COMMISSION DECISION

of 11 January 2005

laying down harmonised standards for the testing for certain residues in products of animal origin imported from third countries

(notified under document number C(2004) 4992)

(Text with EEA relevance)

(2005/34/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries [1], and in particular Articles 4(5) and 17(7) thereof,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, and in particular Articles 11(4) and 63(1)(e) thereof,

Whereas:

(1) Directive 97/78/EC requires that each consignment imported from third countries shall be subject to veterinary controls. These checks may include analytical tests for residues of pharmacologically active substances in order to verify whether the consignments fulfil the requirements of Community legislation.

(2) The maximum residue limits (MRL) to be applied in food control according to Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC [2], have been established for pharmacologically active substances by Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin [3]. MRLs are applicable to imported consignments.

(3) However, Regulation (EEC) No 2377/90 does not provide MRLs for all substances and in particular not for those substances whose use is prohibited or not authorised in the Community. For those substances, the presence of any residue may present grounds to reject or destroy the relevant consignment at import.

(4) It is appropriate that the Community should establish a harmonised approach for the control in imported consignments of residues of substances prohibited or not authorised in the Community.

(5) The minimum required performance limits (MRPLs) set according to Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results [4] have been adopted as the standard of performance ensuring effective control of Community legislation when testing official samples for the presence of certain prohibited or unauthorised substances; the MRPL correspond to the average limit above which the detection of a substance or its residues can be construed as methodologically meaningful.

(6) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [5], in line with the Codex alimentarius *Working Principles for Risk Analysis* [6], requires food law to be based on factors legitimate to the matter under consideration, such as feasibility of controls.

(7) Therefore, the isolated detection of residues of a substance below the MRPLs set by Decision 2002/657/EC should be construed as not of immediate concern but to be monitored by Member States and the MRPLs should be employed where they exist, as the reference point for action to ensure a harmonised implementation of Directive 97/78/EC.

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[1] OJ L 24, 30.1.1998, p. 9. Directive as last amended by Regulation (EC) No 882/2004 of the European Parliament and of the Council (OJ L 165, 30.4.2004, p. 1).

[2] OJ L 125, 23.5.1996, p. 10. Directive as last amended by Regulation (EC) No 882/2004.

[3] OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 2232/2004 (OJ L 379, 24.12.2004, p. 71).

[4] OJ L 221, 17.8.2002, p. 8. Decision as last amended by Decision 2004/25/EC (OJ L 6, 10.1.2004, p. 38).

[5] OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

[6] Available on ftp://ftp.fao.org/codex/alinorm03/Al03_33e.pdf

(8) Where the results of analytical tests indicate the presence of residues of a substance for which MRPLs have been established in accordance with Decision 2002/657/EC, and pending the implementation of Regulation (EC) No 882/2004 on 1 January 2006, it is appropriate to clarify the action to be taken, taking into consideration the seriousness of the threat which the consignment may represent to human health, and the provisions laid down in Directives 96/23/EC and 97/78/EC and in Regulation (EC) No 178/2002.

(9) Member States should in particular monitor the import situation for any evidence of a recurrent problem, since such a finding could suggest a pattern of misuse of a particular substance, or a disregard for guarantees provided by third countries concerning the production of food intended for import into the Community. Member States should notify the Commission of recurring problems.

(10) The measures provided for by this Decision are in conformity with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Scope of the Decision

1. This Decision lays down the reference points for action for residues of substances for which MRPLs have been established in accordance with Decision 2002/657/EC when analytical tests carried out pursuant to Directive 97/78/EC on imported consignments of products of animal origin confirm the presence of such residues, and the action to be undertaken after such confirmation.

2. This Decision applies whether analytical tests are carried out routinely, under reinforced checks procedures or under a safeguard measure on consignments of products of animal origin imported from third countries.

Article 2

Reference points for action

For the purpose of control of residues of certain substances whose use is prohibited or not authorised in the Community, the minimum required performance limits (MRPLs) laid down in Annex II to Decision 2002/657/EC shall be used as reference points for action irrespective of the matrix tested.

Article 3

Action in case of confirmed presence of a prohibited or non-authorised substance

1. Where results of analytical tests are at or above the MRPLs laid down in Decision 2002/657/EC, the consignment concerned shall be considered non-compliant with Community legislation.

2. Pending the application from 1 January 2006 of Articles 19 to 22 of Regulation (EC) No 882/2004, the competent authorities of the Member States shall place under official detention non-compliant consignments from third countries, and having heard the food business operators responsible for the consignment, shall take the following measures:

(a) order that such consignments be destroyed or re-dispatched outside the Community in accordance with paragraph 3;

(b) if the consignments have already been placed on the market, recall the consignments before taking one of the measures referred to above.

3. The competent authorities shall allow re-dispatch of consignments only if:

(a) the destination has been agreed with the feed or food business operator responsible for the consignment; and

(b) the food business operator has first informed the competent authority of the third country of origin or third country of destination, if different, of the reasons and circumstances preventing the placing on the market of the consignments concerned within the Community; and

(c) when the third country of destination is not the third country of origin, the competent authority of the third country of destination has notified the competent authority of its preparedness to accept the consignments.

4. Without prejudice to the national rules of Member States concerning the review of administrative decisions, a re-dispatch shall take place no more than 60 days after the day on which the competent authority decided on the destination of the consignment, unless legal action has been undertaken. If, after the expiry of the 60-day period, re-dispatch does not take place, the consignment shall be destroyed, unless the competent authority is satisfied that a delay is justified.

5. Where the results of analytical tests on products are below the MRPLs laid down in Decision 2002/657/EC, the products will not be prohibited from entering the food chain. The competent authority shall retain a record of the findings in case of recurrence. Where the results of analytical tests on products from the same origin show a recurrent pattern indicating a potential problem related to one or several prohibited or unauthorised substances, including for instance the recording of four or more confirmed results below the reference points for action for the same substance in imports from a particular origin within a period of six months, the competent authority shall inform the Commission and the other Member States in the Standing Committee on the Food Chain and Animal Health. The Commission shall bring the matter to the attention of the competent authority of the country or countries of origin and shall make appropriate proposals.

6. The feed or food business operator responsible for the consignment or its representative shall be liable for the costs incurred by competent authorities for the activities referred to in paragraph 1 to 4 of this Article.

Article 4

This Decision shall apply from 19 February 2005.

Article 5

This Decision is addressed to the Member States.

Done at Brussels, 11 January 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission