Opinion of the European Economic and Social Committee on 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'

COM(2007) 194 final — 2007/0064 (COD)

(2008/C 10/13)

On 22 May 2007, the Council decided to consult the European Economic and Social Committee, under Articles 37 and 152(4)(b) of the Treaty establishing the European Community, on the abovementioned proposal.

The Section for Agriculture, Rural Development and the Environment, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 4 July 2007. The rapporteur was Mr Coupeau.

At its 438th plenary session, held on 26 and 27 September 2007 (meeting of 26 September 2007), the European Economic and Social Committee adopted the following opinion by 151 votes with 6 abstentions.

1. **Conclusions and recommendations**

1.1 The European Economic and Social Committee notes the steps taken by the European Commission.

1.2 The Committee would like any pharmacological substance intended for food-producing animals to be submitted to the European Medicines Agency (EMEA) and the Maximum Residue Limits (MRLs) to be assessed by the Committee for Medicinal Products for Veterinary Use (CVMP).

1.3 Any company producing pharmacological products for animals should be authorised by the EMEA and have had its MRLs assessed by the CVMP.

1.4 In order to prevent any hindrance to the movement of products within the European Community, these authorisations will be valid throughout all the EU Member States.

1.5 The procedure for placing products on the market should be simplified, whilst maintaining a high level of consumer protection.

1.6 Simplifying European documents and making them more readable would benefit all Europeans. Access to such documents would help everyone to discover and understand Europe's contribution to their daily lives.

2. **Aim of the proposal**

2.1 The aim is to continue to limit consumer exposure to pharmacologically active substances.

2.2 Whilst maintaining a high level of consumer protection, the proposal should also help to simplify legislation.

2.3 In order to achieve the desired aim, specific objectives should be borne in mind:

a) improve availability of veterinary medicinal products for food-producing animals in order to ensure animal health and welfare and avoid illegal use of substances;

b) simplify the existing legislation by enhancing readability of the provisions on established MRLs for the end-users;

c) provide clear references for the control of residues of pharmacologically active substances in foodstuffs to improve consumer health protection and the functioning of the Single Market;

d) clarify the Community procedures establishing Maximum Residue Limits (MRLs) by ensuring consistency with international standards.

3. **Current situation**

3.1 The current legal framework for MRLs has led to particular problems:

a) Availability of veterinary medicines has decreased to an extent that creates adverse effects for public and animal health and animal welfare.

b) International standards supported by the EU cannot be included in Community legislation without a new scientific assessment by the European Medicines Agency.

c) Member States' supervisory bodies have no points of reference, in particular for substances detected in foodstuffs from third countries.

d) The current legislation is difficult to understand.

4. **Proposed measures**

4.1 The main changes proposed are as follows:

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

b) introduce an obligation to adapt Community legislation to include Maximum Residue Limits (MRLs) set by Codex with the support of the EU;

c) create a specific legal framework to set maximum residue limits for pharmacologically active substances not intended to be authorised as veterinary medicines in particular for control purposes and for imported foodstuffs.

4.2 The Commission has taken care to consult the parties concerned, in order to determine what changes might be needed.

5. **Recommendations**

5.1 The European Economic and Social Committee notes the steps taken by the European Commission.

5.2 The Committee would like any pharmacological substance intended for food-producing animals to be submitted to the European Medicines Agency (EMEA) and the Maximum Residue Limits (MRLs) to be assessed by the Committee for Medicinal Products for Veterinary Use (CVMP).

5.3 Any company producing pharmacological products for animals should be authorised by the EMEA and have had its MRLs assessed by the CVMP.

5.4 In order to prevent any hindrance to the movement of products within the European Community, these authorisations will be valid throughout Europe.

5.5 The procedure for placing products on the market should be simplified, whilst maintaining a high level of consumer protection.

5.6 Developments in scientific knowledge will help to determine whether products are innocuous and how long to wait between administering the medicine to an animal and slaughtering it for consumption.

5.7 Developments in scientific knowledge should enable the Council to set a maximum residue limit.

5.8 Request for procedures: the current procedure has proved its worth and managing requests for authorisation should still form part of it.

5.9 The classification of pharmacologically active substances should thus take account of the following:

a) a maximum residue limit

b) the absence of a maximum residue limit

c) a ban on administering substances.

5.10 The EMEA should consult the reference laboratories, in order to determine the process for analysing residues.

5.11 The movement of foodstuffs of animal origin in the European Union must not be hindered.

5.12 Simplifying European documents and making them more readable would benefit all Europeans. Access to such documents would help everyone to discover and understand Europe's contribution to their daily lives.

5.13 Meat products from outside the Community treated with medicines not licensed in the EU should be subject to a scientific study proving that these products are innocuous, be submitted to the EMEA, and then have their MRLs validated by the Committee, in order to ensure that consumers are fully protected.

5.14 The Commission should consider the issues surrounding the availability of medicinal substances for certain species, such as goats, rabbits, etc., which laboratories choose not to develop because they are not profitable.

Brussels, 26 September 2007.

The President

of the European Economic and Social Committee

Dimitris DIMITRIADIS