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

2007/0064(COD) - 06/05/2009 - Final act

PURPOSE: to limit consumer exposure to pharmacologically active substances intended to be used in veterinary medicinal products for food producing animals and residues thereof in foodstuffs of animal origin through Community procedures.

LEGISLATIVE ACT: Regulation (EC) No 470/2009 of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council.

CONTENT: the Regulation aims at reviewing and completing existing provisions related to the establishment of Maximum Residue Limits (MRLs) for pharmacologically active substances in foodstuffs of animal origin. The main objective is to improve the availability of veterinary medicinal products for food producing animals whilst ensuring a high level of human health protection.

For the purposes of ensuring food safety, this Regulation lays down rules and procedures in order to establish:

(a) the maximum concentration of a residue of a pharmacologically active substance which may be permitted in food of animal origin ("maximum residue limit");

(b) the level of a residue of a pharmacologically active substance established for control reasons in the case of certain substances for which a maximum residue limit has not been laid down in accordance with this Regulation ("reference point for action").

The main changes planned are as follows:

- an obligation to consider possibilities of extrapolation when scientific evaluation is being carried out to establish a residue limit;
- an obligation for the Community to take over residue limits adopted at *Codex Alimentarius* level if it did not table any objections when they were adopted;
- the creation of a legal framework for the establishment of residue limits for pharmacologically active substances which are not *a priori* intended to be used in veterinary medicinal products in the Community;
- the establishment of reference values when necessary for the purposes of control in cases where there is no residue limit.

A further aim of the new Regulation is to simplify current legislation and to improve its legibility.

By 6 July 2014, the Commission shall submit a report to the European Parliament and to the Council. The report shall, if appropriate, be accompanied by relevant proposals.

ENTRY INTO FORCE: 06/07/2009.