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

2007/0064(COD) - 06/05/2008

The Committee on the Environment, Public Health and Food Safety adopted a report by Avril **DOYLE** (EPP-ED, IE) and amended, in the context of the codecision procedure, 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 main amendments are as follows:

-**purpose**: the Committee 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. The Committee wanted to introduce a more precise definition unrelated to the concept of exposure, which could be interpreted as a weakening of the safety requirement. 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. In addition, the Committee has introduced a new Article on implementing reference points for action;

-**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;

-**extrapolation**: in the event of extrapolation between different animal species, a safety factor should be applied when setting maximum residue limits;

-**scientific risk assessment**: the scientific risk assessment should, inter alia, pay particular attention to the synergetic and cumulative effects of different pharmacologically active substances and to effects on vulnerable categories of people. The risk assessment should comply with the principles for assessing the safety of foodstuffs laid down in Regulation (EC) No 178/2002.

-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. The Committee stated that peer-reviewed science clearly indicates that no such residues would exist in muscle meat e.g. from oral or intravenous administration after six months, which allows a large safety margin on time. 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;

-ur**gent 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. The Committee 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. The Committee states that creating possibilities to fix MRLs in the absence of a marketing authorisation would be a powerful tool for availability. It would enable producer's organisations and scientists to submit an application for an MRL and would provide an incentive to pharmaceutical companies to develop veterinary medicinal products - particularly for minor species or minor uses. It would, in particular, address the medicines availability concerns expressed by honey producers and bee keepers.

The text on requests for the Agency's opinion also applies to authorised pharmacologically active substances for which the cost of the procedure for establishing residue limits is disproportionate in relation to the economic revenue from the substance on account of the limited distribution of the animal species or their minor economic significance ('minor uses'). In the event of extrapolation between different animal species, a safety factor shall be applied when setting maximum residue limits. The Commission may, in accordance with the regulatory procedure with scrutiny, establish more precise requirements for the application of this clause;

-requests for review: the text clarifies who may request a review and under what circumstances;

-comitology: defining the methodology of the risk assessment and of risk management will be done in accordance with the regulatory procedure with scrutiny. Moreover, the Committee 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.

-prohibition on placing on the market: 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 Regulation. Accordingly, imports from third countries of food containing residues resulting from the illegal administration of substances whose use is use is banned within the EU shall be prohibited in the interests of public health. Foodstuffs of animal origin containing pharmacologically active substances for which no maximum residue limits have been set may not be placed on the market. Furthermore, if the maximum residue limits or reference quantities established under the Regulation are exceeded, the product shall not be placed on the market as a foodstuff, transformed into foodstuffs or mixed with foodstuffs.

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, f appropriate, be accompanied by proposals.