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I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 2148/1999
of 8 October 1999
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 9 October 1999.

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

Done at Brussels, 8 October 1999.

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 8 October 1999 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	204	85,7
	999	85,7
0707 00 05	628	136,6
	999	136,6
0709 90 70	052	70,9
	999	70,9
0805 30 10	052	63,0
	388	68,3
	524	56,1
	528	66,7
	999	63,5
0806 10 10	052	101,4
	064	75,2
	400	241,3
	999	139,3
0808 10 20, 0808 10 50, 0808 10 90	060	46,2
	388	54,0
	400	38,8
	480	48,9
	800	184,2
	804	46,6
	999	69,8
0808 20 50	052	96,6
	064	57,2
	388	177,3
	999	110,4

⁽¹⁾ Country nomenclature as fixed by Commission Regulation (EC) No 2645/98 (OJ L 335, 10.12.1998, p. 22). Code '999' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 2149/1999
of 8 October 1999
on the issue of import licences for high-quality fresh, chilled or frozen beef and veal

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Commission Regulation (EC) No 936/97 of 27 May 1997 opening and providing for the administration of tariff quotas for high-quality fresh, chilled and frozen beef and for frozen buffalo meat ⁽¹⁾, as last amended by Regulation (EC) No 134/1999 ⁽²⁾,

- (1) Whereas Regulation (EC) No 936/97 provides in Articles 4 and 5 the conditions for applications and for the issue of import licences for meat referred to in Article 2(f);
- (2) Whereas Article 2(f) of Regulation (EC) No 936/97 fixes the amount of high-quality fresh, chilled or frozen beef and veal originating in and imported from the United States of America and Canada which may be imported on special terms for the period 1 July 1999 to 30 June 2000 at 11 500 t;

- (3) Whereas it should be recalled that licences issued pursuant to this Regulation will, throughout the period of validity, be open for use only in so far as provisions on health protection in force permit,

HAS ADOPTED THIS REGULATION:

Article 1

1. All applications for import licences from 1 to 5 October 1999 for high-quality fresh, chilled or frozen beef and veal as referred to in Article 2(f) of Regulation (EC) No 936/97 shall be granted in full.
2. Applications for licences may be submitted, in accordance with Article 5 of Regulation (EC) No 936/97, during the first five days of November 1999 for 4 162,067 t.

Article 2

This Regulation shall enter into force on 11 October 1999.

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

Done at Brussels, 8 October 1999.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 137, 28.5.1997, p. 10.

⁽²⁾ OJ L 17, 22.1.1999, p. 22.

COMMISSION REGULATION (EC) No 2150/1999**of 8 October 1999****determining the world market price for unginned cotton and the rate for the aid**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

differences in product quality and the nature of offers and quotations; whereas these adjustments are specified in Article 2 of Regulation (EEC) No 1201/89;

Having regard to the Treaty establishing the European Community,

(3) Whereas application of the above rules gives the world market price for unginned cotton indicated hereunder;

Having regard to the Act of Accession of Greece, and in particular paragraphs 3 and 10 of Protocol 4 on cotton, as last amended by Council Regulation (EC) No 1553/95 ⁽¹⁾,

(4) Whereas the second subparagraph of Article 5(3a) of Regulation (EC) No 1554/95 stipulates that the advance payment rate for the aid is to be the guide price less the world market price and less a further amount calculated by the formula applicable when the guaranteed maximum quantity is overrun but with a 15 % increase in the estimate for unginned cotton production; whereas Commission Regulation (EC) No 1870/1999 ⁽⁶⁾ determined estimated production for the 1999/2000 marketing year; whereas application of these rules gives the advance payment rates for each Member State indicated hereunder,

Having regard to Council Regulation (EC) No 1554/95 of 29 June 1995 ⁽²⁾ laying down general rules for the system of aid for cotton and repealing Regulation (EEC) No 2169/81, as last amended by Regulation (EC) No 1419/98 ⁽³⁾, and in particular Articles 3, 4 and 5 thereof,

(1) Whereas Article 3 of Regulation (EC) No 1554/95 requires a world market price for unginned cotton to be periodically determined from the world market price determined for ginned cotton, using the historical relationship between the two prices as specified in Article 1 (2) of Commission Regulation (EEC) No 1201/89 of 3 May 1989 laying down rules for implementing the system of aid for cotton ⁽⁴⁾, as last amended by Regulation (EC) No 1624/1999 ⁽⁵⁾; whereas if it cannot be determined in this way it is to be based on the last price determined;

HAS ADOPTED THIS REGULATION:

Article 1

1. The world market price for unginned cotton as indicated in Article 3 of Regulation (EC) No 1554/95 is set at EUR 20,043/100 kg.

(2) Whereas Article 4 of Regulation (EC) No 1554/95 requires the world market price for ginned cotton to be determined for a product of specific characteristics using the most favourable offers and quotations on the world market of those considered representative of the real market trend; whereas to this end an average is to be calculated of offers and quotations on one or more European exchanges for a cif product to a North European port from the supplier countries considered most representative as regards international trade; whereas these rules for determination of the world market price for ginned cotton provide for adjustments to reflect

2. Advance payment of the aid as indicated in Article 5 (3a), second sentence, of Regulation (EC) No 1554/95 shall be at the rate of:

- EUR 43,524/100 kg in Spain,
- EUR 43,205/100 kg in Greece,
- EUR 86,257/100 kg in other Member States.

Article 2

This Regulation shall enter into force on 11 October 1999.

⁽¹⁾ OJ L 148, 30.6.1995, p. 45.

⁽²⁾ OJ L 148, 30.6.1995, p. 48.

⁽³⁾ OJ L 190, 4.7.1998, p. 4.

⁽⁴⁾ OJ L 123, 4.5.1989, p. 23.

⁽⁵⁾ OJ L 192, 24.7.1999, p. 39.

⁽⁶⁾ OJ L 230, 31.8.1999, p. 3.

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

Done at Brussels, 8 October 1999.

For the Commission

Franz FISCHLER

Member of the Commission

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 19 July 1999

concerning the conclusion of the Agreement on mutual recognition of OECD principles of good laboratory practice (GLP) and compliance monitoring programmes between the European Community and the State of Israel

(1999/662/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133 thereof, in conjunction with the first sentence of Article 300(2) and the first subparagraph of Article 300(3) and Article 300(4),

Having regard to the proposal from the Commission,

Whereas:

- (1) the Agreement on mutual Recognition of OECD principles of good laboratory practice (GLP) and compliance monitoring programmes, initialled in Brussels on 16 January 1997, was negotiated by the Commission in accordance with its negotiating guidelines and should be approved;
- (2) certain aspects of implementation have been assigned to the Joint Committee established by the Agreement, and in particular the power to amend certain parts of the two Annexes;
- (3) it is necessary to lay down the internal procedures required for the proper functioning of the Agreement; the Commission should be empowered to make certain technical changes to the Agreement and to take certain decisions concerning its implementation,

HAS DECIDED AS FOLLOWS:

Article 1

The Agreement on mutual recognition of OECD principles of good laboratory practice (GLP) and compliance monitoring programmes between the European Community and the State of Israel is hereby approved on behalf of the Community.

The text of the Agreement and the Agreed Minutes are attached to this Decision.

Article 2

The President of the Council shall, on behalf of the Community, transmit the note provided for in Article 16 of the Agreement ⁽¹⁾.

Article 3

1. The Commission, assisted by the Special Committee appointed by the Council, shall represent the Community in the Joint Committee provided for in Article 10 of the Agreement. After consulting the Special Committee, the Commission shall carry out the notifications, consultations and exchanges of information, shall make the requests for inspections and for participation in inspections, and, if need be, shall reply to requests, in accordance with Articles 3(2), 5(2), 6, 7, 9 and 12 of the Agreement and in Annex II thereto, and adopt the Decision provided for in Article 11(2) and (3) and the second sentence of Article 12.

2. The position of the Community within the Joint Committee, with regard to amendments to Annex I decided on in accordance with the second sentence of Article 4 of the Agreement and to amendments to Annex II decided on in accordance with Article 5 of the Agreement, shall be adopted by the Commission after it has consulted the Special Committee referred to in paragraph 1 of this Article.

3. All other decisions shall be taken by the Council, acting by a qualified majority on a proposal from the Commission.

Done at Brussels, 19 July 1999.

For the Council

The President

T. HALONEN

⁽¹⁾ The date of entry into force of the Agreement will be published in the *Official Journal of the European Communities* by the General Secretariat of the Council.

AGREED MINUTES**concerning the Agreement on mutual recognition of OECD principles of good laboratory practice (GLP) and compliance monitoring programmes between the European Community and the State of Israel**

Having regard to the Transitional Provisions of the Agreement on mutual recognition of OECD principles of good Laboratory practice (GLP) between the European Community (EC) and the State of Israel, the Contracting Parties state as follows:

TEST FACILITIES CONCERNED

- The list of test facilities that Israel wants to be GLP recognised is annexed to the present minute.

PRELIMINARY MISSION

- Before the signature of the Agreement, a preliminary mission of two experts of the EC will take place in order to:
 - assess the state of affairs concerning the test facilities in Annex that eventually could be GLP recognised,
 - give their advice for the setting up of the national GLP monitoring authority,
- Both parties agree to accept the findings of the report of the experts concerning the above mission as submitted.

INITIAL PERIOD

- All inspections during the initial period will be performed by at least two inspectors designated by the EC.

The reports of these inspections will be sent by the inspectors to the test facility concerned and, in addition, to the authorities of the Contracting Parties ⁽¹⁾,
- inspections will start as soon as possible after the signature of the Agreement and on request of the Israeli Authorities, in order to inspect the test facilities interested to be GLP recognised,
- all the costs pertaining to the missions, both the preliminary mission and the inspections during the initial period, will be supported by the State of Israel.

⁽¹⁾ European Commission
DG I/M/2
Rue de la Loi/Wetstraat 200
B-1049 Bruxelles/Brussel

Israel Laboratory
Accreditation Authority
Habonim Street, 2
Ramat Gan 52522 (Israel)

For the Government of the State of Israel

Henry Kney Aol

For the European Community

Stt. Sathl.
J F Pedes

ANNEX

ISRAELI TEST FACILITIES CANDIDATES TO BE GLP RECOGNISED

1. AGAN CHEMICAL MANUFACTURERS LTD

Address: ASHOD 77102
PO Box 262
Tel. (972) 851 52 11
Fax (972) 851 53 88

2. AMINOLAB LTD ANALYTICAL LABORATORY SERVICES

Address: Weizmann Science Park
PO Box 2407
REHOVOT 76123
Tel. (972) 840 96 90
Fax (972) 840 84 74

3. ANALYST RESEARCH LABORATORIES

Address: Kiriat Weizmann
PO Box 1176
REHOVOT 76111
Tel. (972) 89 36 20 34
Fax (972) 89 36 20 39

4. HARLAN BIOTEC ISRAEL LTD

Address: Weizmann Science Park, building 13B
PO Box 12085
REHOVOT
Tel. (972) 89 40 94 51
Fax (972) 89 40 94 52

AGREEMENT

on mutual recognition of OECD principles of good laboratory practice (GLP) and compliance monitoring programmes between the European Community and the State of Israel

THE EUROPEAN COMMUNITY (hereinafter referred to as 'the Community'),

on the one hand, and

THE STATE OF ISRAEL (hereinafter referred to as 'Israel')

on the other hand,

THE TWO PARTIES subsequently referred to as the 'Contracting Parties',

HAVING REGARD TO their obligations under the World Trade Organisation (WTO) and the WTO Agreement on technical barriers to trade, and especially to Annex I-C thereof, concerning the protection of intellectual property,

HAVING REGARD TO the OECD Council Decision of 12 May 1981 on mutual acceptance of data for the evaluation of chemicals,

HAVING REGARD TO the OECD Council Decision-Recommendation of 2 October 1989 on compliance with principles of good laboratory practice (C(89)87(final)),

HAVING REGARD to the Agreement on the European Economic Area of 2 May 1992 that establishes a zone of free circulation of goods, services, people and capital between the European Community and Iceland, Liechtenstein and Norway and especially to its 12th Protocol,

AFFIRMING the need to ensure the high quality, validity and reliability of health and environmental data generated during the testing of cosmetics, industrial chemicals, pharmaceuticals, food additives, animal feed additives, pesticides (hereinafter referred to as chemicals),

NOTING that in the absence of a national GLP monitoring authority in Israel, there is a need for transitional arrangements during an initial period during which Israel will set up this authority,

HAVE AGREED AS FOLLOWS:

Article 1

Definitions

1. Unless specific definitions are given, the definition of terms in the 'OECD principles of good laboratory practice' (Annex II to OECD Council Decision (C(81)30(final)), the 'Guides for compliance monitoring procedures for good laboratory practice' (Annex I to Council Decision-Recommendation (C(89)87(final)), the 'Application of the good laboratory practice principles to field studies' (GLP consensus document, OECD series on principles of good laboratory practice and compliance monitoring), and all amendments made thereto shall apply.

2. 'Accept' means that the receiving authorities will be obliged to recognise studies and data generated therefrom, from the other party on products subject to this Agreement under the same conditions as data generated on their own territory, provided that:

- the study was conducted by a test facility located on the territory of the Contracting Parties,
- the study is performed by a test facility that has been judged to operate in compliance with the good laboratory practice principles by the relevant national good laboratory practice monitoring Authorities.

3. 'Monitoring authority': a management body with responsibility for monitoring the good laboratory practice compliance of test facilities within the territory of its administration and for discharging other such functions related to good laboratory practice as may be nationally determined.

Article 2

Scope

1. The Contracting Parties shall ensure the high quality, validity and reliability of safety evaluation data obtained during non-clinical testing on all chemicals as identified in Annex I before they are placed on the market.

2. The Contracting Parties shall recognise the equivalence of each others' compliance monitoring programmes on GLP that are in accordance with the principles referred to in Article 3(1).

3. Each Contracting Party shall accept studies and data generated therefrom, on the entirety of their territory as defined in Article 15, produced by the test facilities located on the territory of the other Contracting Party provided they participate in the GLP compliance monitoring programme of that Party in accordance with the principles referred to in Article 3(1).

4. Under the terms of this Agreement, the studies and the data generated therefrom, shall be used by the Contracting Parties for consideration in any administrative action to allow placing on the market of all chemicals as defined in Annex I.

Article 3

Basis of reference

1. For the purposes of this Agreement, the following conditions shall be fulfilled:

- the principles of good laboratory practice shall be in conformity with those adopted by the OECD in its Decision of 12 May 1981 on mutual acceptance of data for the evaluation of chemicals (C(81)30(final)) and all amendments made thereto,
- the provisions regarding test facility inspection and study audits shall be in conformity with those adopted by the Council of the OECD in Annexes I to III to the 1989 Decision-Recommendation (C(89)87(final)), that has been modified by its Decision-Recommendation of 9 March 1995 (C(95)8(final)), and all amendments made thereto,
- the test facilities shall be recognised to be in conformity with good laboratory practice in accordance with the principles applicable respectively in the EC and Israel.

2. The Contracting Parties shall inform each other in a timely manner of changes to their legislation that may affect good laboratory practice compliance standards or programmes.

Article 4

Ambit

This Agreement applies to studies conducted by test facilities on all chemicals either substances or preparations, as identified in Annex I, and to data generated therefrom. Modifications to that Annex shall be decided by the Joint Committee referred to in Article 10.

Article 5

Monitoring authorities

1. The authorities empowered or designated in their respective territories to verify the conformity of the test facilities with the principles of good laboratory practice are listed in Annex II to this Agreement.

2. The Contracting Parties shall inform and consult each other with regard to any further authorities which they wish to be included in this Agreement. Modifications to Annex II, by

either adding or withdrawing authorities, shall be decided by the Joint Committee referred to in Article 10.

Article 6

Information about GLP-recognised test facilities

1. The Contracting Parties shall provide each other at least annually with a list of the test facilities on their territory, which in the light of the results of the inspections and study audits conform to good laboratory practice, as well as of the dates of inspection or audit and their compliance status.

2. The Contracting Parties shall inform each other promptly when a test facility coming under the terms of paragraph 1, which states that it applies good laboratory practice, fails to conform to such practice to an extent which may jeopardise the integrity or authenticity of any studies it conducts.

3. The Contracting Parties shall provide each other promptly with the information referred to in paragraph 1 about test facilities that in the light of the results of the inspections and study audits conform to good laboratory practice but have yet not been included in the list referred to in that paragraph.

Article 7

Additional actions

1. The Contracting Parties shall supply each other with any necessary additional information on a test facility inspection or study audit in response to a reasonable request from the other party.

2. Each Contracting Party may request further test facility inspection or study audits on the other party's territory if there is a documented doubt as to whether a test was conducted in accordance with good laboratory practice.

3. If in exceptional cases doubts persist and the requesting party can justify a special concern, and with the consent of the test facility concerned, it may designate one or more experts of its authorities to participate in a test facility inspection or the audit of a study conducted by the authorities of the other party.

Article 8

Confidentiality

1. The Contracting Parties shall make provision for the maintenance of confidentiality, not only by inspectors but also by any other persons who gain access to confidential information as a result of GLP compliance monitoring activities.

2. The Contracting Parties shall ensure that, unless all commercially sensitive and confidential information has been excised, reports of test facility inspections and study audits are made available only to regulatory authorities and, where appropriate, to the test facilities inspected or concerned with study audits and/or to study sponsors. Test facilities can freely dispose of the reports of test facility inspection and study audits that concern them.

Article 9

Participation as observer

Each Contracting Party may, on request, participate as an observer in an inspection of a test facility conducted by the authorities of the other party with the consent of the test facility concerned in order to maintain a continuing understanding of the other party's inspection procedures.

Article 10

Joint Committee

1. A Joint Committee composed of representatives of both parties shall be established.

2. The Joint Committee shall meet in order to resolve problems resulting from possible differences of view and practice within the two parties, to ensure proper implementation of this Agreement and to seek opportunities for further cooperation.

TRANSITIONAL PROVISIONS

Article 11

For an initial period, as a transitional arrangement, of a maximum of two years starting after the entry into force of this Agreement, the following provisions shall apply.

1. Israel shall establish during this period a national GLP monitoring system.
2. If there is no agreement between the parties that the above requirement has been met satisfactorily during the initial period, and if the two parties do not decide after a joint review to prolong the initial period, this Agreement ceases automatically to be valid.
3. The initial period may be terminated before the two-year period, provided the Community has acknowledged that the

Israeli GLP monitoring system has entered into operation satisfactorily.

Article 12

During the initial period referred to in Article 11, the empowered authorities in the Community shall verify conformity of the test facilities with GLP in Israel, as described in the attached Agreed Minutes. The Community shall recognise any test facility found in conformity with GLP requirements.

Article 13

During the initial period referred to in Article 11, Israel shall accept the data coming from GLP recognised test facilities in the Community and the Community shall accept data coming from the Israeli test facilities GLP recognised by it according to Article 12.

FINAL PROVISIONS

Article 14

Either party may terminate this Agreement by giving the other party six months notice in writing.

Article 15

This Agreement shall apply, on the one and, to the territories in which the Treaty establishing the European Community is applied and under the conditions laid down in that Treaty and, on the other hand, to the territory of the State of Israel.

Article 16

This Agreement shall be approved or ratified by the parties in accordance with their own procedures. It shall enter into force on the first day of the second month following the date on which the parties have exchanged notes confirming the completion of the respective procedures for the entry into force of this Agreement.

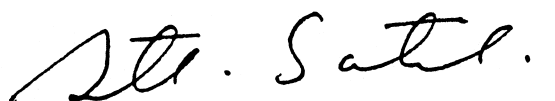
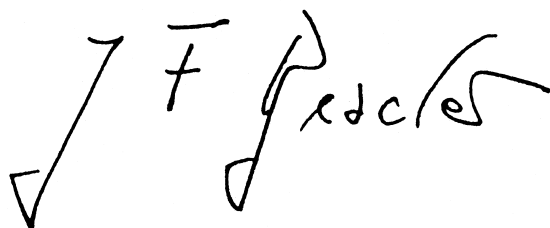
This Agreement is drawn up in two originals in the Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish, Swedish and Hebrew languages, each of these languages being equally authentic.

In witness whereof the undersigned, being duly authorised, have signed this Agreement.

For the Government of the State of Israel

A handwritten signature in cursive script, appearing to read "Henry Kney Arel".

For the European Community

A handwritten signature in cursive script, appearing to read "J. F. Pedraza".A handwritten signature in cursive script, appearing to read "J. F. Pedraza".

ANNEX I

LIST OF CHEMICALS COVERED BY THE AGREEMENT ON MUTUAL RECOGNITION OF THE OECD PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING PROGRAMMES BETWEEN THE EUROPEAN COMMUNITY AND THE STATE OF ISRAEL

Chemicals, either substance or preparations, covered in the Agreement on mutual recognition of the OECD principles of good laboratory practice between the European Community and the State of Israel are:

- cosmetics,
- industrial chemicals,
- medicinal products/pharmaceuticals,
- food additives,
- animal feed additives,
- pesticides.

These chemicals are defined by the legal instruments of the country of destination, which are:

FOR THE EUROPEAN COMMUNITY:

1. Council Directive 87/18/EEC of 18 December 1986 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 15, 17.1.1987, p. 29) as last amended by Commission Directive 1999/11/EC (OJ L 77, 23.3.1999, p. 8).
2. Council Directive 88/320/EEC of 9 June 1988 on the inspection and verification of good laboratory practice (GLP) (OJ L 145, 11.6.1988, p. 35) as last amended by Commission Directive 1999/12/EC (OJ L 77, 23.3.1999, p. 22).
3. Council Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 154, 5.6.1992, p. 1).
4. Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 187, 16.7.1988, p. 14).
5. Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (OJ L 84, 5.4.1993, p. 1).
6. Council Directive 87/19/EEC of 22 December 1986 amending Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products (OJ L 15, 17.1.1987, p. 31).
7. Commission Directive 91/507/EEC of 19 July 1991 modifying the Annex to Council Directive 75/318/EEC on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products (OJ L 270, 26.9.1991, p. 32).
8. Council Directive 87/20/EEC of 22 December 1986 amending Directive 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products (OJ L 15, 17.1.1987, p. 34).
9. Council Directive 92/18/EEC of 20 March 1992 modifying the Annex to Council Directive 81/852/EEC on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products (OJ L 97, 10.4.1992, p. 1).
10. Council Directive 89/397/EC of 14 June 1989 on the official control of foodstuffs (OJ L 186, 30.6.1989, p. 23).
11. Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs (OJ L 290, 24.11.1993, p. 14).
12. Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition (OJ L 64, 7.3.1987, p. 19) as amended by Commission Directive 95/11/EC (OJ L 106, 11.5.1995, p. 23).

13. Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1) as last amended by Commission Directive 95/35/EC (OJ L 172, 22.7.1995, p. 6).
14. Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).
15. Council Directive 93/35/EEC of 14 June 1993 amending for the sixth time Directive 76/68/EEC on the approximation of the laws of the Member States relating to cosmetic products (OJ L 151, 23.6.1993, p. 32).

ISRAELI LAWS AND REGULATIONS

(UNOFFICIAL TRANSLATION)

Drugs

Pharmacists Ordinance (New Version) — 1981

Pharmacist Regulations (Medical Preparations) — 1986

Food additives

Public Health Ordinance (Food) (new version) — 1983

Public Health Regulations (Food) (bases of emulsifier and stabilisers in food products) — 1966

Public Health Regulations (Food) (dietic food and sweeteners) — 1987

Public Health Regulations (Food) (vitamin and mineral additives in food) — 1983

Public Health Regulations (Food) (food colouring) 1984

Public Health Regulations (Food) (sealing of food packaging) — 1993

Public Health Regulations (Food) (pesticide traces) — 1991

Public Health Regulations (Food) (aflatoxins in food) — 1989

Public Health Regulations (Food) (provisions of findings) — 1980

Public Health Regulations (Food) (labelling) — 1935

Public Health Regulations (Food) (nutritional labelling) — 1993

Public Health Regulations (Food) (food products preservation through radiation) — 1988

Common Health Ordinance — 1942

Common Health Regulations (sanitary quality of drinking water) — 1977

Common Health Regulations (mineral and spring water) — 1987

Common Health Regulations (method of taking samples and their transfer for testing) — 1957

Common Health Regulations (preservative bases in food (foods) — 1965

Commodities and Services Control Law — 1957

Commodities and Services Control Order (quality of food) — 1958

Commodities and Services Control Order (production of food products) — 1976

Commodities and Services Control Order (labelling of food additives) — 1968

Animal feed additives

Commodities and Services Control Order (production and sale of fodder) — 1971

Animal Disease Ordinance (new version) — 1985

Animal Disease Regulations (chemical preparations) — 1982

Pesticides

Commodities and Services Control Order (pesticide preparations against hazards to humans) — 1962

Hazardous Substances Regulations (regulation of pesticide preparations against hazards to humans) — 1994

Plant Protection Law — 1956

Plant Protection Regulations (regulation of import and sale of chemical preparations) — 1994

Agricultural Fertilisers Ordinance — 1938

Agricultural Fertilisers Regulations — 1938

Cosmetics

Commodities and Services Control Order (cosmetics) — 1973

Industrial chemicals

Hazardous Substances Law — 1993

Hazardous Substances Regulations — 1994

Hazardous Substances Regulations (import and export of hazardous substances waste) — 1994

Hazardous Substances Regulations (classification and exemption) — 1996

ANNEX II

LIST OF MONITORING AUTHORITIES

ISRAEL:	for all:	Israel Laboratory Accreditation Authority Habonim Street 2 Ramat Gan-52522 (Israel)
EUROPEAN COMMUNITY:		
AUSTRIA:	for all:	Federal Ministry of the Environment, Youth and the Family Department II/2 Stubenbastei 5 A-1010 Wien
BELGIUM:	for all:	Institut de santé publique Louis-Pasteur Rue Juliette Wytsman/Juliette Wytsmanstraat 14 B-1050 Brussels
DENMARK:	for industrial chemicals and pesticides:	National Agency of Industry and Trade Tagensvej 137 DK-2200 Copenhagen N
	for medicinal products:	Danish Medicines Agency Frederikssundsvej 378 DK-2700 Brørshøj
FINLAND:	for all:	National Product Control Agency for Welfare and Health P.O. box 210 FIN-00531 Helsinki
FRANCE:	for chemicals other than medicinal products and cosmetics:	Groupe interministériel des produits chimiques (GIPC) Le Bervil 12, rue Villiot F-75572 Paris Cedex 12
	for human medicinal products and cosmetics:	Agence du médicament 143-147, boulevard Anatole-France F-93200 Saint-Denis
	for veterinary medicinal products:	Agence nationale du médicament vétérinaire AFSSA BP 203 F-35302 Fougères Cedex
GERMANY:	for all:	Federal Ministry for the Environment, Nature Conservation and Nuclear Safety Div. IG II 3 D-53048 Bonn
GREECE:	for all:	General Chemical State Laboratory An. Tsoha street, 16 GR-11521 Athens
IRELAND:	for all:	Irish National Accreditation Board Wilton Park House Wilton Place Dublin 2 Ireland
ITALY:	for all:	Ministero della Sanità Dipartimento Prevenzione GLP Compliance Monitoring Unit Via della Sierra Nevada, 60 I-00144 Roma
NETHERLANDS:	for all:	Ministry of Health, Welfare and Sports Inspectorate for Health Protection, Commodities and Veterinary Public Health GLP Department P.O. box 16108 2500 BC 's-Gravenhage Nederland

PORTUGAL:	for industrial chemicals and pesticides:	Instituto Português da Qualidade (IPQ) Rua C à Avenida dos Três Vales P-2825 Monte da Caparica
	for medicinal products and veterinary medicinal products:	Instituto Nacional de Farmácia e do Medicamento (Infarmed) Avenida do Brasil, 53 P-1700 Lisboa
SPAIN:	for medicinal products:	Agencia Española del Medicamento Subdirección General de Seguridad de Medicamentos Servicio de Inspección Paseo del Prado, 18-20 E-28014 Madrid
SWEDEN:	for medicinal products, hygiene and cosmetic products:	Läkemedelsverket (Medical Products Agency) Box 26 S-75103 Uppsala
	for all other products:	Styrelsen för ackreditering och teknisk kontroll (Swedish Board for Accreditation and Conformity Assessment) Box 2301 S-10315 Stockholm
UNITED KINGDOM:	for all:	UK GLP Compliance Monitoring Authority Department of Health Room 621A, Market Towers 1 Nine Elms Lane London SW8 5NQ United Kingdom

COMMISSION

COMMISSION DECISION

of 9 December 1998

on State aid granted by Germany to Maschinenfabrik Sangerhausen (Samag)

(notified under document number C(1998) 4274)

(Only the German text is authentic)

(Text with EEA relevance)

(1999/663/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular the first subparagraph of Article 93(2) thereof,

Having regard to the Agreement on the European Economic Area, and in particular Article 62(1)(a) thereof,

Having given interested parties notice to submit their comments in accordance with those Articles,

Whereas:

I

Maschinenfabrik Sangerhausen GmbH i.K. (hereinafter referred to as Samag) was privatised in June 1991. On 1 July 1994 insolvency proceedings (*Gesamtvollstreckungsverfahren* — insolvency proceedings prior to a takeover or the winding-up of a company, the procedure in the new Federal *Länder* equivalent to the *Konkursverfahren* in the rest of Germany) were initiated regarding the company and its assets because it was unable to pay its creditors and its debts exceeded its assets. On 14 July 1994 Germany notified aid amounting to DEM 2 million that the *Land* of Saxony-Anhalt had made available to Samag.

On 1 February 1995 the Commission decided to initiate proceedings pursuant to Article 93(2) of the EC Treaty in respect of the aid granted in the form of subsidies intended to finance the recovery of assets located abroad or subject to reservation of title and to keep the business as a going concern for a short time. The *Land* had originally provided the subsidies in order to achieve milder terms in the insolvency proceedings in order to assist employees, suppliers and other creditors while

it tried to identify a new source of capital for the complete or partial takeover of the business or to satisfy the creditors in a winding-up since the assets would otherwise be insufficient. Since the beginning of Samag's insolvency proceedings, the aid has been used towards the orderly liquidation of the business.

Of the DEM 2 million, DEM 50 000 was to be used for paying interest on a bridging loan for redundancy payments on winding-up that had been taken out by the administrator in the winding-up. The Commission was uncertain whether this part of the aid constituted a general measure or aid within the meaning of Article 92(1).

The Commission decision was published in the *Official Journal of the European Communities* ⁽¹⁾ and interested parties were given notice to submit their comments.

II

Germany provided details of the aid by letters of 28 March, 4 May and 23 November 1995 and 12 June and 20 December 1996. It was stated that the aid had been used as follows:

- DEM 50 000 for the payment of interest on a bridging loan for redundancy payments on winding-up taken out by the administrator in the winding-up;
- DEM 770 000 for the purchase of materials to complete outstanding orders and to secure the release of materials held under reservation of title for Samag's core business (other than the foundry);
- DEM 230 000 for complete performance of contracts concerning the foundry;
- DEM 350 000 for payments to public utilities (gas, water and electricity, of which DEM 91 000 were made in July and August), mainly concerning the foundry;
- DEM 600 000 for the repatriation of Samag's assets from abroad.

The aid made it possible to continue the insolvency proceedings in an orderly manner; otherwise the company would have had to be put into liquidation by reason of its insufficient assets.

⁽¹⁾ OJ C 262, 7.10.1995, p. 16.

After completing performance of the contracts outstanding at the time of initiation of the insolvency proceedings, the entire company (that is to say, including the foundry) ceased trading on 31 October 1994. No new orders were taken. The business continued for a further four months and the assets were sold separately following a public call for offers.

III

The United Kingdom supported the Commission's initiation of investigatory proceedings on the grounds that Samag did not appear to be an enterprise that was viable in the long term and the rescue of the machine-tool and foundry business adversely affected competition in the industry.

Germany replied that, since the enterprise had completely ceased trading, no comment was called for.

IV

However, the assistance of DEM 1,95 million constitutes State aid within the meaning of Article 92(1) since it was paid to a specific enterprise in an industry where there is considerable trade between Member States.

It must therefore be ascertained whether this aid can be considered compatible with the common market under Article 92(3).

Although Saxony-Anhalt is indeed an assisted area for the purposes of Article 92(3)(a), the assistance cannot be classified as aid to promote regional development since keeping the enterprise as a going concern for such a short time (four months) does not contribute to the development of the area. The exemption from the prohibition of aid under Article 92(3)(a) is therefore precluded.

Moreover, since the assistance does not facilitate the development of certain economic activities it does not meet the conditions in the Community Guidelines on State aid for rescuing and restructuring firms in difficulty ⁽¹⁾ (hereinafter referred to as 'the Guidelines') for the reasons set out below.

The assistance cannot be considered rescue aid since it has not been provided in forms that are permitted under the Guidelines; only liquidity help in the form of loan guarantees or loans bearing normal commercial interest rates can be approved.

Likewise, the assistance cannot be classified as restructuring aid for the purposes of the guidelines because it is not conditional on a restructuring plan or the creation of new jobs. Since it was solely intended to permit outstanding contracts to be performed and to identify persons interested in taking over the

business, it constitutes operating aid and as such is incompatible with the Community competition rules.

Since an exemption under Article 92(3)(a) or (c) is excluded, the aid of DEM 1,95 million is incompatible with the common market.

The sum of DEM 50 000 was paid by the *Land* to meet interest on a loan taken out by the administrator in the winding-up for bridging finance for redundancy payments on winding-up.

Under Article 141a of the Law on the promotion of labour (the ArbFG), every employee is entitled to redundancy payments up to a maximum of three months' wages which he has not received by reason of the winding-up of the enterprise. The party responsible for payment is the Federal Labour Office (the BfA). Provided the conditions in Articles 141a *et seq.*, of the ArbFG are fulfilled, the BfA does not enjoy any discretion in making redundancy payments on winding-up. Under Article 141m of the ArbFG, when such payment is made, the employee's claims concerning the payment are against the BfA.

The BfA generally does not make redundancy payments on winding-up until three or four months after the initiation of the winding-up. To secure the employee's subsistence, it is recognised practice ⁽²⁾ for a private bank to provide an appropriate loan for the employee.

The BfA has a right of recourse under the general provisions of the law applicable to winding-up. Under Article 13(2) of the Regulations on insolvency proceedings, read in conjunction with Article 17(3) thereof, the BfA's claim ranks as a preferential debt in the winding-up.

This means that such redundancy payments are to be classified as general social measures in the context of a winding-up, over which the BfA does not enjoy any discretion.

In this case, the *Land* of Saxony-Anhalt has provided assistance amounting to DEM 50 000 for the payment of interest on a loan, which was agreed on behalf of the employees between the administrator in the winding-up and a private bank as a bridging loan for redundancy payments on winding-up. The *Land* has not to date presented its claim to the DEM 50 000 against the assets in the winding-up. The interest is regularly paid from the assets being wound up. Since the *Land* has not put forward its claim, the assets in the winding-up have been increased by that amount, which constitutes an economic advantage for the insolvent enterprise. In this particular case, it therefore constitutes aid for the purposes of Article 92(1). On the same grounds as those relating to the other grants of aid of DEM 1,95 million, this aid cannot be exempted under Article 92(3). It is therefore to be considered incompatible with the common market and must be recovered,

⁽¹⁾ OJ C 368, 23.12.1994, p. 12.

⁽²⁾ Implementing Order of the BfA of 11 October 1989, which has been upheld by the Federal Social Court in its settled case-law.

HAS ADOPTED THIS DECISION:

Article 1

Under Article 92(1) of the EC Treaty and Article 61(1) of the EEA Agreement, the State aid paid by Germany to Maschinenfabrik Sangerhausen GmbH i.K. (Samag) in the form of grants amounting in all to over DEM 2,0 million is not compatible with the common market or the functioning of the EEA Agreement.

Article 2

1. Germany shall take the necessary steps to recover from the recipient enterprise the State aid specified in Article 1.
2. The recovery shall be carried out in accordance with the procedures and provisions of German law. Interest shall be payable from the date of payment to the date of actual

recovery, at a rate equal to the reference rate used to calculate the net grant equivalent of regional aid.

Article 3

Germany shall inform the Commission within two months of the date of notification of this Decision of the measures it has taken to comply therewith.

Article 4

This Decision is addressed to the Federal Republic of Germany.

Done at Brussels, 9 December 1998.

For the Commission

Karel VAN MIERT

Member of the Commission

CORRIGENDA**Corrigendum to Commission Regulation (EC) No 2136/1999 of 7 October 1999 prohibiting fishing for saithe by vessels flying the flag of Sweden**

(Official Journal of the European Communities L 262 of 8 October 1999)

The publication of Regulation (EC) No 2136/1999 is to be considered void.
