COMMISSION DECISION

of 8 July 2010

on emergency measures applicable to consignments of aquaculture products imported from India and intended for human consumption

(notified under document C(2010) 4563)

(Text with EEA relevance)

(2010/381/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 12 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.

(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 a maximum residue limit has not been laid down in accordance with that Regulation.

(6) The results of a Commission inspection to India in September 2009 have revealed shortcomings as regards the residue control system in aquaculture products and a lack of appropriate laboratory capacity for detecting certain pharmacologically active substances in such products, as required by Directive 96/23/EC and by Decision 2002/657/EC.

(7) Following that inspection, India has submitted an action plan and guarantees addressing the recommendations in the inspection report. Pending the full implementation of that plan and of those guarantees, the risk remains that aquaculture products originating from India contain residues of certain pharmacologically active substances. Further measures are therefore required at Union level to minimise that risk.

(8) Commission Decision 2009/727/EC of 30 September 2009 on emergency measures applicable to crustaceans imported from India and intended for human consumption or animal feed [5] already provides that consignments of crustaceans of aquaculture origin introduced from India and intended for human consumption or animal feed are to be tested for the presence of nitrofurans or their metabolites before they are imported into the Union. In addition, in aquaculture products other than crustaceans, chloramphenicol and tetracyclines are also known to be used in India.

[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 258, 1.10.2009, p. 31.

(9) Since the adoption of Decision 2009/727/EC, the number of positive findings of nitrofurans or their metabolites in crustaceans reported by the Member States has decreased. Therefore, it is appropriate to adopt measures similar to those laid down in that Decision in respect of all aquaculture products imported from India and intended for human consumption.

(10) In addition a significant proportion of the aquaculture products imported from India should undergo mandatory testing by the Member States for the detection of pharmacology active substances as defined in Regulation (EC) No 470/2009 before those products are placed on the market. The results of that mandatory testing should provide more accurate information on the actual contamination of aquaculture products originating from India with those residues. The testing should also deter producers in India from misusing those substances.

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

(12) The scope of this Decision also includes crustaceans of aquaculture origin currently covered by Decision 2009/727/EC. Accordingly, in the interest of clarity and consistency of Union legislation, that Decision should be repealed.

(13) 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

This Decision shall apply to the importation of consignments of aquaculture products from India intended for human consumption ('consignments').

Article 2

1. Member States shall authorise the importation into the Union of consignments 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 must have been carried out on an official sample, in particular with a view to detecting the presence of chloramphenicol, tetracycline, oxytetracycline and chlortetracycline and of metabolites of nitrofurans.

Those samples must have been analysed using analytical methods in conformity with Articles 3 and 4 of Decision 2002/657/EC.

2. By way of derogation from paragraph 1, Member States shall authorise the importation of consignments that are not accompanied by the results of an analytical test provided that the importing Member State ensures that each consignment undergoes such analytical tests for the detection of chloramphenicol, tetracycline, oxytetracycline, chlortetracycline and of metabolites of nitrofurans on arrival.

Article 3

1. Member States shall, by using appropriate sampling plans, ensure that official samples are taken from at least 20 % of consignments presented for import at border inspection posts on their territory.

2. The official samples taken pursuant to paragraph 1 shall undergo analytical tests for the detection of residues of pharmacologically active substances as defined in Article 2(a) of Regulation (EC) No 470/2009, and in particular of chloramphenicol, tetracycline, oxytetracycline, chlortetracycline and of metabolites of nitrofurans.

Article 4

The consignments from which official samples have been taken pursuant to Articles 2(2) and 3(1) shall be kept under official detention by the competent authority of the Member State concerned, until the analytical tests have been completed.

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

Article 5

1. 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; however, the Member State concerned is not required to immediately inform the Commission of the results of such tests where the level of residues is lower than:

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

(ii) the minimum required performance limit established for that substance pursuant to Decision 2002/657/EC.

The results of those analytical tests shall be notified to the Commission under the rapid alert system established pursuant to Article 50 of Regulation (EC) No 178/2002.

2. Every three months Member States shall submit to the Commission a report on all the results of the analytical tests carried out on the consignments in the previous three months.

The first report shall be submitted to the Commission by 1 October 2010.

Article 6

All expenditure incurred in the application of this Decision shall be charged to the consignor, the consignee or the agent of either the consignor or the consignee.

Article 7

Decision 2009/727/EC is repealed.

Article 8

This Decision is addressed to the Member States.

Done at Brussels, 8 July 2010.

For the Commission
John DALLI
Member of the Commission