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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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EN

[1] Text with EEA relevance

I

(Acts whose publication is obligatory)

REGULATION (EC) No 2160/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Economic and Social Committee [2],

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

Whereas:

(1) Live animals and food of animal origin appear on the list in Annex I to the Treaty. Livestock farming and the placing on the market of food of animal origin constitute an important source of income for farmers. The implementation of veterinary measures aimed at raising the level of public and animal health in the Community assists the rational development of the farming sector.

(2) The protection of human health against diseases and infections transmissible directly or indirectly between animals and humans (zoonoses) is of paramount importance.

(3) Zoonoses transmissible through food may cause human suffering, as well as economic losses to food production and the food industry.

(4) Zoonoses transmitted through sources other than food, especially from wild animal and pet animal populations, are also a matter of concern.

(5) Zoonoses present at the level of primary production must be adequately controlled to ensure that the objectives of this Regulation are achieved. However, in the case of primary production leading to the direct supply of small quantities of primary products, by the food business operator producing them, to the final consumer or to local shops, it is appropriate to protect public health through national law. In this case there is a close relationship between the producer and the consumer. Such production should not make a significant contribution to the average prevalence of zoonoses in animal populations in the Community as a whole. The general requirements for sampling and analysis may not be practical or appropriate for producers with very small numbers of animals who may be located in regions suffering from special geographical constraints.

(6) Council Directive 92/117/EEC of 17 December 1992 concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and intoxications [4] provided for the establishment of monitoring systems for certain zoonoses and controls on salmonella in certain poultry flocks.

(7) That Directive required Member States to submit to the Commission the national measures that they had taken to achieve the objectives of the Directive and to draw up plans for monitoring salmonella in poultry. However, Council Directive 97/22/EC [5] amending Directive 92/117/EEC suspended the requirement pending the review provided for in Article 15a of Directive 92/117/EEC.

[1] OJ C 304 E, 30.10.2001, p. 260.
[2] OJ C 94, 18.4.2002, p. 18.
[3] Opinion of the European Parliament of 15 May 2002 (OJ C 180 E, 31.7.2003, p. 160), Council Common Position of 20 February 2003 (OJ C 90 E, 15.4.2003, p. 25) and Position of the European Parliament of 19 June 2003 (not yet published in the Official Journal). Council Decision of 29 September 2003.
[4] OJ L 62, 15.3.1993, p. 38. Directive as last amended by Council Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).
[5] OJ L 113, 30.4.1997, p. 9.

(8) Several Member States have already submitted their plans for the monitoring of salmonella, which the Commission has approved. Moreover, all Member States were required, with effect from 1 January 1998, to fulfil the minimum measures laid down for salmonella in Annex III, Section I, to Directive 92/117/EEC, and to establish rules specifying the measures to be taken to avoid the introduction of salmonella on to a farm.

(9) Those minimum measures focused on monitoring and controlling salmonella in breeding flocks of the species *Gallus gallus*. When serotypes *Salmonella enteritidis* or *Salmonella typhimurium* were detected and confirmed in samples taken, Directive 92/117/EEC laid down specific measures to control the infection.

(10) Other Community legislation provides for the monitoring and control of certain zoonoses in animal populations. In particular Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine [1] deals with bovine tuberculosis and bovine brucellosis. Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals [2] deals with ovine and caprine brucellosis. This Regulation should not create any unnecessary duplication of these existing requirements.

(11) Moreover, future Community legislation on food hygiene should cover specific elements necessary for the prevention, control and monitoring of zoonoses and zoonotic agents and include specific requirements for the microbiological quality of food.

(12) Directive 92/117/EEC provided for the collection of data on the occurrence of zoonoses and zoonotic agents in feedingstuffs, animals, food and humans. That data collection system, although not harmonised and therefore not allowing comparison between Member States, does provide a basis for evaluating the current situation concerning zoonoses and zoonotic agents in the Community.

(13) The results of the data collection system show that certain zoonotic agents, namely *Salmonella* spp. and *Campylobacter* spp., cause the majority of cases of zoonoses in humans. There seems to be a decreasing trend of human cases of salmonellosis, in particular due to *Salmonella enteritidis* and *Salmonella typhimurium*, thus reflecting the success of related control measures taken in the Community. Nevertheless, it is assumed that many cases remain unreported and therefore the data collected do not necessarily give the full picture of the situation.

(14) In its opinion on zoonoses adopted on 12 April 2000, the Scientific Committee on Veterinary Measures relating to Public Health considered that the measures in place at that time to control food-borne zoonotic infections were insufficient. It further considered that the epidemiological data that Member States were collecting were incomplete and not fully comparable. As a consequence, the Committee recommended improved monitoring arrangements and identified risk management options.

(15) It is therefore necessary to improve the existing control systems for specific zoonotic agents. Simultaneously, the rules laid down in Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC [3] will replace the monitoring and data collection systems established by Directive 92/117/EEC.

(16) In principle, controls should cover the whole food chain, from farm to table.

(17) The rules governing such controls should generally be those laid down under Community legislation on feedingstuffs, animal health and food hygiene.

(18) However, for certain zoonoses and zoonotic agents it is necessary to lay down specific requirements for controls.

(19) Those specific requirements should be based on targets for the reduction of the prevalence of zoonoses and zoonotic agents.

(20) The targets should be established for zoonoses and zoonotic agents in animal populations taking account, in particular, of their frequency and epidemiological trends in animal and human populations, feed and food, their gravity for humans, their potential economic consequences, scientific advice and the existence of appropriate measures to reduce their prevalence. Targets may be established in respect of other parts of the food chain, where necessary.

[1] OJ 121, 29.7.1964, p. 1977/64. Directive as last amended by Commission Regulation (EC) No 1226/2002 (OJ L 179, 9.7.2002, p. 13).

[2] OJ L 46, 19.2.1991, p. 19. Directive as last amended by Regulation (EC) No 806/2003.

[3] See page 31 of this Official Journal.

(21) To ensure the achievement of the targets in good time, Member States should set up specific control programmes, which the Community should approve.

(22) The main responsibility for the safety of food should lie with food and feed business operators. Member States should, therefore, encourage the creation of business-wide control programmes.

(23) Within their control programmes, Member States and food and feed business operators may wish to use specific control methods. However, certain methods may not be acceptable, in particular if they hamper the achievement of the target in general, interfere specifically with necessary testing systems or give rise to potential threats to public health. Appropriate procedures should therefore be laid down enabling the Community to decide that certain control methods should not be used as part of control programmes.

(24) Control methods may also exist or be developed which, as such, do not fall under any specific Community legislation on product approval but would help to achieve the targets for the reduction of the prevalence of specified zoonoses and zoonotic agents. It should, therefore, be possible to approve the use of such methods at Community level.

(25) It will be essential to ensure that restocking of animals takes place from flocks or herds that have been subject to controls in accordance with the requirements of this Regulation. When a specific control programme is in force, the results of testing should be forwarded to purchasers of animals. To that end, specific requirements should be added to the corresponding Community legislation on intra-Community trade and imports from third countries, in particular as regards consignments of live animals and hatching eggs. Directive 64/432/EEC, Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries [1] and Council Directive 90/539/EEC of 15 October 1990 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs [2] should be amended accordingly.

(26) The adoption of this Regulation should not affect the additional guarantees agreed for Finland and Sweden on their accession to the Community and confirmed by Commission Decisions 94/968/EC [3], 95/50/EC [4], 95/160/EC [5], 95/161/EC [6], 95/168/EC [7] and by Council Decisions 95/409/EC [8], 95/410/EC [9] and 95/411/EC [10]. This Regulation should provide a procedure for the granting, for a transitional period, of guarantees to any Member State that has an approved national control programme exceeding the minimum Community requirements in relation to salmonella. The results of tests on live animals and hatching eggs traded with such a Member State should meet the criteria laid down in its national control programme. Future Community legislation on hygiene rules for food of animal origin should provide a similar procedure in respect of meat and table eggs.

(27) Third countries exporting to the Community must implement equivalent measures for the control of zoonoses at the same time as measures are applied in the Community.

(28) As regards control of salmonella, available information tends to show that poultry products are a major source of human salmonellosis. Control measures should, therefore, be applied to production of those products, thus extending the measures initiated under Directive 92/117/EEC. As regards the production of table eggs, it is important to establish specific measures concerning the placing on the market of products originating from flocks that have not been tested free of relevant salmonella. As regards poultry meat, the aim is to place on the market poultry meat with reasonable assurance that it is free from relevant salmonella. A transitional period is necessary for food business operators to adapt to the measures envisaged, which may be adapted further in particular in the light of scientific risk assessment.

(29) It is appropriate to designate national and Community reference laboratories to give guidance and assistance on matters falling within the scope of this Regulation.

(30) To ensure the uniform application of this Regulation, provision should be made for the organisation of Community audits and inspections in accordance with other Community legislation in this field.

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[1] OJ L 302, 31.12.1972, p. 28. Directive as last amended by Commission Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

[2] OJ L 303, 31.10.1990, p. 6. Directive as last amended by Regulation (EC) No 806/2003.

[3] OJ L 371, 31.12.1994, p. 36.

[4] OJ L 53, 9.3.1995, p. 31.

[5] OJ L 105 9.5.1995, p. 40. Decision as last amended by Decision 97/278/EC (OJ L 110, 26.4.1997, p. 77).

[6] OJ L 105, 9.5.1995, p. 44. Decision as last amended by Decision 97/278/EC.

[7] OJ L 109, 16.5.1995, p. 44. Decision as last amended by Decision 97/278/EC.

[8] OJ L 243, 11.10.1995, p. 21. Decision as last amended by Decision 98/227/EC (OJ L 87, 21.3.1998, p. 14).

[9] OJ L 243, 11.10.1995, p. 25. Decision as last amended by Decision 98/227/EC.

[10] OJ L 243, 11.10.1995, p. 29. Decision as last amended by Decision 98/227/EC.

(31) Appropriate procedures should be laid down for amending certain provisions of this Regulation to take account of technical and scientific progress and for the adoption of implementing and transitional measures.

(32) To take account of technical and scientific progress, close and effective cooperation should be ensured between the Commission and the Member States within the Standing Committee set up by 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]).

(33) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([2]),

HAVE ADOPTED THIS REGULATION:

CHAPTER I

INTRODUCTORY PROVISIONS

Article 1

Subject matter and scope

1. The purpose of this Regulation is to ensure that proper and effective measures are taken to detect and to control salmonella and other zoonotic agents at all relevant stages of production, processing and distribution, particularly at the level of primary production, including in feed, in order to reduce their prevalence and the risk they pose to public health.

2. This Regulation shall cover:

(a) the adoption of targets for the reduction of the prevalence of specified zoonoses in animal populations:

(i) at the level of primary production; and

(ii) where appropriate for the zoonosis or zoonotic agent concerned, at other stages of the food chain, including in food and feed;

(b) the approval of specific control programmes established by Member States and food and feed business operators;

(c) the adoption of specific rules concerning certain control methods applied in the reduction of the prevalence of zoonoses and zoonotic agents;

(d) the adoption of rules concerning intra-Community trade and imports from third countries of certain animals and products thereof.

3. This Regulation shall not apply to primary production:

(a) for private domestic use; or

(b) leading to the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the primary products to the final consumer.

4. Member States shall establish, under national law, rules governing the activities referred to in paragraph 3(b). Such national rules shall ensure that the objectives of this Regulation are achieved.

5. This Regulation shall apply without prejudice to more specific Community provisions on animal health, animal nutrition, food hygiene, communicable human diseases, health and safety in the workplace, gene technology and transmissible spongiform encephalopathies.

Article 2

Definitions

For the purposes of this Regulation the following definitions shall apply:

1. the definitions laid down in Regulation (EC) No 178/2002;

2. the definitions laid down in Directive 2003/99/EC; and

3. the following definitions:

(a) 'herd' means an animal or group of animals kept on a holding as an epidemiological unit; and

(b) 'flock' means all poultry of the same health status kept on the same premises or in the same enclosure and constituting a single epidemiological unit; in the case of housed poultry, this includes all birds sharing the same airspace.

Article 3

Competent authorities

1. Each Member State shall designate a competent authority or competent authorities for the purpose of this Regulation and notify the Commission thereof. If a Member State designates more than one competent authority, it shall:

(a) notify the Commission of the competent authority that will act as a contact point for contacts with the Commission; and

(b) ensure that the competent authorities cooperate so as to guarantee the proper implementation of the requirements of this Regulation.

2. The competent authority or authorities shall be responsible in particular for:

(a) drawing up the programmes provided for in Article 5(1) and preparing any amendments thereto which prove necessary, in particular in the light of data and results obtained;

([1]) OJ L 31, 1.2.2002, p. 1.
([2]) OJ L 184, 17.7.1999, p. 23.

(b) collecting the data needed to evaluate the means used and the results obtained in carrying out the national control programmes provided for in Article 5 and for submitting those data and results yearly, including the results of any surveys undertaken, to the Commission, having regard to the rules laid down pursuant to Article 9(1) of Directive 2003/99/EC;

(c) carrying out regular checks on the premises of food and, if needed, feed businesses for the purpose of checking compliance with this Regulation.

CHAPTER II

COMMUNITY TARGETS

Article 4

Community targets for the reduction of the prevalence of zoonoses and zoonotic agents

1. Community targets shall be established for the reduction of the prevalence of zoonoses and zoonotic agents listed in Annex I, column 1, in the animal populations listed in Annex I, column 2, taking account, in particular, of:

(a) the experience gained under existing national measures; and

(b) information forwarded to the Commission or to the European Food Safety Authority under existing Community requirements, in particular in the framework of information provided for in Directive 2003/99/EC, in particular Article 5 thereof.

The targets, and any amendments to them, shall be established in accordance with the procedure referred to in Article 14(2).

2. The targets referred to in paragraph 1 shall consist at least of:

(a) a numerical expression of:

(i) the maximum percentage of epidemiological units remaining positive; and/or

(ii) the minimum percentage of reduction in the number of epidemiological units remaining positive;

(b) the maximum time limit within which the target must be achieved;

(c) the definition of the epidemiological units referred to in (a);

(d) the definition of the testing schemes necessary to verify the achievement of the target; and

(e) the definition, where relevant, of serotypes with public health significance or of other subtypes of zoonoses or zoonotic agents listed in Annex I, column 1, having regard to the general criteria listed in paragraph 6(c) and any specific criteria laid down in Annex III.

3. Community targets shall be established for the first time before the relevant dates indicated in Annex I, Column 4.

4. (a) When defining each Community target, the Commission shall provide an analysis of its expected costs and benefits. This analysis shall take account, in particular, of the criteria laid down in paragraph 6(c). Member States shall, on request, provide the Commission with all the assistance necessary to enable it to prepare the analysis.

(b) Before proposing each Community target, the Commission shall consult Member States within the committee referred to in Article 14(1) on the results of its analysis.

(c) In the light of the results of that analysis and the consultation of Member States, the Commission shall propose Community targets where appropriate.

5. However, by way of derogation from paragraphs 2(e) and 4, the following rules shall apply to poultry for a transitional period.

The Community target established for breeding flocks of *Gallus gallus* for this transitional period shall cover the five most frequent salmonella serotypes in human salmonellosis, which shall be identified on the basis of data collected through EC monitoring systems. The Community targets established for laying hens, broilers and turkeys for the transitional period shall cover *Salmonella enteritidis* and *Salmonella typhimurium*. However, if necessary, these targets may be extended to other serotypes on the basis of the results of an analysis carried out in accordance with paragraph 4.

The transitional period shall apply to each Community target for the reduction of the prevalence of salmonella in poultry. It shall last for three years in each case, starting on the date mentioned in column 5 of Annex I.

6. (a) Annex I may be amended, in accordance with the procedure laid down in Article 14(2), for the purposes listed in subparagraph (b), after taking account in particular of the criteria listed in subparagraph (c).

(b) Amendments to Annex I may alter the scope of the requirements regarding the establishment of Community targets by supplementing, restricting or modifying:

(i) the zoonoses or zoonotic agents;

(ii) the stages of the food chain; and/or

(iii) the animal populations concerned.

(c) The criteria to be considered before amending Annex I include, with respect to the zoonosis or zoonotic agent concerned:

(i) its frequency in animal and human populations, feed and food;

(ii) the gravity of its effects for humans;

(iii) its economic consequences for animal and human health care and for feed and food businesses;

(iv) epidemiological trends in animal and human populations, feed and food;

(v) scientific advice;

(vi) technological developments, particularly relating to the practicality of the available control options; and

(vii) requirements and trends concerning breeding systems and production methods.

7. Annex III may be amended or supplemented in accordance with the procedure referred to in Article 14(2).

8. The Commission shall review the implementation of Community targets and take account of this review when proposing further targets.

9. Measures taken to reduce the prevalence of zoonoses and zoonotic agents listed in Annex I shall be implemented in accordance with the rules laid down in this Regulation and any rules adopted pursuant thereto.

CHAPTER III

CONTROL PROGRAMMES

Article 5

National control programmes

1. To achieve the Community targets provided for in Article 4, Member States shall establish national control programmes for each zoonosis and zoonotic agent listed in Annex I. National control programmes shall have regard to the geographical distribution of zoonoses within each Member State and to the financial implications for primary producers and feed and food business operators of establishing effective controls.

2. National control programmes shall be continuous and cover a period of at least three consecutive years.

3. National control programmes shall:

(a) provide for the detection of zoonoses and zoonotic agents in accordance with the requirements and minimum sampling rules laid down in Annex II;

(b) define the respective responsibilities of competent authorities and food and feed business operators;

(c) specify the control measures to be taken following the detection of zoonoses and zoonotic agents, in particular to protect public health, including implementation of the specific measures laid down in Annex II;

(d) allow for the progress under their provisions to be evaluated and for those programmes to be reviewed, in particular in the light of results obtained from the detection of zoonoses and zoonotic agents.

4. National control programmes shall cover at least the following stages of the food chain:

(a) feed production;

(b) primary production of animals;

(c) processing and preparation of food of animal origin.

5. National control programmes shall contain, where relevant, the provisions laid down in relation to testing methods and criteria against which the results of these tests shall be assessed, for testing animals and hatching eggs despatched within the national territory, as part of the official controls provided for in Annex II, part A.

6. The requirements and minimum sampling rules laid down in Annex II may be amended, adapted or supplemented, in accordance with the procedure referred to in Article 14(2), after taking account in particular of the criteria listed in point (c) of Article 4(6).

7. Within six months of the establishment of the Community targets provided for in Article 4, Member States shall submit their national control programmes to the Commission and set out the measures to be implemented.

Article 6

Approval of the national control programmes

1. After a Member State submits a national control programme in accordance with Article 5, the Commission shall have two months within which to request any further relevant and necessary information from that Member State. The Member State shall provide such further information within two months of receiving such a request. The Commission shall, within two months of receiving such further information or, if it did not request further information, within six months of the submission of the control programme, establish whether it complies with relevant rules, including this Regulation in particular.

2. When the Commission has established the conformity of a national control programme, or at the request of the Member State that submitted it, the programme shall be considered without undue delay with a view to approval in accordance with the procedure referred to in Article 14(2).

3. Amendments to a programme previously approved pursuant to paragraph 2 may be approved, in accordance with the procedure referred to in Article 14(2), to take account of the evolution in the situation in the Member State concerned, in particular in the light of the results referred to in Article 5(3)(d).

Article 7

Food and feed business operators' control programmes

1. Food and feed business operators, or organisations representing such operators, may establish control programmes, covering, as far as possible, all stages of production, processing and distribution.

2. If they wish their control programmes to form part of a national control programme, food and feed business operators, or their representative organisations, shall submit their control programmes, and any amendments thereto, to the competent authority of the Member State in which they are located for approval. If the operations concerned take place in different Member States, the programmes shall be approved separately for each Member State.

3. The competent authority may approve control programmes submitted pursuant to paragraph 2 only if it is satisfied that the control programmes comply with the relevant requirements set out in Annex II and with the objectives of the relevant national control programme.

4. Member States shall maintain up-to-date lists of approved control programmes of food and feed business operators or their representative organisations. The lists shall be made available to the Commission upon request.

5. Food and feed business operators or their representative organisations shall communicate regularly the results of their control programmes to the competent authorities.

CHAPTER IV

CONTROL METHODS

Article 8

Specific control methods

1. At the initiative of the Commission or at the request of a Member State and in accordance with the procedure referred to in Article 14(2):

(a) it may be decided that specific control methods may or shall be applied for the reduction of prevalence of zoonoses and zoonotic agents at the stage of the primary production of animals and other stages in the food chain;

(b) rules may be adopted concerning the conditions for the use of the methods referred to in subparagraph (a);

(c) detailed rules may be adopted concerning necessary documents and procedures as well as minimum requirements for the methods referred to in subparagraph (a); and

(d) it may be decided that certain specific control methods shall not be used as a part of control programmes.

2. The provisions referred to in paragraph 1(a), (b) and (c) shall not apply to methods using substances or techniques covered by Community legislation on animal nutrition, food additives or veterinary medicinal products.

CHAPTER V

TRADE

Article 9

Intra-Community trade

1. As from the dates mentioned in Annex I, column 5, at the latest, flocks and herds of origin of the species listed in column 2 shall be tested for the zoonoses and zoonotic agents listed in column 1 prior to any dispatching of the live animals, or hatching eggs, from the food business of origin. The date and the result of testing shall be included in the relevant health certificates provided for in Community legislation.

2. The Member State of destination may, in accordance with the procedure referred to in Article 14(2), be authorised for a transitional period to require that the results of the tests to be referred to in the relevant health certificates for consignments of animals and hatching eggs subject to testing in the Member State of dispatch fulfil the same criteria as regards salmonella as those laid down under its approved national programme, in accordance with Article 5(5), for consignments despatched within its territory.

The authorisation may be withdrawn in accordance with the same procedure.

3. The special measures concerning salmonella that applied to live animals dispatched to Finland and Sweden prior to the entry into force of this Regulation shall continue to apply as if they had been authorised in accordance with paragraph 2.

4. Without prejudice to Article 5(6), specific rules concerning the setting by Member States of the criteria referred to in Article 5(5) and in paragraph 2 above, may be laid down in accordance with the procedure referred to in Article 14(2).

Article 10

Imports from third countries

1. As from the dates mentioned in Annex I, column 5, admission to or retention on the lists of third countries provided for in Community legislation, for the relevant species or category, from which Member States are authorised to import those animals or hatching eggs covered by this Regulation shall be subject to submission to the Commission by the third country concerned of a programme equivalent to those provided for under Article 5 and its approval in accordance with this Article. The programme shall give details of the guarantees offered by that country as regards inspections and controls for zoonoses and zoonotic agents. Those guarantees must be at least equivalent to the guarantees provided for by this Regulation. The Food and Veterinary Office of the Commission shall be closely involved in monitoring to verify whether equivalent control programmes exist in third countries.

2. These programmes shall be approved in accordance with the procedure referred to in Article 14(2), provided that the equivalence of the measures described under the programme, with the relevant requirements applicable under Community rules, is objectively demonstrated. Alternative guarantees to those provided for in this Regulation may be allowed in accordance with that procedure, provided that they are not more favourable than those applicable to intra-Community trade.

3. For third countries with which a regular trade flow is established, the provisions of Article 5(7) and Article 6(1) concerning time periods for the submission and approval of programmes shall apply. For third countries establishing or resuming a trade flow, the time periods provided for in Article 6 shall apply.

4. Flocks and herds of origin of species listed in Annex I, column 2, shall be tested prior to any dispatching of the live animals or hatching eggs from the food business of origin. Flocks and herds shall be tested for the zoonoses and zoonotic agents listed in Annex I, column 1, or, if necessary to achieve the objective of equivalent guarantees laid down in paragraph 1, such zoonoses and zoonotic agents as may be specified in accordance with the procedure referred to in Article 14(2). The date and the result of testing shall be included in the relevant import certificates, for which the models laid down by Community legislation shall be amended accordingly.

5. The Member State of final destination may be authorised, in accordance with the procedure referred to in Article 14(2), to require for a transitional period that the results of the testing referred to in paragraph 4 fulfil the same criteria as those laid down under its national programme, in accordance with Article 5(5). The authorisation may be withdrawn and, without prejudice to Article 5(6), specific rules concerning such criteria may be laid down, in accordance with the procedure referred to in Article 14(2).

6. Admission to or retention on the lists of third countries provided for in Community legislation, for the relevant category of products, from which Member States are authorised to import those products covered by this Regulation shall be subject to submission to the Commission by the third country concerned of guarantees equivalent to those provided for by this Regulation.

CHAPTER VI

LABORATORIES

Article 11

Reference laboratories

1. Community reference laboratories for the analysis and testing of zoonoses and zoonotic agents listed in Annex I, column 1, shall be designated in accordance with the procedure referred to in Article 14(2).

2. The responsibilities and tasks of the Community reference laboratories, in particular with regard to coordination of their activities and those of the national reference laboratories, shall be laid down in accordance with the procedure referred to in Article 14(2).

3. Member States shall designate national reference laboratories for the analysis and testing of zoonoses and zoonotic agents listed in Annex I, column 1. The names and addresses of laboratories shall be communicated to the Commission.

4. Certain responsibilities and tasks of the national reference laboratories, in particular with regard to coordination of their activities and those of the relevant laboratories in the Member States designated under Article 12(1)(a), may be laid down in accordance with the procedure referred to in Article 14(2).

Article 12

Approval of laboratories, quality requirements and approved testing methods

1. Laboratories participating in control programmes pursuant to Articles 5 and 7 shall, for the purposes of analysing samples to test for the presence of zoonoses and zoonotic agents referred to in Annex I, column 1:

(a) be designated by the competent authority; and

(b) apply quality assurance systems that conform to the requirements of the current EN/ISO standard at the latest within 24 months of entry into force of this Regulation or within 24 months of the addition of new zoonoses or zoonotic agents to Annex I, column 1.

2. Laboratories shall regularly participate in collaborative testing organised or coordinated by the national reference laboratory.

3. Testing for the presence of zoonoses and zoonotic agents referred to in Annex I, column 1, shall be carried out using the methods and protocols recommended by international standardisation bodies, as reference methods.

Alternative methods may be used if they have been validated in accordance with internationally recognised rules and offer equivalent results to those obtained by the relevant reference method.

Where necessary, other methods for testing may be approved in accordance with the procedure referred to in Article 14(2).

CHAPTER VII

IMPLEMENTATION

Article 13

Implementing and transitional measures

Appropriate transitional or implementing measures, including the necessary amendments to the relevant health certificates, may be adopted in accordance with the procedure referred to in Article 14(2).

Article 14

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Regulation (EC) No 178/2002 (hereinafter referred to as 'the Committee').

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

Article 15

Consultation of the European Food Safety Authority

The Commission shall consult the European Food Safety Authority on any matter within the scope of this Regulation that could have a significant impact on public health and, in particular, before proposing Community targets in accordance with Article 4 or specific control methods in accordance with Article 8.

Article 16

Report on financial arrangements

1. The Commission shall, within three years of the entry into force of this Regulation, submit a report to the European Parliament and to the Council.

2. The report shall discuss:

(a) the arrangements in place, at Community and national level, to finance measures taken to control zoonoses and zoonotic agents; and

(b) the effect that such arrangements have on the effectiveness of those measures.

3. The Commission shall, if appropriate, accompany its report with relevant proposals.

4. Member States shall, on request, provide the Commission with all the assistance necessary to enable it to prepare its report.

CHAPTER VIII

GENERAL AND FINAL PROVISIONS

Article 17

Community controls

1. Experts from the Commission shall carry out on-the-spot checks, in cooperation with the competent authorities of Member States, in order to ensure that the provisions of this Regulation, rules adopted pursuant thereto and any safeguard measures are applied uniformly. A Member State on whose territory checks are made shall provide the experts with all the assistance necessary for carrying out their duties. The Commission shall inform the competent authority of the results of the checks made.

2. Rules for the implementation of this Article, in particular those governing the procedure for cooperation with national competent authorities, shall be laid down under the procedure referred to in Article 14(2).

Article 18

Entry into force

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply as from six months following its entry into force.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 17 November 2003.

For the European Parliament	*For the Council*
The President	*The President*
P. COX	G. ALEMANNO

ANNEX I

Specified zoonoses and zoonotic agents for which Community targets for the reduction of prevalence are to be established pursuant to Article 4

1. Zoonosis or zoonotic agent	2. Animal population	3. Stage of food chain	4. Date by which target must be established (*)	5. Date from which testing must take place
All salmonella serotypes with public health significance	Breeding flocks of *Gallus gallus*	Primary production	12 months after the date of entry into force of this Regulation.	18 months after the date referred to in column 4
All salmonella serotypes with public health significance	Laying hens	Primary production	24 months after the date of entry into force of this Regulation.	18 months after the date referred to in column 4
All salmonella serotypes with public health significance	Broilers	Primary production	36 months after the date of entry into force of this Regulation.	18 months after the date referred to in column 4
All salmonella serotypes with public health significance	Turkeys	Primary production	48 months after the date of entry into force of this Regulation.	18 months after the date referred to in column 4
All salmonella serotypes with public health significance	Herds of slaughter pigs	Slaughter	48 months after the date of entry into force of this Regulation.	18 months after the date referred to in column 4
All salmonella serotypes with public health significance	Breeding herds of pigs	Primary production	60 months after the date of entry into force of this Regulation.	18 months after the date referred to in column 4

(*) These dates are based on the assumption that comparable data on prevalence will be available at least six months before the establishment of the target. If such data were not available, the date for the establishment of the target would be postponed accordingly.

ANNEX II

CONTROL OF ZOONOSES AND ZOONOTIC AGENTS LISTED IN ANNEX I

A. **General requirements for national control programmes**

The programme must take into account the nature of the zoonosis and/or zoonotic agent concerned and the specific situation in the Member State. It must:

(a) state the aim of the programme taking into consideration the importance of the zoonosis or zoonotic agent concerned;

(b) comply with the minimum sampling requirements laid down in part B;

(c) where relevant, comply with the specific requirements laid down in parts C to E; and

(d) specify the following points:

1. *General*

1.1. The occurrence of the zoonosis or zoonotic agent concerned in the Member State with specific reference to the results obtained in the framework of monitoring in accordance with Article 4 of Directive 2003/99/EC.

1.2. The geographical area or, where appropriate, the epidemiological units, in which the programme will be implemented.

1.3. The structure and organisation of the relevant competent authorities.

1.4. Approved laboratories where samples collected within the programme are analysed.

1.5. Methods used in the examination of the zoonosis or zoonotic agent.

1.6. Official controls (including sampling schemes) at feed, flock and/or herd level.

1.7. Official controls (including sampling schemes) at other stages of the food chain.

1.8. Measures taken by the competent authorities with regard to animals or products in which zoonoses or zoonotic agents have been detected, in particular to protect public health; and any preventive measures taken, such as vaccination.

1.9. Relevant national legislation, including any national provisions concerning the activities referred to in Article 1(3)(b).

1.10. Any financial assistance provided to food and feed businesses in the context of the national control programme;

2. *Concerning food and feed businesses covered by the programme*

2.1. The structure of the production of the given species and products thereof.

2.2. The structure of the production of feed.

2.3. Relevant guides for good animal husbandry practices or other guidelines (mandatory or voluntary) defining at least:

— hygiene management at farms,

— measures to prevent incoming infections carried by animals, feed, drinking water, people working at farms, and

— hygiene in transporting animals to and from farms.

2.4. Routine veterinary supervision of farms.

2.5. Registration of farms.

2.6. Record-keeping at farms.

2.7. Documents to accompany animals when dispatched.

2.8. Other relevant measures to ensure the traceability of animals.

B. **Minimum sampling requirements**

1. After the relevant control programme referred to in Article 5 has been approved, food business operators must have samples taken and analysed to test for the zoonoses and zoonotic agents listed in Annex I, column 1, respecting the minimum sampling requirements set out in the following table.

1. Zoonosis or zoonotic agent	2. Animal population	3. Phases of production which sampling must cover
All salmonella serotypes with public health significance	Breeding flocks of *Gallus gallus*:	
	— rearing flocks	— day-old chicks — four-week-old birds — two weeks before moving to laying phase or laying unit
	— adult breeding flocks	— every second week during the laying period
All salmonella serotypes with public health significance	Laying hens:	
	— rearing flocks	— day-old chicks — pullets two weeks before moving to laying phase or laying unit
	— laying flocks	— every 15 weeks during the laying phase
All salmonella serotypes with public health significance	Broilers	— birds leaving for slaughter (*)
All salmonella serotypes with public health significance	Turkeys	— birds leaving for slaughter (*)
All salmonella serotypes with public health significance	Herds of pigs: — breeding pigs — slaughter pigs	 — animals leaving for slaughter or carcases at the slaughterhouse — animals leaving for slaughter or carcases at the slaughterhouse

(*) The results of the analysis on the samples must be known before the animals leave for the slaughterhouse.

2. The requirements laid down in point 1 are without prejudice to the requirements of Community legislation concerning *ante mortem* inspection.

3. The results of the analysis must be recorded, together with the following information:

(a) date and place of sampling; and

(b) identification of the flock/herd.

4. Immunological testing may not be used if the animals have been vaccinated, unless it has been proven that the vaccine used does not interfere with the testing method applied.

C. **Specific requirements concerning breeding flocks of *Gallus gallus***

1. The measures laid down in points 3 to 5 must be taken whenever the analysis of samples carried out in accordance with part B indicates the presence of *Salmonella enteritidis* or *Salmonella typhimurium* in a breeding flock of *Gallus gallus* in the circumstances set out in point 2.

2. (a) If the competent authority has approved the method of analysis used for samples taken in accordance with part B, it may require that the measures laid down in points 3 to 5 be taken when such analysis detects the presence of *Salmonella enteritidis* or *Salmonella typhimurium*.

   (b) Otherwise, the measures laid down in points 3 to 5 must be taken whenever the competent authority confirms a suspicion of the presence of *Salmonella enteritidis* or *Salmonella typhimurium* arising from the analysis of samples carried out in accordance with part B.

3. Non-incubated eggs from the flock must be destroyed.

   However, such eggs may be used for human consumption if they are treated in a manner that guarantees the elimination of *Salmonella enteritidis* and *Salmonella typhimurium* in accordance with Community legislation on food hygiene.

4. All birds, including day-old chicks, in the flock must be slaughtered or destroyed so as to reduce as much as possible the risk of spreading salmonella. Slaughtering must be carried out in accordance with Community legislation on food hygiene. Products derived from such birds may be placed on the market for human consumption in accordance with Community legislation on food hygiene and, once applicable, part E. If not destined for human consumption, such products must be used or disposed of in accordance with Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption ([1]).

5. Where eggs for hatching from flocks in which *Salmonella enteritidis* or *Salmonella typhimurium* is present are still present in a hatchery, they must be destroyed or treated in accordance with Regulation (EC) No 1774/2002.

D. **Specific requirements concerning flocks of laying hens**

1. With effect from 72 months after entry into force of this Regulation, eggs must not be used for direct human consumption (as table eggs) unless they originate from a commercial flock of laying hens subject to a national programme established under Article 5 and not under official restriction.

2. Eggs originating from flocks with unknown health status, that are suspected of being infected or from infected flocks may be used for human consumption only if treated in a manner that guarantees the elimination of all salmonella serotypes with public health significance in accordance with Community legislation on food hygiene.

3. When birds from infected flocks are slaughtered or destroyed, steps must be taken to reduce the risk of spreading zoonoses as far as possible. Slaughtering must be carried out in accordance with Community legislation on food hygiene. Products derived from such birds may be placed on the market for human consumption in accordance with Community legislation on food hygiene and, once applicable, part E. If not destined for human consumption, such products must be used or disposed of in accordance with Regulation (EC) No 1774/2002.

E. **Specific requirement concerning fresh meat**

1. With effect from 84 months after entry into force of this Regulation, fresh poultry meat from animals listed in Annex I may not be placed on the market for human consumption unless it meets the following criterion:

   'Salmonella: absence in 25 grams'

2. Within 72 months of entry into force of this Regulation, detailed rules for this criterion will be laid down in accordance with the procedure referred to in Article 14(2). These will specify, in particular, sampling schemes and analytical methods.

3. The criterion laid down in paragraph 1 does not apply to fresh poultry meat destined for industrial heat treatment or another treatment to eliminate salmonella in accordance with Community legislation on food hygiene.

([1]) OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 808/2003 (OJ L 117, 13.5.2003, p. 1).

ANNEX III

Specific criteria to determine salmonella serotypes with public health significance

When determining which are the salmonella serotypes with public health significance to which Community targets will apply, account must be taken of the following criteria:

1. the most frequent salmonella serotypes in human salmonellosis on the basis of data collected through EC monitoring systems;
2. the route of infection (that is, the presence of the serotype in relevant animal populations and feed);
3. whether any serotype shows a rapid and recent ability to spread and to cause disease in humans and animals;
4. whether any serotypes show increased virulence, for instance as regards invasiveness, or resistance to relevant therapies for human infections.

COMMISSION REGULATION (EC) No 2161/2003

of 11 December 2003

establishing the standard import values for determining the entry price of certain fruit and vegetables

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Commission Regulation (EC) No 3223/94 of 21 December 1994 on detailed rules for the application of the import arrangements for fruit and vegetables [1], as last amended by Regulation (EC) No 1947/2002 [2], and in particular Article 4(1) thereof,

Whereas:

(1) Regulation (EC) No 3223/94 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in the Annex thereto.

(2) In compliance with the above criteria, the standard import values must be fixed at the levels set out in the Annex to this Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 4 of Regulation (EC) No 3223/94 shall be fixed as indicated in the Annex hereto.

Article 2

This Regulation shall enter into force on 12 December 2003.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 11 December 2003.

For the Commission
J. M. SILVA RODRÍGUEZ
Agriculture Director-General

[1] OJ L 337, 24.12.1994, p. 66.
[2] OJ L 299, 1.11.2002, p. 17.

ANNEX

to the Commission Regulation of 11 December 2003 establishing the standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	052	79,5
	204	61,9
	212	114,0
	624	111,0
	999	91,6
0707 00 05	052	129,4
	999	129,4
0709 90 70	052	124,8
	204	121,3
	999	123,1
0805 10 10, 0805 10 30, 0805 10 50	052	39,3
	204	40,9
	388	38,1
	999	39,4
0805 20 10	052	62,0
	204	58,4
	999	60,2
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	052	70,2
	464	122,4
	999	96,3
0805 50 10	052	70,0
	388	77,8
	400	41,8
	600	72,7
	999	65,6
0808 10 20, 0808 10 50, 0808 10 90	052	50,2
	060	37,0
	064	51,0
	400	77,9
	404	84,6
	720	76,5
	800	135,4
	999	73,2
0808 20 50	052	90,0
	060	49,1
	064	60,8
	400	104,9
	528	218,0
	720	129,9
	999	108,8

(1) Country nomenclature as fixed by Commission Regulation (EC) No 2020/2001 (OJ L 273, 16.10.2001, p. 6). Code '999' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 2162/2003
of 11 December 2003
fixing the definitive aid on certain grain legumes for the marketing year 2003/04

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1577/96 of 30 July 1996 introducing a specific measure in respect of certain grain legumes [1], and in particular Article 6(1) thereof,

Whereas:

(1) Article 3 of Regulation (EC) No 1577/96 divides the maximum guaranteed area between lentils and chickpeas on the one hand and vetches on the other hand, allowing the unused balance of one maximum guaranteed area to be reallocated to the other maximum guaranteed area before an overrun is determined.

(2) The maximum guaranteed area for lentils and chickpeas referred to in Article 3 of Regulation (EC) No 1577/96 was not exceeded in 2003/04, whereas the maximum guaranteed area for vetches, increased by the unused balance of the maximum guaranteed area for lentils and chickpeas, was exceeded by 10,37 % in 2003/04. The aid provided for in Article 2(2) of Regulation (EC) No 1577/96 should therefore be reduced proportionately for vetches for the marketing year in question.

(3) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Cereals,

HAS ADOPTED THIS REGULATION:

Article 1

The definitive aid for certain grain legumes for the marketing year 2003/04 shall be EUR 181,00 per hectare for lentils and chickpeas and EUR 163,99 per hectare for vetches.

Article 2

This Regulation shall enter into force on the third day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 11 December 2003.

For the Commission
Franz FISCHLER
Member of the Commission

[1] OJ L 206, 16.8.1996, p. 4; Regulation as last amended by Regulation (EC) No 811/2000 (OJ L 100, 20.4.2000, p. 1).

COMMISSION REGULATION (EC) No 2163/2003
of 11 December 2003
fixing the representative prices and the additional import duties for molasses in the sugar sector

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1260/2001 of 19 June 2001 on the common organisation of the market in sugar [1], as amended by Commission Regulation (EC) No 680/2002 [2],

Having regard to Commission Regulation (EC) No 1422/95 of 23 June 1995 laying down detailed rules of application for imports of molasses in the sugar sector and amending Regulation (EEC) No 785/68 [3], as amended by Regulation (EC) No 79/2003 [4], and in particular Article 1(2) and Article 3(1) thereof,

Whereas:

(1) Regulation (EC) No 1422/95 stipulates that the cif import price for molasses, hereinafter referred to as the 'representative price', should be set in accordance with Commission Regulation (EEC) No 785/68 [5]. That price should be fixed for the standard quality defined in Article 1 of the above Regulation.

(2) The representative price for molasses is calculated at the frontier crossing point into the Community, in this case Amsterdam; that price must be based on the most favourable purchasing opportunities on the world market established on the basis of the quotations or prices on that market adjusted for any deviations from the standard quality. The standard quality for molasses is defined in Regulation (EEC) No 785/68.

(3) When the most favourable purchasing opportunities on the world market are being established, account must be taken of all available information on offers on the world market, on the prices recorded on important third-country markets and on sales concluded in international trade of which the Commission is aware, either directly or through the Member States. Under Article 7 of Regulation (EEC) No 785/68, the Commission may for this purpose take an average of several prices as a basis, provided that this average is representative of actual market trends.

(4) The information must be disregarded if the goods concerned are not of sound and fair marketable quality or if the price quoted in the offer relates only to a small quantity that is not representative of the market. Offer prices which can be regarded as not representative of actual market trends must also be disregarded.

(5) If information on molasses of the standard quality is to be comparable, prices must, depending on the quality of the molasses offered, be increased or reduced in the light of the results achieved by applying Article 6 of Regulation (EEC) No 785/68.

(6) A representative price may be left unchanged by way of exception for a limited period if the offer price which served as a basis for the previous calculation of the representative price is not available to the Commission and if the offer prices which are available and which appear not to be sufficiently representative of actual market trends would entail sudden and considerable changes in the representative price.

(7) Where there is a difference between the trigger price for the product in question and the representative price, additional import duties should be fixed under the conditions set out in Article 3 of Regulation (EC) No 1422/95. Should the import duties be suspended pursuant to Article 5 of Regulation (EC) No 1422/95, specific amounts for these duties should be fixed.

(8) Application of these provisions will have the effect of fixing the representative prices and the additional import duties for the products in question as set out in the Annex to this Regulation.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Sugar,

HAS ADOPTED THIS REGULATION:

Article 1

The representative prices and the additional duties applying to imports of the products referred to in Article 1 of Regulation (EC) No 1422/95 are fixed in the Annex hereto.

Article 2

This Regulation shall enter into force on 12 December 2003.

[1] OJ L 178, 30.6.2001, p. 1.
[2] OJ L 104, 20.4.2002, p. 26.
[3] OJ L 141, 24.6.1995, p. 12.
[4] OJ L 13, 18.1.2003, p. 4.
[5] OJ L 145, 27.6.1968, p. 12.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 11 December 2003.

For the Commission
J. M. SILVA RODRÍGUEZ
Agriculture Director-General

ANNEX

to the Commission Regulation of 11 December 2003 fixing the representative prices and additional import duties to imports of molasses in the sugar sector

(in EUR)

CN code	Amount of the representative price in 100 kg net of the product in question	Amount of the additional duty in 100 kg net of the product in question	Amount of the duty to be applied to imports in 100 kg net of the product in question because of suspension as referred to in Article 5 of Regulation (EC) No 1422/95 (2)
1703 10 00 (1)	5,88	0,37	—
1703 90 00 (1)	8,33	—	0

(1) For the standard quality as defined in Article 1 of amended Regulation (EEC) No 785/68.
(2) This amount replaces, in accordance with Article 5 of Regulation (EC) No 1422/95, the rate of the Common Customs Tariff duty fixed for these products.

COMMISSION REGULATION (EC) No 2164/2003
of 11 December 2003
fixing the export refunds on white sugar and raw sugar exported in its unaltered state

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1260/2001 of 19 June 2001 on the common organisation of the markets in the sugar sector [1], and in particular the second subparagraph of Article 27(5) thereof,

Whereas:

(1) Article 27 of Regulation (EC) No 1260/2001 provides that the difference between quotations or prices on the world market for the products listed in Article 1(1)(a) of that Regulation and prices for those products within the Community may be covered by an export refund.

(2) Regulation (EC) No 1260/2001 provides that when refunds on white and raw sugar, undenatured and exported in its unaltered state, are being fixed account must be taken of the situation on the Community and world markets in sugar and in particular of the price and cost factors set out in Article 28 of that Regulation. The same Article provides that the economic aspect of the proposed exports should also be taken into account.

(3) The refund on raw sugar must be fixed in respect of the standard quality. The latter is defined in Annex I, point II, to Regulation (EC) No 1260/2001. Furthermore, this refund should be fixed in accordance with Article 28(4) of that Regulation. Candy sugar is defined in Commission Regulation (EC) No 2135/95 of 7 September 1995 laying down detailed rules of application for the grant of export refunds in the sugar sector [2]. The refund thus calculated for sugar containing added flavouring or colouring matter must apply to their sucrose content and, accordingly, be fixed per 1 % of the said content.

(4) In special cases, the amount of the refund may be fixed by other legal instruments.

(5) The refund must be fixed every two weeks. It may be altered in the intervening period.

(6) The first subparagraph of Article 27(5) of Regulation (EC) No 1260/2001 provides that refunds on the products referred to in Article 1 of that Regulation may vary according to destination, where the world market situation or the specific requirements of certain markets make this necessary.

(7) The significant and rapid increase in preferential imports of sugar from the western Balkan countries since the start of 2001 and in exports of sugar to those countries from the Community seems to be highly artificial.

(8) To prevent any abuse through the re-import into the Community of sugar products in receipt of an export refund, no refund should be set for all the countries of the western Balkans for the products covered by this Regulation.

(9) Import duties and export refunds still apply to certain sugar products traded between the Community, of the one part, and the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia, hereinafter referred to as 'new Member States', of the other part, and the level of export refunds is appreciably greater than the level of import duties. In view of the accession of these countries to the Community on 1 May 2004, the appreciable gap between the level of import duties and the level of export refunds granted for the products in question may result in speculative trade flows.

(10) To prevent any abuse through the re-import or re-introduction into the Community of sugar products in receipt of an export refund, no refund or levy should be set for all the new Member States for the products covered by this Regulation.

(11) In view of the above and of the present situation on the market in sugar, and in particular of the quotations or prices for sugar within the Community and on the world market, refunds should be set at the appropriate amounts.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Sugar,

HAS ADOPTED THIS REGULATION:

Article 1

The export refunds on the products listed in Article 1(1)(a) of Regulation (EC) No 1260/2001, undenatured and exported in the natural state, are hereby fixed to the amounts shown in the Annex hereto.

Article 2

This Regulation shall enter into force on 12 December 2003.

[1] OJ L 178, 30.6.2001, p. 1. Regulation as amended by Commission Regulation (EC) No 680/2002 (OJ L 104, 20.4.2002, p. 26).
[2] OJ L 214, 8.9.1995, p. 16.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 11 December 2003.

For the Commission
Franz FISCHLER
Member of the Commission

ANNEX

REFUNDS ON WHITE SUGAR AND RAW SUGAR EXPORTED WITHOUT FURTHER PROCESSING APPLICABLE FROM 12 DECEMBER 2003

Product code	Destination	Unit of measurement	Amount of refund
1701 11 90 9100	S00	EUR/100 kg	44,89 (1)
1701 11 90 9910	S00	EUR/100 kg	44,91 (1)
1701 12 90 9100	S00	EUR/100 kg	44,89 (1)
1701 12 90 9910	S00	EUR/100 kg	44,91 (1)
1701 91 00 9000	S00	EUR/1 % of sucrose × 100 kg product net	0,4879
1701 99 10 9100	S00	EUR/100 kg	48,79
1701 99 10 9910	S00	EUR/100 kg	48,82
1701 99 10 9950	S00	EUR/100 kg	48,82
1701 99 90 9100	S00	EUR/1 % of sucrose × 100 kg of net product	0,4879

NB: The product codes and the 'A' series destination codes are set out in Commission Regulation (EEC) No 3846/87 (OJ L 366, 24.12.1987, p. 1).

The numeric destination codes are set out in Commission Regulation (EC) No 1779/2002 (OJ L 269, 5.10.2002, p. 6).

The other destinations are:

S00: all destinations (third countries, other territories, victualling and destinations treated as exports from the Community) with the exception of Albania, Croatia, Bosnia and Herzegovina, Serbia and Montenegro (including Kosovo, as defined in UN Security Council Resolution 1244 of 10 June 1999), the former Yugoslav Republic of Macedonia, the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia, save for sugar incorporated in the products referred to in Article 1(2)(b) of Council Regulation (EC) No 2201/96 (OJ L 297, 21.11.1996, p. 29).

(1) This amount is applicable to raw sugar with a yield of 92 %. Where the yield for exported raw sugar differs from 92 %, the refund amount applicable shall be calculated in accordance with Article 28(4) of Regulation (EC) No 1260/2001.

COMMISSION REGULATION (EC) No 2165/2003

of 11 December 2003

fixing the maximum export refund for white sugar to certain third countries for the 16th partial invitation to tender issued within the framework of the standing invitation to tender provided for in Regulation (EC) No 1290/2003

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1260/2001 of 19 June 2001 on the common organisation of the markets in the sugar sector [1], as amended by Commission Regulation (EC) No 680/2002 [2], and in particular Article 27(5) thereof,

Whereas:

(1) Commission Regulation (EC) No 1290/2003 of 18 July 2003 on a standing invitation to tender to determine levies and/or refunds on exports of white sugar [3], for the 2003/2004 marketing year, requires partial invitations to tender to be issued for the export of this sugar to certain third countries.

(2) Pursuant to Article 9(1) of Regulation (EC) No 1290/2003 a maximum export refund shall be fixed, as the case may be, account being taken in particular of the state and foreseeable development of the Community and world markets in sugar, for the partial invitation to tender in question.

(3) Following an examination of the tenders submitted in response to the 16th partial invitation to tender, the provisions set out in Article 1 should be adopted.

(4) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Sugar,

HAS ADOPTED THIS REGULATION:

Article 1

For the 16th partial invitation to tender for white sugar issued pursuant to Regulation (EC) No 1290/2003 the maximum amount of the export refund to certain third countries is fixed at 51,850 EUR/100 kg.

Article 2

This Regulation shall enter into force on 12 December 2003.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 11 December 2003.

For the Commission
Franz FISCHLER
Member of the Commission

[1] OJ L 178, 30.6.2001, p. 1.
[2] OJ L 104, 20.4.2002, p. 26.
[3] OJ L 181, 19.7.2003, p. 7.

COMMISSION REGULATION (EC) No 2166/2003
of 11 December 2003
fixing the export refunds on milk and milk products

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1255/1999 of 17 May 1999 on the common organisation of the market in milk and milk products [1], as last amended by Regulation (EC) No 1787/2003 [2], and in particular Article 31(3) thereof,

Whereas:

(1) Article 31 of Regulation (EC) No 1255/1999 provides that the difference between prices in international trade for the products listed in Article 1 of that Regulation and prices for those products within the Community may be covered by an export refund within the limits resulting from agreements concluded in accordance with Article 300 of the Treaty.

(2) Regulation (EC) No 1255/1999 provides that when the refunds on the products listed in Article 1 of the abovementioned Regulation, exported in the natural state, are being fixed, account must be taken of:

— the existing situation and the future trend with regard to prices and availabilities of milk and milk products on the Community market and prices for milk and milk products in international trade,

— marketing costs and the most favourable transport charges from Community markets to ports or other points of export in the Community, as well as costs incurred in placing the goods on the market of the country of destination,

— the aims of the common organisation of the market in milk and milk products which are to ensure equilibrium and the natural development of prices and trade on this market,

— the limits resulting from agreements concluded in accordance with Article 300 of the Treaty, and

— the need to avoid disturbances on the Community market, and

— the economic aspect of the proposed exports.

(3) Article 31(5) of Regulation (EC) No 1255/1999 provides that when prices within the Community are being determined account should be taken of the ruling prices which are most favourable for exportation, and that when prices in international trade are being determined particular account should be taken of:

(a) prices ruling on third country markets;

(b) the most favourable prices in third countries of destination for third country imports;

(c) producer prices recorded in exporting third countries, account being taken, where appropriate, of subsidies granted by those countries; and

(d) free-at-Community-frontier offer prices.

(4) Article 31(3) of Regulation (EC) No 1255/1999 provides that the world market situation or the specific requirements of certain markets may make it necessary to vary the refund on the products listed in Article 1 of the abovementioned Regulation according to destination.

(5) Article 31(3) of Regulation (EC) No 1255/1999 provides that the list of products on which export refunds are granted and the amount of such refunds should be fixed at least once every four weeks; the amount of the refund may, however, remain at the same level for more than four weeks.

(6) In accordance with Article 16 of Commission Regulation (EC) No 174/1999 of 26 January 1999 on specific detailed rules for the application of Council Regulation (EC) No 804/68 as regards export licences and export refunds on milk and milk products [3], as last amended by Regulation (EC) No 1392/2003 [4], the refund granted for milk products containing added sugar is equal to the sum of the two components; one is intended to take account of the quantity of milk products and is calculated by multiplying the basic amount by the milk products content in the product concerned; the other is intended to take account of the quantity of added sucrose and is calculated by multiplying the sucrose content of the entire product by the basic amount of the refund valid on the day of exportation for the products listed in Article 1(1)(d) of Council Regulation (EC) No 1260/2001 of 19 June 2001 on the common organisation of the markets in the sugar sector [5], as amended by Commission Regulation (EC) No 680/2002 [6], however, this second component is applied only if the added sucrose has been produced using sugar beet or cane harvested in the Community.

[1] OJ L 160, 26.6.1999, p. 48.
[2] OJ L 270, 21.10.2003, p. 121.
[3] OJ L 20, 27.1.1999, p. 8.
[4] OJ L 197, 5.8.2003, p. 3.
[5] OJ L 178, 30.6.2001, p. 1.
[6] OJ L 104, 20.4.2002, p. 26.

(7) Commission Regulation (EEC) No 896/84 [1], as last amended by Regulation (EEC) No 222/88 [2], laid down additional provisions concerning the granting of refunds on the change from one milk year to another; those provisions provide for the possibility of varying refunds according to the date of manufacture of the products.

(8) For the calculation of the refund for processed cheese provision must be made where casein or caseinates are added for that quantity not to be taken into account.

(9) It follows from applying the rules set out above to the present situation on the market in milk and in particular to quotations or prices for milk products within the Community and on the world market that the refund should be as set out in the Annex to this Regulation.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Milk and Milk Products,

HAS ADOPTED THIS REGULATION:

Article 1

The export refunds referred to in Article 31 of Regulation (EC) No 1255/1999 on products exported in the natural state shall be as set out in the Annex.

Article 2

This Regulation shall enter into force on 12 December 2003.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 11 December 2003.

For the Commission
Franz FISCHLER
Member of the Commission

[1] OJ L 91, 1.4.1984, p. 71.
[2] OJ L 28, 1.2.1988, p. 1.

ANNEX

to the Commission Regulation of 11 December 2003 fixing the export refunds on milk and milk products

Product code	Destination	Unit of measurement	Amount of refund
0401 10 10 9000	970	EUR/100 kg	1,911
0401 10 90 9000	970	EUR/100 kg	1,911
0401 20 11 9100	970	EUR/100 kg	0,000
0401 20 11 9500	970	EUR/100 kg	2,953
0401 20 19 9100	970	EUR/100 kg	0,000
0401 20 19 9500	970	EUR/100 kg	2,953
0401 20 91 9000	970	EUR/100 kg	3,737
0401 20 99 9000	970	EUR/100 kg	0,000
0401 30 11 9400	970	EUR/100 kg	8,624
0401 30 11 9700	970	EUR/100 kg	12,95
0401 30 19 9700	970	EUR/100 kg	0,00
0401 30 31 9100	L06	EUR/100 kg	31,46
0401 30 31 9400	L06	EUR/100 kg	49,14
0401 30 31 9700	L06	EUR/100 kg	54,20
0401 30 39 9100	L06	EUR/100 kg	31,46
0401 30 39 9400	L06	EUR/100 kg	49,14
0401 30 39 9700	L06	EUR/100 kg	54,20
0401 30 91 9100	L06	EUR/100 kg	61,77
0401 30 91 9500	L06	EUR/100 kg	0,00
0401 30 99 9100	L06	EUR/100 kg	61,77
0401 30 99 9500	L06	EUR/100 kg	90,78
0402 10 11 9000	L07	EUR/100 kg	57,00
0402 10 19 9000	L07	EUR/100 kg	57,00
0402 10 91 9000	L07	EUR/kg	0,5700
0402 10 99 9000	L07	EUR/kg	0,5700
0402 21 11 9200	L07	EUR/100 kg	57,00
0402 21 11 9300	L07	EUR/100 kg	88,11
0402 21 11 9500	L07	EUR/100 kg	91,96
0402 21 11 9900	L07	EUR/100 kg	98,00
0402 21 17 9000	L07	EUR/100 kg	57,00
0402 21 19 9300	L07	EUR/100 kg	88,11
0402 21 19 9500	L07	EUR/100 kg	91,96
0402 21 19 9900	L07	EUR/100 kg	98,00
0402 21 91 9100	L07	EUR/100 kg	98,61
0402 21 91 9200	L07	EUR/100 kg	99,19
0402 21 91 9350	L07	EUR/100 kg	100,21
0402 21 91 9500	L07	EUR/100 kg	107,70
0402 21 99 9100	L07	EUR/100 kg	98,61
0402 21 99 9200	L07	EUR/100 kg	99,19
0402 21 99 9300	L07	EUR/100 kg	100,21
0402 21 99 9400	L07	EUR/100 kg	105,76
0402 21 99 9500	L07	EUR/100 kg	107,70
0402 21 99 9600	L07	EUR/100 kg	115,29
0402 21 99 9700	L07	EUR/100 kg	119,59
0402 21 99 9900	L07	EUR/100 kg	124,57
0402 29 15 9200	L07	EUR/kg	0,5700
0402 29 15 9300	L07	EUR/kg	0,8811
0402 29 15 9500	L07	EUR/kg	0,9196
0402 29 15 9900	L07	EUR/kg	0,9800
0402 29 19 9300	L07	EUR/kg	0,8811
0402 29 19 9500	L07	EUR/kg	0,9196
0402 29 19 9900	L07	EUR/kg	0,9800
0402 29 91 9000	L07	EUR/kg	0,9861
0402 29 99 9100	L07	EUR/kg	0,9861
0402 29 99 9500	L07	EUR/kg	1,0576
0402 91 11 9370	L07	EUR/100 kg	6,804
0402 91 19 9370	L07	EUR/100 kg	6,804
0402 91 31 9300	L07	EUR/100 kg	8,058
0402 91 39 9300	L07	EUR/100 kg	8,058
0402 91 99 9000	L07	EUR/100 kg	37,96
0402 99 11 9350	L07	EUR/kg	0,1734
0402 99 19 9350	L07	EUR/kg	0,1734
0402 99 31 9150	L07	EUR/kg	0,1816
0402 99 31 9300	L07	EUR/kg	0,2271
0402 99 31 9500	L07	EUR/kg	0,0000
0402 99 39 9150	L07	EUR/kg	0,1816
0403 90 11 9000	L07	EUR/100 kg	56,20
0403 90 13 9200	L07	EUR/100 kg	56,20
0403 90 13 9300	L07	EUR/100 kg	87,33
0403 90 13 9500	L07	EUR/100 kg	91,14
0403 90 13 9900	L07	EUR/100 kg	97,13
0403 90 19 9000	L07	EUR/100 kg	97,72
0403 90 33 9400	L07	EUR/kg	0,8733
0403 90 33 9900	L07	EUR/kg	0,9713
0403 90 51 9100	970	EUR/100 kg	1,911
0403 90 59 9170	970	EUR/100 kg	12,95
0403 90 59 9310	L07	EUR/100 kg	31,46
0403 90 59 9340	L07	EUR/100 kg	46,03
0403 90 59 9370	L07	EUR/100 kg	46,03
0403 90 59 9510	L07	EUR/100 kg	46,03
0404 90 21 9120	L07	EUR/100 kg	48,62
0404 90 21 9160	L07	EUR/100 kg	57,00
0404 90 23 9120	L07	EUR/100 kg	57,00
0404 90 23 9130	L07	EUR/100 kg	88,11
0404 90 23 9140	L07	EUR/100 kg	91,96
0404 90 23 9150	L07	EUR/100 kg	98,00
0404 90 29 9110	L07	EUR/100 kg	98,61
0404 90 29 9115	L07	EUR/100 kg	99,19
0404 90 29 9125	L07	EUR/100 kg	100,21
0404 90 29 9140	L07	EUR/100 kg	107,70
0404 90 81 9100	L07	EUR/kg	0,5700
0404 90 83 9110	L07	EUR/kg	0,5700
0404 90 83 9130	L07	EUR/kg	0,8811
0404 90 83 9150	L07	EUR/kg	0,9196
0404 90 83 9170	L07	EUR/kg	0,9800
0404 90 83 9936	L07	EUR/kg	0,1734
0405 10 11 9500	L05	EUR/100 kg	173,66
0405 10 11 9700	L05	EUR/100 kg	178,00
0405 10 19 9500	L05	EUR/100 kg	173,66
0405 10 19 9700	L05	EUR/100 kg	178,00
0405 10 30 9100	L05	EUR/100 kg	173,66
0405 10 30 9300	L05	EUR/100 kg	178,00
0405 10 30 9700	L05	EUR/100 kg	178,00
0405 10 50 9300	L05	EUR/100 kg	178,00
0405 10 50 9500	L05	EUR/100 kg	173,66
0405 10 50 9700	L05	EUR/100 kg	178,00
0405 10 90 9000	L05	EUR/100 kg	184,52
0405 20 90 9500	L05	EUR/100 kg	162,82
0405 20 90 9700	L05	EUR/100 kg	169,32
0405 90 10 9000	L05	EUR/100 kg	222,55
0405 90 90 9000	L05	EUR/100 kg	178,00
0406 10 20 9100	A00	EUR/100 kg	—
0406 10 20 9230	L03	EUR/100 kg	—
	L04	EUR/100 kg	27,02
	075	EUR/100 kg	28,71
	400	EUR/100 kg	—
	A01	EUR/100 kg	33,77

Product code	Destination	Unit of measurement	Amount of refund
0406 10 20 9290	L03	EUR/100 kg	—
	L04	EUR/100 kg	25,14
	075	EUR/100 kg	26,70
	400	EUR/100 kg	—
	A01	EUR/100 kg	31,42
0406 10 20 9300	L03	EUR/100 kg	—
	L04	EUR/100 kg	11,03
	075	EUR/100 kg	11,71
	400	EUR/100 kg	—
	A01	EUR/100 kg	13,78
0406 10 20 9610	L03	EUR/100 kg	—
	L04	EUR/100 kg	36,65
	075	EUR/100 kg	38,94
	400	EUR/100 kg	—
	A01	EUR/100 kg	45,81
0406 10 20 9620	L03	EUR/100 kg	—
	L04	EUR/100 kg	37,17
	075	EUR/100 kg	39,49
	400	EUR/100 kg	—
	A01	EUR/100 kg	46,46
0406 10 20 9630	L03	EUR/100 kg	—
	L04	EUR/100 kg	41,50
	075	EUR/100 kg	44,08
	400	EUR/100 kg	—
	A01	EUR/100 kg	51,86
0406 10 20 9640	L03	EUR/100 kg	—
	L04	EUR/100 kg	60,97
	075	EUR/100 kg	64,79
	400	EUR/100 kg	—
	A01	EUR/100 kg	76,22
0406 10 20 9650	L03	EUR/100 kg	—
	L04	EUR/100 kg	50,81
	075	EUR/100 kg	53,98
	400	EUR/100 kg	—
	A01	EUR/100 kg	63,51
0406 10 20 9660	A00	EUR/100 kg	—
0406 10 20 9830	L03	EUR/100 kg	—
	L04	EUR/100 kg	18,85
	075	EUR/100 kg	20,03
	400	EUR/100 kg	—
	A01	EUR/100 kg	23,56
0406 10 20 9850	L03	EUR/100 kg	—
	L04	EUR/100 kg	22,85
	075	EUR/100 kg	24,28
	400	EUR/100 kg	—
	A01	EUR/100 kg	28,57
0406 10 20 9870	A00	EUR/100 kg	—
0406 10 20 9900	A00	EUR/100 kg	—
0406 20 90 9100	A00	EUR/100 kg	—
0406 20 90 9913	L03	EUR/100 kg	—
	L04	EUR/100 kg	42,13
	075	EUR/100 kg	44,76
	400	EUR/100 kg	15,39
	A01	EUR/100 kg	52,67
0406 20 90 9915	L03	EUR/100 kg	—
	L04	EUR/100 kg	55,61
	075	EUR/100 kg	59,09
	400	EUR/100 kg	20,51
	A01	EUR/100 kg	69,52
0406 20 90 9917	L03	EUR/100 kg	—
	L04	EUR/100 kg	59,10
	075	EUR/100 kg	62,80
	400	EUR/100 kg	21,80
	A01	EUR/100 kg	73,87
0406 20 90 9919	L03	EUR/100 kg	—
	L04	EUR/100 kg	66,03
	075	EUR/100 kg	70,18
	400	EUR/100 kg	24,32
	A01	EUR/100 kg	82,56
0406 20 90 9990	A00	EUR/100 kg	—
0406 30 31 9710	L03	EUR/100 kg	—
	L04	EUR/100 kg	5,56
	075	EUR/100 kg	11,05
	400	EUR/100 kg	—
	A01	EUR/100 kg	13,00
0406 30 31 9730	L03	EUR/100 kg	—
	L04	EUR/100 kg	8,14
	075	EUR/100 kg	16,22
	400	EUR/100 kg	—
	A01	EUR/100 kg	19,08
0406 30 31 9910	L03	EUR/100 kg	—
	L04	EUR/100 kg	5,56
	075	EUR/100 kg	11,05
	400	EUR/100 kg	—
	A01	EUR/100 kg	13,00
0406 30 31 9930	L03	EUR/100 kg	—
	L04	EUR/100 kg	8,14
	075	EUR/100 kg	16,22
	400	EUR/100 kg	—
	A01	EUR/100 kg	19,08
0406 30 31 9950	L03	EUR/100 kg	—
	L04	EUR/100 kg	11,84
	075	EUR/100 kg	23,59
	400	EUR/100 kg	—
	A01	EUR/100 kg	27,75
0406 30 39 9500	L03	EUR/100 kg	—
	L04	EUR/100 kg	8,14
	075	EUR/100 kg	16,22
	400	EUR/100 kg	—
	A01	EUR/100 kg	19,08
0406 30 39 9700	L03	EUR/100 kg	—
	L04	EUR/100 kg	11,84
	075	EUR/100 kg	23,59
	400	EUR/100 kg	—
	A01	EUR/100 kg	27,75
0406 30 39 9930	L03	EUR/100 kg	—
	L04	EUR/100 kg	11,84
	075	EUR/100 kg	23,59
	400	EUR/100 kg	—
	A01	EUR/100 kg	27,75
0406 30 39 9950	L03	EUR/100 kg	—
	L04	EUR/100 kg	13,39
	075	EUR/100 kg	26,67
	400	EUR/100 kg	—
	A01	EUR/100 kg	31,37
0406 30 90 9000	L03	EUR/100 kg	—
	L04	EUR/100 kg	14,04
	075	EUR/100 kg	27,97
	400	EUR/100 kg	—
	A01	EUR/100 kg	32,91
0406 40 50 9000	L03	EUR/100 kg	—
	L04	EUR/100 kg	64,53
	075	EUR/100 kg	68,57
	400	EUR/100 kg	—
	A01	EUR/100 kg	80,67
0406 40 90 9000	L03	EUR/100 kg	—
	L04	EUR/100 kg	66,27
	075	EUR/100 kg	70,40
	400	EUR/100 kg	—
	A01	EUR/100 kg	82,83
0406 90 13 9000	L03	EUR/100 kg	—
	L04	EUR/100 kg	72,87
	075	EUR/100 kg	88,65
	400	EUR/100 kg	29,31
	A01	EUR/100 kg	104,30

Product code	Destination	Unit of measurement	Amount of refund
0406 90 15 9100	L03	EUR/100 kg	—
	L04	EUR/100 kg	75,30
	075	EUR/100 kg	91,61
	400	EUR/100 kg	30,21
	A01	EUR/100 kg	107,78
0406 90 17 9100	L03	EUR/100 kg	—
	L04	EUR/100 kg	75,30
	075	EUR/100 kg	91,61
	400	EUR/100 kg	30,21
	A01	EUR/100 kg	107,78
0406 90 21 9900	L03	EUR/100 kg	—
	L04	EUR/100 kg	73,79
	075	EUR/100 kg	89,56
	400	EUR/100 kg	21,67
	A01	EUR/100 kg	105,36
0406 90 23 9900	L03	EUR/100 kg	—
	L04	EUR/100 kg	64,80
	075	EUR/100 kg	79,17
	400	EUR/100 kg	—
	A01	EUR/100 kg	93,15
0406 90 25 9900	L03	EUR/100 kg	—
	L04	EUR/100 kg	64,36
	075	EUR/100 kg	78,32
	400	EUR/100 kg	—
	A01	EUR/100 kg	92,14
0406 90 27 9900	L03	EUR/100 kg	—
	L04	EUR/100 kg	58,30
	075	EUR/100 kg	70,93
	400	EUR/100 kg	—
	A01	EUR/100 kg	83,45
0406 90 31 9119	L03	EUR/100 kg	—
	L04	EUR/100 kg	53,58
	075	EUR/100 kg	65,29
	400	EUR/100 kg	12,43
	A01	EUR/100 kg	76,82
0406 90 33 9119	L03	EUR/100 kg	—
	L04	EUR/100 kg	53,58
	075	EUR/100 kg	65,29
	400	EUR/100 kg	12,43
	A01	EUR/100 kg	76,82
0406 90 33 9919	L03	EUR/100 kg	—
	L04	EUR/100 kg	48,96
	075	EUR/100 kg	59,89
	400	EUR/100 kg	—
	A01	EUR/100 kg	70,45
0406 90 33 9951	L03	EUR/100 kg	—
	L04	EUR/100 kg	49,46
	075	EUR/100 kg	59,93
	400	EUR/100 kg	—
	A01	EUR/100 kg	70,50
0406 90 35 9190	L03	EUR/100 kg	—
	L04	EUR/100 kg	75,80
	075	EUR/100 kg	92,63
	400	EUR/100 kg	29,89
	A01	EUR/100 kg	108,97
0406 90 35 9990	L03	EUR/100 kg	—
	L04	EUR/100 kg	75,80
	075	EUR/100 kg	92,63
	400	EUR/100 kg	19,54
	A01	EUR/100 kg	108,97
0406 90 37 9000	L03	EUR/100 kg	—
	L04	EUR/100 kg	72,87
	075	EUR/100 kg	88,65
	400	EUR/100 kg	29,31
	A01	EUR/100 kg	104,30
0406 90 61 9000	L03	EUR/100 kg	—
	L04	EUR/100 kg	80,30
	075	EUR/100 kg	98,76
	400	EUR/100 kg	27,82
	A01	EUR/100 kg	116,19
0406 90 63 9100	L03	EUR/100 kg	—
	L04	EUR/100 kg	79,89
	075	EUR/100 kg	97,95
	400	EUR/100 kg	31,11
	A01	EUR/100 kg	115,23
0406 90 63 9900	L03	EUR/100 kg	—
	L04	EUR/100 kg	76,80
	075	EUR/100 kg	94,61
	400	EUR/100 kg	23,80
	A01	EUR/100 kg	111,30
0406 90 69 9100	A00	EUR/100 kg	—
0406 90 69 9910	L03	EUR/100 kg	—
	L04	EUR/100 kg	76,80
	075	EUR/100 kg	94,61
	400	EUR/100 kg	23,80
	A01	EUR/100 kg	111,30
0406 90 73 9900	L03	EUR/100 kg	—
	L04	EUR/100 kg	66,89
	075	EUR/100 kg	81,45
	400	EUR/100 kg	25,61
	A01	EUR/100 kg	95,83
0406 90 75 9900	L03	EUR/100 kg	—
	L04	EUR/100 kg	67,34
	075	EUR/100 kg	82,34
	400	EUR/100 kg	10,81
	A01	EUR/100 kg	96,86
0406 90 76 9300	L03	EUR/100 kg	—
	L04	EUR/100 kg	60,72
	075	EUR/100 kg	73,89
	400	EUR/100 kg	—
	A01	EUR/100 kg	86,93
0406 90 76 9400	L03	EUR/100 kg	—
	L04	EUR/100 kg	68,01
	075	EUR/100 kg	82,75
	400	EUR/100 kg	11,25
	A01	EUR/100 kg	97,36
0406 90 76 9500	L03	EUR/100 kg	—
	L04	EUR/100 kg	64,70
	075	EUR/100 kg	78,05
	400	EUR/100 kg	11,25
	A01	EUR/100 kg	91,83
0406 90 78 9100	L03	EUR/100 kg	—
	L08	EUR/100 kg	62,75
	075	EUR/100 kg	77,91
	092	EUR/100 kg	—
	400	EUR/100 kg	—
	A01	EUR/100 kg	91,66
0406 90 78 9300	L03	EUR/100 kg	—
	L08	EUR/100 kg	66,53
	075	EUR/100 kg	80,74
	092	EUR/100 kg	—
	400	EUR/100 kg	—
	A01	EUR/100 kg	94,99
0406 90 78 9500	L03	EUR/100 kg	—
	L08	EUR/100 kg	65,90
	075	EUR/100 kg	79,51
	092	EUR/100 kg	—
	400	EUR/100 kg	—
	A01	EUR/100 kg	93,54

Product code	Destination	Unit of measurement	Amount of refund
0406 90 79 9900	L03	EUR/100 kg	—
	L04	EUR/100 kg	53,80
	075	EUR/100 kg	65,72
	400	EUR/100 kg	—
	A01	EUR/100 kg	77,32
0406 90 81 9900	L03	EUR/100 kg	—
	L04	EUR/100 kg	68,01
	075	EUR/100 kg	82,75
	400	EUR/100 kg	23,15
	A01	EUR/100 kg	97,36
0406 90 85 9930	L03	EUR/100 kg	—
	L04	EUR/100 kg	73,45
	075	EUR/100 kg	89,82
	400	EUR/100 kg	28,85
	A01	EUR/100 kg	105,68
0406 90 85 9970	L03	EUR/100 kg	—
	L04	EUR/100 kg	67,34
	075	EUR/100 kg	82,34
	400	EUR/100 kg	25,24
	A01	EUR/100 kg	96,86
0406 90 85 9999	A00	EUR/100 kg	—
0406 90 86 9100	A00	EUR/100 kg	—
0406 90 86 9200	L03	EUR/100 kg	—
	L04	EUR/100 kg	61,79
	075	EUR/100 kg	77,90
	400	EUR/100 kg	15,15
	A01	EUR/100 kg	91,65
0406 90 86 9300	L03	EUR/100 kg	—
	L04	EUR/100 kg	62,68
	075	EUR/100 kg	78,72
	400	EUR/100 kg	16,61
	A01	EUR/100 kg	92,61
0406 90 86 9400	L03	EUR/100 kg	—
	L04	EUR/100 kg	66,59
	075	EUR/100 kg	82,75
	400	EUR/100 kg	18,79
	A01	EUR/100 kg	97,36
0406 90 86 9900	L03	EUR/100 kg	—
	L04	EUR/100 kg	73,45
	075	EUR/100 kg	89,82
	400	EUR/100 kg	22,00
	A01	EUR/100 kg	105,68
0406 90 87 9100	A00	EUR/100 kg	—
0406 90 87 9200	L03	EUR/100 kg	—
	L04	EUR/100 kg	51,50
	075	EUR/100 kg	64,89
	400	EUR/100 kg	13,55
	A01	EUR/100 kg	76,35
0406 90 87 9300	L03	EUR/100 kg	—
	L04	EUR/100 kg	57,55
	075	EUR/100 kg	72,30
	400	EUR/100 kg	15,30
	A01	EUR/100 kg	85,05
0406 90 87 9400	L03	EUR/100 kg	—
	L04	EUR/100 kg	59,06
	075	EUR/100 kg	73,39
	400	EUR/100 kg	16,76
	A01	EUR/100 kg	86,34
0406 90 87 9951	L03	EUR/100 kg	—
	L04	EUR/100 kg	66,79
	075	EUR/100 kg	81,27
	400	EUR/100 kg	23,16
	A01	EUR/100 kg	95,62
0406 90 87 9971	L03	EUR/100 kg	—
	L04	EUR/100 kg	66,79
	075	EUR/100 kg	81,27
	400	EUR/100 kg	18,79
	A01	EUR/100 kg	95,62
0406 90 87 9972	L03	EUR/100 kg	—
	L04	EUR/100 kg	28,46
	075	EUR/100 kg	34,77
	400	EUR/100 kg	—
	A01	EUR/100 kg	40,91
0406 90 87 9973	L03	EUR/100 kg	—
	L04	EUR/100 kg	65,59
	075	EUR/100 kg	79,80
	400	EUR/100 kg	13,19
	A01	EUR/100 kg	93,88
0406 90 87 9974	L03	EUR/100 kg	—
	L04	EUR/100 kg	71,18
	075	EUR/100 kg	86,23
	400	EUR/100 kg	13,19
	A01	EUR/100 kg	101,45
0406 90 87 9975	L03	EUR/100 kg	—
	L04	EUR/100 kg	72,60
	075	EUR/100 kg	87,19
	400	EUR/100 kg	17,48
	A01	EUR/100 kg	102,58
0406 90 87 9979	L03	EUR/100 kg	—
	L04	EUR/100 kg	64,80
	075	EUR/100 kg	79,17
	400	EUR/100 kg	13,19
	A01	EUR/100 kg	93,15
0406 90 88 9100	A00	EUR/100 kg	—
0406 90 88 9300	L03	EUR/100 kg	—
	L04	EUR/100 kg	50,84
	075	EUR/100 kg	63,62
	400	EUR/100 kg	16,61
	A01	EUR/100 kg	74,85

NB: The product codes and the 'A' series destination codes are set out in Commission Regulation (EEC) No 3846/87 (OJ L 366, 24.12.1987, p. 1), as amended.

The numeric destination codes are set out in Commission Regulation (EC) No 1779/2002 (OJ L 269, 5.10.2002, p. 6).

The other destinations are defined as follows:

L03 Ceuta, Melilla, Iceland, Norway, Switzerland, Liechtenstein, Andorra, Gibraltar, Holy See (often referred to as Vatican City), Malta, Turkey, Estonia, Latvia, Lithuania, Poland, Czech Republic, Slovakia, Hungary, Romania, Bulgaria, Canada, Cyprus, Australia and New Zealand,

L04 Albania, Slovenia, Croatia, Bosnia and Herzegovina, Serbia and Montenegro and the Former Yugoslav Republic of Macedonia,

L05 all destinations except Poland, Estonia, Latvia, Lithuania, Hungary, the Czech Republic, Slovakia and the United States of America,

L06 all destinations except Estonia, Latvia, Lithuania, Hungary and the United States of America,

L07 all destinations except Estonia, Latvia, Lithuania, Hungary, the Czech Republic, Slovakia and the United States of America,

L08 Albania, Slovenia, Bosnia and Herzegovina, Serbia and Montenegro and the Former Yugoslav Republic of Macedonia,

'970' includes the exports referred to in Articles 36(1)(a) and (c) and 44(1)(a) and (b) of Commission Regulation (EC) No 800/1999 (OJ L 102, 17.4.1999, p. 11) and exports under contracts with armed forces stationed on the territory of a Member State which do not come under its flag.

COMMISSION REGULATION (EC) No 2167/2003

of 11 December 2003

fixing the maximum export refund on oats in connection with the invitation to tender issued in Regulation (EC) No 1814/2003

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1766/92 of 30 June 1992 on the common organisation of the market in cereals ([1]), as last amended by Regulation (EC) No 1104/2003 ([2]),

Having regard to Commission Regulation (EC) No 1501/95 of 29 June 1995 laying down certain detailed rules for the application of Council Regulation (EEC) No 1766/92 on the granting of export refunds on cereals and the measures to be taken in the event of disturbance on the market for cereals ([3]), as last amended by Regulation (EC) No 1431/2003 ([4]), and in particular Article 4 thereof,

Having regard to Commission Regulation (EC) No 1814/2003 of 15 October 2003 on a special intervention measure for cereals in Finland and Sweden for the marketing year 2003/04 ([5]), and in particular Article 9 thereof,

Whereas:

(1) An invitation to tender for the refund for the export of oats produced in Finland and Sweden for export from Finland or Sweden to all third countries except Bulgaria, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Czech Republic, Romania, Slovakia and Slovenia was opened pursuant to Regulation (EC) No 1814/2003.

(2) Article 9 of Regulation (EC) No 1814/2003 provides that the Commission may, on the basis of the tenders notified, in accordance with the procedure laid down in Article 23 of Regulation (EEC) No 1766/92, decide to fix a maximum export refund taking account of the criteria referred to in Article 1 of Regulation (EC) No 1501/95. In that case a contract is awarded to any tenderer whose bid is equal to or lower than the maximum refund.

(3) The application of the abovementioned criteria to the current market situation for the cereal in question results in the maximum export refund being fixed at the amount specified in Article 1.

(4) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Cereals,

HAS ADOPTED THIS REGULATION:

Article 1

For tenders notified from 5 to 11 December 2003, pursuant to the invitation to tender issued in Regulation (EC) No 1814/2003, the maximum refund on exportation of oats shall be EUR 18,97/t.

Article 2

This Regulation shall enter into force on 12 December 2003.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 11 December 2003.

For the Commission

Franz FISCHLER

Member of the Commission

([1]) OJ L 181, 1.7.1992, p. 21.
([2]) OJ L 158, 27.6.2003, p. 1.
([3]) OJ L 147, 30.6.1995, p. 7.
([4]) OJ L 203, 12.8.2003, p. 16.
([5]) OJ L 265, 16.10.2003, p. 25.

DIRECTIVE 2003/99/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 17 November 2003

on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Economic and Social Committee [2],

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

Whereas:

(1) Live animals and food of animal origin appear on the list in Annex I to the Treaty. Livestock farming and the placing on the market of food of animal origin constitute an important source of income for farmers. The implementation of veterinary measures aimed at raising the level of public and animal health in the Community assists the rational development of the farming sector.

(2) The protection of human health against diseases and infections transmissible directly or indirectly between animals and humans (zoonoses) is of paramount importance.

(3) Zoonoses transmissible through food may cause human suffering, as well as economic losses to food production and the food industry.

(4) Zoonoses transmitted through sources other than food, especially from wild animal and pet animal populations, are also a matter of concern.

(5) Council Directive 92/117/EEC of 17 December 1992 concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and intoxications [4] provided for the establishment of a monitoring system for certain zoonoses both at the level of Member States and at Community level.

(6) With the assistance of the Community reference laboratory for the epidemiology of zoonoses, the Commission collects the results of monitoring yearly from Member States and compiles them. Publication of the results has taken place yearly since 1995. They provide a basis for the evaluation of the current situation concerning zoonoses and zoonotic agents. However, the data collection systems are not harmonised and therefore do not permit comparisons between Member States.

(7) Other Community legislation provides for the monitoring and control of certain zoonoses in animal populations. In particular, Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine [5] deals with bovine tuberculosis and bovine brucellosis. Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals [6] deals with ovine and caprine brucellosis. This Directive should not create any unnecessary duplication of those existing requirements.

(8) Moreover, a future regulation of the European Parliament and of the Council on the hygiene of foodstuffs should cover specific elements necessary for prevention, control and monitoring of zoonoses and zoonotic agents and include specific requirements for the microbiological quality of food.

(9) Directive 92/117/EEC provides for collection of data on human cases of zoonoses. The aim of Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community [7] is to reinforce the collection of such data and to contribute to improving the prevention and control, in the Community, of communicable diseases.

(10) The collection of data on the occurrence of zoonoses and zoonotic agents in animals, food, feed and humans is necessary to determine the trends and sources of zoonoses.

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[1] OJ C 304 E, 30.10.2001, p. 250.
[2] OJ C 94, 18.4.2002, p. 18.
[3] Opinion of the European Parliament of 15 May 2002 (OJ C 180 E, 31.7.2003, p. 161), Council common position of 20 February 2003 (OJ C 90 E, 15.4.2003, p. 9) and position of the European Parliament of 19 June 2003 (not yet published in the Official Journal).
[4] OJ L 62, 15.3.1993, p. 38. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).
[5] OJ 121, 29.7.1964, p. 1977. Directive as last amended by Commission Regulation (EC) No 1226/2002 (OJ L 179, 9.7.2002, p. 13).
[6] OJ L 46, 19.2.1991, p. 19. Directive as last amended by Commission Decision 2003/708/EC (OJ L 258, 10.10.2003, p. 11).
[7] OJ L 268, 3.10.1998, p. 1.

(11) In its opinion on zoonoses adopted on 12 April 2000, the Scientific Committee on Veterinary Measures relating to Public Health considered that the measures in place at that time to control food-borne zoonotic infections were insufficient. It further considered that the epidemiological data that Member States were collecting were incomplete and not fully comparable. As a consequence, the Committee recommended improved monitoring arrangements and identified risk-management options. In particular, the Committee identified *Salmonella* spp., *Campylobacter* spp., verotoxigenic *Escherichia coli* (VTEC), *Listeria monocytogenes*, *Cryptosporidium* spp., *Echinococcus granulosus/multilocularis* and *Trichinella spiralis* as public health priorities.

(12) It is therefore necessary to improve the existing monitoring and data collection systems established by Directive 92/117/EEC. Simultaneously, Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents [1] will replace the specific control measures established by Directive 92/117/EEC. Directive 92/117/EEC should therefore be repealed.

(13) The new framework for scientific advice and scientific support in matters of food safety set up by 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 [2] should be used to collect and analyse the relevant data.

(14) Where necessary to make data easier to compile and compare, monitoring should take place on a harmonised basis. This would make it possible to evaluate trends and sources of zoonoses and zoonotic agents within the Community. The data collected, together with data from other sources, should form the basis for risk assessment of zoonotic organisms.

(15) Priority should be given to those zoonoses posing the greatest risk to human health. However, the monitoring systems should also facilitate the detection of emerging or newly emerging zoonotic diseases and new strains of zoonotic organisms.

(16) The alarming emergence of resistance to antimicrobial agents (such as antimicrobial medicinal products and antimicrobial feed additives) is a characteristic that should be monitored. Provision should be made for such monitoring to cover not only zoonotic agents but also, in so far as they present a threat to public health, other agents. In particular, the monitoring of indicator organisms might be appropriate. Such organisms constitute a reservoir of resistance genes, which they can transfer to pathogenic bacteria.

(17) In addition to general monitoring, specific needs may be recognised which may necessitate the establishment of coordinated monitoring programmes. Attention should be paid in particular to zoonoses listed in Annex I to Regulation (EC) No 2160/2003.

(18) If thoroughly investigated, food-borne outbreaks of zoonoses provide the opportunity to identify the pathogen, the food vehicle involved and the factors in the food preparation and handling that contributed to the outbreak. It is therefore appropriate to make provision for such investigations and for close cooperation between the various authorities.

(19) Transmissible spongiform encephalopathies are covered by Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies [3].

(20) To ensure that information collected on zoonoses and zoonotic agents can be used effectively, appropriate rules should be laid down concerning the exchange of all relevant information. That information should be collected in Member States and transmitted to the Commission in the form of reports, which should be forwarded to the European Food Safety Authority and made available to the public in an appropriate way without delay.

(21) The reports should be submitted on an annual basis. However, additional reports may be appropriate, when warranted by circumstances.

(22) It may be appropriate to designate national and Community reference laboratories for giving guidance and assistance for analysis and testing in relation to zoonoses and zoonotic agents falling within the scope of this Directive.

(23) Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field [4] should be amended in so far as concerns the detailed rules governing the Community's financial contribution towards certain actions relating to the monitoring and control of zoonoses and zoonotic agents.

[1] See page 1 of this Official Journal.
[2] OJ L 31, 1.2.2002, p. 1.
[3] OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 1494/2002 (OJ L 225, 22.8.2002, p. 3).
[4] OJ L 224, 18.8.1990, p. 19. Decision as last amended by Decision 2001/572/EC (OJ L 203, 28.7.2001, p. 16).

(24) Appropriate procedures should be laid down for amending certain provisions of this Directive to take account of technical and scientific progress and for the adoption of implementing and transitional measures.

(25) To take account of technical and scientific progress, close and effective cooperation should be ensured between the Commission and the Member States within the Standing Committee set up by Regulation (EC) No 178/2002.

(26) Member States cannot, acting alone, collect comparable data to provide a basis for risk assessment of zoonotic organisms of significance at Community level. The collection of such data can better be achieved at Community level. The Community may therefore adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives. The responsibility for establishing and maintaining monitoring systems should lie with Member States.

(27) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1],

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

INTRODUCTORY PROVISIONS

Article 1

Subject matter and scope

1. The purpose of this Directive is to ensure that zoonoses, zoonotic agents and related antimicrobial resistance are properly monitored, and that food-borne outbreaks receive proper epidemiological investigation, to enable the collection in the Community of the information necessary to evaluate relevant trends and sources.

2. This Directive covers:

(a) the monitoring of zoonoses and zoonotic agents;

(b) the monitoring of related antimicrobial resistance;

(c) the epidemiological investigation of food-borne outbreaks; and

(d) the exchange of information related to zoonoses and zoonotic agents.

3. This Directive shall apply without prejudice to more specific Community provisions on animal health, animal nutrition, food hygiene, communicable human diseases, health and safety in the workplace, gene technology and transmissible spongiform encephalopathies.

Article 2

Definitions

For the purposes of this Directive, the following definitions shall apply:

1. the definitions laid down in Regulation (EC) No 178/2002, and

2. the following definitions:

(a) 'zoonosis' means any disease and/or infection which is naturally transmissible directly or indirectly between animals and humans;

(b) 'zoonotic agent' means any virus, bacterium, fungus, parasite or other biological entity which is likely to cause a zoonosis;

(c) 'antimicrobial resistance' means the ability of micro-organisms of certain species to survive or even to grow in the presence of a given concentration of an antimicrobial agent, that is usually sufficient to inhibit or kill micro-organisms of the same species;

(d) 'food-borne outbreak' means an incidence, observed under given circumstances, of two or more human cases of the same disease and/or infection, or a situation in which the observed number of cases exceeds the expected number and where the cases are linked, or are probably linked, to the same food source;

(e) 'monitoring' means a system of collecting, analysing and disseminating data on the occurrence of zoonoses, zoonotic agents and antimicrobial resistance related thereto.

Article 3

General obligations

1. Member States shall ensure that data on the occurrence of zoonoses and zoonotic agents and antimicrobial resistance related thereto are collected, analysed and published without delay in accordance with the requirements of this Directive and of any provisions adopted pursuant to it.

2. Each Member State shall designate a competent authority or competent authorities for the purposes of this Directive and notify the Commission thereof. If a Member State designates more than one competent authority, it shall:

(a) notify the Commission of the competent authority that will act as a contact point for contacts with the Commission; and

(b) ensure that the competent authorities cooperate so as to guarantee the proper implementation of the requirements of this Directive.

[1] OJ L 184, 17.7.1999, p. 23.

3. Each Member State shall ensure that effective and continuous cooperation based on free exchange of general information and, where necessary, of specific data, is established between the competent authority or authorities designated for the purposes of this Directive and:

(a) the competent authorities for the purposes of Community legislation on animal health;

(b) the competent authorities for the purposes of Community legislation on feed;

(c) the competent authorities for the purposes of Community legislation on food hygiene;

(d) the structures and/or authorities referred to in Article 1 of Decision No 2119/98/EC;

(e) other authorities and organisations concerned.

4. Each Member State shall ensure that the relevant officials of the competent authority or competent authorities referred to in paragraph 2 undertake suitable initial and ongoing training in veterinary science, microbiology or epidemiology, as necessary.

CHAPTER II

MONITORING OF ZOONOSES AND ZOONOTIC AGENTS

Article 4

General rules on monitoring of zoonoses and zoonotic agents

1. Member States shall collect relevant and comparable data in order to identify and characterise hazards, to assess exposures and to characterise risks related to zoonoses and zoonotic agents.

2. Monitoring shall take place at the stage or stages of the food chain most appropriate to the zoonosis or zoonotic agent concerned, that is:

(a) at the level of primary production; and/or

(b) at other stages of the food chain, including in food and feed.

3. Monitoring shall cover zoonoses and zoonotic agents listed in Annex I, Part A. Where the epidemiological situation in a Member State so warrants, zoonoses and zoonotic agents listed in Annex I, Part B shall also be monitored.

4. Annex I may be amended in accordance with the procedure referred to in Article 12(2) to add zoonoses or zoonotic agents to, or delete them from, the lists therein, taking account in particular of the following criteria:

(a) their occurrence in animal and human populations, feed and food;

(b) the gravity of their effects for humans;

(c) their economic consequences for animal and human health care and for feed and food businesses;

(d) epidemiological trends in animal and human populations, feed and food.

5. Monitoring shall be based on the systems in place in Member States. However, where necessary to make data easier to compile and compare, detailed rules for the monitoring of zoonoses and zoonotic agents listed in Annex I may be laid down in accordance with the procedure referred to in Article 12(2) and taking into consideration other Community rules laid down in the fields of animal health, food hygiene and communicable human diseases.

Such detailed rules shall lay down minimum requirements for the monitoring of certain zoonoses or zoonotic agents. They may, in particular, specify:

(a) the animal population or subpopulations or stages in the food chain to be covered by monitoring;

(b) the nature and type of data to be collected;

(c) case definitions;

(d) sampling schemes to be used;

(e) laboratory methods to be used in testing; and

(f) the frequency of reporting, including guidelines for reporting between local, regional and central authorities.

6. When considering whether to propose detailed rules in accordance with paragraph 5 to harmonise the routine monitoring of zoonoses and zoonotic agents, the Commission shall give priority to zoonoses and zoonotic agents listed in Part A of Annex I.

Article 5

Coordinated monitoring programmes

1. If data collected through routine monitoring in accordance with Article 4 are not sufficient, coordinated monitoring programmes concerning one or more zoonoses and/or zoonotic agents may be established in accordance with the procedure referred to in Article 12(2). Coordinated monitoring programmes may be established, especially when specific needs are identified, to assess risks or to establish base-line values related to zoonoses or zoonotic agents at the level of Member States or at Community level.

2. Where a coordinated monitoring programme is established, special reference shall be made to zoonoses and zoonotic agents in animal populations referred to in Annex I to Regulation (EC) No 2160/2003.

3. Minimum rules concerning the establishment of coordinated monitoring programmes are laid down in Annex III.

Article 6

Food business operators' duties

1. Member States shall ensure that, when food business operators carry out examinations for the presence of zoonoses and zoonotic agents subject to monitoring under Article 4(2), they:

(a) keep the results and arrange for the preservation of any relevant isolate for a period to be specified by the competent authority; and

(b) communicate results or provide isolates to the competent authority on request.

2. Detailed rules for the implementation of this Article may be laid down in accordance with the procedure referred to in Article 12(2).

CHAPTER III

ANTIMICROBIAL RESISTANCE

Article 7

Monitoring of antimicrobial resistance

1. Member States shall ensure, in accordance with the requirements set out in Annex II, that monitoring provides comparable data on the occurrence of antimicrobial resistance in zoonotic agents and, in so far as they present a threat to public health, other agents.

2. Such monitoring shall supplement the monitoring of human isolates conducted in accordance with Decision No 2119/98/EC.

3. Detailed rules for the implementation of this Article shall be laid down in accordance with the procedure referred to in Article 12(2).

CHAPTER IV

FOOD-BORNE OUTBREAKS

Article 8

Epidemiological investigation of food-borne outbreaks

1. Member States shall ensure that, when a food business operator provides information to the competent authority pursuant to Article 19(3) of Regulation (EC) No 178/2002, the foodstuff involved, or an appropriate sample of it, is preserved in order not to impede its investigation in a laboratory or the investigation of any food-borne outbreak.

2. The competent authority shall investigate food-borne outbreaks in cooperation with the authorities referred to in Article 1 of Decision No 2119/98/EC. The investigation shall provide data on the epidemiological profile, the foodstuffs potentially implicated and the potential causes of the outbreak. The investigation shall include, as far as possible, adequate epidemiological and microbiological studies. The competent authority shall transmit to the Commission (which shall send it to the European Food Safety Authority) a summary report of the results of the investigations carried out, containing the information referred to in Part E of Annex IV.

3. Detailed rules concerning the investigation of food-borne outbreaks may be laid down in accordance with the procedure referred to in Article 12(2).

4. Paragraphs 1 and 2 shall apply without prejudice to Community provisions on product safety, early warning and response systems for the prevention and control of communicable human diseases, food hygiene and the general requirements of food law, in particular those concerning emergency measures and procedures for withdrawing food and feed from the market.

CHAPTER V

EXCHANGE OF INFORMATION

Article 9

Assessment of trends and sources of zoonoses, zoonotic agents and antimicrobial resistance

1. Member States shall assess trends and sources of zoonoses, zoonotic agents and antimicrobial resistance in their territory.

Each Member State shall transmit to the Commission every year by the end of May a report on trends and sources of zoonoses, zoonotic agents and antimicrobial resistance, covering the data collected pursuant to Articles 4, 7 and 8 during the previous year. Reports, and any summaries of them, shall be made publicly available.

Reports shall also contain the information referred to in Article 3(2)(b) of Regulation (EC) No 2160/2003.

Minimum requirements concerning the reports are laid down in Annex IV. Detailed rules concerning the assessment of those reports, including the formats and the minimum information that they must include, may be laid down in accordance with the procedure referred to in Article 12(2).

Where the circumstances warrant it, the Commission may request specific additional information and the Member States shall submit reports to the Commission upon such request, or on their own initiative.

2. The Commission shall send the reports referred to in paragraph 1 to the European Food Safety Authority, which shall examine them and publish by the end of November a summary report on the trends and sources of zoonoses, zoonotic agents and antimicrobial resistance in the Community.

When preparing the summary report, the European Food Safety Authority may take into consideration other data provided for in the framework of Community legislation, such as:

— Article 8 of Directive 64/432/EEC,

— Article 14(2) of Directive 89/397/EEC [1],

[1] Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs (OJ L 186, 30.6.1989, p. 23).

— Article 24 of Decision 90/424/EEC,

— Article 4 of Decision No 2119/98/EC.

3. Member States shall provide the Commission with the results of coordinated monitoring programmes established in accordance with Article 5. The Commission shall send the results to the European Food Safety Authority. The results, and any summaries of them, shall be made publicly available.

CHAPTER VI

LABORATORIES

Article 10

Community and national reference laboratories

1. One or more Community reference laboratories for the analysis and testing of zoonoses and zoonotic agents and antimicrobial resistance related thereto may be designated in accordance with the procedure referred to in Article 12(2).

2. Without prejudice to the relevant provisions of Decision 90/424/EEC, the responsibilities and tasks of the Community reference laboratories, in particular with regard to coordination of their activities and those of the national reference laboratories, shall be laid down in accordance with the procedure referred to in Article 12(2).

3. Member States shall designate national reference laboratories for each field where a Community reference laboratory has been established and inform the Commission thereof.

4. Certain responsibilities and tasks of the national reference laboratories, in particular with regard to coordination of their activities and those of relevant laboratories in the Member States, may be laid down in accordance with the procedure referred to in Article 12(2).

CHAPTER VII

IMPLEMENTATION

Article 11

Amendments to the Annexes and transitional or implementing measures

Annexes II, III and IV may be amended and any appropriate transitional or implementing measures adopted in accordance with the procedure referred to in Article 12(2).

Article 12

Committee procedure

1. The Commission shall be assisted by the Committee on the Food Chain and Animal Health instituted by Regulation (EC) No 178/2002 or, where appropriate, by the Committee set up under Decision No 2119/98/EC.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its Rules of Procedure.

Article 13

Consultation of the European Food Safety Authority

The Commission shall consult the European Food Safety Authority on any matter within the scope of this Directive that could have a significant impact on public health, in particular before proposing any amendment to Annexes I or II or before establishing any coordinated monitoring programme in accordance with Article 5.

Article 14

Transposition

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive by 12 April 2004. They shall forthwith inform the Commission thereof.

They shall apply those measures by 12 June 2004.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the provisions of national law that they adopt in the field covered by this Directive.

CHAPTER VIII

FINAL PROVISIONS

Article 15

Repeal

Directive 92/117/EEC shall be repealed with effect from 12 June 2004.

However, measures which Member States have adopted pursuant to Article 8(1) of Directive 92/117/EEC and those implemented in accordance with Article 10(1) thereof and plans approved in accordance with Article 8(3) thereof shall remain in force until corresponding control programmes have been approved in accordance with Article 5 of Regulation (EC) No 2160/2003.

Article 16

Amendment of Decision 90/424/EEC

Decision 90/424/EEC is hereby amended as follows:

1. Article 29 is replaced by the following:

'*Article 29*

1. Member States may seek a Community financial contribution for the monitoring and control of the zoonoses specified in the Annex, Group 2, in the framework of the provisions referred to in Article 24(2) to (11).

2. As regards control of zoonoses, the Community financial contribution shall be introduced as part of a national control programme referred to in Article 5 of Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents (*). The level of Community financial participation shall be fixed at a maximum of 50 % of costs incurred for the implementation of mandatory control measures.

(*) OJ L 325, 12.12.2003, p. 1.'

2. the following Article is inserted:

'*Article 29a*

Member States may seek from the Community the financial contribution referred to in Article 29(2) for a national plan which was approved on the basis of Directive 92/117/EEC, until the date on which corresponding control programmes have been approved in accordance with Article 6 of Regulation (EC) No 2160/2003.'

3. In the Annex, the following indents shall be added to the list under Group 2:

'— Campylobacteriosis and agents thereof

— Listeriosis and agents thereof

— Salmonellosis (zoonotic salmonella) and agents thereof

— Trichinellosis and agents thereof

— Verotoxigenic *Escherichia coli*.'

Article 17

Entry into force

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Article 18

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 17 November 2003.

For the European Parliament	*For the Council*
The President	*The President*
P. COX	G. ALEMANNO

ANNEX I

A. **Zoonoses and zoonotic agents to be included in monitoring**

— brucellosis and agents thereof
— campylobacteriosis and agents thereof
— echinococcosis and agents thereof
— listeriosis and agents thereof
— salmonellosis and agents thereof
— trichinellosis and agents thereof
— tuberculosis due to *Mycobacterium bovis*
— verotoxigenic *Escherichia coli*

B. **List of zoonoses and zoonotic agents to be monitored according to the epidemiological situation**

1. *Viral zoonoses*

— calicivirus
— hepatitis A virus
— influenza virus
— rabies
— viruses transmitted by arthropods

2. *Bacterial zoonoses*

— borreliosis and agents thereof
— botulism and agents thereof
— leptospirosis and agents thereof
— psittacosis and agents thereof
— tuberculosis other than in point A
— vibriosis and agents thereof
— yersiniosis and agents thereof

3. *Parasitic zoonoses*

— anisakiasis and agents thereof
— cryptosporidiosis and agents thereof
— cysticercosis and agents thereof
— toxoplasmosis and agents thereof

4. *Other zoonoses and zoonotic agents*

ANNEX II

Requirements for monitoring of antimicrobial resistance pursuant to Article 7

A. **General requirements**

Member States must ensure that the monitoring system for antimicrobial resistance provided for in Article 7 provides at least the following information:

1. animal species included in monitoring;
2. bacterial species and/or strains included in monitoring;
3. sampling strategy used in monitoring;
4. antimicrobials included in monitoring;
5. laboratory methodology used for the detection of resistance;
6. laboratory methodology used for the identification of microbial isolates;
7. methods used for the collection of the data.

B. **Specific requirements**

Member States must ensure that the monitoring system provides relevant information at least with regard to a representative number of isolates of *Salmonella* spp., *Campylobacter jejuni* and *Campylobacter coli* from cattle, pigs and poultry and food of animal origin derived from those species.

ANNEX III

Coordinated monitoring programmes as referred to in Article 5

When a coordinated monitoring programme is established, at least the following characteristics of the programme must be defined:

— its purpose;
— its duration;
— its geographical area or region;
— the zoonoses and/or zoonotic agents concerned;
— the type of samples and other data units requested;
— minimum sampling schemes;
— the type of laboratory testing methods;
— the tasks of competent authorities;
— the resources to be allocated;
— the estimation of its costs and how they will be covered; and
— the method and time of reporting the results.

ANNEX IV

Requirements for the reports to be submitted pursuant to Article 9(1)

The report referred to in Article 9(1) must provide at least the following information. Parts A to D apply to reports on monitoring carried out in accordance with Article 4 or 7. Part E applies to reports on monitoring carried out in accordance with Article 8.

A. Initially the following must be described for each zoonosis and zoonotic agent (later only changes have to be reported):

(a) monitoring systems (sampling strategies, frequency of sampling, kind of specimen, case definition, diagnostic methods used);

(b) vaccination policy and other preventive actions;

(c) control mechanism and, where relevant, programmes;

(d) measures in case of positive findings or single cases;

(e) notification systems in place;

(f) history of the disease and/or infection in the country.

B. Each year the following must be described:

(a) relevant susceptible animal population (together with the date the figures relate to):
— number of herds or flocks,
— total number of animals, and
— where relevant, methods of production involved;

(b) number and general description of the laboratories and institutions involved in monitoring.

C. Each year the following details on each zoonotic agent and data category concerned must be described with their consequences:

(a) changes in the systems already described;

(b) changes in previously described methods;

(c) results of the investigations and of further typing or other method of characterisation in laboratories (for each category reported on separately);

(d) national evaluation of the recent situation, the trend and the sources of infection;

(e) relevance as zoonotic disease;

(f) relevance to human cases, as a source of human infection, of findings in animals and food;

(g) control strategies recognised that could be used to prevent or minimise transmission of the zoonotic agent to humans;

(h) if necessary, any specific action decided in the Member State or suggested for the Community as a whole on the basis of the recent situation.

D. Reporting of results of examinations

Results shall be given by stating the number of epidemiological units investigated (flocks, herds, samples, batches) and the number of positive samples according to the case definition. The results shall, when necessary, be presented in a way which shows the geographical distribution of the zoonosis or the zoonotic agent.

E. For food-borne outbreak data:

(a) total number of outbreaks over a year;

(b) number of human deaths and illnesses in these outbreaks;

(c) the causative agents of the outbreaks, including, where possible, serotype or other definitive description of the agents. Where the identification of the causative agent is not possible, the reason for such unidentifiability should be stated;

(d) foodstuffs implicated in the outbreak and other potential vehicles;

(e) identification of the type of place where the foodstuff incriminated was produced/purchased/acquired/consumed;

(f) contributory factors, for example, deficiencies in food processing hygiene.

COMMISSION DIRECTIVE 2003/119/EC

of 5 December 2003

amending Council Directive 91/414/EEC to include mesosulfuron, propoxycarbazone and zoxamide as active substances

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ([1]), as last amended by Commission Directive 2003/84/EC ([2]), and in particular Article 6(1) thereof,

Whereas:

(1) In accordance with Article 6(2) of Directive 91/414/EEC, the authorities of France received on 15 December 2000 an application from Aventis Cropscience France (now Bayer CropScience) for the inclusion of the active substance mesosulfuron (in the form of mesosulfuron methyl) in Annex I to Directive 91/414/EEC. Commission Decision 2001/287/EC ([3]) confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(2) Germany received an application under Article 6(2) of Directive 91/414/EEC on 25 January 2000, an application from Bayer AG (now Bayer CropScience) concerning propoxycarbazone (in the form of propoxycarbazone sodium; former name: MKH 65 61). This application was declared complete by Commission Decision 2000/463/EC ([4]).

(3) The United Kingdom received an application under Article 6(2) of Directive 91/414/EEC on 2 June 1999 from Rohm and Haas France SA (now: Dow AgroSciences) concerning zoxamide (former name: RH-7281). This application was declared complete by Commission Decision 2000/540/EC ([5]).

(4) For those active substances, the effects on human health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicants. The nominated rapporteur Member States submitted draft assessment reports concerning the substances to the Commission on 12 December 2001 (mesosulfuron), 26 March 2001 (propoxycarbazone) and 10 August 2001 (zoxamide).

(5) The draft assessment reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. The review was finalised on 3 October 2003 in the format of the Commission review report for mesosulfuron, propoxycarbazone and zoxamide.

(6) The review of mesosulfuron, propoxycarbazone and zoxamide did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants.

(7) It has appeared from the various examinations made, that plant protection products containing the active substances concerned may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include mesosulfuron, propoxycarbazone and zoxamide in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing these active substances can be granted in accordance with the provisions of that Directive.

(8) After inclusion, Member States should be allowed a reasonable period to implement the provisions of Directive 91/414/EEC as regards plant protection products containing mesosulfuron, propoxycarbazone and zoxamide and in particular to review existing provisional authorisations and, by the end of this period at the latest, to transform those authorisations into full authorisations, to amend them or to withdraw them in accordance with the provisions of Directive 91/414/EEC.

(9) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

([1]) OJ L 230, 19.8.1991, p. 1.
([2]) OJ L 247, 30.9.2003, p. 20.
([3]) OJ L 99, 10.4.2001, p. 9.
([4]) OJ L 183, 22.7.2000, p. 21.
([5]) OJ L 230, 12.9.2000, p. 14.

Article 2

1. Member States shall adopt and publish by 30 September 2004 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 October 2004.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

1. Member States shall review the authorisation for each plant protection product containing mesosulfuron, propoxycarbazone or zoxamide to ensure that the conditions relating to these active substances set out in Annex I to Directive 91/414/EEC are complied with. Where necessary, they shall amend or withdraw authorisations in accordance with Directive 91/414/EEC by 30 September 2004 at the latest.

2. For each authorised plant protection product containing mesosulfuron, propoxycarbazone or zoxamide as the only active substance, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III thereto. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC. Where necessary and by 31 August 2005 at the latest, they shall amend or withdraw the authorisation for each such plant protection product.

3. For each plant protection product containing mesosulfuron, propoxycarbazone or zoxamide together with one or more active substances which are all listed in Annex I to Directive 91/414/EEC, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to that Directive, on the basis of a dossier satisfying the requirements of Annex III thereto. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC. Where necessary, they shall amend or withdraw the authorisation for each such plant protection product, by the deadline defined for such an amendment or withdrawal in the respective Directives which amended Annex I so as to add the relevant substances to it. Where the respective Directives set different deadlines, the deadline shall be the latest of the dates defined.

Article 4

This Directive shall enter into force on 1 April 2004.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 5 December 2003.

For the Commission

David BYRNE

Member of the Commission

ANNEX

In Annex I the following rows are added at the end of the table

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
'76	Mesosulfuron CAS No 400852-66-6 CIPAC No 441	2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-α-(methanesulfonamido)-p-toluic acid	930 g/kg	1 April 2004	31 March 2014	Only use as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on mesosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the protection of aquatic plants; — should pay particular attention to the potential of mesosulfuron and its metabolites for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climate conditions. Risk mitigation measures should be applied where appropriate.
77	Propoxycarbazone CAS No 145026-81-9 CIPAC No 655	2-(4,5-dihydro-4-methyl-5-oxo-3-propoxy-1H-1,2,4-triazol-1-yl)carboxamidosulfonylbenzoicacid-methylester	974 g/kg (expressed as propoxycarbazone-sodium)	1 April 2004	31 March 2014	Only use as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on propoxycarbazone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the potential of propoxycarbazone and its metabolites for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climate conditions; — should pay particular attention to the protection of aquatic ecosystems, especially of aquatic plants. Risk mitigation measures should be applied where appropriate. The Member States shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured.
78	Zoxamide CAS No 156052-68-5 CIPAC No 640	(RS)-3,5-Dichloro-N-(3-chloro-1-ethyl-1-methylacetonyl)-p-toluamide	950 g/kg	1 April 2004	31 March 2014	Only use as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on zoxamide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2003 shall be taken into account.

(1) Further details on identity and specification of active substances are provided in the review report.'

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION
of 8 December 2003
concerning analysis and cooperation with regard to counterfeit euro coins

(2003/861/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular the third sentence of Article 123(4) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Central Bank [1],

Whereas:

(1) Council Regulation (EC) No 1338/2001 of 28 June 2001 laying down measures necessary for the protection of the euro against counterfeiting [2], and in particular Article 5 thereof, provides for the analysis and classification of counterfeit euro coins by the Coin National Analysis Centre (CNAC) in each of the Member States and by the European Technical and Scientific Centre (ETSC). The Commission has provided, since the year 2000, the framework for coordination of the relevant actions of those technical authorities.

(2) Since October 2001, the ETSC has been carrying out its tasks on a temporary basis at the French Mint with administrative support and management provided by the Commission, in line with an Exchange of Letters between the President of the Council and the French Minister for Finance of 28 February and 9 June 2000.

(3) In order to ensure the continuity and independence of the protection of euro coins against counterfeiting, the Commission should be given responsibility for performing the activities of the ETSC and for ensuring the coordination of the competent technical authorities in their actions in this field,

HAS ADOPTED THIS DECISION:

Article 1

The Commission shall establish the European Technical and Scientific Centre and ensure its functioning and the coordination of the activities of the competent technical authorities to protect euro coins against counterfeiting.

Article 2

This Decision is addressed to the Member States which have adopted the euro as their single currency.

Done at Brussels, 8 December 2003.

For the Council

The President

F. FRATTINI

[1] OJ C 202, 27.8.2003, p. 31.
[2] OJ L 181, 4.7.2001, p. 6.

COUNCIL DECISION

of 8 December 2003

extending the effects of Decision 2003/861/EC concerning analysis and cooperation with regard to counterfeit euro coins to those Member States which have not adopted the euro as their single currency

(2003/862/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 308 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament [1],

Whereas:

(1) In adopting Decision of 2003/861/EC concerning analysis and cooperation with regard to counterfeit euro coins the Council provided that it is to have effect in those Member States which have adopted the euro as their single currency.

(2) It is important that the euro should enjoy the same level of protection in those Member States which have not adopted it and the necessary provisions should be taken to that end,

HAS ADOPTED THIS DECISION:

Article 1

Council Decision 2003/861/EC concerning analysis and cooperation with regard to counterfeit euro coins shall be extended to those Member States which have not adopted the euro as their single currency.

Article 2

This Decision is addressed to those Member States which have not adopted the euro as their single currency.

Done at Brussels, 8 December 2003.

For the Council

The President

F. FRATTINI

[1] Opinion delivered on 18 November 2003 (not yet published in the Official Journal).

COMMISSION

COMMISSION DECISION
of 2 December 2003
on health certificates for the importation of animal products from the United States of America

(notified under document number C(2003) 4444)

(Text with EEA relevance)

(2003/863/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 98/258/EC of 16 March 1998 on the conclusion of the Agreement between the European Community and the United States of America on sanitary measures to protect public and animal health in trade in live animals and animal products [1], and in particular Article 3 thereof,

Having regard to Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries [2], as last amended by Regulation (EC) No 807/2003 [3], and in particular Article 11(2) and Article 22(2) thereof, and the corresponding provisions of the other directives establishing sanitary conditions and models of certificates for the importation of live animals and animal products from third countries,

Whereas:

(1) Annex V to the Agreement between the European Community and the United States of America on sanitary measures to protect public and animal health in trade in live animals and animal products (the Agreement) establishes, *inter alia*, the sanitary measures for fresh meat, meat products and certain other animal products traded with the United States for which equivalence has been determined.

(2) Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC [4], as last amended by Commission Decision 2003/721/EC [5], provides for special certification requirements for animals and products of animal origin to prevent the spread of animal and human diseases.

(3) Article 10 of Directive 92/118/EEC requires that gelatine and collagen for human consumption intended for import into the EC must be accompanied by a health certificate corresponding to the specimen drawn up in Annex II, chapter 4.

(4) By Commission Decision 2003/833/EC [6] approving on behalf of the European Community amendments to the Annexes to the Agreement between the European Community and the United States of America on sanitary measures to protect public and animal health in trade in live animals and animal products, the recommendations made by the Joint Management Committee established under the Agreement concerning the equivalence of the United States standards for gelatine and collagen with Community standards have been approved and should be implemented; model certificates for the importation of gelatine and collagen from the United States into the Community providing the corresponding guarantees should be established accordingly.

(5) It is appropriate for the Community to implement the recognition of equivalence so granted to the United States on a provisional basis, pending confirmation by the United States of their approval of the changes made to the Agreement.

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

[1] OJ L 118, 21.4.1998, p. 1.
[2] OJ L 302, 31.12.1972, p. 28.
[3] OJ L 122, 16.5.2003, p. 36.
[4] OJ L 62, 15.3.1993, p. 49.
[5] OJ L 260, 11.10.2003, p. 21.
[6] OJ L 316, 29.11.2003, p. 20.

HAS ADOPTED THIS DECISION:

Article 1

The Member States shall authorise the import from the United States of gelatine and collagen for human consumption, provided that they are accompanied by an official health certificate(s) in accordance with the models referred to respectively in Annex A and Annex B.

Article 2

This Decision shall apply from 15 December 2003.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 2 December 2003.

For the Commission

David BYRNE

Member of the Commission

ANNEX A

HEALTH CERTIFICATE

For gelatine derived from ruminant bones or pigskins, intended for human consumption, intended for dispatch from the United States to the European Community

Note for the importer: This certificate is for veterinary purposes only and must accompany the consignment until it reaches the border inspection post.

Reference number of the health certificate: .....

Country of destination: .....

Country of origin: UNITED STATES OF AMERICA

Responsible ministry: FOOD AND DRUG ADMINISTRATION

Certifying department: CENTER FOR FOOD SAFETY & APPLIED NUTRITION

I. **Identification of gelatine**

Type of products: .....

Date of manufacture: .....

Type of packaging: .....

Number of packages: .....

Guaranteed storage period: .....

Net weight (kg): .....

II. **Origin of gelatine**

Address(es) and firm establishment identifier number(s) of production establishment(s) on the responsible ministry's list of export-eligible firms:

.....

.....

III. **Destination of gelatine**

The gelatine will be sent

from: .....
(place of loading)

to: .....
(country and place of destination)

by the following means of transport (1): .....

Name and address of consignor: .....

Name and address of consignee: .....

IV. Health attestation

I, the undersigned, certify that the consignment of gelatine described above,

— was wrapped, packaged, stored and transported in compliance with the relevant United States public health standards requirements of the Code of Federal Regulations which have been recognised for this purpose as equivalent to the European Community standards as prescribed in Council Decision 98/258/EC (2) as last amended by Decision 2003/833/EC (3);

(1) Indicate the name or registration number (railway wagons and lorries), the flight number (aircraft) or the name (ship). This information is to be updated in the case of unloading and reloading.
(2) OJ L 118, 21.4.1998, p. 1.
(3) OJ L 316, 29.11.2003, p. 20.

— comes from an establishment subject to periodic inspection by FDA that has been shown by such inspections

(a) to comply with the relevant US public health standards requirements of the Code of Federal Regulations which have been recognised for this purpose as equivalent to the European Community standards as prescribed in Decision 98/258/EC; and

(b) to maintain records that are subject to review by FDA, during an inspection or otherwise, that substantiate and verify the information contained in the manufacturer's legally binding declaration to FDA specific to this consignment (copy attached).

This declaration has been verified by periodic, on-site inspections by State regulatory officials and confirms, subject to criminal penalties for falsification, that the gelatine has been:

— produced exclusively from ruminant bones or pigskins

(a) derived from animals which have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following ante and post mortem inspection, and, for ruminants, which have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity; and

(b) transported directly from the slaughterhouses or cutting plants to the gelatine establishments in compliance with the relevant US public health standards requirements of the Code of Federal Regulations, which have been recognised for this purpose as equivalent to the European Community standards as prescribed in Council Decision 98/258/EC;

(c) which do not contain and are not derived from specified risk material as defined in Annex XI, section A, to Regulation (EC) No 999/2001 of the European Parliament and of the Council [4] or mechanically recovered meat obtained from bones of bovine, ovine or caprine animals.

This declaration also confirms, subject to criminal penalties for falsification, that the gelatine has been:

— manufactured by a process which ensures that the raw material is subjected to treatment with acid or alkali, followed by one or more rinses, gelatine is then extracted by heating one or several times in succession, followed by purification by means of filtration and sterilisation; during this process no preservatives have been used, other than sulphur dioxide and hydrogen peroxide,

— shown by periodic, representative analyses of finished gelatine products conducted by an accredited, private laboratory and coordinated and reviewed by State regulatory officials not to exceed the following criteria:

— Total aerobic bacteria — 10^3/g

— Coliforms (30 °C) — 0/ g

— Coliforms (44,5 °C) — 0/10 g

— Anaerobic sulphite-reducing bacteria (no gas production) — 10/g

— *Clostridium perfringens* — 0/g

— *Staphylococcus aureus* — 0/g

— *Salmonella* — 0/25 g

— As — 1 ppm

— Pb — 5 ppm

— Cd — 0,5 ppm

— Hg — 0,15 ppm

— Cr — 10 ppm

— Cu — 30 ppm

— Zn — 50 ppm

— Moisture (105 °C) ~ 15 %

— Ash (550 °C) — 2 %

— SO_2 — 50 ppm

— H_2O_2 — 10 ppm.

Done at ..... on .....
(place) (date)

.....
(Stamp and signature of official competent authority) [5]

.....
(Name in block letters)

[4] OJ L 147, 31.5.2001, p. 1.
[5] The signature and stamp must be in a colour different to that of the printing.

DECLARATION TO THE UNITED STATES FOOD AND DRUG ADMINISTRATION

For gelatine derived from pigskins or ruminant bones, intended for human consumption, intended for dispatch from the United States of America to the European Community

Country of destination: .....

Exporting country: UNITED STATES OF AMERICA

Responsible ministry: FOOD AND DRUG ADMINISTRATION

Certifying department: CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

I. **Identification of gelatine**

Type of products: .....

Date of manufacture: .....

Type of packaging: .....

Number of packages: .....

Guaranteed storage period: .....

Net weight (kg): .....

II. **Origin of gelatine**

Address and firm establishment identifier number of production establishment:

.....

.....

.....

III. **Destination of gelatine**

The gelatine will be sent

from: .....

.....

to: .....

.....

by the following means of transport: .....

.....

Name and address of consignor:

.....

.....

Name and address of consignee:

.....

.....

IV. **Production and analysis information**

The product has been made exclusively from pigskins/ruminant bones which have been derived from animals which have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following an ante and post mortem inspection.

This product does not contain and is not derived from specified risk material as defined in Annex XI, section A, to Regulation (EC) No 999/2001 or mechanically recovered meat obtained from bones of bovine, ovine or caprine animals. The bovine, ovine or caprine animals, from which this product is derived (excluding that derived from porcine animals), have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity.

This product has been manufactured by a process which ensures that the raw material is subject to treatment with acid or alkali, followed by one or more rinses. Extraction is by heating one or more times and purification by means of filtration and sterilisation. No preservatives except for sulfur dioxide or hydrogen peroxide have been used (hydrogen peroxide is not allowed in US gelatine as per 21 CFR 184.1366).

The gelatine satisfies the following specifications as determined by analysis:

— Total aerobic bacteria — 10^3/g

— Coliforms (30 °C) — 0/ g

— Coliforms (44,5 °C) — 0/10 g

— Anaerobic sulphite-reducing bacteria (no gas production) — 10/g

— *Clostridium perfringens* — 0/g

— *Staphylococcus aureus* — 0/g

— *Salmonella* — 0/25 g

— As — 1 ppm

— Pb — 5 ppm

— Cd — 0,5 ppm

— Hg — 0,15 ppm

— Cr — 10 ppm

— Cu — 30 ppm

— Zn — 50 ppm

— Moisture (105 °C) ~ 15 %

— Ash (550 °C) — 2 %

— SO_2 — 50 ppm

— H_2O_2 — 10 ppm.

V. **Statement and acknowledgement**

On behalf of (name of establishment), I authorise the United States Food and Drug Administration (FDA) to share the information contained in the declaration with the European Union. I understand that the information may contain confidential commercial or financial information and/or trade secrets, within the meaning of 18 U.S.C. 1905, 21 U.S.C. 331 (j), and 5 U.S.C. 52(b)(4), and that it is exempt from public disclosure. Authorisation is given to FDA sending the information without deletion of confidential commercial or financial information and/or trade secrets. I agree to hold FDA harmless for any injury caused by FDA's sharing the information with the European Union.

As indicated by my signature below, I am authorised to provide this consent on behalf of (name of establishment) and my full name, position, and address are set out below for verification.

(Name of establishment) maintains records to substantiate said declaration and will provide to FDA upon request, during an inspection or otherwise all records supporting the above statement.

(Name of establishment) makes the above statement with full knowledge that submitting false statements is in violation of United States Code title 18, section 1001, and that penalties for such violation include up to USD 250 000 in fines, up to five years imprisonment or both.

Signed: .....

Name/position: .....

Department: .....

Street: .....

City, State: .....

Date: .....

ANNEX B

HEALTH CERTIFICATE

For collagen derived from bovine hides and/or pigskins, intended for human consumption, intended for dispatch from the United States of America to the European Community

Note for the importer: This certificate is for veterinary purposes only and must accompany the consignment until it reaches the border inspection post.

Reference number of the health certificate: .....

Country of destination: .....

Country of origin: UNITED STATES OF AMERICA

Responsible ministry: FOOD AND DRUG ADMINISTRATION

Certifying department: CENTER FOR FOOD SAFETY & APPLIED NUTRITION

I. **Identification of collagen**

Type of products: .....

Animal species and nature of the raw materials used (e.g. bovine hides and skins): .....

.....

Date of manufacture: .....

Type of packaging: .....

Number of packages: .....

Guaranteed storage period: .....

Net weight (kg): .....

II. **Origin of collagen**

Address(es) and firm establishment identifier number(s) of production establishment(s) on the responsible ministry's list of export eligible firms:

.....

.....

III. **Destination of collagen**

The collagen will be sent

from: .....

(place of loading)

to: .....

(country and place of destination)

by the following means of transport (1): .....

Name and address of consignor: .....

Name and address of consignee: .....

(1) Indicate the name or registration number (railway wagons and lorries), the flight number (aircraft) or the name (ship). This information is to be updated in the case of unloading and reloading.

IV. **Health attestation**

I, the undersigned, certify that the consignment of collagen described above,

— was wrapped, packaged, stored and transported in compliance with the relevant US public health standards requirements of the Code of Federal Regulations which have been recognised for this purpose as equivalent to the European Community standards as prescribed in Council Decision 98/258/EC [2] as last amended by Decision 2003/833/EC [3],

— comes from an establishment subject to periodic inspection by FDA that has been shown by such inspections:

(a) to comply with the relevant US public health standards requirements of the Code of Federal Regulations which have been recognised for this purpose as equivalent to the European Community standards as prescribed in Council Decision 98/258/EC, and

(b) to maintain records that are subject to review by FDA, during an inspection or otherwise, that substantiate and verify the information contained in the manufacturer's legally binding declaration to FDA specific to this consignment (copy attached).

This declaration has been verified by periodic, on-site inspections by State regulatory officials and confirms, subject to criminal penalties for falsification, that the collagen has been:

— produced exclusively from bovine hides and/or pigskins

(a) derived from animals which have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following ante and post mortem inspection, and, for ruminants, which have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, and

(b) transported directly from the slaughterhouses or cutting plants to the collagen establishments in compliance with the relevant US public health standards requirements of the Code of Federal Regulations, which have been recognised for this purpose as equivalent to the European Community standards as prescribed in Council Decision 98/258/EC, or

(c) transported from a tannery subject to periodic inspection by FDA that has been shown by such inspections to comply with the relevant US public health standards requirements of the Code of Federal Regulations, which have been recognised for this purpose as equivalent to the European Community standards as prescribed in Council Decision 98/258/EC,

(d) which do not contain and are not derived from specific risk materials as defined in Annex XI, section A, to Regulation (EC) No 999/2001 of the European Parliament and of the Council [4], or mechanically recovered meat obtained from bones of bovine, ovine or caprine animals.

This declaration also confirms, subject to criminal penalties for falsification, that the collagen has been:

— manufactured by a process which ensures that the raw material is subjected to treatment involving washing, pH adjustment using acid or alkali, followed by one or more rinses, filtration and extrusion. During this process no preservatives have been used, other than those authorised for such use by both the European Communities and the United States,

— shown by periodic, representative analyses of finished collagen products conducted by an accredited, private laboratory and coordinated and reviewed by State regulatory officials not to exceed the following criteria:

— Total aerobic bacteria — 10^3/g
— Coliforms (30 °C) — 0/ g
— Coliforms (44,5 °C) — 0/10 g
— Anaerobic sulphite-reducing bacteria (no gas production) — 10/g
— *Clostridium perfringens* — 0/g
— *Staphylococcus aureus* — 0/g
— *Salmonella* — 0/25 g
— As — 1 ppm
— Pb — 5 ppm
— Cd — 0,5 ppm
— Hg — 0,15 ppm
— Cr — 10 ppm
— Cu — 30 ppm
— Zn — 50 ppm
— SO_2 — 50 ppm
— H_2O_2 — 10 ppm.

[2] OJ L 118 , 21.4.1998, p. 1.
[3] OJ L 316, 29.11.2003, p. 20.
[4] OJ L 147, 31.5.2001, p. 1.

Done at ..... on .....
(place) (date)

.....
(Stamp and signature of official competent authority)

.....
(Name in block letters)

(5) The signature and stamp must be in a colour different to that of the printing.

DECLARATION TO THE UNITED STATES FOOD AND DRUG ADMINISTRATION

For collagen derived from bovine hides and/or pigskins, intended for human consumption, intended for dispatch from the United States to the European Community

Country of destination: .....

Exporting country: UNITED STATES OF AMERICA

Responsible ministry: FOOD AND DRUG ADMINISTRATION

Certifying department: CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

I. **Identification of collagen**

Type of products: .....

Animal species and nature of the raw materials used (e.g. bovine hides and skins): .....

.....

Date of manufacture: .....

Type of packaging: .....

Number of packages: .....

Guaranteed storage period: .....

Net weight (kg): .....

II. **Origin of collagen**

Address and firm establishment identifier number of production establishment:

.....

.....

.....

III. **Destination of collagen**

The collagen will be sent

from: .....

.....

to: .....

.....

by the following means of transport (1): .....

.....

(1) Indicate the name or registration number (railway wagons and lorries), the flight number (aircraft) or the name (ship). This information is to be updated in the case of unloading and reloading.

Name and address of consignor:

.....

.....

Name and address of consignee:

.....

.....

IV. **Production and analysis information**

The product has been made exclusively from bovine hides and/or pigskins which have been derived from animals which have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following an ante and post mortem inspection.

The bovine hides and/or pigskins have been either: (1) transported directly from the slaughterhouse or cutting plants to the collagen establishments in compliance with the relevant US public health standards requirements of the Code of Federal Regulations, which have been recognised for this purpose as equivalent to the European Community standards as prescribed in Decision 98/258/EC; or (2) transported from a tannery subject to periodic inspection by FDA that has been shown by such inspections to comply with the relevant US public health standards requirements of the Code of Federal Regulations which have been recognised for this purpose as equivalent to the European Community standards as prescribed in Decision 98/258/EC.

This product does not contain and is not derived from specified risk material as defined in Annex XI, section A, to Regulation (EC) No 999/2001 or mechanically recovered meat obtained from bones of bovine, ovine or caprine animals. The bovine animals, from which this product is derived (excluding that derived from porcine animals), have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity.

This product has been manufactured by a process which ensures that the raw material is subject to treatment involving washing, pH adjustment using acid or alkali, followed by one or more rinses, filtration and extrusion. During this process no preservatives have been used other than those authorised by both the European Community and the United States.

The collagen satisfies the following specifications as determined by analysis:

— Total aerobic bacteria — 10^3/g

— Coliforms (30 °C) — 0/ g

— Coliforms (44,5 °C) — 0/10 g

— Anaerobic sulphite-reducing bacterial (no gas production) — 10/g

— *Clostridium perfringens* — 0/g

— *Staphylococcus aureus* — 0/g

— *Salmonella* — 0/25 g

— As — 1 ppm

— Pb — 5 ppm

— Cd — 0,5 ppm

— Hg — 0,15 ppm

— Cr — 10 ppm

— Cu — 30 ppm

— Zn — 50 ppm

— SO_2 — 50 ppm

— H_2O_2 — 10 ppm.

V. **Statement and acknowledgement**

On behalf of (name of establishment), I authorise the United States Food and Drug Administration (FDA) to share the information contained in the declaration with the European Union. I understand that the information may contain confidential commercial or financial information and/or trade secrets, within the meaning of 18 U.S.C. 1905, 21 U.S.C. 331 (j), and 5 U.S.C. 52(b)(4), and that it is exempt from public disclosure. Authorisation is given to FDA sending the information without deletion of confidential commercial or financial information and/or trade secrets. I agree to hold FDA harmless for any injury caused by FDA's sharing the information with the European Union.

As indicated by my signature below, I am authorised to provide this consent on behalf of (name of establishment) and my full name, position, and address are set out below for verification.

(Name of establishment) maintains records to substantiate said declaration and will provide to FDA upon request, during an inspection or otherwise all records supporting the above statement

((Name of establishment) makes the above statement with full knowledge that submitting false statements is in violation of United States Code title 18, section 1001, and that penalties for such violation include up to USD 250 000 in fines, up to five years imprisonment or both.

Signed: .....

Name/position: .....

Department: .....

Street: .....

City, State: .....

Date: .....

COMMISSION DECISION

of 5 December 2003

concerning a specific financial contribution by the Community relating to the surveillance programme of campylobacter in broilers presented by Sweden for the year 2004

(notified under document number C(2003) 4532)

(Only the Swedish text is authentic)

(2003/864/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field [1], as last amended by Regulation (EC) No 806/2003 [2] and, in particular, Article 19 and Article 20 thereof,

Whereas:

(1) The protection of human health against diseases and infections directly or indirectly transmissible from animals to man (zoonoses) is of paramount importance.

(2) The Community is currently in the process of reviewing its policy on the control and prevention of zoonoses.

(3) In this framework, the Scientific Committee on Veterinary Measures relating to Public Health was requested to express an opinion on the basis of zoonoses control policies, where special attention should be paid to the assessment of risks related to zoonotic diseases causing major concern to public health.

(4) In its conclusions of the opinion of 12 April 2000, the Scientific Committee on Veterinary Measures relating to Public Health identified campylobacter as one of the most important food-borne zoonoses currently, if referring to the number of reported human cases. It recognised that a number of gaps exist in the knowledge of the epidemiology of campylobacter as a food-borne zoonosis. It indicated, in particular, that the efficiency of establishing strict hygiene barriers at poultry farm level should be documented, and that the efficiency of procedures to lower the prevalence of campylobacter at farm level needs further scrutiny.

(5) The Swedish authorities presented in 2000, with a view to obtain financial support from the Community, a multiannual national surveillance programme of campylobacter in broilers, to estimate the baseline prevalence both in primary production and in the food chain, and to progressively reinforce implementation of hygienic measures in farms with a view to lower the prevalence at farm level and subsequently along the food chain. The programme started from 1 July 2001.

(6) In the light of the importance of campylobacter as a zoonosis, it has been considered useful to provide Community financial assistance for an appropriate period of time within a maximum of four years, to cover certain costs incurred by Sweden and to collect valuable technical and scientific information. For budgetary reasons, Community assistance is decided each year. By Commission Decisions 2001/29/EC [3], 2001/866/EC [4] and 2002/989/EC [5], the Community provided financial assistance respectively for the second semester of the year 2001 and for the years 2002 and 2003.

(7) The Swedish authorities have provided the necessary information on the implementation of the programme during the years 2001, 2002 and 2003 that shows its effective implementation.

(8) The Swedish authorities presented on 5 September 2003 a programme for Community financial assistance during 2004, and a revised programme on 8 October 2003. On this basis, it appears appropriate to fix the financial assistance provided by the Community for the period 1 January 2004 up to 31 December 2004 to a maximum of EUR 160 000.

(9) Pursuant to Article 3(2) of Council Regulation (EC) No 1258/1999 [6], veterinary and plant health measures undertaken in accordance with Community rules shall be financed under the Guarantee Section of the European Agricultural Guidance and Guarantee Fund; for financial control purposes, Articles 8 and 9 of Council Regulation (EC) No 1258/1999 apply.

(10) A financial contribution from the Community shall be granted in so far as the actions provided for are effectively carried out and provided that the authorities furnish all the necessary information within the time limits provided for.

[1] OJ L 224, 18.8.1990, p. 19.
[2] OJ L 122, 16.5.2003, p. 1.
[3] OJ L 6, 11.1.2001, p. 22.
[4] OJ L 323, 7.12.2001, p. 26.
[5] OJ L 344, 19.12.2002, p. 45.
[6] OJ L 160, 26.6.1999, p. 103.

(11) There is a need to clarify the rate to be used for the conversion of the payment applications submitted in national currency as defined in Article 1(d) of Council Regulation (EC) No 2799/98 establishing agrimonetary arrangements for the euro [1].

(12) 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

1. The surveillance programme for campylobacter in broilers presented by Sweden is hereby approved for a period of 12 months starting from 1 January 2004.

2. The financial assistance from the Community for the programme referred to in paragraph 1 shall be 50 % of the costs (VAT excluded) incurred by Sweden for laboratory testing, up to SEK 160 per bacteriological test for campylobacter, SEK 320 per test for fingerprinting of campylobacter and up to a maximum of EUR 160 000.

Article 2

1. The financial assistance referred to under Article 1(2) shall be granted to Sweden provided that the implementation of the programme shall be in conformity with the relevant provisions of Community law, including rules on competition and on the award of public contracts and subject to the conditions provided for in points (a) to (e):

(a) bringing into force by 1 January 2004 the laws, regulations and administrative provisions for implementing the programme;

(b) forwarding an intermediate financial and technical evaluation covering the first five months of the programme, at the latest four weeks after the end of the reporting period. The report shall conform to the model as set out in the Annex;

(c) forwarding a final report by 31 March 2005 at the latest on the technical execution of the programme accompanied by justifying evidence as to the costs incurred and the results attained during the period from 1 January to 31 December 2004;

(d) these reports providing substantive and valuable technical and scientific information corresponding to the purpose of the Community intervention;

(e) implementing the programme effectively.

2. When the time limit in subparagraph 1(c) is not respected, the contribution shall be reduced by 25 % on 1 May, 50 % on 1 June, 75 % on 1 July and 100 % on 1 September.

Article 3

The conversion rate for applications submitted in national currency in month 'n' shall be that of the 10th day of month 'n+1' or for the first preceding day for which a rate is quoted.

Article 4

This Decision shall apply from 1 January 2004.

Article 5

This Decision is addressed to the Kingdom of Sweden.

Done at Brussels, 5 December 2003.

For the Commission

David BYRNE

Member of the Commission

[1] OJ L 349, 24.12.1998, p. 1.

ANNEX

Technical and financial information related to implementation of a surveillance programme for campylobacter in broilers, Sweden

Section A. *Technical report on control*

Reporting period, from..... to .....

1. Examination carried out at diagnostic laboratories

(a) Sampling of slaughter groups

	Number of slaughter-groups sampled	Number of swab samples	Number of neck skin samples	Total number of samples
Bacteriology campylobacter				

(b) Sampling for epidemiological studies

	Number of farms sampled	Number of environmental samples	Number of faecal/cloacal samples	Total number of samples
Bacteriology campylobacter				
Fingerprinting campylobacter				

2. Follow-up of sampling

Number of follow-up mails to producers

Number of follow-up farm visits

3. Description of epidemiological situation along the food chain (results and analysis of results from sampling, visits to farms)

4. Description of the epidemiological situation in humans (trends and sources of campylobacteriosis)

5. Name and address of reporting authority

Section B. *Statement on costs incurred for control* [1]

Reporting period, from..... to .....

Reference number of Commission Decision providing financial assistance: .....

Costs incurred related to functions at/by	Costs incurred during the reporting period (national currency)
Bacteriology for campylobacter	
Fingerprinting of campylobacter	

[1] When presenting the final report referred to in Article 2(c), for each item a listing of all expenditures shall be provided together with a copy of supporting documents.

COMMISSION DECISION

of 11 December 2003

setting out the arrangements for Community comparative trials and tests on propagating material of *Pelargonium* l'Hérit. and *Hosta* Tratt., *Euphorbia pulcherrima* Willd. ex Klotzsch and *Rosa* L. under Council Directive 98/56/EC

(notified under document number C(2003) 4626)

(2003/865/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants [1], as last amended by Directive 2003/61/EC [2], and in particular Article 14(4), (5) and (6) thereof,

Whereas:

(1) Directive 98/56/EC provides for the necessary arrangements to be made by the Commission for Community comparative trials and tests of propagating material.

(2) The technical arrangements for the carrying out of the trials and tests have been made within the Standing Committee for Propagating Material of Ornamental Plants.

(3) A call for projects (2003/C 159/08) [3] was published for the carrying out of the above trials and tests.

(4) The proposals have been assessed according to the selection and awarding criteria set out in the above call for projects. The projects, the bodies responsible for the carrying out of tests and trials and the eligible costs as well as the maximum Community financial contribution corresponding to 80 % of the eligible costs should be established.

(5) Community comparative trials and tests should be carried out in the years 2004 and 2005 on propagating material harvested in 2003, and the details of such trials and tests, the eligible costs as well as the maximum Community financial contribution should also be set out yearly by an agreement signed by the authorising officer of the Commission and the body responsible for carrying out of trials.

(6) For Community comparative trials and tests lasting more than one year, the parts of the trials and tests following the first year should be authorised by the Commission without further reference to the Standing Committee on Propagating Material of Ornamental Plants, on condition that the necessary appropriations are available.

(7) Adequate representation of the samples included in the trials and tests should be ensured, at least for certain selected plants.

(8) Member States should participate in the Community comparative trials and tests, in so far as propagating material of the plants concerned are usually reproduced or marketed in their territories, in order to ensure that proper conclusions may be drawn therefrom.

(9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Propagating Material of Ornamental Plants,

HAS ADOPTED THIS DECISION:

Article 1

Community comparative trials and tests shall be carried out in the years 2004 and 2005 on propagating material of the plants listed in the Annex.

The eligible costs as well as the maximum Community financial contribution for the trials and tests for 2004 shall be as set out in the Annex.

The details of the trials and tests are set out in the Annex.

Article 2

In so far as propagating and planting material of the plants listed in the Annex is usually reproduced or marketed in their territories, the Member States shall take samples of this material and make it available to the Commission.

Article 3

Subject to budgetary availability, the Commission may decide to continue the trials and tests set out in the Annex in 2005.

The maximum Community financial contribution corresponding to 80 % of the eligible costs of a trial or test continued on this basis shall not exceed the amount specified in the Annex.

[1] OJ L 226, 13.8.1998, p. 16.
[2] OJ L 165, 3.7.2003, p. 23.
[3] OJ C 159, 8.7.2003, p. 19.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 11 December 2003.

For the Commission
David BYRNE
Member of the Commission

ANNEX

Trials and tests to be carried out in 2004

Species	Responsible body	Conditions to be assessed	Number of samples	Eligible costs (EUR)	Maximum Community financial contribution (equivalent to 80% of the eligible costs) (EUR)
Perennials (*Pelargonium* l'Hérit. and *Hosta* Tratt. (*))	Naktuinbouw Roelofarendsveen (NL)	Varietal identity and purity plant health (field) plant health (laboratory)	50+50	43 367	34 694
Euphorbia pulcherrima Willd. ex Klotzsch	Naktuinbouw Roelofarendsveen (NL)	Varietal identity and purity plant health (field) plant health (laboratory)	60	47 208	37 766
Rosa L. (garden roses)	BSA Bundessortenamt Hannover (D)	Varietal identity and purity plant health (field) plant health (laboratory)	80	17 982	14 386
			Total Community financial contribution	**86 846**	

Trials and tests to be carried out in 2005

Species	Responsible body	Conditions to be assessed	Number of samples	Eligible costs (EUR)	Maximum Community financial contribution (equivalent to 80% of the eligible costs) (EUR)
Perennials (*Hosta* Tratt. (*))	Naktuinbouw Roelofarendsveen (NL)	Varietal identity and purity plant health (field) plant health (laboratory)	50	15 189	12 151
			Total Community financial contribution	**12 151**	

(*) Trial and tests lasting more than one year.