

Official Journal

of the European Communities

ISSN 0378-6978

L 77

Volume 42

23 March 1999

English edition

Legislation

Contents

I *Acts whose publication is obligatory*

Commission Regulation (EC) No 613/1999 of 22 March 1999 establishing the standard import values for determining the entry price of certain fruit and vegetables 1

Commission Regulation (EC) No 614/1999 of 22 March 1999 fixing Community producer and import prices for carnations and roses with a view to the application of the arrangements governing imports of certain floricultural products originating in Cyprus, Israel, Jordan, Morocco and the West Bank and the Gaza Strip..... 3

Commission Regulation (EC) No 615/1999 of 22 March 1999 on the supply of vegetable oil as food aid..... 5

★ **Commission Directive 1999/11/EC of 8 March 1999 adapting to technical progress the principles of good laboratory practice as specified in Council Directive 87/18/EEC 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 ⁽¹⁾ 8**

★ **Commission Directive 1999/12/EC of 8 March 1999 adapting to technical progress for the second time the Annex to Council Directive 88/320/EEC on the inspection and verification of good laboratory practice (GLP) ⁽¹⁾ 22**

Council

1999/216/EC:

- ★ **Decision No 1/1999 of the Association Council between the European Communities and their Member States, of the one part, and the Republic of Poland, of the other part, of 25 January 1999 amending Protocol 4 to the Europe Agreement establishing an association between the European Communities and their Member States, of the one part, and the Republic of Poland, of the other part** 34

Corrigenda

- Corrigendum to Commission Regulation (EC) No 506/1999 of 8 March 1999 amending Regulation (EC) No 340/1999 on the supply of cereals as food aid (OJ L 60 of 9.3.1999) 41

I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 613/1999
of 22 March 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 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;

Whereas, in compliance with the above criteria, the standard import values must be fixed at the levels set out in the Annex to this Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 4 of Regulation (EC) No 3223/94 shall be fixed as indicated in the Annex hereto.

Article 2

This Regulation shall enter into force on 23 March 1999.

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

Done at Brussels, 22 March 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 22 March 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	052	48,2
	204	42,0
	212	54,0
	624	122,8
	999	66,8
0707 00 05	068	117,2
	999	117,2
0709 10 00	220	269,5
	999	269,5
0709 90 70	052	105,8
	204	158,2
	999	132,0
0805 10 10, 0805 10 30, 0805 10 50	052	35,2
	204	46,3
	212	46,9
	220	39,2
	600	42,8
	624	47,7
0805 30 10	999	43,0
	052	57,0
	600	64,0
0808 10 20, 0808 10 50, 0808 10 90	999	60,5
	039	105,2
	064	56,2
	388	97,3
	400	75,1
	404	80,5
	508	84,8
	512	86,4
	524	106,6
	528	73,0
	720	82,5
	999	84,8
0808 20 50	052	133,1
	388	63,0
	400	75,4
	512	66,5
	528	66,0
	624	74,8
	720	68,1
	999	78,1

⁽¹⁾ Country nomenclature as fixed by Commission Regulation (EC) No 2317/97 (OJ L 321, 22. 11. 1997, p. 19). Code '999' stands for 'of other origin'.

**COMMISSION REGULATION (EC) No 614/1999
of 22 March 1999**

fixing Community producer and import prices for carnations and roses with a view to the application of the arrangements governing imports of certain floricultural products originating in Cyprus, Israel, Jordan, Morocco and the West Bank and the Gaza Strip

THE COMMISSION OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 4088/87 of 21 December 1987 fixing conditions for the application of preferential customs duties on imports of certain flowers originating in Cyprus, Israel, Jordan, Morocco and the West Bank and the Gaza Strip ⁽¹⁾, as last amended by Regulation (EC) No 1300/97 ⁽²⁾, and in particular Article 5 (2) (a) thereof,

Whereas, pursuant to Article 2 (2) and Article 3 of above-mentioned Regulation (EEC) No 4088/87, Community import and producer prices are fixed each fortnight for uniflorous (bloom) carnations, multiflorous (spray) carnations, large-flowered roses and small-flowered roses and apply for two-weekly periods; whereas, pursuant to Article 1b of Commission Regulation (EEC) No 700/88 of 17 March 1988 laying down detailed rules for the application of the arrangements for the import into the Community of certain floricultural products originating in Cyprus, Israel, Jordan, Morocco and the West Bank and the Gaza Strip ⁽³⁾, as last amended by Regulation (EC) No 2062/

97 ⁽⁴⁾, those prices are determined for fortnightly periods on the basis of weighted prices provided by the Member States; whereas those prices should be fixed immediately so the customs duties applicable can be determined; whereas, to that end, provision should be made for this Regulation to enter into force immediately,

HAS ADOPTED THIS REGULATION:

Article 1

The Community producer and import prices for uniflorous (bloom) carnations, multiflorous (spray) carnations, large-flowered roses and small-flowered roses as referred to in Article 1b of Regulation (EEC) No 700/88 for a fortnightly period shall be as set out in the Annex.

Article 2

This Regulation shall enter into force on 24 March 1999.

It shall apply from 24 March to 6 April 1999.

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

Done at Brussels, 22 March 1999.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 382, 31. 12. 1987, p. 22.

⁽²⁾ OJ L 177, 5. 7. 1997, p. 1.

⁽³⁾ OJ L 72, 18. 3. 1988, p. 16.

⁽⁴⁾ OJ L 289, 22. 10. 1997, p. 1.

ANNEX

(EUR/100 pieces)

Period from 24 March to 6 April 1999				
Community producer price	Uniflorous (bloom) carnations	Multiflorous (spray) carnations	Large-flowered roses	Small-flowered roses
	9,51	9,65	36,97	18,23
Community import prices	Uniflorous (bloom) carnations	Multiflorous (spray) carnations	Large-flowered roses	Small-flowered roses
Israel	10,43	6,87	17,93	15,73
Morocco	15,54	17,92	25,92	—
Cyprus	—	—	—	—
Jordan	—	—	—	—
West Bank and Gaza Strip	—	—	—	—

COMMISSION REGULATION (EC) No 615/1999
of 22 March 1999
on the supply of vegetable oil as food aid

THE COMMISSION OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1292/96 of 27 June 1996 on food-aid policy and food-aid management and special operations in support of food security ⁽¹⁾, and in particular Article 24(1)(b) thereof,

Whereas the abovementioned Regulation lays down the list of countries and organisations eligible for Community aid and specifies the general criteria on the transport of food aid beyond the fob stage;

Whereas, following the taking of a number of decisions on the allocation of food aid, the Commission has allocated vegetable oil to certain beneficiaries;

Whereas it is necessary to make these supplies in accordance with the rules laid down by Commission Regulation (EC) No 2519/97 of 16 December 1997 laying down general rules for the mobilisation of products to be supplied under Council Regulation (EC) No 1292/96 as Community food aid ⁽²⁾; whereas it is necessary to specify

the time limits and conditions of supply to determine the resultant costs,

HAS ADOPTED THIS REGULATION:

Article 1

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

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

Article 2

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

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

Done at Brussels, 22 March 1999.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 166, 5. 7. 1996, p. 1.

⁽²⁾ OJ L 346, 17. 12. 1997, p. 23.

ANNEX

LOT A

1. **Action No:** 452/97
2. **Beneficiary** ⁽²⁾: Euronaid, PO Box 12, NL-2501 CA Den Haag, Nederland
tel. (31-70) 33 05 757; fax (31-70) 36 41 701; telex 30960 EURON NL
3. **Beneficiary's representative:** to be designated by the recipient
4. **Country of destination:** Democratic Republic of Congo
5. **Product to be mobilised:** refined sunflower oil
6. **Total quantity (tonnes net):** 15
7. **Number of lots:** 1
8. **Characteristics and quality of the product** ⁽³⁾ ⁽⁴⁾: see OJ C 114, 29.4.1991, p. 1 (III.A(1)(b))
9. **Packaging** ⁽⁶⁾: see OJ C 267, 13.9.1996, p. 1 (10.4. A, B and C(2))
10. **Labelling or marking** ⁽⁵⁾: see OJ C 114, 29.4.1991, p. 1 (III.A(3))
 - Language to be used for the markings: French
 - Supplementary markings: —
11. **Method of mobilisation of the product:** mobilisation of refined vegetable oil produced in the Community.
Mobilisation may not involve a product manufactured and/or packaged under inward-processing arrangements.
12. **Specified delivery stage:** free at port of shipment
13. **Alternative delivery stage:** —
14. (a) **Port of shipment:** —
(b) **Loading address:** —
15. **Port of landing:** —
16. **Place of destination:** —
 - port or warehouse of transit: —
 - overland transport route: —
17. **Period or deadline of supply at the specified stage:**
 - first deadline: 26.4 to 16.5.1999
 - second deadline: 10 to 30.5.1999
18. **Period or deadline of supply at the alternative stage:**
 - first deadline: —
 - second deadline: —
19. **Deadline for the submission of tenders (12 noon, Brussels time):**
 - first deadline: 6.4.1999
 - second deadline: 20.4.1999
20. **Amount of tendering guarantee:** EUR 15/t
21. **Address for submission of tenders and tendering guarantees** ⁽¹⁾:
Bureau de l'aide alimentaire, Attn Mr T. Vestergaard, Bâtiment Loi 130, bureau 7/46, Rue de la Loi/
Wetstraat 200, B-1049 Bruxelles/Brussel
telex 25670 AGREC B; fax (32-2) 296 70 03 / 296 70 04 (exclusively)
22. **Export refund:** —

Notes:

- (¹) Supplementary information: André Debongnie (tel. (32-2) 295 14 65),
Torben Vestergaard (tel. (32-2) 299 30 50).
- (²) The supplier shall contact the beneficiary or its representative as soon as possible to establish which consignment documents are required.
- (³) The supplier shall deliver to the beneficiary a certificate from an official entity certifying that for the product to be delivered the standards applicable, relative to nuclear radiation, in the Member State concerned, have not been exceeded. The radioactivity certificate must indicate the caesium-134 and -137 and iodine-131 levels.
- (⁴) The supplier shall supply to the beneficiary or its representative, on delivery, the following document:
— health certificate.
- (⁵) Notwithstanding OJ C 114 of 29.4.1991, point III.A(3)(c) is replaced by the following: 'the words "European Community"'.

(⁶) Shipment to take place in 20-foot containers, condition FCL/FCL.

The supplier shall be responsible for the cost of making the container available in the stack position at the container terminal at the port of shipment. The beneficiary shall be responsible for all subsequent loading costs, including the cost of moving the containers from the container terminal.

The supplier has to submit to the beneficiary's agent a complete packing list of each container, specifying the number of bags belonging to each action number as specified in the invitation to tender.

The supplier has to seal each container with a numbered locktainer (Oneseal, Sysko, Locktainer 180 or a similar high-security seal) the number of which is to be provided to the beneficiary's representative.
-

COMMISSION DIRECTIVE 1999/11/EC
of 8 March 1999

adapting to technical progress the principles of good laboratory practice as specified in Council Directive 87/18/EEC 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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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⁽¹⁾, and in particular Article 4 thereof,

Whereas the principles of good laboratory practice (GLP) referred to in Directive 87/18/EEC have been modified by OECD Council Decision [C(97)186(Final)];

Whereas it is necessary to adapt the reference to the principles of GLP as specified in Directive 87/18/EEC so as to take account of these modifications, and, by publishing the full text of the revised principles of GLP, to facilitate the uniform interpretation and application thereof;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Committee for the adaptation to technical progress of the Directives concerning the elimination of technical barriers to trade in dangerous substances and preparations,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Article 1(1) of Directive 87/18/EEC is replaced by the following:

‘1. Member States shall take all measures necessary to ensure that laboratories carrying out tests on chemical products, in accordance with Directive 67/548/EEC, comply with the principles of good laboratory practice as laid down in the Annex to this Directive.’

Article 2

The Annex hereto is added as Annex to Directive 87/18/EEC.

Article 3

1. Member States shall adopt the laws, regulations and administrative provisions necessary in order to comply with this Directive not later than 30 September 1999 and shall forthwith inform the Commission thereof.

2. When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such a reference shall be adopted by Member States.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 8 March 1999.

For the Commission

Martin BANGEMANN

Member of the Commission

⁽¹⁾ OJ L 15, 17. 1. 1987, p. 29.

ANNEX

THE OECD PRINCIPLES OF GOOD LABORATORY PRACTICE (GLP)

Contents*Section I*

INTRODUCTION

Preface

1. Scope
2. Definitions of terms
 - 2.1. Good laboratory practice
 - 2.2. Terms concerning the organisation of a test facility
 - 2.3. Terms concerning the non-clinical health and environmental safety study
 - 2.4. Terms concerning the test item

Section II

GOOD LABORATORY PRACTICE PRINCIPLES

1. Test facility organisation and personnel
 - 1.1. Test facility management's responsibilities
 - 1.2. Study director's responsibilities
 - 1.3. Principal investigator's responsibilities
 - 1.4. Study personnel's responsibilities
2. Quality assurance programme
 - 2.1. General
 - 2.2. Responsibilities of the quality assurance personnel
3. Facilities
 - 3.1. General
 - 3.2. Test system facilities
 - 3.3. Facilities for handling test and reference items
 - 3.4. Archive facilities
 - 3.5. Waste disposal
4. Apparatus, material, and reagents
5. Test systems
 - 5.1. Physical/chemical
 - 5.2. Biological
6. Test and reference items
 - 6.1. Receipt, handling, sampling and storage
 - 6.2. Characterisation
7. Standard operating procedures
8. Performance of the study
 - 8.1. Study plan
 - 8.2. Content of the study plan
 - 8.3. Conduct of the study
9. Reporting of study results
 - 9.1. General
 - 9.2. Content of the final report
10. Storage and retention of records and materials

Section I

INTRODUCTION

Preface

Government and industry are concerned about the quality of non-clinical health and environmental safety studies upon which hazard assessments are based. As a consequence, OECD Member countries have established criteria for the performance of these studies.

To avoid different schemes of implementation that could impede international trade in chemicals, OECD Member countries have pursued international harmonisation of test methods and good laboratory practice. In 1979 and 1980 an international group of experts, established under the special programme on the control of chemicals, developed the 'OECD principles of good laboratory practice' (GLP), utilising common managerial and scientific practices and experience from various national and international sources. These principles of GLP were adopted by the OECD Council in 1981, as an Annex to the Council Decision on the mutual acceptance of data in the assessment of chemicals. [C(81)30(Final)].

In 1995 and 1996, a new group of experts was formed to revise and update the principles. The current document is the result of the consensus reached by that group. It cancels and replaces the original principles adopted in 1981.

The purpose of these principles of good laboratory practice is to promote the development of quality test data. Comparable quality of test data forms the basis for the mutual acceptance of data among countries. If individual countries can confidently rely on test data developed in other countries, duplicative testing can be avoided, thereby saving time and resources. The application of these principles should help to avoid the creation of technical barriers to trade, and further improve the protection of human health and the environment.

1. Scope

These principles of good laboratory practice should be applied to the non-clinical safety testing of test items contained in pharmaceutical products, pesticide products, cosmetic products, veterinary drugs as well as food additives, feed additives, and industrial chemicals. These test items are frequently synthetic chemicals, but may be of natural or biological origin and, in some circumstances, may be living organisms. The purpose of testing these test items is to obtain data on their properties and/or their safety with respect to human health and/or the environment.

Non-clinical health and environmental safety studies covered by the principles of good laboratory practice include work conducted in the laboratory, in greenhouses, and in the field.

Unless specifically exempted by national legislation, these principles of good laboratory practice apply to all non-clinical health and environmental safety studies required by regulation for the purpose of registering or licensing pharmaceuticals, pesticides, food and feed additives, cosmetic products, veterinary drug products and similar products, and for the regulation of industrial chemicals.

2. Definition of terms

2.1. *Good laboratory practice*

Good laboratory practice (GPL) is a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

2.2. *Terms concerning the organisation of a test facility*

1. *Test facility* means the persons, premises and operational unit(s) that are necessary for conducting the non-clinical health and environmental safety study. For multisite studies, those which are conducted at more than one site, the test facility comprises the site at which the study director is located and all individual test sites, which individually or collectively can be considered to be test facilities.
2. *Test site* means the location(s) at which a phase(s) of a study is conducted.
3. *Test facility management* means the person(s) who has the authority and formal responsibility for the organisation and functioning of the test facility according to these principles of good laboratory practice.

4. *Test site management* (if appointed) means the person(s) responsible for ensuring that the phase(s) of the study, for which he is responsible, are conducted according to these principles of good laboratory practice.
5. *Sponsor* means an entity which commissions, supports and/or submits a non-clinical health and environmental safety study.
6. *Study director* means the individual responsible for the overall conduct of the non-clinical health and environmental safety study.
7. *Principal investigator* means an individual who, for a multisite study, acts on behalf of the study director and has defined responsibility for delegated phases of the study. The study director's responsibility for the overall conduct of the study cannot be delegated to the principal investigator(s); this includes approval of the study plan and its amendments, approval of the final report, and ensuring that all applicable principles of good laboratory practice are followed.
8. *Quality assurance programme* means a defined system, including personnel, which is independent of study conduct and is designed to assure test facility management of compliance with these principles of good laboratory practice.
9. *Standard operating procedures (SOPs)* means documented procedures which describe how to perform tests or activities normally not specified in detail in study plans or test guidelines.
10. *Master schedule* means a compilation of information to assist in the assessment of workload and for the tracking of studies at a test facility.

2.3. *Terms concerning the non-clinical health and environmental safety study*

1. *Non-clinical health and environmental safety study*, henceforth referred to simply as 'study', means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties and/or its safety, intended for submission to appropriate regulatory authorities.
2. *Short-term study* means a study of short duration with widely used, routine techniques.
3. *Study plan* means a document which defines the objectives and experimental design for the conduct of the study, and includes any amendments.
4. *Study plan amendment* means an intended change to the study plan after the study initiation date.
5. *Study plan deviation* means an unintended departure from the study plan after the study initiation date.
6. *Test system* means any biological, chemical or physical system or a combination thereof used in a study.
7. *Raw data* means all original test facility records and documentation, or verified copies thereof, which are the result of the original observations and activities in a study. Raw data also may include, for example, photographs, microfilm or microfiche copies, computer readable media, dictated observations, recorded data from automated instruments, or any other data storage medium that has been recognised as capable of providing secure storage of information for a time period as stated in section 10 below.
8. *Specimen* means any material derived from a test system for examination, analysis, or retention.
9. *Experimental starting date* means the date on which the first study specific data are collected.
10. *Experimental completion date* means the last date on which data are collected from the study.
11. *Study initiation date* means the date the study director signs the study plan.
12. *Study completion date* means the date the study director signs the final report.

2.4. *Terms concerning the test item*

1. *Test item* means an article that is the subject of a study.
2. *Reference item* ('control item') means any article used to provide a basis for comparison with the test item.
3. *Batch* means a specific quantity or lot of a test item or reference item produced during a defined cycle of manufacture in such a way that it could be expected to be of a uniform character and should be designated as such.
4. *Vehicle* means any agent which serves as a carrier used to mix, disperse, or solubilise the test item or reference item to facilitate the administration/application to the test system.

Section II

GOOD LABORATORY PRACTICE PRINCIPLES

1. **Test facility organisation and personnel**

1.1. *Test facility management's responsibilities*

1. Each test facility management should ensure that these principles of good laboratory practice are complied with, in its test facility.
2. At a minimum it should:
 - (a) ensure that a statement exists which identifies the individual(s) within a test facility who fulfil the responsibilities of management as defined by these principles of good laboratory practice;
 - (b) ensure that a sufficient number of qualified personnel, appropriate facilities, equipment, and materials are available for the timely and proper conduct of the study;
 - (c) ensure the maintenance of a record of the qualifications, training, experience and job description for each professional and technical individual;
 - (d) ensure that personnel clearly understand the functions they are to perform and, where necessary, provide training for these functions;
 - (e) ensure that appropriate and technically valid standard operating procedures are established and followed, and approve all original and revised standard operating procedures;
 - (f) ensure that there is a quality assurance programme with designated personnel and assure that the quality assurance responsibility is being performed in accordance with these principles of good laboratory practice;
 - (g) ensure that for each study an individual with the appropriate qualifications, training, and experience is designated by the management as the study director before the study is initiated. Replacement of a study director should be done according to established procedures, and should be documented;
 - (h) ensure, in the event of a multisite study, that, if needed, a principal investigator is designated, who is appropriately trained, qualified and experienced to supervise the delegated phase(s) of the study. Replacement of a principal investigator should be done according to established procedures, and should be documented;
 - (i) ensure documented approval of the study plan by the study director;
 - (j) ensure that the study director has made the approval study plan available to the quality assurance personnel;
 - (k) ensure the maintenance of a historical file of all standard operating procedures;
 - (l) ensure that an individual is identified as responsible for the management of the archive(s);

- (m) ensure the maintenance of a master schedule;
 - (n) ensure that test facility supplies meet requirements appropriate to their use in a study;
 - (o) ensure for a multisite study that clear lines of communication exist between the study director, principal investigator(s), the quality assurance programme(s) and study personnel;
 - (p) ensure that test and reference items are appropriately characterised;
 - (q) establish procedures to ensure that computerised systems are suitable for their intended purpose, and are validated, operated and maintained in accordance with these principles of good laboratory practice.
3. When a phase(s) of a study is conducted at a test site, test site management (if appointed) will have the responsibilities as defined above with the following exceptions: 1.1.2(g), (i), (j) and (o).

1.2. *Study director's responsibilities*

1. The study director is the single point of study control and has the responsibility for the overall conduct of the study and for its final report.
2. These responsibilities should include, but not be limited to, the following functions. The study director should:
 - (a) approve the study plan and any amendments to the study plan by dated signature;
 - (b) ensure that the quality assurance personnel have a copy of the study plan and any amendments in a timely manner and communicate effectively with the quality assurance personnel as required during the conduct of the study;
 - (c) ensure that study plans and amendments and standard operating procedures are available to study personnel;
 - (d) ensure that the study plan and the final report for a multisite study identify and define the role of any principal investigator(s) and any test facilities and test sites involved in the conduct of the study;
 - (e) ensure that the procedures specified in the study plan are followed, and assess and document the impact of any deviations from the study plan on the quality and integrity of the study, and take appropriate corrective action if necessary; acknowledge deviations from standard operating procedures during the conduct of the study;
 - (f) ensure that all raw data generated are fully documented and recorded;
 - (g) ensure that computerised systems used in the study have been validated;
 - (h) sign and date the final report to indicate acceptance of responsibility for the validity of the data and to indicate the extent to which the study complies with these principles of good laboratory practice;
 - (i) ensure that after completion (including termination) of the study, the study plan, the final report, raw data and supporting material are archived.

1.3. *Principal investigator's responsibilities*

The principal investigator will ensure that the delegated phases of the study are conducted in accordance with the applicable principles of good laboratory practice.

1.4. *Study personnel's responsibilities*

1. All personnel involved in the conduct of the study must be knowledgeable in those parts of the principles of good laboratory practice which are applicable to their involvement in the study.

2. Study personnel will have access to the study plan and appropriate standard operating procedures applicable to their involvement in the study. It is their responsibility to comply with the instructions given in these documents. Any deviation from these instructions should be documented and communicated directly to the study director, and/or if appropriate, the principal investigator(s).
3. All study personnel are responsible for recording raw data promptly and accurately and in compliance with these principles of good laboratory practice, and are responsible for the quality of their data.
4. Study personnel should exercise health precautions to minimise risk to themselves and to ensure the integrity of the study. They should communicate to the appropriate person any relevant known health or medical condition in order that they can be excluded from operations that may affect the study.

2. Quality assurance programme

2.1. General

1. The test facility should have a documented quality assurance programme to assure that studies performed are in compliance with these principles of good laboratory practice.
2. The quality assurance programme should be carried out by an individual or by individuals designated by and directly responsible to management and who are familiar with the test procedures.
3. This individual(s) should not be involved in the conduct of the study being assured.

2.2. Responsibilities of the quality assurance personnel

The responsibilities of the quality assurance personnel include, but are not limited to, the following functions. They should:

- (a) maintain copies of all approved study plans and standard operating procedures in use in the test facility and have access to an up-to-date copy of the master schedule;
- (b) verify that the study plan contains the information required for compliance with these principles of good laboratory practice. This verification should be documented;
- (c) conduct inspections to determine if all studies are conducted in accordance with these principles of good laboratory practice. Inspections should also determine that study plans and standard operating procedures have been made available to study personnel and are being followed.

Inspections can be of three types as specified by quality assurance programme standard operating procedures:

- study-based inspections,
- facility-based inspections,
- process-based inspections.

Records of such inspections should be retained;

- (d) inspect the final reports to confirm that the methods, procedures, and observations are accurately and completely described, and that the reported results accurately and completely reflect the raw data of the studies;
- (e) promptly report any inspection results in writing to management and to the study director, and to the principal investigator(s) and the respective management, when applicable;
- (f) prepare and sign a statement, to be included with the final report, which specifies types of inspections and their dates, including the phase(s) of the study inspected, and the dates inspection results were reported to management and the study director and principal investigator(s), if applicable. This statement would also serve to confirm that the final report reflects the raw data.

3. Facilities

3.1. *General*

1. The test facility should be of suitable size, construction and location to meet the requirements of the study and to minimise disturbance that would interfere with the validity of the study.
2. The design of the test facility should provide an adequate degree of separation of the different activities to assure the proper conduct of each study.

3.2. *Test system facilities*

1. The test facility should have a sufficient number of rooms or areas to assure the isolation of test systems and the isolation of individual projects, involving substances or organisms known to be or suspected of being biohazardous.
2. Suitable rooms or areas should be available for the diagnosis, treatment and control of diseases, in order to ensure that there is no unacceptable degree of deterioration of test systems.
3. There should be storage rooms or areas as needed for supplies and equipment. Storage rooms or areas should be separated from rooms or areas housing the test systems and should provide adequate protection against infestation, contamination, and/or deterioration.

3.3. *Facilities for handling test and reference items*

1. To prevent contamination or mix-ups, there should be separate rooms or areas for receipt and storage of the test and reference items, and mixing of the test items with a vehicle.
2. Storage rooms or areas for the test items should be separate from rooms or areas containing the test systems. They should be adequate to preserve identity, concentration, purity, and stability, and ensure safe storage for hazardous substances.

3.4. *Archive facilities*

Archive facilities should be provided for the secure storage and retrieval of study plans, raw data, final reports, samples of test items and specimens. Archive design and archive conditions should protect contents from untimely deterioration.

3.5. *Waste disposal*

Handling and disposal of wastes should be carried out in such a way as not to jeopardise the integrity of studies. This includes provision for appropriate collection, storage and disposal facilities, and decontamination and transportation procedures.

4. Apparatus, material, and reagents

1. Apparatus, including validated computerised systems, used for the generation, storage and retrieval of data, and for controlling environmental factors relevant to the study should be suitably located and of appropriate design and adequate capacity.
2. Apparatus used in a study should be periodically inspected, cleaned, maintained, and calibrated according to standard operating procedures. Records of these activities should be maintained. Calibration should, where appropriate, be traceable to national or international standards of measurement.
3. Apparatus and materials used in a study should not interfere adversely with the test systems.

4. Chemicals, reagents, and solutions should be labelled to indicate identity (with concentration if appropriate), expiry date and specific storage instructions. Information concerning source, preparation date and stability should be available. The expiry date may be extended on the basis of documented evaluation or analysis.

5. Test systems

5.1. *Physical/chemical*

1. Apparatus used for the generation of physical/chemical data should be suitably located and of appropriate design and adequate capacity.
2. The integrity of the physical/chemical test systems should be ensured.

5.2. *Biological*

1. Proper conditions should be established and maintained for the storage, housing, handling and care of biological test systems, in order to ensure the quality of the data.
2. Newly received animal and plant test systems should be isolated until their health status has been evaluated. If any unusual mortality or morbidity occurs, this lot should not be used in studies and, when appropriate, should be humanely destroyed. At the experimental starting date of a study, test systems should be free of any disease or condition that might interfere with the purpose or conduct of the study. Test systems that become diseased or injured during the course of a study should be isolated and treated, if necessary to maintain the integrity of the study. Any diagnosis and treatment of any disease before or during a study should be recorded.
3. Records of source, date of arrival, and arrival condition of test systems should be maintained.
4. Biological test systems should be acclimatised to the test environment for an adequate period before the first administration/application of the test or reference item.
5. All information needed to properly identify the test systems should appear on their housing or containers. Individual test systems that are to be removed from their housing or containers during the conduct of the study should bear appropriate identification, wherever possible.
6. During use, housing or containers for test systems should be cleaned and sanitised at appropriate intervals. Any material that comes into contact with the test system should be free of contaminants at levels that would interfere with the study. Bedding for animals should be changed as required by sound husbandry practice. Use of pest control agents should be documented.
7. Test systems used in field studies should be located so as to avoid interference in the study from spray drift and from past usage of pesticides.

6. Test and reference items

6.1. *Receipt, handling, sampling and storage*

1. Records including test item and reference item characterisation, date of receipt, expiry date, quantities received and used in studies should be maintained.
2. Handling, sampling, and storage procedures should be identified in order that the homogeneity and stability are assured to the degree possible and contamination or mix-up are precluded.
3. Storage container(s) should carry identification information, expiry date, and specific storage instructions.

6.2. *Characterisation*

1. Each test and reference item should be appropriately identified (e.g. code, chemical abstracts service registry number (CAS number), name, biological parameters).
2. For each study, the identity, including batch number, purity, composition, concentrations, or other characteristics to appropriately define each batch of the test or reference items should be known.
3. In cases where the test item is supplied by the sponsor, there should be a mechanism, developed in cooperation between the sponsor and the test facility, to verify the identity of the test item subject to the study.
4. The stability of test and reference items under storage and test conditions should be known for all studies.
5. If the test item is administered or applied in a vehicle, the homogeneity, concentration and stability of the test item in that vehicle should be determined. For test items used in field studies (e.g. tank mixes), these may be determined through separate laboratory experiments.
6. A sample for analytical purposes from each batch of test item should be retained for all studies except short-term studies.

7. **Standard operating procedures**

1. A test facility should have written standard operating procedures approved by test facility management that are intended to ensure the quality and integrity of the data generated by that test facility. Revisions to standard operating procedures should be approved by test facility management.
2. Each separate test facility unit or area should have immediately available current standard operating procedures relevant to the activities being performed therein. Published text books, analytical methods, articles and manuals may be used as supplements to these standard operating procedures.
3. Deviations from standard operating procedures related to the study should be documented and should be acknowledged by the study director and the principal investigator(s), as applicable.
4. Standard operating procedures should be available for, but not be limited to, the following categories of test facility activities. The details given under each heading are to be considered as illustrative examples.

1. Test and reference items

Receipt, identification, labelling, handling, sampling and storage.

2. Apparatus, materials and reagents

(a) Apparatus:

use, maintenance, cleaning and calibration.

(b) Computerised systems:

validation, operation, maintenance, security, change control and back-up.

(c) Materials, reagents and solutions:

preparation and labelling.

3. Record keeping, reporting, storage, and retrieval

Coding of studies, data collection, preparation of reports, indexing systems, handling of data, including the use of computerised systems.

4. Test system (where appropriate)
 - (a) Room preparation and environmental room conditions for the test system.
 - (b) Procedures for receipt, transfer, proper placement, characterisation, identification and care of the test system.
 - (c) Test system preparation, observations and examinations, before, during and at the conclusion of the study.
 - (d) Handling of test system individuals found moribund or dead during the study.
 - (e) Collection, identification and handling of specimens including necropsy and histopathology.
 - (f) Siting and placement of test systems in test plots.
5. Quality assurance procedures

Operation of Quality Assurance personnel in planning, scheduling, performing, documenting and reporting inspections.

8. Performance of the study

8.1. Study plan

1. For each study, a written plan should exist prior to the initiation of the study. The study plan should be approved by dated signature of the study director and verified for GLP compliance by quality assurance personnel as specified in 2.2(b) of Section II. The study plan should also be approved by the test facility management and the sponsor, if required by national regulation or legislation in the country where the study is being performed.
2.
 - (a) Amendments to the study plan should be justified and approved by dated signature of the study director and maintained with the study plan.
 - (b) Deviations from the study plan should be described, explained, acknowledged and dated in a timely fashion by the study director and/or principal investigator(s) and maintained with the study raw data.
3. For short-term studies, a general study plan accompanied by a study specific supplement may be used.

8.2. Content of the study plan

The study plan should contain, but not be limited to the following information:

1. Identification of the study, the test item and reference item:
 - (a) a descriptive title;
 - (b) a statement which reveals the nature and purpose of the study;
 - (c) identification of the test item by code or name (IUPAC; CAS number, biological parameters, etc.);
 - (d) the reference item to be used.
2. Information concerning the sponsor and the test facility:
 - (a) name and address of the sponsor;
 - (b) name and address of any test facilities and test sites involved;
 - (c) name and address of the study director;
 - (d) name and address of the principal investigator(s), and the phase(s) of the study delegated by the study director and under the responsibility of the principal investigator(s).

3. Dates:

- (a) the date of approval of the study plan by signature of the study director. The date of approval of the study plan by signature of the test facility management and sponsor if required by national regulation or legislation in the country where the study is being performed;
- (b) the proposed experimental starting and completion dates.

4. Test methods:

Reference to the OECD test guideline or other test guideline or method to be used.

5. Issues (where applicable):

- (a) the justification for selection of the test system;
- (b) characterisation of the test system, such as the species, strain, substrain, source of supply, number, body weight range, sex, age and other pertinent information;
- (c) the method of administration and the reason for its choice;
- (d) the dose levels and/or concentration(s), frequency, and duration of administration/application;
- (e) detailed information on the experimental design, including a description of the chronological procedure of the study, all methods, materials and conditions, type and frequency of analysis, measurements, observations and examinations to be performed, and statistical methods to be used (if any).

6. Records:

a list of records to be retained.

8.3. *Conduct of the study*

- 1. A unique identification should be given to each study. All items concerning this study should carry this identification. Specimens from the study should be identified to confirm their origin. Such identification should enable traceability, as appropriate for the specimen and study.
- 2. The study should be conducted in accordance with the study plan.
- 3. All data generated during the conduct of the study should be recorded directly, promptly, accurately, and legibly by the individual entering the data. These entries should be signed or initialled and dated.
- 4. Any change in the raw data should be made so as not to obscure the previous entry, should indicate the reason for change and should be dated and signed or initialled by the individual making the change.
- 5. Data generated as a direct computer input should be identified at the time of data input by the individual(s) responsible for direct data entries. Computerised system design should always provide for the retention of full audit trails to show all changes to the data without obscuring the original data. It should be possible to associate all changes to data with the persons having made those changes, for example, by use of timed and dated (electronic) signatures. Reason for changes should be given.

9. Reporting of study results

9.1. *General*

- 1. A final report should be prepared for each study. In the case of short-term studies, a standardised final report accompanied by a study specific extension may be prepared.

2. Reports of principal investigators or scientists involved in the study should be signed and dated by them.
3. The final report should be signed and dated by the study director to indicate acceptance of responsibility for the validity of the data. The extent of compliance with these principles of good laboratory practice should be indicated.
4. Corrections and additions to a final report should be in the form of amendments. Amendments should clearly specify the reason for the corrections or additions and should be signed and dated by the study director.
5. Reformatting of the final report to comply with the submission requirements of a national registration or regulatory authority does not constitute a correction, addition or amendment to the final report.

9.2. *Content of the final report*

The final report should include, but not be limited to, the following information:

1. Identification of the study, the test item and reference item:
 - (a) a descriptive title;
 - (b) identification of the test item by code or name (IUPAC, CAS number, biological parameters, etc.);
 - (c) identification of the reference item by name;
 - (d) characterisation of the test item including purity, stability and homogeneity.
2. Information concerning the sponsor and the test facility:
 - (a) name and address of the sponsor;
 - (b) name and address of any test facilities and test sites involved;
 - (c) name and address of the study director;
 - (d) name and address of the principal investigator(s) and the phase(s) of the study delegated, if applicable;
 - (e) name and address of scientists having contributed reports to the final report.
3. Dates:

experimental starting and completion dates.
4. Statement:

a quality assurance programme statement listing the types of inspections made and their dates, including the phase(s) inspected, and the dates any inspection results were reported to management and to the study director and principal investigator(s), if applicable. This statement would also serve to confirm that the final report reflects the raw data.
5. Description of materials and test methods:
 - (a) description of methods and materials used;
 - (b) reference to OECD test guideline or other test guideline or method.
6. Results:
 - (a) a summary of results;
 - (b) all information and data required by the study plan;

- (c) a presentation of the results, including calculations and determinations of statistical significance;
- (d) an evaluation and discussion of the results and, where appropriate, conclusions.

7. Storage:

the location(s) where the study plan, samples of test and reference items, specimens, raw data and the final report are to be stored.

10. Storage and retention of records and materials

10.1. The following should be retained in the archives for the period specified by the appropriate authorities:

- (a) the study plan, raw data, samples of test and reference items, specimens, and the final report of each study;
- (b) Records of all inspections performed by the quality assurance programme, as well as master schedules;
- (c) records of qualifications, training, experience and job descriptions of personnel;
- (d) records and reports of the maintenance and calibration of apparatus;
- (e) validation documentation for computerised systems;
- (f) the historical file of all standard operating procedures;
- (g) environmental monitoring records.

In the absence of a required retention period, the final disposition of any study materials should be documented. When samples of test and reference items and specimens are disposed of before the expiry of the required retention period for any reason, this should be justified and documented. Samples of test and reference items and specimens should be retained only as long as the quality of the preparation permits evaluation.

10.2. Material retained in the archives should be indexed so as to facilitate orderly storage and retrieval.

10.3. Only personnel authorised by management should have access to the archives. Movement of material in and out of the archives should be properly recorded.

10.4. If a test facility or an archive contracting facility goes out of business and has no legal successor, the archive should be transferred to the archives of the sponsor(s) of the study(s).

COMMISSION DIRECTIVE 1999/12/EC
of 8 March 1999

adapting to technical progress for the second time the Annex to Council Directive 88/320/EEC on the inspection and verification of good laboratory practice (GLP)

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

HAS ADOPTED THIS DIRECTIVE:

Having regard to the Treaty establishing the European Community,

Article 1

The Annex to Directive 88/320/EEC is replaced by the Annex hereto.

Having regard to Council Directive 88/320/EEC of 9 June 1988 on the inspection and verification of good laboratory practice (GLP) ⁽¹⁾ as amended by Commission Directive 90/18/EEC ⁽²⁾, and in particular Article 7(2) thereof,

Article 2

1. Member States shall adopt the laws, regulations and administrative provisions necessary in order to comply with this Directive not later than 30 September 1999 and shall forthwith inform the Commission thereof.

Whereas, on 9 March 1995, the OECD Council adopted a Decision amending the Annexes to the Council Decision-Recommendation on compliance with principles of good laboratory practice which affects the texts included in the Annex to Directive 88/320/EEC;

2. When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Whereas it is necessary to adapt for a second time the Annex to Directive 88/320/EEC so as to take account of the OECD Council Decision of 9 March 1995, and, by publishing the full text of the annexes on the inspection and verification of good laboratory practice, to facilitate the uniform interpretation thereof;

Article 3

This Directive is addressed to the Member States.

Whereas the measures provided for in this Directive are in accordance with the opinion of the Committee for the adaptation to technical progress of the Directives concerning the elimination of technical barriers to trade in dangerous substances and preparations,

Done at Brussels, 8 March 1999.

For the Commission

Martin BANGEMANN

Member of the Commission

⁽¹⁾ OJ L 145, 11. 6. 1988, p. 35.

⁽²⁾ OJ L 11, 13. 1. 1990, p. 37.

ANNEX

The provisions for the inspection and verification of GLP which are contained in parts A and B are those contained in Annexes I (Guides for compliance monitoring procedures for good laboratory practice) and II (Guidance for the conduct of test facility inspections and study audits) respectively of the OECD Council Decision-Recommendation on compliance with principles of good laboratory practice [C(89)87(Final)] of 2 October 1989 as revised by the OECD Council Decision amending the Annexes to the Council Decision-Recommendation on compliance with principles of good laboratory practice of 9 March 1995 [C(95)8(Final)].

PART A

REVISED GUIDES FOR COMPLIANCE MONITORING PROCEDURES FOR GOOD LABORATORY PRACTICE

To facilitate the mutual acceptance of test data generated for submission to Regulatory Authorities of the OECD member countries, harmonisation of the procedures adopted to monitor good laboratory practice compliance, as well as comparability of their quality and rigour, are essential. The aim of this part of the Annex is to provide detailed practical guidance to the Member States on the structure, mechanisms and procedures they should adopt when establishing national good laboratory practice compliance monitoring programmes so that these programmes may be internationally acceptable.

It is recognised that Member States will adopt GLP principles and establish compliance monitoring procedures according to national legal and administrative practices, and according to priorities they give to, for example the scope of initial and subsequent coverage concerning categories of chemicals and types of testing. Since Member States may establish more than one Good Laboratory Practice Monitoring Authority due to their legal framework for chemicals control, more than one good laboratory practice compliance programme may be established. The guidance set forth in the following paragraphs concerns each of these Authorities and compliance programmes, as appropriate.

Definitions of terms

The definitions of terms in the OECD principles of good laboratory practice adopted in Article 1 of Council Directive 87/18/EEC⁽¹⁾ are applicable to this part of the Annex. In addition, the following definitions apply:

- *GLP principles*: principles of good laboratory practice that are consistent with the OECD principles of good laboratory practice as adopted in Article 1 of Directive 87/18/EEC,
- *GLP compliance monitoring*: the periodic inspection of test facilities and/or auditing of studies for the purpose of verifying adherence to GLP principles,
- *(National) GLP compliance programme*: the particular scheme established by a Member State to monitor good laboratory practice compliance by test facilities within its territories, by means of inspections and study audits,
- *(National) GLP Monitoring Authority*: a body established within a Member State with responsibility for monitoring the good laboratory practice compliance of test facilities within its territories and for discharging other such functions related to good laboratory practice as may be nationally determined. It is understood that more than one such body may be established in a Member State,
- *Test facility inspection*: an on-site examination of the test facility's procedures and practices to assess the degree of compliance with GLP principles. During inspections, the management structures and operational procedures of the test facility are examined, key technical personnel are interviewed, and the quality and integrity of data generated by the facility are assessed and reported,
- *Study audit*: a comparison of raw data and associated records with the interim or final report in order to determine whether the raw data have been accurately reported, to determine whether testing was carried out in accordance with the study plan and standard operating procedures, to obtain additional information not provided in the report, and to establish whether practices were employed in the development of data that would impair their validity,
- *Inspector*: a person who performs the test facility inspections and study audits on behalf of the (national) GLP Monitoring Authority,

⁽¹⁾ OJ L 15, 17. 1. 1987, p. 29.

- *GLP compliance status*: the level of adherence of a test facility to the GLP principles as assessed by the (national) GLP Monitoring Authority,
- *Regulatory Authority*: a national body with legal responsibility for aspects of the control of chemicals.

Components of good laboratory practice compliance monitoring procedures

Administration

A (national) GLP compliance programme should be the responsibility of a properly constituted, legally identifiable body adequately staffed and working within a defined administrative framework.

Member States should:

- ensure that the (national) GLP Monitoring Authority is directly responsible for an adequate 'team' of inspectors having the necessary technical/scientific expertise or is ultimately responsible for such a team,
- publish documents relating to the adoption of GLP principles within their territories,
- publish documents providing details of the (national) GLP compliance programme, including information on the legal or administrative framework within which the programme operates and references to published acts, normative documents (e.g., regulations, codes of practice), inspection manuals, guidance notes, periodicity of inspections and/or criteria for inspection schedules, etc.,
- maintain records of test facilities inspected (and their GLP compliance status) and of studies audited for both national and international purposes.

Confidentiality

(National) GLP Monitoring Authorities will have access to commercially valuable information and, on occasion, may even need to remove commercially sensitive documents from a test facility or refer to them in detail in their reports.

Member States should:

- 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,
- 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.

Personnel and training

(National) GLP Monitoring Authorities should:

- ensure that an adequate number of inspectors is available.

The number of inspectors required will depend on:

- (a) the number of test facilities involved in the (national) GLP compliance programme;
 - (b) the frequency with which the GLP compliance status of the test facilities is to be assessed;
 - (c) the number and complexity of the studies undertaken by those test facilities;
 - (d) the number of special inspections or audits requested by Regulatory Authorities,
- ensure that inspectors are adequately qualified and trained.

Inspectors should have qualifications and practical experience in the range of scientific disciplines relevant to the testing of chemicals. (National) GLP Monitoring Authorities should:

- (a) ensure that arrangements are made for the appropriate training of GLP inspectors, having regard to their individual qualifications and experience;
 - (b) encourage consultations, including joint training activities where necessary, with the staff of (national) GLP Monitoring Authorities in other OECD member countries in order to promote international harmonisation in the interpretation and application of GLP principles, and in the monitoring of compliance with such principles,
- ensure that inspectorate personnel, including experts under contract, have no financial or other interests in the test facilities inspected, the studies audited or the firms sponsoring such studies,

- provide inspectors with a suitable means of identification (e.g., an identity card).

Inspectors may be:

- on the permanent staff of the (national) GLP Monitoring Authority,
- on the permanent staff of a body separate from the (national) GLP Monitoring Authority, or
- employed on contract, or in another way, by the (national) GLP Monitoring Authority to perform test facility inspections or study audits.

In the latter two cases, the (national) GLP Monitoring Authority should have ultimate responsibility for determining the GLP compliance status of test facilities and the quality/acceptability of a study audit, and for taking any action based on the results of test facility inspections or study audits which may be necessary.

(National) GLP compliance programmes

GLP compliance monitoring is intended to ascertain whether test facilities have implemented GLP principles for the conduct of studies and are capable of assuring that the resulting data are of adequate quality. As indicated above, Member States should publish the details of their (national) GLP compliance programmes. Such information should, *inter alia*:

- define the scope and extent of the programme.

A (national) GLP compliance programme may cover only a limited range of chemicals, for example, industrial chemicals, pesticides, pharmaceuticals, etc., or may include all chemicals. The scope of the monitoring for compliance should be defined, both with respect to the categories of chemicals and to the types of tests subject to it, for example, physical, chemical, toxicological and/or ecotoxicological,

- provide an indication as to the mechanism whereby test facilities enter the programme.

The application of GLP principles to health and environmental safety data generated for regulatory purposes may be mandatory. A mechanism should be available whereby test facilities may have their compliance with GLP principles monitored by the appropriate (national) GLP Monitoring Authority,

- provide information on categories of test facility inspections/study audits.

A (national) GLP compliance programme should include:

- (a) provision for test facility inspections. These inspections include both a general test facility inspection and a study audit of one or more on-going or completed studies;
- (b) provisions for special test facility inspections/study audits at the request of a Regulatory Authority, for example, prompted by a query arising from the submission of data to a Regulatory Authority,

- define the powers of inspectors for entry into test facilities and their access to data held by test facilities (including specimens, SOPs (standard operating procedures) other documentation, etc.).

While inspectors will not normally wish to enter test facilities against the will of the facility's management, circumstances may arise where test facility entry and access to data are essential to protect public health or the environment. The powers available to the (national) GLP Monitoring Authority in such cases should be defined,

- describe the test facility inspection and study audit procedures for verification of GLP compliance.

The documentation should indicate the procedures which will be used to examine both the organisational processes and the conditions under which studies are planned, performed, monitored and recorded. Guidance for such procedures is available in part B of this Annex,

- describe actions that may be taken as follow-up test facility inspections and study audits.

Follow-up to test facility inspections and study audits

When a test facility inspection or study audit has been completed, the inspector should prepare a written report of the findings.

Member States should take action where deviations from GLP principles are found during or after a test facility inspection or study audit. The appropriate actions should be described in documents from the (national) GLP Monitoring Authority.

If a test facility inspection or study audit reveals only minor deviations from GLP principles, the facility should be required to correct such minor deviations. The inspector may need, at an appropriate time, to return to the facility to verify that corrections have been introduced.

Where no, or where only minor deviations have been found, the (national) GLP Monitoring Authority may:

- issue a statement that the test facility has been inspected and found to be operating in compliance with GLP principles. The date of the inspections and, if appropriate, the categories of test inspected in the test facility at that time should be included. Such statements may be used to provide information to (national) GLP Monitoring Authorities in other OECD member countries,

and/or

- provide the Regulatory Authority which requested a study audit with a detailed report of the findings.

Where serious deviations are found, the action taken by (national) GLP Monitoring Authorities will depend on the particular circumstances of each case and the legal or administrative provisions under which GLP compliance monitoring has been established within their countries. Actions which may be taken include, but are not limited to, the following:

- issuance of a statement, giving details of the inadequacies or faults found which might affect the validity of studies conducted in the test facility,
- issuance of a recommendation to a Regulatory Authority that a study be rejected,
- suspension of test facility inspections or study audits of a test facility and, for example and where administratively possible, removal of the test facility from the (national) GLP compliance programme or from any existing list or register of test facilities subject to GLP test facility inspections,
- requiring that a statement detailing the deviations be attached to specific study reports,
- action through the courts, where warranted by circumstances and where legal/administrative procedures so permit.

Appeals procedures

Problems, or differences of opinion, between inspectors and test facility management will normally be resolved during the course of a test facility inspection or study audit. However, it may not always be possible for agreement to be reached. A procedure should exist whereby a test facility may make representations relating to the outcome of a test facility inspection or study audit for GLP compliance monitoring and/or relating to the action the GLP Monitoring Authority proposes to take thereon.

PART B

REVISED GUIDANCE FOR THE CONDUCT OF TEST FACILITY INSPECTIONS AND STUDY AUDITS

Introduction

The purpose of this part of the Annex is to provide guidance for the conduct of test facility inspections and study audits which would be mutually acceptable to OECD member countries. It is principally concerned with test facility inspections, an activity which occupies much of the time of GLP inspectors. A test facility inspection will usually include a study audit or review as a part of the inspection, but study audits will also have to be conducted from time to time at the request, for example, of a Regulatory Authority. General guidance for the conduct of study audits will be found at the end of this Annex.

Test facility inspections are conducted to determine the degree of conformity of test facilities and studies with GLP principles and to determine the integrity of data to assure that resulting data are of adequate quality for assessment and decision-making by national Regulatory Authorities. They result in reports which describe the degree of adherence of a test facility to the GLP principles. Test facility inspections should be conducted on a regular, routine basis to establish and maintain records of the GLP compliance status of test facilities.

Further clarification of many of the points in this part of the Annex may be obtained by referring to the OECD consensus documents on GLP (on, e.g., the role and responsibilities of the study director).

Definitions of terms

The definitions of terms in the OECD principles of good laboratory practice adopted in Article 1 of Directive 87/18/EEC and in part A of the Annex to this Directive are applicable to this part of the Annex.

Test facility inspections

Inspections for compliance with GLP principles may take place in any test facility generating health or environmental safety data for regulatory purposes. Inspectors may be required to audit data relating to the physical, chemical, toxicological or ecotoxicological properties of a substance or preparation. In some cases, inspectors may need assistance from experts in particular disciplines.

The wide diversity of facilities (in terms both of physical layout and management structure), together with the variety of types of studies encountered by inspectors, means that the inspectors must use their own judgment to assess the degree and extent of compliance with GLP principles. Nevertheless, inspectors should strive for a consistent approach in evaluating whether, in the case of a particular test facility or study, an adequate level of compliance with each GLP principle has been achieved.

In the following sections, guidance is provided on the various aspects of the testing facility, including its personnel and procedures, which are likely to be examined by inspectors. In each section, there is a statement of purpose, as well as an illustrative list of specific items which could be considered during the course of a test facility inspection. These lists are not meant to be comprehensive and should not be taken as such.

Inspectors should not concern themselves with the scientific design of the study or the interpretation of the findings of studies with respect to risks for human health or the environment. These aspects are the responsibility of those Regulatory Authorities to which the data are submitted for regulatory purposes.

Test facility inspections and study audits inevitably disturb the normal work in a facility. Inspectors should therefore carry out their work in a carefully planned way and, so far as practicable, respect the wishes of the management of the test facility as to the timing of visits to certain sections of the facility.

Inspectors will, while conducting test facility inspections and study audits, have access to confidential, commercially valuable information. It is essential that they ensure that such information is seen by authorised personnel only. Their responsibilities in this respect will have been established within their (national) GLP compliance monitoring programme.

Inspection procedures

Pre-inspection

Purpose: to familiarise the inspector with the facility which is about to be inspected in respect of management structure, physical layout of buildings and range of studies.

Prior to conducting a test facility inspection or study audit, inspectors should familiarise themselves with the facility which is to be visited. Any existing information on the facility should be reviewed. This may include previous inspection reports, the layout of the facility, organisation charts, study reports, protocols and curricula vitae (CVs) of personnel. Such documents would provide information on:

- the type, size and layout of the facility,
- the range of studies likely to be encountered during the inspection,
- the management structure of the facility.

Inspectors should note, in particular, any deficiencies from previous test facility inspections. Where no previous test facility inspections have been conducted, a pre-inspection visit can be made to obtain relevant information.

Test facilities may be informed of the date and time of inspector's arrival, the objective of their visit and the length of time they expect to be on the premises. This could allow the test facility to ensure that the appropriate personnel and documentation are available. In cases where particular documents or records are to be examined, it may be useful to identify these to the test facility in advance of the visit so that they will be immediately available during the test facility inspection.

Starting conference

Purpose: to inform the management and staff of the facility of the reason for the test facility inspection or study audit that is about to take place, and to identify the facility areas, study(ies) selected for audit, documents and personnel likely to be involved.

The administrative and practical details of a test facility inspection or study audit should be discussed with the management of the facility at the start of the visit. At the starting conference, inspectors should:

- outline the purpose and scope of the visit,
- describe the documentation which will be required for the test facility inspection, such as lists of on-going and completed studies, study plans, standard operating procedures, study reports, etc. Access to and, if necessary, arrangements for the copying of relevant documents should be agreed on at this time,
- clarify or request information as to the management structure (organisation) and personnel of the facility,
- request information as to the conduct of studies not subject to GLP principles in the areas of the test facility where GLP studies are being conducted,
- make an initial determination as to the parts of the facility to be covered during the test facility inspection,
- describe the documents and specimens that will be needed for on-going or completed study(ies) selected for study audit,
- indicate that a closing conference will be held at the completion of the inspection.

Before proceeding further with a test facility inspection, it is advisable for the inspector(s) to establish contact with the facility's quality assurance (QA) unit.

As a general rule, when inspecting a facility, inspectors will find it helpful to be accompanied by a member of the QA unit.

Inspectors may wish to request that a room be set aside for examination of documents and other activities.

Organisation and personnel

Purpose: to determine whether the test facility has sufficient qualified personnel, staff resources and support services for the variety and number of studies undertaken; the organisational structure is appropriate, and management has established a policy regarding training and staff health surveillance appropriate to the studies undertaken in the facility.

The management should be asked to produce certain documents, such as:

- floor plans,
- facility management and scientific organisation charts,
- CVs of personnel involved in the type(s) of studies selected for the study audit,
- list(s) of on-going and completed studies with information on the type of study, initiation/completion dates, test system, method of application of test substance and name of study director,
- staff health surveillance policies,
- staff job descriptions and staff training programmes and records,
- an index to the facility's standard operating procedures (SOPs),
- specific SOPs as related to the studies or procedures being inspected or audited,
- list(s) of the study directors and sponsors associated with the study(ies) being audited.

The inspector should check, in particular:

- lists of on-going and completed studies to ascertain the level of work being undertaken by the test facility,
- the identity and qualifications of the study director(s), the head of the quality assurance unit and other personnel,
- existence of SOPs for all relevant areas of testing.

Quality assurance programme

Purpose: to determine whether the mechanisms used to assure management that studies are conducted in accordance with GLP principles are adequate.

The head of the quality assurance (QA) unit should be asked to demonstrate the systems and methods for QA inspection and monitoring of studies, and the system for recording observations made during QA monitoring. Inspectors should check:

- the qualifications of the head of QA, and of all QA staff,
- that the QA unit functions independently from the staff involved in the studies,

- how the QA unit schedules and conducts inspections, how it monitors identified critical phases in a study, and what resources are available for QA inspections and monitoring activities,
- that where studies are of such short duration that monitoring of each study is impracticable, arrangements exist for monitoring on a sample basis,
- the extent and depth of QA monitoring during the practical phases of the study,
- the extent and depth of QA monitoring of routine test facility operation,
- the QA procedure for checking the final report to ensure its agreement with the raw data,
- that management receives reports from QA concerning problems likely to affect the quality or integrity of a study,
- the actions taken by QA when deviations are found,
- the QA role, if any, if studies or parts of studies are done in contract laboratories,
- the part played, if any, by QA in the review, revision and updating of SOPs.

Facilities

Purpose: to determine if the test facility, whether indoor or outdoor, is of suitable size, design and location to meet the demands of the studies being undertaken.

The inspector should check that:

- the design enables an adequate degree of separation so that, for example, test substances, animals, diets, pathological specimens, etc. of one study cannot be confused with those of another,
- environmental control and monitoring procedures exist and function adequately in critical areas, for example, animal and other biological test systems rooms, test substance storage areas, laboratory areas,
- the general housekeeping is adequate for the various facilities and that there are, if necessary, pest control procedures.

Care, housing and containment of biological test systems

Purpose: to determine whether the test facility, if engaged in studies using animals or other biological test systems, has support facilities and conditions for their care, housing and containment, adequate to prevent stress and other problems which could affect the test system and hence the quality of data.

A test facility may be carrying out studies which require a diversity of animal or plant species as well as microbial or other cellular or sub-cellular systems. The type of test systems being used will determine the aspects relating to care, housing or containment that the inspector will monitor. Using his judgment, the inspector will check, according to the test systems, that:

- there are facilities adequate for the test systems used and for testing needs,
- there are arrangements to quarantine animals and plants being introduced into the facility and that these arrangements are working satisfactorily,
- there are arrangements to isolate animals (or other elements of a test system, if necessary) known to be, or suspected of being, diseased or carriers of disease,
- there is adequate monitoring and record-keeping of health, behaviour or other aspects, as appropriate to the test system,
- the equipment for maintaining the environmental conditions required for each test system is adequate, well maintained, and effective,
- animal cages, racks, tanks and other containers, as well as accessory equipment, are kept sufficiently clean,
- analyses to check environmental conditions and support systems are carried out as required,
- facilities exist for removal and disposal of animal waste and refuse from the test systems and that these are operated so as to minimise vermin infestation, odours, disease hazards and environmental contamination,

- storage areas are provided for animal feed or equivalent materials for all test systems; that these areas are not used for the storage of other materials such as test substances, pest control chemicals or disinfectants, and that they are separate from areas in which animals are housed or other biological test systems are kept,
- stored feed and bedding are protected from deterioration by adverse environmental conditions, infestation or contamination.

Apparatus, materials, reagents and specimens

Purpose: to determine whether the test facility has suitably located, operational apparatus in sufficient quantity and of adequate capacity to meet the requirements of the tests being conducted in the facility and that the materials, reagents and specimens are properly labelled, used and stored.

The inspector should check that:

- apparatus is clean and in good working order,
- records have been kept of operation, maintenance, verification, calibration and validation of measuring equipment and apparatus (including computerised systems),
- materials and chemical reagents are properly labelled and stored at appropriate temperatures and that expiry dates are not being ignored. Labels for reagents should indicate their source, identity and concentration and/or other pertinent information,
- specimens are well identified by test system, study, nature and date of collection,
- apparatus and materials used do not alter to any appreciable extent the test systems.

Test systems

Purpose: to determine whether adequate procedures exist for the handling and control of the variety of test systems required by the studies undertaken in the facility, for example, chemical and physical systems, cellular and microbic systems, plants or animals.

Physical and chemical systems

The inspector should check that:

- where required by study plans, the stability of test and reference substances was determined and that the reference substances specified in test plans were used,
- in automated systems, data generated as graphs, recorder traces or computer print-outs are documented as raw data and archived.

Biological test systems

Taking account of the relevant aspects referred to above relating to care, housing or containment of biological test systems, the inspector should check that:

- test systems are as specified in study plans,
- test systems are adequately and, if necessary and appropriate, uniquely identified throughout the study, and that records exist regarding receipt of the test systems and document fully the number of test systems received, used, replaced or discarded,
- housing or containers of test systems are properly identified with all the necessary information,
- there is an adequate separation of studies being conducted on the same animal species (or the same biological test systems) but with different substances,
- there is an adequate separation of animal species (and other biological test systems) either in space or in time,
- the biological test system environment is as specified in the study plan or in SOPs for aspects such as temperature, or light/dark cycles,
- the recording of the receipt, handling, housing or containment, care and health evaluation is appropriate to the test systems,

- written records are kept of examination, quarantine, morbidity, mortality, behaviour, diagnosis and treatment of animal and plant test systems or other similar aspects as appropriate to each biological test system,
- there are provisions for the appropriate disposal of test systems at the end of tests.

Test and reference substances

Purpose: to determine whether the test facility has procedures designed (i) to ensure that the identity, potency, quantity and composition of test and reference substances are in accordance with their specifications, and (ii) to properly receive and store test and reference substances.

The inspector should check that:

- there are written records on the receipt (including identification of the person responsible), and for the handling, sampling, usage and storage of tests and reference substances,
- test and reference substances containers are properly labelled,
- storage conditions are appropriate to preserve the concentration, purity and stability of the test and reference substances,
- there are written records on the determination of identity, purity, composition, stability, and for the prevention of contamination of test and reference substances, where applicable,
- there are procedures for the determination of the homogeneity and stability of mixtures containing test and reference substances, where applicable,
- containers holding mixtures (or dilutions) of the test and reference substances are labelled and that records are kept of the homogeneity and stability of their contents, where applicable,
- when the test is of longer than four weeks duration, samples from each batch of test and reference substances have been taken for analytical purposes and that they have been retained for an appropriate time,
- procedures for mixing substances are designed to prevent errors in identification or cross-contamination.

Standard operating procedures

Purpose: to determine whether the test facility has written SOPs relating to all the important aspects of its operations, considering that one of the most important management techniques for controlling facility operations is the use of written SOPs. These relate directly to the routine elements of tests conducted by the test facility.

The inspector should check that:

- each test facility area has immediately available relevant, authorised copies of SOPs,
- procedures exist for revision and updating of SOPs,
- any amendments or changes to SOPs have been authorised and dated,
- historical files of SOPs are maintained,
- SOPs are available for, but not necessarily limited to, the following activities:
 - (i) receipt; determination of identity, purity, composition and stability; labelling; handling; sampling; usage; and storage of test and reference substances;
 - (ii) use, maintenance, cleaning, calibration and validation of measuring apparatus, computerised systems and environmental control equipment;
 - (iii) preparation of reagents and dosing formulations;
 - (iv) record-keeping, reporting, storage and retrieval of records and reports;
 - (v) preparation and environmental control of areas containing the test systems;
 - (vi) receipt, transfer, location, characterisation, identification and care of test systems;
 - (vii) handling of the test systems before, during and at the termination of the study;
 - (viii) disposal of test systems;
 - (ix) use of pest control and cleaning agents;
 - (x) quality assurance programme operations.

Performance of the study

Purpose: to verify that written study plans exist and that the plans and the conduct of the study are in accordance with GLP principles.

The inspector should check that:

- the study plan was signed by the study director,
- any amendments to the study plan were signed and dated by the study director,
- the date of the agreement to the study plan by the sponsor was recorded (where applicable),
- measurements, observations and examinations were in accordance with the study plan and relevant SOPs,
- the results of these measurements, observations and examinations were recorded directly, promptly, accurately and legibly and were signed (or initialled) and dated,
- any changes in the raw data, including data stored in computers, did not obscure previous entries, included the reason for the change and identified the person responsible for the change and the date it was made,
- computer-generated or stored data have been identified and that the procedures to protect them against unauthorised amendments or loss are adequate,
- the computerised systems used within the study are reliable, accurate and have been validated,
- any unforeseen events recorded in the raw data have been investigated and evaluated,
- the results presented in the reports of the study (interim or final) are consistent and complete and that they correctly reflect the raw data.

Reporting of study results

Purpose: to determine whether final reports are prepared in accordance with GLP principles.

When examining a final report, the inspector should check that:

- it is signed and dated by the study director to indicate acceptance of responsibility for the validity of the study and confirming that the study was conducted in accordance with GLP principles,
- it is signed and dated by other principal scientists, if reports from cooperating disciplines are included,
- a quality assurance statement is included in the report and that it is signed and dated,
- any amendments were made by the responsible personnel,
- it lists the archive location of all samples, specimens and raw data.

Storage and retention of records

Purpose: to determine whether the facility has generated adequate records and reports and whether adequate provision has been made for the safe storage and retention of records and materials;

The inspector should check:

- that a person has been identified as responsible for the archive,
- the archive facilities for the storage of study plans, raw data (including that from discontinued GLP studies), final reports, samples and specimens and records of education and training of personnel,
- the procedures for retrieval of archived materials,
- the procedures whereby access to the archives is limited to authorised personnel and records are kept of personnel given access to raw data, slides, etc.,
- that an inventory is maintained of materials removed from, and returned to, the archives,
- that records and materials are retained for the required or appropriate period of time and are protected from loss or damage by fire, adverse environmental conditions, etc.

Study audits

Test facility inspections will generally include, *inter alia*, study audits, which review on-going or completed studies. Specific study audits are also often requested by Regulatory Authorities, and can be conducted independently of test facility inspections. Because of the wide variation in the types of studies which might be audited, only general guidance is appropriate, and inspectors and others taking part in study audits will always need to exercise judgment as to the nature and extent of their examinations. The objective should be to reconstruct the study by comparing the final report with the study plan, relevant SOPs, raw data and other archived material.

In some cases, inspectors may need assistance from other experts in order to conduct an effective study audit, for example, where there is a need to examine tissue sections under the microscope.

When conducting a study audit, the inspector should:

- obtain names, job descriptions and summaries of training and experience for selected personnel engaged in the study(ies) such as the study director and principal scientists,
- check that there is sufficient staff trained in relevant areas for the study(ies) undertaken,
- identify individual items of apparatus or special equipment used in the study and examine the calibration, maintenance and service records for the equipment,
- review the records relating to the stability of the test substances, analyses of test substance and formulations, analyses of feed, etc.,
- attempt to determine, through the interview process if possible, the work assignments of selected individuals participating in the study to ascertain if these individuals had the time to accomplish the tasks specified in the study plan or report,
- obtain copies of all documentation concerning control procedures or forming integral parts of the study, including:
 - (i) the study plan;
 - (ii) SOPs in use at the time the study was done;
 - (iii) logbooks, laboratory notebooks, files, worksheets, print-outs of computer-stored data, etc.; checking of calculations, where appropriate;
 - (iv) the final report.

In studies in which animals (i.e., rodents and other mammals) are used, the inspectors should follow a certain percentage of individual animals from their arrival at the test facility to autopsy. They should pay particular attention to the records relating to:

- animal body weight, food/water intake, dose formulation and administration, etc.,
- clinical observations and autopsy findings,
- clinical chemistry,
- pathology.

Completion of inspection or study audit

When a test facility inspection or study audit has been completed, the inspector should be prepared to discuss his findings with representatives of the test facility at a closing conference and should prepare a written report, i.e., the inspection report.

A test facility inspection of any large facility is likely to reveal a number of minor deviations from GLP principles but, normally, these will not be sufficiently serious to affect the validity of studies emanating from that test facility. In such cases, it is reasonable for an inspector to report that the facility is operating in compliance with GLP principles according to the criteria established by the (national) GLP Monitoring Authority. Nevertheless, details of the inadequacies or faults detected should be provided to the test facility and assurances sought from its senior management that action will be taken to remedy them.

The inspector may need to revisit the facility after a period of time to verify that necessary action has been taken.

If a serious deviation from the GLP principles is identified during a test facility inspection or study audit which, in the opinion of the inspector, may have affected the validity of that study, or of other studies performed at the facility, the inspector should report back to the (national) GLP Monitoring Authority. The action taken by that Authority and/or the Regulatory Authority, as appropriate, will depend on the nature and extent of the non-compliance and the legal and/or administrative provisions within the GLP compliance programme.

Where a study audit has been conducted at the request of a Regulatory Authority, a full report of the findings should be prepared and sent via the relevant (national) GLP Monitoring Authority.

II

(Acts whose publication is not obligatory)

COUNCIL

DECISION No 1/1999 OF THE ASSOCIATION COUNCIL

between the European Communities and their Member States, of the one part,
and the Republic of Poland, of the other part

of 25 January 1999

amending Protocol 4 to the Europe Agreement establishing an association
between the European Communities and their Member States, of the one part,
and the Republic of Poland, of the other part

(1999/216/EC)

THE ASSOCIATION COUNCIL,

Having regard to the Europe Agreement establishing an association between the European Communities and their Member States, of the one part, and the Republic of Poland, of the other part⁽¹⁾, signed in Brussels on 16 December 1991, and in particular Article 38 of Protocol 4⁽²⁾ thereof,

Whereas the definition of the term 'originating products' in Protocol 4 needs to be amended to ensure the proper operation of the extended system of cumulation which permits the use of materials originating in the European Community, Poland, Hungary, the Czech Republic, the Slovak Republic, Bulgaria, Romania, Latvia, Lithuania, Estonia, Slovenia, the European Economic Area (hereinafter referred to as the EEA), Iceland, Norway and Switzerland;

Whereas it would seem advisable to maintain in operation until 31 December 2000 the system of flat rate charges provided for in Article 15 of Protocol 4 in connection with the prohibition of drawback and exemption from customs duty;

Whereas, in view of the particular arrangements on industrial products obtaining between the Community and

Turkey, it would also be appropriate to extend the cumulation system to such products originating in Turkey;

Whereas to facilitate trade and simplify administrative tasks it is desirable to amend the wording of Articles 3, 4 and 12 of Protocol 4;

Whereas, to take account of changes in processing techniques and shortages of certain raw materials, some corrections must be made to the list of working and processing requirements which non-originating materials have to fulfil to qualify for originating status,

HAS DECIDED AS FOLLOWS:

Article 1

Protocol 4 concerning the definition of the concept of 'originating products' and methods of administrative cooperation is hereby amended as follows:

1. Article 1(i) shall be replaced by:

'(i) "added value" shall be taken to be the ex-works price minus the customs value of each of the materials incorporated which originate in the other

⁽¹⁾ OJ L 348, 31. 12. 1993, p. 2.

⁽²⁾ Protocol 4 was replaced by Association Council Decision No 1/97 (OJ L 221, 11. 8. 1997, p. 1).

countries referred to in Articles 3 and 4 or, where the customs value is not known or cannot be ascertained, the first price verifiably paid for the products in the Community or Poland.'

2. Articles 3 and 4 shall be replaced by the following:

Article 3

Cumulation in the European Community

1. Without prejudice to the provisions of Article 2(1), products shall be considered as originating in the Community if such products are obtained there, incorporating materials originating in the Community, Poland, Bulgaria, Hungary, the Czech Republic, the Slovak Republic, Romania, Lithuania, Latvia, Estonia, Slovenia, Iceland, Norway, Switzerland (including Liechtenstein^(*)) or Turkey^(**) in accordance with the provisions of the Protocol on rules of origin annexed to the Agreements between the Community and each of these countries, provided that the working or processing carried out in the Community goes beyond that referred to in Article 7 of this Protocol. It shall not be necessary that such materials have undergone sufficient working or processing.

2. Where the working or processing carried out in the Community does not go beyond the operations referred to in Article 7, the product obtained shall be considered as originating in the Community only where the value added there is greater than the value of the materials used originating in any one of the other countries referred to in paragraph 1. If this is not so, the product obtained shall be considered as originating in the country which accounts for the highest value of originating materials used in the manufacture in the Community.

3. Products, originating in one of the countries referred to in paragraph 1, which do not undergo any working or processing in the Community, retain their origin if exported into one of these countries.

4. The cumulation provided for in this Article may only be applied to materials and products which have acquired originating status by an application of rules of origin identical to those given in this Protocol.

The Community shall provide Poland, through the Commission of the European Communities, with details of the Agreements and their corresponding rules of origin, which are applied with the other countries referred to in paragraph 1. The Commission of the European Communities shall publish in the *Official Journal of the European Communities* (C series) the date on which the cumulation, provided for in this Article may be applied by those countries listed in paragraph 1 which have fulfilled the necessary requirements.

Article 4

Cumulation in Poland

1. Without prejudice to the provision of Article 2(2), products shall be considered as originating in Poland if such products are obtained there, incorporating materials originating in the Community, Poland, Bulgaria, Hungary, the Czech Republic, the Slovak Republic, Romania, Lithuania, Latvia, Estonia, Slovenia, Iceland, Norway, Switzerland (including Liechtenstein^(*)) or Turkey^(**) in accordance with the provisions of the Protocol on rules of origin annexed to the Agreements between Poland and each of these countries, provided that the working or processing carried out in Poland goes beyond that referred to in Article 7 of this Protocol. It shall not be necessary that such materials have undergone sufficient working or processing.

2. Where the working or processing carried out in Poland does not go beyond the operations referred to in Article 7, the product obtained shall be considered as originating in Poland only where the value added there is greater than the value of the materials used originating in any one of the other countries referred to in paragraph 1. If this is not so, the product obtained shall be considered as originating in the country which accounts for the highest value of originating materials used in the manufacture in Poland.

3. Products, originating in one of the countries referred to in paragraph 1, which do not undergo any working or processing in Poland, retain their origin if exported into one of these countries.

4. The cumulation provided for in this Article may only be applied to materials and products which have acquired originating status by an application of rules of origin identical to those given in this Protocol.

Poland shall provide the Community, through the Commission of the European Communities, with details of the Agreements and their corresponding rules of origin, which are applied with the other countries referred to in paragraph 1. The Commission of the European Communities shall publish in the *Official Journal of the European Communities* (C series) the date on which the cumulation, provided for in this Article, may be applied by those countries listed in paragraph 1 which have fulfilled the necessary requirements.

(*) The Principality of Liechtenstein has a customs union with Switzerland, and is a Contracting Party to the Agreement on the European Economic Area.

(**) Cumulation as provided for in this Article does not apply to materials originating in Turkey which are mentioned in the list at Annex V to this Protocol.'

3. Article 12 shall be replaced by the following:

Article 12

Principle of territoriality

1. Except as provided for in Article 2(1)(c), Articles 3 and 4 and paragraph 3 of this Article, the conditions for acquiring originating status set out in Title II must continue to be fulfilled at all times in the Community or Poland.

2. Except as provided for in Articles 3 and 4, where originating goods exported from the Community or Poland to another country return, they must be considered as non-originating, unless it can be demonstrated to the satisfaction of the customs authorities that:

(a) the returning goods are the same as those that were exported

and

(b) they have not undergone any operation beyond that necessary to preserve them in good condition while in that country or while being exported.

3. The acquisition of originating status in accordance with the conditions set out in Title II shall not be affected by working or processing done outside the Community or Poland on materials exported from the Community or Poland and subsequently reimported there, provided:

(a) the said materials are wholly obtained in the Community or Poland or have undergone working or processing beyond the insufficient operations listed in Article 7 prior to being exported

and

(b) it can be demonstrated to the satisfaction of the customs authorities that:

(i) the reimported goods have been obtained by working or processing the exported materials

and

(ii) the total added value acquired outside the Community or Poland by applying the provisions of this Article does not exceed 10 % of the ex-works price of the end product for which originating status is claimed.

4. For the purposes of paragraph 3, the conditions for acquiring originating status set out in Title II shall not apply to working or processing done outside the Community or Poland. But where, in the list in Annex II, a rule setting a maximum value for all the non-originating materials incorporated is applied in determining the originating status of the end product, the

total value of the non-originating materials incorporated in the territory of the party concerned, taken together with the total added value acquired outside the Community or Poland by applying the provisions of this Article, shall not exceed the stated percentage.

5. For the purposes of applying the provisions of paragraphs 3 and 4, "total added value" shall be taken to mean all costs arising outside the Community or Poland, including the value of the materials incorporated there.

6. The provisions of paragraphs 3 and 4 shall not apply to products which do not fulfil the conditions set out in the list in Annex II or which can be considered sufficiently worked or processed only if the general values fixed in Article 6(2) are applied.

7. The provisions of paragraphs 3 and 4 shall not apply to products coming under chapters 50 to 63 of the Harmonised System.

8. Any working or processing of the kind covered by the provisions of this Article and done outside the Community or Poland shall be done under the outward processing arrangements, or similar arrangements.'

4. In Articles 13, 14, 15, 17, 21, 27, 30 and 32, the phrase 'referred to in Article 4' shall be replaced by 'referred to in Articles 3 and 4'.

5. In the last paragraph of Article 15(6), the date '31 December 1998' shall be replaced by '31 December 2000'.

6. In Article 26(1), the terms 'C2/CP3' shall be replaced by 'CN22/CN23'.

7. In Annex I, note 5.2:

(a) between the indents:

'— artificial man-made filaments'

and

'— synthetic man-made staple fibres of polypropylene'

the following shall be inserted:

'— current conducting filaments';

(b) the fifth example ('A carpet with tufts ... are met.') shall be deleted.

8. Annex II shall be amended as follows:

(a) the following shall be inserted between the entries for HS heading Nos 2202 and 2208:

'HS heading No	Description of product	Working or processing carried out on non-originating materials that confers originating status	
(1)	(2)	(3)	or (4)
2207	Undenatured ethyl alcohol of an alcoholic strength by volume of 80 % vol or higher; ethyl alcohol and other spirits, denatured, of any strength	Manufacture: — using materials not classified in heading Nos 2207 or 2208'	

(b) the entry for chapter 57 shall be replaced by:

'Chapter 57	Carpets and other textile floor coverings: — Of needleloom felt — Of other felt — Other	Manufacture from (1): — Natural fibres or — Chemical materials or textile pulp However: — polypropylene filament of heading No 5402, — polypropylene fibres of heading Nos 5503 or 5506 — polypropylene filament tow of heading No 5501, of which the denomination in all cases of a single filament or fibre is less than 9 decitex, may be used provided their value does not exceed 40 % of the ex-works price of the product — jute fabric may be used as backing Manufacture from (1): — natural fibres not carded or combed or otherwise processed for spinning or — chemical materials or textile pulp Manufacture from (1): — coir or jute yarn (6) — synthetic or artificial filament yarn — natural fibres, or — man-made staple fibres not carded or combed or otherwise processed for spinning — jute fabric may be used as backing	
-------------	---	--	--

(1) For special conditions relating to products made of a mixture of textile materials, see Introductory Note 5.

(6) The use of jute yarn is authorised from 1 July 2000.

(c) the entry for HS heading No 7006 shall be replaced by:

7006	Glass of heading Nos 7003, 7004 or 7005, bent, edgeworked, engraved, drilled, enamelled or otherwise worked, but not framed or fitted with other materials: — glass plate substrate coated with dielectric thin film, semiconductor grade, in accordance with SEMII standards⁽¹⁾ — other	Manufacture from non-coated glass plate substrate of heading No 7006 Manufacture from materials of heading No 7001	
------	--	--	--

⁽¹⁾ SEMII — Semiconductor Equipment and Materials Institute Incorporated.

(d) the rule for HS heading No 7601 shall be replaced by:

7601	Unwrought aluminium	Manufacture in which: — all the materials used are classified within a heading other than that of the product and — the value of all the materials used does not exceed 50 % of the ex-works price of the product or manufacture by thermal or electrolytic treatment from unalloyed aluminium or waste and scrap of aluminium'	
------	---------------------	--	--

9. the following Annex shall be added:

ANNEX V

List of products originating in Turkey to which the provisions of Articles 3 and 4 do not apply, listed in the order of HS chapters and headings

Chapter 1	Buttermilk, curdled milk and cream, yoghurt, kephir and other fermented or acidified milk and cream, whether or not concentrated or containing added sugar or other sweetening matter
Chapter 2	
Chapter 3	
0401 to 0402	
ex 0403	
0404 to 0410	
0504	
0511	
Chapter 6	
0701 to 0709	

ex 0710	Vegetables, except sweetcorn of heading No 0710 40 00 (uncooked or cooked by steaming or boiling in water), frozen
ex 0711	Vegetables, except sweetcorn of heading No 0711 90 30, provisionally preserved (for example, by sulphur dioxide gas, in brine, in sulphur water or in other preservative solutions), but unsuitable in that state for immediate consumption
0712 to 0714	
Chapter 8	
ex Chapter 9	Coffee, tea and spices, excluding maté of heading No 0903
Chapter 10	
Chapter 11	
Chapter 12	
ex 1302	Pectic substances, pectinates and pectates
1501 to 1514	
ex 1515	Other fixed vegetable fats and oils (excluding jojoba oil and its fractions) and their fractions, whether or not refined, but not chemically modified
ex 1516	Animal or vegetable fats and oils and their fractions, partly or wholly hydrogenated, inter-esterified, re-esterified or elaidinised, whether or not refined, but not further prepared, excluding hydrogenated castor oil known as "opalwax"
ex 1517 and ex 1518	Margarines; imitation lard and other prepared edible fats
ex 1522	Residues resulting from the treatment of fatty substances or animal or vegetable waxes, excluding degreas
Chapter 16	
1701	
ex 1702	Other sugars, including chemically pure lactose, maltose, glucose and fructose, in solid form; sugar syrups not containing added flavouring or colouring matter; artificial honey, whether or not mixed with natural honey; caramel excluding that of heading Nos 1702 11 00, 1702 30 51, 1702 30 59, 1702 50 00 and 1702 90 10
1703	
1801 and 1802	
ex 1902	Pasta, stuffed, containing more than 20 % by weight of fish, crustaceans, molluscs or other aquatic invertebrates, sausages and the like or meat and meat offal of any kind, including fats of all kinds
ex 2001	Cucumbers and gherkins, onions, mango chutney, fruit of the genus <i>Capsicum</i> other than sweet peppers or pimentos, mushrooms and olives, prepared or preserved by vinegar or acetic acid
2002 and 2003	
ex 2004	Other vegetables prepared or preserved otherwise than by vinegar or acetic acid, frozen, other than products of heading No 2006, excluding potatoes in the form of flour, meal or flakes, and sweetcorn
ex 2005	Other vegetables prepared or preserved otherwise than by vinegar or acetic acid, not frozen, other than products of heading No 2006, excluding potatoes in the form of flour, meal or flakes, and sweetcorn
2006 and 2007	
ex 2008	Fruits, nuts and other edible parts of plants, otherwise prepared or preserved, whether or not containing added sugar or other sweetening matter or spirit, not elsewhere specified or included, excluding peanut butter, palm hearts, maize, yams, sweet potatoes and similar edible parts of plants containing 5 % or more by weight of starch, vine leaves, hop shoots and other similar edible parts of plants
2009	

ex 2106	Flavoured and coloured sugar, syrups
2204	
2206	
ex 2207	Undenatured ethyl alcohol of an alcoholic strength by volume of 80 % vol or higher obtained from agricultural produce listed here
ex 2208	Undenatured ethyl alcohol of an alcoholic strength by volume of less than 80 % vol obtained from agricultural produce listed here'
2209	
Chapter 23	
2401	
4501	
5301 and 5302	

Article 2

This Decision shall enter into force on the day of its adoption.

It shall apply as from 1 January 1999.

Done at Brussels, 25 January 1999.

For the Association Council

The President

B. GEREMEK

CORRIGENDA**Corrigendum to Commission Regulation (EC) No 506/1999 of 8 March 1999 amending Regulation (EC) No 340/1999 on the supply of cereals as food aid***(Official Journal of the European Communities L 60 of 9 March 1999)*

On page 10 in the Annex against points 1 and 6:

for: '1. **Action Nos:** 115/98 (A); 124/98 (B)'

'6. **Total quantity (tonnes net):** 9 143',

read: '1. **Action Nos:** 115/98 (A); 124/98 (A2)',

'6. **Total quantity (tonnes net):** 9 130'.
