Foodstuffs of animal origin: procedures for the establishment of residue limits of pharmacologically active substances

2007/0064(COD) - 17/04/2007 - Legislative proposal

PURPOSE: to apply new procedures for establishing residue limits of pharmacologically active substances in foodstuffs of animal origin.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

BACKGROUND: Council Regulation (EEC) No 2377/90 lays down the Community procedure for establishing the maximum residue limits (MRLs) of veterinary medicinal products in foodstuffs of animal origin. However, the current legal framework for MRLs has led to a number of problems. For example, the availability of veterinary medicines has decreased to such an extent that it has created adverse effects on public and animal health as well as on animal welfare. Also, international standards (that have the support of the EU) can not be included into EU legislation without a new scientific assessment by the European Medicines Agency. Control services of Member State haves no points of reference for substances detected in food from third countries and, lastly, the current legislation is intransparent and hence difficult to understand.

CONTENT: the purpose of this proposal, therefore, is to address the shortcomings of the current situation by amending, on substance, the existing legal framework relating specifically to MRLs whilst, at the same time, leaving the overall system of setting maximum residue limits based on scientific assessment intact. In brief the main changes being proposed are as follows:

- to make the assessment of possibilities for extrapolation a compulsory part of the overall scientific assessment and to create a legal basis for the Commission to lay down the principles for applying extrapolation;

- to introduce an obligation to adapt Community legislation to include MRLs set by Codex with the support of the EU;

- to create a specific legal framework and to set MRLs for pharmacologically active substances not intended to be authorised as veterinary medicines in particular for control and purpose and for imported food;

- to rearrange the sequence of articles in order to create a logical structure, differentiating in particular risk assessment and risk management provisions; and

- to integrate, in a separate Commission Regulation, the rules (MRLs, conditions of use, prohibition etc.) relating to individual substances, which can currently be found in 4 annexes of the current basic act.

The proposal provides for significant improvements in terms of simplification – i.e. the restructuring of the Articles and the integration into a single Annex of all the rules concerning MRLs, conditions of use, prohibition etc. The public authorities, in particular, will benefit from the improved readability of the residue legislation. Consolidating, into one single Regulation all residue limits will make the work of enforcement by control authorities much easier. Further, the timelines for procedural management will be

clearly fixed for all parties. International standards supported by the Community would be automatically recognised without the need to submit any specific application at Community level – thereby avoiding duplication of work.

In addition, veterinarians will have access to a single document in which all relevant information is collated. It will include data on all substances evaluated. Similarly, third countries exporting foodstuffs of animal origin into the Community will benefit from further simplification and the clarification of Community requirement.

As far as the budget is concerned the proposal will have no impact on the Community budget but could have a negligible (or even no) cost on the European Medicines Agency (EMEA). The proposed Regulation's financial impact on revenues is uncertain. An increase in applications for authorisations of veterinary medicinal products could lead to an increase of fee revenues for the EMEA. As far as expenditure is concerned, the proposal will not change the principle whereby the system of residue limits is operated by the EMEA and the Commission. Additional scientific assessments will be required for residue limits for control purposes while less assessments will result from the taking over of limits set by Codex alimentarius and from extrapolation requirements. In overall terms the review will thus have a very limited impact on resources which can not be quantified.