

## PROPOSED REPLACEMENT OF REGULATION 2377/90

### **What is Regulation 2377/90?**

Regulation 2377/90 is the community procedure under which the veterinary medicinal products are assessed for safety. Where appropriate, the procedure sets Maximum Residue Limits for the residues of the substance. This is the maximum concentration of a residue of a veterinary medicine that is legally allowable in or on a food.

### **Why is it being replaced?**

The Commission is reviewing this and other related pieces of legislation. This is because while the legislation has greatly increased the level of consumer protection, it has contributed to reducing the number of medicines available for food-producing animals.

There have also been problems when foods imported from third countries<sup>1</sup> have been found to contain residues of substances not authorised in the EU. Such substances should not be present in imports to the EU. Different Member States have been able to detect such substances at differing concentrations. This meant that residues that could be detected by some Member States were not detected by others. So, a consignment of food that would be accepted by some Member states would be rejected by others. This led to claims of inconsistency by the third countries. The full picture on this is described below.

### **What is the current proposal?**

The proposal for replacing Regulation 2377/90 has four main elements:

1. A provision for Codex MRLs to be adopted by the EU where the EU agrees the science, without a further risk assessment;
2. making greater use of extrapolation of MRLs set for specific matrix/analyte combinations to other species where an authorised product is not available;
3. helping international trade in foodstuffs of animal trade by setting Reference Points for Action (RPAs). This should clarify the position in dealing with imports containing substances not authorised for use in the EU, and which therefore should not be present in imports, and
4. assessing the substances used as biocides in animal husbandry (such as disinfectants) for MRLs by the same mechanism used for veterinary medicines.

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<sup>1</sup> Third countries are those that are neither members of the EU nor associate members, such as Norway.

## 1. Codex MRLs accepted without a further risk assessment

The EU sets its own MRLs. But, MRLs are also set by the Codex Alimentarius. This is an international body that sets standards for foods. This is jointly administered by the World Health Organisation and Food and Agriculture Organisation.

The EU is a member of Codex and contributes to setting Codex MRLs. However, currently, MRLs set by Codex are subject to a further risk assessment by the European Medicines Evaluation Agency before they are incorporated into EU law.

**Current UK Position** – we can support the EU adopting Codex MRLs without further risk assessment, provided that the scientific basis underpinning the new procedures are scientifically sound and do not compromise consumer protection.

## 2. Extrapolation of existing MRLs to other species

When MRLs were introduced, they were often set for all food-producing animals, but more recently they have been set for specific species. This has led to few authorised medicines for minor species, such as goats and bees. This is because the cost of generating the residues data necessary for authorising a product in these species makes it economically unattractive.

The idea of extrapolation is to take all of the data we have in one or more species and see if could be used to set MRLs in other species. For example, we may have an MRL for a particular substance in sheep and cows. For these we would have data on metabolism and how residues are distributed in tissues of these animals after treatment. Where these data are similar in both species, it might be possible to extrapolate to allow the MRL to apply to all ruminants.

The work would be done by independent assessors, such as those at VMD. We understand that it would not require companies to provide new data.

**Current UK Position** – we can support extrapolation if the scientific basis is sound and consumer protection is not compromised. We recognise that such an approach could benefit areas such as the honey industry.

## 3. 'Reference Points for Action' for unauthorised substances

Where an MRL has been set, we have a clear reference point for enforcement action. However, for a number of reasons, an MRL may not have been set for a particular substance in some foods. This is a particular problem in foods imported into the EU. While some substances are banned because of health concerns, there are also others, which would not be of immediate health concern, but have never been assessed in the EU.

Where a substance has not been assessed, or is banned, the EU has previously had a 'zero tolerance' for residues. But, as analytical techniques become more and more sensitive, this approach has been called into question. The hunt for lower and lower concentrations has resulted in much higher analytical costs and

this can lead to fewer samples being analysed. This could compromise consumer safety.

Because of the increasing analytical sophistication, some EU countries started to set their own informal 'action limits' for some substances. This led to an inconsistent approach, where food with a particular residue concentration was being rejected at some countries' Border Inspection Posts, but accepted at others.

The third countries expressed concern at the inconsistency and felt that the limits were arbitrary and a barrier to trade. Because a substance is not authorised in the EU, it does not follow that its residues are unsafe. On the other hand, substances that are banned on health grounds in the EU have been found in imports to the Community.

The Commission introduced the concept of Minimum Required Performance Limits (MRPLs) for the banned substances most commonly found in third country exports. These are based on the analytical limits Community Reference Laboratories felt that laboratories in all Member States should be able to achieve, rather than having a scientific basis on the level adequate to protect human health.

The Commission is now proposing it may establish reference points for enforcement action for a wider range of substances where no MRL has been set. The Commission may then submit the reference point to the European Food Safety Authority (EFSA). EFSA will carry out a risk assessment as to whether the reference points for action are adequate to protect human health. This would be an improvement on the current position, but again the science underpinning the reference point will need to be robust to ensure stakeholder confidence.

**Current UK Position** – we could support a solution that aids international trade, but not at the expense of consumer safety. There is some work yet to be done before we have an acceptable solution. The UK wishes to see unauthorised substances referred to the European Food Safety Authority for assessment, preferably **before** RPAs are set, to give consumers a greater degree of confidence in the safety of these substances.

#### **4. Setting MRLs for biocides used in animal husbandry**

Biocides, such as disinfectants are widely used in animal husbandry. There is a possibility that residues of these substances could occur in food. The Commission want to use the assessment method used for assessing medicinal substances to help set MRLs for biocides that contain pharmacologically active substances. The Commission would refer a candidate substance to the European Medicines Evaluation Agency (EMA). It would use its expertise, built up from assessing medicinal substances to evaluate the biocide.

If there are potential health concerns over any residues, a good case can be made for regulation. The EMA has much expertise in assessing toxicological data and setting MRLs. However, there is existing legislation for controlling the use of biocides. This is due to be reviewed shortly and a case could be made for including the assessment process in this biocides legislation.

When a pharmaceutical company submits a new substance as a candidate medicine, it pays a fee. The Member State that takes on the lead in assessing the active substance is paid for time its official take on the process. However, it is not clear where the funds would come from for assessing biocides that contain pharmacologically active substances for EU MRLs.

**UK Position** – The UK recognises the logic in the EMEA in assessing biocides containing pharmacologically active substances for EU MRLs. But, we are concerned that the funding and resourcing issues remain unresolved. There needs to be a clear way forward on this before the decision is taken to include biocides in Regulation 2377/90.

The legislation on biocides will be reviewed in 2008. And, the UK is recommending that the issue of MRLs for biocides is considered in that review.