COMMISSION DECISION

of 12 July 2010

amending Decision 2008/630/EC on emergency measures applicable to crustaceans imported from Bangladesh and intended for human consumption

(notified under document C(2010) 4739)

(Text with EEA relevance)

(2010/387/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 [1], and in particular Article 53(1)(b)(ii) thereof,

Whereas:

(1) Regulation (EC) No 178/2002 lays down the general principles governing food and feed in general, and food and feed safety in particular, at Union and national level. It provides for emergency measures where it is evident that food or feed imported from a third country is likely to constitute a serious risk to human health, animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned.

(2) Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products [2] provides that the production process of animals and primary products of animal origin is to be monitored for the purpose of detecting the presence of certain residues and substances in live animals, their excrements and body fluids and in tissue, animal products, animal feed and drinking water.

(3) Commission Decision 2002/657/EC of 14 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results [3] provides rules for the analytical methods to be used in the testing of official samples taken pursuant to Directive 96/23/EC, and specifies common criteria for the interpretation of analytical results of official control laboratories for such samples.

(4) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin [4] lays down rules and procedures for the classification of pharmacologically active substances and for establishing the maximum concentration of residues of such substances which may be permitted in food of animal origin, namely maximum residue limits (MRLs).

(5) In addition, Regulation (EC) No 470/2009 lays down rules and procedures in order to establish the level of residues of a pharmacologically active substance for control reasons in the case of certain substances for which an MRL has not been laid down in accordance with that Regulation, namely reference points for action.

(6) Commission Decision 2008/630/EC of 24 July 2008 on emergency measures applicable to crustaceous imported from Bangladesh and intended for human consumption [5] was adopted following the detection of the presence of residues of veterinary medicinal products and unauthorised substances in crustaceans imported from that third country and intended for human consumption. It provides that consignments of crustaceans imported into the Union from Bangladesh and intended for human consumption are to be tested for the presence of chloramphenicol, metabolites of nitrofurans, tetracycline, malachite green and crystal violet.

(7) The results of a Commission inspection to Bangladesh in January 2010 have revealed that the previously identified lack of appropriate laboratory capacity for the testing of certain residues of veterinary medicinal products in live animals and animal products still persists. In addition, oxytetracycline and chlortetracycline are also known to be used in Bangladesh.

(8) Since the measures taken to date by Bangladesh are not sufficient, it is appropriate to review the emergency measures laid down in Decision 2008/630/EC to ensure the effective and uniform protection of human health in all Member States. In particular, it is necessary to allow the importation of crustaceans imported from Bangladesh and intended for human consumption into the Union, provided that appropriate tests are carried out at the place of origin.

[1] OJ L 31, 1.2.2002, p. 1.
[2] OJ L 125, 23.5.1996, p. 10.
[3] OJ L 221, 17.8.2002, p. 8.
[4] OJ L 152, 16.6.2009, p. 11.
[5] OJ L 205, 1.8.2008, p. 49.

(9) In addition, a significant proportion of crustaceans imported from Bangladesh should undergo analytical testing by the Member States for the detection of the presence of residues of pharmacologically active substances before they are placed on the market in the Union. The results of such testing should provide more accurate information on the actual level of contamination with those residues in crustaceans originating from Bangladesh.

(10) It is appropriate that Member States notify the Commission of the results of the analytical tests carried out, where those results reveal the presence of pharmacologically active substances not authorised for use in food-producing animals, or exceeding the maximum residue limits laid down in Union law. Member States should also regularly submit reports to the Commission on all the tests carried out by them.

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

HAS ADOPTED THIS DECISION:

Article 1

Articles 2, 3 and 4 of Decision 2008/630/EC are replaced by the following:

'*Article 2*

1. Member States shall authorise the importation into the Union of consignments of the products provided that they are accompanied by the results of an analytical test carried out at the place of origin to ensure that they do not present a danger to human health ("the analytical test").

2. The analytical test must have been carried out on an official sample, in order to detect the presence of residues of pharmacologically active substances, as defined in Article 2(a) of Regulation (EC) No 470/2009 of the European Parliament and of the Council (*), and in particular they must have been tested for the presence of:

— chloramphenicol, tetracycline, oxytetracycline, chlortetracycline,

— metabolites of nitrofurans,

— malachite green and crystal violet and their respective leuco-metabolites.

3. By way of derogation from paragraph 1, Member States shall authorise the importation of consignments of the products that are not accompanied by the results of the analytical test provided that the Member State concerned ensures that each consignment undergoes appropriate checks including the analytical test of official samples on arrival at the border inspection post of the point of entry into the Union to ensure that they do not present a danger to human health.

Article 3

Member States shall, by using appropriate sampling plans, ensure that official samples are taken from at least 20 % of the consignments referred to in Article 1.

Those official samples shall undergo analytical tests for the detection of the presence of residues of pharmacologically active substances, as defined in Article 2(a) of Regulation (EC) No 470/2009, and in particular they must have been tested for the presence of chloramphenicol, tetracycline, oxytetracycline, chlortetracycline and metabolites of nitrofurans.

Article 4

The consignments from which official samples have been taken pursuant to Article 2(3) and Article 3 shall be kept under official detention by the competent authority of the Member State concerned, until the analytical tests have been completed.

Those consignments can be placed on the market only if the results of the analytical tests confirm that the consignments comply with Article 23 of Regulation (EC) No 470/2009.

Article 4a

Member States shall immediately inform the Commission of the results of the analytical tests if those tests reveal the presence of residues of any pharmacologically active substance:

(a) classified in accordance with Article 14(2)(a), (b) or (c) of Regulation (EC) No 470/2009 at a level exceeding the maximum residue limit established pursuant to that Regulation; or

(b) not classified in accordance with Article 14(2)(a), (b) or (c) of Regulation (EC) No 470/2009.

The results of those analytical tests shall be notified to the Commission via the rapid alert system established pursuant to Article 50(1) of Regulation (EC) No 178/2002. The Member State concerned is not required to notify the Commission of the results of such tests via the rapid alert system where the level of residues of pharmacologically active substance is lower than:

(i) the reference point for action established for that substance pursuant to Article 18 of Regulation (EC) No 470/2009; or

(ii) the minimum required performance limit established for that substance referred to in Article 4 of Commission Decision 2002/657/EC (**).

Article 4b

Member States shall prepare a report every three months, giving an account of all the results of all analytical tests carried out in the previous three months on consignments of the products from Bangladesh.

Those reports shall be submitted to the Commission during the month following each three-month period, in April, July, October, and January.

(*) OJ L 152, 16.6.2009, p. 11.
(**) OJ L 221, 17.8.2002, p. 8.'.

Article 2

This Decision shall apply from 15 July 2010.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 12 July 2010.

For the Commission
John DALLI
Member of the Commission