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

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EN

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I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 1850/2002

of 17 October 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 18 October 2002.

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

Done at Brussels, 17 October 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 17 October 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	052	85,3
	096	29,0
	204	87,4
	999	67,2
0707 00 05	052	96,3
	999	96,3
0709 90 70	052	82,0
	999	82,0
0805 50 10	052	58,2
	388	75,3
	524	54,4
	528	51,6
	999	59,9
0806 10 10	052	106,1
	064	135,5
	400	203,3
	999	148,3
0808 10 20, 0808 10 50, 0808 10 90	388	88,3
	400	84,0
	404	91,9
	512	93,8
	800	179,7
	804	95,4
	999	105,5
0808 20 50	052	90,5
	999	90,5

(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 1851/2002

of 17 October 2002

amending Regulation (EC) No 1080/2002 opening a standing invitation to tender for exportation to certain third countries of rye held by the German intervention agency

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1766/92 on the common organisation of the market in cereals [1], as last amended by Regulation (EC) No 1666/2000 [2], and in particular Article 5 thereof,

Whereas:

(1) Commission Regulation (EC) No 1080/2002 [3] opened an invitation to tender for exportation of rye held by the German intervention agency to any country outside the Union except those of zone VII as listed in the Annex to Regulation (EEC) No 2145/92 [4], as amended by Regulation (EC) No 3304/94 [5], and except Estonia, Lithuania, Latvia, Poland, the Czech Republic, the Slovak Republic, Hungary, Norway, the Faeroe Islands, Iceland, Russia, Belarus, Bosnia and Herzegovina, Croatia, Slovenia, the territories of the former Yugoslavia other than Slovenia, Croatia and Bosnia and Herzegovina, Albania, Romania, Bulgaria, Armenia, Georgia, Azerbaijan, Moldova, the Ukraine, Kazakhstan, Kyrgyzstan, Uzbekistan, Tajikistan and Turkmenistan. Given the situation in the various markets outside the Union Switzerland and Liechtenstein should also be excluded from this list.

(2) Regulation (EC) No 1080/2002 should therefore be amended as regards the export destinations.

(3) The measures of this Regulation accord with the opinion of the Management Committee for Cereals,

HAS ADOPTED THIS REGULATION:

Article 1

Article 2(1) of Regulation (EC) No 1080/2002 is replaced by:

'1. The invitation covers a maximum of 1 000 000 tonnes of rye for exportation to any country outside the Union except those of zone VII as specified in the Annex to Regulation (EEC) No 2145/92 and except Switzerland, Liechtenstein, Estonia, Lithuania, Latvia, Poland, the Czech Republic, the Slovak Republic, Hungary, Norway, the Faeroe Islands, Iceland, Russia, Belarus, Bosnia and Herzegovina, Croatia, Slovenia, the territories of the former Yugoslavia other than Slovenia, Croatia and Bosnia and Herzegovina, Albania, Romania, Bulgaria, Armenia, Georgia, Azerbaijan, Moldova, the Ukraine, Kazakhstan, Kyrgyzstan, Uzbekistan, Tajikistan and Turkmenistan.'

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, 17 October 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 164, 22.6.2002, p. 11.
[4] OJ L 214, 30.7.1992, p. 20.
[5] OJ L 341, 30.12.1994, p. 48.

COMMISSION REGULATION (EC) No 1852/2002

of 17 October 2002

on the rate of interest to be used for calculating the costs of financing intervention measures comprising buying-in, storage and disposal

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1883/78 of 2 August 1978 laying down general rules for the financing of interventions by the European Agricultural Guidance and Guarantee Fund (EAGGF), Guarantee Section ([1]), as last amended by Regulation (EC) No 1259/96 ([2]), and in particular Article 5 thereof,

Whereas:

(1) Article 3 of Commission Regulation (EEC) No 411/88 of 12 February 1988 on the method and the rate of interest to be used for calculating the costs of financing intervention measures comprising buying-in, storage and disposal ([3]), as last amended by Regulation (EC) No 2623/1999 ([4]), lays down that the uniform interest rate used for calculating the costs of financing intervention measures is to correspond to the three months' and twelve months' forward Euribor rates with a weighting of one third and two thirds respectively.

(2) The Commission fixes this rate before the beginning of each EAGGF Guarantee Section accounting year on the basis of the rates recorded in the six months preceding fixing.

(3) Article 4(1) of Regulation (EEC) No 411/88 lays down that if the rate of interest costs borne by a Member State is lower for at least six months than the uniform interest rate fixed for the Community, a specific interest rate is to be fixed for that Member State; the Member State notify these costs to the Commission before the end of the accounting year; where no costs are notified by a Member State, the rate to be applied is determined on the basis of the reference interest rates set out in the Annex to the said Regulation.

(4) The interest rates for the accounting year 2003 must be set, in line with those provisions.

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

HAS ADOPTED THIS REGULATION:

Article 1

For expenditure incurred during the EAGGF Guarantee Section accounting year 2003:

1. the interest rate referred to in Article 3 of Regulation (EEC) No 411/88 shall be 3,6 %;

2. the specific interest rate referred to in Article 4 of Regulation (EEC) No 411/88 shall be:
   — 3,5 % for Greece and France,
   — 3,4 % for Austria,
   — 3,3 % for Ireland.

Article 2

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

It shall apply from 1 October 2002.

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

Done at Brussels, 17 October 2002.

For the Commission
Franz FISCHLER
Member of the Commission

([1]) OJ L 216, 5.8.1978, p. 1.
([2]) OJ L 163, 2.7.1996, p. 10.
([3]) OJ L 40, 13.2.1988, p. 25.
([4]) OJ L 318, 11.12.1999, p. 14.

COMMISSION REGULATION (EC) No 1853/2002

of 17 October 2002

amending Regulation (EC) No 2305/95 establishing detailed rules for application in the pigmeat sector of the arrangements provided for in the free trade agreements between the Community, of the one part, and Estonia, Latvia and Lithuania, of the other part, and amending Regulation (EC) No 1117/2002 establishing the quantity of certain pigmeat products available for the fourth quarter of 2002 under the arrangements provided for by the free trade agreements between the Community, of the one part, and Latvia, Lithuania and Estonia, of the other part

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1151/2002 of 27 June 2002 establishing certain concessions in the form of Community tariff quotas for certain agricultural products and providing for an adjustment, as an autonomous and transitional measure, of certain agricultural concessions provided for in the Europe Agreement with Estonia [1], and in particular Article 1(3) thereof,

Whereas:

(1) Commission Regulation (EC) No 2305/95 [2], as last amended by Regulation (EC) No 1539/2002 [3], lays down rules for the application in the pigmeat sector of the arrangements provided for in these Agreements. The latter amendment omitted in error a new group of products as provided for in Annex C(b) to Regulation (EC) No 1151/2002. Annex I, Part C to Regulation (EC) No 2305/95 should therefore be amended.

(2) Commission Regulation (EC) No 1117/2002 [4] determines the quantities, pursuant to Regulation (EC) No 2305/95, available for the period 1 October to 31 December 2002. It should be amended in line with the new group of products and related quantities as set out in Annex II to this Regulation.

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

HAS ADOPTED THIS REGULATION:

Article 1

Annex I.C to Regulation (EC) No 2305/95 is replaced by Annex I to this Regulation.

Article 2

The Annex to Regulation (EC) No 1117/2002 is replaced by Annex II to this Regulation.

Article 3

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

Article 1 shall apply from 1 July 2002.

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

Done at Brussels, 17 October 2002.

For the Commission
Franz FISCHLER
Member of the Commission

[1] OJ L 170, 29.6.2002, p. 15.
[2] OJ L 233, 30.9.1995, p. 45.
[3] OJ L 233, 30.8.2002, p. 3.
[4] OJ L 168, 27.6.2002, p. 38.

ANNEX I

'C. **PRODUCTS ORIGINATING IN ESTONIA**

Reduction of 100 % in Common Customs Tariff duty

(tonnes)

Group No	Order number	CN code	1.7.2002 to 30.6.2003	Annual increase as from 1.7.2003
21	09.4583	ex 0203 (1) (2) Meat of swine, fresh, chilled or frozen	2 000	375
22	09.4584	ex 1601 00 Sausages and similar products, of meat, meat offal or blood, excluding CN code 1601 00 10 ex 1602 41 Other prepared or preserved meat, meat offal or blood: of swine: hams and cuts thereof, excluding CN code 1602 41 90 ex 1602 42 Other prepared or preserved meat, meat offal or blood: of swine: shoulders and cuts thereof, excluding CN code 1602 42 90 ex 1602 49 Other prepared or preserved meat, meat offal or blood: of swine: other, including mixtures, excluding CN code 1602 49 90	960	180
E1	09.4853	0210 19 Meat of swine, dried or smoked, other	100	30

(1) Excluding tenderloin presented alone.
(2) Excluding CN codes 0203 11 90, 0203 12 90, 0203 19 90, 0203 21 90, 0203 22 90, 0203 29 90.'

ANNEX II

'*ANNEX*

(tonnes)

Group	Total quantity available for the period 1 October to 31 December 2002
18	900,0
L1	180,0
19	750,0
20	90,0
21	1 000,0
22	480,0
E1	50,0'

COMMISSION REGULATION (EC) No 1854/2002

of 17 October 2002

amending Regulation (EC) No 2879/2000 laying down detailed rules for applying Council Regulation (EC) No 2702/1999 on measures to provide information on, and to promote, agricultural products in third countries

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2702/1999 of 14 December 1999 on measures to provide information on, and to promote, agricultural products in third countries [1], and in particular Article 11 thereof,

Whereas:

(1) Commission Regulation (EC) No 2879/2000 [2], as last amended by Regulation (EC) No 1955/2001 [3], lays down the detailed rules for applying the above Regulation.

(2) Article 9(3) of Regulation (EC) No 2879/2000 sets the deadline of 30 September for the Commission decision on the programmes and the implementing bodies to be selected.

(3) The proposals for programmes presented by the Member States in 2002 require additional information, which will reach the Commission shortly.

(4) In these circumstances, in order that the examination and selection of the programmes can be completed, the deadline for the Commission decision should be prolonged until 15 November 2002.

(5) The measures provided for in this Regulation are in accordance with the opinion issued at the joint meeting of Management Committees on the promotion of agricultural products,

HAS ADOPTED THIS REGULATION:

Article 1

The last subparagraph of Article 9(3) of Regulation (EC) No 2879/2000 is replaced by the following:

'For programmes presented in 2002, the Commission shall take a decision by 15 November 2002 at the latest.'

Article 2

This Regulation shall enter into force on the day 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, 17 October 2002.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ L 327, 21.12.1999, p. 7.
[2] OJ L 333, 29.12.2000, p. 63.
[3] OJ L 266, 6.10.2001, p. 8.

COMMISSION REGULATION (EC) No 1855/2002

of 17 October 2002

laying down to what extent applications for issue of export licences submitted during October 2002 for beef products which may benefit from special import treatment in a third country may be accepted

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Commission Regulation (EC) No 1445/95 of 26 June 1995 on rules of application for import and export licences in the beef sector and repealing Regulation (EEC) No 2377/80 [1], as last amended by Regulation (EC) No 2492/2001 [2], and in particular Article 12(8) thereof,

Whereas:

(1) Regulation (EC) No 1445/95 lays down, in Article 12, detailed rules for export licence applications for the products referred to in Article 1 of Commission Regulation (EEC) No 2973/79 [3], as last amended by Regulation (EEC) No 3434/87 [4].

(2) Regulation (EEC) No 2973/79 fixed the quantities of meat which might be exported on special terms for the fourth quarter of 2002. No applications were submitted for export licences for beef,

HAS ADOPTED THIS REGULATION:

Article 1

No applications for export licences were lodged for the beef referred to in Regulation (EEC) No 2973/79 for the fourth quarter of 2002.

Article 2

Applications for licences in respect of the meat referred to in Article 1 may be lodged in accordance with Article 12 of Regulation (EC) No 1445/95 during the first 10 days of the first quarter of 2003 the total quantity available being 1 250 t.

Article 3

This Regulation shall enter into force on 18 October 2002.

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

Done at Brussels, 17 October 2002.

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

[1] OJ L 143, 27.6.1995, p. 35.
[2] OJ L 337, 20.12.2001, p. 18.
[3] OJ L 336, 29.12.1979, p. 44.
[4] OJ L 327, 18.11.1987, p. 7.

COMMISSION REGULATION (EC) No 1856/2002

of 17 October 2002

fixing representative prices in the poultrymeat and egg sectors and for egg albumin, and amending Regulation (EC) No 1484/95

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2771/75 of 29 October 1975 on the common organisation of the market in eggs [1], as last amended by Commission Regulation (EC) No 493/2002 [2], and in particular Article 5(4) thereof,

Having regard to Council Regulation (EEC) No 2777/75 of 29 October 1975 on the common organisation of the market in poultrymeat [3], as last amended by Regulation (EC) No 493/2002, and in particular Article 5(4) thereof,

Having regard to Council Regulation (EEC) No 2783/75 of 29 October 1975 on the common system of trade for ovalbumin and lactalbumin [4], as last amended by Commission Regulation (EC) No 2916/95 [5], and in particular Article 3(4) thereof,

Whereas:

(1) Commission Regulation (EC) No 1484/95 [6], as last amended by Regulation (EC) No 1659/2002 [7], fixes detailed rules for implementing the system of additional import duties and fixes representative prices in the poultrymeat and egg sectors and for egg albumin.

(2) It results from regular monitoring of the information providing the basis for the verification of the import prices in the poultrymeat and egg sectors and for egg albumin that the representative prices for imports of certain products should be amended taking into account variations of prices according to origin. Therefore, representative prices should be published.

(3) It is necessary to apply this amendment as soon as possible, given the situation on the market.

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

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 1484/95 is hereby replaced by the Annex hereto.

Article 2

This Regulation shall enter into force on 18 October 2002.

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

Done at Brussels, 17 October 2002.

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

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[1] OJ L 282, 1.11.1975, p. 49.
[2] OJ L 77, 20.3.2002, p. 7.
[3] OJ L 282, 1.11.1975, p. 77.
[4] OJ L 282, 1.11.1975, p. 104.
[5] OJ L 305, 19.12.1995, p. 49.
[6] OJ L 145, 29.6.1995, p. 47.
[7] OJ L 251, 19.9.2002, p. 4.

ANNEX

to the Commission Regulation of 17 October 2002 fixing representative prices in the poultrymeat and egg sectors and for egg albumin, and amending Regulation (EC) No 1484/95

'ANNEX I

CN code	Description	Representative price (EUR/100 kg)	Security referred to in Article 3(3) (EUR/100 kg)	Origin (1)
0207 12 90	Chickens, plucked and drawn, without heads and feet and without necks, hearts, livers and gizzards, known as "65 % chickens", or otherwise presented, frozen	88,0	9	01
0207 14 10	Boneless cuts of fowl of the species *Gallus domesticus*, frozen	186,5 187,7 188,1 286,5	37 36 36 4	01 02 03 04
0207 14 60	Chicken legs and cuts thereof, frozen	94,6	15	01
0207 27 10	Boneless cuts of turkey, frozen	225,5	21	01
1602 32 11	Preparations of uncooked fowl of the species *Gallus domesticus*	205,0 208,7	25 23	01 02

(1) Origin of imports:
01 Brazil
02 Thailand
03 Argentina
04 Chile.'

COMMISSION REGULATION (EC) No 1857/2002
of 17 October 2002
fixing the export refunds on eggs

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2771/75 of 29 October 1975 on the common organization of the market in eggs [1], as last amended by Commission Regulation (EC) No 493/2002 [2], and in particular Article 8(3) thereof,

Whereas:

(1) Article 8 of Regulation (EEC) No 2771/75 provides that the difference between prices on the world market for the products listed in Article 1(1) of that Regulation and prices for those products within the Community may be covered by an export refund.

(2) The present market situation in certain third countries and that regarding competition on particular third country markets make it necessary to fix a refund differentiated by destination for certain products in the egg sector.

(3) It follows from applying these rules and criteria to the present situation on the market in eggs that the refund should be fixed at an amount which would permit Community participation in world trade and would also take account of the nature of these exports and their importance at the present time.

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

HAS ADOPTED THIS REGULATION:

Article 1

The list of codes of products for which, when they are exported, the export refund referred to in Article 8 of Regulation (EEC) No 2771/75 is granted, and the amount of that refund shall be as shown in the Annex hereto.

Article 2

This Regulation shall enter into force on 18 October 2002.

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

Done at Brussels, 17 October 2002.

For the Commission
Franz FISCHLER
Member of the Commission

[1] OJ L 282, 1.11.1975, p. 49.
[2] OJ L 77, 20.3.2002, p. 7.

ANNEX

to the Commission Regulation of 17 October 2002 fixing the export refunds on eggs

Product code	Destination	Unit of measurement	Amount of refund
0407 00 11 9000	E07	EUR/100 pcs	1,70
0407 00 19 9000	E07	EUR/100 pcs	0,80
0407 00 30 9000	E09	EUR/100 kg	10,00
	E10	EUR/100 kg	35,00
	E11	EUR/100 kg	5,00
0408 11 80 9100	E04	EUR/100 kg	20,00
0408 19 81 9100	E04	EUR/100 kg	10,00
0408 19 89 9100	E04	EUR/100 kg	10,00
0408 91 80 9100	E06	EUR/100 kg	60,00
0408 99 80 9100	E04	EUR/100 kg	15,00

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

The numeric destination codes are set out in Commission Regulation (EC) No 2020/2001 (OJ L 273, 16.10.2001, p. 6).

The other destinations are defined as follows:

E04 all destinations except Switzerland and Estonia

E06 all destinations except Switzerland, Estonia and Lithuania

E07 all destinations except the United States of America, Estonia and Lithuania

E09 Kuwait, Bahrain, Oman, Qatar, the United Arab Emirates, Yemen, Hong Kong SAR, Russia and Turkey

E10 South Korea, Japan, Malaysia, Thailand, Taiwan and the Philippines

E11 all destinations except Switzerland, Estonia, Lithuania and those of E09 and E10.

COMMISSION REGULATION (EC) No 1858/2002
of 17 October 2002
fixing the export refunds on poultrymeat

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2777/75 of 29 October 1975 on the common organization of the market in poultrymeat [1], as last amended by Commission Regulation (EC) No 493/2002 [2], and in particular Article 8(3) thereof,

Whereas:

(1) Article 8 of Regulation (EEC) No 2777/75 provides that the difference between prices on the world market for the products listed in Article 1(1) of that Regulation and prices for those products within the Community may be covered by an export refund.

(2) It follows from applying these rules and criteria to the present situation on the market in poultrymeat that the refund should be fixed at an amount which would permit Community participation in world trade and would also take account of the nature of these exports and their importance at the present time.

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

HAS ADOPTED THIS REGULATION:

Article 1

The list of product codes for which, when they are exported, the export refund referred to in Article 8 of Regulation (EEC) No 2777/75 is granted, and the amount of that refund shall be as shown in the Annex hereto.

Article 2

This Regulation shall enter into force on 18 October 2002.

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

Done at Brussels, 17 October 2002.

For the Commission
Franz FISCHLER
Member of the Commission

[1] OJ L 282, 1.11.1975, p. 77.
[2] OJ L 77, 20.3.2002, p. 7.

ANNEX

to the Commission Regulation of 17 October 2002 fixing the export refunds on poultrymeat

Product code	Destination	Unit of measurement	Amount of refund
0105 11 11 9000	V04	EUR/100 pcs	0,80
0105 11 19 9000	V04	EUR/100 pcs	0,80
0105 11 91 9000	V04	EUR/100 pcs	0,80
0105 11 99 9000	V04	EUR/100 pcs	0,80
0105 12 00 9000	V04	EUR/100 pcs	1,70
0105 19 20 9000	V04	EUR/100 pcs	1,70
0207 12 10 9900	V01	EUR/100 kg	44,00
0207 12 10 9900	A24	EUR/100 kg	44,00
0207 12 90 9190	V01	EUR/100 kg	44,00
0207 12 90 9190	A24	EUR/100 kg	44,00
0207 12 90 9990	V01	EUR/100 kg	44,00
0207 12 90 9990	A24	EUR/100 kg	44,00
0207 14 20 9900	V03	EUR/100 kg	5,00
0207 14 60 9900	V03	EUR/100 kg	5,00
0207 14 70 9190	V03	EUR/100 kg	5,00
0207 14 70 9290	V03	EUR/100 kg	5,00

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

The numeric destination codes are set out in Commission Regulation (EC) No 2020/2001 (OJ L 273, 16.10.2001, p. 6).

The other destinations are defined as follows:

V01 Angola, Saudi Arabia, Kuwait, Bahrain, Qatar, Oman, the United Arab Emirates, Jordan, Yemen, Lebanon, Iraq, Iran

V03 All destinations except the United States of America and zones A24 and A26.

V04 All destinations except the United States of America and Estonia.

COMMISSION REGULATION (EC) No 1859/2002
of 17 October 2002
fixing the representative prices and the additional import duties for molasses in the sugar sector

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

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

Whereas:

(1) Regulation (EC) No 1422/95 stipulates that the cif import price for molasses, hereinafter referred to as the 'representative price', should be set in accordance with Commission Regulation (EEC) No 785/68 [4]. That price should be fixed for the standard quality defined in Article 1 of the above Regulation.

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

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

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

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

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

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

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

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

This Regulation shall enter into force on 18 October 2002.

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

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

Done at Brussels, 17 October 2002.

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

ANNEX

to the Commission Regulation of 17 October 2002 fixing the representative prices and additional import duties to imports of molasses in the sugar sector

(in EUR)

CN code	Amount of the representative price in 100 kg net of the product in question	Amount of the additional duty in 100 kg net of the product in question	Amount of the duty to be applied to imports in 100 kg net of the product in question because of suspension as referred to in Article 5 of Regulation (EC) No 1422/95 (2)
1703 10 00 (1)	8,35	—	0
1703 90 00 (1)	11,71	—	0

(1) For the standard quality as defined in Article 1 of amended Regulation (EEC) No 785/68.

(2) This amount replaces, in accordance with Article 5 of Regulation (EC) No 1422/95, the rate of the Common Customs Tariff duty fixed for these products.

COMMISSION REGULATION (EC) No 1860/2002
of 17 October 2002
fixing the export refunds on white sugar and raw sugar exported in its unaltered state

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

Whereas:

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

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

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

(4) The world market situation or the specific requirements of certain markets may make it necessary to vary the refund for sugar according to destination.

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

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

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

(8) Regulation (EC) No 1260/2001 does not make provision to continue the compensation system for storage costs from 1 July 2001. This should accordingly be taken into account when fixing the refunds granted when the export occurs after 30 September 2001.

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

This Regulation shall enter into force on 18 October 2002.

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

Done at Brussels, 17 October 2002.

For the Commission
Franz FISCHLER
Member of the Commission

[1] OJ L 178, 30.6.2001, p. 1.
[2] OJ L 104, 20.4.2002, p. 26.
[3] OJ L 214, 8.9.1995, p. 16.

ANNEX

to the Commission Regulation of 17 October 2002 fixing the export refunds on white sugar and raw sugar exported in its unaltered state

Product code	Destination	Unit of measurement	Amount of refund
1701 11 90 9100	A00	EUR/100 kg	42,17 (1)
1701 11 90 9910	A00	EUR/100 kg	41,14 (1)
1701 11 90 9950	A00	EUR/100 kg	(2)
1701 12 90 9100	A00	EUR/100 kg	42,17 (1)
1701 12 90 9910	A00	EUR/100 kg	41,14 (1)
1701 12 90 9950	A00	EUR/100 kg	(2)
1701 91 00 9000	A00	EUR/1 % of sucrose × net 100 kg of product	0,4584
1701 99 10 9100	A00	EUR/100 kg	45,84
1701 99 10 9910	A00	EUR/100 kg	44,72
1701 99 10 9950	A00	EUR/100 kg	44,72
1701 99 90 9100	A00	EUR/1 % of sucrose × net 100 kg of product	0,4584

(1) Applicable to raw sugar with a yield of 92 %; if the yield is other than 92 %, the refund applicable is calculated in accordance with the provisions of Article 28(4) of Council Regulation (EC) No 1260/2001.

(2) Fixing suspended by Commission Regulation (EEC) No 2689/85 (OJ L 255, 26.9.1985, p. 12), as amended by Regulation (EEC) No 3251/85 (OJ L 309, 21.11.1985, p. 14).

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

The numeric destination codes are set out in Commission Regulation (EC) No 2020/2001 (OJ L 273, 16.10.2001, p. 6).

COMMISSION REGULATION (EC) No 1861/2002

of 17 October 2002

fixing the maximum export refund for white sugar for the 11th partial invitation to tender issued within the framework of the standing invitation to tender provided for in Regulation (EC) No 1331/2002

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

Whereas:

(1) Commission Regulation (EC) No 1331/2002 of 23 July 2002 on a standing invitation to tender to determine levies and/or refunds on exports of white sugar [3], for the 2002/2003 marketing year, requires partial invitations to tender to be issued for the export of this sugar.

(2) Pursuant to Article 9(1) of Regulation (EC) No 1331/2002 a maximum export refund shall be fixed, as the case may be, account being taken in particular of the state and foreseeable development of the Community and world markets in sugar, for the partial invitation to tender in question.

(3) Following an examination of the tenders submitted in response to the 11th partial invitation to tender, the provisions set out in Article 1 should be adopted.

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

HAS ADOPTED THIS REGULATION:

Article 1

For the 11th partial invitation to tender for white sugar issued pursuant to Regulation (EC) No 1331/2002 the maximum amount of the export refund is fixed at 47,815 EUR/100 kg.

Article 2

This Regulation shall enter into force on 18 October 2002.

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

Done at Brussels, 17 October 2002.

For the Commission
Franz FISCHLER
Member of the Commission

[1] OJ L 178, 30.6.2001, p. 1.
[2] OJ L 104, 20.4.2002, p. 26.
[3] OJ L 195, 24.7.2002, p. 6.

COMMISSION REGULATION (EC) No 1862/2002

of 17 October 2002

concerning tenders notified in response to the invitation to tender for the export of barley issued in Regulation (EC) No 901/2002

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1766/92 of 30 June 1992 on the common organisation of the market in cereals ([1]), as last amended by Regulation (EC) No 1666/2000 ([2]),

Having regard to Commission Regulation (EC) No 1501/95 of 29 June 1995 laying down certain detailed rules for the application of Council Regulation (EEC) No 1766/92 on the granting of export refunds on cereals and the measures to be taken in the event of disturbance on the market for cereals ([3]), as last amended by Regulation (EC) No 1163/2002 ([4]), as amended by Regulation (EC) No 1324/2002 ([5]), and in particular Article 4 thereof,

Whereas:

(1) An invitation to tender for the refund for the export of barley to all third countries except the United States of America, Canada, Estonia and Latvia was opened pursuant to Commission Regulation (EC) No 901/2002 ([6]), as amended by Regulation (EC) No 1230/2002 ([7]).

(2) Article 7 of Regulation (EC) No 1501/95, allows the Commission to decide, in accordance with the procedure laid down in Article 23 of Regulation (EEC) No 1766/92 and on the basis of the tenders notified, to make no award.

(3) On the basis of the criteria laid down in Article 1 of Regulation (EC) No 1501/95 a maximum refund should not be fixed.

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

HAS ADOPTED THIS REGULATION:

Article 1

No action shall be taken on the tenders notified from 11 to 17 October 2002 in response to the invitation to tender for the refund for the export of barley issued in Regulation (EC) No 901/2002.

Article 2

This Regulation shall enter into force on 18 October 2002.

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

Done at Brussels, 17 October 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 147, 30.6.1995, p. 7.
([4]) OJ L 170, 29.6.2002, p. 46.
([5]) OJ L 194, 23.7.2002, p. 26.
([6]) OJ L 127, 9.5.2002, p. 11.
([7]) OJ L 180, 10.7.2002, p. 3.

COMMISSION REGULATION (EC) No 1863/2002

of 17 October 2002

concerning tenders notified in response to the invitation to tender for the export of rye issued in Regulation (EC) No 900/2002

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1766/92 of 30 June 1992 on the common organisation of the market in cereals ([1]), as last amended by Regulation (EC) No 1666/2000 ([2]),

Having regard to Commission Regulation (EC) No 1501/95 of 29 June 1995 laying down certain detailed rules for the application of Council Regulation (EEC) No 1766/92 on the granting of export refunds on cereals and the measures to be taken in the event of disturbance on the market for cereals ([3]), as last amended by Regulation (EC) No 1163/2002 ([4]), as amended by Regulation (EC) No 1324/2002 ([5]), and in particular Article 7 thereof,

Whereas:

(1) An invitation to tender for the refund for the export of rye to all third countries excluding Hungary, Estonia, Lithuania and Latvia was opened pursuant to Commission Regulation (EC) No 900/2002 ([6]), as amended by Regulation (EC) No 1632/2002 ([7]).

(2) Article 7 of Regulation (EC) No 1501/95 allows the Commission to decide, in accordance with the procedure laid down in Article 23 of Regulation (EEC) No 1766/92 and on the basis of the tenders notified, to make no award.

(3) On the basis of the criteria laid down in Article 1 of Regulation (EC) No 1501/95 a maximum refund should not be fixed.

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

HAS ADOPTED THIS REGULATION:

Article 1

No action shall be taken on the tenders notified from 11 to 17 October 2002 in response to the invitation to tender for the refund for the export of rye issued in Regulation (EC) No 900/2002.

Article 2

This Regulation shall enter into force on 18 October 2002.

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

Done at Brussels, 17 October 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 147, 30.6.1995, p. 7.
([4]) OJ L 170, 29.6.2002, p. 46.
([5]) OJ L 194, 23.7.2002, p. 26.
([6]) OJ L 142, 31.5.2002, p. 14.
([7]) OJ L 247, 14.9.2002, p. 3.

COMMISSION REGULATION (EC) No 1864/2002

of 17 October 2002

concerning tenders notified in response to the invitation to tender for the export of common wheat issued in Regulation (EC) No 899/2002

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1766/92 of 30 June 1992 on the common organisation of the market in cereals ([1]), as last amended by Regulation (EC) No 1666/2000 ([2]),

Having regard to Commission Regulation (EC) No 1501/95 of 29 June 1995 laying down certain detailed rules for the application of Council Regulation (EEC) No 1766/92 on the granting of export refunds on cereals and the measures to be taken in the event of disturbance on the market for cereals ([3]), as last amended by Regulation (EC) No 1163/2002 ([4]), as amended by Regulation (EC) No 1324/2002 ([5]), and in particular Article 4 thereof,

Whereas:

(1) An invitation to tender for the refund for the export of common wheat to all third countries, with the exclusion of Poland, Estonia, Lithuania and Latvia was opened pursuant to Commission Regulation (EC) No 899/2002 ([6]), as amended by Regulation (EC) No 1520/2002 ([7]).

(2) Article 7 of Regulation (EC) No 1501/95 allows the Commission to decide, in accordance with the procedure laid down in Article 23 of Regulation (EEC) No 1766/92 and on the basis of the tenders notified, to make no award.

(3) On the basis of the criteria laid down in Article 1 of Regulation (EC) No 1501/95 a maximum refund should not be fixed.

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

HAS ADOPTED THIS REGULATION:

Article 1

No action shall be taken on the tenders notified from 11 to 17 October 2002 in response to the invitation to tender for the refund for the export of common wheat issued in Regulation (EC) No 899/2002.

Article 2

This Regulation shall enter into force on 18 October 2002.

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

Done at Brussels, 17 October 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 147, 30.6.1995, p. 7.
([4]) OJ L 170, 29.6.2002, p. 46.
([5]) OJ L 194, 23.7.2002, p. 26.
([6]) OJ L 133, 16.5.2001, p. 3.
([7]) OJ L 228, 24.8.2002, p. 18.

COMMISSION REGULATION (EC) No 1865/2002

of 17 October 2002

fixing the rates of the refunds applicable to eggs and egg yolks exported in the form of goods not covered by Annex I to the Treaty

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2771/75 of 29 October 1975 on the common organisation of the market in eggs [1], as last amended by Commission Regulation (EC) No 493/2002 [2], and in particular Article 8(3) thereof,

Whereas:

(1) Article 8(1) of Regulation (EEC) No 2771/75 provides that the difference between prices in international trade for the products listed in Article 1(1) of that Regulation and prices within the Community may be covered by an export refund where these goods are exported in the form of goods listed in the Annex to that Regulation. Whereas Commission Regulation (EC) No 1520/2000 of 13 July 2000 laying down common detailed rules for the application of the system of granting export refunds on certain agricultural products exported in the form of goods not covered by Annex I to the Treaty, and the criteria for fixing the amount of such refunds [3], as last amended by Regulation (EC) No 1052/2002 [4], specifies the products for which a rate of refund should be fixed, to be applied where these products are exported in the form of goods listed in the Annex to Regulation (EEC) No 2771/75.

(2) In accordance Article 4(1) of Regulation (EC) No 1520/2000, the rate of the refund per 100 kilograms for each of the basic products in question must be fixed for a period of the same duration as that for which refunds are fixed for the same products exported unprocessed.

(3) Article 11 of the Agreement on Agriculture concluded under the Uruguay Round lays down that the export refund for a product contained in a good may not exceed the refund applicable to that product when exported without further processing.

(4) It is necessary to ensure continuity of strict management taking account of expenditure forecasts and funds available in the budget.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Poultrymeat and Eggs,

HAS ADOPTED THIS REGULATION:

Article 1

The rates of the refunds applicable to the basic products appearing in Annex A to Regulation (EC) No 1520/2000 and listed in Article 1(1) of Regulation (EEC) No 2771/75, exported in the form of goods listed in the Annex I to Regulation (EEC) No 2771/75, are hereby fixed as shown in the Annex hereto.

Article 2

This Regulation shall enter into force on 18 October 2002.

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

Done at Brussels, 17 October 2002.

For the Commission
Erkki LIIKANEN
Member of the Commission

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[1] OJ L 282, 1.11.1975, p. 49.
[2] OJ L 77, 20.3.2002, p. 7.
[3] OJ L 177, 15.7.2000, p. 1.
[4] OJ L 160, 18.6.2002, p. 16.

ANNEX

to the Commission Regulation of 17 October 2002 fixing the rates of the refunds applicable to eggs and egg yolks exported in the form of goods not covered by Annex I to the Treaty

(EUR/100 kg)

CN code	Description	Destination (1)	Rate of refund
0407 00	Birds' eggs, in shell, fresh, preserved or cooked:		
	– Of poultry:		
0407 00 30	– – Other:		
	a) On exportation of ovalbumin of CN codes 3502 11 90 and 3502 19 90	02	10,00
		03	35,00
		04	5,00
	b) On exportation of other goods	01	5,00
0408	Birds' eggs, not in shell and egg yolks, fresh, dried, cooked by steaming or by boiling in water, moulded, frozen or otherwise preserved, whether or not containing added sugar or other sweetening matter:		
	– Egg yolks:		
0408 11	– – Dried:		
ex 0408 11 80	– – – Suitable for human consumption:		
	not sweetened	01	20,00
0408 19	– – Other:		
	– – – Suitable for human consumption:		
ex 0408 19 81	– – – – Liquid:		
	not sweetened	01	10,00
ex 0408 19 89	– – – – Frozen:		
	not sweetened	01	10,00
	– Other:		
0408 91	– – Dried:		
ex 0408 91 80	– – – Suitable for human consumption:		
	not sweetened	01	60,00
0408 99	– – Other:		
ex 0408 99 80	– – – Suitable for human consumption:		
	not sweetened	01	15,00

(1) The destinations are as follows:
01 Third countries,
02 Kuwait, Bahrain, Oman, Qatar, United Arab Emirates, Yemen, Turkey, Hong Kong SAR and Russia,
03 South Korea, Japan, Malaysia, Thailand, Taiwan and the Philippines,
04 All destinations except Switzerland and those of 02 and 03.

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION
of 8 October 2002
appointing a German alternate member of the Committee of the Regions

(2002/809/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 263 thereof,

Having regard to the Council Decision of 22 January 2002 [1] appointing the members and alternate members of the Committee of the Regions,

Whereas the seat of an alternate member of the Committee of the Regions has become vacant following the resignation of Mr Werner BALLHAUSEN, of which the Council was notified on 15 May 2002,

Having regard to the proposal from the German Government,

HAS DECIDED AS FOLLOWS:

Sole Article

Mr Michael SCHNEIDER is hereby appointed an alternate member of the Committee of the Regions in place of Mr Werner BALLHAUSEN for the remainder of his term of office, which expires on 25 January 2006.

Done at Luxembourg, 8 October 2002.

For the Council
The President
T. PEDERSEN

[1] OJ L 24, 26.1.2002, p. 38.

COUNCIL DECISION
of 8 October 2002
appointing two members and two alternate members of the Committee of the Regions

(2002/810/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 263 thereof,

Having regard to the Council Decision of 22 January 2002 [1] appointing the members and alternate members of the Committee of the Regions,

Whereas two seats as full members and two seats as alternate members of the Committee of the Regions have become vacant following the resignations of Mr Jan TINDEMANS, notified to the Council on 10 April 2002, Mr H.J.M. KEMPERMAN, notified to the Council on 22 May 2002, Ms C.W. JACOBS, notified to the Council on 22 August 2002, Mr A.M.C.A. HOOIJMAIJERS, notified to the Council on 19 June 2002,

Having regard to the proposal from the Netherlands Government,

HAS DECIDED AS FOLLOWS:

Sole Article

— Mr H.F.M. EVERS is hereby appointed a full member of the Committee of the Regions in place of Mr Jan TINDEMANS,

— Ms C.W. JACOBS is hereby appointed a full member of the Committee of the Regions in place of Mr H.J.M. KEMPERMAN,

— Mr P. JANSEN is hereby appointed an alternate member of the Committee of the Regions in place of Ms C.W. JACOBS,

— Mr G.D. DALES is hereby appointed an alternate member of the Committee of the Regions in place of Mr A.M.C.A. HOOIJMAIJERS,

for the remainder of their terms of office, which run until 25 January 2006.

Done at Luxembourg, 8 October 2002.

For the Council
The President
T. PEDERSEN

[1] OJ L 24, 26.1.2002, p. 38.

COUNCIL DECISION

of 3 October 2002

establishing guidance notes supplementing Annex VII 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

(2002/811/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/18/EC of the European Parliament and of the Council [1], and in particular the first paragraph of Annex VII thereto,

Having regard to the proposal from the Commission,

Whereas:

(1) Directive 2001/18/EC stipulates that, before a genetically modified organism (hereinafter referred to as GMO) as or in products is placed on the market, a notification must be submitted to the competent authority of the Member State where such a GMO is to be placed on the market for the first time.

(2) According to Directive 2001/18/EC, the notifier must ensure that monitoring and reporting on the deliberate release of GMOs are carried out in accordance with the conditions specified in the authorisation for the placing on the market of a GMO pursuant to Article 13(2), Article 19(3) and Article 20 of that Directive. Therefore, such notification must contain a plan for monitoring, including a proposal for the time-period of the monitoring plan, in accordance with Annex VII to Directive 2001/18/EC.

(3) Annex VII to Directive 2001/18/EC should be supplemented by notes providing detailed guidance on the objectives, general principles and design of the monitoring plan referred to in that Annex.

(4) The committee set up under Article 30(2) of Directive 2001/18/EC was consulted on 12 June 2002 and has not delivered an opinion on the Commission's proposal for a Decision,

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 VII of Directive 2001/18/EC.

Article 2

This Decision is addressed to the Member States.

Done at Luxembourg, 3 October 2002.

For the Council

The President

F. HANSEN

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

ANNEX

INTRODUCTION

Directive 2001/18/EC introduces an obligation for notifiers to implement monitoring plans in order to trace and identify any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment of GMOs as or in products after they have been placed on the market.

Notifiers are required, under Article 13(2)(e) of that Directive, to submit as part of the notification for the placing on the market of a GMO, a plan for monitoring in accordance with Annex VII of that Directive. This should include a proposal for the time-period of the monitoring plan, which may be different from the proposed period for the consent. Annex VII describes in general terms the objective to be achieved and the general principles to be followed to design a monitoring plan referred to in Article 13(2), Article 19(3) and Article 20.

This guidance note supplements the information provided in Annex VII, and in the context of the Directive:

— expands on the objectives for monitoring,

— expands on the general principles for monitoring,

— provides an outline for a general framework for the development of appropriate post-market monitoring plans.

Following the placing on the market of a GMO, the notifier, under Article 20(1) of the Directive, has a legal obligation to ensure that monitoring and reporting are carried out according to the conditions specified in the consent. Article 19(3)(f) details that the written consent should, in all cases, explicitly specify monitoring requirements in accordance with Annex VII, including obligations to report to the Commission and competent authorities. In addition, to ensure transparency in accordance with Article 20(4), the results of the monitoring should also be made publicly available.

Monitoring plans for GMOs to be placed on the market will clearly need to be developed on a case by case basis taking account of the environmental risk assessment, the modified characteristics specific to the GMO in question, their intended use and the receiving environment. This guidance note makes reference to a general framework but does not attempt to provide explicit details for the development of monitoring plans to cover all GMOs.

It might be necessary to complement this framework with more specific, supplementary guidance on monitoring plans or checklists with regard to particular traits, crops or groups of GMOs.

Monitoring can be defined, in general as the systematic measurement of variables and processes over time and assumes that there are specific reasons for collection of such data, for example, to ensure that certain standards or conditions are being met or to examine potential changes with respect to certain baselines. Against this background, it is essential to identify the type of effects or variables to be monitoring and importantly, the tools and systems to measure them and an appropriate time-period for measurements. Monitoring results may, however, be important in the development of further research.

Effective monitoring and general surveillance requires that appropriate methodology has been developed and is available prior to the commencement of monitoring programmes. Monitoring should not be regarded as research per se but as a means to evaluate or verify results and assumptions arising from previous research and evaluation of potential risk and research.

A. **OBJECTIVES**

Before a GMO or a combination of GMOs as or in products is placed on the market, a notification must be submitted to the competent authority of the Member State where the GMO is to be placed on the market for the first time. This notification should, in accordance with Article 13(2), contain a technical dossier of information including a full environmental risk assessment.

The environmental risk assessment aims, 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 arising from its placing on the market. This assessment may also need to take account of potential long-term effects associated with the interaction with other organisms and the environment. The evaluation of such potential adverse effects should be founded on common methodology based on independently verifiable scientific evidence.

Individual GMOs are likely to differ considerably in terms of the inherent characteristics of the modified species as well as the specific modification and resultant characteristics. These characteristics will largely determine the nature of any potential effects arising from the placing on the market of a GMO.

It is also necessary to confirm that the pre-market risk assessment for a GMO is accurate, following its placing on the market. Moreover, the possibility of the occurrence of potential adverse effects that were not foreseen in the evaluation cannot be ignored. Post-market monitoring, as required under Article 20 of the Directive, is foreseen for this purpose.

Against this background, it is foreseen that the objectives of post-market monitoring, as detailed under Annex VII, are to:

— confirm that any assumptions regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment are correct, and

— identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the environmental risk assessment.

B. **GENERAL PRINCIPLES**

Monitoring as detailed in Articles 13, 19 and 20 of Directive 2001/18/EC and in the context of this guidance note refers to post-market monitoring, which takes place after consent for the placing of a GMO on the market has been granted.

Article 13(2)(e) of the Directive requires notifiers to submit, as part of their notifications, a plan for monitoring in accordance with Annex VII.

The consent should, under Article 19(3)(f), specify the time period of the monitoring plan and, where appropriate, any obligations on persons selling the product or any user of it, *inter alia*, in the case of cultivation, concerning a level of information deemed appropriate on their location.

On the basis of reports submitted by notifiers, in accordance with the consent and the framework for the monitoring plan specified, the competent authority receiving the original notification should inform the Commission and the Competent Authorities about the results and may, as detailed in Article 20(1), and, where necessary, in consultation with the other Member states, adapt the monitoring plan after the first monitoring period.

Planning is essential with respect to all types of monitoring and when developing monitoring plans, both case-specific monitoring and general surveillance should be considered. In addition, monitoring of potential adverse cumulative long-term effects should be considered as a compulsory part of the monitoring plan.

Case-specific monitoring should, when included in the monitoring plan, focus on potential effects arising from the placing on the market of a GMO that have been highlighted as a result of the conclusions and assumptions of the environmental risk assessment. However, whilst it is possible to predict that certain effects may occur, on the basis of risk assessment and available scientific information, it is considerably more difficult to plan for potential effects or variables that cannot be foreseen or predicted. It may, however, be possible through appropriate planning of monitoring and surveillance plans to optimise the chances for early detection of such effects. The design of the monitoring plan should, therefore incorporate general surveillance for unanticipated or unforeseen adverse effects.

The cost-effectiveness of case-specific monitoring and general surveillance should be taken into account in this context. Furthermore, the monitoring plan should be in accordance with the latest scientific insights and practices.

Member States may themselves also assist with monitoring via the general duty under Article 4(5), which requires that the competent authority organises inspections and other control measures as appropriate, to ensure compliance with the Directive. Indeed, Member States are entitled, in accordance with the Treaty, to take further measures for monitoring and inspection, for example by national authorities, of GMOs as or in products placed on the market. However, it should be recognised that such action is not a substitute for the monitoring plan for which notifiers are responsible (although, with the consent of the relevant parties, may form part of it).

Interpretation of the data collected via monitoring should take account of existing environmental conditions and activities in order to determine an appropriate baseline. General surveillance and environmental monitoring programmes in general may similarly assist in this context. Where unexpected changes in the environment are observed, further risk assessment may need to be considered to establish whether they have arisen as a consequence of the placing on the market of the GMO or as a result of other factors. Against this background, measures necessary to protect human health and the environment may also have to be considered.

C. **DESIGN OF MONITORING PLAN**

The design of monitoring plans should be founded on a framework comprising three key sections, namely:

1. Monitoring strategy;

2. Monitoring methodology;

3. Analysis, reporting, review.

1. **Monitoring strategy**

The monitoring strategy importantly requires identification of the potential effects that may arise from the placing on the market of a GMO, the degree to which they need to be monitored and an appropriate approach(s) and time-scale(s) over which to monitor.

In the first instance, the likelihood of potential direct, indirect, immediate or delayed adverse effects arising from the GMO should be considered in line with its intended use and the receiving environment.

Direct effects refer to primary effects on human health or the environment that are a result of the GMO itself and which do not occur through a causal chain of events. For example, when considering a crop modified for resistance against a specific insect, direct effects may include death and changes in the population of both target and non-target insects that arise as a result of the toxin produced by the GMO.

Indirect effects refer to effects on human health or the environment occurring through a causal chain of events. For example, in the above case indirect effects may arise where a reduction in the population of target insects impacts on populations of other organisms that normally feed on these insects.

Indirect effects may involve interactions between a number of organisms and the environment making it more difficult to predict any potential effect. Observations of indirect effects are also likely to be delayed. These factors must, however, be considered as part of the strategy.

Immediate effects refer to effects on human health or the environment that are observed during the period of the release of the GMO. Immediate effects may be direct or indirect.

Delayed effects refer 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. The build-up of resistance by insects to the Bt-toxin through continued exposure is an example of a delayed effect.

Immediate and delayed effects may themselves be either direct or indirect but imply a time-scale for change. Direct effects are more likely to appear in the immediate or short term at a level that can be detected. Indirect effects may take a longer time period to manifest but nevertheless may need to be taken into account.

It is very difficult if not impossible to predict the appearance of potential unforeseen or unanticipated effects that were not highlighted in the risk assessment. General surveillance for potential unforeseen or unanticipated effects should, therefore, be considered as a part of the monitoring strategy.

1.1. Risk assessment

The monitoring strategy should identify how evaluations obtained from the risk assessment are to be confirmed in line with the use of that GMO and the receiving environment. This should take account of the conclusions and assumptions from the risk assessment, based on scientific evaluation and the recommendations of expert committees. In addition, issues arising from the risk assessment that are subject to a degree of uncertainty, for example possible effects that may appear only where releases are of a large-scale, may also be required as part of the monitoring strategy. Reference to the guidance notes to supplement Annex II, on the principles for the environmental risk assessment, of Directive 2001/18/EC should assist in this respect.

1.2. Background information

Background information pertaining to the GMO in question, including data and information from experimental releases, scientific publications and relevant comparable evidence from other releases, may all be used in the planning and design of the monitoring plan. In particular, data gained through available risk research studies and monitoring of experimental releases will importantly assist in this context.

1.3. Approach

The approach of the monitoring strategy should be described. In many cases, focus is likely to be placed on primary concerns (needs to know) and the establishment of a cyclic monitoring process in order to be able to continuously improve the quality of the programme.

The approach should provide the means to detect potential adverse effects at an early stage of manifestation. Early detection of any adverse effects attributable to a GMO will allow for more rapid reassessment and implementation of measures to reduce any consequences to the environment.

The design of monitoring plans for GMOs should be built using a step-by-step approach taking account of existing data and monitoring methodology. A step-by-step approach will in many cases also need to take account of the scale of release. The first step may be founded on evidence from experimental trials with subsequent steps based on large-scale field trials and ultimately to surveys on commercial plots. Experience and information gained through the monitoring of experimental releases of GMOs is, therefore, likely to be useful in designing the post marketing monitoring regime required for the placing on the market of GMOs.

Existing observation programmes could also be adapted to the needs of monitoring GMOs as a means to ensure comparability and to limit the expenditure of resources in developing the approach. This would include existing environment observation programmes in the field of agriculture, food surveys, nature conservation, ecological long-term monitoring programmes, soil observation and veterinary surveys. Inclusion of such programmes as part of the monitoring plan would firstly require that notifiers gain an appropriate agreement with the persons or organisations, including national authorities, conducting such work.

This section focuses on case-specific monitoring and general surveillance in accordance with the two general objectives under Annex VII although consideration of other types of monitoring system is not precluded.

1.3.1. *Case-specific monitoring*

Case-specific monitoring serves to confirm that scientifically sound assumptions, in the environmental risk assessment, regarding potential adverse effects arising from a GMO and its use are correct.

The approach should:

— focus on all the potential effects on human health and the environment identified in the risk assessment, taking into account i.e. different locations, soil types, climatic conditions, and

— define a specified time period in which to obtain results.

The first step in developing a monitoring plan for case-specific monitoring is to determine the case-specific objectives of the monitoring strategy. This includes determining which assumptions regarding the occurrence and impact of potential adverse effects of the GMO or its use were made in the environmental risk assessment and should to be confirmed by the case-specific monitoring. Where the conclusions of the risk assessment identifies an absence of risk or negligible risk, however, then case-specific monitoring may not be required.

Potential adverse effects that are identified in the environmental risk assessment should only be included in the monitoring plan on the basis that monitoring could contribute to the confirmation or rejection of the assumptions associated with these effects.

If the intended use of a GMO includes cultivation, then consideration may have to be given to the monitoring of potential risks arising from pollen transfer, dissemination and persistence of these GMOs. The degree to which these phenomena are likely to occur will also be dependent on the scale of this use and the receiving environment including the proximity to and scale of production of sexually compatible conventional crop species and wild relatives.

Conversely, potential environmental risks arising from GMOs approved only for import and processing will likely often be assessed as extremely limited given that they will not be intentionally introduced into the environment and that they are unlikely to disseminate.

Potential effects on human health or the environment arising from the release or placing on the market of a GMO will firstly depend on the inherent nature of a GMO and its specific genetic modification. For example, potential effects arising from transfer of pollen from genetically modified crops to non GM-crops or related wild-type plants will, in the first instance be largely dependent on whether the genetically modified crop is out-crossing or self-pollinating. The presence of wild relatives may also need to be considered in this context.

However, any subsequent effects for example, the potential development of insect resistance to the Bt-toxin will only be linked to GMOs modified to express this specific toxin. This would not be the case for GMOs modified for herbicide tolerance alone, as these GMOs do not contain a Bt-toxin gene.

Similarly, it would only be relevant to monitor the potential transfer of antibiotic resistance genes and the possible consequences with respect to GMOs that include antibiotic marker genes as part of the modification.

After identification of the objectives on the basis of potential adverse effects, the next step should be to identify the parameters that need to be measured in order to achieve these objectives. Parameters as well as the methods used to measure and evaluate them must be valid and fit-for-purpose.

1.3.2. *General surveillance*

General surveillance is largely based on routine observation ('look — see' approach) and should be used to identify the occurrence of unforeseen adverse effects of the GMO or its use for human health and the environment that were not predicted in the risk assessment. This is likely to involve observation of phenotypic characteristics but more detailed analyses are not precluded.

In contrast to case-specific monitoring, general surveillance should:

— Seek to identify and record any indirect, delayed and/or cumulative adverse effects that have not been anticipated in the risk assessment,

— Be carried out over a longer time period and possibly a wider area.

The type of general surveillance, including locations, areas and any parameters to be measured, will largely depend on the type of unanticipated adverse effect is being surveyed. For example, any unanticipated adverse effects on the cultivated ecosystem such as changes in bio-diversity, cumulative environmental impacts from multiple releases and interactions may require a different approach to general surveillance of other effects arising from gene transfer.

General surveillance could, where compatible, make use of established routine surveillance practises such as monitoring of agricultural crops, plant protection, veterinary and medical products as well as ecological monitoring, environmental observation and nature conservation programmes. The monitoring plan may also provide details as to how relevant information collected through established routine surveillance practices conducted by third parties will be retrieved by, or made available to, the consent holder.

If established routine surveillance practise is used in the general surveillance, this practise should be described as well as the changes in the practise needed to fulfil a relevant general surveillance.

1.4. Baselines

Determination of the baseline status of the receiving environment is a pre-requisite for the identification and evaluation of changes observed via monitoring. In short, the baseline serves as a point of reference against which any effects arising from the placing on the market of a GMO can be compared. This baseline should, therefore, be determined prior to attempting to detect and monitor any such effects. Parallel monitoring of 'GMO-areas' and comparable 'non-GMO reference areas' may provide an alternative and may be important where environments are highly dynamic.

Reliable information about the status of the receiving environment, on the basis of adequate environmental observation systems, may, therefore, be required prior to implementation of monitoring programmes and environmental policy actions. Environment observation programmes are designed to take proven or suspected and plausible ecosystem relationships into account and may assist in the determination of, the:

— status of the environment and changes therein,

— causes of such changes, and

— expected development of the environment.

Examples of indicators of the status of the receiving environment may include animals, plants and micro-organisms from different organism groups and ecosystems. Relevant indicators may be considered on the basis of the characteristics of the GMO in question and the parameters to be monitored. Sexual compatibility of other organisms with the GMO may also be relevant in this context. For a particular indicator species, a number of possible measurement parameters or fitness variables will exist, including the likes of numbers, growth rate, bio-mass, reproductive effort, population rate of increase/decrease and genetic diversity.

It may also be appropriate to consider baselines in relation to changes in management practice resulting from the use of GMOs. This could include changes in pesticide usage with respect to the cultivation of crop species modified for tolerance to herbicides and resistance to insects. It may also be appropriate when considering the monitoring plan for herbicide-tolerant genetically modified crops, to consider herbicide use for conventional crops as part of an appropriate baseline.

1.5. Time-period

Monitoring should be carried out over a time period of sufficient length to detect not only immediate potential effects, where appropriate, but also delayed effects which have been identified in the environmental risk assessment. Consideration should also be given to the interplay between the estimated level of risk and the duration of the release. A prolonged period of release may increase the risk of cumulative effects. The non-appearance of immediate effects over a prolonged period, on the other hand, may allow monitoring to focus on delayed and indirect effects. It should also be considered whether it is necessary to extend the monitoring plan beyond the period of the consent. This may be the case, for example, where the persistence of GMOs in the environment has the potential to be significant.

The proposed time-period of the monitoring plan should be indicated, including an outline of the likely frequency of visits/inspections and any intervals for review of the monitoring plan. This should take account of the likely appearance of any potential effects as highlighted in the risk assessment. For example, consideration should be given to any adverse effect resulting from the dissemination, reproduction and persistence/survival of a GMO in the environment following its placing on the market. This may be a matter of days or months for genetically modified microbes released in bio-remediation programmes but could extend to a number of years where certain crop species are concerned. The likelihood of dissemination and persistence of the modified sequences themselves should also be considered in terms of crosses with sexually compatible species.

The planning of inspections will largely be dependent on the type of effect to be monitored. For example, effects arising from pollen transfer will only be visible following flowering although it would be pertinent to visit a site prior to flowering to establish the extent to which sexually compatible species are present in the vicinity. Similarly, monitoring for the appearance of volunteers in subsequent growing seasons will be linked to the time of seed shed and persistence and germination of the subsequent seed bank.

Prior visits may also be necessary, as appropriate, prior to the onset of monitoring in order to establish relevant baselines.

Monitoring plans and their time-periods should not be fixed indefinitely but reviewed and amended in light of results obtained during the monitoring programme.

1.6. Assigning responsibilities

Ultimately, it is the notifier/consent holder who is responsible, under the Directive, for ensuring that a monitoring plan is included in the notification, put in place and appropriately implemented.

In the first instance, responsibility is placed on notifiers to submit as part of their notification, under Article 13(2)(e) of the Directive, a plan for monitoring in accordance with Annex VII. The suitability of the proposed monitoring plan is one of the criteria by which any application for the placing on the market of a GMO should be judged. The plan should be judged solely on the basis of whether or not it is adequate, which requires fulfilment of the requirements laid down in the Directive itself as opposed to strict alignment with this guidance note.

Article 20(1) subsequently requires that following the placing on the market of a GMO as or in a product, the notifier shall ensure that monitoring and reporting on it are carried out according to the conditions specified in the consent. This should be achieved through appropriate implementation of the monitoring plan.

Responsibilities for each step of the monitoring plan should, therefore, be clearly assigned in the notification. This would apply to both case-specific monitoring and also general surveillance as part of the monitoring plan. Whilst the notifier retains responsibility for ensuring that monitoring is carried out, this does not preclude that third parties such as consultants and users could be involved in the monitoring by carrying out various tasks the monitoring plan requires. In case of general surveillance this could include the Commission, Member States and/or CAs. Where third parties are employed or contracted to conduct monitoring studies, the structure of their involvement should be detailed. The notifier/consent holder is responsible for the compilation of the monitoring data and results and has to ensure the transmission of this information to Commission and the Competent Authorities according to the monitoring plan particularly with respect to the identification of any adverse effects.

It should similarly be noted that it is not precluded that Member States carry out additional monitoring in the form of case-specific monitoring or general surveillance. The aim of such surveillance is to enable the risk manager to take appropriate measures without delay should any undesirable and unidentified effects arise in the framework of prior risk assessment. This should not, however, be considered a substitute for the monitoring plan, which remains under the responsibility of the notifier for implementation (although, with the consent of relevant parties, may form part of it).

1.7. Existing systems

It may be possible to extend existing monitoring or general surveillance systems to address potential adverse effects arising from the placing on the market of GMOs. These systems may include observation programmes in the field of agriculture, food surveys, nature conservation, long-term ecological monitoring systems, environment observation programmes and veterinary surveys.

For example, seed production systems that follow OECD certification rules and therefore include routine inspections of fields and surrounding areas could be adapted to on-field monitoring for specified parameters.

Monitoring and surveillance of conventional commercial crops is already carried out, as a matter of course in Member States, with regard to calculation of fertiliser application as well as pest, disease and weed control. This type of monitoring and surveillance is conducted on a regular basis throughout the growing season by consultants selling the relevant agronomic products and the growers themselves.

It may, therefore, be possible to attach a similar service to sales of genetically modified seed, where representatives of the company, or contracted consultants, to provide at least some form of general surveillance. Instruction concerning surveillance, monitoring and reporting could be distributed to growers purchasing genetically modified seed stocks and contractual agreements could be formulated as a condition of sale or use.

It is certainly feasible that growers or agronomic consultants could conduct surveys of major unforeseen changes or effects such as dissemination and establishment of volunteer plants in adjacent areas if clear instructions are provided. Under these circumstances, it is foreseen that monitoring and surveillance for adverse effects could be incorporated into routine practices for determining agronomic inputs for pest and weed control.

2. **Monitoring methodology**

This section provides guidance as to the types of parameters and elements that may need to be identified and monitored as part of a monitoring programme as well as the means to conduct such monitoring, including areas to monitor and frequency of monitoring.

2.1. Monitoring parameters/elements

Firstly, it will be necessary to identify the relevant parameters/elements to be monitored with appropriate justification for their selection. This will largely be dependent upon the conclusions of the environmental risk assessment. Decisions as to the parameters or elements to be monitored must be taken on a case-by-case basis in line with the modified characteristics of the GMO in question. This would include the likes of monitoring of intended effects on target organisms arising from the modification, an example of which would be monitoring of corn borer populations with respect to the cultivation of Bt-maize varieties.

However, non-specific elements may also need to be considered as part of the monitoring plan and examples of such elements are presented as follows although others are not precluded:

— Effects on non-target organisms arising from the modification, including development of resistance in wild relatives or pest organisms, change in the host range or in the dispersal of pest organisms and viruses, development of new viruses,

— Dispersal, establishment and persistence into non-target environments or eco-systems,

— Out-crossing/breeding (e.g. occurrence, means and rates of out-crossing/breeding), with sexually compatible wild relatives in natural populations,

— Unintended changes in the basic behaviour of the organism, for example, changes in reproduction, number of progeny, growth behaviour and survival ability of the seeds,

— Changes in bio-diversity (e.g. in number or composition of species).

2.2. Areas/samples

The monitoring plan may include details as to where the monitoring will be carried out and over what area. This may be at the level of individual Member States, geographical regions, individual sites, plots or any other area(s) deemed appropriate.

The areas and/or samples to be monitored with respect to possible effects arising from the placing on the market of the GMO should be identified, including those for the purpose of reference or control. Any reference or control areas and/or samples must be sufficiently representative in terms of environment and conditions of use for meaningful conclusions to be drawn. Moreover, any sampling methodology should be scientifically and statistically sound. On this basis, such data can provide important information on the variation of indicators, which will increase the power of the effect detection.

When considering the areas to be monitored with regard to, for example, a genetically modified crop species, its characteristics (both inherent and modified) as well as its reproduction and dissemination and the types of ecosystems that may be affected could be considered in determining the habitats selected for monitoring. Relevant areas to monitor would include selected agricultural fields where the crop is commercially grown as well as surrounding habitats.

It may also be necessary to extend monitoring/surveillance to adjacent or neighbouring cultivated and non-cultivated areas, post-harvest surveillance areas for volunteer plants and protected areas. Certain types of habitats, such as disturbed areas and species-rich plant communities, are more prone to invasion than others. Disturbed areas with low vegetation and high abundance of herbs and grasses are particularly suitable for the purpose of monitoring. Firstly, they are widely distributed and often found close to more intensively cultivated agricultural areas. Secondly, these areas are often typical of roadsides, ditches and edges of fields where accidental loss and dispersal of seeds is most likely to occur in the first instance.

Monitoring for the possibility of transfer of genetic material to sexually compatible organic and conventional crops may also be considered. This will require evaluation of the extent to which such crops are grown in adjacent or neighbouring areas.

2.3. Inspections

The monitoring plan should indicate the likely frequency of inspections. This may include a timetable to indicate the timing and number of intended visits to a site. In this respect, as already detailed in sections 1.5 and 2.2, consideration should importantly be given to the time when potential adverse effects are most likely to appear as well as the area(s) to be monitored.

2.4. Sampling and analysis

The methodology to subsequently monitor these parameters/elements should also be clearly identified and outlined, including techniques for sampling and analysis. Standard methodology, as provided for by the likes of European CEN Standards and OECD-methods for monitoring organisms in the environment, should be followed where appropriate and reference to the source of the methodology provided. Methods used for monitoring should be scientifically sound and valid under the experimental conditions in which they are to be applied; therefore, consideration should be given to the characteristics of the methods, such as selectivity, specificity, reproducibility, any limitations, detection limits, and the availability of appropriate controls.

The monitoring plan should also indicate how the methodology is expected to be updated, if appropriate, according to the selected monitoring approach/strategy.

Statistical analysis could also be employed when designing the appropriate sampling and testing methodology, in order to determine optimal sample sizes and minimum monitoring periods for the required statistical level of effect detection.

2.5. Collection and collation of data

The monitoring plan should, for both case-specific monitoring and general surveillance, identify how, by whom and how often data is to be collected and collated. This may be of particular importance where third parties are employed or contracted to collect data. Notifiers may need to provide standard mechanisms, formats and protocols for data collection and recording as a means to ensure consistency. For example, standardised recording sheets or direct logging or registration of data on standardised 'spread-sheets' via portable computers could be provided. The notifier may also need to detail how the data will be collated, importantly how information is to be retrieved from third parties, such as consultants or users.

Deadlines and intervals for reports detailing the results of the monitoring should also be indicated.

3. **Analysis, reporting, review**

The monitoring plan should indicate how often the data is reviewed and discussed in an overall analysis.

3.1. Evaluation

Evaluation of data should, where appropriate, include statistical analysis with appropriate standard error values to enable subsequent decisions to be taken on a sound basis. These will include decisions as to whether evaluations highlighted in the risk assessment are correct. In this respect, correct baselines and/or controls relating to the status of the receiving environment are also paramount for accurate evaluations. Use of statistical analysis should also provide information as to whether the type of methodology, including sampling and testing, is appropriate.

The evaluation of results from monitoring and surveys may reveal whether other parameters should be monitored under the programme. Appropriate responses to any preliminary findings may also need to be examined, in particular, where potential negative impacts on vulnerable habitats and organism groups are suggested.

The interpretation of the data collected by monitoring may need to be considered in the light of other existing environmental conditions and activities. Where changes in the environment are observed, further assessment may be required to establish whether they are a consequence of the GMO or its use, or whether such changes may be the result of environmental factors other than the placing of the GMO on the market. It may be necessary to re-evaluate the baselines used for comparison in this respect.

The monitoring plan should be structured in such a way, that the results of both the case-specific monitoring and general surveillance as well as additional research could clearly be used in the decision-making process for renewal of approval for products.

3.2. Reporting

Following the placing on the market of a GMO, the notifier under Article 20(1) of the Directive, has a legal obligation to ensure that monitoring and reporting are carried out according to the conditions specified in the consent. The reports of this monitoring must be submitted to the Commission and the competent authorities of the Member States although no time frame for submission is laid down. This information should also be made publicly available in line with the requirements of Article 20(4) of the Directive. Against this background, notifiers should describe the conditions of reporting in the monitoring plan.

In addition, an indication as to how relevant information collected through any established or routine surveillance practises will be made available to the consent holder and competent authorities should also be provided in the monitoring plan.

Notifiers/consent holders should ensure transparency of the results and measures of the monitoring programmes and the monitoring plan should identify how the gathered information is reported/published. This could for example be achieved via:

— information sheets to users and other stakeholders,

— workshops to present and exchange information with stakeholders,

— archived in-company documents,

— inclusion on company web-sites,

— publication of information in trade and scientific publications.

The provisions of Article 20 of the Directive also relate to reporting. In accordance with Article 20(2), if new information concerning risk becomes available from users or other sources, the notifier is immediately required to take the measures necessary to protect human health and the environment, and inform the competent authority thereof.

In addition, the notifier is also required to revise the information and conditions specified in the notification.

3.3. Review and adaptation

Monitoring plans should not be viewed as static. It is fundamental that the monitoring plan and associated methodology is reviewed at appropriate intervals and updated or adapted as necessary.

Article 20(1) of the Directive allows the competent authority receiving the original notification, on the basis of reports submitted by notifiers and in accordance with the consent and the framework for the specified monitoring plan, to adapt the monitoring plan after the first monitoring period. However, implementation of the revised monitoring plan again remains under the responsibility of the notifier.

Reviews should examine the effectiveness and efficiency of data measurements and collection, including sampling and analysis. The review should also evaluate whether the monitoring measures are effective in addressing the evaluations and any questions arising from the risk assessments.

For example, if specific models are used for predictive purposes, a validation based on the data collected and subsequent appraisal may be conducted. Similarly, new developments and progress in sampling and analytic techniques should also be taken into account where appropriate.

Following such reviews, the adjustment of methods, monitoring goals and the monitoring programme may be necessary and should be adapted or upgraded as appropriate.

COUNCIL DECISION

of 3 October 2002

establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council the summary information format relating to the placing on the market of genetically modified organisms as or in products

(2002/812/EC)

THE COUNCIL OF THE EUROPEAN UNION,

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 Directive 90/220/EEC [1], and in particular Article 13(2)(h) thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) Under Part C of Directive 2001/18/EC, prior notification must be given to the competent national authority of the planned placing on the market of a genetically modified organism (hereinafter referred to as GMO), or a combination of such organisms.

(2) That notification comprises, *inter alia*, a summary of the relevant dossier, which the competent authority must send to the competent authorities of the other Member States and to the Commission, and which the Commission must immediately make available to the public. That summary must be drawn up in accordance with a particular format.

(3) That format should reflect the need to enable the fullest possible exchange of relevant information, presented in a standardised and easily comprehensible manner, without prejudice to the fact that the information thus provided cannot serve as the basis for an environmental risk assessment.

(4) The committee set up under Article 30(2) of Directive 2001/18/EC was consulted on 12 June 2002 and has not delivered an opinion on the Commission's proposal for a Decision,

HAS ADOPTED THIS DECISION:

Article 1

For the purposes of drawing up the summary of the dossier for submission to the competent national authority pursuant to Article 13(2)(h) of Directive 2001/18/EC, the notifier shall use the Summary Information Format set out in the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Luxembourg, 3 October 2002.

For the Council

The President

F. HANSEN

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

ANNEX

SUMMARY INFORMATION FORMAT IN RELATION TO THE PLACING ON THE MARKET OF A GMO OR A COMBINATION OF GMOs AS OR IN PRODUCTS

INTRODUCTION

The following format must be used for the summary of the dossier to accompany a notification, for submission to the competent national authority, concerning the placing on the market of a GMO or a combination of GMOs as or in products.

This document, when completed, will present a summary of the information entered under the corresponding points of the full dossier. It is recognised, therefore, that the risk assessment required under Directive 2001/18/EC cannot be carried out solely on the basis of this document.

The space provided after each question is not indicative of the depth of the information required for the purposes of the Summary Information Format.

The Summary Information Format is divided into Parts 1 and 2.

Part 1 applies to products consisting of or containing genetically modified organisms other than higher plants and contains the following sections:

A General Information

B Nature of the GMOs contained in the product

C Predicted behaviour of the product

D Information relating to previous releases

E Information relating to the monitoring plan

Part 2 applies to products consisting of or containing genetically modified higher plants. The term 'higher plants' means plants which belong to the taxonomic group Gymnospermae and Angiospermae. Part 2 contains the following sections:

A General Information

B Nature of the GMHP contained in the product

C Information relating to previous releases

D Information relating to the monitoring plan

PART 1

SUMMARY INFORMATION FORMAT FOR PRODUCTS CONTAINING GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS

A. **General information**

1. *Details of notification*

(a) Member State of notification	
(b) Notification number	
(c) Name of the product (commercial and other names)	
(d) Date of acknowledgement of notification	

2. *Notifier/producer/importer*

(a) Name of notifier		
(b) Address of notifier		
(c) The notifier is	domestic producer importer	☐ ☐
(d) In the case of an import (i) Name of producer (ii) Address of producer		

3. *Characterisation of the GMOs contained in the product*

Indicate the name and nature of each type of GMO contained in the product

4. *General description of the product*

(a) Type of product
(b) Composition of the product
(c) Specificity of the product
(d) Types of users

(e) Any special conditions of use and handling suggested as a condition of the authorisation applied for
(f) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for
(g) Any type of environment to which the product is unsuited
(h) Estimated potential annual demand (i) in the Community (ii) in export markets for EC supplies
(i) Unique identification code(s) of the GMO(s)

5. *Has the combination of GMOs contained in the product been notified under Part B of Directive 2001/18/EC by the same notifier?*

Yes ☐	No ☐
(i) If yes, give country and notification number	
(ii) If no, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC.	

6. *Is the product being simultaneously notified to another Member State by the same notifier?*

Yes ☐	No ☐
If yes, specify:	

7. *Has another product with the same combination of GMOs been placed on the EC market by another notifier?*

Yes ☐	No ☐	Not known ☐
If yes, specify		

8. *Summary of data obtained on releases of the same GMOs or of the same combination of GMOs previously or currently carried out in conditions representative of the different environments where it will be possible to use GMOs*

9. *Specify instructions and or recommendations for storage and handling, including any mandatory restrictions proposed as a condition of the authorisation applied for*

10. *Proposed packaging*

11. *Any proposed labelling requirements, in addition to those required by law*

12. *Measures suggested by the notifier to take in the event of unintended release or misuse*

13. *Measures for waste disposal and treatment (if applicable)*

B. **Nature of the GMOs contained in the product**

INFORMATION RELATING TO THE RECIPIENT OR PARENTAL ORGANISM(S) FROM WHICH THE GMO IS DERIVED

14. *Scientific name and common names*

15. *Phenotypic and genetic traits*

16. *Geographical distribution and natural habitat of the organism*

17. *Genetic stability of the organism and factors affecting it*

18. *Potential for genetic transfer and exchange with other organisms and the likely consequences of gene transfer*

19. *Information concerning reproduction and factors affecting it*

20. *Information on survival and factors affecting it*

21. *Ways of dissemination and factors affecting it*

22. *Interactions with the environment*

23(a) Detection techniques

23(b) Identification techniques

24. *Classification under existing Community rules concerning the protection of human health and/or environment*

25(a) Pathogenic characteristics

25(b) Other harmful characteristics of the organisms living or dead, including its extracellular products

26. *Nature and description of known extrachromosomal genetic elements*

27. *Summary of known history of previous genetic modifications*

INFORMATION RELATING TO THE GENETIC MODIFICATION

28. *Methods used for the genetic modification*

29. *Characteristics of the vector*

(a) Nature and source of the vector

(b) Description of the vector construction
(c) Genetic map and/or restriction map of the vector
(d) Sequence data
(e) Information on the degree to which the vector contains sequences whose product or function area is not known
(f) Genetic transfer capabilities of the vector
(g) Frequency of mobilisation of the vector
(h) Part of the vector which remains in the GMO

30. *Information on the insert*

(a) Methods used to construct the insert

(b) Restriction sites
(c) Sequence of the insert
(d) Origin and function of each constituent part of the insert in the GMO
(e) Information on the degree to which the insert is limited to the required function
(f) Location of the insert in the GMO

INFORMATION ON THE ORGANISM(S) FROM WHICH THE INSERT IS DERIVED (DONOR)

31. *Scientific and other names*

32. *Indicate whether the donor organism has pathogenic or harmful characteristics; if so, indicate the nature of these characteristics*

33. *If the donor organism has any pathogenic or harmful characteristics, indicate whether the donated sequences are in any way involved in them*

34. *Classification under existing Community rules relating to the protection of human health and the environment*

35. *State whether natural exchanges of genetic material between the donor(s) and recipient organism are possible or have been observed*

INFORMATION RELATING TO THE GMO(S) CONTAINED IN THE PRODUCT

36. *Description of genetic traits or phenotypic characteristics, if different from that of the recipient or parental organism(s)*

37. *Genetic stability of the GMO, if different from that of the recipient or parental organism(s)*

38. *Rate and level of expression of the new genetic material*

39. *Activity of the expressed proteins*

40(a) Description of detection techniques for the GMO in the environment, if different from that of the recipient or parental organism(s)

40(b) Description of identification techniques to distinguish the GMO from the recipient or parental organism

41. *Health considerations*

(a) Toxic or allergenic effects of the GMOs and/or their metabolic products, if significantly different from those of the recipient/parental organism
(b) Product hazards, if significant
(c) Comparison of the GMO with the donor, recipient or parental organism regarding pathogenicity, if significantly different
(d) Capacity for colonisation, if significantly different from the recipient or parental organism(s)
(e) If the organism is more pathogenic than the recipient or parental organism(s) to humans who are immuno competent, supply the information specified in Annex III A, Part II C 2(i) (iv)

INTERACTIONS OF THE GMO WITH THE ENVIRONMENT

42. *Survival, multiplication and dissemination of the GMO(s) in the environment if different from the recipient or parental organism*

43. *Environmental impacts of the GMOS(s) if different from the recipient or parental organism*

C. **Predicted behaviour of the product, if different from the recipient or parent organism(s)**

ENVIRONMENTAL IMPACT OF THE PRODUCT

HUMAN HEALTH EFFECTS OF THE PRODUCT, IF DIFFERENT FROM THE RECIPIENT OR PARENT ORGANISM(S)

D. **Information relating to previous releases**

HISTORY OF PREVIOUS RELEASES NOTIFIED UNDER PART B OF THE DIRECTIVE (IF APPLICABLE)

1. *Notification number*

2. *Release site*

3. *Aim of the release*

4. *Duration of the release*

5. *Duration of post-release monitoring*

6. *Aim of post-release monitoring*

7. *Conclusions of post-release monitoring*

8. *Results of the release with respect to any risk to human heath and the environment according to Article 8 of Directive 90/220/EEC or Article 10 of Directive 2001/18/EC*

HISTORY OF PREVIOUS RELEASES CARRIED OUT INSIDE OR OUTSIDE THE COMMUNITY

1. *Release country*

2. *Authority overseeing the release*

3. *Release site*

4. *Aim of the release*

5. *Duration of post-release monitoring*

6. *Aim of post-release monitoring*

7. *Conclusions of post-release monitoring*

8. *Results of the release with respect to any risk to human health and the environment*

HISTORY OF PREVIOUS WORK RELEVANT TO RISK ASSESSMENT PRIOR TO COMMERCIALISATION

E. **Information relating to the monitoring plan — identified traits, characteristics and uncertainties related to the GMO or its interaction with the environment that should be addressed in the post-commercialisation monitoring plan**

PART 2

SUMMARY INFORMATION FORMAT FOR PRODUCTS CONTAINING GENETICALLY MODIFIED HIGHER PLANTS (GMHPs)

A. General information

1. *Details of notification*

(a) Member State of notification
(b) Notification number
(c) Name of the product (commercial and other names)
(d) Date of acknowledgement of notification

2. *Notifier*

(a) Name of notifier
(b) Address of notifier
(c) Is the notifier domestic manufacturer ☐ importer ☐
(d) In the case of an import the name and address of the manufacturer shall be given

3. *General description of the product*

(a) Name of the recipient or parental plant and the intended function of the genetic modification
(b) Any specific form in which the product must not be placed on the market (seeds, cut-flowers, vegetative parts, etc.) as a proposed condition of the authorisation applied for
(c) Intended use of the product and types of users
(d) Any specific instructions and/or recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for
(e) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for
(f) Any type of environment to which the product is unsuited
(g) Any proposed packaging requirements

(h) Any proposed labelling requirements in addition to those required by law
(i) Estimated potential demand (i) in the Community (ii) in export markets for EC supplies
(j) Unique identification code(s) of the GMO(s)

4. *Has the GMHP referred to in this product been notified under Part B of Directive 2001/18/EC and/or Directive 90/220/EEC?*

Yes ☐	No ☐
(i) If no, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC	

5. *Is the product being simultaneously notified to another Member State?*

Yes ☐	No ☐
(i) If no, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC	

or

Has the product been notified in a third country either previously or simultaneously?

Yes ☐	No ☐
If yes, specify	

6. *Has the same GMHP been previously notified for marketing in the Community?*

Yes ☐	No ☐
If yes, give notification number and Member State	

7. *Measures suggested by the notifier to take in case of unintended release or misuse as well as measures for disposal and treatment*

B. **Nature of the GMHP contained in the product**

INFORMATION RELATING TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS

8. *Complete name*

(a) Family name
(b) Genus
(c) Species
(d) Subspecies
(e) Cultivar/breeding line
(f) Common name

9(a) Information concerning reproduction

(i) Mode(s) of reproduction
(ii) Specific factors affecting reproduction, if any
(iii) Generation time

9(b) Sexual compatibility with other cultivated or wild plant species

10. *Survivability*

(a) Ability to form structures for survival or dormancy
(b) Specific factors affecting survivability, if any

11. *Dissemination*

(a) Ways and extent of dissemination
(b) Specific factors affecting dissemination, if any

12. *Geographical distribution of the plant*

13. *In the case of plant species not normally grown in the Member State(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts*

14. *Potentially significant interactions of the plant with other organisms in the ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms*

15. *Phenotypic and genetic traits*

INFORMATION RELATING TO THE GENETIC MODIFICATION

16. *Description of the methods used for the genetic modification*

17. *Nature and source of the vector used*

18. *Size, source [name of donor organism(s)] and intended function of each constituent fragment of the region intended for insertion*

INFORMATION RELATING TO THE GMHP

19. *Description of the trait(s) and characteristics which have been introduced or modified*

20. *Information on the sequences actually inserted/deleted/modified*

(a) Size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced in the GMHP or any carrier or foreign DNA remaining in the GMHP
(b) In case of deletion, size and function of the deleted region(s)

(c) Location of the insert in the plant cells (integrated in the chromosome, chloroplast, mitochondrion, or maintained in a non-integrated form), and methods for its determination
(d) Copy number and genetic stability of the insert
(e) In case of modifications other than insertion or deletion, describe function of the modified genetic material before and after the modification as well as direct changes in expression of genes as a result of the modification

21. *Information on the expression of the insert*

(a) Information on the expression of the insert and methods used for its characterisation
(b) Parts of the plant where the insert is expressed (e.g. roots, stem, pollen, etc.)

22. *Information on how the GMHP differs from the recipient plant in*

(a) Mode(s) and/or rate of reproduction
(b) Dissemination
(c) Survivability
(d) Other differences

23. *Potential for transfer of genetic material from the GMHP to other organisms*

24. *Information on any harmful effects on human health and the environment, arising from the genetic modification*

25. *Information on the safety of the GMHP to animal health, where the GMHP is intended to be used in animal feedstuffs, if different from that of the recipient/parental organism(s)*

26. *Mechanism of interaction between the GMHP and target organisms (if applicable), if different from that of the recipient/parental organism(s)*

27. *Potentially significant interactions with non-target organisms, if different from the recipient or parental organism(s)*

28. *Description of detection and identification techniques for the GMHP, to distinguish it from the recipient or parental organism(s)*

INFORMATION ON THE POTENTIAL ENVIRONMENTAL IMPACT FROM THE RELEASE OF THE GMHP

29. *Potential environmental impact from the release or the placing on the market of GMOs (Annex II, D2 of Directive 2001/18/EC), if different from a similar release or placing on the market of the recipient or parental organism(s)*

30. *Potential environmental impact of the interaction between the GMHP and target organisms (if applicable), if different from that of the recipient or parental organism(s)*

31. *Possible environmental impact resulting from potential interactions with non-target organisms, if different from that of the recipient or parental organism(s)*

(a) Effects on biodiversity in the area of cultivation
(b) Effects on biodiversity in other habitats
(c) Effects on pollinators
(d) Effects on endangered species

C. **Information relating to previous releases**

32. *History of previous releases notified under Part B of the Directive 2001/18/EC and under Part B of Directive 90/220/EEC by the same notifier*

(a) Notification number
(b) Conclusions of post-release monitoring
(c) Results of the release in respect to any risk to human health and the environment (submitted to the competent authority according to Article 10 of Directive 2001/18/EC)

33. *History of previous releases carried out inside or outside the Community by the same notifier*

(a) Release country
(b) Authority overseeing the release
(c) Release site
(d) Aim of the release
(e) Duration of the release
(f) Aim of post-releases monitoring
(g) Duration of post-releases monitoring

(h) Conclusions of post-release monitoring
(i) Results of the release in respect to any risk to human health and the environment

D. **Information relating to the monitoring plan — identified traits, characteristics and uncertainties related to the GMO or its interaction with the environment that should be addressed in the post-commercialisation monitoring plan**

COUNCIL DECISION

of 3 October 2002

establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market

(2002/813/EC)

THE COUNCIL OF THE EUROPEAN UNION,

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 Directive 90/220/EEC [1], and in particular Article 11(1) thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) Under Part B of Directive 2001/18/EC, prior notification must be given to the competent national authority of the planned release of a genetically modified organism (hereinafter referred to as GMO), or of a combination of such organisms, for purposes other than for placing on the market.

(2) Within the framework established by the Directive 2001/18/EC for the exchange of information between the competent authorities and the Commission, the authority must then send a summary, in accordance with a specific format, of the notification to the Commission, which in turn must forward copies to the other Member States.

(3) That format should reflect the need to enable the fullest possible exchange of relevant information, presented in a standardised and easily comprehensible manner, without prejudice to the fact that the information thus provided cannot serve as the basis for an environmental risk assessment.

(4) The committee set up under Article 30(2) of Directive 2001/18/EC was consulted on 12 June 2002 and has not delivered an opinion on the Commission's proposal for a Decision,

HAS ADOPTED THIS DECISION:

Article 1

For the purposes of summarising, for transmission to the Commission, notifications received pursuant to Article 6 of Directive 2001/18/EC, the competent authorities appointed by Member States under that Directive shall use the Summary Notification Information Format set out in the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Luxembourg, 3 October 2002.

For the Council

The President

F. HANSEN

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

ANNEX

SUMMARY NOTIFICATION INFORMATION FORMAT FOR THE DELIBERATE RELEASE OF A GMO OR A COMBINATION OF GMOs FOR PURPOSES OTHER THAN FOR PLACING ON THE MARKET

INTRODUCTION

The Summary Notification Information Format for deliberate releases of a GMO or of a combination of GMOs, has been established for the purposes and according to the procedures envisaged by Article 11 of Directive 2001/18/EC.

It is recognized that this Format is not designed to accommodate all the information required for carrying out an environmental risk assessment.

The space provided after each question is not indicative of the depth of the information required for the purposes of the Summary Notification Information Format.

The Summary Notification Information Format consists of a Part 1 and a Part 2.

Part 1 applies to products consisting of or containing genetically modified organisms other than higher plants and contains the following sections:

A General Information

B Information relating to the recipient or parental organisms from which the GMO is derived

C Information relating to the genetic modification

D Information on the organism(s) from which the insert is derived (donor)

E Information relating to the genetically modified organism

F Information relating to the release

G Interactions of the GMO with the environment and potential impact on the environment

H Information relating to monitoring

I Information on post-release and waste treatment

J Information on emergency response plans

In Part 1 the information entered should, however, adequately reflect (in a condensed form) the information submitted to the competent authority in accordance with Articles 6 and 7 of Directive 2001/18/EC under the conditions specified in the preface to Annex IIIA.

Part 2 applies to products consisting of or containing genetically modified higher plants. The term 'higher plants' means plants which belong to the taxonomic group *Gymnospermae* and *Angiospermae*. Part 1 contains the following sections:

A General information

B Information on the genetically modified plant

C Information relating to the experimental release

D Summary of the potential environmental impact of the release of the GMPts

E Brief description of any measures taken for the management of risks

F Summary of planned field trials designed to gain new data on the environmental and human health impact of the release.

In Part 2 the information entered should, however, adequately reflect (in a condensed form) the information submitted to the competent authority in accordance with Articles 6 and 7 of Directive 2001/18/EC under the conditions specified in the preface to Annex IIIB.

PART 1

SUMMARY NOTIFICATION INFORMATION FORMAT FOR THE RELEASE OF GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS IN ACCORDANCE WITH ARTICLE 11 OF DIRECTIVE 2001/18/EC

A. **General information**

1. *Details of notification*

(a) Member State of notification
(b) Notification number
(c) Date of acknowledgement of notification
(d) Title of the project
(e) Proposed period of release

2. *Notifier*

Name of institution or company

3. *GMO characterisation*

(a) Indicate whether the GMO is a:	viroid	☐
	RNA virus	☐
	DNA virus	☐
	bacterium	☐
	fungus	☐
	animal	☐
	— mammals	☐
	— insect	☐
	— fish	☐
	— other animal	☐ specify phylum, class
other, specify (kingdom, phylum and class)		
(b) Identity of the GMO (genus and species)		
(c) Genetic stability - according to Annex IIIa, II, A(10)		

4. *Is the same GMO release planned elsewhere in the Community (in conformity with Article 6(1)), by the same notifier?*

Yes ☐	No ☐
If yes, insert the country code(s):	

5. *Has the same GMO been notified for release elsewhere in the Community by the same notifier?*

Yes ☐	No ☐
If yes: — Member State of notification — Notification number	

6. *Has the same GMO been notified for release or placing on the market outside the Community by the same or other notifier?*

Yes ☐	No ☐
If yes: — Member State of notification — notification number	

7. *Summary of the potential environmental impact of the release of the GMOs*

B. **Information relating to the recipient or parental organisms from which the GMO is derived**

1. *Recipient or parental organism characterisation:*

(a) Indicate whether the recipient or parental organism is a:

viroid ☐
RNA virus ☐
DNA virus ☐
bacterium ☐
fungus ☐
animal ☐
— mammals ☐
— insect ☐
— fish ☐
— other animal ☐ (specify phylum, class)

other, specify

2. *Name*

(i) order and/or higher taxon (for animals)
(ii) genus
(iii) species
(iv) subspecies
(v) strain
(vi) pathovar (biotype, ecotype, race, etc.)
(vii) common name

3. *Geographical distribution of the organism*

(a) Indigenous to, or otherwise established in, the country where the notification is made:

Yes ☐ No ☐ Not known ☐

(b) Indigenous to, or otherwise established in, other EC countries:

(i) Yes ☐

If *yes*, indicate the type of ecosystem in which it is found:

Atlantic ☐
Mediterranean ☐
Boreal ☐
Alpine ☐
Continental ☐
Macaronesian ☐

(ii) No ☐

(iii) Not known ☐

(c) Is it frequently used in the country where the notification is made?

Yes ☐ No ☐

(d) Is it frequently kept in the country where the notification is made?

Yes ☐ No ☐

4. *Natural habitat of the organism*

(a) If the organism is a microorganism	
water	☐
soil, free-living	☐
soil in association with plant-root systems	☐
in association with plant leaf/stem systems	☐
in association with animals	☐
other, specify	
(b) If the organism is an animal: natural habitat or usual agroecosystem:	

5(a) Detection techniques

5(b) Identification techniques

6. *Is the recipient organism classified under existing Community rules relating to the protection of human health and/or the environment?*

Yes ☐	No ☐
If yes, specify	

7. *Is the recipient organism significantly pathogenic or harmful in any other way (including its extracellular products), either living or dead?*

Yes ☐	No ☐	Not known ☐
If yes:		
(a) to which of the following organisms: humans ☐		
animals ☐		
plants ☐		
other ☐		
(b) give the relevant information specified under Annex III A, point II. (A)(11)(d) of Directive 2001/18/EC		

8. *Information concerning reproduction*

(a) Generation time in natural ecosystems:
(b) Generation time in the ecosystem where the release will take place:
(c) Way of reproduction: Sexual ☐ Asexual ☐
(d) Factors affecting reproduction:

9. *Survivability*

(a) ability to form structures enhancing survival or dormancy: (i) endospores ☐ (ii) cysts ☐ (iii) sclerotia ☐ (iv) asexual spores (fungi) ☐ (v) sexual spores (fungi) ☐ (vi) eggs ☐ (vii) pupae ☐ (viii) larvae ☐ (ix) other, specify
(b) relevant factors affecting survivability:

10(a) Ways of dissemination

10(b) Factors affecting dissemination

11. *Previous genetic modifications of the recipient or parental organism already notified for release in the country where the notification is made (give notification numbers)*

C. **Information relating to the genetic modification**

1. *Type of the genetic modification*

(i) insertion of genetic material	☐
(ii) deletion of genetic material	☐
(iii) base substitution	☐
(iv) cell fusion	☐
(v) other, specify	

2. *Intended outcome of the genetic modification*

3(a) Has a vector been used in the process of modification?

Yes ☐	No ☐
If no, go straight to question 5.	

3(b) If yes, is the vector wholly or partially present in the modified organism?

Yes ☐	No ☐
If no, go straight to question 5.	

4. *If the answer to 3(b) is yes, supply the following information*

(a) Type of vector	
plasmid	☐
bacteriophage	☐
Virus	☐
cosmid	☐
transposable element	☐
other, specify	

(b) Identity of the vector
(c) Host range of the vector
(d) Presence in the vector of sequences giving a selectable or identifiable phenotype Yes ☐ No ☐ antibiotic resistance ☐ Other, specify Indication of which antibiotic resistance gene is inserted
(e) Constituent fragments of the vector
(f) Method for introducing the vector into the recipient organism (i) transformation ☐ (ii) electroporation ☐ (iii) macroinjection ☐ (iv) microinjection ☐ (v) infection ☐ (vi) other, specify

5. *If the answer to question B.3(a) and (b) is no, what was the method used in the process of modification?*

(i) transformation ☐ (ii) mikroinjection ☐ (iii) microencapsulation ☐ (iv) macroinjection ☐ (v) other, specify

6. *Composition of the insert*

(a) Composition of the insert
(b) Source of each constituent part of the insert
(c) Intended function of each constituent part of the insert in the GMO

(d) Location of the insert in the host organism

— on a free plasmid ☐

— integrated in the chromosome ☐

— other, specify

(e) Does the insert contain parts whose product or function are not known?

Yes ☐ No ☐

If yes, specify

D. **Information on the organism(s) from which the insert is derived**

1. *Indicate whether it is a:*

viroid ☐

RNA virus ☐

DNA virus ☐

bacterium ☐

fungus ☐

animal ☐

— mammals ☐

— insect ☐

— fish ☐

— other animal ☐ (please specify phylum, class)

other, specify

2. *Complete name*

(i) order and/or higher taxon (for animals)

(ii) family name (for plants)

(iii) genus

(iv) species

(v) subspecies

(vi) strain

(vii) cultivar/breeding line

(viii) pathovar
(ix) common name

3. *Is the organism significantly pathogenic or harmful in any other way (including its extracellular products), either living or dead?*

Yes ☐	No ☐	Not known ☐
If *yes*, specify the following (a) to which of the following organisms?	Humans ☐ animals ☐ plants ☐ other ☐	
(b) are the donated sequences involved in any way to the pathogenic or harmful properties of the organism? Yes ☐ No ☐ Not known ☐		
If *yes*, give the relevant information under Annex III A, point II(A)(11)(d):		

4. *Is the donor organism classified under existing Community rules relating to the protection of human health and the environment, such as Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work?*

Yes ☐	No ☐
If yes, specify	

5. *Do the donor and recipient organism exchange genetic material naturally?*

Yes ☐	No ☐	Not known ☐

E. **Information relating to the genetically modified organism**

1. *Genetic traits and phenotypic characteristics of the recipient or parental organism which have been changed as a result of the genetic modification*

(a) is the GMO different from the recipient as far as survivability is concerned? Yes ☐ No ☐ Not known ☐ Specify
(b) is the GMO in any way different from the recipient as far as mode and/or rate of *reproduction* is concerned? Yes ☐ No ☐ Unknown ☐ Specify

(c) is the GMO in any way different from the recipient as far as *dissemination* is concerned? Yes ☐ No ☐ Not known ☐ Specify
(d) is the GMO in any way different from the recipient as far as *pathogenicity* is concerned? Yes ☐ No ☐ Not known ☐ Specify

2. *Genetic stability of the genetically modified organism*

3. *Is the GMO significantly pathogenic or harmful in any way (including its extracellular products), either living or dead?*

Yes ☐	No ☐	Unknown ☐
(a) to which of the following organisms?	humans ☐ animals ☐ plants ☐ other ☐	
(b) give the relevant information specified under Annex III A, point II(A)(11)(d) and II(C)(2)(i)		

4. *Description of identification and detection methods*

(a) Techniques used to detect the GMO in the environment
(b) Techniques used to identify the GMO

F. **Information relating to the release**

1. *Purpose of the release (including any significant potential environmental benefits that may be expected)*

2. *Is the site of the release different from the natural habitat or from the ecosystem in which the recipient or parental organism is regularly used, kept or found?*

Yes ☐	No ☐
If *yes*, specify	

3. *Information concerning the release and the surrounding area*

(a) Geographical location (administrative region and where appropriate grid reference):
(b) Size of the site (m^2): (i) actual release site (m^2): (ii) wider release area (m^2):
(c) Proximity to internationally recognised biotopes or protected areas (including drinking water reservoirs), which could be affected:
(d) Flora and fauna including crops, livestock and migratory species which may potentially interact with the GMO

4. *Method and amount of release*

(a) Quantities of GMOs to be released:
(b) Duration of the operation:
c) Methods and procedures to avoid and/or minimise the spread of the GMOs beyond the site of the release

5. *Short description of average environmental conditions (weather, temperature, etc.)*

6. *Relevant data regarding previous releases carried out with the same GMO, if any, specially related to the potential environmental and human health impacts from the release*

G. **Interactions of the GMO with the environment and potential impact on the environment, if significantly different from the recipient or parent organism**

1. *Name of target organisms (if applicable)*

(i) order and/or higher taxon (for animals)
(ii) family name (for plants)
(iii) genus
(iv) species
(v) subspecies
(vi) strain
(vii) cultivar/breeding line
(viii) pathovar
(ix) common name

2. *Anticipated mechanism and result of interaction between the released GMOs and the target organism (if applicable)*

3. *Any other potentially significant interactions with other organisms in the environment*

4. *Is post-release selection such as increased competitiveness, increased invasiveness for the GMO likely to occur?*

Yes ☐	No ☐	Not known ☐
Give details		

5. *Types of ecosystems to which the GMO could be disseminated from the site of release and in which it could become established*

6. *Complete name of non-target organisms which (taking into account the nature of the receiving environment) may be unintentionally significantly harmed by the release of the GMO*

(i) order and/or higher taxon (for animals)
(ii) family name (for plants)
(iii) genus
(iv) species
(v) subspecies
(vi) strain
(vii) cultivar/breeding line
(viii) pathovar
(ix) common name

7. *Likelihood of genetic exchange in vivo*

(a) from the GMO to other organisms in the release ecosystem:
(b) from other organisms to the GMO:
(c) likely consequences of gene transfer:

8. *Give references to relevant results (if available) from studies of the behaviour and characteristics of the GMO and its ecological impact carried out in simulated natural environments (e.g. microcosms, etc.):*

9. *Possible environmentally significant interactions with biogeochemical processes (if different from the recipient or parental organism)*

H. **Information relating to monitoring**

1. *Methods for monitoring the GMOs*

2. *Methods for monitoring ecosystem effects*

3. *Methods for detecting transfer of the donated genetic material from the GMO to other organisms*

4. *Size of the monitoring area (m²)*

5. *Duration of the monitoring*

6. *Frequency of the monitoring*

I. **Information on post-release and wate treatment**

1. *Post-release treatment of the site*

2. *Post-release treatment of the GMOs*

3(a) Type and amount of waste generated

3(b) Treatment of waste

J. **Information on emergency response plans**

1. *Methods and procedures for controlling the dissemination of the GMO(s) in case of unexpected spread*

2. *Methods for removal of the GMO(s) of the areas potentially affected*

3. *Methods for disposal or sanitation of plants, animals, soils, etc. that could be exposed during or after the spread*

4. *Plans for protecting human health and the environment in the event of an undesirable effect*

PART 2

SUMMARY NOTIFICATION INFORMATION FORMAT FOR THE RELEASE OF GENETICALLY MODIFIED HIGHER PLANTS

(ANGIOSPERMAE AND GYMNOSPERMAE)

A. General information

1. *Details of notification*

(a) Notification number
(b) Date of acknowledgement of notification
(c) Title of the project
(e) Proposed period of release

2. *Notifier*

(a) Name of institute or company

3. *Is the same GMPt release planned elsewhere, inside or outside the Community [in conformity with Article 6(1)] by the same notifier?*

Yes ☐	No ☐
If yes, insert the country code(s):	

4. *Has the same GMPt been notified for release elsewhere, inside or outside the Community, by the same notifier?*

Yes ☐	No ☐
If yes, notification number:	

B. Information of the genetically modified plant

1. *Identity of the recipient or parental plant*

(a) Family name
(b) Genus
(c) Species
(d) Subspecies (if applicable)
(e) Cultivar/breeding line (if applicable)
(f) Common name

2. *Description of the traits and characteristics which have been introduced or modified, including marker genes and previous modifications*

3. *Type of the genetic modification*

(a) Insertion of genetic material
(b) Deletion of genetic material
(c) Base substitution
(d) Cell fusion
(e) Other, specify

4. *In the case of insertion of genetic material, give the source and intended function of each constituent fragment of the region to be inserted*

5. *In the case of deletion or other modification of genetic material, give information on the function of the deleted or modified sequences*

6. *Brief description of the method used for the genetic modification*

7. *If the recipient or parental plant is a forest tree species, describe ways and extent of dissemination and specific factors affecting dissemination*

C. **Information relating to the experimental release**

1. *Purpose of the release (including any relevant information available at this stage) such as agronomic purposes, test of hybridisation, changed survivability or dissemination, test of effects on target or non-target organisms*

2. *Geographical location of the release site*

3. *Size of the site (m^2)*

4. *Relevant data regarding previous releases carried out with the same GM-plant, if any, specifically related to the potential environmental and human health impacts from the release*

D. **Summary of the potential environmental impact of the release of the GMPTS in accordance with Annex II, D2 to Directive 2001/18/EC**

Note especially if the introduced traits could directly or indirectly confer an increased selective advantage in natural environments; also explain any significant expected environmental benefits

E. **Brief description of any measures taken by the notifier for the control of risks including isolation designed to limit dispersal, for example for monitoring and post-harvest monitoring proposals**

F. **Summary of planned field trials designed to gain new data on the environmental and human health impact of the release (where appropriate)**

DECISION No 2/2002 OF THE EU-ROMANIA ASSOCIATION COUNCIL

of 14 May 2002

adopting the terms and conditions for Romania's participation in the Community Fiscalis programme

(2002/814/EC)

THE ASSOCIATION COUNCIL,

Having regard to the Europe Agreement establishing an association between the European Communities and their Member States, of the one part, and Romania, of the other part [1],

Having regard to the Additional Protocol [2] to the Europe Agreement concerning Romania's participation in Community programmes, and in particular Articles 1 and 2 thereof,

Whereas:

(1) According to Article 1 of the Additional Protocol, Romania may participate in Community framework programmes, specific programmes, projects or other actions dealing with a wide range of areas.

(2) Article 1 also provides that fields of Community activities other than those listed therein may be included too.

(3) According to Article 2 of the Additional Protocol, the Association Council is to decide upon the terms and conditions for Romania's participation in the activities referred to in Article 1 thereof,

HAS DECIDED AS FOLLOWS:

Article 1

Romania shall participate in the Community Fiscalis programme (hereinafter referred to as 'the Programme') according to the terms and conditions set out in Annexes I and II which shall form an integral part of this Decision.

Article 2

This Decision shall apply for the duration of the remaining lifetime of the Programme. Nevertheless, should the Community decide to extend the duration without any substantial change within the Programme, this Decision would also be extended correspondingly and automatically if no Party denounces it.

Article 3

This Decision shall enter into force the day of its adoption by the Association Council.

Done at Brussels, 14 May 2002.

For the Association Council

The President

M. GEOANA

[1] OJ L 357, 31.12.1994, p. 2.
[2] OJ L 317, 30.12.1995, p. 40.

ANNEX I

TERMS AND CONDITIONS FOR ROMANIA'S PARTICIPATION IN THE FISCALIS PROGRAMME

1. As stated in Article 7 of Decision No 888/98/EC of the European Parliament and of the Council of 30 March 1998 establishing a programme of Community action to ameliorate the indirect taxation systems of the internal market (Fiscalis programme) [1], Romania's participation in the Fiscalis Programme (hereinafter referred to as the 'Programme') shall take place in accordance with the conditions laid down in the Europe Agreement, the Additional Protocol and insofar as Community law on indirect taxation so permits. Accordingly, Romania's participation in the Programme's activities shall take place under the following conditions:

   — activities envisaged by Article 4 (communication and information-exchange systems, manuals and guides) will be allowed insofar as Community indirect taxation provisions make it possible,

   — activities envisaged by Article 5(1) (exchanges of officials) and (2) (seminars) as well as those envisaged by Article 6 (common training initiative) will be allowed under the conditions laid down in these Articles,

   — activities envisaged by Article 5(3) (multilateral controls) will not be allowed, as the Community legal framework for cooperation in this domain, pursuant to Directive 77/799/EEC [2] and Regulation (EEC) No 218/92 [3], is applicable only to countries which are Member States of the European Union.

2. The terms and conditions for the submission, assessment and selection of applications for seminars and exchanges related to officials of Romania shall be the same as those applicable to officials of the 15 national administrations of the Member States of the European Union.

3. Annex II establishes the financial contribution to the general budget of the European Union that Romania will have to pay at the beginning of every financial year to cover the costs resulting from its participation in the Programme, from 2001 to 2002. The Association Committee is entitled to adapt this contribution whenever necessary in accordance with the principles laid down in Article 110(2) of the Europe Agreement between the European Communities and their Member States, of the one part, and Romania, of the other part.

4. Representatives of Romania will participate, as observers and for the points which concern them, in the Standing Committee on Administrative Cooperation in the field of Indirect Taxation provided for in Article 11(1) of Decision No 888/98/EC. This Committee shall meet without the presence of representatives of Romania for the rest of the points, as well as at the time of voting.

5. The Member States of the European Union and Romania will make every effort, within the framework of the existing provisions, to facilitate the free movement and residence of all persons eligible under the Programme moving between Romania and the EU Member States for the purpose of participating in activities covered by the Decision.

6. Without prejudice to the responsibilities of the Commission of the European Communities and the Court of Auditors of the European Communities in relation to the monitoring and evaluation of the Programme pursuant to Decision No 888/98/EC, the participation of Romania in the Programme will be continuously monitored on a partnership basis involving Romania and the Commission. Romania will submit the necessary reports to the Commission and take part in other specific activities set out by the Community in that context.

7. The language to be used as regards the application process, contracts, reports to be submitted and other administrative arrangements for the Programme, will be one of the official languages of the European Community.

8. The Community and Romania may terminate activities under this Decision at any time upon 12 months' notice in writing. Activities in progress at the time of termination shall continue until their completion under the conditions laid down in this Decision.

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[1] OJ L 126, 28.4.1998, p. 1.
[2] OJ L 336, 27.12.1977, p. 15. Directive as last amended by the 1994 Act of Accession.
[3] OJ L 24, 1.2.1992, p. 1.

ANNEX II

ROMANIA'S FINANCIAL CONTRIBUTION TO THE FISCALIS PROGRAMME

1. Romania's financial contribution will be added to the amount available each year in the general budget of the European Union for commitment appropriations to meet the Commission's financial obligations stemming from work to be carried out for the implementation, management and operation of the Fiscalis programme (hereinafter referred to as the 'Programme').

2. The financial contribution has been calculated considering an average daily allowance of EUR 146 and an average travel allowance of EUR 695 representing costs incurred for participating in seminars and exchanges. It is estimated for the calculation of the financial contribution that Romania will participate in 15 seminars and 25 exchanges, as an average number of activities per year. The financial contribution may be adjusted at the beginning of each year to take into account the actual number of activities in which Romania plans to participate during that year. The adjustment will take place by means of the required call for funds that Romania will receive from the Commission, as referred to under point 6.

3. Romania's contribution will be EUR 109 638 for every single year of participation, unless determined otherwise within the conditions under point 2. From this sum, an amount of EUR 7 173 will cover supplementary costs of an administrative nature related to the management of the Programme by the Commission stemming from Romania's participation.

4. Romania will pay the annual supplementary costs of an administrative nature referred to under point 3 from its national budget.

5. Romania will pay 50 % of the annual remaining cost of its participation from its national budget for the year 2001; 60 % for the year 2002.

   Subject to PHARE separate programming procedures, the remaining 50 % will be paid from Romania's annual PHARE allocations, subject to the availability of the relevant budgetary appropriations, for the year 2001; 40 % for the year 2002. The requested PHARE funds will be transferred to Romania by means of a separate Financing Memorandum. Together with the part coming from Romania's State budget, these funds will constitute Romania's national contribution, out of which it will make payments in response to annual calls for funds from the Commission.

6. The Financial Regulation of 21 December 1977 applicable to the general budget of the European Union ([1]) will apply, in particular to the management of Romania's contribution.

   Upon entry into force of this Decision, the Commission will send to Romania one or more call(s) for funds corresponding to its contribution to the costs of the activities for the current year. The contribution will be expressed in euro and paid into a euro bank account of the Commission.

   Romania will pay its contribution according to the call for funds:

   — for the part financed from its national budget, at the latest three months after the call for funds is sent out,

   — for the part financed from PHARE, at the latest within a period of 30 days after the corresponding PHARE funds have been sent to the country.

   Any delay in the payment of the contribution shall give rise to the payment of interest by Romania on the outstanding amount from the due date. The interest rate corresponds to the rate applied by the European Central Bank, on the due date, for its operations in euro, increased by 1,5 percentage points.

7. The daily subsistence allowances are applicable to all participants in the Programme and are determined on a country per country basis by the Commission. Romania will receive a first budget advance from the Commission at the beginning of every year. A second advance may be paid at the middle of the year depending on the actual participation of Romania in the Programme activities and on the expected participation for the rest of the year. The Romanian department concerned will use these advances to pay for the travel tickets and daily subsistence allowances for Romania participants.

8. Travel costs and subsistence costs incurred by representatives and experts of Romania for the purposes of taking part as observers in the work of the committee referred to in point 4 of Annex I, shall be reimbursed by the Commission on the same basis as for the Member States of the European Union.

([1]) OJ L 356, 31.12.1977, p. 1. Regulation as last amended by Regulation (EC) No 762/2001 (OJ L 111, 20.4.2001, p. 1).

DECISION No 1/2002 OF THE EU-LITHUANIA ASSOCIATION COUNCIL

of 18 June 2002

adopting the general terms and conditions for the participation of the Republic of Lithuania in Community programmes

(2002/815/EC)

THE ASSOCIATION COUNCIL,

Having regard to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Republic of Lithuania, of the other part [1], and in particular Article 110 thereof,

Whereas:

(1) According to Article 110 of the Europe Agreement and Annex XX thereto, Lithuania may participate in Community framework programmes, specific programmes, projects or other actions dealing with a wide range of fields. It also provides for the addition of other Community fields.

(2) According to the said Article 110, the terms and conditions for the participation of Lithuania in these activities should be decided by the Association Council.

(3) The specific participating conditions, including financial implications, in each Community programme should be determined between the Commission of the European Communities and the competent authorities of Lithuania,

HAS DECIDED AS FOLLOWS:

Article 1

Lithuania may participate in all Community programmes opened to participation of candidate countries of central and eastern Europe, in accordance with the provisions adopting these programmes.

Article 2

Lithuania shall contribute financially to the European Union's general budget corresponding to the specific programmes in which Lithuania participates.

Article 3

Lithuania's representatives shall be allowed to take part, as observers and for the points which concern Lithuania, in the management committees responsible for monitoring the programmes to which Lithuania contributes financially.

Article 4

Projects and initiatives submitted by participants from Lithuania shall be subject, as far as possible, to the same conditions, rules and procedures pertaining to the programmes concerned, as are applied to Member States.

Article 5

The specific terms and conditions, including financial contribution, regarding the participation of Lithuania in each particular programme shall be determined between the Commission and the competent authorities of Lithuania. Should Lithuania apply for Community external assistance pursuant to Council Regulation (EEC) No 3906/89 of 18 December 1989 on economic aid to certain countries of central and eastern Europe [2], such specific terms and conditions may be determined on the basis of a Financing Memorandum.

Article 6

This Decision shall apply for an indeterminate period.

It may be denounced by either Party by giving six months' notice in writing.

Article 7

No later than three years after the date of the entry into force of this Decision, and every three years thereafter, the Association Council may review the implementation of this Decision on the basis of the actual participation of Lithuania in one or more Community programmes.

Article 8

This Decision shall enter into force on the first day of the month following its adoption by the Association Council.

Done at Brussels, 18 June 2002.

For the Association Council

The President

J. PIQUÉ I CAMPS

[1] OJ L 51, 20.2.1998, p. 3.

[2] OJ L 375, 23.12.1989, p. 11. Regulation as last amended by Regulation (EC) No 2666/2000 (OJ L 306, 7.12.2000, p. 1).

COMMISSION

COMMISSION DECISION

of 14 October 2002

amending Decision 1999/187/EC on the clearance of accounts presented by the Member States in respect of the expenditure for 1995 of the Guarantee Section of the European Agricultural Guidance and Guarantee Fund (EAGGF)

(notified under document number C(2002) 3771)

(Only the Greek text is authentic)

(2002/816/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 729/70 of 21 April 1970 on the financing of the common agricultural policy [1], as last amended by Regulation (EC) No 1287/95 [2], and in particular Article 5(2) thereof,

After consulting the Committee of the European Agricultural Guidance and Guarantee Fund,

Whereas:

(1) By Decision 2002/524/EC [3], the Commission imposed a financial correction on Greece because of shortcomings in its system for controlling arable crops in the financial years 1996 to 1999. As the same shortcomings existed before then, a similar financial correction must be imposed for the 1995 financial year. To this end, it is necessary to amend Commission Decision 1999/187/EC of 3 February 1999 on the clearance of the accounts presented by the Member States in respect of the expenditure for 1995 of the Guarantee Section of the European Agricultural Guidance and Guarantee Fund (EAGGF), as last amended by Decision 2000/448/EC.

(2) This Decision is without prejudice to any financial consequences which may be determined in any subsequent clearance of accounts in respect of State aid or infringements for which the procedures initiated under Articles 88 and 226 of the Treaty are now in progress or were terminated after 15 May 2002.

(3) This Decision is without prejudice to any financial consequences drawn by the Commission during a subsequent accounts clearance procedure from current investigations under way at the time of this Decision, from irregularities within the meaning of Article 8 of Regulation (EC) No 729/70 or from judgments of the Court of Justice in cases pending on 15 May 2002 and relating to matters covered by this Decision,

HAS ADOPTED THIS DECISION:

Article 1

The sections of the Annex to Decision 1999/187/EC relating to Greece are replaced by the Annex to this Decision.

Article 2

The additional amount of GRD – 1 827 922 367 arising under point 3 of the Annex and chargeable by virtue of this Decision shall be taken into account as part of the expenditure referred to in Article 4(1) of Commission Regulation (EC) No 296/96 [4] for the month of August 2002.

Article 3

This Decision is addressed to the Hellenic Republic.

Done at Brussels, 14 October 2002.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ L 94, 28.4.1970, p. 13.
[2] OJ L 125, 8.6.1995, p. 1.
[3] OJ L 170, 29.6.2002, p. 77.
[4] OJ L 39, 17.2.1996, p. 5.

ANNEX

GREECE

EAGGF Guarantee Section expenditure Financial year: 1995	(GRD)
1. **Expenditure recognised**	
(a) Expenditure declared by the Member State in respect of the present clearance	760 186 802 122
(b) Expenditure declared during the preceding year but excluded from that clearance	14 056 031 234
(c) Expenditure declared, excluded from the present clearance	0
(d) Expenditure declared, which is already subject to at clearance decision	0
(e) Expenditure declared, coming under the present clearance ((a) + (b) + (c) + (d))	774 242 833 356
(f) Expenditure disallowed	– 26 082 443 724
(g) Total expenditure recognised ((e) + (f))	748 160 389 632
2. **Expenditure charged**	
(a) Expenditure charged in respect of the present year	758 830 725 324
(b) Expenditure charged in respect of the preceding year, but excluded from that clearance	14 056 031 234
(c) Expenditure charged in respect of the present year, but excluded from the present clearance	0
(d) Expenditure charged in respect of the present year, which is already subject to a clearence decision	0
(e) Expenditure charged to a later exercice	0
(f) Total expenditure charged, coming under the present clearance ((a) + (b) + (c) + (d) + (e))	772 886 756 558
3. **Expenditure chargeable to or payable to the Member State following clearance of the accounts (2f – 1g)**	24 726 366 926