ISSN 0378-6978

Official Journal

of the European Communities

L 74

Volume 43

23 March 2000

English edition

Legislation

Contents

(Continued overleaf)

EN

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

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

Contents (continued)

I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 611/2000

of 22 March 2000

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 23 March 2000.

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

Done at Brussels, 22 March 2000.

For the Commission

Franz FISCHLER

Member of the Commission

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

ANNEX

to the Commission Regulation of 22 March 2000 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	154,0
	204	109,3
	999	131,7
0707 00 05	052	109,0
	068	130,6
	628	146,6
	999	128,7
0709 10 00	220	309,8
	999	309,8
0709 90 70	052	109,0
	204	48,8
	628	116,0
	999	91,3
0805 10 10, 0805 10 30, 0805 10 50	052	48,3
	204	35,7
	212	38,1
	220	31,0
	600	41,1
	624	52,1
	999	41,0
0805 30 10	052	33,7
	220	71,3
	600	66,1
	999	57,0
0808 10 20, 0808 10 50, 0808 10 90	039	90,1
	388	95,2
	400	93,8
	404	88,2
	508	83,1
	512	95,2
	528	99,7
	720	56,6
	999	87,7
0808 20 50	052	77,4
	388	72,3
	400	106,6
	512	69,8
	528	71,6
	720	71,3
	999	78,2

(1) Country nomenclature as fixed by Commission Regulation (EC) No 2543/1999 (OJ L 307, 2.12.1999, p. 46). Code '999' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 612/2000
of 22 March 2000
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 2038/1999 of 13 September 1999 on the common organization of the market in sugar [1],

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 [2], and in particular Articles 1(2) and 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 [3]. 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 23 March 2000.

[1] OJ L 252, 25.9.1999, p. 1.
[2] OJ L 141, 24.6.1995, p. 12.
[3] 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, 22 March 2000.

For the Commission
Franz FISCHLER
Member of the Commission

ANNEX

fixing the representative prices and additional import duties applying 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)	7,76	0,00	—
1703 90 00 (1)	7,94	—	0,27

(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 613/2000
of 22 March 2000
altering the export refunds on white sugar and raw sugar exported in the natural state

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2038/1999 of 13 September 1999 on the common organisation of the markets in the sugar sector [1], and in particular the third subparagraph of Article 18(5) thereof,

Whereas:

(1) The refunds on white sugar and raw sugar exported in the natural state were fixed by Commission Regulation (EC) No 558/2000 [2],

(2) It follows from applying the detailed rules contained in Regulation (EC) No 558/2000 to the information known to the Commission that the export refunds at present in force should be altered to the amounts set out in the Annex hereto,

HAS ADOPTED THIS REGULATION:

Article 1

The export refunds on the products listed in Article 1(1)(a) of Regulation (EC) No 2038/1999, undenatured and exported in the natural state, as fixed in the Annex to Regulation (EC) No 558/2000 are hereby altered to the amounts shown in the Annex hereto.

Article 2

This Regulation shall enter into force on 23 March 2000.

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

Done at Brussels, 22 March 2000.

For the Commission
Franz FISCHLER
Member of the Commission

[1] OJ L 252, 25.9.1999, p. 1.
[2] OJ L 68, 16.3.2000, p. 10.

ANNEX

to the Commission Regulation of 22 March 2000 altering the export refunds on white sugar and raw sugar exported in its unaltered state

Product code	Amount of refund
	— EUR/100 kg —
1701 11 90 9100	43,23 (1)
1701 11 90 9910	42,81 (1)
1701 11 90 9950	(2)
1701 12 90 9100	43,23 (1)
1701 12 90 9910	42,81 (1)
1701 12 90 9950	(2)
	— EUR/1 % of sucrose × 100 kg —
1701 91 00 9000	0,4699
	— EUR/100 kg —
1701 99 10 9100	46,99
1701 99 10 9910	48,75
1701 99 10 9950	46,54
	— EUR/1 % of sucrose × 100 kg —
1701 99 90 9100	0,4699

(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 19 (4) of Regulation (EC) No 2038/1999.

(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).

COMMISSION REGULATION (EC) No 614/2000

of 22 March 2000

fixing the maximum export refund for white sugar for the 32nd partial invitation to tender issued within the framework of the standing invitation to tender provided for in Regulation (EC) No 1489/1999

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2038/1999 of 13 September 1999 on the common organisation of the markets in the sugar sector [1], and in particular the second subparagraph of Article 18(5) thereof,

Whereas:

(1) Commission Regulation (EC) No 1489/1999 of 7 July 1999 on a standing invitation to tender to determine levies and/or refunds on exports of white sugar [2], requires partial invitations to tender to be issued for the export of this sugar.

(2) Pursuant to Article 9(1) of Regulation (EC) No 1489/1999 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 32nd 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 32nd partial invitation to tender for white sugar issued pursuant to Regulation (EC) No 1489/1999 the maximum amount of the export refund is fixed at EUR 52,193 kg.

Article 2

This Regulation shall enter into force on 23 March 2000.

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

Done at Brussels, 22 March 2000.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ L 252, 25.9.1999, p. 1.
[2] OJ L 172, 8.7.1999, p. 27.

COMMISSION REGULATION (EC) No 615/2000

of 22 March 2000

fixing the minimum selling prices for beef put up for sale under the invitation to tender referred to in Regulation (EC) No 397/2000

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1254/1999 of 17 May 1999 on the common organisation of the market in beef and veal [1], and in particular Article 28(2) thereof,

Whereas:

(1) Tenders have been invited for certain quantities of beef fixed by Commission Regulation (EC) No 397/2000 [2].

(2) Pursuant to Article 9 of Commission Regulation (EEC) No 2173/79 [3], as last amended by Regulation (EC) No 2417/95 [4], the minimum selling prices for meat put up for sale by tender should be fixed, taking into account tenders submitted.

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

HAS ADOPTED THIS REGULATION:

Article 1

The minimum selling prices for beef for the invitation to tender held in accordance with Regulation (EC) No 397/2000 for which the time limit for the submission of tenders was 13 March 2000 are as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 23 March 2000.

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

Done at Brussels, 22 March 2000.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ L 160, 26.6.1999, p. 21.
[2] OJ L 50, 23.2.2000, p. 3.
[3] OJ L 251, 5.10.1979, p. 12.
[4] OJ L 248, 14.10.1995, p. 39.

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

Estado miembro Medlemsstat Mitgliedstaat Κράτος μέλος Member State État membre Stato membro Lidstaat Estado-Membro Jäsenvaltio Medlemsstat	Productos Produkter Erzeugnisse Προϊόντα Products Produits Prodotti Producten Produtos Tuotteet Produkter	Precio mínimo expresado en euros por tonelada Mindstepriser i EUR/ton Mindestpreise ausgedrückt in EUR/Tonne Ελάχιστες πωλήσεις εκφραζόμενες σε Ευρώ ανά τόνο Minimum prices expressed in EUR per tonne Prix minimaux exprimés en euros par tonne Prezzi minimi espressi in euro per tonnellata Minimumprijzen uitgedrukt in euro per ton Preço mínimo expresso em euros por tonelada Vähimmäishinnat euroina tonnia kohden ilmaistuna Minimipriser i euro per ton

a) **Carne con hueso — Kød, ikke udbenet — Fleisch mit Knochen — Κρέατα με κόκαλα — Bone-in beef — Viande avec os — Carni non disossate — Vlees met been — Carne com osso — Luullinen naudanliha — Kött med ben**

DEUTSCHLAND	— Vorderviertel I	1 095
	— Hinterviertel I	1 803
	— Vorderviertel II	1 030
	— Hinterviertel II	1 753
ESPAÑA	— Cuartos traseros	2 164
PORTUGAL	— Quasrtos dianteiros	—
	— Quartos traseiros	—

b) **Carne deshuesada — Udbenet kød — Fleisch ohne Knochen — Κρέατα χωρίς κόκαλα — Boneless beef — Viande désossée — Carni senza osso — Vlees zonder been — Carne desossada — Luuton naudanliha — Benfritt kött**

IRELAND	— Intervention fillet (INT 15)	14 755
	— Intervention striploin (INT 17)	8 401
	— Intervention rump (INT 16)	4 380
	— Intervention silverside (INT 14)	3 539
	— Intervention flank (INT 18)	1 211
	— Intervention forerib (INT 19)	3 917
	— Intervention shoulder (INT 22)	1 913
	— Intervention brisket (INT 23)	1 337
	— Intervention thick flank (INT 12)	3 205
	— Intervention forequarter (INT 24)	1 827
	— Intervention topside (INT 13)	3 334
	— Intervention shin (INT 21)	1 721
	— Intervention thank (INT 11)	1 721

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 10 November 1999

on the aid scheme which Italy intends implementing to assist small and medium-sized enterprises in Objective 1 regions

(notified under document number C(1999) 3867)

(Only the Italian text is authentic)

(2000/235/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular the first subparagraph of Article 88(2) thereof,

Having called on interested parties to submit their comments in accordance with the abovementioned provisions [1] and having regard to those comments,

Whereas:

I. **Procedure**

(1) By letter of 10 April 1997, the Permanent Representation of Italy notified the Commission, in accordance with Article 88(3) of the Treaty, of a draft amendment to the CIPE (Interministerial Committee for Economic Planning) Decision on the rules for applying the Guarantee Fund for SMEs in Objective 1 regions provided for in Article 2 of Law 341 of 8 August 1995.

(2) Examination of the measures in question was divided up as follows:

As regards Aid N 249/A/97, in the light of Articles 87 and 88 of the Treaty (Commission letter SG(97)D/7216 of 25 August 1997), the Commission examined and authorised the amendments to the measure covered by the CIPE Decision of 10 May 1995 applying to sectors other than agriculture, fisheries and aquaculture.

The application in the agricultural, fisheries and aquaculture sectors of the measures provided for in Article 2 of Decree-Law 244 of 23 June 1995 laying down the general principles governing the Fund, ratified in Law 341 of 8 August 1995 (hereinafter referred to as 'Law 341/1995'), and in the CIPE Decision of 10 May 1995 laying down rules for the application of Law 341/95, as amended by the provisions notified by the Italian authorities in their letter of 10 April 1997, was examined by the Commission in connection with Aid N 249/B/97.

(3) Additional information was requested by telexes 52140 of 5 May 1997, 31756 of 5 August 1997 and 14/3786 of 19 September 1997. By telex 2326 of 12 January 1998, the Commission called on the Italian authorities to reply to the telex of 19 September 1997.

Additional information was forwarded by letter of the Permanent Representation of Italy of 2 June 1997, recorded as received on 5 June 1997, by fax of 21 July 1997, recorded as received on 22 July 1997, by letter of 27 November 1997, recorded as received on 3 December 1997, and by letter of 18 February 1998, recorded as received on 4 March 1998.

(4) By letter of 20 May 1998 (SG(98)D/4034), the Commission informed the Italian authorities of its decision to initiate the procedure provided for in Article 88(2) of the EC Treaty in respect of the application of those measures in the agricultural, fisheries and aquaculture sectors.

(5) The Commission decision to initiate the procedure was published in the *Official Journal of the European Communities* [2]. The Commission invited interested parties to submit their comments on the aid measure.

[1] OJ C 245, 5.8.1998, p. 3.

[2] See footnote 1.

(6) The Italian authorities submitted their observations to the Commission by letters of 24 June and 26 November 1998 and 9 March and 11 May 1999. No comments were received from other Parties. The Commission did, however, receive a letter from a potential beneficiary under the aid scheme, protesting at the delay in authorising it.

(7) This Decision relates solely to the applicability of the measures concerned to the sectors referred to in Annex I to the Treaty (i.e. agriculture, whether primary production or the processing and marketing of agricultural products, fisheries and aquaculture).

II. **Description**

(8) Article 2 of Law 341/1995 and the relevant rules of application laid down by the CIPE Decision of 10 May 1995 and subsequent amendments provide for a system of guarantees for small and medium-sized enterprises operating in Objective 1 areas in Italy. The scheme will apply until 31 December 1999. It provides for guarantees and interest rate subsidies on debt consolidation operations, guarantees for equity loans, and guarantees for contributions from banks and other public or private institutions to the capital of SMEs. Beneficiaries may receive aid in the form of debt consolidation and equity investments in combination. The budget is ITL 3 500 billion (approximately EUR 1 750 million). The aim of the measure is to permit one-off consolidation of short-term debts by reducing the cost of loans available on the market and to facilitate SMEs' access to new forms of financing by promoting their capitalisation.

(9) In order to qualify for guarantees for debt consolidation operations, the consolidation must extend over a period of six years and repayment can be made up to one year early. The Fund provides the banks concerned with a guarantee covering 60 % of the consolidated capital at a fee of 2 % of the latter. The guarantee cannot be called upon if the undertaking is declared bankrupt within 18 months of the granting of the financing. Where bankruptcy occurs after that period, the guarantee covers 60 % of the bank loan outstanding at the time the undertaking becomes insolvent. The guarantee is paid when debt recovery procedures are initiated. In the interests of the Fund, the banks are also responsible for following the debt recovery procedures. The Fund may also grant the undertakings an interest rate rebate of 4,5 percentage points on the annual rate for the consolidation operation. The rebate may not exceed 40 % of the reference rate applying at the time the contract covering the consolidation is concluded.

(10) Consolidation must cover the smallest of the following amounts:

(a) the short-term debt outstanding at 30 September 1994;

(b) outstanding short-term debt as set out in the latest balance sheet;

(c) 10 times the undertaking's turnover as set out in the latest balance sheet.

To qualify for the aid, the permanent financial resources must not represent less than 0,75 % of the tangible and intangible assets after consolidation. In no case may the consolidated capital be more than 10 times the undertaking's turnover. In accordance with Article 88(3) of the EC Treaty, the Commission must be notified of any cases where consolidation involving individual undertakings exceeds ITL 40 billion (EUR 20 million).

(11) The Fund may also provide guarantees of a maximum of 10 years' duration covering up to 60 % of equity loans advanced by banks or other institutions at a flat-rate fee of 1 % of the principal. Such guarantees cannot be called upon if the undertaking is declared bankrupt within 30 months of the granting of the loan. The rate of interest on the loan is agreed between the bank and the undertaking. The Fund may also grant guarantees on public and private equity investments in SMEs, with the exception of equity investments by institutions that are completely controlled, either directly or indirectly, by the State. The fee for the guarantee is 0,75 % of the investment, which must be for a maximum of five years.

(12) As regards debt consolidation loans and guarantees as referred to in recitals 8 and 9, in its decision to initiate the procedure the Commission noted that, on the basis of the information provided by the Italian authorities, it was not possible to determine whether the debit-consolidation measures were intended for undertakings that are viable or whether they were intended for the rescue of undertakings in difficulty. Where the debt consolidation measures were intended for viable companies, the Commission noted that they would appear to constitute operating aid, which is prohibited in the agricultural, fisheries and aquaculture sectors. In so far as the debt consolidation measures were intended for undertakings in difficulty, the Commission noted that they did not appear to meet the conditions laid down in the 1994 and 1997 Community guidelines on State aid for rescuing and restructuring firms in difficulty [3]. As regards rescue aid, the Commission noted in particular that the loans and guarantees provided for were of greater than six months' duration and were not granted at market rates. As regards aid for restructuring, the Commission noted that the beneficiaries were not required to present a restructuring plan and that the measures could therefore prove not to be compatible with the guidelines.

[3] OJ C 368, 23.12.1994, p. 12 and OJ C 283, 19.9.1997, p. 2.

(13) As regards guarantees on equity loans granted by banks and guarantees on public or private equity investments in undertakings, the Commission noted that such measures would constitute aid in so far as they allowed the beneficiaries to obtain access to equity capital at below normal market rates. Furthermore, where guarantees were granted to companies in difficulty, the entire amount guaranteed should be considered aid. Where such aid was granted to viable companies in order to finance specific investments by the beneficiary, the Commission noted that the aid could only be considered compatible with the common market if it met the specific conditions applicable to the sector concerned. Aid that is granted to viable companies and is not linked to specific investments is considered to constitute operating aid, which is prohibited in the agricultural, fisheries and aquaculture sectors.

(14) In its decision to open the procedure, the Commission also drew attention to point 20 of the CIPE Decision of 20 May 1995, as amended by the notification, which contains a sentence to the following effect.

'In its capacity as a public financial institution, in accordance with Law 662/96 and solely in the agri-food sector, RIBS SpA may take part in operations to increase capital; it shall present an annual report on operations carried out and developments in them to the Ministry of Agricultural Resources, which shall inform the CIPE.'

(15) The Commission pointed out that operations carried out by RIBS SpA, a public financial institution for the agri-food sector (hereinafter referred to as 'RIBS'), were not guaranteed by the Fund and took note of the Italian authorities' declaration to the effect that such operations were carried out in accordance with Article 2(132) of Law 662/96 (1997 Budget Law), i.e. at market rates, and did not constitute aid. The Commission observed, however, that contrary to its Communication on the provision of capital by public authorities [4], it had received no information from the Italian authorities about such operations, despite the fact that it had requested the Italian authorities to provide the relevant information.

III. **Remarks from Italy**

(16) The Italian authorities' written observations relate both to questions of procedure and to matters of substance.

Procedure

(17) As regards procedure, the Italian authorities first point out that the general system of regional aid, including aid awarded under the Guarantee Fund for SMEs operating in Objective 1 areas, was notified to the European Commission in accordance with Article 88(3) of the EC Treaty by letters of the Ministry of the Treasury, the Budget and Economic Planning of 16 December 1994 and 17 and 26 January 1995. The system was approved (aid N 40/95) by the Commission Decision of 1 March 1995, notified by letter SG(95)D/3693 of 24 March 1995.

(18) By letter of 31 May 1995, the national authorities notified the Permanent Representation of the CIPE Decision of 10 May 1995 on the criteria, rules of application and operating procedures for the Guarantee Fund for SMEs (aid N 662/95). In letter SG(95)D/11306 of 7 November 1995, the Commission stated that the abovementioned CIPE Decision fell within the scope — approved by the Decision of 1 March 1995 — of the Guarantee Fund and that it complied with the limits and requirements laid down in that Decision.

(19) By letter of 28 March 1997, the Ministry of the Treasury, the Budget and Economic Planning notified the Commission of a draft CIPE Decision amending the detailed rules applicable to the Fund. By Communication SG(97)D/7216 of 25 August 1997, the Commission noted that the proposed amendments fell with the scope of the Guarantee Fund — approved by the Decision of 1 March 1995 — and stated that a separate Commission Decision would be adopted on the application of the scheme to the agricultural, fishing and aquaculture sectors.

(20) The Italian authorities emphasise that the draft scheme was notified in accordance with Article 88(3) of the EC Treaty and was approved by the abovementioned Commission Decision of 1 March 1995 (see recital 17). The detailed implementing rules set out in the CIPE Decision of 10 May 1995 and notified by the abovementioned letter of 31 May 1995 fall, according to the Commission, within the scope of the approved Guarantee Fund (letter SG(95)D/11306 of 7 November 1995). Furthermore, the Commission has decided that the proposed amendments notified to it in the letter of 28 March 1997 fall within the scope of the approved scheme and that the other implementing rules are unchanged (letter SG(97)D/7216 of 25 August 1997).

(21) The Italian authorities therefore conclude that the scheme was notified in accordance with Article 88(3) of the EC Treaty, that it was approved by the Commission, and that the subsequent detailed implementing rules, which were duly notified to the Commission, do not comprise any aid components. Accordingly the Italian authorities conclude that the scheme is an 'existing scheme' within the meaning of the Commission's

[4] Bull. 9-1984.

consolidated procedural rules for State aids. In the case of existing schemes, pursuant to Article 88(1) of the EC Treaty, 'appropriate measures' must be proposed before the Article 88(2) procedure is initiated. The Italian authorities note that no such measures have been put forward in the case in point.

Substance

(22) As regards substance, the Italian authorities first point out that their remarks refer exclusively to debt consolidation operations and not to the acquisition of shareholdings or equity loans, because the Fund has not been used for that purpose.

(23) They emphasise that the aid is intended for firms in regions falling with the scope of Article 87(3)(a) and should therefore qualify, by virtue of the Commission Communication on the method for the application of Article 92(3)(a) and (c) now 87(3)(a) and (c) to national regional aid ([5]), for the exemption applicable to regions covered by Article 87(3)(a).

(24) The Italian authorities point out that the application of the Community guidelines on State aid for rescuing and restructuring firms in difficulty ([6]) to the aid concerned is without prejudice to the application of aid schemes authorised for purposes other than rescues or restructuring, such as regional development or the development of SMEs, provided that aid for rescues or restructuring granted under such schemes fulfils the conditions that the Commission has approved for the schemes (second paragraph of point 2.5 of the guidelines).

(25) The Italian authorities have provided the following comments on the way the scheme operates. The purpose of the Guarantee Fund provided for in Article 2 of Law 341/95 is to rationalise the financial balance of SMEs operating in Objective 1 areas by encouraging proper access to loans and helping to overcome the structural handicaps besetting small firms in those areas as a result of undercapitalisation and the particularly high cost of borrowing recorded in the first half of the 1990s. The aim is accordingly to overcome the major financial obstacles to the development of the productive fabric of southern Italy by granting SMEs one-off benefits that are designed to alleviate their additional financial costs but do not constitute rescue aid or aid for restructuring.

(26) This is accordingly fully in line with the aid scheme authorised by the Commission in its letter of 24 March 1995 setting out detailed rules and operational criteria that are clear, substantiated and limited to SMEs operating in areas that qualify under the exception provided for in Article 87(3)(a) of the EC Treaty. In Molise and Abruzzo (in the latter case until the end of 1996) this scheme has brought real benefits, has been widely utilised and has provided satisfaction, so much so that the funds set aside for the subsidised loans will by all accounts be exhausted by the autumn of 1998, i.e. well before the end of the period originally set, the end of 1999.

(27) Generally speaking, the SMEs that qualify for the subsidised loans must be small firms that:

— are substantially sound and are able to produce a profit, but suffer from a financial imbalance as a result of the interest they have to pay on short-term borrowing,

— have debts towards banking institutions at a certain date (30 September 1994). These must be banking liabilities (there is no provision for consolidating liabilities vis-a-vis suppliers or financial services and factoring firms),

— are economically sound and are not the subject of bankruptcy proceedings,

— have the potential to break even, on the basis of adequate financial flows, and structural indices that match predetermined criteria,

— do not already receive similar benefits and accordingly qualify for aid granted on a one-off basis for a given period that cannot, therefore, be regarded as operating or rescue aid for economically unsound production sectors, or as aid for the restructuring of firms experiencing difficulties,

— throughout the period after qualifying for the benefit, can provide evidence that they are not the subject of an enforcement procedure,

— can also prove, in respect of the interest rate subsidy for the consolidation operation authorised, that they are not involved in any illegal or money laundering operations.

(28) As well as being located in Objective 1 areas, SMEs that operate in agriculture, the processing/marketing of agricultural products, fishing and aquaculture sectors must, in addition to meeting the above requirements, overwhelmingly operate in southern Italian regions specialising in farming (Apulia and Campania).

(29) There are a total of 41 SMEs operating in the agricultural and fisheries sectors who are potential beneficiaries of the aid, accounting for not more than 1 % of the 3 800 applications for aid submitted to the Guarantee Fund up to 31 May. Aid applications submitted by SMEs

([5]) OJ C 212, 12.8.1988, p. 9.
([6]) OJ C 283, 19.9.1997, p. 2.

operating in sectors that have been 'suspended' since November 1997 concern the consolidation of liabilities only, i.e. excluding aid for the acquisition of shareholdings and equity loans, operations for which no subsidies have been granted even for authorised sectors. Aid applications for sectors that have been 'suspended' since November 1997 represent a total of ITL 44,686 billion with an interest-rate subsidy of ITL 5,4 billion, while possible guarantees total ITL 24 billion. None of the 41 SMEs in suspended sectors has received, even temporarily, a subsidy or other form of aid from the Guarantee Fund, and even if the suspension were to be lifted, the aid which might be granted would be limited.

(30) The essential soundness of the 41 SMEs concerned by the benefits provided for in Article 2 of Law 341/95 has already been established by the banks, which paid close attention to the assessment of the applicant firms when they carried out the liability consolidation operation. Moreover, the applications received are for non-automatic aid and take into account the fact that 40 % of the risk is to be borne by the bank and that the Fund guarantee cannot be called on in the first 18 months after payment of the aid.

(31) The Italian authorities emphasise that the SMEs operating in sectors that are still suspended have already concluded costly financing contracts (mostly before November 1997) by taking out mortgages that are already applicable, without receiving any benefits in terms of subsidies and with the prospect, should the suspensions be lifted, of obtaining variable assistance in respect of loans contracted at variable rates, based on reference rates that will undoubtedly be lower than those notified to the European Commission in November 1997.

(32) In the light of the above, the Italian authorities stress the need to authorise and grant assistance, particularly to smaller firms, in order to put them in a better position, thanks to aid paid on a one-off basis, to cope with their financial imbalances, which have represented a particularly high cost in recent years. Recognising and authorising aid, in particular in agriculture, the processing/marketing of agricultural products, the fisheries and aquaculture sectors, will help eliminate the structural factors that are external to firms in southern Italy and that, in so many cases, jeopardise and destroy their attempts to compete freely on the market and distort fair competition between businesses.

(33) In conclusion, the Italian authorities emphasise that this regional aid scheme was approved by the Commission and it only comprises aid granted from the Guarantee Fund which meets the requirements set out in the Commission Decision approving the scheme. They consider that the characteristics of the scheme are specifically linked to the attainment of the objective — provided for in the Pagliarini-Van Miert Agreement and referred to in point 1 of the CIPE Decision — of rationalising the financial balance of the SMEs (which have suffered as a result of the discontinuation of the *Cassa per il Mezzogiorno* and the general economic crisis) and of encouraging proper access to loans by facilitating relations between banks and firms.

(34) As regards RIBS' involvement in the scheme (recitals 14 and 15), the Italian authorities stated in their letter of 11 May 1999 that, on the basis on the Decision at issue (which is not yet operational), RIBS has never carried out operations within the scope of the Guarantee Fund provided for in Article 2 of Law 341/95. Moreover, all the operations carried out by RIBS 'at market rates' (in accordance with Law 662/96) have been notified to the Commission, which has approved one only to date and is currently considering the others. Those operations meet the conditions laid down by the Commission for contributions granted by RIBS under Law 662/96 not to be deemed State aid.

IV. **Evaluation**

Procedure

(35) The Italian authorities maintain that the Commission has committed an error of procedure in initiating the procedure in respect of the application of the scheme in the agricultural and fisheries sectors. They claim that the measures notified (aid N 249/97) concern only one-off amendments to an aid scheme previously authorised by the Commission (aid N 40/95 and N 662/95). As stated in recital 21, since the issues raised by the Commission in its decision to initiate the procedure concern the implementation of an aid scheme already authorised, the Italian authorities consider that before opening the Article 88(2) procedure, the Commission should have proposed 'appropriate measures' to the Italian authorities in accordance with the procedure laid down in Article 88(1) of the Treaty.

(36) Although they do make no explicit reference to it, the Italian authorities appear to have in mind the judgment of the Court of Justice in the *Italgrani* Case [7]. In that case the Court ruled that when the Commission has before it a specific grant of an aid claimed to be made in pursuance of a previously authorised scheme, it cannot at the outset examine it directly in relation to the Treaty. Prior to initiating any procedure, it must first determine whether the aid falls within the scope of the general scheme and satisfies the conditions laid down in the decision approving it. If it did not do so, when it considered an individual aid the Commission could go back on its decision approving the aid scheme, which decision presupposed that it had conducted an examination in the light of Article 87(1) of the Treaty. This would jeopardise the principles underlying the protection of

[7] Judgment of 5 October 1994 in Case C-47/91, *Italian Republic* v *Commission* [1994] ECR I-4635.

legitimate expectations and legal certainty from the point of view of both the Member States and the operators, since individual aid in strict compliance with the decision approving the aid scheme could at any time be called in question by the Commission. If, following an examination thus restricted, the Commission finds that the individual aid is in compliance with its decision approving the relevant scheme, the aid in question must be regarded as authorised, and thus as existing aid. In such cases the Commission is required to propose 'appropriate measures' to the Member State concerned under Article 88(1) of the Treaty prior to any decision to open the Article 88(2) procedure. Conversely, where the Commission finds that the individual aid is not covered by its decision approving the scheme, the aid must be regarded as new aid, and the Commission is entitled to initiate the Article 88(2) procedure.

(37) As Italy has pointed out in its written observations (see recitals 17 and 18 above), the general system of regional aid, including aid granted in connection with the Guarantee Fund for SMEs operating in Objective 1 areas, was approved by letter SG(95)D/3693 of 24 March 1995 (aid N 40/95). The criteria, detailed rules and operating procedures for the Guarantee Fund for SMEs were approved by letter SG(95)D/11306 of 7 November 1995 (aid N 662/95).

(38) However, the two Commission Decisions authorising the Guarantee Fund for SMEs operating in Objective 1 areas in Italy were not unconditional. Both the Commission letter of 24 March 1995 (SG(95)D/3693) authorising State aid N 40/95 and the letter of 7 November 1995 (SG(95)D/11306) authorising State aid N 662/95 contain a final paragraph to the following effect.

'Lastly, the Commission draws the Italian authorities' attention to the fact that the scheme in question is to apply to the Community rules and provisions on the receipt in combination of aid for various purposes and the rules and provisions on certain sectors of industry, including those covered by the ECSC Treaty, transport, agricultural and fisheries.'

(39) It follows that so far as the application of the scheme in the agricultural and fisheries sectors is concerned, Commission approval was conditional on the fact that assistance from the Guarantee Fund for SMEs was to be granted in accordance with the various Community rules and provisions on these sectors.

(40) After receiving the Italian authorities' letter of 10 April 1997 notifying the amendments to the implementing rules for the scheme introduced by the CIPE, the Commission realised that the scheme might in fact be applied in the agricultural and fisheries sectors in a manner which was not in accordance with the various Community provisions and rules on those sectors. In particular, the explicit reference, for the first time, to RIBS' role in the capitalisation operations for SMEs in Objective 1 areas raised doubts that aid might be granted in favour of those sectors in a manner which was not in accordance with the relevant rules. Those doubts were confirmed by the Italian authorities' replies to the Commission's four telexes requesting additional information on the application of the scheme.

(41) Under the circumstances, the Commission cannot accept the Italian authorities' argument that the scheme is an 'existing scheme' within the meaning of the Commission's consolidated rules of procedure for State aids. The Commission regards aid granted in contravention of a condition laid down in the Decision authorising it as misuse of aid, and this entitles it to open the Article 88(2) procedure directly, without first proposing appropriate measures pursuant to Article 88(1) of the Treaty.

Substance

(42) In accordance with Article 87(1) of the Treaty, any aid granted by a Member State or using State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods is, in so far as it affects trade between Member States, incompatible with the common market. In the case in point the Commission considers that all the conditions for the application of Article 87(1) are fulfilled. Furthermore, the Commission notes that this is not disputed by the Italian authorities.

(43) The description of the aid scheme and the comments from the Italian authorities set out above show that the objective of the scheme is to provide SMEs located in the Objective 1 areas of Italy with access to finance on more favourable terms than those currently provided by the capital markets. The aid measures provided for consist of guarantees and subsidised loans.

As regards guarantees, the Commission's consistent policy, in accordance with its letter to the Member States of 5 April 1989 (SG(89)D/4328), is to regard all guarantees granted by the State directly or through financial institutions entrusted with that task as falling within the scope of Article 87(1) of the Treaty. In its decision to initiate the procedure, on the basis of the information provided by the Italian authorities in their letter of 27 November 1997, the Commission calculated the current value of the guarantees on loans for debt consolidation as equal to 0,2 % [8].

[8] The calculation was worked out as follows: the reference rate was 8,2 %; the interest paid by the State on loans of a similar duration (6 %) and the fee payable for the guarantee (2 % for debt consolidation loans) were deducted from that amount.

As regards the subsidised loans, the Fund may grant undertakings an interest rate rebate reducing the annual rate for the consolidation operation by 4,5 percentage points. However, the amount of the subsidy may not exceed 40 % of the national reference rate applying at the time the contract is concluded. In its decision to open the procedure, using the same information the Commission calculated the grant equivalent of the subsidised loans to be 12,9 %.

The Commission therefore concluded that the cumulative rate of aid was 13,1 % and that it could rise to 100 % in the case of companies in difficulty ([9]).

In their written observations, the Italian authorities note that since the national reference rate has subsequently fallen, the actual rate of aid at the time the loans and guarantees are granted could be below that calculated by the Commission.

It is therefore not possible to calculate the amount of aid precisely, because this will depend upon the relevant interest rates applying at the time the loan is granted and the conditions attaching thereto. The Commission therefore concludes that granting the subsidised loans and guarantees constitutes State aid within the meaning of Article 87(1). Furthermore, this has not been contested by Italy.

(44) In addition, the scheme distorts competition and affects trade between Member States. According to the information provided by the Italian authorities, 41 SMEs in the agricultural and fisheries sectors could qualify for aid. Although payments are currently suspended pending the Commission's final decision on the application of the scheme in those sectors, if approval were granted the aid would represent interest rate subsidies amounting to ITL 5,4 billion on consolidation operations, with possible guarantees covering a total of ITL 24 billion. Given the lack of information to the contrary from the Italian authorities, the Commission considers that it is entitled to assume that at least some of these companies are active in sectors where substantial intra-Community trade takes place. In 1996, agri-food products consigned to Italy from the other Member States totalled ITL 28,734 billion, while Italian consignments to the other Member States amounted to ITL 17,821 billion ([10]).

(45) The prohibition on State aid in Article 87(1) of the Treaty is not unconditional. However, the exceptions provided for in Article 87(2) are manifestly inapplicable, and they have not, moreover, been invoked by the Italian authorities. Similarly, the aid is not intended to promote the execution of an important project of common European interest or to remedy a serious disturbance of the economy of a Member State within the meaning of Article 87(3)(c), nor is it intended to promote culture or heritage conservation within the meaning of Article 87(3)(d). Consideration must therefore be given to whether the application of the measures provided for can qualify as an exception under Article 87(3)(a) or (c) of the Treaty.

(46) As regards debt consolidation operations involving the Guarantee Fund, the Commission notes first of all that in accordance with the relevant guidelines on State aid in the agricultural ([11]) and fisheries ([12]) sectors, these aid measures are not intended to finance new investments.

(47) Furthermore, the Italian authorities have insisted that the beneficiary SMEs cannot be considered enterprises in difficulty. In this connection, the Italian authorities emphasise that the guarantees granted under the scheme cover only 60 % of the sums loaned and that they cannot be called upon if the undertaking is declared bankrupt within 18 months of the granting of the loan. According to the Italian authorities, the beneficiary undertakings are substantially sound and are able to produce a profit, but they suffer from a financial imbalance as a result of the interest they have to pay on short-term borrowing. In the light of these explanations, the Commission accepts that the Community guidelines on State aid for rescuing and restructuring firms in difficulty ([13]) should not apply to the measures in question. The inapplicability of those guidelines is confirmed by the fact that the beneficiary is not required to present a restructuring plan in order to qualify for the aid.

(48) In its decision to initiate the procedure, the Commission observed that in so far as the aid measures were not linked to investments and were not intended for the rescue or restructuring of enterprises in difficulty, doubts remained as to whether the measures applied by the Italian authorities could be considered compatible with Article 87 of the Treaty. The measures concerned appear to constitute operating aid, which cannot be approved by the Commission under Article 87(3)(c) of the Treaty. The Italian authorities' observations confirm that the

([9]) Commission communication to the Member States — Application of Articles 92 and 93 of the Treaty and of Article 5 of Commission Directive 80/723/EEC to public undertakings in the manufacturing sector (OJ C 307, 13.11.1993, p. 3).

([10]) *Source*: Ministry of Agricultural Policies.

([11]) Guidelines for State aid in connection with investments in the processing and marketing of agricultural products (OJ C 29, 2.2.1996, p. 4).

([12]) Guidelines for the examination of State aid to fisheries and aquaculture (OJ C 100, 27.3.1997, p. 12).

([13]) See footnote 6.

objective of the measure is to ease the costs borne by the beneficiaries and that there is no corresponding benefit contributed by the beneficiaries that might be seen as furthering the development of certain economic activities or certain regions. Having regard to the principles laid down in the decisions of the Court [14], the Commission is therefore bound to conclude that the measure in question cannot qualify as an exception under Article 87(3)(c) of the Treaty.

(49) In their observations, the Italian authorities emphasise that the aid is intended for firms located in regions falling within the scope of Article 87(3)(a), which should therefore qualify for exemption under those provisions in accordance with the Commission's regional aid guidelines [15].

(50) In accordance with point 6.1 of the 1998 guidelines on national regional aid [16], aid proposals notified to the Commission before the guidelines were communicated to Member States were to be assessed on the basis of the criteria in force at the time of notification. Point I.6 of the 1988 Commission Communication [17] on the method for the application of Article 92 [18] (3)(a) and (c) to regional aid provides that in recognition of their special difficulties, the Commission may, by way of a derogation, authorise certain operating aid measures in those regions under specific conditions, which are set out thereinafter. The second indent of point I.6 specifies that the aid should 'be designed to promote a durable and balanced development of economic activity and not give rise to a sectoral overcapacity at the Community level such that the resulting Community sectoral problem produced is more serious that the original regional problem; in this context a sectoral approach is required and in particular the Community rules, directives and guidelines applicable to certain industrial (steel, shipbuilding, synthetic fibres, textiles and clothing) and agricultural sectors, and those concerning certain industrial enterprises involving the transformation of agricultural products are to be observed'.

(51) In the agricultural and fisheries sectors, which cover the production, processing and marketing of Annex I products, it has been the Commission's consistent policy for many years to prohibit the payment of operating aid in all regions, including regions which fall within the scope of Article 87(3)(a) of the Treaty. By its very nature, such aid is likely to interfere with the mechanisms of the common organisation of the markets, which take precedence over the competition rules laid down in the Treaty [19]. This policy has been confirmed many times [20]. In particular, the Commission has adopted several final negative decisions in respect of aid measures notified by Italy, in which it has expressly stated that operating aid in the agricultural sector cannot qualify under the exception laid down in Article 87(3)(a) of the Treaty [21].

(52) Furthermore, in accordance with the Commission guidelines on State aid in connection with investments in the processing and marketing of agricultural products, no aid may be granted in respect of investments which contravene the sectoral limitations set out in Commission Decision 94/173/EC [22]. Those sectoral limitations preclude investments in processing and marketing activities in agricultural sectors where there is overcapacity within the Community and, in accordance with the conditions set out in Decision 94/173/EC, they apply throughout the Community, including in regions falling within the scope of Article 87(3)(a). It would clearly be inconsistent for the Commission to prohibit aids for investments in favour of certain activities in the agricultural sector while at the same time allowing operating aid in favour of the same activities, particularly as there is no guarantee that funds intended for debt alleviation purposes might not be used to finance investments incompatible with the common market.

(53) In the light of the above, it must be concluded that the manner in which Italy intends granting interest rate subsidies for debt consolidation operations and guarantees to undertakings operating in the agricultural and fisheries sectors pursuant to Article 2 of Law 341/1995 and the relevant rules of application laid down by the CIPE Decision of 10 May 1995, as subsequently amended, constitutes State aid within the meaning of Article 87(1) that does not qualify under any of the exceptions provided for in Article 87(2) or (3).

[14] See in particular the judgment of the Court of First Instance in Case T-459/93, *Siemens* v *Commission*, [1995] ECR II-1675 and the decisions cited therein.
[15] See footnote 5.
[16] OJ C 74, 10.3.1998, p. 9.
[17] See footnote 5.
[18] Now Article 87.
[19] Judgment of the Court of Justice in Case 177/78, *Pigs and Bacon, Commission* v *McCarren* [1979], ECR 2161.
[20] 20th Report on Competition Policy, 1990, paragraphs 337 and 347; 21st Report on Competition Policy, 1991, paragraphs 316 and 317; 22nd Report on Competition Policy, 1992, paragraphs 503 and 504; 23rd Report on Competition Policy, 1993, paragraphs 547 and 548; 25th Report on Competition Policy, 1995, p. 238 to 240; 26th Report on Competition Policy, 1996, p. 251 to 255.
[21] Commission Decision 95/366/EC of 14 March 1995 on aid granted by Italy (Sardinia) in the agricultural sector (OJ L 218, 14.9.1995, p. 20); Commission Decision 97/106/EC on aid measures provided for in Sicilian regional Law 25/93 (OJ L 37, 7.2.1997, p. 11); Commission Decision of 16 April 1997 on aid granted by the Region of Sardinia, Italy, in the agricultural sector (OJ L 248, 11.9.1997, p. 27).
[22] Commission Decision of 22 March 1994 on the selection criteria to be adopted for investments for improving the processing and marketing conditions for agricultural and forestry products and repealing Decision 90/342/EEC (OJ L 79, 23.3.1994).

(54) In view of the Italian authorities' explanations to the effect that the Fund has not been used to guarantee equity loans or equity investments, there is no need to consider this aspect further in this Decision.

(55) Furthermore, in view of the Italian authorities' statement to the effect that the CIPE Decision concerning the participation of RIBS in capitalisation operations does not provide for any grants of aid going beyond the provisions of Law 662/96 (see recital 15) and that all capitalisation operations undertaken by RIBS under that Law are notified individually to the Commission, there is no need to consider this aspect further in this Decision.

V. **Conclusions**

(56) The Commission finds that by failing to take account of the specific rules applicable in the agricultural and fisheries sectors, Italy has unlawfully adopted the aid measures provided for in Article 2 of Law 341/1995 and the relevant rules of application laid down in the CIPE Decision of 10 May 1995, as subsequently amended, and in breach of the conditions laid down in the Commission's Decision of 10 March 1995, notified by letter of 24 March 1995.

(57) However, in view of the Italian authorities' statement that all procedures for the payment of the aid were suspended following the intervention of the Commission and that no aid was paid previously, there is no need to take any steps to recover the aid,

HAS ADOPTED THIS DECISION:

Article 1

The State aid which Italy intends granting to undertakings operating in the agricultural and fisheries sectors for debt consolidation operations in accordance with Article 2 of Decree-Law 244 of 23 June 1995, ratified in Law 341 of 8 August 1995, is hereby deemed incompatible with the common market and the EEA Agreement. That aid shall accordingly not be implemented.

Article 2

Within two months of notification of this Decision, Italy shall inform the Commission of the steps it has taken to comply therewith.

Article 3

This Decision is addressed to the Italian Republic.

Done at Brussels, 10 November 1999.

For the Commission

Franz FISCHLER

Member of the Commission

COMMISSION DECISION

of 22 March 2000

amending Council Decision 79/542/EEC drawing up a list of third countries from which the Member States authorise imports of bovine animals, swine, equidae, sheep and goats, fresh meat and meat products

(notified under document number C(2000) 815)

(2000/236/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems on importation of bovine, ovine and caprine animals and swine, fresh meat or meat products from third countries [1] as last amended by Directive 97/79/EC [2], and in particular Article 3(1) thereof,

Having regard to Council Directive 96/23/EC of 29 April 1996 concerning measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC [3], and in particular Article 29 thereof,

Whereas:

(1) Member States can only import fresh meat including offal from third countries or parts of third countries appearing on a list established by the Council on a proposal from the Commission.

(2) The list of these third countries or parts thereof is contained in Council Decision 79/542/EEC [4] as last amended by Commission Decision 2000/162/EC [5].

(3) Inclusion and retention of a third country on the lists of third countries provided for in Community legislation from which Member States are authorised to import products of animal origin covered by Directive 96/23/EC is subject to submission by the third country concerned of a plan setting out the guarantees which it offers as regards the monitoring of the groups of residues and substances referred to in Annex I of the Directive referred to; this plan must be updated at the request of the Commission, particularly when the checks referred to in Article 29(3) of the abovementioned Directive render it necessary.

(4) If the requirements of Article 29(1) of Directive 96/23/EC are not complied with, inclusion of a third country on the lists of third countries laid down by Community legislation may be suspended in accordance with the procedure laid down in Article 33 of the Directive referred to.

(5) The application of residue monitoring plans, and the follow up to evidence of the use of unauthorised substances or of residue levels exceeding the Community maximum residue limits, are necessary to protect public health.

(6) Following deficiencies in the implementation of the residue monitoring programme identified by inspections carried out in the United States of America by the Commission in November 1999 and January/February 2000, the United States of America took measures to rectify the deficiencies reported; these measures were communicated to the Commission.

(7) In the light of the measures communicated by the United States of America the Commission carried out an evaluation of the adequacy and effectiveness of these measures.

(8) The evaluation by the Commission of the actions taken showed that the remedial measures taken by the United States of America were generally satisfactory.

(9) It is, therefore, no longer necessary to suspend the United States of America from the list of third countries from which the Member States are authorised to import fresh meat and meat products for human consumption with effect from 15 March 2000.

(10) The measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

Part I of the Annex to Decision 79/542/EEC is amended as follows:

[1] OJ L 302, 31.12.1972, p. 28.
[2] OJ L 24, 30.1.1998, p. 31.
[3] OJ L 125, 23.5.1996, p. 10.
[4] OJ L 146, 14.6.1979, p. 15.
[5] OJ L 51, 24.2.2000, p. 41.

1. the line

   'US | United States of America | s | s | s | s | s | x | x | x | x | # | # | #'

   is replaced by:

   'US | United States of America | x | x | x | x | x | x | x | x | x | # | # | #'

2. Footnote 's = suspended for export of fresh meat and meat products for human consumption,' is hereby deleted.

Article 2

This Decision shall apply from 15 March 2000.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 22 March 2000.

For the Commission

David BYRNE

Member of the Commission

EUROPEAN ECONOMIC AREA

EFTA SURVEILLANCE AUTHORITY

RECOMMENDATION OF THE EFTA SURVEILLANCE AUTHORITY
No 153/99/COL
of 2 July 1999
concerning a coordinated monitoring programme for 1999 to ensure compliance with maximum levels of pesticide residues in and on cereals and certain products of plant origin, including fruit and vegetables

THE EFTA SURVEILLANCE AUTHORITY,

Having regard to the EEA Agreement, and in particular Article 109 and Protocol 1 thereof,

Having regard to the Surveillance and Court Agreement, and in particular Article 5(2)(b) and Protocol 1 thereof,

Having regard to the Act referred to in point 38 of chapter XII of Annex II to the EEA Agreement on the fixing of maximum levels for pesticide residues in and on cereals (Council Directive 86/362/EEC) [1], and in particular Article 7(2)(b) thereof,

Having regard to the Act referred to in point 54 of Chapter XII of Annex II to the EEA Agreement on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables (Council Directive 90/642/EEC) [2], and in particular Article 4(2)(b) thereof,

After consulting the EFTA Foodstuffs Committee assisting the EFTA Surveillance Authority,

Whereas Article 7(2)(b) of Directive 86/362 and Article 4(2)(b) of Directive 90/642 require the EFTA Surveillance Authority to submit to the EFTA Foodstuffs Committee assisting the EFTA Surveillance Authority by 30 September each year a recommendation to the EFTA States setting out a coordinated monitoring programme to ensure compliance for maximum levels of pesticide residues set out in the Annex II to the said Directives;

Whereas the EFTA Surveillance Authority should recommend a monitoring programme each year; whereas experience, gained by the European Commission and its Member States in establishing, carrying out and reporting on the three previous annual coordinated monitoring programmes, indicates that multiannual programmes appear to be most effective and practical; whereas it appears appropriate to indicate in this Recommendation the framework of future programmes;

Whereas the EFTA Surveillance Authority should progressively work towards a system which would permit the estimation of actual pesticide dietary exposure, as provided for in the second paragraph of Article 7(3) of Directive 86/362 and the second paragraph of Article 4(3) of Directive 90/642; whereas to facilate examination of the feasibility of such estimations, data concerning the monitoring of residues of pesticides in a number of food products which constitute major components of European diets should be available; whereas in view of the resources available at national level for pesticide residue monitoring, EFTA States are only able to analyse samples of four products each year within a coordinated monitoring programme; whereas each pesticide should generally be monitored in 20 food products over a series of five year cycles;

[1] Hereinafter referred to as Directive 86/362.
[2] Hereinafter referred to as Directive 90/642.

Whereas the residues recommended to be monitored in 1999 and 2000 will allow examination of the feasibility of using the data concerning the pesticides acephate, the benomyl group, chlorpyriphos, iprodione and methamidophos as these compounds (identified as Group A in Annex I) have been recommended to be monitored for estimation of actual dietary exposure in 1996 and 1997 and information on the monitoring has been requested for 1998;

Whereas the residues recommended to be monitored in 1999, 2000 and 2001 will allow examination of the feasibility of using the data concerning the pesticides diazinon, metalaxyl, methidathion, thiabendazole and triazophos as these compounds (identified as Group B in Annex I) have been recommended to be monitored for estimation of actual dietary exposure in 1997 and information on the monitoring has been requested for 1998;

Whereas the residues recommended to be monitored in 1999, 2000, 2001 and 2002 will allow examination of the feasibility of using the data concerning the pesticides chlorpyriphosmethyl, deltamethrin, endosulfan, imazalil, lambda-cyhalothrin, the maneb group, mecarbam, permethrin, pirimiphos-methyl an vinclozolin as information on the monitoring has been requested for 1998 of these compounds (idenfitife as Group C in Anned I) for estimation of actual dietary exposure;

Whereas a systematic statistical approach to numbers of samples to be taken in the specific coordinated exercise is necessary; whereas such an approach has been set out by the Commission of the Codex Alimentarius [1]. Based on a binomial probability distribution it can be calculated that examination of a total sample number of 459 gives a 99 % confidence of detecting one sample containing pesticide residues above the limit of determination (LOD) if it is anticipated that 1 % of products of plant origin will contain residues above the LOD; whereas the total number of samples to be taken by each EFTA State should be apportioned on the basis of population and consumer numbers, with a minimum of 12 samples per product and per year;

Whereas draft guidelines concerning quality control procedures for pesticide residue analysis, published in Annex II [2] have been discussed by the experts of the EU Member States at Oeiras, Portugal on 15 and 16 September 1997 and discussed and taken note of in the pesticide residues subgroup of the Working Group on Plant Health on 20 and 21 November 1997; whereas it is agreed by the EU Member States that these draft guidelines should be implemented as far as possible by the analytical laboratories of the EU Member States and should be reviewed in the light of this;

Whereas Article 4(2)(a) of Directive of Directive 90/642 requires the EFTA States to secify the criteria a applied in drawing up their national inspection programmes when sending to the EFTA Surveillance Authority information on their implementation during the previous year; whereas such information should include the criteria applied in determining the numbers of samples to be taken and analyses to be carried out and the reporting levels applied and the criteria by which the reporting levels have been fixed; whereas details of accreditation under the Act referred to in point 54n of Chapter XII of Annex II to the EEA Agreement on the subject of additional measures concerning the official control of foodstuffs (Council Directive 93/99/EEC) [3] of the laboratories carrying out analyses should be indicated:

Whereas information on the results of monitoring programmes is particulary appropriate for treatment, storage and transmission by electronic/informatic methods; whereas formats have been developed for supply in diskette form to the EU Member States by the Commission; whereas the same format could be used by the EFTA States; whereas the EFTA States should therefore be able to send their reports to the EFTA Surveillance Authority in the standard format; whereas the further development of such a standard format is most effectively undertaken by the development of guidelines;

Whereas Liechtenstein shall comply with the provisions of the acts referred to in Chapter XII of Annex II to the EEA Agreement by 1 January 2000, whereas Liechtenstein was to do its utmost to comply with the provisions of the acts referred to in that Chapter by 1 January 1997; whereas therefore Liechtenstein is included in this recommendation for 1999,

[1] Codex Alimentarius, Pesticide Residues in Foodstuffs, Rome 1994, ISBN 92-5-203271-1; Vol 2, p. 372.
[2] Previously published as Commission document VI/7826/97.
[3] Hereinafter referred to as Directive 93/99.

HAS ADOPTED THIS RECOMMENDATION:

It is recommended that Iceland, Liechtenstein and Norway:

1. sample and analyse for the product/pesticide residue combinations set out in the Annex I, on the basis of target number of 12 samples of each product, reflecting as appropriate, national, EEA and third country share of the EFTA State's market: for at least one pesticide possibly posing an acute risk, one of the products will be subjected to individual analysis of the items in the composite sample: two samples of an appropriate number of items will be taken, where possible the produce of a single producer; if in the first, composite sample a detectable level of the pesticide is found, the items of the second sample will be analyses second sample will be analyses individually; in 1999 this will include the combination peppers and methamidophos;

2. by 31 August 2000 report the results for the part of the specific exercise allocated for 1999 in Annex I, together with the analytical methods used and reporting levels achieved, in accordance with the quality control procedures set out in Annex I, together with the analytical methods used and reporting levels achieved, in accordance with the quality control procedures set out in Annex III [1];

3. by 31 August 1999, send to the EFTA Surveillance Authority and to EEA/EFTA States all the information as required by Article 7(3) of Directive 86/362 and Article 4(3) of directive 90/642 concerning the 1998 monitoring exercise, as requested by the EFTA Surveillance Authority in a letter of 27 November 1998 to the EEA/EFTA States, to ensure, at least by check sampling, compliance with maximum pesticide residue levels including:

3.1. — the results of their national programmes concerning pesticides listed in Annexes II of Directives 86/362 and 90/642, in relation to harmonised levels and, where these have not yet been fixed at Community level, in relation to the national levels in force;

3.2. — information on their laboratories' quality control procedures and, in particular, information concerning aspects of the guidelines concerning quality control procedures for pesticide residue analysis (Annex II) which they have not been able to apply or have had difficulty in applying;

3.3. — information on accreditation in accordance with the provisions of Article 3 of Directive 93/99 (including type of accreditation, accreditation body and copy and copy of accreditation certificate) of the laboratories carrying out the analyses.

4. This recommendation is addressed to Iceland, liechtenstein and Norway.

Done at Brussels, 2 July 1999.

For the EFTA Surveillance Authority

Hannes HAFSTEIN

College Member

[1] Previously published as Commission document VI/1609/97.

ANNEX I

Pesticide/product combinations to be monitored in the specific exercise set out in point 1 of the Recommendation

Pesticide residue to be analysed for	Years [1]			
	1999	2000	2001 [2]	2002 [3]
Group A				
Acephate	(a)	(b)		
Benomyl group	(a)	(b)		
Chlorpyriphos	(a)	(b)		
Iprodione	(a)	(b)		
Methamidophos	(a)	(b)		
Group B				
Diazinon	(a)	(b)	(c)	
Metalaxyl	(a)	(b)	(c)	
Methidathion	(a)	(b)	(c)	
Thiabendazol	(a)	(b)	(c)	
Triazophos	(a)	(b)	(c)	
Group C				
Chlorpyriphos-methyl	(a)	(b)	(c)	(d)
Deltamethrin	(a)	(b)	(c)	(d)
Endosulfan	(a)	(b)	(c)	(d)
Imazalil	(a)	(b)	(c)	(d)
Lambda-cyhalothrin	(a)	(b)	(c)	(d)
Maneb group	(a)	(b)	(c)	(d)
Mecarbam	(a)	(b)	(c)	(d)
Permethrin	(a)	(b)	(c)	(d)
Pirimiphos-methyl	(a)	(b)	(c)	(d)
Vinclozolin	(a)	(b)	(c)	(d)

[1] Group D to be specified later.

[2] Group D and E to be specified later.

[3] Indicative for 2000, 2001 and 2002, subject to programmes which will be recommended for these years.

(a) Cauliflower (fresh or frozen), pepper, wheat (grain), melon (not squash or watermelon).

(b) Rice (husked or polished), cucumber, head cabbage, peas (frozen or fresh, analysed without pods).

(c) Apples, barley, tomatoes, lettuce.

(d) Pears, bananas, beans (fresh or frozen), potatoes.

ANNEX II

QUALITY CONTROL PROCEDURES FOR PESTICIDE RESIDUES ANALYSIS

Introduction

1. Data on pesticide residues may be used for checking compliance with maximum residue limits (MRLs), to support enforcement actions or to assess consumer exposure to pesticides. Analysis of residues is challenging and appropriate quality control procedures are essential to demonstrate the validity of results, without incurring unnecessary costs. Pesticide residues must be identified correctly in order to be quantified. Where knowledge of the quantity of the residue detected is important, the more stringent of the requirements in this document will apply. Less stringent alternatives are provided if the exact level of residues is relatively unimportant — for example, where it is sufficient to know that the residues comply with MRLs. A glossary of terms is appended.

Operating principles

2. Laboratory operations should meet the requirements of a recognised accreditation scheme, which complies with EN45001 or good laboratory practice (GLP).

3. The laboratory must participate in appropriate proficiency testing schemes, such as those organised by the European Commission, FAPAS and CHEK. Where unacceptable z-scores are achieved, the problems should be rectified before proceeding with further analyses for the pesticides involved.

4. For quantitative results, critical weights and volumes must be measured using equipment of accuracy within ± 1 %. Weighing and volumetric equipment must be calibrated, maintained and used according to the manufacturer's instructions. A similar approach should be adopted for spectrometric equipment requiring calibration for wavelength, mass-to-charge ratio, etc. As far as practicable, analyses should encompass the components defined by MRLs.

Sampling, transport, processing and storage of samples

Sampling

5. Samples should be taken in accordance with the Act referred to in point 20 of Chapter XII of Annex II to the EEA Agreement establishing Community methods of sampling for the official control of pesticide residues in and on fruit and vegetables (Commission Directive 79/700/EEC), or superseding legislation. Where it is impractical to take primary samples randomly within a lot, the method of sampling must be recorded.

Sample transportation

6. Samples must be transported to the laboratory in clean containers and robust packaging. Polythene bags, ventilated if appropriate, are acceptable for most samples but low-permeability bags (e.g. nylon film) must be used for samples to be analysed for residues of fumigants. Samples of commodities pre-packed for retail sale should not be removed from their packaging before transport. Very fragile or perishable products (e.g. ripe raspberries) may have to be frozen to avoid spoilage and then transported in 'dry ice' or similar, to avoid thawing in transit. Similarly, samples which are frozen at the time of collection must be transported without thawing. Samples which may be damaged by chilling (e.g. bananas) must be protected from both high and low temperatures. Samples must be identified clearly and indelibly, using labels which cannot be detached inadvertently. The use of marker pens containing organic solvents should be avoided for labelling bags containing samples to be analysed for fumigant residues. Rapid transmission to the laboratory, prefereably within on day, is essential for most samples. Perishable, fragile or heavy samples, which are likely to deteriorate and/or be damaged in transit, require special care in packing. The condition of samples delivered to the laboratory should approximate to that acceptable to a discerning purchaser, otherwise samples should normally be considered unfit for analysis.

Sample processing for analysis

7. On receipt, each sample must be allocated a unique reference code by the laboratory.

8. Sample processing and subsampling must take place before visible deterioration of the sample occurs. Canned, dried or similarly processed samples must be analysed within the shelf-life, unless stored in deep freeze.

9. Sample processing and storage procedures should be demonstrate as having no significant effect on measured residues. Samples should be homogenised, comminuted and/or mixed before withdrawing portions for analysis. Where labile residues could otherwise be lost in this process, samples may be comminuted frozen (i.e. in the presence of 'dry ice' or similar). Where comminution, etc., is known to affect residues (e.g. of dithiocarbamates or fumigants) and practical alternative procedures are not available, the analytical portion may consist of whole units of the commodity, or segments removed from whole units. If the analytical portion thus consists of few units or segments, it is unlikely to be representative of the analytical sample and replicate portions must be analysed from the outset, to provide a better indication of the mean value. All analyses should be undertaken within the shortest time practicable, to minimise the need for sample storage. Analyses for residues of very labile or volatile pesticides may have to be completed on the day of sample receipt.

Pesticide standards, calibration solutions, etc.

Identity and purity of standards

10. Reference standards (including pesticides, their metabolites, derivatives or degradation products) and internal standards should be of known purity, where possible. On receipt, they must be dated, given a unique reference, and allocated an expiry date. The expiry date allocated may differ from that given by the supplier of the reference standard, if it is known to be appropriate to the pesticide under the storage conditions employed. Certified standards should, and uncertified standards must, be checked for identity and (approximate) purity by chromatography, infra-red spectrophotometry, mass spectrometry (MS) or nuclear magnetic resonance spectrometry. As far as practicable, the reference spectrum used for this purpose should have been, or should be, rationalised as compatible with the chemical structure of analyte. After the allocated expiry date, reference standards may be retained if the purity is shown to remain acceptable but a new expiry date must be allocated. Otherwise they must be replaced. The relative purity of new and old reference standards of the same pesticide may be determined by comparing the detector responses obtained from concurrent, freshly-prepared dilutions of the old and new materials (see also paragraph 15). Differences between old and new references standards that are not attributable to differences in quoted purity should be investigated and the length and/or conditions of storage revised, as appropriate.

11. The chromatographic response, etc., obtained from the standard must be demonstrated as attributable to the analyte, prior to analysis of samples and preferably by MS. Where the detected species is a pyrolysis product which is also a metabolite of the pesticide [1] an alternative detection system must be used if the metabolite is not included in the definition of the MRL.

Storage of standards

12. Reference standards may be stored in their original containers, if suitable, but the caps must not be of rubber materials. If a standard changes visibly during storage it must not be used without checking the purity, unless this is due to simple freezing and melting. Standards of pesticides should be stored according to manufacturers' instructions (where given), to minimise degradation. Generally storage at low temperature (refrigerator or freezer) in the dark is satisfactory. The containers must be sealed to avoid entry of water, which is especially likely during equilibration to room temperature.

Preparation, use and storage of analyte standard solutions, suspensions, etc.

13. Preparation of pesticide solutions (or solid dilutions) requires careful attention to detail. The identity and mass (or volume, for highly volatile compounds) of the reference standard, the identity of the solvent (or other diluent) employed, and the calibrated volumes of flasks and pipettes used, must be recorded. Amorphous solid compounds should be homogenised before removing a portion for weighing. Initial (stock) and subsequent (working) dilutions should be uniquely identified, permanently labelled and the concentrations corrected for the purity of the reference standard (where this is known with certainty). Individual aliquots of solutions used for calibration need not be uniquely identified but their origin and method of preparation must be recorded.

14. The pesticide must not react with, and should have adequate solubility in, the solvents used to prepare solutions. The solvents must be appropriate to the method of analysis and be compatible with the determination system used. Adsorption onto containers, particularly of ionic pesticides, must be avoided by addition of acid, silanisation of glassware, or use of plastic containers, as appropriate, but such measures must not lead to interference with the subsequent detection of the pesticide. Not less than about 10 mg of the pesticide reference standard should be weighed, directly into a volumetric flask if practicable. Alternatively, the pesticide may be weighed into a pre-weighed (or tared) vessel and quantitatively transferred by rinsing with solvent to a volumetric flask. Volatile liquid pesticides should be dispensed by weight or volume (if the density is known) directly into a less volatile solvent in a volumetric flask. Gaseous fumigants may be dispensed by bubbling into solvent and weighing the mass transferred, or by preparing gaseous dilutions (e.g. with a gas-tight syringe). In the latter case, the mixture must not contact reactive metals.

[1] For example, 4,4′-dichlorobenzophenone from dicofol, tetrahydrophthalimide from captars and captafol, phthalimide from folpet, 2-chlorobenzontrile from clofentazine.

15. Pesticide solutions (or solid phase dilutions) must be allocated an expiry date, after which they should normally be discarded. Newly prepared stock solutions should be diluted (in a matrix extract, if appropriate) and compared with those to be discarded. If the mean response of the detector to the new solution differs by more than ± 5 % from the old one ([1]), the new solution should be checked for accuracy against a further newly prepared one. The number of determintions required for this comparison is dependent upon the precision of the detection system used. If the response from the old stock standard is confirmed as > 5 % lower than the new standard, the storage period for solutions must be shortened or the storage conditions improved. If the responses from old and new stock standards do not differ significantly, a longer storage period may be considered. Aqueous suspensions of dithiocarbamates and solutions (or gaseous dilutions) of highly volatile fumigant pesticides must be prepared freshly and comparison of new and old standards is inappropriate. The validity of such a standard may be checked by comparison with one that is freshly, and independently, prepared.

16. The response of some detection systems (e.g. GC, LC-MS, ELISA) to certain pesticides may be affected by the presence of co-extractives from the sample. These 'matrix effects' may be observed as increased or decreased responses, compared with those produced by simple solvent solutions of the analyte. Partition in headspace analyses and SPME is also frequently affected by components present in the samples. GC enhancement or suppression effects may reflect increased or decreased transmission efficiency of the pesticide through the injector, compared with that in solvent only. Effects on MS response may be produced by co-eluting matrix components influencing the efficiency of ionisation or ion collection. The presence, or absence, of such effects may be demonstrated by comparing detector response to the analyte in a simple solvent solution with that obtained from the matrix-matched equivalent. Matrix effects can be very variable and unpredictable in occurrence and an initial demonstration of a measurable effect, or none, does not indicate that this situation will not change subsequently. More reliable calibration may be obtained in such cases if the calibration solutions are matrix-matched. The 'matrix concentration' employed should be consistent for all analyses in a batch. Samples known not to contain detectable residues or interfering compounds (i.e. 'blanks') may be used to prepare extracts for matrix-matched calibration solutions, etc. The blank extracts required for this may be prepared most conveniently during the extraction of batches of samples. These blank extracts may also be analysed without addition of pesticides, to demonstrate whether contamination has occurred during extraction and clean-up, and whether detector responses to matrix components interfere with analyte determination. Calibration solutions that are matrix-matched and/or that are of mixed pesticides may be less stable than solutions of individual pesticides in pure solvent.

17. Solutions should not be exposed to direct sunlight and should be stored at low temperature in the dark, in a refrigerator or freezer, sealed to avoid loss of solvent or entry of water. Solutions removed from low temperature storage should be equilibrated to room temperature and remixed before use.

18. Unless calibration solutions and extracts are internally standardised, unmeasured losses of the solvent by evaporation are unacceptable. Solvent losses from small volumes are difficult to monitor and, in the absence of an internal standard, great care is required to avoid evaporation. Where an internal standard is used, evaporation losses should also be minimised, to avoid influencing matrix effects (see paragraph 16). Septum closures are particularly prone to evaporation losses (in addition to being a source of contamination) and should be replaced as soon as practicable after piercing, if extracts in vials are to be retained.

Extraction and concentration

Extraction conditions and efficiency

19. Analytical portions should be disintegrated thoroughly before or during extraction, to maximise extraction efficiency, except where it has been demonstrated that the nature of the process (e.g. supercritical fluid extraction (SFE) of certain sample types) renders disintegration unnecessary. Overheating during extraction must be avoided to minimise solvent or pesticide losses. Temperature, pH, etc., must be controlled if they are known to affect extraction efficiency and/or pesticide stability.

20. Where total extraction of the residue from the analytical portion is not intended, with only an aliquot of the extract removed from the extraction mixture, the volume of solvent added initially should be measured to within ± 1 %. Solvent evaporation prior to removing the aliquot must be avoided or measured (by weight or by internal standard addition). Where solvent loss exceeding 1 % may occur with this type of extraction, the loss should be measured routinely.

Extract concentration and dilution to volume

21. Great care is required where extracts are to be evaporated to dryness, as trace quantities of many pesticides may be lost from surfaces in this way. A small quantity of a high boiling point solvent may be used as a 'keeper' and the evaporation temperature should be as low as practical. Frothing and vigorous boiling of extracts, or dispersion of droplets, must be avoided. A stream of dry nitrogen or centrifugal evaporation is generally preferable to the use of an airstream for small-scale evaporation, as air is more likely to lead to oxidation or to introduce water and other contaminants.

([1]) Alternatively, a-test of the means should not show a significant difference at the 5 % level.

22. Where extracts are to be made up to a specified volume, accurately calibrated vessels of not less than 1 ml capacity should be used. Where dried extracts are dissolved in a fixed volume of solvent delivered from a syringe, or similar, the solvent should have a boiling point high enough to avoid further evaporation. Where the final solvent volume is not measured directly, a fixed mass of internal standard should be added to enable measurment of the volume, particularly for volumes less than 1 ml.

23. The stability of pesticides in extracts can vary greatly according to the pesticide and the nature of the extract. Although storage of extracts in a refrigerator or freezer may be helpful, the loss during a day at the temperature of an autosampler rack mounted on a GC may equal that occurring during a month's storage in deep freeze. Pesticide stability in extracts should be investigated during method validation.

Contamination and interference

Contamination

24. Samples must be separated from each other, and from other sources of potential contamination, during transit to, and storage at, the laboratory. This is particularly important with surface or dusty residues, or with volatile pesticides, and samples which could bear such residues should be doubly-sealed in polythene or nylon bags and transported and processed separately. Pest control measures taken in or near the laboratory, if essential, must be limited to the use of products which will not be sought as residues.

25. Solvents (including water), reagents, filter aids, etc., should be checked for possible interference problems. Solvents used for fumigant residues analysis may be particularly problematic because solvent impurities and the pesticide may have similar volatilities and could be chemically identical to the residues.

26. Equipment and containers used for residues analysis must be free from significant interfering contaminants. Reusable volumetric equipment, such as flasks, pipettes and syringes, must be cleaned scrupulously. Separate glassware, etc., should be allocated to calibration standards and to sample extracts. Rubber and plastic items (e.g. seals, protective gloves, wash bottles), polishes and lubricants are potential sources of analytical interference. Contamination by dithiocarbamates, ethylenethiourea and diphenylamine from rubber articles or some lubricating oils is particularly problematic, because it is indistinguishable from pesticide residues.

27. Vial seals should by PTFE-lined. Extracts should be kept out of contact with seals, especially after piercing, by keeping vials upright. Vial seals must be replaced quickly after piercing, if reanalysis of the extracts is necessary. Disposable vials should not be reused.

28. Where an internal standard is used, unintended contamination of extracts or pesticide solutions with the internal standard, or *vice versa*, must be avoided.

Interference

29. Interference from natural constituents of samples, co-extracted during residues analysis, is frequent and must be recognised. Where the analyte occurs naturally in, or is produced from, the sample (e.g. inorganic bromide in all commodities; sulfur in soil; or carbon disulfide produced from the Cruciferaceae), low-level residues from pesticide use cannot be distinguished from natural levels. Natural occurrence of these analytes must be taken into account in planning analyses and in the interpretation of results. Not all interference produces simple, positive detector responses. Suppression or enhancement effects on gas chromatographic transmission, or on ion generation/collection efficiency in MS, may be produced by co-eluting pesticides or sample matrix components. Wherever this could occur, the response of the detection system to pesticides should be assessed, individually and with other pesticides, in pure solvent and in relevant 'blank' extracts. Reagent blanks (procedural blanks) should be analysed at method validation, and at any time thereafter that it is necessary to distinguish interference due to the matrix from that which could be introduced during analysis.

Analytical calibration and chromatographic integration

Basic requirements for acceptable calibration

30. In a batch of determinations, the calibration should derive from two or more replicate measurements of detector response at each level. In all cases, the detector responses used to quantify residue levels must be within the dynamic range of the detection system.

31. In determining the presence or absence of measurable residues in samples, residues below the lowest calibrated level (LCL, corresponding to the intended reporting limit) should be reported as '< [LCL] mg/kg', whether or not a reponse to the analyte is evident. Where it is considered necessary to report measurable residues that are below the LCL initially used, further determinations must be performed using a new and lower LCL.

32. Where an analysis batch includes samples with residues about, or below, the LCL, the detector response to the analyte must be qualitatively distinguishable and measurable at the LCL. Where the response to the intended LCL is inadequate, a higher calibration level which meets the criteria must be adopted as the LCL. In general, a minimum signal-to-noise ratio (S/N) of 3:1 is acceptable for the LCL, although this may apply to summed signals, for example with MS data. Although S/N is often expressed in terms of 'electronic' or 'detector noise', 'chemical noise' from co-eluting interfering compounds must also be taken into account.

33. Calibration by interpolation between two levels is acceptable where the mean response factors for each level indicate linearity of response (i.e. the lower being not less than 90 % of the higher response factor). Where three or more levels are utilised, an appropriate calibration line may be fitted. The calibration line should not normally be forced through the origin. Where calculations are computerised, the fit of the calibration must be inspected visually, avoiding reliance on correlation coefficients, to ensure that the fit is satisfactory in the region relevant to the residues detected. Where the difference between calibration levels is large and interpolation appears questionable, the individual levels may used as single-point calibrations.

34. Calculation of residues or recovery data by extrapolation from the calibrated level(s) may introduce inaccuracies related to the degree of extrapolation. Calculation from a single calibration point is most likely to involve extrapolation and assumes a linear response, with the intercept at the origin. Extrapolation is acceptable for calculation of results exceeding the LCL, if the sample response is within ± 10 % of the calibration response where the MRL is exceeded, or is within ± 50 % where the MRL is not exceeded. Where the level of addition for recovery corresponds to the LCL, recovery < 100 % may be calculated by extrapolation, although the estimate may be inaccurate.

35. Calibration at two or more levels, with, for example, additional calibration at two times the target LCL, provides a back-up LCL if the target level is not measurable and usually allows a wider range of residue levels to be estimated more accurately. Single-level calibration may be used in screening to determine whether or not the calibration level is exceeded by residues or, alternatively, to quantify residues that are at, or close to, the calibration level. The latter application may provide more accurate results than multi-level calibration where the detector response is variable.

36. Extracts containing high-level residues may be diluted to bring them within the calibrated range but it may be necessary to adjust the 'concentration of matrix' in the calibration solutions, because the matrix effects on the response may be diminished by dilution of the matrix components present in sample extracts (etc.).

Calibration in batches of determinations

37. In a sequence of determinations (e.g. chromatography), the calibration determinations must bracket the samples. That is, each sequence must begin and end with calibration. Intermediate calibrations may be required if the response of the detection system is too variable. In parallel determinations (e.g. ELISA using 96-well plates), the calibrations should be distributed to detect differences in response due to position.

38. In general, batch sizes for determination should be adjusted so that detector responses to replicate bracketing calibrations do not differ by more than 20 %. Where the response differs by more than 20 %, the determinations should be repeated in smaller batches. Repeat of determinations is not necessary for samples which contain residues < LCL, if the LCL response remains measurable throughout the batch.

39. Residues to be quantified accurately must be accompanied by appropriate calibration. Whereever practicable, the detection system should be calibrated for all analytes sought, in every batch of analyses. Where, for multi-residue screening, this would require a disproportionately large number of calibration determinations in each batch (for example, where many analytes must be determined in separate solutions, because they would otherwise interfere with one another), the detection system must be calibrated for 'reference' pesticides, as a minimum, in each batch of sample analyses. 'Reference' pesticides are defined in sub-paragraphs 39.1 and 39.2, below. The 'reference' pesticides may be combined in a single solution. The minimum acceptable frequency of calibration during screening analysis is given in Table 1. Where a particular pesticide is not calibrated in a batch of determinations, the results for that pesticide must be considered tentative.

39.1. In the following cases, all analytes sought must be considered as 'reference' analytes:

(i) where an MRL has bene exceeded;

(ii) where for any other reason, the analytes sought must be quantified with demostrable accuracy;

(iii) where single-residue methods are employed.

39.2. In all other cases, the 'reference' analytes must include those listed below:

(i) the pesticides likely to be detected in the samples analysed; and

(ii) two or more pesticides most likely to give poor or variable response or recovery; and

(iii) one pesticide expected to give repeatably good response and recovery.

Category (i) may incorporate the requirements of categories (ii) aqnd (iii).

Table 1

Minimum frequencies for calibration and recovery determination

	'Reference' pesticides	Pesticides infrequently found in the commodities analysed	Pesticides not previously found, or no longer found, in the commodities analysed
Calibration	Two levels, two bracketing injections (etc.) of all analytes, in every batch of determinations. Batch size should be adjusted so that bracketing calibration responses do not differ by > 20 %.	A rolling programme, to include all such pesticides once per 10 determination batches or three months. Two levels, two injections of each, bracketing the batch of determinations	Once per year or survey. Two levels, two injections of each, bracketing the batch of determinations.
Recovery	One for each pesticide in every batch of analyses/extractions	One for each pesticide, synchronised with the corresponding calibration series, as above	One for each pesticide, synchronised with the corresponding calibration series, as above

Observations:

a) 'Reference' pesticides are defined in subparagraphs 39.1 and 39.2, above.

b) Where additional pesticides are intended to be encompassed in analyses, the reference pesticides must be chosen with great care, to ensue that detector esponses to the reference pesticides show that residues of the other pesticides will be detected with the claimed sensivity.

c) Where calibration and recovery of a particular pesticide are not conducted in the batches, there is a risk that subsequent measurements may show that the results for the pesticide are not valid for the batches.

Matrix-matched calibration

40. Chromatographic transmission, detector response, or partition in headspace analysis, may be altered by components from the sample matrix or solvents, etc. (see paragraph 16). In general, pesticide calibration standards should be prepared freshly in a matrix extract which provides accurate calibration (i.e. 'matrix-matched'). The blank commodity used for matrix-matching may, or may not, have to be identical to the samples but the variable and unpredictable nature of matrix effects require that the use of a non-identical matrix should be revalidated at intervals. For any particular pesticide and sample, the validity of the matrix used for preparation of calibration soutions may be checked by addition of a known quantity of the pesticide to the sample extract (etc.) and comparing the increase in analyte response produced with the response produced by the supposedly equivalent matrix-matched calibration standard.

41. Care is required where the material used to prepare matrix-matched calibrations either contains the analyte or produces a detector signal which intereferes with the determination of the analyte. There are several cases and each is likely to create additional uncertainty about the final result.

41.1. Where the analyte is naturally present in all samples and only levels much higher than those occurring naturally are important. For example, inorganic bromide in celery. A 'zero' level must be included in the calibration and the blank material should be chosen for its low level of analyte. The analyte concentration in the blank is determined from the slope and intercept ('zero' level) of the calibration curve and this value must be added to the nominal calibration levels. The blank value must not be subtracted from the level found in the samples. The 'zero' becomes equivalent to the level in the blank material and this is thus the LCL. The blank material should be made homogeneous, to ensure that the LCL remains similar from batch to batch. Results below the 'zero' level should be expressed as in point 31.

41.2. Where the analyte is of natural orgin and dectable in all or most samples but the level is close to, or above, the target LCL. For example, carbon disulfide produced from brassicas. A more specific method (for dithiocarbarnates in this case) may be used or the target LCL may be set at a substantially higher level and the results interpreted with caution.

41.3. Where the analyte is detected in all samples but is not naturally present. For example imazalil in certain citrus. Following rigorous confirmation that measurable residues are truly present in high frequency, a sample containing a particualrly low level of the analyte should be utilised for calibration, as described in point 41.1

41.4. Where the 'background' is not due to the analyte but due to an interfering natural or synthetic chemical, present in some or all samples. A more efficient clean-up or a more specific detection system should be used. Where this is not practicable and the maximum level found in 'blank' material is below the target LCL, an approach similar to that in point 41.1 may be adopted. In this case, results must be interpeted with caution and residues > LCL should be confirmed rigorously.

42. In GC analysis, both matrix-matching of calibration solutions and column/injector 'primining' are normally required. The priming effect resembles a long-lasting matrix effect but is rarely permanent and rarely eliminates matrix effects. Where required, priming should be performed immediately prior to the first of calibration determinations in a batch of analyses.

Effects of pesticide mixtures on calibration

43. Calibration and recovery using mixed standards of pesticides is acceptable but the detection system should be checked for similarity of response to the matrix-matched pesticides, individually and in mixture. In the unusual cases where these responses differ significantly, residues of single pesticides must be quantified using individual calibration standards. In exceptional cases, multiple residues may require a specially-prepared calibration standard.

Calibration for pesticides which are mixture of isomers etc.

44. Where a pesticide calibration standard is a mixture of isomers, etc., detector response generally may be assumed to be similar, on a molar basis, for each component. However, enzyme assays (.e.g cholinesterase) and immuno-assays may give calibration errors if the componet ratio of the standard differs signfiicantly from that of the measured residue. An alternative detection system should be used to quantify such residues.

Calibration using derivatives or degradation products

45. Where the pesticide is detected as a degradation product or derivative, the calibration solutions should be prepared from a reference standard of that degradation product or derivative, if available.

46. Determination of pesticides as unstable derivatives (e.g. some Schiff bases), which cannot be prepared as pure standards, should be avoided.

Chromatographic integration

47. All chromatograms must be scrutinised and the baseline checked and adjusted, as required, by the analyst. Where interfering peaks are present, a consistent approach to the positioning of the baseline must be adopted for all analyses, although such peaks cannot be integrated 'correctly'. A similarly consistent approach must be adopted for the integration of tailing peaks. Peak height or peak area data may be used, whichever yields the more accurate and repeatable results (as assessed from recovery and calibration data).

48. Calibration by mixed isomer (or similar) standards may utilise summed peak areas, summed peak heights, or measurement of a single component, whichever is demonstrated to be the more accurate.

Analytical methods

Acceptability of analytical methods

49. Adequate validation of an analytical method provides guidance on its suitability for the intended purpose, although good performance in practice usually remains dependent upon the analyst. Validation information, used to support the selection, of a method, should relate to an appropriate range of pesticides and sample matrices and may include: (i) the accuracy and precision (reproducibility or repeatability) achieved, preferably over an appropriate range of concentrations; (ii) the sensitivity achieved; (iii) evidence of the specificity; (iv) a test of robustness or ragardness.

50. The analytical method normally should be capable of providing repeatable recovery (for pesticides added at levels greater than approximately five times their limits of determination) within the range 70 to 110 %, for all compounds sought by the method, ideally with a mean recovery for each compound between 80 to 100 %. Where the difficulty of the analysis does not permit this accuracy and precision and there is no satisfactory alternative method, this issue must be considered before taking enforcement action. Before adopting it for monitoring, the analyst's performance of the method should be assessed by means of two or more recovery determinations from each appropriate sample matrix. Where a residue is, to be determined as a moiety derived from two or more components of the residue, method performance should be assessed for all components.

Methods for determination of fat or dry weight content

51. Where results are expressed on the basis of dry weight or fat content, the method used to determine the dry weight or fat content must be consistent. Ideally it should be validated against a recognised standard method.

Recovery determinations

Samples, spiking levels, inclusion in analysis batches

52. Residues to be quantified accurately must be accompanied by concurrent recovery determinations. Where practicable, recovery of all analytes sought should be determined with each batch of analyses. However, where this would require a disproportionately large number of recovery analyses, for example where a very large number of analytes is sought using selective detectors (e.g. ECD, NPD), the minimum acceptable frequency of recovery determinations for various classes of pesticides is given in Table 1. Analysis of a reference material may provide an alternative to recovery determination, providing the material contains the relevant analytes at appropriate levels and that the residues are stable in storage.

53. Pesticide recovery should be determined by addition (spiking) of the analytes to a sample of 'blank' matrix, similar to that under study. The spiking level may be 1 to 10 times the LCL, at the MRL, or at some other level relevant to the particular samples. The blank material chosen should preferably be known not to contain measurable levels of the analytes. Where the blank material contains the analyte at detectable levels (e.g. inorganic bromide) or an interfering compound, the spiking level for recovery should be five times the level present in the blank material. The analyte (or apparent analyte) concentration in such a blank matrix should be determined by multiple analysis. The signal from the blank should be confirmed as due to the analyte, or otherwise, as the case may be.

54. As far as practicable, the recovery of all components defined by the MRL should be determined. Where a residue is determined as a common moiety, routine recovery (see Table 1) may be determined for the component which either normally predominates in residues or is likely to provide the lowest recovery.

Acceptability of analytical performance

55. Irrespective of the levels of addition, routine recovery data may be more variable than indicated by repeatability data from validation of the method. Recovery should be monitored and corrective action must be taken when either a significant drift in the mean recovery, or an unacceptable result, occurs. Care must be taken in assessing recovery at the LCL for this purpose. Recoveries which differ from the routine mean by more than two standard deviations should, and those differing by more than three standard deviations must, be investigated. Although this does not automatically mean that such recoveries are unacceptable, the batch should normally be re-analysed. Generally, routine recovery within the range 60 to 140 % may be considered acceptable (great care may be required in the interpretation of recovery where the spilling level is at or about the LOD or at the LCL). Where the mean for routine recovery approaches an extreme of this range and a recovery result is significantly beyond it, results for the batch of samples must be considered cautiously. Exceptionally, where recovery is low but consistent and the basis for this is well established (e.g. due to pesticide distribution in partition), a mean. recovery below 60 % may be acceptable, However, wherever practicable, a more accutate method should be used. Where recovery for the batch is unacceptable, either acceptable recovery should be reestablished and all samples in the batch re-analysed, or the results must be considered to be no more than semi-quantitative.

56. Where recovery for a pesticide is outside 70 to 110 % for the batch, samples found to contain violative residues of that pesticide should re-analysed, to provide accurate results supported by recovery data within the 70 to 110 % range. If recovery within this range cannot be achieved, decisions on the action to be taken must acknowledge that the residue level may not be known with good accuracy.

57. In certain cases, determination of recovery may not be possible: for example, in direct analysis of liquid samples and various SPME or headspace analyses. In direct analysis of liquids, accuracy and precision are determined by the calibration, assuming that losses of the pesticide (e.g. by adsorption) do not occur between sampling and analysis. In SPME and headspace analysis, accuracy and precision may be a function of the extent to which the analyte is equilibrated within and between the phases and, where practical, this should be demonstrated.

Proficiency testing and analysis of reference materials

58. As indicated in point 3, regular participation in relevant proficiency tests is essential, with appropriate action taken to remedy problems that become evident. In addition, previously characteristed and homogeneous in-house reference materials may be analysed to help provide continuing evidence of the quality of analytical performance, if the residues present are known to be stable in storage.

Confirmation of results

Principles of confirmation

59. It is impossible to prove the complete absence of residues but results which are below the LCL, and therefore not to be reported as absolute numbers, are considered conformed if the recovery and LCL. data for the batch are acceptable. Adoption of a 'reporting limit' at the LCL avoids the high and unjustifiable cost of proving the presence, or absence, of residues at such low levels that the data are not meaningful. Where a batch of analyses did not include calibration or recovery of the particular pesticide(s), the corresponding data for the reference pesticides provide only indirect evidence of a satisfactory analysis. Such results cannot be considered confirmed, although the data may be adequate for some purposes.

60. Results at or above the LCL require additional support in order to be considered confirmed. Where the batch of analyses was performed without calibration for the particular pesticide, the results must be regarded as very tentative and confirmation is essential. In this case, the minimum requirement is re-analysis of the extracts, with appropriate calibration for the pesticide detected. As the pesticide involved should be detected infrequently (see Table 1) and may therefore be unusual, re-analysis of the sample with concurrent recovery determination is to be preferred.

61. Where enforcement action will be taken, or other important decisions made, on the basis of results a exceeding the LCL, acceptable concurrent calibration and recovery data are essential, supported by further confirmation. The nature and extent of the further confirmation required depends on the relative importance of the particular result and the frequency with which similar residues are found. Quality control procedures for confirmatory analysis must be rigorous.

Approaches to confirmation

62. Confirmation of the analyse detected should be quantitative and qualitative.

63. Assays based on immunochoemistry, colorimetry, thin-layer chromatography or electron-capture detectors tend to require the most confirmatory support, because of their lack of specificity. Where 'selective' detectors are used with GC or LC, a second chromatographic column of significantly different polarity (or a second 'specific' detection system) provide only limited confirmatory evidence. This may be acceptable for frequent, low-level residues where a proportion of the residues is also confirmed by a more definitive technique but the use throughout of the more definitive technique is preferable.

64. Where a residue exceeds the MRL or where it should not be present in the sample, the result must be confirmed by the least equivocal method available and by analysis of one or more additional analytical portions. Residues in replicate portions may be quantified by either the screening or the confirmatory technique. The number of replicate portions to be analysed should be determined by the variation in results obtained.

Confirmation by mass spectrometry

65. MS is capable of providing almost unequivocal confirmation of residues of most pesticides but the confirmatory data must comply with certain minimum requirements. Matrix-matched calibration standards should normally be used for confirmation of quantity but the reference mass spectrum should derive from the reference standard, or a solution of it in pure solvent. To avoid distortion of ion ratios, the quantity of material used for the reference spectrum must not overload the detector. Confirmation of high-level residues may be straightforward but results close to the limit of MS determination must be considered on a case-by-case basis.

66. Chromatograms of relevant ions should have peaks (minimum three scans, minimum summed S/N 3:1) with similar retention time, peak shape and response ratio as those obtained from a calibration standard, analysed in the same batch. Where chromatograms of nationally unrelated ions include peaks with a similar retention time and shape, or where this information is not available (e.g. from 'limited scanning' or selected ion monitoring), additional confirmation may be required. Where an ion-chromatogram shows evidence of significant chromatographic interference, that ion must not be relied upon to quantify or identify residue.

67. Spectra should be background-subtracted, if appropriate, but the background must be selected with care to avoid distortion of the data. Where ions unrelated to the analyte in a peak-averaged 'full-scan' spectrum (i.e. from m/z 50 to 50 mass units greater than the 'molecular ion') do not exceed a quarter of base peak intensity in electron-impact

ionisation spectra, or one-10 for all other ionisation methods, the spectrum may be accepted as sufficient evidence of identity. Where these limits are exceeded and the unrelated ions derive from chromatographically overlapping species, an alternative background may be subtracted, and/or additional evidence may be sought. Intensity ratios for principal ions should be within 80 to 120 % of those obtained from the standard. Where an ion-chromatogram shows significant chromatographic interference that ion should not be used to determine an intensity ratio and additional supporting evidence may be required. The most abundant ion that shows no evidence of chromatographic interference should be used to quantify a residue. With electron-impact ionisation, in particular, the absence of interfering ions may be used to support identification where the analyte spectrum is very simple.

68. Ionisation by electron-impact, or by further fragmentation of selected ions (MS/MS), coupled with acquisition of full-scan spectra, generally provides the most definitive evidence of identity and quantity. Mass spectra produced by less energetic processes (e.g. chemical ionisation, atmospheric pressure ionisation) may be too simple to confirm identity without further evidence. Unless the isotope ratio of the ion(s) or the chromatographic profile of isomers of the analyte is highly characteristic, additional supporting evidence is likely to be required. This may be provided by: (i) a different chromatographic separation system; (ii) a different ionisation technique; (iii) MS/MS; (iv) the use of medium/high resolution MS; or (v) altering fragmentation by changing the 'cone voltage' in LC-MS. In using medium/high resolution MS or MS/MS, wherever possible the ions selected should be characteristic of the pesticide rather than common to many organic compounds.

69. Full-scan spectra provide the most convincing identification but sensitivity may be improved by scanning a limited mass range or by selected ion monitoring. With these techniques, the minimum requirement is for data from two ions of m/z > 200; or three ions of m/z > 100. Additional supporting evidence (see point 68) may be required in some cases and must be provided where the analyte spectrum does not permit these requirements to be met.

Confirmation in an independent laboratory

70. Where important residues cannot be confirmed locally, the confirmation may be carried out in another laboratory, if practicable.

Reporting of results

Expression of results

71. Results should normally be expressed as defined by the MRL and in mg/kg. Samples in which residues are lower than the LCL should be reported as < LCL) mg/kg.

Calculation of results

72. In general, residue data should not be corrected for recovery. Routine recovery enables analytical performance to be monitored and provides general guidance as to the accuracy of results. It does not necessarily establish the accuracy and uncertainty (see point 77) achieved for a particular sample. Results must not be corrected for blank values where these are due to the analyte (see point 41).

73. Where confirmed data are derived from a single analytical portion (i.e. the residue is not violative or unusual), the reported result should be that derived from the detection technique considered to be the most accurate. Generally this will be the technique providing the best specificity. Where results are obtained by two or more equally accurate techniques, the mean value may be reported.

74. Where two or more analytical portions have been analysed, the arithmetic mean of the most accurate results obtained from each portion should be reported. Where good comminution and/or mixing of samples is undertaken, the RSD of results between analytical portions should not exceed 30 % if the residue measured is significantly greater than the LOD. Close to the LCD, the variation in results may be much higher and this should be takes into account in deciding what action should be taken.

75. Where the definition of an MRL includes two or more compounds, one component often predominates in residues. Where the components are detected separately (rather than as a common moiety), the overall reporting limit for the pesticide should be the LCL of the component producing the lowest response on a molar basis. For example, if the LCL for endosulfan isomers is 0,05 mg/kg and that of the sulphate metabolite is 0,1 mg/kg, then the overall reporting limit for endosulfan should be quoted as 0,1 mg/kg. Where the reference standard contains two or more components producing similar molar responses but which differ in concentration, for example chlorfenvinphos mixed isomers, the reporting limit may apply to the component producing the largest absolute response. If this approach is adopted, the lack of a characteristic component profile supporting the identification of residues at or about the reporting limit may require the use of a more rigorous confirmation technique.

Rounding of data

76. When reporting results < 0,1 mg/kg, data should be rounded to one significant figure; results > 0,1 but < 10 mg/kg should be rounded to two significant figures; results ≥ 10 mg/kg may be rounded to three significant figures or to a whole number. These requirements do not necessarily reflect the uncertainty associated with the data.

Quantifiying the uncertainty of results

77. Measurement uncertainty is a useful quantitative indicator of the confidence that can be placed on results. Uncertainty data do not replace the need for confirmation and they are required primarily to support very important results. ISO rules for evaluating and expressing uncertainty in measurement [1] require identiication of the potential sources of uncertainty that influence the result. This formal approach may be adapted, if required, but a simpler method may be employed, such the use of the standard deviation of either repeatability or internal reproducibility. These values may be derived from recovery data or the analysis of reference materials. However, the uncertainty data must relate to the specific pesticide and should have been generated from the relevant matrix, at a level approximating that in the sample. It may therefore be necessary to produce uncertainty data from recoveries over a range of concentrations. Ideally, uncertainty data should be derived from replicate analysis of 5 to 10 portions of the sample and thus embrace the uncertainties of both sub-sampling and analysis. The uncertainty may be expressed as the 95 % confidence interval for the result.

Compliance decisions

78. A decision on whether or not results indicate that a residue exceeds an MRL should take into account the concentration found and the validity of measurement indicated by the corresponding quality control data. Decisions on the consequent action should be made on a case-by-case basis.

79. Where residues measured in the sample(s) taken from a lot do not exceed the MRL(s), the lot is compliant with the MRL(s).

80. Where results for the laboratory sample(s) taken from a lot exceed the MRL, a decision that the lot is non-compliant must take into account (i) the range of results obtained from replicate laboratory samples and/or replicate analytical portions, as applicable; and (ii) the accuracy and uncertainty of analysis. In general, a non-compliance decision will require acceptable calibration, concurrent recovery determination and confirmatory data. Where the presence of a pesticide is uneccaptable regardless of level, the lot is none-compliant if the residue is at or above the LCL sad its identity is confirmed.

81. Where the a presence of a low level of a pesticide is to initiate enforcement action, the possilsility of cross-contamination having occurred before, during or after sampling must be considered.

Retention of information.

82. Sample data records, laboratory notebooks, chromatograms, tables of results, disks or tapes bearing chromatographic or spectral data, etc., must be retained for scrutiny. Following submission of the report, data should be retained for five years for violative samples, or two years for non-violative sample.

Glossery

Batch	For extraction, clean-up and similar processes, a batch is a series of samples dealt with by an analyst (or team of analysts) in parallel, usually in one day, and should incorporate at least one recovery determination. For the detection procedure, a batch is a series of determinations undertaken without a significant time break and which incorporates all relevant calibration determinations. Batches of determinations may also be referred to as 'analysis runs', 'run sequences', 'chromatography runs', etc., but with formats such as 96-well plates, a plate will form a batch. A determination batch may incorporate more than one extraction batch.
Blank	(i) A sample known not to contain detectable levels of the analytes sought. An extract (or equivalent) of such a sample may be known as a matrix blank. (ii) A complete analysis conducted using the solvents and reagents only, in the absence of any sample (in certain cases it may be necessary to substitute water for the sample in order to make the analysis realistic). Also known as a reagent blank or proecedural bank.

[1] Anonymous (1993) *Guide to the expression of uncertainty in measurement* (ISBN 92-67-10188-9). ISO, Geneva, Switzerland.

Bracketing	Organisation of a batch of determinations such that the detection system is calibrated immediately before and after the analysis of the samples. For example, calibrant 1, calibrant 2, sample 1 ...sample *n* calibrant 1, calibrant 2.
Calibration	Determination of the response produced from the analyte by the detection system, over the range of concentrations to be reported and at the time the samples are analysed. The solutions etc., used for this purpose may be termed calibration solutions, calibration standards or calibration extracts. Calibration of detector response is wholly distinct from calibration of weighing and volumetric equipment, from mass calibration of mass spectromedters, and so on.
CHEK	A proficiency testing scheme organised by the Inspectorate for Health Protection, Groningen, The Netherlands.
ECD	Electron-capture detector.
ELISA	Enzyme-linked immuno-sorbent assay.
EU	European Union.
FAPAS	Food analysis performance assessment scheme, a proficiency testing scheme organised by the Ministry of Agriculture, Fisheries and Food, Norwich, United Kingdom
FPD	Flame-photometric detector (may be specific to sulphur or phosphorus detection).
GC	Gas chromatography (gas-liquid chromatography).
Internal reproducibility	The repeatability of recovery of an analyte, achieved within a laboratory using the same method on several or many occasions.
LC	Liquid chromatogrpahy (primarily high performance liquid chromatography, HPLC).
LCL	Lowest calibrated level. The lowest concentration of analyte with which the detection system is calibrated, in seeking to determing to presence or absence of measurable residues. It will normally form the reporting limit.
Level	Usually refers to concentration (e.g. mg/kg, µg/ml) but may refer to quantity (e.g., ng, pg).
LOD	Limit of determination (or limit of quantitation).
Matrix blank	See blank.
Matrix-matched calibration	See also 'calibration'. The use of calibration solutions, or headspace partitions, or SPME fibres, etc., in which all constituents (other than the analyte) are similar to, or produce the same effect on analytical response as, the equivalent solutions (etc.) produced from the samples to be analysed. The matrix blank (see 'blank', above) should be prepared making similar solvents reagents, clean-up, etc., to those used for the analysis of the corresponding samples. In practice, the pesticide is added to a blank extract (or a blank sample for headspace analysis) of a matrix similar to that analysed. The objectives are: (i) to compensate for analyte response enhancement or suppression effects induced by sample coextractives; (ii) to provide a chromatogram for integration which has underlying interference comparable to that of the sample. The matrix used may differ from that of the samples if it is shown to achieve these objectives.

MRL	Maximum residue limit.
MS	Mass spectrometry.
MS/MS	Tandem-mass spectrometry, here taken to include MS. An MS procedure in which a particular ion from the primary ionisation process is isolated, fragmented by collision or otherwise, and the product ions separated (MS/MS or MS^2). The procedure may be carried out repetitively on a sequence of product ions (MS), although this is not usually practical with low-level residues.
NPD	Nitrogen-phosphorus detector.
Priming	Preliminary deactivation of a GC column and/or injector, by injection of a suitable solution or extract immediately before starting a batch of determinations. The increase in resposne to the analyte, which normally occurs, is due to increased transmission. Extracts used for priming do not normally need to be from a matrix identical to that of the samples to be analysed. To avoid carry-over, it is usually prefereable that priming extracts contains little or no detectable pesticide.
Procedural blank	See blank.
Reagent blank	See blank.
Reference pesticide	A pesticide which must be incorporated into recovery and calibration detreminations in each batch of analyses (points 33 to 35).
Reference material	A sample which has been characterised with respect to the content of a pesticide. Certified reference materials are normally characteristed in a number of laboratories, for concentration and homogeneity of distribution of the pesticide. In-house reference materials are characterised in a single laboratory and, as far as practicable, they should be shown to be homogeneous and stable.
Reference spectrum	A spectrum of absorption (e.g. UV, IR), fluorescence, ionisation products (MS), etc., derived from the analyte and which may be characteristic of it. The reference mass spectrum preferably should be produced from the reference standard (or a solution of the reference standard) by the instrument used for analysis of the samples, and similar ionisation conditions must be used.
Reference standard	A relatively pure sample of an analyte (or internal standard), of known purity. Usually > 90 % purity, except for technical concentrates of certain pesticides.
Reporting limit	The lowest level at which residues will be reported as absolute numbers. It may represent the practical limit of determination, or it may be above that level to limit analysis costs. It should equal the lowest calibrated level (LCL), the level below which there is no experimental evidence to prove that residues will have been detected and calibrated satisfactorily.
RSD	Relative standard deviation (coefficient of variation).
SFE	Supercritical fluid extraction
Solid phase dilution	Dilution of a pesticide by distribution within a finely divided solid, such as starch powder. Normally used only for insoluble analytes such as the complex dithiocarbamates.
S/N	Signal-to-noise ratio.
SPME	Solid phase micro-extraction.

ANNEXE III

WORKING DOCUMENT

for guidance to the EFTA States with regard to the implementation of EFTA Surveillance Authority recommendations concerning coordinated monitoring programmes to ensure compliance with maximum levels of pesticide residues in and on certain products of plant origin, including fruit and vegetables and the presentation of the EFTA States' reports on national monitoring

Introduction

1. The purpose of this working document is to indicate solutions to questions and confusing situations which have arisen. It is hoped that all EFTA States can implement the various changes in this version of the guidelines in the presentation of their reports on their 1998 monitoring.

Distribution

2. The EFTA States should send their monitoring reports to the EFTA Surveillance Authority and to each of the other EFTA States (contact point list — Annex 1).

2.1. The EFTA States should, in particular, send their reports directly by e-mail or on diskette to the EFTA Surveillance Authority, following the guidance set out in this note so that the task of collating and compiling a report is facilitated.

Report format

3. Reports should be made in the format set out in Tables A, B, C and D of the Annex to working document (VI/1609/97-rev.5).

3.1. The EFTA States' reports should also be made in text/narrative. In particular, the EFTA States should draft, if possible with a version in English, a one page (400 to 500 words) summary of their reported monitoring activities during the year, which could be incorporated into a European report. The summary report should distinguish between the coordinated EEA monitoring programme and national monitoring and should, in particular, contain the following information:

3.1.1. the summarised statistical situation, including:

— total number of samples (not analyses) of all food items (not to be itemised) examined,

— total number of samples (not analyses) in which pesticide residues which were looked for were not detected,

— total number of samples (not analyses) in which one or more residues were detected below the MRL,

— total number of samples (not analyses) in which one or more residues were detected exceeding the MRL (record total and EC MRL exceedence separately);

3.1.2. a summary statement of the total number of residues analysed for or an estimate, if appropriate;

3.1.3. a list of the 10 most frequently reported pesticide residues in descending order of findings;

3.1.4. a summary of the detailed information given about sample numbers and quality assurance (see point 12).

Report format — Diskette/informatic requirements

4. For the coordinated Community monitoring results the information should be compiled in Excel tables.

4.1. Pesticides should be listed in English alphabetical order or in the order set out in the Recommendation.

Reports in tabular form

5. In addition on to the summary report described in point 3.1, reports in the form of Tables as set out in the Annex should be made:

— Table A: summarised statistical report (all pesticide monitoring)

— Table B: notification of the coordinated programme (specific exercise) to the EFTA Surveillance Authority

— Table C: notification of check sampling and monitoring to the EFTA Surveillance Authority

— Table D: details of confirmed residues exceeding the MRL (EC harmonised MRL only, excluding national MRLs in open positions)

— Table E: details of samples with multiple residues (two and more) in single sample.

EC and national MRLs

6. Recommendations for coordinated monitoring programmes up to that for 1997 cover only MRLs established in Annex II of Directive 90/642. Recommendations for 1999 onwards will also cover MRLs established in Annex II of Directive 86/362. The EFTA States may set national MRLs for pesticides or products not covered by these Directives and may, of course, set national MRLs for pesticides and products which are covered but for which, at present, the position is 'open'.

Reporting levels

Reporting levels for each pesticide residue have been indicated by the Council of the European Union when setting MRLs. In principle, the reporting level is the routinely achievable limit of quantification practical for the monitoring laboratories.

7. The EFTA States should make specific reports with supporting information on reporting level problems and/or high-light such cases for remedial action.

Routine monitoring — check sampling — surveillance

8. Historically, national monitoring programmes have not been random as they have always sought to maximise the use of restricted resources by concentrating on known or suspect problem areas. Frequently national multi-annual programmes will concentrate on certain products on a rolling basis and will always tend to be targeted in accordance with certain criteria.

Compliance monitoring — enforcement — targeted

9. Article 4 of the Act referred to in point 50 of Chapter XII of Annex II to the EEA Agreement on the official control of foodstuffs (Council Directive 89/397/EEC), also covers inspections where non-compliance is suspected. Compliance monitoring is clearly more than targeted routine monitoring and will normally be in reaction to an earlier finding of residues above the MRL this may be a reaction within days or weeks of such a finding and/or during the following production/import season and the monitoring may involve the holding of consignments until analyses are completed.

9.1. It is commonly argued that compliance monitoring is likely to result in the detection of a greater number of MRL exceeding but, of course, the deterrent nature of publicised compliance monitoring may result in a lower number of MRL exceeding being detected.

9.2. The EFTA States should consider what parts of their monitoring programmes constitute clearly identifiable compliance monitoring and should report these on separate Tables C and D as amended.

Exceeding of MRL

10. Table D of the Annex requires certain information concerning each sample exceeding MRLs. In making their annual reports, EFTA States should clearly indicate what they have included as exceeding of MRLs. These may include:

— cases where the analytical laboratory has certified an exceeding within the application of the quality assurance applicable to the analysis,

— cases where official warnings have been issued to the holders of the products inspected and sampled,

— cases where legal or administrative consequences have followed, e.g. prosecution, the levying of penalties or fines.

Multiple residues

11. Table E of the Annex covers details of samples with more than two pesticide residues detected in single samples. This table responds to current concerns about multiple residue effects in seeking data on such cases, which will be passed to experts for evaluation (both toxicologically and in relation to authorisation policies). The EFTA States should report on residues of both harmonised and, where possible, national pesticides.

Quality assurance

12. Information concerning quality assurance relating to the data supplied to the EFTA Surveillance Authority are an essential underpinning of the pesticide residue monitoring work and will be included in the annual reports.

12.1. The EFTA States should report on national actions assuring quality of information supplied to the EFTA Surveillance Authority; this should include, in particular, actions additional to those covered by the three elements where quality assurance actions are implemented at EC/EEA level; accreditation of laboratories, EC proficiency tests and quality control procedures for pesticide residue analysis — Guidelines for residues monitoring.

12.1.1. Accreditation, in accordance with the provisions of Article 3 of Directive 93/99/EC on the subject of additional measures concerning the official control of foodstuffs: laboratories undertaking analyses of foodstuffs for pesticide residues are required to obtain the appropriate accreditation by 1 November 1998. EFTA Surveillance Authority recommendation for 1997 requires details of accreditation; EFTA Surveillance Authority recommendations for 1999 onwards specify the detail as including 'type of accreditation, accreditation body and copy of accreditation certificate'. For 1999 onwards, the EFTA Surveillance Authority will not be able to accept information from EFTA States' laboratories which are not accredited.

12.1.2. EC profiency tests were first conducted in 1997 and it is intended that proficiency test will be conducted annually. Participation of laboratories in EC proficiency tests will assist them in gaining accreditation and it should be a condition of acceptability of data by the EFTA States for submission to the EFTA Surveillance Authority that the laboratory concerned has participated in such a test as well as being accredited (see point 12.1.1).

ANNEX 1

National authority and contact point for pesticide residue monitoring

National Authority	*Contact point*
Norwegian Food Control Authority Box 8187 Dep. N-0034 Oslo, Norway	Ms G. Torp Varran Tel 47 22 24 66 50 Fax 47 22 24 66 99 E-mail: postmottak@SNT.Dep.telemax.no

(Concerning other EEA States, see EC report on 1996)

ANNEX 2

Pesticides for which MRLs are established in Annex II to Directives 76/895 [1], 86/362, 86/363 [2] and 90/642

Acephate

Chlorothalonil

Chlorpyriphos

Chlorpyriphos-metyl

Cypermethrin

Deltamethrin

Fenvalerate

Glyphosate

Imazalil

Iprodione

Permethrin

Carbendazim (Benomyl, Carbendazim, Thiophanate-Methyl)

CS_2 (Maneb, Mancozeb, Metiram, Propineb, Zineb)

Methamidophos

Procymidone

Vinclozolin

DDT

Amitrole

Atrazine

Binpacryl

Bromophos-ethyl

Captafol

Dichlorprop

Dinoseb

Dioxathion

Endrin

Ethylene dibromide

Fenchlorphos

Heptachlor

Maleic hydrazide

Methyl bromide

Paraquat

TEPP

Camphechlor (toxaphene)

2,4,5-T

Daminozide

Lambda-cyhalothrin

Propiconazole

Carbofuran

Carbosulfan

[1] The Act referred to in point 13 of Chapter XII of Annex II to the EEA Agreement
[2] The Act referred to in point 39 of Chapter XII of Annex II to the EEA Agreement

Benfurocarb

Furathiocarb

Cyfluthrin

Metalaxyl

Benalaxyl

Fenarimol

Etephon

Methidathion

Methomyl (Thiodicarb)

Amitraz

Pirimiphos-methyl

Aldicarb

Thiabendazole

Triforine

Endosulfan

Fentin

Phorate

Dicofol

Chlormequat

Propyzamide

Propoxur

Disulfoton

Fenbutatin oxide

Triazaphos

Diazinon

Mecarbam