminants?

Contaminants are substances that can unintentionally enter food during its production or marketing. These can include environmental pollutants, such as dioxins and heavy metals.

Can the presence of residues and contaminants be avoided?

Residues of substances can be avoided by not using the substance in animal production. Contaminants however can be difficult to exclude entirely due to the background level of pollution in the environment.

What are maximum residue limits?

A high level of health protection is a primary aim of EU food law. Maximum residue limits (MRLs) are therefore determined in order to lay down officially the permissible limits of residues and contaminants so as not to pose a risk to human health. These limits depend on the toxicity of the substance in question. MRLs are not set for every substance. No thresholds are set for substances which are considered to be too dangerous as regards their potential effect on public health. Chloramphenicol and nitrofurans are examples of dangerous antimicrobial substances for which no MRLs are set.

How are MRLs determined and by whom?

Decisions on whether or not substances are acceptable and, if so, at what levels, are taken following a comprehensive risk analysis procedure. The European Parliament and the Council decide on levels of protection on the basis of a proposal from the European Commission. In many cases the EP and the Council have delegated the decision-making powers to the Commission (the comitology procedure). The Commission must seek the agreement of the Standing Committee for the Food Chain and Animal Health, composed of representatives of the Member States and chaired by the Commission, before measures can be adopted.

For residues of veterinary medicinal products in food, the scientific risk assessment is performed by the European Medicines Evaluation Agency (EMA); for contaminants, it is carried out by the European Food Safety Authority (EFSA).

What about controls – how it is ensured that limits and bans are respected?

Under Regulation No 178/2002, food business operators are primarily responsible for ensuring the compliance of their products with EU food law. With effect from 2005, commercial operators will be obliged to report unfavourable test results to Member State authorities.

Official controls and enforcement measures are undertaken by the Member States who are required to adopt and implement a national residue monitoring plan for specific groups of residues and contaminants (Directive 96/23/EC). The aim is to ensure that permitted levels are not exceeded and that forbidden substances are not present in food products.

In addition the Food and Veterinary Office of the Commission undertakes inspections to monitor Member States' compliance with EU food law.

What about residue monitoring plans?

Member States are required to submit monitoring plans to the Commission as are exporting third countries (covering the exported products). In evaluating the residue monitoring plans of third countries, the Commission seeks equivalence rather than identity of requirements.

Is there a different approach to imports from third countries?

For practical reasons, arrangements for third country imports differ from those applicable to Member States. Third countries must present guarantees to demonstrate that their residue monitoring systems achieve equivalent levels of protection to those applicable within the EU. But this does not mean that controls are weaker. The bottom line remains the same: conditions for prohibited substances and residues apply equally to Member States and third countries.

The legislative framework and the control activities of countries exporting food to the EU are evaluated regularly. Export approval is dependent on the results of these evaluations, which may include on-site inspections.

Additionally, imports are checked and tested on a random basis at the borders of the EU as part of the responsibilities of the Member State control authorities for food safety.

What happens when a sample is found to be positive – i.e. a prohibited substance is found or a MRL exceeded?

If test results show that products are harmful to human health, those products are seized and destroyed, and testing activities on relevant products and substances are increased. Member States are informed through the Rapid Alert System. Affected third countries are also informed if the product in question has been imported.

Where a regular pattern of contamination emerges from a particular third **country**, the Community may decide to increase testing levels at point of entry into the EU to up to 100%. Where testing or other surveillance (such as inspections) reveals fundamental problems posing a threat to EU food safety, the country in question may be excluded from importing certain products into the EU.

Is there a particular problem with third country imports?

Where problems are identified, swift and effective action is taken to nullify any risk to food safety whilst preserving, as far as possible, normal trading relations. There has however been recently a significant increase in findings of residues of banned substances in third country imports, in particular as regards imports from certain countries of shrimps and poultry meat. There are two main reasons for this: tougher controls at Community borders and more sophisticated testing techniques.

Why are better testing techniques deemed to be a problem?

Better testing techniques are not a problem *per se* – indeed they are welcome, but they can cause practical difficulties for some third countries, and in particular some developing countries. For example we can now detect routinely chloramphenicol at levels as low as 3 parts per 10 billion – some 3-15 times more sensitive than even one year ago. And sensitive tests are now available for metabolites of nitrofurans – a recent development. Developing countries often lack the equipment and the trained staff to enable testing at such levels.

The way to address this issue is to encourage better control measures and improved infrastructure to bring developing countries up to EU standards to the benefit of all. The European Commission is assisting such efforts through trade related technical assistance.

Shouldn't the EU take a tougher line over third country imports?

Our efforts are geared towards ensuring high standards of food safety. The same standards should apply to all. Where problems are found, action must be taken. This applies equally to home-produced food products as it does to imports. It is worth pointing out that the Rapid Alert System is triggered by a significant number of findings which occur within the EU. Dioxin, MPA, nitrofen and antibiotics are examples of problems that have arisen within EU borders within the relatively recent past.

**REGULATORY FRAMEWORK ON RESIDUES AND CONTAMINANTS
IN FOOD OF ANIMAL ORIGIN**

Regulation (EC) No 178/2002 of the European Parliament and the Council of 28 January 2002 - OJ L 31 of 1.2.2002 – “The General Food Law ”

This Regulation lays down the general principles and requirements of food law, establishes the European Food Safety Authority and lays down procedures in matters of food safety.

Regulation (EEC) No 2377/90 of 26 June 1990 - OJ L 224 of 18.8.1990

This Regulation lays down a Community procedure for the establishment of maximum residue limits (MRL) of veterinary medicinal products in foodstuffs of animal origin.

Directive 2000/24/EC of 28 April 2000 amending the Annexes to Council Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC OJ L 107 of 4.5.2000

This Directive establishes the maximum levels for pesticide residues in and on cereals, foodstuffs of animal origin and certain products of plant origin, including fruit and vegetables.

Regulation (EC) No 315/1993 of 8 February 1993 - OJ L 37 of 13.2.1993

This Regulation lays down general requirements and Community procedures for certain contaminants in foodstuffs.

Regulation (EC) No 466/2001 of 8 March 2001– OJ L 77 of 16.3.2001

This Regulation establishes maximum levels for certain contaminants (heavy metals, mycotoxins and nitrates) in foodstuffs.

Regulation (EC) No 2375/2001 of 29 November 2001 amending Regulation (EC) No 466/2001 –OJ L 321 of 6.12.2001

This Regulation establishes maximum levels of dioxin in certain products of animal and vegetable origin, such as meat, offal, fish, milk and milk products, eggs and oils.

Directive 96/23/EC of 29 April 1996 – OJ L 125 of 23.5.1996

This Directive establishes measures to monitor certain substances and residues thereof in live animals and animal products.

Decision 2002/657/EC of 12 August 2002 – OJ L 221 of 17.8.02

This Decision lays down performance criteria for analytical methods as well as the principle of establishing minimum required performance limits (MRPLs) of analytical methods to be used for substances for which no permitted limit has been established.