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Legislation

Contents

(Continued overleaf)

EN

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.

The titles of all other Acts are printed in bold type and preceded by an asterisk.

Contents (continued)

(1) Text with EEA relevance

I

(Acts whose publication is obligatory)

COUNCIL REGULATION (EC) No 1310/97

of 30 June 1997

amending Regulation (EEC) No 4064/89 on the control of concentrations between undertakings

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 87 and 235 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

(1) Whereas concentrations with a significant impact in several Member States that fall below the thresholds referred to in Council Regulation (EEC) No 4064/89 of 21 December 1989 on the control of concentrations between undertakings (4) may qualify for examination under a number of national merger control systems; whereas multiple notification of the same transaction increases legal uncertainty, effort and cost for companies and may lead to conflicting assessments;

(2) Whereas extending the scope of Community merger control to concentrations with a significant impact in several Member States will ensure that a 'one-stop shop' system applies and will allow, in compliance with the subsidiarity principle, for an appreciation of the competition impact of such concentrations in the Community as a whole;

(3) Whereas additional criteria should be established for the application of Community merger control in order to meet the abovementioned objectives; whereas those criteria should consist of new thresholds established in terms of the total turnover of the undertakings concerned achieved world-wide, at Community level and in at least three Member States;

(4) Whereas at the end of the initial phase of application of this Regulation the Commission should report to the Council on the implementation of all applicable thresholds and criteria, so that the Council is in a position, acting in accordance with Article 145 of the Treaty, to change the criteria or adjust the thresholds laid down in this Regulation;

(5) Whereas it is appropriate to define the concept of concentration in such a manner as to cover operations bringing about a lasting change in the structure of the undertakings concerned; whereas in the specific case of joint ventures it is appropriate to include within the scope and procedure of Regulation (EEC) No 4064/89 all full-function joint ventures; whereas, in addition to the dominance test set out in Article 2 of that Regulation, it should be provided that the Commission apply the criteria of Article 85 (1) and (3) of the Treaty to such joint ventures, to the extent that their creation has as its direct consequence an appreciable restriction of competition between undertakings that remain independent; whereas, if the effects of such joint ventures on the market are primarily structural, Article 85 (1) does not as a general rule apply; whereas Article 85 (1) may apply if two or more parent companies remain active in the market of the joint venture, or, possibly, if the creation of the joint venture has as its object or effect the prevention, restriction or distortion of competition between the parent companies in upstream, downstream or neighbouring markets; whereas, in this context, the appraisal of all competition aspects of the creation of the joint venture must be made within the same procedure;

(1) OJ No C 350, 21. 11. 1996, pp. 8 and 10.
(2) OJ No C 362, 2. 12. 1996, p. 130.
(3) OJ No C 56, 24. 2. 1997, p. 71.
(4) OJ No L 395, 30. 12. 1989, p. 1. Regulation rectified by OJ No L 257, 21. 9. 1990, p. 13 and amended by the 1994 Act of Accession.

(6) Whereas, for the purposes of calculating the turnover of credit and financial institutions, banking income is a better criterion than a proportion of assets, because it reflects more accurately the economic reality of the whole banking sector;

(7) Whereas it should be expressly provided that decisions taken at the end of the first phase of the procedure cover restrictions directly related and necessary for the implementation of a concentration;

(8) Whereas the Commission may declare a concentration compatible with the common market in the second phase of the procedure, following commitments by the parties that are proportional to and would entirely eliminate the competition problem; whereas it is also appropriate to accept commitments in the first phase of the procedure where the competition problem is readily identifiable and can easily be remedied; whereas it should be expressly provided that in these cases the Commission may attach to its decision conditions and obligations; whereas transparency and effective consultation of Member States and interested third parties should be ensured in both phases of the procedure;

(9) Whereas, to ensure effective control, concentrations should be suspended until a final decision has been taken; whereas, on the other hand, it should be possible to waive a suspension, where appropriate; whereas, in deciding whether or not to grant a waiver, the Commission should take account of all pertinent factors, such as the nature and gravity of damage to the undertakings concerned by a concentration or to third parties, and the threat to competition posed by the concentration;

(10) Whereas the rules governing the referral of concentrations between the Commission and Member States should be reviewed at the same time as the additional criteria for implementation of Community merger control are established; whereas these rules protect the competition interests of the Member States in an adequate manner and take due account of legal security and the 'one-stop shop' principle; whereas, however, certain aspects of the referral procedures should be improved or clarified;

(11) Whereas, in particular, the Commission can declare a concentration incompatible with the common market only if it impedes effective competition in a substantial part thereof; whereas the application of national competition law is, therefore, particularly appropriate where a concentration affects competition on a distinct market within a Member State that does not constitute a substantial part of the common market; whereas in this case it should not be necessary to demonstrate, in the request for referral, that the concentration threatens to create or to strengthen a dominant position on this distinct market;

(12) Whereas it should be possible to suspend exceptionally the period within which the Commission must take a decision within the first phase of the procedure;

(13) Whereas it should be expressly provided that two or more Member States may make a joint request pursuant to Article 22 of Regulation (EEC) No 4064/89; whereas to ensure effective control, provision should be made for the suspension of concentrations referred to the Commission by one or more Member States;

(14) Whereas the Commission should be given the power to adopt implementing provisions where necessary,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EEC) No 4064/89 is hereby amended as follows:

1. in Article 1:

(a) paragraph 1 shall be replaced by the following:

'1. Without prejudice to Article 22, this Regulation shall apply to all concentrations with a Community dimension as defined in paragraphs 2 and 3.';

(b) paragraph 3 shall be replaced by the following:

'3. For the purposes of this Regulation, a concentration that does not meet the thresholds laid down in paragraph 2 has a Community dimension where:

(a) the combined aggregate worldwide turnover of all the undertakings concerned is more than ECU 2 500 million;

(b) in each of at least three Member States, the combined aggregate turnover of all the undertakings concerned is more than ECU 100 million;

(c) in each of at least three Member States included for the purpose of point (b), the aggregate turnover of each of at least two of the undertakings concerned is more than ECU 25 million; and

(d) the aggregate Community-wide turnover of each of at least two of the undertakings concerned is more than ECU 100 million;

unless each of the undertakings concerned achieves more than two-thirds of its aggregate Community-wide turnover within one and the same Member State.';

(c) the following paragraphs shall be added:

'4. Before 1 July 2000 the Commission shall report to the Council on the operation of the thresholds and criteria set out in paragraphs 2 and 3.

5. Following the report referred to in paragraph 4 and on a proposal from the Commission, the Council, acting by a qualified majority, may revise the thresholds and criteria mentioned in paragraph 3.';

2. in Article 2, the following paragraph shall be added:

'4. To the extent that the creation of a joint venture constituting a concentration pursuant to Article 3 has as its object or effect the coordination of the competitive behaviour of undertakings that remain independent, such coordination shall be appraised in accordance with the criteria of Article 85 (1) and (3) of the Treaty, with a view to establishing whether or not the operation is compatible with the common market.

In making this appraisal, the Commission shall take into account in particular:

— whether two or more parent companies retain to a significant extent activities in the same market as the joint venture or in a market which is downstream or upstream from that of the joint venture or in a neighbouring market closely related to this market,

— whether the coordination which is the direct consequence of the creation of the joint venture affords the undertakings concerned the possibility of eliminating competition in respect of a substantial part of the products or services in question.';

3. in Article 3, paragraph 2 shall be amended as follows:

(a) the first subparagraph shall be deleted;

(b) in the second subparagraph the phrase 'which does not give rise to the coordination of the competitive behaviour of the parties amongst themselves or between them and the joint venture' shall be deleted.

4. in Article 5:

— paragraph 3 shall be replaced by the following:

'3. In place of turnover the following shall be used:

(a) for credit institutions and other financial institutions, as regards Article 1 (2) and (3), the sum of the following income items as defined in Council Directive 86/635/EEC of 8 December 1986 on the annual accounts and consolidated accounts of banks and other financial institutions (*), after deduction of value added tax and other taxes directly related to those items, where appropriate:

(i) interest income and similar income;

(ii) income from securities:

— income from shares and other variable yield securities,

— income from participating interests,

— income from shares in affiliated undertakings;

(iii) commissions receivable;

(iv) net profit on financial operations;

(v) other operating income.

The turnover of a credit or financial institution in the Community or in a Member State shall comprise the income items, as defined above, which are received by the branch or division of that institution established in the Community or in the Member State in question, as the case may be;

(b) for insurance undertakings, the value of gross premiums written which shall comprise all amounts received and receivable in respect of insurance contracts issued by or on behalf of the insurance undertakings, including also outgoing reinsurance premiums, and after deduction of taxes and parafiscal contributions or levies charged by reference to the amounts of individual premiums or the total volume of premiums; as regards Article 1 (2) (b) and (3) (b), (c) and (d) and the final part of Article 1 (2) and (3), gross premiums received from Community residents and from residents of one Member State respectively shall be taken into account.

(*) OJ No L 372, 31. 12. 1986, p. 1.';

— in paragraph 4, the introductory sentence shall be replaced by the following:

'4. Without prejudice to paragraph 2, the aggregate turnover of an undertaking concerned within the meaning of Article 1 (2) and (3) shall be calculated by adding together the respective turnovers of the following:';

— in paragraph 5, the introductory sentence shall be replaced by the following:

'5. Where undertakings concerned by the concentration jointly have the rights or powers listed in paragraph 4 (b), in calculating the aggregate turnover of the undertakings concerned for the purposes of Article 1 (2) and (3):';

5. in Article 6:

(a) in paragraph 1:

— in point (b) the following subparagraph shall be added:

'The decision declaring the concentration compatible shall also cover restrictions directly related and necessary to the implementation of the concentration.';

— point (c) shall be replaced by the following:

'(c) Without prejudice to paragraph 1 (a), where the Commission finds that the concentration notified falls within the scope of this Regulation and raises serious doubts as to its compatibility with the common market, it shall decide to initiate proceedings.';

(b) the following paragraphs shall be inserted:

'1a. Where the Commission finds that, following modification by the undertakings concerned, a notified concentration no longer raises serious doubts within the meaning of paragraph 1 (c), it may decide to declare the concentration compatible with the common market pursuant to paragraph 1 (b).

The Commission may attach to its decision under paragraph 1 (b) conditions and obligations intended to ensure that the undertakings concerned comply with the commitments they have entered into vis-à-vis the Commission with a view to rendering the concentration compatible with the common market.

1b. The Commission may revoke the decision it has taken pursuant to paragraph 1 (a) or (b) where:

(a) the decision is based on incorrect information for which one of the undertakings is responsible or where it has been obtained by deceit,

or

(b) the undertakings concerned commit a breach of an obligation attached to the decision.

1c. In the cases referred to in paragraph 1 (b), the Commission may take a decision under paragraph 1, without being bound by the deadlines referred to in Article 10 (1).';

6. in Article 7:

(a) paragraph 1 shall be replaced by the following:

'1. A concentration as defined in Article 1 shall not be put into effect either before its notification or until it as been declared compatible with the common market pursuant to a decision under Article 6 (1) (b) or Article 8 (2) or on the basis of a presumption according to Article 10 (6).';

(b) paragraph 2 shall be deleted;

(c) paragraph 3 shall be amended as follows:

the words 'paragraphs 1 and 2' at the beginning of the paragraph shall be replaced by the words 'paragraph 1';

(d) paragraph 4 shall be replaced by the following:

'4. The Commission may, on request, grant a derogation from the obligations imposed in paragraphs 1 or 3. The request to grant a derogation must be reasoned. In deciding on the request, the Commission shall take into account inter alia the effects of the suspension on one or more undertakings concerned by a concentration or on a third party and the threat to competition posed by the concentration. That derogation may be made subject to conditions and obligations in order to ensure conditions of effective competition. A derogation may be applied for and granted at any time, even before notification or after the transaction.';

(e) paragraph 5 shall be replaced by the following:

'5. The validity of any transaction carried out in contravention of paragraph 1 shall be dependent on a decision pursuant to Article 6 (1) (b) or Article 8 (2) or (3) or on a presumption pursuant to Article 10 (6).

This Article shall, however, have no effect on the validity of transactions in securities including those convertible into other securities admitted to trading on a market which is regulated and supervised by authorities recognized by public bodies, operates regularly and is accessible directly or indirectly to the public, unless the buyer and seller knew or ought to have known that the transaction was carried out in contravention of paragraph 1.';

7. in Article 8:

(a) paragraph 2 shall be replaced by the following:

'2. Where the Commission finds that, following modification by the undertakings concerned if necessary, a notified concentration fulfils the criterion laid down in Article 2 (2) and, in the cases referred to in Article 2 (4), the criteria laid down in Article 85 (3) of the Treaty, it shall issue a decision declaring the concentration compatible with the common market.

It may attach to its decision conditions and obligations intended to ensure that the undertakings concerned comply with the commitments they have entered into *vis-à-vis* the Commission with a view to rendering the concentration compatible with the common market. The decision declaring the concentration compatible with the common market shall also cover restrictions directly related and necessary to the implementation of the concentration.';

(b) paragraph 3 shall be replaced by the following:

'3. Where the Commission finds that a concentration fulfils the criterion defined in Article 2 (3) or, in the cases referred to in Article 2 (4), does not fulfil the criteria laid down in Article 85 (3) of the Treaty, it shall issue a decision declaring that the concentration is incompatible with the common market.';

8. in Article 9:

(a) paragraph 2 shall be replaced by the following:

'2. Within three weeks of the date of receipt of the copy of the notification a Member State may inform the Commission, which shall inform the undertakings concerned, that:

(a) a concentration threatens to create or to strengthen a dominant position as a result of which effective competition will be significantly impeded on a market within that Member State, which presents all the characteristics of a distinct market, or

(b) a concentration affects competition on a market within that Member State, which presents all the characteristics of a distinct market and which does not constitute a substantial part of the common market.';

(b) in paragraph 3:

— point (b) shall be replaced by the following:

'(b) it shall refer the whole or part of the case to the competent authorities of the Member State concerned with a view to the application of that State's national competition law.',

— the following subparagraph shall be added:

'In cases where a Member State informs the Commission that a concentration affects competition in a distinct market within its territory that does not form a substantial part of the common market, the Commission shall refer the whole or part of the case relating to the distinct market concerned, if it considers that such a distinct market is affected.';

(c) paragraph 10 shall be replaced by the following:

'10. This Article may be re-examined at the same time as the thresholds referred to in Article 1.';

9. in Article 10:

(a) in paragraph 1, the following text shall be added at the end of the second subparagraph:

'or where, after notification of a concentration, the undertakings concerned submit commitments pursuant to Article 6 (1a), which are intended by the parties to form the basis for a decision pursuant to Article 6 (1) (b).';

(b) at the beginning of paragraph 4 the phrase 'The period set by paragraph 3' shall be replaced by the phrase 'The periods set by paragraphs 1 and 3';

10. in Article 18:

(a) in paragraph 1 the words: 'Article 7 (2) and (4)' shall be replaced by the words 'Article 7 (4)';

(b) paragraph 2 shall be replaced by the following:

'2. By way of derogation from paragraph 1, a decision to grant a derogation from suspension as referred to in Article 7 (4) may be taken provisionally, without the persons, undertakings or associations of undertakings concerned being given the opportunity to make known their views beforehand, provided that the Commission gives them that opportunity as soon as possible after having taken its decision.';

11. in Article 19, the following text shall be added at the end of paragraph 1:

'Such documents shall include commitments which are intended by the parties to form the basis for a decision pursuant to Articles 6 (1) (b) or 8 (2).';

12. in Article 22:

(a) paragraphs 1 and 2 shall be replaced by the following:

'1. This Regulation alone shall apply to concentrations as defined in Article 3, and Regulations No 17 [1], (EEC) No 1017/68 [2], (EEC) No 4056/86 [3] and (EEC) No 3975/87 [4] shall not apply, except in relation to joint ventures that do not have a Community dimension and which have their object or effect the coordination of the competitive behaviour of undertakings that remain independent.';

(b) paragraph 3 shall be amended as follows:

'3. If the Commission finds, at the request of a Member State or at the joint request of two or more Member States, that a concentration as defined in Article 3 that has no Community dimension within the meaning of Article 1 creates or strengthens a dominant position as a result of which effective competition would be significantly impeded within the territory of the Member State or States making the joint request, it may, insofar as that concentration affects trade between Member States, adopt the decisions provided for in Article 8 (2), second subparagraph, (3) and (4).';

(c) paragraph 4 shall be replaced by the following:

'4. Articles 2 (1) (a) and (b), 5, 6, 8 and 10 to 20 shall apply to a request made pursuant to paragraph 3. Article 7 shall apply to the extent that the concentration has not been put into effect on the date on which the Commission informs the parties that a request has been made.

The period within which proceedings may be initiated pursuant to Article 10 (1) shall begin on the day following that of the receipt of the request from the Member State or States concerned. The request must be made within one month at most of the date on which the concentration was made known to the Member State or to all Member States making a joint request or effected. This period shall begin on the date of the first of those events.';

(d) in paragraph 5 the phrase 'or States' shall be inserted after the phrase 'within the territory of the Member State';

(e) paragraph 6 shall be deleted;

13. in Article 23:

(a) these phrase 'time limits pursuant to Article 10' shall be replaced by the phrase 'time limits pursuant to Articles 7, 9, 10 and 22';

(b) the following subparagraph shall be added:

'The Commission shall have the power to lay down the procedure and time limits for the submission of commitments pursuant to Articles 6 (1a) and 8 (2).'

Article 2

This Regulation shall not apply to any concentration which was the subject of an agreement or announcement or where control was acquired within the meaning of Article 4 (1) of Regulation (EEC) No 4064/89, before 1 March 1998 and it shall not in any circumstances apply to any concentration in respect of which proceedings were initiated before 1 March 1998 by a Member State's authority with responsibility for competition.

Article 3

This Regulation shall enter into force on 1 March 1998.

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

Done at Luxembourg, 30 June 1997.

For the Council

The President

A. NUIS

COMMISSION REGULATION (EC) No 1311/97

of 8 July 1997

amending for the third time Regulation (EC) No 2177/96 introducing preventive distillation as provided for in Article 38 of Council Regulation (EEC) No 822/87 for the 1996/97 wine year

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 822/87 of 16 March 1987 on the common organization of the market in wine [1], as last amended by Regulation (EC) No 536/97 [2], and in particular Article 38 (5) thereof,

Whereas the administrative authorities in some wine-growing regions have been facing insurmountable difficulties in meeting the time limits for approving the distillation contracts and declarations indicated in Commission Regulation (EC) No 2177/96 [3], as last amended by Regulation (EC) No 814/97 [4]; whereas, for that reason, the time limit for approval of contracts and that for notification to the Commission of the volumes of wine under contract should be put back to 5 June 1997 and 15 June 1997 respectively;

Whereas distilleries in some wine-growing regions are facing insurmountable difficulties in meeting the time limits laid down in Article 2 (2) of Regulation (EC) No 2177/96 for the delivery of wine; whereas, for that reason, the time limit for delivery of the wine should be put back to 31 July 1997;

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Wine,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 2177/96 is hereby amended as follows:

1. in Article 1b (3), '16 May 1997' is replaced by '5 June 1997' and '23 May 1997' is replaced by '15 June 1997';

2. in Article 2 (2), '15 June 1997' is replaced by '31 July 1997'.

Article 2

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

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

Done at Brussels, 8 July 1997.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ No L 84, 27. 3. 1987, p. 1.
[2] OJ No L 83, 25. 3. 1997, p. 5.
[3] OJ No L 291, 14. 11. 1996, p. 17.
[4] OJ No L 116, 6. 5. 1997, p. 21.

COMMISSION REGULATION (EC) No 1312/97

of 8 July 1997

amending Regulation (EC) No 3582/93 on detailed rules for the application of Council Regulation (EEC) No 2073/92 on promoting consumption in the Community and expanding the markets for milk and milk products

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2073/92 of 30 June 1992 on promoting consumption in the Community and expanding the markets for milk and milk products [1], and in particular Article 4 thereof,

Whereas Article 4 (4) (b) of Commission Regulation (EC) No 3582/93 of 21 December 1993 on detailed rules for the application of Council Regulation (EEC) No 2073/92 on promoting consumption in the Community and expanding the markets for milk and milk products [2], as last amended by Regulation (EC) No 750/97 [3], provides that applications for funding under the Regulation shall be valid only where they are accompanied by a written undertaking to commission an assessment study, at the applicant's expense, if this is requested by the Commission or by the competent body;

Whereas, in the light of experience, and to ensure a uniform approach with promotion measures for other agricultural products, these provisions should be modified; whereas evaluation studies should be carried out on all contracts for promotion measures; whereas the assessment studies should be considered a part of the measures in the programme and, as a consequence, should be financed under the same conditions as other planned measures; whereas the assessment study should be executed by an independent body selected by the competent authority after prior approval by the Commission;

Whereas, as a result of the latest enlargement of the European Community, the Annex comprising the list of competent bodies pursuant to Article 4 (2) must be amended;

Whereas 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

Regulation (EC) No 3582/93 is hereby amended as follows:

1. Article 4 (4) (b) is replaced by the following:

   '(b) to forward to the competent authority and to the Commission the results of an assessment study which shall be executed by an independent body selected by the competent authority after prior approval by the Commission; the assessment study shall be financed under the same conditions as other planned measures;'

2. the Annex is replaced by the Annex hereto.

Article 2

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

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

Done at Brussels, 8 July 1997.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ No L 215, 30. 7. 1992, p. 67.
[2] OJ No L 326, 28. 12. 1993, p. 23.
[3] OJ No L 110, 26. 4. 1997, p. 28.

ANNEX

LIST OF COMPETENT BODIES PURSUANT TO ARTICLE 4 (2)

Member State	Competent body
Austria	Agrarmarkt Austria (AMA) Dresdner Straße 70 A-1201 Wien
Belgium	Bureau d'intervention et de restitution belge (BIRB) Rue de Trèves 82 B-1040 Bruxelles Belgische Interventie- en Restitutiebureau (BIRB) Trierstraat, 82 B-1040 Brussel
Denmark	EU-Direktoratet Kampmannsgade 3 DK-1780 København V
Finland	Maa- ja metsätalousministeriö (MMM) Kluuvikatu 4A PO BOX 232 FIN-00171 Helsinki
France	Office national interprofessionnel du lait et des produits laitiers (ONILAIT) 2, rue Saint-Charles F-75740 Paris Cedex 15
Germany	Bundesanstalt für Landwirtschaft und Ernährung (BLE) Postfach 18 02 30 D-60083 Frankfurt am Main
Greece	Direction for the management of agricultural products (DIDAGEP) 241 Acharnon Street GR-104-46 Athens
Ireland	Department of Agriculture, Food and Forestry Milk Policy Division Agriculture House IRL-Dublin 2
Italy	Azienda di Stato per gli Interventi nel Mercato Agricolo (AIMA) Via Palestro 81 I-00185 Rome
Luxembourg	Administration des services techniques de l'agriculture Division agronomique Service de la production animale 16 route d'Esch Boîte postale 1904 L-1019 Luxembourg
Netherlands	Productschap Zuivel Sir Winston Churchillaan 275 Postbus 5806 NL-2280 HV Rijswijk
Sweden	Jordbruksverket Vallgatan 8 S-551 82 Jönköping

Member State	Competent body
United Kingdom	Intervention Board Kings House, 33 Kings Road PO Box 69 UK-Reading RG1 3BU
Spain	Secretaría General de Alimentación Ministerio de Agricultura, Pesca y Alimentación Paseo Infanta Isabel 1 E-28014 Madrid
Portugal	Instituto Nacional de Intervenção e Garantia Agrícola (INGA) Rua Camilo Castelo Branco, 45, 2º P-1000 Lisboa

COMMISSION REGULATION (EC) No 1313/97

of 8 July 1997

altering, for the 1997/98 marketing year, the adjustment aid and additional aid to the sugar refining industry

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1785/81 of 30 June 1981 on the common organization of the markets in the sugar sector [1], as last amended by Regulation (EC) No 1599/96 [2], and in particular Article 36 (6) thereof,

Whereas Article 36 of Regulation (EEC) No 1785/81 provides that during the 1995/96 to 2000/01 marketing years adjustment aid of ECU 0,10 per 100 kilograms of sugar expressed as white sugar is to be granted as an intervention measure to the Community's imported preferential raw cane sugar refining industry; whereas, as provided for in those provisions, additional aid equal to that amount is to be granted during the same period for the refining of raw cane sugar produced in the French overseas departments;

Whereas Aricle 36 (4) of Regulation (EEC) No 1785/81 provides that the adjustment aid and the additional aid referred to above shall be altered in respect of a given marketing year in the light of the storage levy fixed for that year and previous adjustments; whereas the storage levy for the 1997/98 marketing year was fixed by Commission Regulation (EC) No 1208/97 [3] at ECU 2,00 per 100 kilograms of white sugar; whereas that amount is less than that applicable for the 1996/97 marketing year; whereas, after taking into account previous adjustments, the amount of these aids should consequently be fixed for the 1997/98 marketing year at ECU 2,92 per 100 kilograms of sugar exported as white sugar;

Whereas 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 amounts of the adjustment aid and of the additional aid provided for respectively in paragraphs 1 and 3 of Article 36 of Regulation (EEC) No 1785/81 shall be fixed at ECU 2,92 per 100 kilograms of sugar expressed as white sugar for the 1997/98 marketing year.

Article 2

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

It shall apply with effect from 1 July 1997.

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

Done at Brussels, 8 July 1997.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ No L 177, 1. 7. 1981, p. 4.
[2] OJ No L 206, 16. 8. 1996, p. 43.
[3] OJ No L 170, 28. 6. 1997, p. 34.

COMMISSION REGULATION (EC) No 1314/97

of 8 July 1997

opening import quotas in respect of special preferential raw cane sugar from the ACP States and India for supply to refineries in the period 1 July 1997 to 28 February 1998

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1785/81 of 30 June 1981 on the common organization of the market in sugar [1], as last amended by Regulation (EC) No 1599/96 [2], and in particular Articles 14 (2) and 37 (6) thereof,

Whereas Article 37 of Regulation (EEC) No 1785/81 lays down that, during the marketing years 1995/96 to 2000/01 and in order to ensure adequate supplies to Community refineries, a special reduced duty is to be levied on imports of raw cane sugar originating in States with which the Community has concluded supply arrangements on preferential terms; whereas at present such agreements have been concluded by Council Decision 95/284/EC [3] only with the ACP States party to Protocol 8 on ACP sugar annexed to the Fourth ACP-EEC Lomé Convention, and with the Republic of India;

Whereas the quantities of special preferential sugar to be imported are calculated in accordance with the said Article 37 of Regulation (EEC) No 1785/81 on the basis of a Community forecast supply balance; whereas the balance indicates the need to import raw sugar and to open at this stage for the 1997/98 marketing year a tariff quota at the special reduced rate of duty as provided for in the abovementioned agreements so that the Community refineries' supply need can be met for part of the year; whereas the production forecasts for raw cane sugar are now available for the 1997/98 marketing year; whereas a tariff quota should be opened at this stage for part of the marketing year; whereas, because of the presumed maximum refining needs fixed by Member State and the shortfall resulting from the forecast supply balance, provision should be made to authorize imports for each refining Member State, for the period 1 July 1997 to 28 February 1998;

Whereas the above agreements lay down that the refiners in question must pay a minimum purchase price equal to the guaranteed price for raw sugar, minus the adjustment aid fixed for the marketing year in question; whereas this minimum price must accordingly be fixed by taking account of the factors applying in the 1997/98 marketing year;

Whereas 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 following tariff quotas are hereby opened for the period 1 July 1997 to 28 February 1998 under Decision 95/284/EC in respect of imports of raw cane sugar for refining:

(a) 255 000 tonnes expressed as white sugar originating in the ACP States covered by that Decision; and

(b) 10 000 tonnes expressed as white sugar originating in the Republic of India.

Article 2

1. A special reduced duty of ECU 5,41 per 100 kg of standard quality raw sugar shall apply to imports of the quantities referred to in Article 1.

2. Article 7 of Commission Regulation (EC) No 1916/95 [4] notwithstanding, the minimum purchase price to be paid by the Community refiners shall be fixed for the period referred to in Article 1 at ECU 49,68 per 100 kg of standard quality raw sugar.

Article 3

The following Member States are hereby authorized to import under the quotas referred to in Article 1 and on the terms laid down in Article 2 (1) the following shortfall expressed as white sugar:

[1] OJ No L 177, 1. 7. 1981, p. 4.
[2] OJ No L 206, 16. 8. 1996, p. 43.
[3] OJ No L 181, 1. 8. 1995, p. 22.
[4] OJ No L 184, 3. 8. 1995, p. 18.

(a) Finland: 48 000 tonnes;

(b) metropolitan France: 12 000 tonnes,

(c) mainland Portugal: 205 000 tonnes,

(d) United Kingdom: 0 tonnes.

Article 4

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

It shall apply with effect from 1 July 1997.

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

Done at Brussels, 8 July 1997.

For the Commission

Franz FISCHLER

Member of the Commission

COMMISSION REGULATION (EC) No 1315/97

of 8 July 1997

on the issue of import licences for garlic originating in China

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2200/96 of 28 October 1996 on the common organization of the market in fruit and vegetables [1],

Having regard to Council Regulation (EC) No 903/97 of 21 May 1997 concerning a protective measure applicable to imports of garlic from China [2], and in particular Article 1 (3) thereof,

Whereas pursuant to Commission Regulation (EEC) No 1859/93 [3], as amended by Regulation (EC) No 1662/94 [4], the release for free circulation in the Community of garlic imported from third countries is subject to presentation of an import licence;

Whereas Article 1 (1) of Regulation (EC) No 903/97, restricts the issue of import licences for garlic originating in China to a maximum monthly quantity in the case of applications lodged from 1 June 1997 to 31 May 1998;

Whereas, given the criteria laid down in Article 1 (2) of that Regulation and the import licences already issued, the quantity applied for on 4 July 1997 is in excess of the maximum monthly quantity given in the Annex to that Regulation for the month of July 1997; whereas it is therefore necessary to determine to what extent import licences may be issued in response to these applications; whereas the issue of licences in response to applications lodged after 4 July 1997 and before 5 August 1997 should be refused,

HAS ADOPTED THIS REGULATION:

Article 1

Import licences applied for on 4 July 1997 under Article 1 of Regulation (EEC) No 1859/93 for garlic falling within CN code 0703 20 00 originating in China shall be issued for 0,16877 % of the quantity applied for, having regard to the information available to the Commission on 7 July 1997.

For the abovementioned products applications for import licences lodged after 4 July 1997 and before 5 August 1997 shall be refused.

Article 2

This Regulation shall enter into force on 9 July 1997.

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

Done at Brussels, 8 July 1997.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ No L 297, 21. 11. 1996, p. 1.
[2] OJ No L 130, 22. 5. 1997, p. 6.
[3] OJ No L 170, 13. 7. 1993, p. 10.
[4] OJ No L 176, 9. 7. 1994, p. 1.

COMMISSION REGULATION (EC) No 1316/97

of 8 July 1997

fixing, for June 1997, the specific agricultural conversion rate for the amount of the reimbursement of storage costs in the sugar sector

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1785/81 of 30 June 1981 on the common organization of the markets in the sugar sector [1], as last amended by Regulation (EC) No 1599/96 [2],

Having regard to Council Regulation (EEC) No 3813/92 of 28 December 1992 on the unit of account and the conversion rates to be applied for the purposes of the common agricultural policy [3], as last amended by Regulation (EC) No 150/95 [4],

Having regard to Commission Regulation (EEC) No 1713/93 of 30 July 1993 establishing special detailed rules for applying the agricultural conversion rate in the sugar sector [5], as last amended by Regulation (EC) No 59/97 [6], and in particular Article 1 (3) thereof,

Whereas Article 1 (2) of Regulation (EEC) No 1713/93 provides that the amount of the reimbursement of storage costs referred to in Article 8 of Regulation (EEC) No 1785/81 is to be converted into national currency using a specific agricultural conversion rate equal to the average, calculated *pro rata temporis*, of the agricultural conversion rates applicable during the month of storage; whereas that specific rate must be fixed each month for the previous month;

Whereas application of these provisions will lead to the fixing, for June 1997, of the specific agricultural conversion rate for the amount of the reimbursement of storage costs in the various national currencies as indicated in the Annex to this Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

The specific agricultural conversion rate to be used to convert the amount of the reimbursement of storage costs referred to in Article 8 of Regulation (EEC) No 1785/81 into each of the national currencies for June 1997 shall be as indicated in the Annex hereto.

Article 2

This Regulation shall enter into force on 9 July 1997.

It shall apply with effect from 1 June 1997.

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

Done at Brussels, 8 July 1997.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ No L 177, 1. 7. 1981, p. 4.
[2] OJ No L 206, 16. 8. 1996, p. 43.
[3] OJ No L 387, 31. 12. 1992, p. 1.
[4] OJ No L 22, 31. 1. 1995, p. 1.
[5] OJ No L 159, 1. 7. 1993, p. 94.
[6] OJ No L 14, 17. 1. 1997, p. 25.

ANNEX

to the Commission Regulation of 8 July 1997 fixing, for June 1997, the specific agricultural conversion rate for the amount of the reimbursement of storage costs in the sugar sector

Agricultural conversion rates		
ECU 1 =	40,4285	Belgian and Luxembourg francs
	7,49997	Danish kroner
	1,95929	German marks
	312,011	Greek drachmas
	165,571	Spanish pesetas
	6,61023	French francs
	0,759189	Irish punt
	1 973,93	Italian lire
	2,20397	Dutch guilders
	13,7910	Austrian schillings
	198,202	Portuguese escudos
	6,02811	Finnish marks
	8,88562	Swedish kroner
	0,723694	Pound sterling

COMMISSION REGULATION (EC) No 1317/97

of 8 July 1997

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 2375/96 [2], and in particular Article 4 (1) thereof,

Having regard to Council Regulation (EEC) No 3813/92 of 28 December 1992 on the unit of account and the conversion rates to be applied for the purposes of the common agricultural policy [3], as last amended by Regulation (EC) No 150/95 [4], and in particular Article 3 (3) thereof,

Whereas 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;

Whereas, 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 9 July 1997.

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

Done at Brussels, 8 July 1997.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ No L 337, 24. 12. 1994, p. 66.
[2] OJ No L 325, 14. 12. 1996, p. 5.
[3] OJ No L 387, 31. 12. 1992, p. 1.
[4] OJ No L 22, 31. 1. 1995, p. 1.

ANNEX

to the Commission Regulation of 8 July 1997 establishing the standard import values for determining the entry price of certain fruit and vegetables

(ECU/100 kg)

CN code	Third country code (1)	Standard import value
ex 0707 00 25	052	53,5
	999	53,5
0709 90 77	052	81,3
	999	81,3
0805 30 30	388	77,1
	524	57,9
	528	57,3
	999	64,1
0808 10 71, 0808 10 73, 0808 10 79	388	85,4
	400	78,9
	508	87,1
	512	70,6
	524	68,4
	528	71,6
	800	140,9
	804	96,8
	999	87,5
0808 20 47	388	70,0
	512	34,0
	528	68,2
	804	124,8
	999	74,3
0809 20 49	052	270,8
	064	209,5
	068	193,3
	400	210,1
	616	218,3
	999	220,4
0809 30 31, 0809 30 39	052	99,9
	999	99,9

(1) Country nomenclature as fixed by Commission Regulation (EC) No 68/96 (OJ No L 14, 19. 1. 1996, p. 6). Code '999' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 1318/97

of 8 July 1997

amending representative prices and additional duties for the import of certain products in the sugar sector

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1785/81 of 30 June 1981 on the common organization of the markets in the sugar sector [1], as last amended by Regulation (EC) No 1599/96 [2],

Having regard to Commission Regulation (EC) No 1423/95 of 23 June 1995 laying down detailed implementing rules for the import of products in the sugar sector other than molasses [3], as last amended by Regulation (EC) No 1143/97 [4], and in particular the second subparagraph of Article 1 (2), and Article 3 (1) thereof,

Whereas the amounts of the representative prices and additional duties applicable to the import of white sugar, raw sugar and certain syrups are fixed by Commission Regulation (EC) No 1222/97 [5], as amended by Regulation (EC) No 1286/97 [6];

Whereas it follows from applying the general and detailed fixing rules contained in Regulation (EC) No 1423/95 to the information known to the Commission that the representative prices and additional duties at present in force should be altered to the amounts set out in the Annex hereto,

HAS ADOPTED THIS REGULATION:

Article 1

The representative prices and additional duties on imports of the products referred to in Article 1 of Regulation (EC) No 1423/95 shall be as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 9 July 1997.

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

Done at Brussels, 8 July 1997.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ No L 177, 1. 7. 1981, p. 4.
[2] OJ No L 206, 16. 8. 1996, p. 43.
[3] OJ No L 141, 24. 6. 1995, p. 16.
[4] OJ No L 165, 24. 6. 1997, p. 11.
[5] OJ No L 173, 1. 7. 1997, p. 3.
[6] OJ No L 175, 3. 7. 1997, p. 18.

ANNEX

to the Commission Regulation of 8 July 1997 amending representative prices and the amounts of additional duties applicable to imports of white sugar, raw sugar and products covered by CN code 1702 90 99

(ECU)

CN code	Amount of representative prices per 100 kg net of product concerned	Amount of additional duty per 100 kg net of product concerned
1701 11 10 (1)	23,43	4,58
1701 11 90 (1)	23,43	9,82
1701 12 10 (1)	23,43	4,39
1701 12 90 (1)	23,43	9,39
1701 91 00 (2)	27,77	11,35
1701 99 10 (2)	27,77	6,83
1701 99 90 (2)	27,77	6,83
1702 90 99 (3)	0,28	0,37

(1) For the standard quality as defined in Article 1 of amended Council Regulation (EEC) No 431/68 (OJ No L 89, 10. 4. 1968, p. 3).

(2) For the standard quality as defined in Article 1 of Council Regulation (EEC) No 793/72 (OJ No L 94, 21. 4. 1972, p. 1).

(3) By 1 % sucrose content.

COUNCIL DIRECTIVE 97/40/EC

of 25 June 1997

amending Directive 93/113/EC concerning the use and marketing of enzymes, micro-organisms and their preparations in animal nutrition

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (4) lays down the principles relating to the admission and the use of additives;

Whereas Directive 93/113/EC (5) authorizes the Member States to permit provisionally the use and marketing of the products in question provided that, on the basis of available scientific evidence, they do not present any danger to human or animal health;

Whereas Directive 93/113/EC requires the Commission to decide before 1 January 1997 on case files submitted by the Member States before 1 January 1996 for the purpose of obtaining Community authorization under Directive 70/524/EEC;

Whereas the large number of case files submitted by the Member States has made it impossible to decide, in full knowledge of the facts, on all the authorization applications by 31 December 1996; whereas the date by which the Commission must decide should thus be postponed by 18 months so that the Commission and the Member States have sufficient time to give serious consideration to the files submitted to them,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The date of 1 January 1997 in Article 5 of Directive 93/113/EC shall be replaced by 1 July 1998.

Article 2

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

Article 3

This Directive is addressed to the Member States.

Done at Luxembourg, 25 June 1997.

For the Council

The President

J. VAN AARTSEN

(1) OJ No C 95, 24. 3. 1997, p. 30.
(2) OJ No C 85, 17. 3. 1997, p. 176.
(3) OJ No C 133, 28. 4. 1997, p. 26.
(4) OJ No L 270, 14. 12. 1970, p. 1. Directive as last amended by Commission Directive 96/66/EC (OJ No L 272, 25. 10. 1996, p. 32).
(5) OJ No L 334, 31. 12. 1993, p. 17.

COUNCIL DIRECTIVE 97/43/EURATOM

of 30 June 1997

on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 31 thereof,

Having regard to the proposal from the Commission, drawn up after obtaining the opinion of a group of persons appointed by the Scientific and Technical Committee,

Having regard to the opinion of the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee (2),

(1) Whereas the Council has adopted Directives laying down the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation, as last amended by Directive 96/29/Euratom (3);

(2) Whereas in accordance with Article 33 of the Treaty, each Member State is to lay down the appropriate provisions, whether by legislation, regulation or administrative action, to ensure compliance with the basic standards which have been established and take the necessary measures with regard to teaching, education and vocational training;

(3) Whereas, on 3 September 1984 the Council adopted Directive 84/466/Euratom laying down the basic measures for the radiation protection of persons undergoing medical examination or treatment (4);

(4) Whereas, as in 1984, medical exposure continues to constitute the major source of exposure to artificial sources of ionizing radiation of European Union citizens; whereas the use of ionizing radiation has enabled great progress to be made in many aspects of medicine; whereas practices causing medical exposure need to be carried out in optimized radiation protection conditions;

(5) Whereas, recognizing the development of scientific knowledge in the field of radiation protection applied to medical exposure, the International Commission on Radiological Protection reviewed the subject in its 1990 and 1996 recommendations;

(6) Whereas such developments make it necessary to repeal Directive 84/466/Euratom;

(7) Whereas Directive 96/29/Euratom lays down basic safety standards for the protection of the workers administering the medical exposure and of the members of the public; whereas the same Directive ensures that the total of contributions to the exposure of the population as a whole, is kept under review;

(8) Whereas health and safety requirements, including radiation protection aspects, regarding the design, manufacture and placing on the market of the medical devices are dealt with by Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (5); whereas pursuant to Article 1 (8) of that Directive, the relevant Directives adopted under the Euratom Treaty are not to be affected by its provisions; whereas it is necessary to set out radiation protection requirements for the medical use of radiological installations from the date of the commencement of their operation;

(9) Whereas provisions need to be adapted for the protection as regards exposure incurred by volunteers and persons knowingly and willingly helping persons undergoing medical examination or treatment;

(10) Whereas the Committee of Ministers of the Council of Europe adopted on 6 February 1990 Recommendation R(90)3 on medical research on human beings, concerning *inter alia* the setting up of an ethics committee;

(11) Whereas detailed requirements are needed for the correct application of the justification and optimization principles in relation to exposure within the scope of this Directive;

(12) Whereas responsibilities for administering medical exposure need to be set out;

(1) OJ No C 167, 2. 6. 1997.
(2) OJ No C 212, 22. 7. 1996, p. 32.
(3) OJ No L 159, 29. 6. 1996, p. 1.
(4) OJ No L 265, 5. 10. 1984, p. 1.
(5) OJ No L 169, 12. 7. 1993, p. 1.

(13) Whereas appropriate training for the staff involved, the establishment of quality assurance and audit programmes, and inspections by the competent authorities are necessary to ensure that medical exposure is delivered under good radiation protection conditions;

(14) Whereas specific provisions are necessary as regards special practice, pregnant and breastfeeding females, volunteers in research and helping persons;

(15) Whereas potential exposure needs to be taken into account,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Purpose and scope

1. This Directive supplements Directive 96/29/Euratom and lays down the general principles of the radiation protection of individuals in relation to the exposure referred to in paragraphs 2 and 3.

2. This Directive shall apply to the following medical exposure:

(a) the exposure of patients as part of their own medical diagnosis or treatment;

(b) the exposure of individuals as part of occupational health surveillance;

(c) the exposure of individuals as part of health screening programmes;

(d) the exposure of healthy individuals or patients voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes;

(e) the exposure of individuals as part of medico-legal procedures.

3. This Directive shall also apply to exposure of individuals knowingly and willingly helping (other than as part of their occupation) in the support and comfort of individuals undergoing medical exposure.

Article 2

Definitions

For the purpose of this Directive, the following terms have the meaning hereby assigned them:

— Clinical audit: a systematic examination or review of medical radiological procedures which seeks to improve the quality and the outcome of patient care through structured review whereby radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices where indicated and the application of new standards if necessary.

— Clinical Responsibility: responsibility regarding individual medical exposures attributed to a practitioner, notably: justification; optimization; clinical evaluation of the outcome; cooperation with other specialists and the staff, as appropriate, regarding practical aspects; obtaining information, if appropriate, of previous examinations; providing existing radiological information and/or records to other practitioners and/or prescribers, as required; giving information on the risk of ionizing radiation to patients and other individuals involved, as appropriate.

— Competent Authorities: any authority designated by a Member State.

— Diagnostic Reference Levels: dose levels in medical radiodiagnostic practices or, in the case of radiopharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment. These levels are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied.

— Dose Constraint: a restriction on the prospective doses to individuals which may result from a defined source, for use at the planning stage in radiation protection whenever optimization is involved.

— Exposure: the process of being exposed to ionizing radiation.

— Health screening: a procedure using radiological installations for early diagnosis in population groups at risk.

— Holder: any natural or legal person who has the legal responsibility under national law for a given radiological installation.

— Individual Detriment: clinically observable deleterious effects that are expressed in individuals or their descendants, the appearance of which is either immediate or delayed and, in the latter case, implies a probability rather than a certainty of appearance.

— Inspection: inspection is an investigation by any competent authority to verify compliance with national provisions on radiological protection for medical radiological procedures, equipment in use or radiological installations.

— Medical Physics Expert: an expert in radiation physics or radiation technology applied to exposure, within the scope of this Directive, whose training and competence to act is recognized by the competent authorities; and who, as appropriate, acts or gives

advice on patient dosimetry, on the development and use of complex techniques and equipment, on optimization, on quality assurance, including quality control, and on other matters relating to radiation protection, concerning exposure within the scope of this Directive.

— Medical Radiological Procedure: any procedure concerning medical exposure.

— Medico-legal procedures: procedures performed for insurance or legal purposes without a medical indication.

— Occupational health surveillance: the medical surveillance for workers as specified by Member States or competent authorities.

— Patient dose: the dose, concerning patients or other individuals undergoing medical exposure.

— Patient dosimetry: the dosimetry concerning patients or other individuals undergoing medical exposure.

— Practical Aspects: the physical conduct of any of the exposure referred to in Article 1 (2) and any supporting aspects including handling and use of radiological equipment, and the assessment of technical and physical parameters including radiation doses, calibration and maintenance of equipment, preparation and administration of radio-pharmaceuticals and the development of films.

— Practitioner: a medical doctor, dentist or other health professional, who is entitled to take clinical responsibility for an individual medical exposure in accordance with national requirements.

— Prescriber: a medical doctor, dentist or other health professional, who is entitled to refer individuals for medical exposure to a practitioner, in accordance with national requirements.

— Quality Assurance: all those planned and systematic actions necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily complying with agreed standards.

— Quality control: is a part of quality assurance. The set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It covers monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled.

— Radiological: pertaining to radiodiagnostic and radiotherapeutic procedures, and interventional radiology or other planning and guiding radiology.

— Radiological installation: a facility containing radiological equipment.

— Radiodiagnostic: pertaining to *in vivo* diagnostic nuclear medicine, medical diagnostic radiology, and dental radiology.

— Radiotherapeutic: pertaining to radiotherapy including nuclear medicine for therapeutic purposes.

Article 3

Justification

1. Medical exposure referred to in Article 1 (2) shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct health benefits to an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionizing radiation.

In particular:

(a) — all new types of practices involving medical exposure shall be justified in advance before being generally adopted,

— existing types of practices involving medical exposure may be reviewed whenever new, important evidence about their efficacy or consequences is acquired.

(b) all individual medical exposures shall be justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved.

If a type of practice involving a medical exposure is not justified in general, a specific individual exposure of this type could be justified in special circumstances, to be evaluated on a case-by-case basis.

The prescriber and the practitioner as specified by Member States, shall seek, where practicable, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider these data to avoid unnecessary exposure.

(c) medical exposure for biomedical and medical research shall be examined by an ethics committee, set up in accordance with national procedures and/or by the competent authorities.

(d) special attention shall be given to the justification of those medical exposures where there is no direct health benefit for the person undergoing the exposure and especially for those exposures on medico-legal grounds.

2. Exposure referred to in Article 1 (3) shall show a sufficient net benefit, taking into account also the direct health benefits to a patient, the benefits to individuals referred to in Article 1 (3) and the detriment that the exposure might cause.

3. If an exposure can not be justified, it should be prohibited.

Article 4

Optimization

1. (a) All doses due to medical exposure for radiological purposes except radiotherapeutic procedures referred to in Article 1 (2) shall be kept as low as reasonably achievable consistent with obtaining the required diagnostic information, taking into account economic and social factors.

(b) For all medical exposure of individuals for radiotherapeutic purposes, as mentioned in Article 1 (2) (a), exposures of target volumes shall be individually planned; taking into account that doses of non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.

2. Member States shall:

(a) promote the establishment and the use of diagnostic reference levels for radiodiagnostic examinations, as referred to in Article 1 (2) (a), (b), (c) and (e), and the availability of guidance for this purpose having regard to European diagnostic reference levels where available;

(b) ensure that for each biomedical and medical research project as mentioned in Article 1 (2) (d):

— the individuals concerned shall participate voluntarily,

— these individuals shall be informed about the risks of this exposure,

— a dose constraint is established for individuals for whom no direct medical benefit is expected from this exposure,

— in the case of patients, who voluntarily accept to undergo an experimental diagnostic or therapeutic practice and who are expected to receive a diagnostic or therapeutical benefit from this practice, the target levels of doses shall be planned on an individual basis by the practitioner and/or prescriber;

(c) ensure that special attention be given, to keep the dose arising from the medico-legal exposure referred to in Article 1 (2) (e) as low as reasonably achievable.

3. The optimization process shall include the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcome as well as the practical aspects, quality assurance including quality control and the assessment and evaluation of patient doses or administered activities, taking into account economic and social factors.

4. Member States shall ensure that:

(a) dose constraints are established for exposure, as referred to in Article 1 (3), of those individuals knowingly and willingly helping (other than as part of their occupation) in the support and comfort of patients undergoing medical diagnosis or treatment where appropriate;

(b) appropriate guidance is established for exposure as referred to in Article 1 (3);

(c) in the case of a patient undergoing a treatment or diagnosis with radionuclides, where appropriate the practitioner or the holder of the radiological installation provides the patient or legal guardian with written instructions, with a view to the restriction of doses to persons in contact with the patient as far as reasonably achievable and to provide information on the risks of ionizing radiation.

These instructions shall be handed out before leaving the hospital or clinic or a similar institution.

Article 5

Responsibilities

1. The prescriber as well as the practitioner shall be involved as specified by Member States in the justification process at the appropriate level.

2. Member States shall ensure that any medical exposure referred to in Article 1 (2) is effected under the clinical responsibility of a practitioner.

3. The practical aspects for the procedure or part of it may be delegated by the holder of the radiological installation or the practitioner, as appropriate, to one or more individuals entitled to act in this respect in a recognized field of specialization.

4. Member States shall ensure the laying down of procedures to be observed in case of medico-legal examinations.

Article 6

Procedures

1. Written protocols for every type of standard radiological practice shall be established for each equipment.

2. Member States shall ensure that recommendations concerning referral criteria for medical exposure, including radiation doses, are available to the prescribers of medical exposure.

3. In radiotherapeutic practices, a medical physics expert shall be closely involved. In standardized therapeutical nuclear medicine practices and in diagnostic nuclear medicine practices, a medical physics expert shall be available. For other radiological practices, a medical physics expert shall be involved, as appropriate, for consultation on optimization including patient dosimetry and quality assurance including quality control, and also to give advice on matters relating to radiation protection concerning medical exposure, as required.

4. Clinical audits shall be carried out in accordance with national procedures.

5. Member States shall ensure that appropriate local reviews are undertaken whenever diagnostic reference levels are consistently exceeded and that corrective actions are taken where appropriate.

Article 7

Training

1. Member States shall ensure that practitioners and those individuals mentioned in Articles 5 (3) and 6 (3) have adequate theoretical and practical training for the purpose of radiological practices, as well as relevant competence in radiation protection.

For this purpose Member States shall ensure that appropriate curricula are established and shall recognize the corresponding diplomas, certificates or formal qualifications.

2. Individuals undergoing relevant training programmes may participate in practical aspects for the procedures mentioned in Article 5 (3).

3. Member States shall ensure that continuing education and training after qualification is provided and, in the special case of the clinical use of new techniques, the organization of training related to these techniques and the relevant radiation protection requirements.

4. Member States shall encourage the introduction of a course on radiation protection in the basic curriculum of medical and dental schools.

Article 8

Equipment

1. Member States shall take such steps as they may consider necessary with a view to avoiding unnecessary proliferation of radiological equipment.

2. Member States shall ensure that:

— all radiological equipment in use is kept under strict surveillance regarding radiation protection,

— an up-to-date inventory of radiological equipment for each radiological installation is available to the competent authorities,

— appropriate quality assurance programmes including quality control measures and patient dose or administered activity assessments are implemented by the holder of the radiological installation, and

— acceptance testing is carried out before the first use of the equipment for clinical purposes, and thereafter performance testing on a regular basis, and after any major maintenance procedure.

3. Competent authorities shall take steps to ensure that necessary measures are taken by the holder of the radiological installation to improve inadequate or defective features of the equipment. They shall also adopt specific criteria of acceptability for equipment in order to indicate when appropriate remedial action is necessary, including, if appropriate, taking the equipment out of service.

4. In the case of fluoroscopy, examinations without an image intensification or equivalent techniques are not justified and shall therefore be prohibited.

5. Fluoroscopic examinations without devices to control the dose rate shall be limited to justified circumstances.

6. If new radiodiagnostical equipment is used, it shall have, where practicable, a device informing the practitioner of the quantity of radiation produced by the equipment during the radiological procedure.

Article 9

Special Practices

1. Member States shall ensure that appropriate radiological equipment, practical techniques and ancillary equipment are used for the medical exposure

— of children,

— as part of a health screening programme,

— involving high doses to the patient, such as interventional radiology, computed tomography or radiotherapy.

Special attention shall be given to the quality assurance programmes, including quality control measures and patient dose or administered activity assessment, as mentioned in Article 8, for these practices.

2. Member States shall ensure that practitioners and those individuals referred to in Article 5 (3) performing the exposure referred to in the first paragraph obtain appropriate training on these radiological practices as required by Article 7 (1) and (2).

Article 10

Special protection during pregnancy and breast-feeding

1. (a) In the case of a female of childbearing age, the prescriber and the practitioner shall inquire as specified by Member States whether she is pregnant, or breastfeeding, if relevant; and

(b) if pregnancy cannot be excluded, depending on the type of medical exposure, in particular if abdominal and pelvic regions are involved, special attention shall be given to the justification, particularly the urgency, and to the optimization of the medical exposure taking into account the exposure both of the expectant mother and the unborn child.

2. In the case of breastfeeding females, in nuclear medicine depending on the type of medical examination or treatment, special attention shall be given to the justification, particularly the urgency, and to the optimization of the medical exposure, taking into account the exposure both for the mother and the child.

3. Without prejudice to Article 10 (1) and (2), any measure contributing to increasing the awareness of women subject to this Article, such as public notices in appropriate places, could be helpful.

Article 11

Potential exposure

Member States shall ensure that all reasonable steps to reduce the probability and the magnitude of accidental or unintended doses of patients from radiological practices are taken, economic and social factors being taken into account.

The main emphasis in accident prevention should be on the equipment and procedures in radiotherapy, but some attention should be paid to accidents with diagnostic equipment.

Working instructions and written protocols as referred to in Article 6 (1) and quality assurance programmes as referred to in Article 8 (2) and the criteria referred to in Article 8 (3) are of particular relevance for this purpose.

Article 12

Estimates of population doses

Member States shall ensure that the distribution of individual dose estimates from medical exposure referred to in Article 1 (2) is determined for the population and for relevant reference groups of the population as may be deemed necessary by the Member State.

Article 13

Inspection

Member States shall ensure that a system of inspection as defined in Article 2 enforces the provisions introduced in compliance with this Directive.

Article 14

Transposition into Member State law

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 13 May 2000. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be adopted by Member States.

2. Member States shall communicate to the Commission the text of the main laws, regulations or administrative provisions which they adopt in the field covered by this Directive.

Article 15

Repeal

Directive 84/466/Euratom is hereby repealed with effect from 13 May 2000.

Article 16

This Directive is addressed to the Member States.

Done at Luxembourg, 30 June 1997.

For the Council

The President

A. NUIS

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 30 June 1997

amending Decision 93/24/EEC and Decision 93/244/EEC and concerning additional guarantees relating to Aujeszky's disease for pigs destined to regions free of the disease in Austria

(Text with EEA relevance)

(97/423/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine [1], as last amended by Directive 97/12/EC [2], and in particular Article 9 (3) and Article 10 (2) thereof,

Whereas Austria considers that part of its territory is free from Aujeszky's disease and has submitted supporting documentation to the Commission as provided for in Article 10 of Directive 64/432/EEC;

Whereas an eradication programme was undertaken in these regions for Aujeszky's disease;

Whereas Commission Decision 93/244/EEC [3], as last amended by Decision 97/30/EC [4], lays down additional guarantees relating to Aujeszky's disease for pigs destined to certain parts of the territory of the Community where an eradication programme has been approved and lists those regions in Annex I;

Whereas the programme is regarded to have been successful in eradicating this disease from Lower Austria, north of the Danube in Austria; whereas it is therefore appropriate to remove these regions from the list of regions in Annex I of Decision 93/244/EEC;

Whereas the authorities of Austria apply for national movement of pigs rules at least equivalent to those provided by the present Decision;

Whereas these additional guarantees must not be requested from Member States or regions of Member States which are themselves regarded as free from Aujeszky's disease;

Whereas Commission Decision 93/24/EEC of 11 December 1992 [5] as last amended by Decision 97/30/EC lays down additional guarantees relating to Aujeszky's disease for pigs destined to Member States or regions free of the disease and lists those regions in Annex I;

Whereas those parts of Austria which are free of the disease should be added to Annex I of Decision 93/24/EEC;

Whereas the measures provided for in this decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

1. Annex I of Decision 93/24/EC is replaced by Annex I of this Decision.

2. Annex I of Decision 93/244/EEC is replaced by Annex II of this Decision.

[1] OJ No 121, 29. 7. 1964, p. 1977/64.
[2] OJ No L 109, 25. 4. 1997, p. 1.
[3] OJ No L 111, 5. 5. 1993, p. 21.
[4] OJ No L 12, 15. 1. 1997, p. 39.
[5] OJ No L 16, 25. 1. 1993, p. 18.

Article 2

This Decision shall apply from 1 July 1997.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 30 June 1997.

For the Commission

Franz FISCHLER

Member of the Commission

ANNEX I

'ANNEX I

Regions free of Aujeszky's disease which do not permit vaccination

Denmark:	all regions
United Kingdom:	all regions in England, Scotland and Wales
France:	the Departments of Maine-et-Loire, Sarthe, Vendée, Charente, Charente-Maritime, Deux-Sèvres, Vienne, Aude, Dordogne, Gironde, Landes, Lot-et-Garonne, Pyrénées-Atlantiques, Ariège, Aveyron, Haute-Garonne, Gers, Lot, Hautes-Pyrénées, Tarn, Tarn-et-Garonne
Finland:	all regions
Germany:	the *Länder* of Thüringen, Sachsen, Brandenburg, Mecklenburg-Vorpommern, Sachsen-Anhalt
Austria:	all regions
Sweden:	all regions.'

ANNEX II

'ANNEX I

Luxembourg:	Member State
Germany:	all regions except the *Länder* of Thüringen, Sachsen, Brandenburg, Mecklenburg-Vorpommern, Sachsen-Anhalt.'

COMMISSION DECISION

of 30 June 1997

providing for the release of the minimum stocks and the partial release of the carried forward stocks held by the sugar undertakings established in Spain, in order to ensure supplies to the southern region of Spain during the period from 1 July to 30 November 1997

(Only the Spanish text is authentic)

(97/424/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1785/81 of 30 June 1981 on the common organization of the markets in the sugar sector [1], as last amended by Regulation (EC) No 1599/96 [2], and in particular Article 12 (3), Article 27 (2a) and Article 39 thereof,

Whereas in order to ensure normal supplies to the Community as a whole or to one of its areas, there is a standing obligation in the European territories of the Community, for minimum stocks to be maintained by each sugar-producing undertaking or sugar refinery;

Whereas Article 1 of Council Regulation (EEC) No 1789/81 of 30 June 1981 laying down general rules concerning the system of minimum stocks in the sugar sector [3], as last amended by Commission Regulation (EC) No 725/97 [4], fixes the level of minimum stocks to be held, as the case may be, at 5 % of actual production within the A quota or 5 % of the quantity of sugar refined during the 12 months preceding the month in question;

Whereas by virtue of Article 12 (1) of Regulation (EEC) No 1785/81 this percentage may be reduced; whereas Article 4 of Regulation (EEC) No 1789/81 lays down that where the supplies of sugar required by the Community can no longer be ensured under normal conditions, provision may be made for the undertaking concerned to be released, in whole or in part, from the obligation to stock the sugar in question; whereas this percentage has already been brought down to 3 % by Commission Regulation (EC) No 1436/96 [5];

Whereas the south of Spain has been struck in succession by heavy floods and by severe drought leading to a disaster situation involving the loss of around 15 000 hectares planted with sugar beet; whereas there consequently exists a short term shortage in this region with regard to the supplies amounting to around 100 000 tonnes of sugar which are needed to cover the critical bridging period from July to October 1997;

Whereas in order to ensure supplies under normal conditions and in view of the urgency, the minimum stocks maintained by the sugar undertakings established in Spain should be released making available in this way 29 000 tonnes of sugar; whereas this measure is not sufficient to cover the short term shortage in its entirety and, in view of the reasons for the shortage, it is necessary to implement the provisions of Article 27 (2) (a) of Regulation (EEC) No 1785/81 by releasing the appropriate quantity of carried forward stocks held by the sugar undertakings established in Spain;

Whereas the Management Committee for Sugar has not delivered an opinion within the time limit set by its Chairman,

HAS ADOPTED THIS DECISION:

Article 1

1. In derogation from Article 1 (2) of Regulation (EC) No 1436/96 for the period 1 June to 30 November 1997, the percentages referred to in Article 1 of Regulation (EC) No 1436/96 are hereby reduced to 0 % for the sugar undertakings established in Spain.

2. The percentages referred to in points (a) and (b) of Article 1 of Regulation (EEC) No 1789/81 are hereby reduced to 3 % from 1 December 1997 for the sugar undertakings established in Spain.

Article 2

1. The period of compulsory storage referred to in paragraph 2, second indent, of Article 27 of Regulation (EEC) No 1785/81 shall end on 1 July 1997 for the sugar undertakings established in Spain within the limit of a total quantity of 71 000 tonnes of sugar expressed as white sugar.

2. Spain shall proceed with the breakdown of the quantity referred to in paragraph 1 between the sugar undertakings maintaining carried over sugar, in proportion to the carried over quantities which they are maintaining.

3. Spain shall without delay notify the Commission of the quantities of carried over sugar released by each undertaking.

[1] OJ No L 177, 1. 7. 1981, p. 4.
[2] OJ No L 206, 16. 8. 1996, p. 43.
[3] OJ No L 177, 1. 7. 1981, p. 39.
[4] OJ No L 108, 25. 4. 1997, p. 13.
[5] OJ No L 184, 24. 7. 1996, p. 27.

Article 3

This Decision is addressed to Spain.

Done at Brussels, 30 June 1997.

For the Commission
Franz FISCHLER
Member of the Commission