COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 05.03.1999
COM(1999) 33 final

99/0008 (ACC)

Proposal for a

COUNCIL DECISION

on the conclusion of an agreement between the European Community and Israe on mutual recognition of OECD principles of good laboratory practice and compliance monitoring programmes

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(presented by the Commission)

EXPLANATORY MEMORANDUM

I. The agreement

On the basis of the negotiating directives issued by the Council, the European Commission has negotiated and initialled an agreement on the mutual recognition of good laboratory practice and compliance monitoring programmes (mutual recognition agreement on GLP). The text of the agreement initialled in January 1997 is attached at annex.

This Explanatory Memorandum provides an assessment of the agreement in the light of the negotiating directives issued by the Council, and recommends that the Council adopt a decision approving the agreement.

I.1 Assessment of the agreement

The Commission considers that the initialled agreement is in conformity with the Council's negotiating directives, takes account of the views expressed by the Article 113 Committee's Technical Group on Mutual Recognition, which gave detailed advice to the Commission during the negotiations, and provides benefits to the European Community.

The Member States have at present a considerable number of GLP-recognised test facilities. The list will be sent to Israel, which at present has only two test facilities applying for GLP recognition.

Both parties are sufficiently confident for work to continue.

I.1.1 The content of the agreement

The agreement consists of a preamble and 16 articles, and two annexes. Its content is examined below.

The preamble sets out the objectives of the mutual recognition agreement on good laboratory practice.

Article 1, Definitions, defines certain terms used.

Article 2, Purpose, lays down the objective of the agreement, i.e. the parties' commitment to ensure the quality, validity and reliability of the data on the evaluation of the safety of chemicals covered by the agreement, recognition of GLP compliance monitoring programmes, mutual acceptance of data and studies generated by each party's test facilities and the use of these data and studies for the administrative procedures required to authorise the marketing of the chemicals referred to in the annex.

Article 3, Legal Basis, lays down the conditions which must be fulfilled to obtain recognition, i.e. the principles of good laboratory practice and the provisions regarding test facility inspection must be in accordance with the OECD decisions.

Article 4, Field of application, lays down that the agreement applies to the studies conducted on chemicals as listed in Annex 1.

Article 5, Monitoring Authorities, lays down that Annex 2 will contain the list of authorities which monitor test facilities' conformity and that the joint committee set up under the agreement will decide on changes to the list.

Article 6, Information about GLP-recognised Test Facilities, provides for the exchange of information between the two sides on the test facilities recognised as conforming to good laboratory practice, the results of the inspections, and laboratories which fail to conform.

Article 7, Additional Actions, lays down the obligation to supply in response to a reasoned request any necessary information on inspections. In the event of reasonable doubt, one party may ask the other to conduct additional inspections or audits on its territory. In exceptional cases, a party may designate, with the other party's agreement, one or more experts to take part in the inspection or audit.

Article 8, Confidentiality, obliges the parties to maintain confidentiality in the case of confidential information resulting from GLP compliance monitoring. It lays down that the test facilities inspected will have access to the reports which concern them.

Article 9, Participation as Observer, lays down that a party may, on request, participate as an observer in an inspection of a test facility. In particular it lays down that the Israeli authority may take part in the Community mutual joint visit programme.

Article 10, Joint Committee, sets up a committee of representatives of the two sides to try and settle possible differences in views and practices, and to ensure the proper working of the agreement and strengthen cooperation.

Transitional provisions

Transitional provisions are described in Articles 11, 12 and 13.

Article 11 lays down that these provisions apply during an initial period (transitional arrangements) of a maximum of two years from the entry into force of the agreement. This period should make it possible to introduce a national compliance monitoring scheme in Israel.

Under Article 12 the authorities empowered by the Community will monitor, over the transitional period, the conformity of the test facilities in Israel with GLP.

Article 13 lays down that, during the transitional period, Israel will accept data from GLP-recognised test facilities in the Community and that Member States will accept data from the Israeli test facilities which are GLP-recognised by a Member State's monitoring authority .

Final provisions

The final provisions are laid down by Articles 14, 15 and 16.

Article 14 lays down that the agreement may be terminated with six months' notice.

Article 15 lays down that the agreement applies to the territories in which the Treaty establishing the European Community applies and the territory of Israel.

Article 16 contains the standard institutional and legal provisions. It should be noted that the agreement is of unlimited duration.

I.1.2 Annexes

Annex 1

This Annex contains the list of chemicals covered by the agreement, and the references to the legislation of each of the parties to the agreement.

Annex 2

This Annex contains the list of the monitoring authorities.

I.1.3 Relations with EFTA countries and the EEA Member States

In accordance with the general information and consultation procedures set out in the EEA Agreement and Protocol 12 of the EEA Agreement, the Commission has kept the EFTA countries and the EEA Member States regularly informed of the progress and outcome of the negotiations.

I.1.4 Overall assessment

The Commission considers that the agreement has benefits for the two sides.

The Community studies and data generated by non-clinical experiments with the chemicals concerned will be recognised by Israel as soon as the agreement enters into force. Community exporters may therefore use these data and studies from Community test facilities in the procedures for authorising marketing in Israel, and this will help Community exports.

The two-year transitional period will make it possible to set up Israel's compliance monitoring system. The empowered authorities in the Community will have to assess the reliability of this system and will therefore have to decide when the transitional period can be ended.

II. Proposal for a Council Decision

A proposal for a Council Decision on the conclusion of the Agreement is attached. The Decision has two objectives:

(a) to approve the draft agreement on the basis of Articles 113 and 228 of the Treaty; and

(b) to establish a Community procedure to enable the Commission, assisted by the Article 113 Committee (Technical Group on Mutual Recognition), to represent the Community in the joint committee and to determine the Community position in that joint committee in case of changes to the annexes or any other matter set out in the Decision, in accordance with Article 228(4) of the Treaty, following consultation of the Article 113 Committee.

On this second aspect, it is noted that Article 10 of the agreement sets up a joint committee. It is responsible for the management of the agreement and has the delegated power to amend the two annexes. Such right of amendment is restricted to procedural issues concerned with implementation, namely mainly amending the references to the chemicals concerned and to the legislation applicable, and amending the list of compliance monitoring authorities.

It is therefore proposed that:

(a) the Commission, assisted by the Article 113 Committee (Technical Group on Mutual Recognition), should represent the Community within the joint committee set up and determine in the committee the Community position on any change to the annexes or any other matter concerning the management of the agreement, in accordance with Article 228(4) of the Treaty, following consultation of the Committee mentioned above.

(b) for all other matters, the Community position should be adopted by the Council, acting by a qualified majority on a proposal from the Commission.

The Commission therefore proposes that the Council adopt the attached Decision, and indicate the person empowered to sign the agreement on behalf of the Community.

Proposal for a

COUNCIL DECISION

on the conclusion of an agreement between the European Community and Israel on mutual recognition of OECD principles of good laboratory practice and compliance monitoring programmes

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 113 thereof, read in conjunction with the first sentence of Article 228(2) and the first subparagraph of Article 228(3) and Article 228(4),

Having regard to the proposal from the Commission,

Whereas the Agreement on mutual recognition of OECD principles of good laboratory practice 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;

Whereas 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;

Whereas it is necessary to lay down the internal procedures required for the proper functioning of the Agreement; whereas 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 between the European Community and Israel on mutual recognition of OECD principles of good laboratory practice and compliance monitoring programmes is hereby approved on behalf of the European 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*.

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* The date of entry into force of the Agreement will be published in the *Official Journal of the European Communities*.

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 2 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 1 decided upon in accordance with the second sentence of Article 4 of the Agreement and to amendments to Annex 2 decided upon 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,

For the Council
The President

Draft

AGREED MINUTES

Concerning

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

I. **Preliminary <u>AGREED MINUTES</u>**

- 1 annex: List of Israeli test facilities candidates to be GLP recognised.

II. **<u>AGREEMENT</u> (DRAFT) containing:**

- 16 Articles
- 2 Annexes:

  Annex 1: List of Chemicals covered by the Agreement on Mutual Recognition of OECD Principles of Good Laboratory Practice and Compliance Monitoring Programmes between the European Community and the State of Israel.

  Annex 2: List of Monitoring Authorities.

AGREED MINUTES

CONCERNING

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 draft Agreement enclosed 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 upon 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.

For the Government of the State of Israel **For the European Community**

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1 European Commission:
DG I/M/2
Rue de la Loi, 200
1049 Brussels (Belgium).

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

ANNEX:

ISRAELI TEST FACILITIES

CANDIDATES TO BE GLP RECOGNISED

1. ***AGAN CHEMICAL MANUFACTURERS LTD***

Address:	ASHOD 77102
	P.O.B. 262
Tel.:	+972 8 515 211
Fax:	+972 8 515 388

2. ***AMINOLAB LTD Analytical Laboratory Services***

Address:	Weizmann Science Park
	P.O.B. 2407
	REHOVOT 76123
Tel.:	+972 8 409 690
Fax:	+972 8 408 474

3. ***ANALYST Research Laboratories***

Address:	Kiriat Weizmann
	P.O.B. 1176
	REHOVOT 76111
Tel.:	+972 8 936 2034
Fax:	+972 8 936 2039

4. ***HARLAN BIOTEC Israel Ltd.***

Address:	Weizmann Science Park, building 13B
	P.O.B. 12085
	REHOVOT
Tel.:	+972 8 940 9451
Fax:	+972 8 940 9452

DRAFT

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 (herinafter referred to as "the Community")

on the one hand,

and The State of Israel (herinafter 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 assure the high quality, validity and reliability of safety evaluation data obtained during non-clinical testing on all chemicals as identified in Annex 1 to this Agreement 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, paragraph 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, paragraph 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 1 to this Agreement.

ARTICLE 3 - *Basis of Reference*

1. For the purpose 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 the Annexes I-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 recognized 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 - *Field of Application*

This Agreement applies to studies conducted by test facilities on all chemicals either substances or preparations, as identified in Annex 1, and to data generated therefrom. Modifications to this 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 2 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 2, by either adding or withdrawing authorities, shall be decided by the Joint Committee, referred to in Article 10.

ARTICLE 6 - *Information about GLP-recognized 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 of this Article, which states that it applies Good Laboratory Practice, fails to conform to such practice to an extent which may jeopardize 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 the 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, the present 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 Article11, 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 hand, 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, Hebrew, Italian, Portuguese, Spanish and Swedish 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 **For the European Community**

ANNEX 1

LIST
of
Chemicals Covered by the Agreement on Mutual Recogntion 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
- pharmaceuticals / medicinal products
- 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 92/32/EEC of 30.4.1992
   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

2. Council Directive 83/228/EEC of 18.4.1983
   on the fixing of guidelines for the assessment of certain products used in animal nutrition.
   OJ L 126, 13.5.1983, p. 23

3. Council Directive 87/18/EEC of 18.12.1986
   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

4. Council Directive 87/19/EEC of 22.12.1986
amending Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products.
OJ L 15, 17.1.1987, p. 31

5. Council Directive 87/20/EEC of 22.12.1986
amending Directive 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products.
OJ L 15, 17.1.1987, p. 34

6. Council Directive 87/21/EEC of 22.12.1986
amending Directive 65/65/EEC on the approximation of previsions laid down by law, regulation or administrative action relating to proprietary medicinal products.
OJ L 15, 17.1.1987, p. 36

7. Council Directive 87/153/EEC of 16.2.1987
fixing guidelines for the assessment of additives in animal nutrition.
OJ 64, 7.3.1987, p. 19

8. Council Directive 88/320/EEC of 9.6.1988
on the inspection and verification of Good Laboratory Practice (GLP).
OJ L 145, 11.6.1988, p. 35

9. Council Directive 88/379/EEC of 7.6.1988
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

10. Council Decision 89/569/EEC of 28.7.1989
on the acceptance by the European Economic Community of an OECD decision/recommendation on compliance with principles of Good Laboratory Practice.
OJ L 315, 28.10.1989, p. 1

11. Commission Directive 90/18/EEC of 18.12.1989
adapting to technical progress the Annex of Council Directive 88/320/EEC on the inspection and verification of Good Laboratory Practice (GLP).
OJ L 11, 13.1.1990, p. 37

12. Council Directive 91/414/EEC of 15.7.1991
concerning the placing of plant protection products on the market.
OJ L 230, 19.8.1991, p. 1

13. Commission Directive 91/507/EEC of 19.7.1991
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

(the Standing Committee for Propriety Medicinal Products adopted a list of 10 tests that must be considered as safety tests under GLP testing requirements, that is included in part II b of the Notice to the Applicant for Authorisation of a Medicinal Product for Human Use in the Community, document III/3024/92 Rev. 1).

14. Council Regulation (EEC) No 793/93 of 23.3.1993
on the evaluation and control of the risks of existing substances.
OJ L 84, 5.4.1993, p. 1

15. Council Directive 93/35/EEC of 14.6.1993
amending for the sixth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products.
OJ 151, 23.6.1993, p. 32

16. Commission Directive 93/71/EEC of 27.7.1993
amending Council Directive 91/414 concerning the placing of plant protection products on the market.
OJ L 221, 31.8.1993, p. 27

17. Commission Directive 95/35/EC of 14.7.1995
amending Council Directive 91/414/EEC concerning the placing on the market of plant protection products on the market (text with EEA relevance).
OJ L 172, 22.7.1995, p. 6

For Israel: See next page

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 Stabilizers in Food Products) - 1966
Public Health Regulations (Food) (Dietetic Food and Sweeteners) - 1987
Public Health Regulations (Food) (Vitamin and Mineral Additives in Food) - 1983
Public Health Regulations (Food) (Food Coloring) - 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) (Labeling) - 1935
Public Health Regulations (Food) (Nutritional Labeling) - 1993
Public Health Regulations (Food) (Food Product Preservation through Radiation) - 1988

Common Health Ordinance - 1942
Common Health Regulations (Sanitory 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 Goods) - 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 (Labeling 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 (Registration 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 Fertilizers Ordinance - 1938
Agricultural Fertilizers 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

Note: the translation of this legislation list into English is unofficial.

ANNEX 2

LIST
of
Monitoring Authorities

ISRAEL:

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-1010Wien
BELGIUM	for all:	Institut d'Hygiène et d'Epidémiologie Rue Juliette Wytsmanstraat 14 B-1050 Bruxelles/Brussel
DENMARK	for industrial chemicals and pesticides:	National Agency of Industry and Trade Tagensvej 137 DK-220 Copenhagen N
	for medicinal products:	National Board of Health, Medicines Division 378, Frederikssundsvej DK-2700 Bronshoj
FINLAND	for all	The National Product Control Agency for Welfare and Health P.O. Box 210 SF-00531 Helsinki Finland

FRANCE	for industrial chemicals, pesticides and others than pharmaceuticals:	Groupe Interministériel des Produits Chimiques (GIPC) 3/5 Rue Barbet de Jouy F-75353 Paris 07 SP
	for pharmaceuticals other : than veterinary products	Agence du Médicament 143/147 Boulevard Anatole France F-93200 Saint Denis
	for cosmetics	Ministère de la Santé, Direction Générale de la Santé, Sous-direction pharmacie 1, place de Fontenoy F-75350 Paris 07 SP
	for veterinary products	CNEVA, Agence du médicament vétérinaire, service inspections et controles 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 IRL-Dublin 2
ITALY	for all:	Ministero della Sanita, Dipartimente Prevenzione GLP Compliance Monitoring Unit Via della Sierra Nevada, 60 I-00144 Roma

NETHERLANDS	for all:	Inspectorate for Health Protection, Commodities and Veterinary Public Health GLP Department Ministry of Health, Welfare and Sports P.O. Box 16.108 NL- 2500 BC 's-Gravenhage
PORTUGAL	for industrial chemicals and pesticides:	Instituto Portugues da Qualidade Rua Jose Estevao, 83-A P-1199 Lisboa Codex Portugal
	for pharmaceuticals and veterinary drugs:	Direcçao Gearl dos Assuntos Farmaceuticos Av. Estados Unidos da America, 37, 10° P-1700 Lisboa Portugal
SPAIN	for pharmaceuticals	Direción General de Farmacia y Productos Sanitarios Passeo del Prado, 18-20 E-28014 Madrid
SWEDEN	for pharmaceuticals, hygiene and comestic products	Läkemedelsverket (Medical Products Agency) Box 26 S-751 03 Uppsala
	for all other products	Styrelsen för ackreditering och teknisk kontroll (Swedish Board for Accreditation and conformity Assessment). Box 2231 S-10315 Stockholm
UNITED KINGDOM	for all:	GLP Monitoring Unit, Division of Medical Toxicology and Environment Health, Department of Health Hannibal House Elephant and Castle UK-London SE1 6TE

Financial Statement 1998-2002

External trade relations - Mutual Recognition Agreement

1. TITLE

External Trade Relations-

Mutual Recognition Agreements with United States, Canada, Australia, New Zealand and Israel.

2. BUDGETARY HEADINGS: B7-8500

A-7010

3. LEGAL BASIS

- Article 113 of the Treaty of Rome
- Proposal for Council Decisions No .... on the implementation by the European Commission of mutual recognition agreements with United States, Canada, Australia, New Zealand and Israel.

4. DESCRIPTION OF OPERATION:

4.1 General objective:

The purpose of these agreements is to establish mutual recognition of certification of conformity of products with technical regulations or standards of partners to the agreement.

The major actions which will be pursued by the Commission under this budget line will be the following:

- Confidence-building activities to facilitate the proper implementation of the Agreement.
- Management of the Agreements and maintenance of the necessary degree of confidence.

The Commission will be assisted by experts, particularly in regard to sectoral activities. It will however remain the final arbiter in the management of these agreements.

4.2 Duration of the action; means foreseen for its renewal:

The general action undertaken will be of an indefinite duration. The initial period of confidence-building required by the Agreements will require a more intensive effort and expenditure, but this should be substantially less after 2 years. However, during the life of the Agreements a continued effort will be needed to ensure management and maintenance of confidence.

5. CLASSIFICATION OF EXPENDITURE/REVENUE

5.1 Non-compulsory expenditure ("DNO")

5.2 Differentiated appropriation ("CD")

5.3 Type of revenue involved:

None

6. TYPE OF EXPENDITURE/REVENUE

- *100% subsidy: No*
- *subsidy for co-financing with other sources in the public or private sector?*

Yes, this may be envisaged as a method of funding. Subsidies not normally exceeding 50% will be provided to professional associations and other responsible organisations for activities related to the implementation of the Agreement.

- *Interest subsidy: No*
- *Others*

Financing of events, acquisition of studies, publications and conferences.

- *Should the action prove an economic success, is there provision for all, or part of, the Community contribution to be reimbursed?*

  Not relevant

- *Will the proposed operation cause any changes in the level of revenue?*

  No

7. FINANCIAL IMPACT ON APPROPRIATIONS FOR OPERATIONS

7.1 Method of calculating the total cost of the operation:

The estimation of costs is based on the anticipated requirements in terms of expenses related to training, seminars, workshops, travel of experts, verification of conformity assessment bodies, information and studies. The total estimated cost is based on the sum of the individual actions.

A range of different actions are foreseen to meet the objectives of the budget-line and costs will vary depending on the nature of action undertaken. Even for similar types of action (e.g. seminars) costs will vary depending on the scope of the action and the degree of specialisation needed.

The costs of specific actions will be determined either:

- by the Commission when it organises activities itself, e.g. seminars
- following invitations to tender issued by the Commission
- following requests for subsidies. In such cases, projects are selected according to how well they meet the criteria which have been established for selection. Subsidies are based on a percentage of total costs and usually the Community funding is limited to a maximum of 50%.

A. Attendance at Joint Committee

These will be attended by Commission officials and some national experts. Travel and per diem expenses should be foreseen within the normal range of such expenses.

B. Attendance at Joint Sectoral Groups

These will also be attended by Commission officials and given the nature of these meetings a larger contingent of national experts. Travel and per diem expenses should be foreseen within the normal range of such expenses.

C. Workshops and Seminars

These will be held to familiarise economic and other operators with the requirements of the Agreement. The cost of these seminars will vary according to the subject matter and location, and will include organisational costs (when in Europe) and substantial travel costs when in the territory of the partner country. Organisational costs in Europe will cost EUR 3 000 each. The number of seminars will vary depending on the individual industrial sectors covered by the Agreement.

D. Verification actions

The competence of the conformity assessment bodies (CABs) will in many cases have to be checked, more so in the initial period of the Agreement, but as a matter of course throughout the life of the Agreement to maintain confidence in the system.

This will involve on-site assessment by teams of experts of conformity assessment bodies in the partner country in the initial stages, and subsequently investigation of complaints. This expenditure will be essential in all sectors of the Agreement (... in number) and may involve numerous CABs in each sector including at subfederal or local level in certain cases.

E. Production and dissemination of information

Certain costs may need to be incurred for the dissemination of information. Guides to regulations and assessment procedures may be needed typically at a cost of EUR 10 000.

7.2 Breakdown by elements of the operation

"Trade Agreements with important Trading Partners"

For 1998, this involves the following calculation:

Budget Heading	Amounts (EUR)	Method of calculation		
		No. of missions		Standard Unit cost
Joint Committee B7-8500	12 940	Bxl Bxl Aus / NZ Israël	2 2 2 1	US: Travel: EUR 2 000; per diem: EUR 185
Sectoral Groups B7-8500	57 680	Bxl US CAN	16 8 8	CAN: Travel: EUR 1 750; per diem: EUR 170
Seminars B7-8500	103 540	US CAN Aus / NZ Bxl	10 10 14 28	Aus / NZ: Travel: EUR 3 200; per diem: EUR 190
Verifications B7-8500	142 150	US CAN Aus / NZ Israël	18 18 12 1	Brussels: Travel: EUR 800; perdiem: EUR 110
Information B7-8500	10 000			
B7-8500 Total	326 310		150	

In EUR
(current prices)

Breakdown	Year 1998	Year 1999	2000	2001	2002	Total 1998-2002
A. Joint Committee B7-8500	12.940	13 760	12 940	13 760	12 940	66 340
B. Joint Sectoral Groups B7-8500	57 680	57 680	57 680	57 680	57 680	288 400
C. Seminars B7-8500	103 540	96 310				199 850
D. Verifications B7-8500	142 150	142 150	48 430	48 430	48 430	429 590
E. Information B7-8500	10 000	10 000	10 000			30 000
B7-8500 Total	326 310	319 900	129 050	119 870	119 050	1 014 180

Indicative financial programming subject to the annual budget procedure.

7.3 Indication of the timetable for commitment and payment appropriations

1 000 EUR

	Year 1998	1999	2000	2001	2002	2003 and following years	Total
Schedule of Commitment	326	319	129	119	119	119	1 131
Payment appropriations							
1998	326						326
1999		319					319
2000			129				129
2001				119			119
2002					119		119
2003						119	119
Total	326	319	129	119	119	119	1 131

8. WHAT ANTI-FRAUD MEASURES ARE PLANNED IN THE PROPOSAL FOR THE OPERATION?

Methods of control (submission of reports, etc.) will be included in all contracts between the Commission and beneficiaries.

A close cooperation with the delegations of the Commission and the participation of a representative of the Commission at events in third countries will check on the spot the work to ensure that it corresponds with the terms of reference, contract provisions and required professionalism.

The checks take place before the final payment. The same rule applies to the financial incentives paid to participating companies. Where appropriate, agreements also require organisations to submit financial accounts certified by their auditors.

In those cases involving cooperation with EU industrial federations the accounts are further checked at the Annual General Meeting of the federations concerned.

9. ELEMENTS OF COST-EFFECTIVENESS ANALYSIS

9.1. Specific objectives of the proposed operation, population targeted

- *The specific objectives of mutual recognition agreements are:*

- to avoid duplication of certification by economic operators.
- to promote exports, employment, competitivity and investment.
- to reduce costs, in particular for small and medium-sized enterprises and ultimately for the consumer.

- *Target population*

The target population are the exporting companies, business associations, chambers of commerce and public institutions of the European Union and the general consumer which will benefit, or have an interest in, the mutual recognition of certification.

9.2. Reasons for the operation

- *Need for intervention from the Community budget*

Under Article 113 of the Treaty of Rome the Community has exclusive competence for commercial policy and these agreements have been negotiated in accordance with a mandate of the Council of Ministers and in consultation with the 113 Committee. The Commission will be responsible for implementation and management of the agreements.

- *Choice of methods of intervention*

  * *advantages over alternative measures (comparative advantages)*

  * *analysis of similar operations at Community or national level*

  * *results and expected multipliers*

The choice of management method (Joint Committee and Joint Sectoral Groups) have been set out in the Agreements and constitute a minimum necessary for the proper functioning of the Agreement. The Agreements also contain provisions for the use of seminars in the initial phases to ensure familiarity with other systems.

These seminars and verifications are also designed to build mutual confidence; verifications will also be required to ensure this confidence is maintained throughout the life of the agreements. Confidence and its maintenance are keys to the successful operation of the agreements.

The importance of this budget is justified when put in perspective with the trade involved in these agreements and the yearly savings for EU exporters which are expected (estimated on a yearly basis at EUR 190 million for EU exporters to the US, EUR 20 million in the case of exports to Canada and 40 mio in the case of exports to Australia and New Zealand).

- *Main factors of uncertainty which could affect the specific results of the operation.*

  * None

9.3 Monitoring and evaluation of the operation

- *Performance indicators selected*

  * *Output indicators*

  * *indicators of impact, following the objectives chosen*

In the case of these Agreements, success can be quantified by trade facilitation through avoidance of duplication of testing and certification and costs. Yearly estimated savings for the European Community are indicated above (9.2).

Success can also be measured by increased EU exports and this factor will be taken into consideration although export performance is subject to such a wide range of variables (e.g. changes in exchange rates) that this can never be the sole factor for evaluation.

- *Evaluation of results*

Progress in the attainment of the Agreements objectives will be monitored by Commission officials, Committees established under the Agreements and by the economic operators concerned.

Details and frequency of the planned evaluation

The evaluation of the effectiveness and usefulness of the agreements wil be regularly monitored by the Commission and by the Committees established under the agreements at their annual meetings. The first major evaluation will be at the end of the confidence-building period.

10. ADMINISTRATIVE EXPENSES

Actual mobilisation of the necessary administrative resources will depend on the Commission's annual decision on the allocation of resources, taking into account the number of staff and additional amounts authorised by the budgetary authority. There is no request for additional staff.

10.1 Effect on the number of posts

Type of post		Staff to be assigned to managing the operation		Source		Duration
		Permanent posts DG I + sectoral DGs	Temporary posts	Existing resources in the DGs or departments concerned	Additional resources	
Officials	A	3.5	None	3.5	None	Permanent
	B					
	C	1		1		
Other resources		None				
Total		4.5		4.5		

10.2 Overall financial impact of human resources: 4.5 staff (EUR 107 500 per staff member per year = EUR 483 750).

10.3 Increase in other administrative expenditure as a result of the operation (A-7010: travel expenses)

The expenses set out below relate to travel expenses for officials of the Commission attending meetings of the Joint Committee, joint sectoral groups, seminars and verifications, when these are outside Brussels. These will be taken care of by the relevant budget allocations of various Directorates Generals involved.

For 1998 this involves the following calculation:

Budget heading	Amounts (EUR)	Method of calculation	
		No. of missions	Standard Unit cost
Joint Committee A-7010	 22 120	Aus / NZ 4 Israel 4	US: Travel: EUR 2 000; per diem: EUR 185
Sectoral Groups A-7010	 20 680	US 4 CAN 4	CAN: Travel: EUR 1 750; per diem: EUR 170
Seminars A-7010	 20 680	US 4 CAN 4 Aus / NZ	Aus / NZ: Travel: EUR 3 200; per diem: EUR 190
Verifications A-7010	 142 150	US 18 CAN 18 Aus / NZ 12 Israel 1	
A-7010 Total	205 630	73	

In EUR

	Year 1998	Year 1999	2000	2001	2002	Total 1998-2002
A. Joint Committee A-7010	22 120	20 680	22 120	20 680	22 120	107 720
B Joint Sectoral Groups A-7010	20 680	20 680	20 680	20 680	20 680	103 400
C. Seminars A-7010	20 680	18 260				38 940
D. Verifications A-7010	142 150	142 150	48 430	48 430	48 430	429 590
A-7010 TOTAL	205 630	201 770	91 230	89 790	91 230	679 650

IMPACT ASSESSMENT FORM

THE IMPACT OF THE PROPOSAL ON BUSINESS
with special reference to small and medium-sized enterprises

Title of proposal

Proposal for a Council Decision on the conclusion of an agreement between the European Community and Israel on mutual recognition of OECD principles of good laboratory practice and compliance monitoring programmes.

Reference number

The proposal

A Council Decision is needed to conclude an agreement between the European Community and Israel on mutual recognition of OECD principles of good laboratory practice and compliance monitoring programmes. The agreement was negotiated and initialled by the Commission in accordance with the mandate and negotiating directives provided by the Council.

The impact on business

The products involved are chemicals used in cosmetics, industrial chemicals, pharmaceuticals, food additives, animal feed additives and pesticides.

Studies and data from the laboratories of the two parties to the agreement can be used, so that no further studies are needed before marketing.

The agreement therefore has important advantages from the point of view of transparency, market access, and ease of trade and in particular makes it possible to avoid duplicating costs. All this is of particular importance for small and medium-sized enterprises.

The agreement covers a wide range of products manufactured throughout the Community and a large number of firms, both big and small, in these sectors. The advantages are not limited to specific geographical areas in the Community.

The agreement will substantially reduce marketing costs and will improve European firms' prospects for exports, employment, investment and competitiveness.

The agreement does not contain measures to take account of the specific situation of small and medium-sized firms, but by its nature and by reducing costs that are the same for all firms, the agreement will, proportionately, be of greater benefit to small and medium-sized enterprises than to large companies.

Consultation

The main trade organisations in the industrial sectors concerned have been consulted (CEFIC, COLIPA, EFPIA, AESGP) and have declared their full support for the Agreement.

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DOCUMENTS

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