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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.

II *Acts whose publication is not obligatory*

Commission

EN

[1] Text with EEA relevance

I

(Acts whose publication is obligatory)

DECISION No 1376/2002/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 July 2002

amending Decision No 1336/97/EC on a series of guidelines for trans-European telecommunications networks

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 156 thereof,

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

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

Following consultation of the Committee of the Regions,

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

Whereas:

(1) Article 14 of Decision No 1336/97/EC of the European Parliament and the Council [4] requires the Commission to submit a report every three years on the implementation of the Decision to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions.

(2) The Commission submitted this report on 10 December 2001.

(3) The aforementioned Article 14 requires the Commission to submit appropriate proposals for revision of Annex I to the Decision on the basis of technical developments and experience gained.

(4) The Court of Auditors Special Report No 9/2000 made recommendations which have been addressed in the report of the Commission.

(5) In its Communication on a Commission Initiative for the Special European Council of Lisbon, 23 and 24 March 2000, the Commission set out the *e*Europe initiative emphasising the social dimension of the Information Society.

(6) On 28 January 2002 the Council adopted a resolution on a common approach and specific actions in the area of network and information security [5].

(7) Annex I to Decision No 1336/97/EC should therefore be revised accordingly.

(8) The measures necessary for the implementation of this Decision 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 [6],

HAVE ADOPTED THIS DECISION:

Article 1

Decision No 1336/97/EC is hereby amended as follows:

1. The following paragraph shall be added to Article 1:

   'For the purpose of this Decision, "telecommunications infrastructure" shall refer to the electronic data transmission networks and the services which make use of them.'

2. Article 8 shall be replaced by the following:

   '*Article 8*

   1. The Commission shall be assisted by a Committee (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.'

3. Article 14 is hereby amended as follows:

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

   '1. Before 31 January 2005, the Commission shall submit a report on the implementation of this Decision during the period July 2000 to June 2004, to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions.'

[1] OJ C 103 E, 30.4.2002, p. 23.
[2] Opinion delivered on 29 May 2002 (not yet published in the Official Journal).
[3] Opinion of the European Parliament of 14 May 2002 (not yet published in the Official Journal) and Council Decision of 18 June 2002.
[4] OJ L 183, 11.7.1997, p. 12.
[5] OJ C 43, 16.2.2002, p. 2.
[6] OJ L 184, 17.7.1999, p. 23.

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

'4. In the absence of a decision by 31 December 2006, Annex I shall be deemed to have lapsed except in respect of calls for proposals which have already been published in the *Official Journal of the European Communities* before that date.'

4. Annex I shall be replaced by the text of the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 12 July 2002.

For the European Parliament	*For the Council*
The President	*The President*
P. COX	P. S. MØLLER

ANNEX

'ANNEX I

IDENTIFICATION OF PROJECTS OF COMMON INTEREST

1. Trans-European telecommunications networks will contribute to the introduction of innovative trans-European services in the general interest. The services will contribute to the development of the information society in terms of growth, employment, social cohesion and participation for all in the knowledge-based economy.

2. TEN-Telecom supports the technical and economic feasibility, validation and deployment of services. Services must be innovative, trans-European and based on proven technology:

   — a service may be launched in separate Member States with appropriate adaptation in each State,

   — a service that has already been deployed in a single Member State without support under this programme may be extended to other Member States,

   — a service of demonstrably trans-European interest may be implemented in a single Member State.

3. As services should be considered to be trans-European, the participation of organisations from more than one Member State and implementation in more than one Member State, though not required, will be encouraged.

4. In this context, projects of common interest shall be identified on the basis of their operational capability to support the objectives laid down in this Decision.

5. The projects of common interest described below shall be on three levels, forming a coherent structure.

   (i) **Applications**

   Applications serve user needs, taking into account cultural and linguistic differences and the requirements for accessibility, in particular for disabled people. Where it is applicable, they shall accommodate the specific needs of less developed or less populated regions. They shall use the potential of broadband, mobile and other communications networks as appropriate.

   (ii) **Generic Services**

   Generic Services shall support applications' common requirements by providing common tools for the development and implementation of new applications based on interoperable standards. They shall provide services for the transfer and integrity of data across networks, including broadband and mobile communication networks.

   (iii) **Interconnection and interoperability of networks**

   Support will be provided for the interconnection, interoperability and security of networks underpinning the operation of specific public interest applications and services.

   The following sections identify at each level of the trans-European networks the projects of common interest that must be specified in accordance with Article 9 and under the procedure laid down in Article 8.

I. **Applications**

— e-Government and e-Administration: more efficient, interactive, and integrated governmental services benefiting citizens and SME's constitute a major opportunity for the information society. On-line services including those in the field of electronic procurement, secured access to on-line public services for citizens and SME's, personal security, environment and tourism, business support for SME's (including information services and electronic commerce), and services aimed at broadening participation in the democratic decision-making process will be supported at all levels: European, national, regional and local. Services may be provided by, or with the support of, public authorities as a service in the public interest benefiting citizens and SME's.

— Health: health telematics networks and services offer significant opportunities for the improvement of access and quality of care, as well as handling the impacts of medical advances and demographic changes. Innovative services will be supported linking health care institutions and other points of care, and providing health services directly to the public, in particular supporting actions on disease prevention and health promotion.

— Disabled and elderly: developments in network communications offer significant opportunities for the participation of older people and people with disabilities in the information society. Network applications and services addressing their specific needs are able to contribute to the overcoming of socio-economic, geographical and cultural barriers. Services will be supported catering for the requirements of older people and people with disabilities with the purpose of promoting their full integration and participation in the information society.

— Learning and culture: high levels of education, training and cultural awareness are crucial to economic development and social cohesion. Their importance will continue to be underlined in future with the increasing influence of technology in the information society. Services will be supported providing new innovative ways of presenting educational and cultural information, including services for lifelong learning.

II. **Generic services**

— Advanced mobile services: trials are under way on the interoperability aspects of innovative applications for 2,5 to 3G mobile networks. They will establish the basis for advanced end-to-end solutions in the mobile environment providing location-based, personalised, and context-sensitive services. Support will be provided for the launch of advanced mobile applications and services in the general interest including those for navigation and guidance, traffic and travel information, network security and billing, m-commerce, m-business and mobile work, learning and culture, emergency services and health.

— Trust and confidence services: the active involvement of businesses and citizens in the information society is dependent on their trust and confidence in the available services. Security is therefore a priority issue presenting a major challenge for the future. Support will be provided for services in the public interest aimed at all aspects of security including cooperation for effective networking within the European Union on national CERT systems.

III. **Interconnection and interoperability of networks**

— Interconnection and interoperability: the interconnection and interoperability of networks is a pre-requisite for effective trans-European services. Support will be provided for the interconnection, interoperability and security of networks necessary for the operation of specific public interest services. Projects concerning the development and enhancement of telecommunications networks will receive particular scrutiny to ensure that there is no interference with free market conditions.

IV. **Supplementary support and coordination actions**

In addition to its support for projects of common interest, the Community shall initiate actions aimed at providing the appropriate environment for the realisation of the projects. The financing of these actions should not take away in any significant manner from the amounts allocated to the rest of the programme. The actions will contribute to programme awareness, consensus development and concerted efforts concerning European, national, regional and local activities for stimulation and promotion of new applications and services, in conformity with the implementation of programmes in other areas, as well as the development of broadband networks. They will involve consultation with European standardisation and strategic planning bodies and coordination with actions funded by the different Community financial instruments, including:

— strategic studies toward target specifications, and transition towards these targets. These specifications will help sector actors to make sound economic investment decisions,

— definition of means of accessing broadband networks,

— establishment of common specifications based on European and world standards,

— furthering cooperation among sector actors, including public and private partnerships (PPP),

— coordination of the activities undertaken under this Decision with related Community and national programmes.'

COMMISSION REGULATION (EC) No 1377/2002

of 29 July 2002

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 1498/98 [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 30 July 2002.

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

Done at Brussels, 29 July 2002.

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

[1] OJ L 337, 24.12.1994, p. 66.
[2] OJ L 198, 15.7.1998, p. 4.

ANNEX

to the Commission Regulation of 29 July 2002 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	064	75,1
	096	30,6
	999	52,8
0707 00 05	052	83,4
	999	83,4
0709 90 70	052	75,8
	999	75,8
0805 50 10	388	58,4
	524	63,4
	528	53,8
	999	58,5
0806 10 10	052	141,5
	064	114,9
	220	191,1
	508	75,3
	512	89,8
	600	139,7
	624	191,3
	999	134,8
0808 10 20, 0808 10 50, 0808 10 90	388	90,4
	400	117,7
	404	94,8
	508	78,6
	512	95,9
	524	62,5
	528	70,5
	720	143,5
	800	99,9
	804	100,7
	999	95,5
0808 20 50	388	90,8
	512	80,1
	528	74,2
	804	114,1
	999	89,8
0809 10 00	052	142,7
	064	144,5
	999	143,6
0809 20 95	052	389,7
	400	287,4
	404	250,3
	999	309,1
0809 30 10, 0809 30 90	052	117,9
	064	88,7
	999	103,3
0809 40 05	064	59,9
	999	59,9

(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 1378/2002
of 29 July 2002
prohibiting fishing for yellowtail flounder by vessels flying the flag of a Member State

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2847/93 of 12 October 1993 establishing a control system applicable to the common fisheries policy [1], as last amended by Regulation (EC) No 2846/98 [2], and in particular Article 21(3) thereof,

Whereas:

(1) Council Regulation (EC) No 2555/2001 of 18 December 2001 fixing for 2002 the fishing opportunities and associated conditions for certain fish stocks and groups of fish stocks, applicable in Community waters and, for Community vessels, in waters where limitations in catch are required [3] lays down the share of the total allowable catch of yellowtail flounder allocated to the Community for 2002.

(2) In order to ensure compliance with the provisions relating to the quantity limits on catches of stocks subject to quotas, the Commission must fix the date by which catches made by vessels flying the flag of a Member State are deemed to have exhausted the share of the total allowable catch allocated to the Community.

(3) According to the information received by the Commission, catches of yellowtail flounder in the waters of NAFO zone 3LNO by vessels flying the flag of a Member State or registered in a Member State have exhausted the share of the total allowable catch allocated to the Community for 2002,

HAS ADOPTED THIS REGULATION:

Article 1

Catches of yellowtail flounder in the waters of NAFO zone 3LNO by vessels flying the flag of a Member State or registered in a Member State are hereby deemed to have exhausted the share of the total allowable catch allocated to the Community for 2002.

Fishing for yellowtail flounder in the waters of NAFO zone 3LNO by vessels flying the flag of a Member State or registered in a Member State is hereby prohibited, as are the retention on board, transhipment and landing of this stock caught by the above vessels after the date of entry into force of this Regulation.

Article 2

This Regulation shall enter into force on the 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, 29 July 2002.

For the Commission
Franz FISCHLER
Member of the Commission

[1] OJ L 261, 20.10.1993, p. 1.
[2] OJ L 358, 31.12.1998, p. 5.
[3] OJ L 347, 31.12.2001, p. 1.

COMMISSION REGULATION (EC) No 1379/2002
of 29 July 2002
on the supply of vegetable oil as food aid

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1292/96 of 27 June 1996 on food-aid policy and food-aid management and special operations in support of food security [1], as amended by Regulation (EC) No 1726/2001 of the European Parliament and of the Council [2], and in particular Article 24(1)(b) thereof,

Whereas:

(1) The abovementioned Regulation lays down the list of countries and organisations eligible for Community aid and specifies the general criteria on the transport of food aid beyond the fob stage.

(2) Following the taking of a number of decisions on the allocation of food aid, the Commission has allocated vegetable oil to certain beneficiaries.

(3) It is necessary to make these supplies in accordance with the rules laid down by Commission Regulation (EC) No 2519/97 of 16 December 1997 laying down general rules for the mobilisation of products to be supplied under Council Regulation (EC) No 1292/96 as Community food aid [3]. It is necessary to specify the time limits and conditions of supply to determine the resultant costs.

(4) In order to ensure that the supplies are carried out for a given lot, provision should be made for tenderers to be able to mobilise either rapeseed oil or sunflower oil. The contract for the supply of each such lot is to be awarded to the tenderer submitting the lowest tender,

HAS ADOPTED THIS REGULATION:

Article 1

Vegetable oil shall be mobilised in the Community, as Community food aid for supply to the recipient listed in the Annex, in accordance with Regulation (EC) No 2519/97 and under the conditions set out in the Annex.

The supply shall cover the mobilisation of vegetable oil produced in the Community. Mobilisation may not involve a product manufactured and/or packaged under inward processing arrangements.

Tenders shall cover either rapeseed oil or sunflower oil. Tenders shall be rejected unless they specify the type of oil to which they relate.

The tenderer is deemed to have noted and accepted all the general and specific conditions applicable. Any other condition or reservation included in his tender is deemed unwritten.

Article 2

This Regulation shall enter into force on the 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, 29 July 2002.

For the Commission
Franz FISCHLER
Member of the Commission

[1] OJ L 166, 5.7.1996, p. 1.
[2] OJ L 234, 1.9.2001, p. 10.
[3] OJ L 346, 17.12.1997, p. 23.

ANNEX

LOT A

1. **Action No:** 300/01
2. **Beneficiary** [2]**:** World Food Programme (WFP), Via Cesare Giulio Viola 68, I-00148 Roma; tel.: (39-06) 6513 2988; fax: 6513 2844/3; telex: 626675 WFP I
3. **Beneficiary's representative:** to be designated by the beneficiary
4. **Country of destination:** Zimbabwe
5. **Product to be mobilised:** refined rapeseed oil or refined sunflower oil
6. **Total quantity (tonnes net):** 600
7. **Number of lots:** 1
8. **Characteristics and quality of the product** [3] [4] [6]**:** see OJ C 312, 31.10.2000, p. 1 (D.1 or D.2)
9. **Packaging:** see OJ C 267, 13.9.1996, p. 1 (10.8 A, B and C.2)
   Weight of the empty container 135 g minimum
10. **Labelling or marking** [5]**:** see OJ C 114, 29.4.1991, p. 1 (III.A(3))
    — language to be used for the markings: English
    — supplementary markings: —
11. **Method of mobilisation of the product:** the Community market.
    The mobilisation may not involve a product manufactured and/or packaged under inward-processing arrangements.
12. **Specified delivery stage** [7]**:** free at port of shipment
13. **Alternative delivery stage:** —
14. a) **Port of shipment:** —
    b) **Loading address:** —
15. **Port of landing:** —
16. **Place of destination:**
    — port or warehouse of transit: —
    — overland transport route: —
17. **Period or deadline of supply at the specified stage:**
    — first deadline: 9.9.2002 to 29.9.2002
    — second deadline: 23.9.2002 to 13.10.2002
18. **Period or deadline of supply at the alternative stage:**
    — first deadline: —
    — second deadline: —
19. **Deadline for the submission of tenders (at 12 noon, Brussels time):**
    — first deadline: 20.8.2002
    — second deadline: 3.9.2002
20. **Amount of tendering guarantee:** EUR 15 per tonne
21. **Address for submission of tenders and tendering guarantees** [1]**:** M. Vestergaard, Commission européenne, Bureau: L130 7/46, B-1049 Bruxelles; telex 25670 AGREC B; fax (32-2) 296 70 03/296 70 04
22. **Export refund:** —

LOT B

1. **Action No:** 294/01
2. **Beneficiary** ([2])**:** EuronAid, PO Box 12, 2501 CA Den Haag, Nederland; tel. (31-70) 33 05 757; fax 36 41 701; telex 30960 EURON NL
3. **Beneficiary's representative:** to be designated by the beneficiary
4. **Country of destination:** Eritrea
5. **Product to be mobilised:** refined rapeseed oil or refined sunflower oil
6. **Total quantity (tonnes net):** 810
7. **Number of lots:** 1 in 3 parts (B1: 540 tonnes; B2: 135 tonnes; B3: 135 tonnes)
8. **Characteristics and quality of the product** ([3]) ([4]) ([6])**:** see OJ C 312, 31.10.2000, p. 1 (D.1 or D.2)
9. **Packaging:** see OJ C 267, 13.9.1996, p. 1 (10.8, A, B and C.2)
   Weight of the empty container 135 g minimum
10. **Labelling or marking** ([5])**:** see OJ C 114, 29.4.1991, p. 1 (III.A.(3))
    — Language to be used for the markings: English
    — Supplementary markings: —
11. **Method of mobilisation of the product:** the Community market
    The mobilisation may not involve a product manufactured and/or packaged under inward-processing arrangements.
12. **Specified delivery stage:** free at port of landing — container terminal
13. **Alternative delivery stage:** free at port of shipment
14. a) **Port of shipment:** —
    b) **Loading address:** —
15. **Port of landing:** B1 and B2: Massawa; B3: Assab
16. **Place of destination:**
    — port or warehouse of transit: —
    — overland transport route: —
17. **Period or deadline of supply at the specified stage:**
    — first deadline: 20.10.2002
    — second deadline: 3.11.2002
18. **Period or deadline of supply at the alternative stage:**
    — first deadline: 16.9.2002 to 29.9.2002
    — second deadline: 30.9.2002 to 13.10.2002
19. **Deadline for the submission of tenders (at 12 noon, Brussels time):**
    — first deadline: 20.8.2002
    — second deadline: 3.9.2002
20. **Amount of tendering guarantee:** EUR 15 per tonne
21. **Address for submission of tenders and tendering guarantees** ([1])**:** M. Vestergaard, European Commission, Office L 130 7/46, B-1049 Brussels; telex 25670 AGREC B; fax (32-2) 296 70 03/296 70 04
22. **Export refund:** —

Notes

(1) Supplementary information Torben Vestergaard (tel. (32-2) 299 30 50; fax (32-2) 296 20 05).

(2) The supplier shall contact the beneficiary or its representative as soon as possible to establish which consignment documents are required.

(3) The supplier shall deliver to the beneficiary a certificate from an official entity certifying that for the product to be delivered the standards applicable, relative to nuclear radiation, in the Member State concerned, have not been exceeded. The radioactivity certificate must indicate the caesium-134 and -137 and iodine-131 levels.

(4) The supplier shall supply to the beneficiary or its representative, on delivery, the following document

— health certificate.

(5) Notwithstanding OJ C 114, 29.4.1991, point III.A(3)(c) is replaced by the following 'the words "European Community"'.

The containers may be marked by the application of labels.

(6) Tenders shall be rejected unless they specify the type of oil to which they relate.

(7) The tenderer's attention is drawn to the second subparagraph of Article 7(6) of Regulation (EC) No 2519/97.

COMMISSION REGULATION (EC) No 1380/2002

of 29 July 2002

concerning the classification of certain goods in the Combined Nomenclature

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff [1], as last amended by Commission Regulation (EC) No 969/2002 [2], and in particular Article 9 thereof,

Whereas:

(1) In order to ensure uniform application of the Combined Nomenclature annexed to Regulation (EEC) No 2658/87, it is necessary to adopt measures concerning the classification of the goods referred to in the Annex to this Regulation.

(2) Regulation (EEC) No 2658/87 has laid down the general rules for the interpretation of the Combined Nomenclature. Those rules also apply to any other nomenclature which is wholly or partly based on it or which adds any additional subdivision to it and which is established by specific Community provisions, with a view to the application of tariff and other measures relating to trade in goods.

(3) Pursuant to the said general rules, the goods described in column 1 of the table set out in the Annex to this Regulation should be classified under the CN codes indicated in column 2, by virtue of the reasons set out in column 3.

(4) It is appropriate that binding tariff information issued by the customs authorities of Member States in respect of the classification of goods in the Combined Nomenclature and which is not in accordance with the provisions of this Regulation, can continue to be invoked by the holder, under the provisions of Article 12(6) of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code [3], as last amended by Regulation (EC) No 2700/2000 of the European Parliament and of the Council [4], for a period of three months.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The goods described in column 1 of the table set out in the Annex are classified within the Combined Nomenclature under the CN codes indicated in column 2 of that table.

Article 2

Binding tariff information issued by the customs authorities of Member States which is not in accordance with the provisions of this Regulation can continue to be invoked under the provisions of Article 12(6) of Regulation (EEC) No 2913/92 for a period of three months.

Article 3

This Regulation shall enter into force on the twentieth 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, 29 July 2002.

For the Commission

Frederik BOLKESTEIN

Member of the Commission

[1] OJ L 256, 7.9.1987, p. 1.
[2] OJ L 149, 7.6.2002, p. 20.
[3] OJ L 302, 19.10.1992, p. 1.
[4] OJ L 311, 12.12.2000, p. 17.

ANNEX

Description of the goods	Classification CN code	Reasons
(1)	(2)	(3)
1. Liquid product consisting of lemon juice, added citric acid (7,6 % by total weight) and preservatives, put up for retail sale in a plastic bottle (e.g., 100 ml) with a nozzle. That nozzle holds lemon essential oils. The product is used to impart a tart taste to foods or beverages.	2106 90 92	Classification is determined by the provisions of General Rules 1 and 6 for the interpretation of the Combined Nomenclature and by the wording of CN codes 2106, 2106 90 and 2106 90 92. The product cannot be classified under heading 2009 since, due to the addition of citric acid, it has lost its original character of a fruit juice (see the Harmonised System Explanatory Note to heading 2009, Item (4)). Taking into account its composition, it cannot be considered as a mixed condiment or a mixed seasoning of heading 2103 (see the Harmonised System Explanatory Note to heading 2103)
2. Oily spreadable paste with the following composition (percentage by weight): — water 23,3 — tomato puree 17,7 — cheese 15,4 — salami 11,3 — tomato powder 9,6 — butter 6,0 — yogurt 3,6 — garlic preparation 2,8 — sweet whey powder 2,4 — cooking salt 2,3 — capers 1,3 — olive oil 1,2 and small quantities of emulsifying salts, sugar, pepper, oregano, parsley, flavouring, lecithin and potassium sorbate. The preparation is an intermediate product used in the food industry.	2106 90 98	Classification is determined by the provisions of General Rules 1 and 6 for the interpretation of the Combined Nomenclature and by the wording of CN codes 2106, 2106 90 and 2106 90 98. The product cannot be regarded as a sauce or mixed condiment of heading 2103 because it is an intermediate product which is not added to a food as it cooks or as it is served. Nor is it, within the meaning of heading 2103, considered to be a preparation used to flavour certain dishes (see the Harmonised System Explanatory Note to heading 2103, Part (A)).
3. Saturated solution of essential oils in ethyl alcohol (60 % by volume) containing approximately 3 grams of orange essential oils per litre, used as a raw material in the food industry (e.g., bakers' wares, chocolate).	3302 10 90	Classification is determined by the provisions of General Rules 1 and 6 for the interpretation of the Combined Nomenclature, Note 2 to Chapter 33 and by the wording of CN codes 3302, 3302 10 and 3302 10 90. Given the high content of essential oils, the product cannot be consumed as a beverage. Nor is it intended for the manufacture of beverages, for example, simply by dilution with water (see also the Harmonised System Explanatory Note to heading 3302)

COMMISSION REGULATION (EC) No 1381/2002

of 29 July 2002

laying down detailed rules for opening and administration of the tariff quotas for raw cane sugar for refining, originating in the least developed countries, for the marketing years 2002/03 to 2005/06

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2501/2001 of 10 December 2001 applying a scheme of generalised tariff preferences for the period 1 January 2002 to 31 December 2004 [1], and in particular Article 9(6) thereof,

Whereas:

(1) Article 9(5) of Regulation (EC) No 2501/2001 lays down that, until Common Customs Tariff duties are entirely suspended, a global tariff quota at zero duty is to be opened for every marketing year for products of CN code 1701 11 10, originating in a country that according to Annex I to that Regulation, benefits from the special arrangements for least developed countries. The tariff quota for the marketing year 2002/03 is to be equal to 85 313 tonnes, white sugar equivalent, for products of CN code 1701 11 10. For each of the following marketing years, the quotas shall be increased by 15 % over the quotas of the previous marketing year.

(2) Those provisions have to be implemented within the framework of the common trading system established by Council Regulation (EC) No 1260/2001 of 19 June 2001 on the common organisation of the markets in the sugar sector [2], as last amended by Commission Regulation (EC) No 680/2002 [3].

(3) The quantities of raw sugar benefiting from the global tariff quotas should be imported under conditions which meet the refining needs of the Member States referred to in Article 39(2) of Regulation (EC) No 1260/2001.

(4) The experience gained under Commission Regulation (EC) No 1978/2001 of 10 October 2001 on opening a tariff quota for raw cane sugar for refining, originating in the least developed countries, for the marketing year 2001/02 [4], justifies establishing detailed rules governing the opening and management of the quotas for a longer period. That period should cover four marketing years.

(5) To ensure an adequate price for the raw cane sugar exported by the least developed countries to the Community, a minimum price to be paid by the refiners should be fixed. The minimum price should take into account the factors applying for the marketing years 2002/03 to 2005/06.

(6) The general rules as regards import licences of Commission Regulation (EC) No 1291/2000 of 9 June 2000 laying down common detailed rules for the application of the system of import and export licences and advance fixing certificates for agricultural products [5], as last amended by Regulation (EC) No 2299/2001 [6], as well as the special detailed rules for the sugar sector established by Commission Regulation (EC) No 1464/95 [7], as last amended by Regulation (EC) No 996/2002 [8], should apply. To facilitate the administration of the quotas under the present Regulation and to ensure the respect of the annual quota quantity, detailed rules concerning the issue of the licences for the import of raw sugar expressed as white sugar equivalent should be decided.

(7) The provisions concerning the proof of origin set out in Articles 67 to 97 of Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code [9], as last amended by Regulation (EC) No 444/2002 [10], establish the definition of the concept of originating products to be used for the purposes of generalised tariff preferences.

(8) Since the Council in fixing the global tariff quotas has not provided for a margin to exceed these quantities, the full Common Customs Tariff duty should apply to all quantities converted into white sugar equivalent, imported in excess of those figuring on the import licence. In order to avoid excess of imported raw sugar in the Community from the least developed countries, provisions are necessary to ensure that the imported quantities of sugar are effectively refined by the end of the marketing year concerned or before a certain date set by the Member State.

[1] OJ L 346, 31.12.2001, p. 1.
[2] OJ L 178, 30.6.2001, p. 1.
[3] OJ L 104, 20.4.2002, p. 26.
[4] OJ L 270, 11.10.2001, p. 9.
[5] OJ L 152, 24.6.2000, p. 1.
[6] OJ L 308, 27.11.2001, p. 19.
[7] OJ L 144, 28.6.1995, p. 14.
[8] OJ L 152, 12.6.2002, p. 11.
[9] OJ L 253, 11.10.1993, p. 1.
[10] OJ L 68, 12.3.2002, p. 11.

(9) In order to respect the annual quota quantity as set out by Regulation (EC) No 2501/2001, the Member States should communicate to the Commission quantities of raw sugar expressed in white sugar equivalent.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Generalised Preferences Committee,

HAS ADOPTED THIS REGULATION:

Article 1

This Regulation lays down the rules for opening and administration of the tariff quotas for raw cane sugar for refining referred to in Article 9(5) of Regulation (EC) No 2501/2001, for the marketing years 2002/03, 2003/04, 2004/05 and 2005/06.

Article 2

For the purposes of this Regulation:

— 'marketing year' shall mean the marketing year referred to in Article 1(2)(m) of Regulation (EC) No 1260/2001,

— 'refiner' shall mean a person who imports for the needs of his refinery within the meaning of Article 7(4), fourth indent, of Regulation (EC) No 1260/2001.

Article 3

1. The following global tariff quotas at zero duty of products of CN code 1701 11 10, expressed as white sugar equivalent, are opened for the following marketing years for imports originating in a country that according to Annex I to Regulation (EC) No 2501/2001 benefits from the special arrangements for least developed countries:

— 85 313 tonnes for the marketing year 2002/03,

— 98 110 tonnes for the marketing year 2003/04,

— 112 827 tonnes for the marketing year 2004/05, and

— 129 751 tonnes for the marketing year 2005/06.

Each of these quotas shall bear the order No of respectively 09.4302; 09.4303; 09.4304 and 09.4305.

These quotas shall be opened on the first day of the marketing year concerned and remain open until the last day of that marketing year.

2. All Common Customs Tariff duties, as well as any additional duties referred to in Article 24 of Regulation (EC) No 1260/2001, on imports under these quotas are suspended.

Article 4

1. A minimum purchase price of standard quality raw sugar (cif, free out of European ports of the Community) to be paid by the refiners shall apply to imports under the quotas referred to in Article 3(1).

2. The minimum purchase price for each marketing year corresponds to the intervention price for raw sugar referred to in Article 2(2) of Regulation (EC) No 1260/2001, reduced by the amount, multiplied by the yield of 0,92 for raw sugar, of the adjustment aid to the refining industry applicable for the marketing year in question, in conformity with Article 38(1) and (4) of the said Regulation

Article 5

1. Imports under the quotas referred to in Article 3(1) shall require an import licence issued in accordance with Regulation (EC) No 1291/2000 and Regulation (EC) No 1464/95, subject to the provisions of this Regulation.

2. Applications for licences shall be submitted by the refiners to the competent body of the Member States referred to in Article 39(2) of Regulation (EC) No 1260/2001. This application shall be accompanied by a declaration by which the refiner undertakes to refine the quantity of raw sugar in question before the end of the marketing year during which it is imported.

3. Import licences may be issued only within the limits of the quotas referred to in Article 3(1). These licences shall be issued by the Member States of import concerned.

4. Refiners may transfer licences to other refiners. In this case, the refiner informs without delay the competent authority of the Member State having issued the original licences. However, the obligations to import and refine are not transferable and Article 9 of Regulation No 1291/2000 shall continue to apply.

5. Import licences shall be valid from the date on which they are issued until the end of the marketing year in respect of which they are issued. However, where in accordance with paragraph 8 a licence is issued before the quota has been opened, the licence shall be valid only from the date of the quota opening.

6. The security relating to the licences shall be EUR 0,30 per 100 kg net weight of sugar.

7. Import licence applications and licences themselves shall include the following entries:

— in Section 8: the country or countries of origin (country or countries included in the special arrangements for least developed countries according to column H of Annex I to Regulation No 2501/2001),

— in Sections 17 and 18: the quantity of raw sugar, expressed as white sugar equivalent,

— in Section 20: 'Raw sugar for refining imported pursuant to Article 9(5) of Regulation (EC) No 2501/2001. Quota order No … (No referred to in Article 3(1))'.

8. The period during which applications for import licences may be submitted shall start three weeks before the first day of the marketing year concerned.

9. Import licence applications shall be submitted from Monday to Friday of each week to the competent authorities of the Member State of import concerned. Member States shall notify the Commission on the first working day of the following week the quantities of raw sugar, expressed as white sugar equivalent, for which applications of import licences have been submitted during the preceding week, in specifying the quantities by countries of origin.

10. The licences shall be issued on the fourth working day following that of the notification referred to in paragraph 9, provided that the Commission has not objected.

11. The Commission shall draw up a weekly total of the quantities for which import licences have been submitted. Where licence applications exceed the quota quantity for the current marketing year, the Commission shall limit the issue of licences pro rata to the quantity remaining and, if appropriate, shall inform the Member States that the maximum quantity of the quota concerned has been reached.

Article 6

1. Proof of the originating status of the imports under the quota referred to in Article 3(1) shall be furnished by a certificate of origin Form A issued in accordance with Articles 67 to 97 of Regulation (EEC) No 2454/93.

2. The certificate of origin form A shall bear, in box 4:

— the phrase 'Quota order No … (No referred to in Article 3(1)) — Regulation (EC) No …/…',

— the date of loading of the sugar in the exporting beneficiary country, and the marketing year in respect of which delivery is being made,

— CN code 1701 11 10.

3. The customs authorities of the importing Member State shall indicate on the certificate of origin form A:

— the date, established on the basis of a shipping document, on which loading of the sugar in the port of export was completed,

— information relating to the import operation and the quantities of raw sugar actually imported.

4. Where refiners transfer import licences to other refiners pursuant to Article 5(4), the Member State shall collect the completed certificates of origin form A and send a copy of the certificates to the Member State which initially issued the import licence.

Article 7

1. Each Member State shall keep the record of the quantities actually imported with the certificates of origin referred to in Article 6 of raw sugar and shall convert these quantities in white sugar equivalent on the basis of the polarisation stated, applying the provisions under point II(3) of Annex I to Regulation (EC) No 1260/2001.

2. Pursuant to Article 50(1) of Regulation (EC) No 1291/2000, the full Common Customs Tariff duty applicable on the date of release for free circulation shall apply to all quantities, converted in white sugar equivalent, imported in excess of those shown on the import licence referred to in Article 5.

3. The refiner who applied for the licence must, within three months following that of the end of the time limit for refining according to Article 5(2), show to the Member State which issued the licence proof of refining acceptable to it.

4. Except in the event of force majeure, if the sugar is not refined within the time limit, the refiner who applied for the licence shall pay an amount equal to the full duty applicable to raw sugar in that marketing year plus, where applicable, the highest additional rate of duty recorded during that marketing year.

5. Except in the event of force majeure, where it has not been possible for a quantity of sugar to be delivered in sufficient time to enable it to be refined by the end of the marketing year concerned, the Member State of importation may, at the request of the refiner, extend the validity of the licence for 30 days from the beginning of the following marketing year. In that case the raw sugar in question shall count against and be within the limits of the quota for the preceding marketing year.

6. Where it has not been possible to refine a quantity of sugar by the end of a marketing year, the Member State in question may, at the request of the refiner, extend the time limit by a maximum of 90 days from the beginning of the following marketing year. In that case, the raw sugar in question shall be refined within that extended time limit and shall count against and be within the limits of the quota for the preceding marketing year.

Article 8

Member States referred to in Article 39(2) of Regulation (EC) No 1260/2001 shall communicate to the Commission:

(a) at the beginning of the marketing year, the provisional quantities of raw sugar to be imported from the different countries concerned;

(b) every month in respect of the preceding month, the quantities of raw sugar by weight expressed in white sugar equivalent for which import licences referred to in Article 5 have been issued;

(c) every month:

— the quantities of raw 'tel quel' sugar by weight and in white sugar equivalent actually imported three months before under licences referred to in Article 5, broken down by country of origin,

— the quantities of raw 'tel quel' sugar by weight and in white sugar equivalent refined three months before;

(d) before 1 November:

— the quantity of raw 'tel quel' sugar by weight and in white sugar equivalent actually imported with licences referred to in Article 5 during the preceding marketing year, broken down by country of origin,

— the quantity of raw 'tel quel' sugar by weight and in white sugar equivalent refined that is counted against the quota of the preceding marketing year.

Article 9

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

It shall apply until 30 June 2006.

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

Done at Brussels, 29 July 2002.

For the Commission
Pascal LAMY
Member of the Commission

COMMISSION REGULATION (EC) No 1382/2002

of 29 July 2002

fixing the refunds applicable to cereal and rice sector products supplied as Community and national food aid

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 Commission Regulation (EC) No 1666/2000 ([2]), and in particular the third subparagraph of Article 13(2) thereof,

Having regard to Council Regulation (EC) No 3072/95 of 22 December 1995 on the common organisation of the market in rice ([3]), as last amended by Commission Regulation (EC) No 411/2002 ([4]), and in particular Article 13(3) thereof,

Whereas:

(1) Article 2 of Council Regulation (EEC) No 2681/74 of 21 October 1974 on Community financing of expenditure incurred in respect of the supply of agricultural products as food aid ([5]) lays down that the portion of the expenditure corresponding to the export refunds on the products in question fixed under Community rules is to be charged to the European Agricultural Guidance and Guarantee Fund, Guarantee Section.

(2) In order to make it easier to draw up and manage the budget for Community food aid actions and to enable the Member States to know the extent of Community participation in the financing of national food aid actions, the level of the refunds granted for these actions should be determined.

(3) The general and implementing rules provided for in Article 13 of Regulation (EEC) No 1766/92 and in Article 13 of Regulation (EC) No 3072/95 on export refunds are applicable *mutatis mutandis* to the abovementioned operations.

(4) The specific criteria to be used for calculating the export refund on rice are set out in Article 13 of Regulation (EC) No 3072/95.

(5) 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 Community and national food aid operations under international agreements or other supplementary programmes, and other Community free supply measures, the refunds applicable to cereals and rice sector products shall be as set out in the Annex.

Article 2

This Regulation shall enter into force on 1 August 2002.

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

Done at Brussels, 29 July 2002.

For the Commission

Franz FISCHLER

Member of the Commission

([1]) OJ L 181, 1.7.1992, p. 21.
([2]) OJ L 193, 29.7.2000, p. 1.
([3]) OJ L 329, 30.12.1995, p. 18.
([4]) OJ L 62, 5.3.2002, p. 27.
([5]) OJ L 288, 25.10.1974, p. 1.

ANNEX

to the Commission Regulation of 29 July 2002 fixing the refunds applicable to cereal and rice sector products supplied as Community and national food aid

(EUR/t)

Product code	Refund
1001 10 00 9400	0,00
1001 90 99 9000	1,00
1002 00 00 9000	39,00
1003 00 90 9000	0,00
1005 90 00 9000	26,00
1006 30 92 9100	105,00
1006 30 92 9900	105,00
1006 30 94 9100	105,00
1006 30 94 9900	105,00
1006 30 96 9100	105,00
1006 30 96 9900	105,00
1006 30 98 9100	105,00
1006 30 98 9900	105,00
1006 30 65 9900	105,00
1007 00 90 9000	26,00
1101 00 15 9100	1,37
1101 00 15 9130	1,37
1102 10 00 9500	61,65
1102 20 10 9200	34,72
1102 20 10 9400	29,76
1103 11 10 9200	0,00
1103 13 10 9100	44,64
1104 12 90 9100	0,00

NB: The product codes are defined in Commission Regulation (EEC) No 3846/87 (OJ L 366, 24.12.1987, p. 1), amended.

COMMISSION REGULATION (EC) No 1383/2002

of 29 July 2002

fixing the minimum selling prices for beef put up for sale under the second invitation to tender referred to in Regulation (EC) No 1197/2002

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1254/1999 of 17 May 1999 on the common organisation of the market in beef and veal [1], as last amended by Commission Regulation (EC) No 2345/2001 [2], and in particular Article 28(2) thereof,

Whereas:

(1) Tenders have been invited for certain quantities of beef fixed by Commission Regulation (EC) No 1197/2002 [3].

(2) Pursuant to Article 9 of Commission Regulation (EEC) No 2173/79 [4], as last amended by Regulation (EC) No 2417/95 [5], the minimum selling prices for meat put up for sale by tender should be fixed, taking into account tenders submitted.

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

HAS ADOPTED THIS REGULATION:

Article 1

The minimum selling prices for beef for the second invitation to tender held in accordance with Regulation (EC) No 1197/2002 for which the time limit for the submission of tenders was 22 July 2002 are as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 30 July 2002.

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

Done at Brussels, 29 July 2002.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ L 160, 26.6.1999, p. 21.
[2] OJ L 315, 1.12.2001, p. 29.
[3] OJ L 174, 4.7.2002, p. 19.
[4] OJ L 251, 5.10.1979, p. 12.
[5] OJ L 248, 14.10.1995, p. 39.

ANEXO — BILAG — ANHANG — ΠΑΡΑΡΤΗΜΑ — ANNEX — ANNEXE — ALLEGATO — BIJLAGE — ANEXO — LIITE — BILAGA

Estado miembro Medlemsstat Mitgliedstaat Κράτος μέλος Member State État membre Stato membro Lidstaat Estado-Membro Jäsenvaltio Medlemsstat	Productos Produkter Erzeugnisse Προϊόντα Products Produits Prodotti Producten Produtos Tuotteet Produkter	Precio mínimo Expresado en euros por tonelada Mindstepriser i EUR/t Mindestpreise Ausgedrückt in EUR/Tonne Ελάχιστες πωλήσεις εκφραζόμενες σε ευρώ ανά τόνο Minimum prices Expressed in EUR per tonne Prix minimaux exprimés en euros par tonne Prezzi minimi Espressi in euro per tonnellata Minimumprijzen Uitgedrukt in euro per ton Preço mínimo Expresso em euros por tonelada Vähimmäishinnat euroina tonnia kohden ilmaistuna Minimipriser i euro per ton
Carne con hueso — Kød, ikke udbenet — Fleisch mit Knochen — Κρέατα με κόκαλα — Bone-in beef — Viande avec os — Carni non disossate — Vlees met been — Carne com osso — Luullinen naudanliha — Kött med ben		
ITALIA	— Quarti posteriori	—
DEUTSCHLAND	— Hinterviertel	1 446
ESPAÑA	— Cuartos traseros	1 450
ÖSTERREICH	— Hinterviertel	1 421
FRANCE	— Quartiers arrière	—

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 24 July 2002

establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

(notified under document number C(2002) 2715)

(Text with EEA relevance)

(2002/623/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC [1], and in particular the first paragraph of Annex II thereto,

Whereas:

(1) Under Directive 2001/18/EC, Member States and, where appropriate, the Commission must ensure that potential adverse effects on human health and the environment, which may occur directly or indirectly through gene transfer from genetically modified organisms (hereinafter GMOs) to other organisms, are accurately assessed on a case-by-case basis in accordance with Annex II to that Directive.

(2) Under Article 6(2)(b) and Article 13(2)(b) of Directive 2001/18/EC, notifications for the release or placing on the market of GMOs must include an environmental risk assessment and the conclusions on the potential environmental impact of the release or the placing on the market of those GMOs in accordance with Annex II to that Directive.

(3) Annex II to Directive 2001/18/EC should be supplemented by notes providing detailed guidance on the objective, elements, general principles and methodology of the environmental risk assessment referred to in that Annex.

(4) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 30(1) of Directive 2001/18/EC,

HAS ADOPTED THIS DECISION:

Article 1

The guidance notes set out in the Annex to this Decision shall be used as a supplement to Annex II to Directive 2001/18/EC.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 24 July 2002.

For the Commission

Margot WALLSTRÖM

Member of the Commission

[1] OJ L 106, 17.4.2001, p. 1.

ANNEX

GUIDANCE NOTES ON THE OBJECTIVE, ELEMENTS, GENERAL PRINCIPLES AND METHODOLOGY OF THE ENVIRONMENTAL RISK ASSESSMENT REFERRED TO IN ANNEX II TO DIRECTIVE 2001/18/EC

1. **INTRODUCTION**

Environmental risk assessment (ERA) is defined in Article 2(8) of Directive 2001/18/EC as 'the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose'. As one of the general obligations under the Directive, Article 4(3) requires Member States and, where appropriate, the Commission to ensure that potential adverse effects on human health and the environment, which may occur in particular directly or indirectly, are accurately assessed on a case-by-case basis taking into account the environmental impact according to the nature of the organism introduced and the receiving environment. ERA is carried out in accordance with Annex II to the Directive, and is also referred to in Parts B and C thereof. Annex II describes in general terms the objective to be achieved, the elements to be considered and the general principles and methodology to be followed to perform the ERA, taking into account the impact on human health and the environment according to the nature of the organism introduced and the receiving environment.

Notifiers must submit a notification including an ERA for deliberate release under Article 6(2) or for placing on the market under Article 13(2).

This guidance note supplements Annex II to Directive 2001/18/EC and outlines the objectives and principles as well as the methodology for the ERA, in order to assist notifiers, to facilitate the performance by the competent authorities of a comprehensive and appropriate ERA under Directive 2001/18/EC and to make the process of ERA transparent to the general public.

The six steps in the ERA are set out in Chapter 4.2.

2. **OBJECTIVE**

In accordance with Annex II to Directive 2001/18/EC, *the objective of an ERA is, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment which the deliberate release or placing on the market of GMOs may have. The ERA should be conducted with a view to identifying if there is a need for risk management and if so, the most appropriate methods to be used* [1].

The ERA therefore covers deliberate release (Part B) and placing on the market (Part C) as referred to in Directive 2001/18/EC. Placing on the market very often, but not necessarily, includes deliberate release into the environment, but is always an intentional introduction on the market (for example, agricultural products containing or consisting of GMOs, only for the use of food, feed and processing). In these cases too an ERA has to be included in the notification process. In general there may be a difference between the ERA for deliberate release and that for placing on the market, due, for example, to the differences in existing data, time-scale and area.

In addition, these guidance notes cover all GMOs, including microorganisms, plants and animals. Although so far most GMOs deliberately released or placed on the market are higher plants, this may change in future.

The ERA will serve as the basis for identifying the need for risk management and, if so, the most appropriate methods to be used, and for focused monitoring (see Chapter 3).

The overall case-by-case assessment covers the GMO(s) concerned (GMO-by-GMO assessment) and the environment(s) in which the GMO is to be released (for example, site-by-site assessment and region-by-region assessment, if applicable).

Future developments in genetic modification may make it necessary to adapt Annex II and these guidance notes to technical progress. Further differentiation of information requirements for different types of GMOs, like single cell organisms, fish or insects, or for particular uses of GMOs, like the development of vaccines, may be possible once there is sufficient experience with notifications for the release of particular GMOs in the Community (Annex III, fourth paragraph, and Chapter 6).

Risk assessment of the use of antibiotic resistance marker genes is a very specific issue and further guidance on this item may be recommended.

[1] The text in italics is taken directly from Annex II to Directive 2001/18/EC.

Different 'effect categories' of GMOs on human health or the environment are described in Annex II to Directive 2001/18/EC. In the interests of a common interpretation, the definitions given in the Directive of the following terms are illustrated as follows:

— *'direct effects' refers to primary effects on human health or the environment which are a result of the GMO itself and which do not occur through a causal chain of events* (for example, the direct effect of the Bt toxin on target organisms, or the pathogenic effect of a GM microorganism on human health),

— *'indirect effects' refers to effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management; observations of indirect effects are likely to be delayed* (for example, where reducing the target population of insects affects the population of other insects, or where the development of multiple resistance or systemic effects will require assessment of long-term interaction; however, some indirect effects such as reductions in usage of pesticides could be immediate),

— *'immediate effects' refers to effects on human health or the environment which are observed during the period of the release of the GMO. Immediate effects may be direct or indirect* (for example, death of insects foraging on transgenic plants that have pest-resistant traits, or the induction of allergies in susceptible humans due to exposure to a particular GMO),

— *'delayed effects' refers to effects on human health or the environment, which may not be observed during the period of the release of the GMO but become apparent as a direct or indirect effect either at a later stage or after termination of the release* (for example, establishment or invasive behaviour of a GMO after several generations following deliberate release, which is very important if the GMO lives for a long time, for example, genetically modified tree species; or hybrids of close relatives of a transgenic crop becoming invasive in natural ecosystems).

The delayed effects in particular may be difficult to determine, especially if they become apparent only in the long term. Appropriate measures such as monitoring (see below) can help in detecting these effects.

3. **GENERAL PRINCIPLES**

In accordance with the precautionary principle, the ERA should be based on the following general principles:

— *Identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations.*

A baseline of the receiving environment, including its organisms and their interactions and their known variations, should be determined before any (harmful) characteristics of the GMO can be identified. The baseline serves as a point of reference against which future changes can be compared. For example, in the case of vegetatively propagated crops, comparative analysis should include the parental species used to generate the transgenic lines. In the case of crops that reproduce sexually, comparators would include appropriate isogenic lines. If crops are developed using back-crossing, it is important that in such cases substantial equivalence testing uses the most appropriate controls and does not simply rely on comparisons with original parental material.

If the existing data are not sufficient, a baseline has to be defined on other references to allow a comparison. The baseline will depend to a considerable extent on the receiving environment, including biotic and abiotic factors (for example, natural preserved habitats, agricultural farmland or contaminated land) or a combination of different environments.

— *The ERA should be carried out in a scientifically sound and transparent manner based on available scientific and technical data.*

Evaluation of potential adverse effects should be based on scientific and technical data and on common methodology for the identification, gathering and interpretation of the relevant data. Data, measurements and tests should be clearly described. In addition, the use of scientifically sound modelling procedures could provide missing data useful for ERA.

ERA has to take into account uncertainty at various levels. Scientific uncertainty results usually from five characteristics of the scientific method: the variable chosen, the measurements made, the samples taken, the models used and the causal relationships employed. Scientific uncertainty may also arise from a controversy on existing data or lack of some relevant data. Uncertainty may relate to qualitative or quantitative elements of the analysis. The level of knowledge or data for a baseline is reflected by the level of uncertainty, which has to be provided by the notifier (assessment of uncertainty, including lack of data, knowledge gaps, standard deviation, complexity, etc.) in comparison with the scientific uncertainties in current practice.

The ERA may not always result in definitive answers to all the questions considered because of lack of data. For potential long-term effects, in particular, the availability of data may be very low. In these cases in particular appropriate risk management (safeguards) has to be considered in accordance with the precautionary principle in order to prevent adverse effects on human health and the environment.

As a general principle, the ERA should include the results of adequate research into the potential risks involved in the deliberate release or placing on the market of GMOs, along with any clearly documented comparable experience.

Use of the step-by-step approach (i.e. all the steps beginning with experiments in the contained use system through deliberate release up to placing on the market) can be useful. Data from each step should be collected as early as possible during the procedure. Simulated environmental conditions in a contained system could give results of relevance to deliberate release (for example, the behaviour of microorganisms can be simulated in microcosms, or the behaviour of plants can be simulated in greenhouses to a certain extent).

For GMOs to be placed on the market, relevant and available data from deliberate releases should be provided from the types of environment where the GMO will be used.

— *The ERA should be carried out on a case by case basis, meaning that the required information may vary depending on the type of the GMOs concerned, their intended use and the potential receiving environment, taking into account,* inter alia*, GMOs already in the environment*.

The ERA should use the case-by-case principle because of the broad range of individual characteristics of different organisms (GMO by GMO) and different environments (site by site and region by region).

There may be a huge variety in the environmental effects of genetically modified microorganisms (because of their small size and their often unknown interactions), plants (for example, higher plants used for food and feed, or trees because of their potential longevity), and animals (for example, insects because of their small size and their high potential for overcoming barriers; or saltwater fish because of their high distribution potential).

Moreover, there may be a broad range of environmental characteristics (site-specific or regional-specific) to be taken into account. To support a case-by-case assessment, it may be useful to classify regional data by habitat area, reflecting aspects of the receiving environment relevant to GMOs (for example, botanical data on the occurrence of wild relatives of GMO plants in different agricultural or natural habitats of Europe).

The notifier must also take into account potentially harmful interactions of the GMO with any relevant GMOs that may have been deliberately released or placed on the market in the past, including repeated releases of the same GMO, such as the use of plant protection products. Repeated releases, as compared to occasional releases, might in time cause a high background level of the GMO to become permanent in the environment.

If new information on the GMO and its effects on human health or the environment becomes available, the ERA may need to be re-addressed in order to:

— determine whether the risk has changed,

— determine whether there it is necessary to amend the risk management accordingly.

In the case of new information, irrespective of whether immediate measures need to be taken, there may have to be a new ERA to assess the need to change the terms of authorisation for the GMO's release or placing on the market, or to adjust risk management measures (see also Chapter 6). New information can arise from research or from monitoring plans, or from relevant experience elsewhere.

ERA and monitoring are closely linked. The ERA provides the basis for the monitoring plans, which focus on adverse effects on human health and the environment. The requirements for the monitoring plans for the deliberate release of GMOs (Part B in accordance with the relevant parts of Annex III) and the placing on the market of GMOs (Part C in accordance with Annex VII) are different. The Part C monitoring, including general surveillance, may also play an important role in providing data for long-term, potentially adverse effects of GMOs. Monitoring results may confirm the ERA or may lead to re-evaluation of the ERA.

— *A general principle for ERA is also that an analysis of the 'cumulative long-term effects' relevant to the release and the placing on the market is to be carried out. 'Cumulative long-term effects' refers to the accumulated effects of consents on human health and the environment, including flora and fauna, soil fertility, soil degradation of organic material, the feed/food chain, biological diversity, animal health and resistance problems in relation to antibiotics.*

In considering the potential cumulative long-term effects, the ERA should take into account issues such as:

— the long-term interactions of the GMO and the receiving environment,

— the characteristics of a GMO which become important on a long-term basis,

— repeated deliberate releases or placings on the market over a long period,

— the GMOs deliberately released or placed on the market in the past.

Further information may be required on long-term effects in particular (for instance, multiple herbicide resistances) and there must be adequate research, partly within the framework of the monitoring plans, which can provide important data for assessing cumulative long-term effects. Further guidance on this item may be recommended.

4. **METHODOLOGY**

4.1. **Characteristics of GMOs and releases**

The ERA has to take into account the relevant technical and scientific details regarding characteristics of:

— *the recipient or parental organism(s),*

— *the genetic modification(s), be it inclusion or deletion of genetic material, and relevant information on the vector and the donor,*

— *the GMO,*

— *the intended release or use including its scale,*

— *the potential receiving environment, and*

— *the interaction between these.*

Information from releases of similar organisms and organisms with similar traits and their interaction with similar environments can assist the ERA.

Prior to deliberate release of a GMO or a combination of GMOs under Part B or to the placing on the market under Part C of the Directive, a notification including the information set out in Annexes IIIA and IIIB to the Directive (information on the GMO, the donor, the recipient, the vector, the conditions of the release and the environment, the interactions between the GMOs and the environment and of monitoring GMOs) should be submitted to the competent authority of the Member State where the release or the placing on the market is to take place for the first time.

Those notifications should contain a technical dossier of information including a full ERA in accordance with Article 6(2) and Article 13(2) of the Directive, the amount of detail needed to substantiate any point depending on its importance in the ERA. Notifiers shall provide bibliographic references and indicate the methods used.

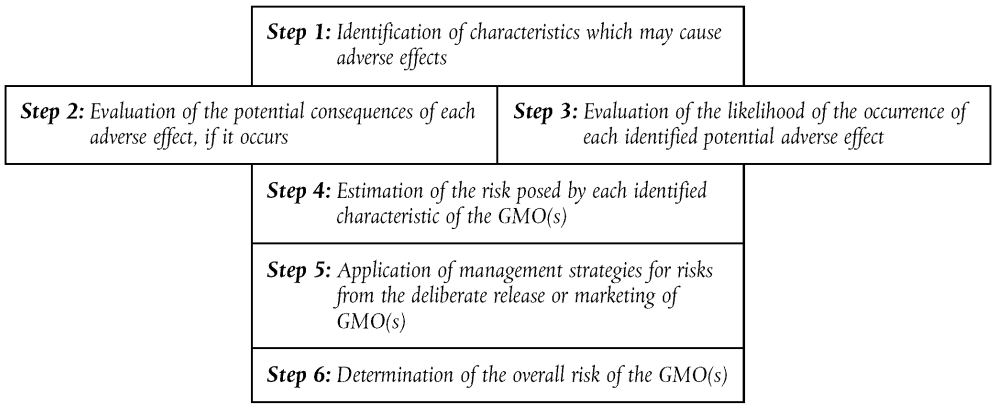
The information on recipient, donor, vector, genetic modification and the GMO, on the basis of information requested in Annexes IIIA and IIIB to the Directive, is independent of the environment in which the GMO is to be experimentally released or placed on the market, and the conditions under which it will be experimentally released or marketed. This information is the basis for identifying any potential harmful characteristics (potential hazards) of the GMO. Knowledge and experience gained in releases of the same or similar GMOs may provide important information on the potential hazards of the release in question.

Information on intended release, receiving environment and interaction between these, as requested in Annexes IIIA and IIIB to the Directive relates to the particular environment into which the GMO will be released, and the conditions, including the scale of the release. This information will determine the extent of any potentially harmful characteristics of the GMO.

4.2. **Steps in the analysis of ERA**

In drawing conclusions for the ERA referred to in Articles 4, 6, 7 and 13 of Directive 2001/18/EC, the following points should be addressed as main steps in the ERA.

Diagram 1: The six steps in the analysis of ERA



A 'hazard' (harmful characteristics) is defined as the potential of an organism to cause harm to or adverse effects on human health and/or the environment.

A 'risk' is the combination of the magnitude of the consequences of a hazard, if it occurs, and the likelihood that the consequences occur.

4.2.1. *Step 1: Identification of characteristics which may cause adverse effects*

Any characteristics of the GMOs linked to the genetic modification that may result in adverse effects on human health or the environment must be identified. A comparison of the characteristics of the GMO(s) with those of the non-modified organism under corresponding conditions of the release or use will assist in identifying the particular potential adverse effects arising from the genetic modification in the GMO. It is important not to discount any potential adverse effect on the basis that it is unlikely to occur.

Potential adverse effects of GMOs will vary from case to case, and may include:

— *disease to humans including allergenic or toxic effects,*

— *disease to animals and plants including toxic, and where appropriate, allergenic effects,*

— *effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations,*

— *altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors,*

— *compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine,*

— *effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material.*

Examples of the above potential adverse effects are given in Annexes IIIA and IIIB to Directive 2001/18/EC.

Most of the identifiable hazards (harmful characteristics) which may cause adverse effects will be related to the gene or genes of interest, deliberately introduced into the GMO and the corresponding protein(s) being expressed from these genes. Additional adverse effects, for example, pleiotropic effects, might have been generated as a result of the method used to create the transgenes, and of the location of the construction in the genome of the GMO where the transgenes were inserted. Where more than one transgene is transferred into a recipient or where a transgene is transferred into a GMO, the potential interaction of the different transgenes has to be taken into account considering potentially epigenetic or regulatory effects.

While it is important to define the hazard as accurately as possible, it will, in many cases, be useful to consider hazards under the headings set out below, and then to specify the particular hazard identified for the purposes of ERA (for example, if in a specific case a potential for adverse effects on human health — allergenicity and toxigenicity — were identified, these should be considered separately in the ERA).

If a hazard is present in the GMO, it is always present and it can be regarded as an inherent property. Hazards can give rise — with a given likelihood (step 3) — to negative consequences and these consequences in turn can have different orders of magnitude (step 2). Finally, the individual hazards have to be summarised for the GMO.

At this stage of the ERA, however, it is only necessary to consider the hazards introduced as a result of genetic modification that could cause adverse effects. Step 1 provides the scientific basis for the following steps in the ERA. Even at this stage, it is critical to identify, for each potential hazard, the specific level of scientific uncertainty so that it can be taken into account at a later stage.

Adverse effects may occur directly or indirectly through mechanisms, which may include:

— *The spread of the GMO(s) in the environment*

Distribution pathways show the potential pathways of distribution of the GMO or of the potential hazard into and within the environment (for example, human toxicity: inhalation of toxic microorganisms or toxic proteins).

The potential of a GMO to spread into the environment will depend, for example, on:

— its biological fitness (GMOs designed for better performance in the environment of interest by the expression of traits leading to increased competitiveness in natural environments, or qualitative and quantitative change in composition of ingredients, or GMOs with resistance to natural selection pressure like disease, or abiotic stress like heat, cold, salt, or production of anti-microbial substances in microorganisms),

— the conditions of the deliberate release or placing on the market (particularly the area of release and the scale, that is to say, the number of GMOs released),

— the likelihood of a deliberate release or placing on the market, or unintentional releases into the environment (for example, GMOs for processing),

— pathways of dispersal of viable material (for example, seeds, spores and so on) by wind, water, animals, etc.,

— particular environmental considerations (site-specific or regional-specific): to allow a site-by-site or a region-by-region assessment it may be useful to classify data by habitat area, reflecting aspects of the receiving environment relevant to the GMO (for example, botanical data on the occurrence of crossable wild relatives of GMO plants in different agricultural or natural habitats of Europe).

It is also important to assess the length of time an individual GMO or a specific number of GMOs of a certain species is generally likely to survive, and the readiness with which it can be disseminated and become established in a variety of habitats. Consideration will need to be given to reproductive, survival and dormant forms, including, for example:

— for plants: the viability of pollen, seeds and vegetative structures,

— for microorganisms: the viability of spores as survival forms, or the potential of the microorganisms to enter the viable but not cultivable state.

The overall spread potential may vary considerably, depending on the species, the genetic modification and the receiving environment, for example plant cultivation in the desert or fish cultivation in the sea.

— *The transfer of the inserted genetic material to other organisms, or the same organism whether genetically modified or not*

A hazard could result in adverse effects through gene transfer within the same species or to other species (vertical and horizontal gene transfer). The speed and extent of gene transfer to other species (usually sexually compatible in the case of higher organisms) will depend, for example, on:

— the reproductive properties of the GMO itself, including the modified sequences,

— the conditions of release, and particular environmental considerations such as climate (for example, wind),

— differences in reproduction biology,

— agricultural practices,

— the availability of potential crossing partners,

— transport and pollinating vectors (for example, insects or birds, animals in general),

— the availability of hosts for parasites.

The occurrence of specific adverse effects through gene transfer may be linked to the number of GMOs released. Large fields of transgenic plants may have a completely different potential for gene transfer from small fields, even on a proportional basis. Moreover, qualitative and quantitative information about the existence of potential crossing partners or recipients (for plants within relevant distances) is very important.

For higher plants and animals, further distinctions should be made regarding possible gene transfer to the same, closely related, distantly related and unrelated species.

In the case of microorganisms, horizontal gene transfer plays a more important role. Certain genetic material can be easy transferred between more closely related organisms, for example, via plasmids or phages. The potential rapid growth rate of microorganisms can enable gene transfer at relatively high levels compared to higher organisms.

Transfer of transgenes may lead to a mixed population of GMOs or to different gene-plant combinations after a time, which can then give rise to complex patterns of especially long-term adverse effects. These will become more complex as more transgenic material is transferred into a population (for example, gene stacking).

In some cases, the method of genetic modification may change the potential for gene transfer, such as in the case of non-integrating plasmids or viral vectors. The method of genetic modification may also decrease the potential for gene transfer, for example, chloroplast transformation.

Gene transfer may result in persistence of the introduced genetic material in natural populations. If a GMO has the potential for gene transfer, this does not necessarily mean intrinsic risk, or a change in the capacity to survive, to become established or cause adverse effects. This will depend on the genetic material inserted, the species and the receiving environment, including the potential recipients.

— *Phenotypic and genetic instability*

The extent to which genetic (in)stability might lead to phenotypic (in)stability and result in a hazard should be considered. Instability of the genetic modification may in certain cases result in reversion into the wild type phenotype. Other cases should be considered, for example:

— if in a transgenic plant line that contains more than one transgene, the subsequent segregation process results in these transgenes being divided up in the progeny, there could be plants with less transgenes but new phenotypes,

— if attenuated mutants may, due to instability (because of the construction of the particular mutation) revert to virulence,

— if duplication of transgenes leads to gene silencing,

— if copy numbers are very high,

— if re-insertion of transposable elements results in new phenotypes, due to inactivation of the transgene by the insertion of mobile genetic elements,

— if the level of transgene expression is important (for example, a very low expression of a toxic substance), the genetic instability of the regulatory element(s) may result in a higher transgene expression.

Phenotypic instability could result from interaction with the environment during cultivation, so the effects of environmental and agronomic factors on expression of transgenes should be considered in the ERA.

If transgene expression is limited to a certain compartment in the GMO (such as a certain plant tissue), instability of regulation could result in expression of the transgene in the entire organism. In this context regulatory signals (such as promoters) play an important role and should be considered.

Also the expression of the transgene at a certain time in the life cycle of the organism or under specific environmental conditions should be considered.

Specific infertility transgenes may have been introduced into the GMO to make it infertile (for example, to prevent transfer and spread of certain transgenes). Instability of the infertility transgenes could result in reactivation of the fertility of the plant allowing the spread of the transgenes, which could have adverse affects.

The stability of the different transgene(s) not only in the primary GMO but also in its progeny is of importance for long-term effects in particular.

— *Interactions with other organisms (other than exchange of genetic material/pollen)*

Possible interactions with other organisms, including other GMOs, have to be carefully assessed, taking into account the complexity of multitrophic interactions. Directly hazardous interactions which could cause adverse effects might include:

— exposure to humans (such as farmers, consumers),

— exposure to animals,

— competition for natural resources like soil, area, water, light,

— displacement of natural populations of other organisms,

— delivery of toxic substances,

— different growth patterns.

In general, if biological fitness is enhanced by the genetic modification, the GMO may invade new environments and replace existing species. Often the occurrence of specific adverse effects is proportionally linked to scale of release.

— *Changes in management, including, where applicable, in agricultural practices*

The relevance of changes in management procedures as an unavoidable consequence of the deliberate release of the GMO has to be assessed on the basis of existing procedures. Changes in farm management could, for example, relate to:

— sowing, planting, growing, harvesting or transporting crops (for example, planting in small or large fields), timing,

— crop rotation (for example, cultivating the same plant species every year or every fourth year),

— disease and pest control (for example, type and dose of insecticide for plants, or antibiotics for animals, or alternative measures),

— resistance management (for example, type and dose of herbicide for herbicide-tolerant plants, or change in use of biological control via Bt proteins, or impact of viruses),

— isolation in land agricultural and aquatic agricultural systems (for example, isolation distances in plant cultivation or quality of isolation in fish farms),

— agricultural practices (farming GMOs and non transgenic farming, including organic farming),

— management in non-agricultural systems (for example, isolation distances of natural habitats from GMO planting areas).

4.2.2. *Step 2: Evaluation of the potential consequences of each adverse effect, if it occurs*

The magnitude of the consequences of each potential adverse effect should be evaluated.

Apart from the likelihood that the potential harmful characteristics will occur (see Chapter 4.2.3, step 3), evaluating the magnitude of the consequences is an important part of risk assessment. The magnitude is the extent to which the consequences of any potential hazards of the GMOs to be deliberately released or placed on the market will be realised.

The magnitude is to be seen in relation to the baseline and likely to be influenced by:

— genetic construction,

— each adverse effect identified,

— the number of GMOs released (scale),

— the environment into which the GMO(s) is (are) to be released,

— the conditions of the release, including control measures,

— combinations of the above.

For each adverse effect identified, the consequences for other organisms, populations, species or ecosystems exposed to the GMO have to be evaluated. This requires detailed knowledge of the environment into which the GMO is to be released (site, region) and the method of release. Consequences will range from 'negligible' or insignificant and self-limiting to 'high' or significant, either having an immediate and serious adverse effect or possibly leading to long-term, permanent adverse effects.

In quantitative terms the magnitude should, if possible, be expressed as 'high', 'moderate', 'low' or 'negligible'. In some cases, it is not possible to identify an adverse effect in a particular environment. In such cases, the risk associated with that particular adverse effect could be assessed as 'negligible' or insignificant.

The following are suggested as illustrative and qualitative examples in a very broad sense. They are not intended to be definitive or exclusive, but to give an indication of the considerations that might be taken into account when weighing up the consequences:

— 'high level consequences' might be significant changes in the numbers of one or more species of other organisms, including endangered and beneficial species in the short or long term. Such changes might include a reduction in or complete eradication of a species leading to a negative effect on the functioning of the ecosystem and/or other connected ecosystems. Such changes would probably not be readily reversible and any recovery of the ecosystem that did take place would probably be slow,

— 'moderate consequences' might be significant changes in population densities of other organisms, but not a change which could result in the total eradication of a species or any significant effect on endangered or beneficial species. Transient and substantial changes in populations might be included if likely to be reversible. There could be long-term effects, provided there are no serious negative effects on the functioning of the ecosystem,

— 'low level consequences' might be non-significant changes in population densities of other organisms, which do not result in the total eradication of any population or species of other organisms and have no negative effects on functioning of the ecosystem. The only organisms that might be affected would be non-endangered, non-beneficial species in the short or long term,

— 'negligible consequences' would mean that no significant changes had been caused in any of the populations in the environment or in any ecosystems.

The above examples reflect the potential adverse effects of GMOs on populations, although in some cases, it may be more appropriate to consider the likely effects on individual organisms. One single hazard could have more than one adverse effect, and in fact the magnitudes of the individual adverse effects could be different. The adverse effects of one single hazard on human health, and agricultural and natural habitats could vary.

The potential consequences could be summarised in such a way as to cover all the ecological entities which could be affected (such as species, populations, trophic levels, ecosystems) including the potential effect and the level of uncertainty.

4.2.3. *Step 3: Evaluation of the likelihood of the occurrence of each identified potential adverse effect*

A major factor in evaluating the likelihood or probability of adverse effects occurring is the characteristics of the environment into which the GMO(s) is intended to be released, and the manner of the release.

Besides the magnitude of the consequences of the hazards (see Chapter 4.2.2, step 2) evaluating the likelihood of adverse effects occurring is another important part in assessing risks. This step is to estimate how likely it is that adverse effects will actually occur. In some cases both the likelihood and the frequency should be addressed. As in step 2 (evaluate the potential consequences of each adverse effect if it occurs), besides the hazard itself, the number of GMOs, the receiving environment and the conditions of the release are important for defining the likelihood. Climatic, geographical, soil and demographic conditions, and the types of flora and fauna in the potential receiving environment are some of the important considerations.

For capability of survival, therefore, it is appropriate to assess the proportion of GMOs that are likely to survive, outside the intended risk management measures proposed for the deliberate release or placing on the market. Where gene transfer is likely, the probable number of such events or the extent to which transfer will occur should be considered. If the GMO has pathogenic or toxic characteristics, the proportion of target organisms in the environment likely to be affected should be assessed.

Moreover, the likelihood of the occurrence of an effect will depend on the specific risk management measures that may prevent that risk from occurring (for example, if pollen dispersal is impossible due to the destruction of the inflorescences).

For each adverse effect identified, the relative likelihood of the consequence can probably not be assessed quantitatively, but it can be expressed in terms of 'high', 'moderate', 'low' or 'negligible'.

The above examples reflect the potential adverse effect of the GMO on populations, although in some cases, it may be more appropriate to consider the likely effects on individual organisms. One single hazard could have more than one adverse effect, so the likelihood of individual adverse effects could also be different. The adverse effects of one single hazard on human health, agricultural and natural habitats could vary.

Likelihood could be summarised in a way which covers all the ecological entities which could be affected (such as species, populations, trophic levels, ecosystems) including measures about the potential effect as well as the level of uncertainty.

4.2.4. *Step 4: Estimation of the risk posed by each identified characteristic of the GMO(s)*

An estimation of the risk to human health or the environment posed by each identified characteristic of the GMO which has the potential to cause adverse effects should be made as far as possible, given the state of the art, by combining the likelihood of the adverse effect occurring and the magnitude of the consequences, if it occurs.

On the basis of the conclusions reached in steps 2 and 3, an estimate of the risk of adverse effects should be made for each hazard identified in step 1. Again quantitative evaluation is unlikely to be possible. The evaluation for each hazard should consider:

— the magnitude of the consequences ('high', 'moderate', 'low' or 'negligible'),

— the likelihood of the adverse effect ('high', 'moderate', 'low' or 'negligible'),

— if a hazard has more than one adverse effect, the magnitude and likelihood of each individual adverse effect.

Each GMO has to be considered on a case-by-case basis. Any general attempt to quantify what has been described before has to be made very carefully. For example, in one case the high magnitude of the consequences of an adverse effect may be combined with a negligible likelihood of it occurring, resulting in the whole range from high risk down to negligible risk. The result will depend on the circumstances of the case and the weighting of certain factors by the notifier, all of which should be set out clearly and justified in the recorded ERA.

The overall uncertainty for each identified risk has to be described, possibly including documentation relating to:

— assumptions and extrapolations made at various levels in the ERA,

— different scientific assessments and viewpoints,

— uncertainties,

— the known limits of mitigation measures,

— conclusions that can be derived from the data.

Although the ERA should be based on quantifiable outcomes, it is likely that many of the results of the ERA will have to be qualitative. But it is necessary, wherever possible, to have ERA results which are relative (compared with a non-GM reference, for instance), even if they are qualitative.

4.2.5. *Step 5: Application of management strategies for risks from the deliberate release or marketing of GMO(s)*

The ERA may identify risks that require measures to manage them, and a risk management strategy should be defined.

Before applying risk management, consideration should be given, with a view to prevention, to modifying the release, preferably until the risk is negligible. For example, genetic elements, which may cause adverse effects or are undefined, should be avoided in the gene construction process. If this is not possible, these genetic elements should preferably be removed from the GMO at a later stage, prior to its deliberate release or placing on the market.

This should be taken into account in steps 1 to 4. Risk management should control an identified risk and cover the uncertainties. Safeguard measures should be proportionate to the level of risk and to the level of uncertainty. When relevant data becomes available at a later stage, risk management should be adapted in line with that new data.

To reduce the risk by management, the measures should clearly achieve that end. For example, if there is a risk of a gene toxic to insects inserted into a crop plant being transferred to related plant species, suitable control measures might include spatial or temporal isolation from those related species or perhaps changing the release site to an area where there is no exposure to a specific risk (such as plant species).

Management strategies can include isolation measures at every relevant stage of the handling and use of GMOs. They can also include a wide range of measures, including various means to isolate reproduction, physical or biological barriers, and cleaning machines or containers in contact with GMOs, and so on.

Detailed risk management procedures will depend on:

— the use of the GMO (type and scale of deliberate release or placing on the market),

— the type of GMO (for example, genetically modified microorganisms, higher annual plant, higher long-life plant or animal, GMO with single or multiple modification, one or different kinds of GMOs),

— the general type of habitat (for example, biogeochemical status, climate, availability of inter- and interspecific crossing partners, centres of origin, connection of different habitats),

— the type of agricultural habitat (for example, agriculture, forestry, aquatic culture, rural areas, size of sites, number of different GMOs),

— the type of natural habitat (for example, status of preserved areas).

There should be a clear statement of the implications of risk management in terms of the necessary adjustments to experiments, conditions for placing on the market, and so on, and the consequent reduction in risk likely to be achieved.

4.2.6. *Step 6: Determination of the overall risk of the GMO(s)*

An evaluation of the overall risk of the GMO(s) should be made taking into account any risk management strategies which are proposed.

On the basis of step 4 and, if appropriate, step 5, a final evaluation should be made of the overall risk, including the magnitude and likelihood of the adverse effects of the GMO, based on the combination of the risks from each individual adverse effect, including cumulative effects from other GMOs. This final evaluation should be expressed in the form of a summary of the overall risks from deliberate release or placing on the market, including the overall uncertainties.

5. CONCLUSIONS ON THE POTENTIAL ENVIRONMENTAL IMPACT FROM THE RELEASE OR THE PLACING ON THE MARKET OF GMOs

On the basis of an ERA, carried out in accordance with the general principles and methodology outlined in sections 3 and 4, information on the points listed in sections D1 or D2 of Annex II to Directive 2001/18/EC should be included, as appropriate, in notifications with a view to assisting in drawing conclusions on the potential environmental impact from the release or the placing on the market of GMOs.

Future developments, especially in the non-plant area, may give further guidance on the information to be included in the notifications.

6. REVIEW AND ADAPTATION

6.1. Review and adaptation of an ERA

An ERA should not be viewed as static. It should be regularly reviewed and updated or perhaps changed to take account of relevant new data (in accordance with Articles 8 or 20 of Directive 2001/18/EC). Any reviews should consider the effectiveness, efficiency and accuracy of the ERA and risk management, taking account of data from research, other deliberate releases and monitoring data. This will also depend on the level of uncertainty determined by the ERA.

Following any such reviews, the ERA and risk management should be adapted or upgraded as appropriate.

6.2. Review and adaptation of the ERA guidance

Future developments in genetic modification may make it necessary to adapt to technical progress Annex II and these guidance notes. Further differentiation of information requirements for different types of GMOs, like single cell organisms, fish or insects, or for particular use of GMOs, like the development of vaccines, may be possible once there is sufficient experience with notifications for the release of particular GMOs in the Community (Annex III, fourth paragraph).

The review and adaptation of the ERA guidance should also take into account, where appropriate, the need to adapt to technical progress and the need to develop further guidance based on experience — where sufficient — with releases of certain GMOs into certain ecosystems, in accordance with the criteria set out in Annex V (Article 7(1)) of the Directive, as well as experience and scientific evidence relating to the safety of human health and the environment in connection with the placing on the market of certain GMOs (Article 16(2)).

COMMISSION DECISION

of 24 July 2002

authorising Italy to allow the export of an aromatised wine-based drink not complying with Council Regulation (EEC) No 1601/91 laying down general rules on the definition, description and presentation of aromatised wines, aromatised wine-based drinks and aromatised wine-product cocktails

(notified under document number C(2002) 2773)

(Only the Italian text is authentic)

(2002/624/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1601/91 of 10 June 1991 laying down general rules on the definition, description and presentation of aromatised wines, aromatised wine-based drinks and aromatised wine-product cocktails [1], as last amended by Regulation (EC) No 2061/96 of the European Parliament and of the Council [2], and in particular Article 11 thereof,

Whereas:

(1) Italy has sent the Commission a request for a derogation as provided for in Article 11 of Regulation (EEC) No 1601/91 submitted by an Italian trader relating to an aromatised wine-based drink intended for export to certain third countries.

(2) The trader in question wishes to use the colour tartrazine (E 102) in the manufacture of this aromatised wine-based drink.

(3) No colours may be used in the manufacture of aromatised wine-based drinks as defined in Article 2(1)(b) of Regulation (EEC) No 1601/91.

(4) Tartrazine is a foodstuff colour authorised under Directive 94/36/EC of the European Parliament and of the Council of 30 June 1994 on colours for use in foodstuffs [3] in the preparation of other alcoholic drinks and foodstuffs placed on the Community market.

(5) It is intended to use tartrazine for an aromatised wine-based drink for export to third countries in which that additive is legally permitted in this type of product. The quantity involved is 30 000 hectolitres per year. Its use poses no threat to human health at the levels of use provided for in the legislation of the third countries concerned.

(6) The aromatised drinks thus produced will not be sold on the Community market.

(7) This derogation will apply for a limited period so that the technical need for it can be reconsidered at a future date or its conditions and scope can be amended in the light of experience.

(8) The derogation provided for in this Decision is in accordance with the opinion of the Implementation Committee on Aromatised Wine-Based Drinks,

HAS ADOPTED THIS DECISION:

Article 1

Italy is authorised to allow, until 31 December 2005, the manufacture and export to certain third countries of an aromatised wine-based drink coloured with tartrazine (E 102).

The resultant products shall meet the regulatory requirements of the third countries concerned. This derogation shall apply to an annual production quantity of 30 000 hl.

Article 2

This Decision is addressed to the Italian Republic.

Done at Brussels, 24 July 2002.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ L 149, 14.6.1991, p. 1.
[2] OJ L 277, 30.10.1996, p. 1.
[3] OJ L 237, 10.9.1994, p. 13.

COMMISSION DECISION

of 25 July 2002

amending for the second time Decision 2002/383/EC concerning certain protection measures relating to classical swine fever in France, Germany and Luxembourg

(notified under document number C(2002) 2824)

(Text with EEA relevance)

(2002/625/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market [1], as last amended by Directive 92/118/EEC [2], and in particular Article 10(4) thereof,

Having regard to Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever [3], and in particular Article 29(4) thereof,

Whereas:

(1) Classical swine fever has occurred in certain bordering areas of France, Germany and Luxembourg.

(2) In view of the trade in live pigs, these outbreaks are liable to endanger the herds of other parts of the Community.

(3) France, Luxembourg and Germany have taken measures within the framework of Directive 2001/89/EC.

(4) The Commission has adopted Decision 2002/383/EC of 23 May 2002 concerning certain protection measures relating to classical swine fever in France, Germany and Luxembourg [4], which was then amended by Decision 2002/538/EC [5].

(5) In the light of the evolution of the epidemiological situation in the feral pigs in Germany it is appropriate to slightly modify the area concerned by these measures. Decision 2002/383/EC should therefore be amended accordingly.

(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,

HAS ADOPTED THIS DECISION:

Article 1

Annex to Decision 2002/383/EC is replaced by the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 25 July 2002.

For the Commission

David BYRNE

Member of the Commission

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[1] OJ L 224, 18.8.1990, p. 29.
[2] OJ L 62, 15.3.1993, p. 49.
[3] OJ L 316, 1.12.2001, p. 5.
[4] OJ L 136, 24.5.2002, p. 22.
[5] OJ L 173, 3.7.2002, p. 39.

ANNEX

France:

— the territory of the department Moselle located northern of the river Moselle from the border with Germany until the city of Thionville and of the motorway A30 from the city of Thionville until the border with Meurthe-et-Moselle,

— the territory of the department Meurthe-et-Moselle located northern of the motorway A30/national road N52, from the border with Moselle until the city of Longwy, at the border with Belgium.

Germany:

— the whole territory of Rhineland-Palatinate, except those areas located eastern of the river Rhine,

— in Saarland: in the Kreise Merzig-Wadern: Mettlach, Merzig, Beckingen, Losheim, Weiskirchen, Wadern; in the Kreis Saarlouis: Dillingen, Bous, Ensdorf, Schwalbach, Saarwellingen, Nalbach, Lebach, Schmelz, Saarlouis; in the Kreis Sankt Wendel: Nonnweiler, Nohfelden, Tholey,

— the following areas of North Rhine-Westfalia: in the Kreis Euskirchen: the Gemeinden of Dahlem, Blankenheim, Bad Münstereifel, Schleiden and Stadt Euskirchen; Hellenthal; the Gemeinde Kall; the Stadt Mechernich: the Gemeinde Nettersheim; in the Kreis Rhein-Sieg: Stadt Rheinbach, the Gemeinde Swisttal, Stadt Meckenheim; in the Kreis Aachen: the Gemeinden of Simmerath and Monschau.

Luxembourg:

— the whole territory.

COMMISSION DECISION

of 25 July 2002

approving the plan submitted by France for the eradication of classical swine fever from feral pigs in Moselle and Meurthe-et-Moselle

(notified under document number C(2002) 2826)

(Only the French text is authentic)

(Text with EEA relevance)

(2002/626/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever [1], and in particular Article 16(1) thereof,

Whereas:

(1) In April 2002 classical swine fever was confirmed in the feral pig population in the department of Moselle in France, at the border with the department Meurthe-et-Moselle, Luxembourg and Germany.

(2) In accordance with Article 16 of Directive 2001/89/EC, the French authorities have submitted a plan for the eradication of classical swine fever from feral pigs in Moselle and in the bordering department of Meurthe-et-Moselle.

(3) The submitted plan has been examined and found to comply with the provisions of Directive 2001/89/EC.

(4) 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

The plan submitted by France for the eradication of classical swine fever from feral pigs in Moselle and Meurthe-et-Moselle is hereby approved.

Article 2

This Decision is addressed to the French Republic.

Done at Brussels, 25 July 2002.

For the Commission

David BYRNE

Member of the Commission

[1] OJ L 316, 1.12.2001, p. 5.

COMMISSION DECISION

of 29 July 2002

establishing the European Regulators Group for Electronic Communications Networks and Services

(Text with EEA relevance)

(2002/627/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Whereas:

(1) A new regulatory framework for electronic communications networks and services has been established in accordance with European Parliament and Council Directives 2002/21/EC of 7 March 2002 on a common regulatory framework for electronic communications networks and services (Framework Directive) ([1]), 2002/19/EC of 7 March 2002 on access to, and interconnection of, electronic communications networks and associated facilities (Access Directive) ([2]), 2002/20/EC of 7 March 2002 on the authorisation of electronic communications networks and services (Authorisation Directive) ([3]) and 2002/22/EC of 7 March 2002 on the universal services and users' rights related to electronic communications networks and services (Universal Service Directive) ([4]).

(2) National regulatory authorities have been set up in all Member States to carry out the regulatory tasks specified in these Directives and as to be notified to the Commission in accordance with Article 3(6) of the Framework Directive. In accordance with the Framework Directive, Member States must guarantee the independence of national regulatory authorities by ensuring that they are legally distinct from and functionally independent of all organisations providing electronic communications networks, equipment or services. Member States that retain ownership or control of undertakings providing electronic communications networks and/or services must also ensure effective structural separation of the regulatory function from activities associated with ownership or control.

(3) Detailed responsibilities and tasks of the national regulatory authorities differ among the various Member States, but all of them have at least one national regulatory authority who is charged with application of the rules once they have been transposed into national law, in particular the rules concerning day-to-day supervision of the market.

(4) The need for the relevant rules to be consistently applied in all Member States is essential for the successful development of an internal market for electronic communications networks and services. The new regulatory framework sets out objectives to be achieved and provides a framework for action by national regulatory authorities, whilst granting them flexibility in certain areas to apply the rules in the light of national conditions.

(5) A European Regulators Group for Electronic Communications Networks and Services (hereinafter referred to as the Group) should be established to provide an interface for advising and assisting the Commission in the electronic communications field.

(6) The Group should provide an interface between national regulatory authorities and the Commission in such a way as to contribute to the development of the internal market. It should also allow cooperation between national regulatory authorities and the Commission in a transparent manner so as to ensure the consistent application in all Member States of the regulatory framework for electronic communications networks and services.

(7) The Group should serve as a body for reflection, debate and advice for the Commission in the electronic communications field, including on matters related to the implementation and revision of Recommendation on Relevant Product and Service Markets and in drawing up the Decision on transnational markets.

(8) Close cooperation should be maintained between the Group and the Communications Committee established under the Framework Directive. The work of the Group should not interfere with the work of the Committee.

(9) Coordination should be ensured with the Radio Spectrum Committee established under a Decision No 676/2002/EC of the European Parliament and Council of 7 March 2002 on a regulatory framework for radio spectrum policy in the European Community (Radio Spectrum Decision) ([5]), the Radio Spectrum Policy Group established under the Commission Decision 2002/622/EC of 26 July 2002 establishing a Radio Spectrum Policy

([1]) OJ L 108, 24.4.2002, p. 33.
([2]) OJ L 108, 24.4.2002, p. 7.
([3]) OJ L 108, 24.4.2002, p. 21.
([4]) OJ L 108, 24.4.2002, p. 51.
([5]) OJ L 108, 24.4.2002, p. 1.

Group [1] and the Television Without frontiers Contact Committee, created pursuant to Directive 97/36/EC of the European Parliament and of the Council [2] on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities,

HAS DECIDED AS FOLLOWS:

Article 1

Subject matter

An advisory group of the independent national regulatory authorities on electronic communications networks and services, called the European Regulators Group for Electronic Communications Networks and Services (hereinafter referred to as the Group), is hereby established.

Article 2

Definition

For the purpose of this Decision: 'relevant national regulatory authority' means the public authority established in each Member State to oversee the day-to-day interpretation and application of the provisions of the Directives relating to electronic communications network and services as defined in 'Framework' Directive.

Article 3

Aims

The role of the Group shall be to advise and assist the Commission in consolidating the internal market for electronic communications networks and services.

The Group shall provide an interface between national regulatory authorities and the Commission in such a way as to contribute to the development of the internal market and to the consistent application in all Member States of the regulatory framework for electronic communications networks and services.

Article 4

Membership

The Group shall be composed of the heads of each relevant national regulatory authority in each Member State or their representatives.

The Commission shall be represented at an appropriate level and shall provide the secretariat to the Group.

Article 5

Operational arrangements

At its own initiative or at the Commission's request the Group shall advise and assist the Commission on any matter related to electronic communications networks and services.

The Group shall elect a chairperson from among its members. The work of the group may be organised into subgroups and expert working groups as appropriate.

The chairperson shall convene the meetings of the Group in agreement with the Commission.

The Group shall adopt its rules of procedure by consensus or, in the absence of consensus, by a two-thirds majority vote, one vote being expressed per Member State, subject to the approval of the Commission.

The Commission shall be represented at all meetings of the Group and be able to attend all meetings of its subgroups and expert working groups.

Experts from EEA States and those states that are candidates for accession to the European Union may participate as observers in the Group. The Group may invite other experts and observers to attend its meetings

Article 6

Consultation

The Group shall consult extensively and at an early stage with market participants, consumers and end-users in an open and transparent manner.

Article 7

Confidentiality

Without prejudice to the provisions of Article 287 of the Treaty, where the Commission informs them that the advice requested or the question raised is of a confidential nature, members of the Group as well as observers and any other person shall be under an obligation not to disclose information which has come to their knowledge through the work of the Group, its subgroups or expert groups. The Commission may decide in such cases that only members of the Group may be present at meetings.

Article 8

Annual report

The Group shall submit an annual report of its activities to the Commission. The Commission shall transmit the report to the European Parliament and to the Council, where appropriate with comments.

Article 9

Entry into force

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

[1] OJ L 198, 27.7.2002, p. 49.
[2] OJ L 202, 30.7.1997, p. 60.

The Group shall take up its duties on the date of entry into force of this Decision.

Done at Brussels, 29 July 2002.

For the Commission
Erkki LIIKANEN
Member of the Commission