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

2007/0064(COD) - 17/06/2008 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 660 votes to 13 with 5 abstentions, a legislative resolution amending the proposal for a regulation 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, and repealing Regulation (EEC) No 2377/90. The report had been tabled for consideration in plenary by Avril **DOYLE** (EPP-ED, IE) on behalf of the Committee on the Environment, Public Health and Food Safety.

The amendments - adopted under 1st reading of the codecision procedure – are as follows:

-**purpose:** Parliament emphasises the general purpose of this Regulation, which is that of ensuring food safety;

-**reference points for action**: this is now defined as 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. In addition, Parliament introduced a new Article on implementing reference points for action. The reference points for action shall be reviewed in the light of any new data concerning the protection of human health and the food chain;

-**European Food Safety Authority**: the risk management recommendations should take into account any relevant scientific findings of the European Food Safety Authority, by way of letters of cooperation;

-**scientific risk assessment**: the principles of risk assessment pursuant to Articles 4 to 8 shall be applied in order to guarantee a high level of health protection.

-**toxicological,** as well as pharmacological or microbiological effects in human beings should be considered;

-**equidae:** a new clause states that veterinary medicinal products which do not have a maximum residue limit for equidae, which are not included in Annex IV of Regulation (EEC) No 2377/90 or in Article 13(2) of this Regulation, and which are used "off-label", as defined in Article 1(16) of Directive 2001/82/EC, and "under the provisions of the cascade" and not administered intra-muscularly or subcutaneously, shall have a nominal withdrawal period of six months. Furthermore, the use of pharmaceuticals containing pharmacologically active ingredients not on "the essential" substances list or the "positive list" for equidae referred to in Article 10(3) of Directive 2001/82/EC and not administered intra-muscularly or subcutaneously, shall have a nominal withdrawal period of six months;

-**urgent authorisation**: in specific cases where urgent authorisation is required to ensure the protection of human health and animal health and welfare, the Commission may, in accordance with the regulatory procedure with scrutiny, establish a provisional maximum residue limit for a period not exceeding five years;

-**requests for an opinion on maximum residue limits**: the proposal had stated that the Commission or Member States may forward to the Agency requests for an opinion for substances not intended for use in

veterinary medicinal products to be placed on the market in the Community and where no application for such substances has been made. Parliament introduced wording which states that the Commission, Member States or a third party pursuing legitimate interests may forward to the Agency requests for an opinion on MRLs for pharmacologically active substances in certain circumstances which are prescribed in the text;

-comitology: defining the methodology of the risk assessment and of risk management will be done in accordance with the regulatory procedure with scrutiny. Moreover, Parliament altered the time limits for the adoption of decisions;

-accelerated procedure for an Agency opinion: a new clause states that, in specific cases where a veterinary medicinal product or a biocidal product needs to be authorised as a matter of urgency for reasons relating to the protection of public health or of animal health or welfare, the Commission, any person who has requested an opinion, or a Member State may ask the Agency to carry out an accelerated procedure for the assessment of the maximum residue limit of a pharmacologically active substance contained in those products. The Agency shall ensure that the Committee is able to issue its opinion within 150 days following receipt of the application;

-placing on the market: a new Article states that if the maximum residue limits or reference quantities established under this Regulation are exceeded, the product shall not be placed on the market as a foodstuff, transformed into foodstuffs or mixed with foodstuffs.

Foodstuffs of animal origin containing pharmacologically active substances for which no maximum residue limits have been set may not be placed on the market;

-import: Member States shall prohibit the import and placing on the market of food of animal origin containing residues resulting from the illegal administration of pharmacologically active substances which are not subject to a classification in accordance with the text. Accordingly, imports from third countries of food containing residues resulting from the illegal administration of substances whose use is use is banned within the European Union shall be prohibited in the interests of public health;

-report: the Commission shall, not later than five years after the entry into force of the Regulation, submit a report which will, in particular, review the experience gained from the application of the Regulation, and, if appropriate, be accompanied by proposals.