COUNCIL OF THE EUROPEAN UNION

Brussels, 14 July 1999 (OR. en)

9752/99

Interinstitutional File: 99/0107 (AVC)

LIMITE

AELE 66
ECO 247

Subject: Consolidated versions of the Agreement between the European Community and the Swiss Confederation on Mutual Recognition in relation to Conformity Assessment and the Final Act, including all corrigenda

AGREEMENT
BETWEEN THE EUROPEAN COMMUNITY AND THE SWISS CONFEDERATION ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT

The European Community, hereinafter referred to as "the Community", and

the Swiss Confederation, hereinafter referred to as "Switzerland",

together hereinafter referred to as "the Parties",

Considering the close ties that exist between the Community and Switzerland;

Considering the Free Trade Agreement of 22 July 1972 between Switzerland and the European Economic Community;

Desiring to conclude an Agreement providing for the mutual recognition of the results of conformity assessment procedures required for access to the respective markets of the Parties;

Considering that mutual recognition in relation to conformity assessment will facilitate trade between the Parties and ensure protection for health, safety, the environment and consumers;

Considering the alignment of legislation will facilitate mutual recognition;

Considering their obligations as Contracting Parties to the Agreement establishing the World Trade Organisation and, in particular, to the Agreement on Technical Barriers to Trade, which encourages the negotiation of mutual recognition agreements;

Considering that mutual recognition agreements contribute to harmonisation at international level of the technical regulations, standards and principles governing implementation of conformity assessment procedures;

Considering that the close ties between the Community and Switzerland, of the one part, and Iceland, Liechtenstein and Norway, of the other, makes the conclusion of parallel agreements between those countries and Switzerland appropriate,

Have agreed to conclude the following Agreement:

Article 1

PURPOSE

1. The Community and Switzerland hereby grant mutual acceptance of reports, certificates, authorisations and conformity marks issued by the bodies listed in Annex 1 and of the manufacturer's declarations of conformity certifying conformity to the requirements of the other Party in the areas covered by Article 3.
2. In order to avoid duplication of procedures when Swiss and Community requirements are deemed equivalent, the Community and Switzerland shall mutually accept reports, certificates and authorisations issued by the bodies listed in Annex 1 and manufacturer's declarations of conformity certifying conformity to their respective requirements in the areas covered by Article 3. Reports, certificates, authorisations and manufacturer's declarations of conformity shall in particular indicate conformity with the Community legislation. Conformity marks required by the legislation of one of the Parties must be affixed to products placed on the market of that Party.
3. The Committee provided for in Article 10 shall specify the cases in which paragraph 2 shall apply.

Article 2

DEFINITIONS

1. For the purposes of this Agreement:

"Conformity assessment" shall mean systematic examination to determine the extent to which a product, process or service fulfils specified requirements;

"Conformity assessment body" shall mean a public or private law body whose activities include performance of all or any stage of the conformity assessment process;

"Designating authority" shall mean an authority with the legal power to designate, suspend, withdraw designation or remove suspension of conformity assessment bodies under its jurisdiction.

2. The definitions laid down by ISO/IEC Guide 2 (1996 edition) and in European standard EN 45020 (1993 edition) in relation to "General terms and their definitions concerning standardisation and related activities" may be used to establish the meaning of the general terms relating to conformity assessment contained in this Agreement.

Article 3

SCOPE

1. This Agreement covers the obligatory conformity assessment procedures ensuing from the legislative, regulatory and administrative provisions listed in Annex 1.

2. Annex 1 defines the product sectors covered by this Agreement. The Annex is divided up into sectoral chapters and these are subdivided in principle as follows:

section I	legislative, regulatory and administrative provisions;
section II	conformity assessment bodies;
section III	designating authorities;
section IV	special rules relating to the designation of conformity assessment bodies;
section V	any additional provisions.

3. Annex 2 sets out general rules applicable to the designation of conformity assessment bodies.

Article 4

ORIGIN

1. This Agreement shall cover products originating in the Parties, without prejudice to the special provisions laid down in Annex 1.

2. In the event that such products are also covered by agreements on mutual recognition in relation to conformity assessment between Switzerland and Member States of both EFTA and the EEA, the present Agreement shall also cover products of those EFTA Member States.

3. Origin shall be determined in accordance with the rules governing non-preferential origin applicable in each of the Parties or, where appropriate, in the countries referred to in paragraph 2. In the event of divergent rules, the rules of the Party in which the goods will be placed on the market shall apply.

4. Proof of origin may be provided by presentation of a certificate of origin. This certificate shall not be required in the case of imports covered by an EUR 1 movement certificate or by an invoice declaration issued in accordance with Protocol No 3 to the Free Trade Agreement of 22 July 1972 between Switzerland and the EEC, provided that that document indicates as the country of origin one of the Parties or a Member State of both EFTA and the EEA.

Article 5

CONFORMITY ASSESSMENT BODIES

The Parties hereby recognise that the bodies listed in Annex 1 fulfil the conditions of eligibility to assess conformity.

Article 6

DESIGNATING AUTHORITIES

1. The Parties hereby undertake to ensure that their designating authorities have the necessary power and competence to designate or withdraw designation, suspend or remove suspension of the bodies listed in Annex 1. For the designation of conformity assessment bodies, the authorities shall observe the general principles for designation set out in Annex 2, subject to the provisions of the respective section IV in Annex 1. These authorities shall observe the same principles when withdrawing designation, suspending or removing suspension.

2. The decision to include conformity assessment bodies in or remove them from Annex 1 shall be taken on a proposal from one of the Parties in accordance with the procedure set out in Article 11.

3. In the event of the suspension or withdrawal of the suspension by a designating authority of a conformity assessment body listed in Annex 1 under its jurisdiction, the Party concerned shall immediately notify the other Party and the Chairman of the Committee. Reports, certificates, authorisations and conformity marks issued by the conformity assessment body while under suspension need not be recognised by the Parties.

Article 7

VERIFICATION OF DESIGNATION PROCEDURES

1. The Parties shall exchange information concerning the procedures used to ensure that the conformity assessment bodies under their jurisdiction listed in Annex 1 comply with the general principles of designation outlined in Annex 2 subject to the provisions of the respective section IV in Annex 1.

2. The Parties shall compare methods used to verify conformity of the bodies with the general principles of designation outlined in Annex 2, subject to the provisions of the respective section IV in Annex 1. Existing systems for the accreditation of conformity assessment bodies in the Parties may be used for the purpose of such comparisons.

3. Verification shall be carried out in accordance with the procedure implemented by the Committee under Article 10 below.

Article 8

VERIFICATION OF COMPLIANCE OF CONFORMITY ASSESSMENT BODIES

1. Each Party shall, in exceptional circumstances, have the right to contest the technical competence of the conformity assessment bodies proposed by the other Party or listed in Annex 1 under the jurisdiction of the other Party.

For this purpose, it shall submit in writing an objective and reasoned argument to the other Party and to the Chairman of the Committee.

2. In the event of a disagreement between the Parties, confirmed in the Committee, a verification of the technical competence of the conformity assessment body in question shall be undertaken in accordance with requirements jointly by the Parties, with the participation of the competent authorities concerned.

The result of that verification shall be discussed in the Committee with a view to resolving the issue as soon as possible.

3. Each Party shall ensure that the conformity assessment bodies under its jurisdiction are available for verification of their technical competence as required.

4. Unless otherwise decided by the Committee, the disputed body shall be suspended by the competent designating authority from the time disagreement has been established until agreement has been reached in the Committee.

Article 9

IMPLEMENTATION OF THE AGREEMENT

1. The Parties shall cooperate with a view to ensuring the satisfactory application of the legislative, regulatory and administrative provisions listed in Annex 1.

2. The designating authorities shall ascertain by appropriate means whether the conformity assessment bodies under their jurisdiction listed in Annex 1 are observing the general principles of designation listed in Annex 2, subject to the provisions listed in the respective section IV in Annex 1.

3. The conformity assessment bodies listed in Annex 1 shall cooperate in an appropriate way in the framework of the coordination and comparison work conducted by each of the Parties in respect of the sectors covered by Annex 1 in order to ensure that the conformity assessment procedures provided for in the laws and regulations of the Parties covered by this Agreement are applied in a consistent manner.

Article 10

COMMITTEE

1. A Committee on mutual recognition in relation to conformity assessment (hereinafter referred to as the "Committee"), is hereby established. It shall be composed of representatives of the Parties, and shall be responsible for the management and monitoring of the smooth functioning of this Agreement. To that end, it shall issue recommendations and take decisions in the circumstances provided for in this Agreement. It shall act by mutual agreement.

2. The Committee shall establish its own rules of procedure, which shall contain, *inter alia*, provisions on the convening of meetings, the appointment of the chairman and the chairman's term of office.

3. The Committee shall meet as and when necessary and at least once a year. Either Party may request the convening of a meeting.

4. The Committee may consider any matter related to this Agreement. In particular, it shall be responsible for:

(a) the inclusion of conformity assessment bodies in Annex 1;

(b) the removal of conformity assessment bodies from Annex 1;

(c) drawing up the procedure for carrying out the verifications provided for in Article 7;

(d) drawing up the procedure for carrying out the verifications provided for in Article 8;

(e) examining any legislative, regulatory and administrative provisions notified by one Party to another pursuant to Article 12 in order to assess their repercussions on the Agreement and to amend the appropriate sections in Annex 1.

5. The Committee may, on a proposal from one of the Parties, modify the Annexes to this Agreement.

Article 11

INCLUSION OF CONFORMITY ASSESSMENT BODIES IN ANNEX 1 AND THEIR REMOVAL

The Committee shall decide to include a conformity assessment body in Annex 1 or to remove it from Annex 1 in accordance with the following procedure:

(a) A Party wishing to add to or remove from Annex 1 any conformity assessment body shall notify the Chairman of the Committee and the other Party of the proposal for a decision to that effect, adding the appropriate information to its request.

(b) If the other Party agrees to the proposal or raises no objection within 60 days of the notification of the proposal, the proposed decision shall be adopted by the Committee.

(c) If the other Party raises objections within that 60-day period, the procedure provided for in Article 8(2) shall be applied.

(d) The Chairman of the Committee shall notify the Parties without delay of all decisions of the Committee. They shall take effect from the date fixed in the decision.

(e) If the Committee decides to include a conformity assessment body in Annex 1, the Parties shall recognise the reports, certificates, authorisations and conformity marks issued by that body with effect from the date of entry into force of the decision. If the Committee decides to remove a body from Annex 1, the Parties shall recognise the reports, certificates, authorisations and conformity marks issued by that body until the date on which that decision takes effect.

Article 12

INFORMATION EXCHANGE

1. The Parties shall exchange all relevant information regarding implementation and application of the legislative, regulatory and administrative provisions listed in Annex 1.

2. Each Party shall inform the other Party of the changes it intends to make to the legislative, regulatory and administrative provisions relating to the subject matter of this Agreement and shall notify the other Party of the new provisions at least 60 days before their entry into force.

3. Where the legislation of one of the Parties stipulates that a specific item of information must be made available to the competent authority by a person established in its territory, that authority may also approach the competent authority of the other Party or enter into direct contact with the manufacturer or, if appropriate, the latter's agent in the territory of the other Party, in order to obtain that information.

4. Each Party shall immediately notify the other Party of safeguard measures taken in its territory.

Article 13

CONFIDENTIALITY

Representatives, experts and other agents of the Parties shall be required, even after their duties have ceased, not to disclose information acquired under this Agreement which is of the kind covered by the obligation of professional secrecy. This information may not be used for purposes other than those envisaged by this Agreement.

Article 14

DISPUTE SETTLEMENT

Each Party may refer any dispute relating to the interpretation or application of this Agreement to the Committee. The Committee shall endeavour to settle the dispute, and must be supplied with any information which may facilitate a thorough examination of the situation with a view to finding an acceptable solution. For that purpose, the Committee shall consider every possible means of maintaining the smooth functioning of this Agreement.

Article 15

AGREEMENTS WITH THIRD COUNTRIES

The Parties hereby agree that mutual recognition agreements concluded by either Party with a country that is not party to this Agreement shall in no circumstances entail an obligation upon the other Party in terms of the acceptance of manufacturer's declarations of conformity as well as of reports, certificates, authorisations and marks issued by conformity assessment bodies in that third country, unless there is an explicit agreement between the Parties.

Article 16

ANNEXES

The Annexes to this Agreement shall form an integral part thereof.

Article 17

TERRITORIAL APPLICATION

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

Article 18

REVISION

1. If a Party wishes to have this Agreement revised, it shall inform the Committee. Modifications to this Agreement shall enter into force after the respective internal procedures have been completed.

2. The Committee may modify Annexes 1 and 2 to this Agreement on a proposal from one of the Parties.

Article 19

SUSPENSION

Where a Party establishes that the other Party is failing to comply with the conditions of this Agreement, it may, after consulting the Committee, suspend application of Annex 1 in full or in part.

Article 20

ACQUIRED RIGHTS

The Parties shall continue to recognise reports, certificates, authorisations and conformity marks and manufacturers' declarations of conformity issued in accordance with, and prior to the expiry of, this Agreement, provided that the request for conformity evaluation to be started was made before the notice of non-renewal or denunciation was given.

Article 21

ENTRY INTO FORCE AND DURATION

1. This Agreement shall be ratified or approved by the Parties in accordance with their own procedures. It shall enter into force on the first day of the second month following the last notification of deposit of the instruments for ratification or approval of all the following seven agreements:

Agreement on the mutual recognition in relation to conformity assessment

Agreement on the free movement of persons

Agreement on air transport

Agreement on the carriage of goods and passengers by rail and road

Agreement on trade in agricultural products

Agreement on certain aspects of public procurement

Agreement on scientific and technical cooperation.

2. This Agreement shall be concluded for an initial period of seven years. It shall be tacitly extended, unless the Community or Switzerland notifies the other Party to the contrary before the expiry of that period. Where such notification is given, the provisions of paragraph 4 shall apply.

3. The Community or Switzerland may denounce this Agreement by notifying the other Party. Where such notification is given, the provisions of paragraph 4 shall apply.

4. The seven agreements referred to in paragraph 1 shall cease to apply six months after receipt of the non-renewal notice described in paragraph 2 or the denunciation notice described in paragraph 3.

Done at Luxembourg on the twenty-first day of June in the year one thousand nine hundred and ninety-nine.

This Agreement is drawn up in duplicate in the Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish and Swedish languages, each text being equally authentic.

Annex 1

Product sectors

This Annex is divided up into the following Chapters by sector:

Chapter 1	Machinery
Chapter 2	Personal protective equipment
Chapter 3	Toys
Chapter 4	Medical devices
Chapter 5	Gas appliances and boilers
Chapter 6	Pressure vessels
Chapter 7	Telecommunications terminal equipment
Chapter 8	Equipment and protective systems intended for use in potentially explosive atmospheres
Chapter 9	Electrical equipment and electromagnetic compatibility
Chapter 10	Construction plant and equipment
Chapter 11	Measuring instruments and prepackages
Chapter 12	Motor vehicles
Chapter 13	Agricultural and forestry tractors
Chapter 14	Good laboratory practice (GLP)
Chapter 15	Medicinal products GMP Inspection and Batch Certification

CHAPTER

MACHINERY

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

Provisions covered by Article 1 paragraph 2

European Community	Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery (OJ L 207, 23.7.1998, p. 1)
Switzerland	*Loi fédérale du 19 mars 1976 sur la sécurité d'installations et d'appareils techniques* (RO 1977 2370), as last amended on 18 June 1993 (RO 1995 2766) *Ordonnance du 12 juin 1995 sur la sécurité d'installations et d'appareils techniques* (RO 1995 2770), as last amended on 17 June 1996 (RO 1996 1867) *Ordonnance du 12 juin 1995 sur les procédures d'évaluation de la conformité des installations et appareils techniques* (RO 1995 2783)

SECTION II

CONFORMITY ASSESSMENT BODIES

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

DESIGNATING AUTHORITIES

European Community:

- Austria: Bundesministerium für wirtschaftliche Angelegenheiten
- Belgium: Ministère des Affaires économiques
Ministerie van Economische Zaken
- Denmark: Direktoratet for Arbejdstilsyner

- Finland: Sosiaali-ja terveysministeriö/Social-och hälsovårdsministeriet

- France: Ministère de l'emploi et de la solidarité
  Direction des relations du travail Bureau CT 5
  Ministère de l'économie, des finances et de l' industries
  Secrétariat d'Etat à l'industrie
  Direction générale des stratégies industrielles
  Sous direction de la qualité et de la normalisation

- Germany: Bundesministerium für Arbeit und Sozialordnung

- Greece: Ministry of Development

- Ireland: Department of Enterprise and Employment

- Italy: Ministero dell'Industria, del Commercio e dell'Artiginiato

- Luxembourg: Ministère des Transports

- Netherlands: Staat der Nederlanden

- Portugal: Under the authority of the Government of Portugal:
  Instituto Português da Qualidade

- Spain: Ministerio de Industria y Energía

- Sweden: Under the authority of the Government of Sweden:
  Styrelsen för ackreditering och teknisk kontroll (SWEDAC)

- United Kingdom: Department of Trade and Industry

Switzerland: Federal Office for Economic Development and Employment

SECTION IV

SPECIAL RULES RELATING TO THE DESIGNATION OF CONFORMITY ASSESSMENT BODIES

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 and those in Annex VII to Directive 98/37/EC.

SECTION V

SUPPLEMENTARY PROVISIONS

1. Second-hand machinery

The legislative, regulatory and administrative provisions listed in section I shall not apply to second-hand machinery.

The principle contained in Article 1paragraph 2 of this Agreement shall apply, however, to machinery legally placed on the market and/or put into service in one of the Parties and exported as second-hand machinery to the market of the other Party.

The other provisions relating to second-hand machinery, e.g. those relating to safety in the place of work in force in the importing state, shall remain applicable.

CHAPTER 2

PERSONAL PROTECTIVE EQUIPMENT

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

Provisions covered by Article 1 paragraph 2

European Community	Council Directive of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (89/686/EEC), as last amended by Directive 96/58/EC of the European Parliament and of the Council of 3 September 1996 (OJ L 236, 18.9.1996, p. 44)

Switzerland	*Loi fédérale du 19 mars 1976 sur la sécurité d'installations et d'appareils techniques* (RO 1977 2370), as last amended on 18 June 1993 (RO 1995 2766)
	Ordonnance du 12 juin 1995 sur la sécurité d'installations et d'appareils techniques (RO 1995 2770), as last amended on 17 June 1996 (RO 1996 1867)
	Ordonnance du 12 juin 1995 sur les procédures d'évaluation de la conformité des installations et appareils techniques (RO 1995 2783)

SECTION II

CONFORMITY ASSESSMENT BODIES

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

DESIGNATING AUTHORITIES

European Community:

Switzerland: Federal Office for Economic Development and Employment

SECTION IV

SPECIAL RULES RELATING TO THE DESIGNATION OF CONFORMITY ASSESSMENT BODIES

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 and those in Annex V to Directive 89/686/EEC.

CHAPTER 3
TOYS

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

Provisions covered by Article 1 paragraph 1

European Community	Council Directive of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys (88/378/EEC) (OJ L 187, 16.7.1988, p. 1), as subsequently amended
Switzerland	*Loi fédérale du 9 octobre 1992 sur les denrées alimentaires et les objets usuels* (RS 817.0), as subsequently amended
	Ordonnance du 1er mars 1995 sur les objets usuels (RS 817.04), as subsequently amended
	Ordonnance du 26 mai 1995 sur la sécurité des jouets (RS 817.044.1), as subsequently amended

SECTION II

CONFORMITY ASSESSMENT BODIES

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

DESIGNATING AUTHORITIES

European Community:

Switzerland: **Swiss** Federal Office of Public Health

SECTION IV

SPECIAL RULES RELATING TO THE DESIGNATION OF CONFORMITY ASSESSMENT BODIES

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 and those in Annex III to Directive 88/378/EEC.

SECTION V

SUPPLEMENTARY PROVISIONS

1. Information concerning the certificate and the technical file

In accordance with Article 10(4) of Directive 88/378/EEC, the authorities listed in section III may obtain on request a copy of the certificate and, on reasoned request, a copy of the technical file and the reports on the examinations and tests carried out.

2. Notification of grounds for refusal by approved bodies

In accordance with Article 10(5) of Directive 88/378/EEC, the Swiss bodies shall inform the Swiss Federal Office of Public Health when refusing to issue an EC type-examination certificate. The Federal Office shall likewise notify the Commission of the European Communities thereof.

CHAPTER 4

MEDICAL DEVICES

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

Provisions covered by Article 1 paragraph 2

European Community	Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC), as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1)
	Council Directive of 14 June 1993 concerning medical devices (93/42/EEC), as last amended by Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 (OJ L 331, 7.12.1998, p.1.)
Switzerland	*Loi fédérale du 19 mars 1976 sur la sécurité d'installations et d'appareils techniques* (RO 1977 2370), as last amended on 18 June 1993 (RO 1995 2766)
	Loi fédérale du 24 juin 1902 concernant les installations électriques à faible et fort courant (RO 19 252 et RS 4 798), as last amended on 3 February 1993 (RO 1993 901)
	Loi fédérale du 9 juin 1977 sur la métrologie (RO 1977 2394), as last amended on 18 June 1993 (RO 1993 3149)

Loi fédérale du 22 mars 1991 sur la radioprotection
(RO 1994 1933)

Ordonnance du 24 janvier 1996 sur les dispositifs médicaux
(RO 1996 987), as last amended on 17 June 1996
(RO 1996 1868)

SECTION II

CONFORMITY ASSESSMENT BODIES

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

DESIGNATING AUTHORITIES

European Community

- Austria: Bundesministerium für Arbeit, Gesundheit und Soziales
- Belgium: Ministère de la Santé publique, de l'Environnement et de l'Intégration sociale. Inspection Pharmaceutique
  Ministerie van Volksgenzondheid, Leefmilieu en Sociale Integratie. Farmaceutische Inspectie
- Denmark: Sundhedsministeriet
- Finland: Sosiaali-ja terveysministeriö/Social-och hälsovårdsministeriet
- France: Ministère de l'emploi et de la solidarité
  Ministère de l'économie, des finances et de l'industrie
- Germany: Bundesministerium für Gesundheit
- Greece: Ministry of Health
- Ireland: Department of Health
- Italy: Ministero Sanità

- Luxembourg: Ministère de la Santé
- Netherlands: Ministerie van Welzijn, Volksgezondheid en Cultuur
- Portugal: Ministerio da Saude
- Spain: Ministerio Sanidad y Consumo
- Sweden: Under the authority of the Government of Sweden:
  Styrelsen för ackreditering och teknisk kontroll (SWEDAC)
- U.K.: Department of Health

Switzerland Swiss Federal Office of Public Health

SECTION IV

SPECIAL RULES RELATING TO THE DESIGNATION OF CONFORMITY ASSESSMENT BODIES LISTED IN SECTION II

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and those in Annex XI to Directive 93/42/EEC, in respect of the bodies designated under that Directive, and in Annex VIII to Directive 90/385/EEC, in respect of the bodies designated thereunder.

SECTION V

SUPPLEMENTARY PROVISIONS

1. Registration of the person responsible for placing devices on the market

Any manufacturer who places on the market of one of the Parties the medical devices referred to in Article 14 of Directive 93/42/EEC shall inform the competent authorities of the Party in which he has his registered place of business of the particulars referred to in that Article. The Parties shall mutually recognise that registration. The manufacturer shall not be obliged to designate a person responsible for placing devices on the market established in the territory of the other Party.

2. Labelling of medical devices

Manufacturers of both Parties shall indicate their name or trade name and address on the label of medical devices as specified in Annex 1, point 13.3(a) to Directive 93/42/EEC. They shall not be obliged to indicate the name and address of the person responsible for placing the device on the market, of the representative or of the importer established within the territory of the other Party on the label, outer packaging or instructions for use.

3. Information exchanges

In accordance with Article 9 of the Agreement, the Parties shall in particular exchange the information referred to in Article 8 of Directive 90/385/EEC and in Article 10 of Directive 93/42/EEC.

CHAPTER 5

GAS APPLIANCES AND BOILERS

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

Provisions covered by Article 1 paragraph 1

European Community	Council Directive of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels (92/42/EEC) (OJ L 167, 22.06.1992, p. 17), as subsequently amended
Switzerland	*Ordonnance du 16 décembre 1985 sur la protection de l'air* (Annexes 3 and 4) (RS 814.318.142.1), as subsequently amended

Provisions covered by Article 1 paragraph 2

European Community	Council Directive of 29 June 1990 on the approximation of the laws of the Member States relating to appliances burning gaseous fuels (90/396/EEC), as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1)
Switzerland	*Loi fédérale du 19 mars 1976 sur la sécurité d'installations et d'appareils techniques* (RO 1977 2370), as last amended on 18 June 1993 (RO 1995 2766) *Ordonnance du 12 juin 1995 sur la sécurité d'installations et d'appareils techniques* (RO 1995 2770), as last amended on 17 June 1996 (RO 1996 1867) *Ordonnance du 12 juin 1995 sur les procédures d'évaluation de la conformité des installations et appareils techniques* (RO 1995 2783)

SECTION II

CONFORMITY ASSESSMENT BODIES

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

DESIGNATING AUTHORITIES

Provisions covered by Article 1 paragraph 1

European Community:

Switzerland: Federal Office of Environment, Forests and Landscape

Provisions covered by Article 1 paragraph 2

European Community:

Switzerland: Federal Office for Economic Development and Employment

SECTION IV

SPECIAL RULES RELATING TO THE DESIGNATION OF CONFORMITY ASSESSMENT BODIES

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and those in Annex V to Directive 92/42/EEC, in respect of the bodies designated under that Directive, and in Annex V to Directive 90/396/EEC, in respect of the bodies designated thereunder.

CHAPTER 6

PRESSURE VESSELS

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

Provisions covered by Article 1 paragraph 1

European Community Council Directive of 17 September 1984 on the approximation of the laws of the Member States relating to seamless, steel gas cylinders (84/525/EEC) (OJ L 300, 19.11.1984, p.1), as subsequently amended

Council Directive of 17 September 1984 on the approximation of the laws of the Member States relating to seamless, unalloyed aluminium and aluminium alloy gas cylinders (84/526/EEC) (OJ L 300, 19.11.1984, p.20), as subsequently amended

Council Directive of 17 September 1984 on the approximation of the laws of the Member States relating to welded unalloyed steel gas cylinders (84/527/EEC) (OJ L 300, 19.11.1984, p.48), as subsequently amended

Council Directive of 25 June 1987 on the approximation of the laws of the Member States relating to simple pressure vessels (87/404/EEC) (OJ L 220, 8.8.1987, p.48), as subsequently amended

Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment (OJ L 181, 9.7.1997, p. 1), as subsequently amended

Switzerland Directives 84/525/EEC, 84/526/EEC and 84/527/EEC: no related legislation.

Directive 87/404/EEC:

Loi fédérale du 20 mars 1981 sur l'assurance-accidents (RS 832.20), as subsequently amended

Ordonnance du 19 mars 1938 concernant l'installation et l'exploitation des récipients sous pression (RS 832.312.12), as subsequently amended

SECTION II

CONFORMITY ASSESSMENT BODIES

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

DESIGNATING AUTHORITIES

European Community:

- Austria: Bundesministerium für Wirtschaftliche Angelegenheiten

- Belgium: Ministère des Affaires Economiques
  Ministerie van Economische Zaken
- Denmark: Direktoratet for Arbejdstilsynet
- Finland: Kauppa-ja teollisuusministeriö/Handels- och industriministeriet
- France: Ministère de l'économie, des finances et de l'industrie
  Secrétariat d'Etat à l'industrie
  Direction de l'action régionale de la petite et moyenne industrie
  Sous-direction de la sécurité industrielle

  Ministère de l'économie, des finances et de l'industrie
  Secrétariat d'Etat à l'industrie
  Direction Générale des stratégies industrielles
  Sous-direction de la qualité et de la normalisation
- Germany: Bundesministerium für Arbeit und Sozialordnung
- Greece: Ministry of Development
- Ireland: Department of Enterprise and Employment
- Italy: Ministero dell'Industria, del Commercio e dell'Artigianato
- Luxembourg: Ministère des Transports
- Netherlands: Staat der Nederlanden

- Portugal: Under the authority of the Government of Portugal:
  Instituto Português da Qualidade

- Spain: Ministerio de Industria y Energía

- Sweden: Under the authority of the Government of Sweden:
  Styrelsen för ackreditering och teknisk kontroll (SWEDAC)

- UK: Department of Trade and Industry

Switzerland: Federal Office for Economic Development and Employment

SECTION IV

SPECIAL RULES RELATING TO THE DESIGNATION OF CONFORMITY ASSESSMENT BODIES

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 and those in Annex III to Directive 87/404/EEC.

SECTION V

SUPPLEMENTARY PROVISIONS

Recognition of certificates by Switzerland

Where the provisions of Swiss legislation listed in section I lay down a conformity assessment procedure, Switzerland shall recognise certificates issued by a designated Community body listed in section II which certifies that the product conforms to standard EN 286.

CHAPTER 7

TELECOMMUNICATIONS TERMINAL EQUIPMENT

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

Provisions covered by Article 1 paragraph 2

European Community	Directive 98/13/EC of the European Parliament and of the Council of 12 February 1998 relating to telecommunications terminal equipment and satellite earth station equipment, including the mutual recognition of their conformity (OJ L 074, 12.3.1998, p. 1) Commission Decision of 9 July 1997 on a common technical regulation for terminal equipment to be connected to public circuit switched data networks and ONP leased circuits using a CCITT Recommendation X.21 type interface (97/544/EC) (OJ L 223,13.8.1997, p. 18) Commission Decision of 9 July 1997 on a common technical regulation for the general attachment requirements for Data Terminal Equipment (DTE) to connect to Packet Switched Public Data Networks (PSPDNs) offering CCITT Recommendation X.25 interfaces (97/545/EC) (OJ L 223, 13.8.1997, p. 21) Commission Decision of 9 July 1997 on a common technical regulation for the general terminal attachment requirements for digital enhanced cordless telecommunications (DECT) (edition 2) (97/523/EC) (OJ L 215, 7.8.1997, p. 48)

Commission Decision of 9 July 1997 on a common technical regulation for the telephony application requirements for digital enhanced cordless telecommunications (DECT) (edition 2) (97/524/EC) (OJ L 215, 07.08.1997, p. 50)
Commission Decision of 28 November 1995 on a common technical regulation for attachment requirements for terminal equipment for digital European cordless telecommunications (DECT), public access profile (PAP) applications (95/525/EC) (OJ L 300, 13.12.1995, p. 35)
Commission Decision of 9 July 1997 on a common technical regulation for the attachment requirements for the terminal equipment interface for connection to 2 048 kbit/s digital unstructured ONP leased lines (Amendment 1) (97/520/EC) (OJ L 215, 07.08.1997, p. 41)
Commission Decision of 9 July 1997 on a common technical regulation for the attachment requirements for the terminal equipment interface for connection to 2 048 kbit/s digital structured ONP leased lines (97/521/EC) (OJ L 215, 07.08.1997, p. 44)
Commission Decision of 9 July 1997 on a common technical regulation for the attachment requirements for the terminal equipment interface for connection to 64 kbit/s digital unrestricted ONP leased lines (Amendment 1) (97/522/EC) (OJ L 215, 07.08.1997, p. 46)

Commission Decision of 9 July 1997 on a common technical regulation for the general attachment requirements for terminal equipment to interface to Open Network Provision (ONP) two-wire analogue leased lines (97/486/EC) (OJ L 208, 02.08.1997, p. 44)
Commission Decision of 9 July 1997 on a common technical regulation for the general attachment requirements for terminal equipment to interface to Open Network Provision (ONP) four-wire analogue leased lines (97/487/EC) (OJ L 208, 02.08.1997, p. 47)
Commission Decision of 28 November 1995 on a common technical regulation for Integrated Services Digital Network (ISDN)+ Telephony 3.1 kHz teleservice, attachment requirements for handset terminals (95/526/EC) (OJ L 300, 13.12.1995, p.38)
Commission Decision of 9 July 1997 on a common technical regulation for the attachment requirements for terminal equipment for digital enhanced cordless telecommunications (DECT) generic access profile (GAP) applications (97/525/EC) (OJ L 215, 07.08.1997, p. 52)
Commission Decision of 19 September 1997 on a common technical regulation for the attachment requirements for the terminal equipment interface for connection to 34 Mbit/s digital unstructured and structured leased lines (97/639/EC) (OJ L 271, 03.10.1997, p. 16)

Commission Decision of 31 October 1997 on a common technical regulation for the attachment requirements for the terminal equipment interface for connection to 140 Mbit/s digital unstructured and structured leased lines (97/751/EC) (OJ L 305, 08.11.1997, p. 66)

Commission Decision of 17 June 1998 on a common technical Regulation for the pan-European integrated services digital (ISDN) basic access (Amendment 1) (notified under document number C(1998) 1607) (98/515/EC) (OJ L 232,19.08.98, p.7)

Commission Decision of 17 June 1998 on a common technical Regulation for the pan-European integrated services digital network (ISDN) primary rate access (Amendment 1) (notified under document number C(1998) 1613) (98/520/EC) (OJ L 232, 19.08.98, p.19)

Commission Decision of 17 June 1998 on a common technical Regulation for public land-based enhanced radio message system (ERMES) receiver requirements (second edition) (notified under document number C(1998) 1615) (98/522/EC) (OJ L 232, 19.08.98, p.25)

Council Decision of 20 July 1998 on a common technical Regulation for the attachment requirements for connection to the analogue public switched telephone networks (PSTNs) of terminal equipment (excluding terminal equipment supporting the voice telephony justified case service) in which network addressing, if provided, is by means of dual tone multi-frequency (DTMF) signalling (98/482/EC) (OJ L 216, 04.08.98, p.8)

Commission Decision of 4 September 1998 on a common technical regulation for telephony application requirements for public pan-European cellular digital land-based mobile communications, phase II (edition 2) (notified under document number C(1998) 2561) (98/542/EC) (OJ L 254, 16.09.98, p.28)

Commission Decision of 3 September 1998 on a common technical Regulation for the terrestrial flight telecommunications system (TFTS) (notified under document number C(1998)2378) (98/535/EC) (OJ L 251, 11.09.98, p.36)

Commission Decision of 17 June 1998 on a common technical Regulation for low data rate land mobile satellite earth stations (LMES) operating in the 11/12/14 GHz frequency bands (notified under document number C(1998) 1608) (98/516/EC) (OJ L 232, 19.08.1998, p.10)

Commission Decision of 17 June 1998 on a common technical Regulation for satellite news gathering transportable earth stations (SNG TES) operating in the 11-12/13-14 GHz frequency bands (notified under document number C(1998) 1609) (98/517/EC) (OJ L 232, 19.08.1998, p. 12)

Commission Decision of 17 June 1998 on a common technical Regulation for ISDN packet mode using ISDN primary rate access (notified under document number C(1998) 1610) (98/518/EC) (OJ L 232, 19. 08.1998, p. 14)

Commission Decision of 17 June 1998 on a common technical Regulation for very small aperture terminals (VSATs) operating in the 11/12/14 GHz frequency bands (notified under document number C(1998) 1612) (98/519/EC) (OJ L 232, 19.08.98, p.17)

Commission Decision of 17 June 1998 on a common technical Regulation for ISDN packet mode using ISDN basic access (notified under document number C(1998) 1614) (98/521/EC) (OJ L 232, 19.08.98, p.22)

Commission Decision of 3 September 1998 on a common technical Regulation for Satellite Personal Communications Networks (S-PCN) Mobile Earth Stations (MESs), including handheld earth stations, for S-PCN operating in the 1,6/2,4 GHz frequency bands under the Mobile Satellite Service (MSS) (notified under document number C(1998) 2375) (98/533/EC) (OJ L 247, 05.09.98, p.11)

Commission Decision of 3 September 1998 on a common technical Regulation for Satellite Personal Communications Networks (S-PCN) Mobile Earth Stations (MESs), including handheld earth stations, for S-PCN operating in the 2,0 GHz frequency bands under the Mobile Satellite Service (MSS) (notified under document number C(1998) 2376) (98/534/EC)(OJ L 247, 05.09.98, p.13)

Commission Decision of 4 September 1998 on a common technical regulation for the telephony application requirements for mobile stations intended to be used with phase II public digital cellular telecomunications networks operating in the DCS 1800 band (edition 2) (notified under document number C(1998) 2562) (98/543/EC) (OJ L 254, 16.09.98, p.32)

Commission Decision of 16 September 1998 on a common technical regulation for the general attachment requirements for public pan-European cellular digital land-based mobile communications, Phase II (Edition 2) (notified under document number C(1998) 2720) (98/574/EC) (OJ L 278, 15.10.98, p.30)

Commission Decision of 16 September 1998 on a common technical regulation for the general attachment requirements for mobile stations intended to be used with Phase II public digital cellular telecommunications networks operating in the GSM 1800 band (Edition 2) (notified under document number C(1998) 2721) (98/575/EC) (OJ L 278, 15.10.98, p.35)

Commission Decision of 16 September 1998 on a common technical regulation for the attachment requirements for terminal equipment to connect to public switched telephone networks (PSTNs) and incorporating an analogue handset function (notified under document number C(1998) 2722) (98/576/EC) (OJ L 278, 15.10.98, p.40)

Commission Decision of 16 September 1998 on a common technical regulation for very small aperture terminals (VSATs) satellite earth stations operating in the 4 GHz and 6 GHz frequency bands (notified under document number C(1998) 2723) (98/577/EC) (OJ L 278, 15.10.98, p.43)

	Commission Decision of 16 September 1998 on a common technical regulation for low data rate land mobile satellite earth stations (LMES) operating in the 1,5/1,6 GHz frequency bands (notified under document number C(1998) 2724) (98/578/EC) (OJ L 278, 15.10.98, p.46) Commission Decision of 30 November 1998 on a common technical Regulation for land mobile satellite earth stations (LMES) operating in the 1,5/1,6 GHz frequency bands (notified under document number C(1998) 3695) (98/734/EC) (OJ L 351, 29.12.1998, p.37)
Switzerland	*Loi fédérale du 30.4.97 sur les télécommunications* (LTC; RO 1997 2187) *Ordonnance du Conseil Fédéral du 6.10.97 sur les installations de télécommunication* (ITU; RO 1997 2853) *Ordonnance de lOffice fédéral de la communication du 9.12.97 sur les installations de télécommunication* (RO 1998 485) Annex 1 to the *Ordonnance de l'OFCOM sur les installations de télécommunication* (RO 1998 488), as last amended on 9 March 1999 (RO 1999 1191) Technical standards declared to be obligatory: 10.1 based on CTR1 (97/544/EC) 10.2 based on CTR2 edition 2 (97/545/EC) 10.3 based on CTR3 amendment 1(98/515/EC) 10.4 based on CTR4 amendment 1 (98/520/EC) 10.6 based on CTR6 edition 2 (97/523/EC) 10.7 based on CTR7 edition 2 (98/522/EC) 10.8 based on CTR8 (95/526/EC) 10.10 based on CTR10 edition 2 (97/524/EC) 10.11 based on CTR11 (95/525/EC) 10.12 based on CTR12 amendment 1 (97/520/EC)

10.13 based on CTR13 (97/521/EC)
10.14 based on CTR14 amendment 1 (97/522/EC)
10.15 based on CTR15 (97/486/EC)
10.17 based on CTR17 (97/487/EC)
10.19 based on CTR19 edition 2 (98/574/EC)
10.20 based on CTR20 edition 2 (98/542/EC)
10.21 based on CTR21 (98/482/EC)
10.22 based on CTR22 (97/525/EC)
10.23 based on CTR23 (98/535/EC)
10.24 based on CTR24 (97/639/EC)
10.25 based on CTR25 (97/751/EC)
10.26 based on CTR26 (98/578/EC)
10.27 based on CTR27 (98/516/EC)
10.28 based on CTR28 (98/519/EC)
10.30 based on CTR30 (98/517/EC)
10.31 based on CTR31 edition 2 (98/575/EC)
10.32 based on CTR32 edition 2 (98/543/EC)
10.33 based on CTR33 (98/521/EC)
10.34 based on CTR34 (98/518/EC)
10.38 based on CTR38 (98/576/EC)
10.41 based on CTR41 (98/533/EC)
10.42 based on CTR42 (98/534/EC)
10.43 based on CTR43 (98/577/EC)
10.44 based on CTR44 (98/734/EC)

SECTION II

CONFORMITY ASSESSMENT BODIES

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

DESIGNATING AUTHORITIES

European Community

Austria: Bundesministerium für Wissenschaft und Verkehr

Belgium: Institut belge des services postaux et des télécommunications
Belgisch Instituut voor Postdiensten en Telecommunicatie

Denmark: Telestyrelsen

Finland: Liikenneministeriö/Trafikministeriet

France: Ministère de l'Economie, des Finances et de l'Industrie
Secrétariat d'Etat à l'industrie

Direction des postes et télécommunications. Service des télécommunications

Direction Générale des stratégies industrielles. Sous-direction de la qualité et de la normalisation

Germany: Bundesministerium für Wissenschaft und Technologie

Greece: Ministry of Transport

Ireland: Department of Transport, Energy and Communications

Italy: Ministero delle Comunicazione (for EMC aspects)
Ministero dell'Industria, del Commercia e dell'Artigianato

Luxembourg: Ministère des Transports (for EMC aspects)
Administration des Postes et Télécommunications

Netherlands: Ministerie van Verkeer en Waterstaat

Portugal: Instituto das Communicações de Portugal

Spain: Ministerio de Fomento

Sweden: Under the authority of the Government of Sweden : Styrelsen för ackreditering och teknisk kontrol (SWEDAC)

U.K.: Department of Trade and Industry

Switzerland Federal Office for Communications

SECTION IV

SPECIAL RULES RELATING TO THE DESIGNATION OF CONFORMITY ASSESSMENT BODIES

For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex 2 and those in Annex V to Directive 98/13/EC.

SECTION V

SUPPLEMENTARY PROVISIONS

1. Administrative Decision

The two Parties shall mutually recognise the administrative Decision (Art. 11(6), Directive 98/13/EC + Art. 31 of the Federal Law of 30 April 1997 on telecommunications (LTC; RO 1977 2187) and Article 8*ff* of the Federal Council Order of 6.10.97 on telecommunications installations (ITU; RO 1997 2853) approving connection of the terminal equipment concerned to the public telecommunications network.[1]

2. Notification of the manufacturer's or supplier's declaration

When placing on the market of one of the Parties the telecommunications equipment referred to in Article 3(1) of Directive 98/13/EC, the person responsible shall notify the manufacturer's or supplier's declaration to the notified body of the Party where the equipment is first placed on the market.

---

[1] In the context of this Agreement, the expression "public telecommunications network" is to be interpreted for the purpose of Swiss law as "installations provided by a telecommunications services provider".

3. Test laboratories

Each Party shall notify the other of the test laboratories designated to carry out the tests pertaining to the procedures referred to in Article 10 of Directive 98/13/EC. The criteria fixed by the relevant harmonised standards for the designation of such laboratories shall be applied.

4. Exchanges of information between conformity assessment bodies

4.1 In accordance with Annex I, point *7f of* Directive 98/13/EC, the conformity assessment bodies listed in section II of this Annex shall make available to the other bodies the relevant information concerning type-examination certificates issued and withdrawn.

4.2 In accordance with Annex III, point 6, and Annex IV, point 6 of Directive 98/13/EC, the conformity assessment bodies listed in section II of this Annex shall make available to the other bodies the relevant information concerning quality system approvals issued and withdrawn.

CHAPTER 8

EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

Provisions covered by Article 1 paragraph 2

European Community	Directive of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres (94/9/EC) (OJ L 100, 19.04.1994, p.1) Council Directive of 18 December 1975 on the approximation of the laws of the Member States concerning electrical equipment for use in potentially explosive atmospheres (76/117/EEC) (OJ L 24, 30.01.1976, p. 45)

	Council Directive of 6 February 1979 on the approximation of the laws of the Member States concerning electrical equipment for use in potentially explosive atmospheres employing certain types of protection (79/196/EEC), as last amended by Commission Directive 97/53/EC of 11 September 1997 (OJ L 257, 20.09.1997, p. 27) Council Directive of 15 February 1982 on the approximation of the laws of the Member States concerning electrical equipment for use in potentially explosive atmospheres in mines susceptible to firedamp (82/130/EEC), as last amended by Commission Directive 98/65/EC of 3 September 1998 (OJ L 257, 19/09/1998, p. 29)
Switzerland	*Loi fédérale du 24 juin 1902 concernant les installations électriques à faible et fort courant* (RO 19 252 et RS 4 798), as last amended on 3 February 1993 (RO 1993 901) *Ordonnance du 2 mars 1998 sur les appareils et les systèmes de protection destinés à être utilisés en atmosphères explosibles* (RO 1998 963) *Loi fédérale du 19 mars 1976 sur la sécurité d'installations et d'appareils techniques* (RO 1977 2370), as last amended on 18 June 1993 (RO 1995 2766) *Ordonnance du 12 juin 1995 sur la sécurité d'installations et d'appareils techniques* (RO 1995 2770), as last amended on 17 June 1996 (RO 1996 1867) *Ordonnance du 12 juin 1995 sur les procédures d'évaluation de la conformité des installations et appareils techniques* (RO 1995 2783)

SECTION II

CONFORMITY ASSESSMENT BODIES

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

DESIGNATING AUTHORITIES

European Community:

Switzerland	Swiss Federal Office of Energy

SECTION IV

SPECIAL RULES RELATING TO THE DESIGNATION OF CONFORMITY ASSESSMENT BODIES

For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex 2 and those in Annex XI to Directive 94/9/EC.

SECTION V

SUPPLEMENTARY PROVISIONS

1. Information exchange

The conformity assessment bodies listed in section II shall provide the Member States, the competent Swiss authorities and/or the other conformity assessment bodies with the information provided for in Article 9(2) of Directive 76/117/EEC.

2. Technical documentation

It shall be sufficient for manufacturers, their authorised representatives or the person responsible for placing products on the market to hold the technical documents required by the national authorities for inspection purposes at their disposal in the territory of one of the Parties for a period of at least ten years after the last date of manufacture of the product.

The Parties hereby undertake to forward all relevant technical documents at the request of the authorities of the other Party.

CHAPTER 9

ELECTRICAL EQUIPMENT AND ELECTROMAGNETIC COMPATIBILITY

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

Provisions covered by Article 1 paragraph 2

European Community	Council Directive of 19 February 1973 on the approximation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits (73/23/EEC), as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.08.1993, p. 1) Council Directive of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility (89/336/EEC), as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.08.1993, p. 1)
Switzerland	*Loi fédérale du 24 juin 1902 concernant les installations électriques à faible et fort courant* (RO 19 252 et RS 4 798), as last amended on 3 February 1993 (RO 1993 901) *Ordonnance du 30 mars 1994 sur les installations électriques à courant faible* (RO 1994 1185) *Ordonnance du 30 mars 1994 sur les installations électriques à courant fort* (RO 1994 1199), as last amended on 5 December 1995 (RO 1995 1024) *Ordonnance du 9 avril 1997 sur les matériels électriques à basse tension* (RO 1997 1016) *Ordonnance du 9 avril 1997 sur la compatibilité électromagnétique* (RO 1997 1008)

SECTION II

CONFORMITY ASSESSMENT BODIES

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

DESIGNATING AUTHORITIES

European Community:

Austria:	Bundesministerium für wirtschaftliche Angelegenheiten
Belgium:	Ministère des Affaires Economiques
	Ministerie van Economische Zaken
Denmark:	For electrical aspects: Boligministeriet
	For EMC aspects: Telestyrelsen
Finland:	Kauppa-ja teollisuusministeriö / Handels-och industriministeriet
	Liikenneministeriö/Trafikministeriet (for EMC aspects of telecommunication and radio equipment)
France	Ministère de l'économie, des finances et de l'industrie. Secrétariat d'Etat à l'industrie. Direction générale des stratégies industrielles
Germany:	For electrical aspects: Bundesministerium für Arbeit und Sozialordung
	For EMC aspects: Bundesministerium für Wirtschaft und Technologie
Greece:	Ministry of Development
Ireland:	Department of Enterprise and Employment
Italy:	Ministero dell' Industria, del Commercio e dell' Artigianato
Luxembourg:	Ministère des Transports
Netherlands:	Staat der Nederlanden
	For EMC aspects: De Minister van Verkeer en Waterstaat
Portugal:	Under the authority of the Government of Portugal: Instituto Português da Qualidade.
Spain:	Ministerio de Industria y Energia
Sweden:	Under the authority of the Government of Sweden : Styrelsen för ackreditering och teknisk kontrol (SWEDAC)
United Kingdom:	Department of Trade and Industry

Switzerland Swiss Federal Office of Energy

SECTION IV

SPECIAL RULES RELATING TO THE DESIGNATION OF CONFORMITY ASSESSMENT BODIES

For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex 2 and those in Annex II to Directive 89/336/EEC.

SECTION V

SUPPLEMENTARY PROVISIONS

1. Technical documentation

It shall be sufficient for manufacturers, their authorised representatives or the person responsible for placing products on the market to hold the technical documents required by the national authorities for inspection purposes at their disposal in the territory of one of the Parties for a period of at least ten years after the last date of manufacture of the product.

The Parties hereby undertake to forward all relevant documents at the request of the authorities of the other Party.

2. Standardisation bodies

In accordance with Article 11 of Directive 73/23/EEC, the Parties shall notify each other of the bodies responsible for drawing up the standards referred to in Article 5 of this Directive.

3. Competent bodies

The Parties shall inform each other of and mutually recognise the bodies made responsible for drawing up technical reports and/or certificates pursuant to Article 8(2) of Directive 73/23/EEC and Article 10(2) of Directive 89/336/EEC.

4. Special measures

In accordance with Article 6(2) of Directive 89/336/EEC, each Party shall inform the other of the special measures taken pursuant to paragraph 1 of that Article.

5. Competent authorities

In accordance with Article 10(6) of Directive 89/336/EEC, each Party shall notify the other of the competent authorities referred to in that Article.

CHAPTER 10

CONSTRUCTION PLANT AND EQUIPMENT

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

Provisions covered by Article 1 paragraph 1

European Community	Council Directive of 19 December 1978 on the approximation of the laws of the Member States relating to the determination of the noise emission of construction plant and equipment (79/113/EEC) (OJ L 33, 08.02.1979, p. 15), as subsequently amended Council Directive of 17 September 1984 on the approximation of the laws of the Member States relating to common provisions for construction plant and equipment (84/532/EEC) (OJ L 300, 19.11.1984, p. 111), as subsequently amended Council Directive of 17 September 1984 on the approximation of the laws of the Member States relating to the permissible sound power level of compressors (84/533/EEC) (OJ L 300, 19.11.1984, p. 123), as subsequently amended Council Directive of 17 September 1984 on the approximation of the laws of the Member States relating to the permissible sound power level of tower cranes (84/534/EEC) (OJ L 300, 19.11.1984, p. 130), as subsequently amended Council Directive of 17 September 1984 on the approximation of the laws of the Member States relating to the permissible sound power level of welding generators (84/535/EEC) (OJ L 300, 19.11.1984, p. 142), as subsequently amended Council Directive of 17 September 1984 on the approximation of the laws of the Member States relating to the permissible sound power level of power generators (84/536/EEC) (OJ L 300, 19.11.19784, p. 149), as subsequently amended

	Council Directive of 17 September 1984 on the approximation of the laws of the Member States relating to the permissible sound power level of powered hand-held concrete-breakers and picks (84/537/EEC) (OJ L 300, 19.11.1984, p. 156), as subsequently amended Council Directive of 22 December 1986 on the limitation of noise emitted by hydraulic excavators, rope-operated excavators, dozers, loaders and excavator-loaders (86/662/EEC) (OJ L 384, 31.1.1986, p. 1), as subsequently amended Council Directive of 17 September 1984 on the approximation of the laws of the Member States relating to the permissible sound power level of lawnmowers (84/538/EEC) (OJ L 300, 19.11.1984, p. 171), as subsequently amended
Switzerland	No legislation

SECTION II

CONFORMITY ASSESSMENT BODIES

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

DESIGNATING AUTHORITIES

European Community:

Switzerland: Federal Office of Environment, Forests and Landscape

SECTION IV

SPECIAL RULES RELATING TO THE DESIGNATION OF CONFORMITY ASSESSMENT BODIES

For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex 2 and those in Annex II to Council Directive 84/532/EEC, as amended by Council Directive 88/665/EEC.

CHAPTER 11

MEASURING INSTRUMENTS AND PREPACKAGES

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

Provisions covered by Article 1 paragraph 1

European Community	Council Directive of 12 October 1971 on the approximation of the laws of the Member States relating to the measuring of the standard mass per storage volume of grain (71/347/EEC) (OJ L 239, 25.10.1971, p. 1), as subsequently amended Council Directive of 12 October 1971 on the approximation of the laws of the Member States relating to the calibration of the tanks of vessels (71/349/EEC) (OJ L 239, 25.10.1971, p. 15), as subsequently amended Council Directive of 17 December 1974 on the approximation of the laws of the Member States relating to cold-water meters (75/33/EEC) (OJ L 14, 20.01.1975, p.1), as subsequently amended Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to alcoholometers and alcohol hydrometers (76/765/EEC) (OJ L 262, 27.09.1976, p.143), as subsequently amended Council Directive of 21 December 1976 on the approximation of the laws of the Member States relating to taximeters (77/95/EEC) (OJ L 26,31.01.1977, p.59), as subsequently amended Council Directive of 5 December 1978 on the approximation of the laws of the Member States relating to automatic checkweighing and weight grading machines (78/1031/EEC) (OJ L 364, 27.12.1978, p.1),as subsequently amended Council Directive of 11 September 1979 on the approximation of the laws of the Member States relating to hot-water meters (79/830/EEC) (OJ L 259, 15.10.1979, p.1), as subsequently amended Council Directive of 26 May 1986 on the approximation of the laws of the Member States relating to tyre pressure gauges for motor vehicles (86/217/EEC) (OJ L 152, 06.06.1986, p.48), as subsequently amended Council Directive of 20 June 1990 on the harmonisation of the laws of the Member States relating to non-automatic weighing instruments (90/384/EEC) (OJ L 189, 20.07.1990, p.1), as subsequently amended

	Council Directive of 19 December 1974 on the approximation of the laws of the Member States relating to the making-up by volume of certain prepackaged liquids (75/106/EEC) (OJ L 42, 15.02.1975, p.1), as subsequently amended Council Directive of 19 December 1974 on the approximation of the laws of the Member States relating to bottles used as measuring containers (75/107/EEC) (OJ L 42, 15.02.1975, p.14), as subsequently amended Council Directive of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products (76/211/EEC) (OJ L 46, 21.02.1976, p.1), as subsequently amended Council Directive of 15 January 1980 on the approximation of the laws of the Member States relating to the ranges of nominal quantities and nominal capacities permitted for certain prepackaged products (80/232/EEC) (OJ L 51, 25.02.1980, p.1), as subsequently amended
Switzerland	*Ordonnance du 21 mai 1986 sur les appareils mesureurs de l'énergie thermique* (RS 941.231), as subsequently amended *Ordonnance du 15 juillet 1970 concernant les déclarations qui valent engagements dans le commerce des biens en quantités mesurables* (RS 941.281), as subsequently amended *Ordonnance du 25 octobre 1972 sur les déclarations* (RS 941.281.1), as subsequently amended *Ordonnance du 3 décembre 1973 sur les mesures de volume* (RS 941.211), as subsequently amended *Ordonnance du 17 décembre 1984 sur la qualification des instruments de mesure* (RS 941.210) *Ordonnance du 15 août 1986 sur les instruments de pesage* (RS 941.221.1)

Provisions covered by Article 1 paragraph 2

European Community	Council Directive of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (80/181/EEC), as last amended by Council Directive 89/617/EEC of 27 November 1989 (OJ L 357, 7/12/1989, p. 28)

Council Directive of 26 July 1971 on the approximation of the laws of the Member States relating to common provisions for both measuring instruments and methods of metrological control (71/316/EEC), as last amended by Council Directive 88/665/EEC of 21 December 1988 (OJ L 382, 31/12/1988, p. 42)
Council Directive of 26 July 1971 on the approximation of the laws of the Member States relating to 5 to 50 kilogramme medium accuracy rectangular bar weights and 1 to 10 kilogramme medium accuracy cylindrical weights (71/317/EEC) (OJ L 202, 6/9/1971, p. 14)
Council Directive of 26 July 1971 on the approximation of the laws of the Member States relating to gas volume meters (71/318/EEC), as last amended by Commission Directive 82/623/EEC of 1 July 1982 (OJ L 252, 27/8/1982, p. 5)
Council Directive of 26 July 1971 on the approximation of the laws of the Member States relating to meters for liquids other than water (71/319/EEC) (OJ L 202, 6/9/1971, p. 32)
Council Directive of 12 October 1971 on the approximation of the laws of the Member States relating to ancillary equipment for meters for liquids other than water (71/348/EEC) (OJ L 239, 25/10/1971, p. 9)
Council Directive of 19 November 1973 on the approximation of the laws of the Member States relating to material measures of length (73/362/EEC), as last amended by Commission Directive 85/146/EEC of 31 January 1985 (OJ L 54, 23/2/1985, p. 29)
Council Directive of 4 March 1974 on the approximation of the laws of the Member States relating to weights of from 1 mg to 50 kg of above-medium accuracy (74/148/EEC) (OJ L 84, 28/3/1974, p. 3)
Council Directive of 24 June 1975 on the approximation of the laws of the Member States relating to continuous totalising weighing machines (75/410/EEC) (OJ L 183, 14/7/1975, p. 25)
Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to alcohol tables (76/766/EEC) (OJ L 262, 27/9/1976, p. 149)

	Council Directive of 4 November 1976 on the approximation of the laws of the Member States relating to electrical energy meters (76/891/EEC), as last amended by Commission Directive 82/621/EEC of 1 July 1982 (OJ L 252, 27/8/1982, p. 1) Council Directive of 5 April 1977 on the approximation of the laws of the Member States relating to measuring systems for liquids other than water (77/313/EEC), as last amended by Commission Directive 82/625/EEC of 1 July 1982 (OJ L 252, 27/8/1982, p. 10)
Switzerland	*Loi fédérale du 9 juin 1977 sur la métrologie* (RO 1977 2394), as last amended on 18 June 1993 (RO 1993 3149) Ordonnance du 23 novembre 1994 sur les unités (RO 1994 3109) Ordonnance du 8 avril 1991 sur les instruments de mesure de longueur (RO 1991 1306) Ordonnance du 1er décembre 1986 sur les appareils mesureurs de liquide autres que l'eau (RO 1987 216) Ordonnance du 15 août 1986 sur les poids (RO 1986 2022), as last amended on 21 November 1995 (RO 1995 5646) Ordonnance du 4 août 1986 sur les appareils de mesure de quantité de gaz (RO 1986 1491) Ordonnance du 4 août 1986 sur les appareils mesureurs pour la energie et la puissance électrique (RO 1986 1496)

SECTION II

CONFORMITY ASSESSMENT BODIES

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

DESIGNATING AUTHORITIES

Provisions covered by Article 1 paragraph 1

European Community:

Switzerland: Swiss Federal Office of Metrology

Provisions covered by Article 1 paragraph 2

European Community:

Switzerland: Swiss Federal Office of Metrology

SECTION IV

SPECIAL RULES RELATING TO THE DESIGNATION OF CONFORMITY ASSESSMENT BODIES

For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex 2 and those in Annex V to Directive 90/384/EEC, as regards the products covered by that Directive.

SECTION V

SUPPLEMENTARY PROVISIONS

1. Information exchange

The conformity assessment bodies listed in section II shall periodically provide the Member States and the competent Swiss authorities with the information provided for in point 1.5 of Annex II to Directive 90/384/EEC.

The conformity assessment bodies listed in section II may request the information provided for in point 1.6 of Annex II to Directive 90/384/EEC.

2. Prepackages

Switzerland shall recognise checks carried out in accordance with the provisions of Community legislation listed in section I by a Community body listed in section II in the case of Community prepackages placed on the market in Switzerland.

As regards statistical checking of the quantities declared on prepackages, the European Community shall recognise the Swiss method laid down in Articles 24 to 40 of the "*Ordonnance sur les déclarations*" (RS 941.281.1) as equivalent to the Community method laid down in Annex II of Directives 75/106/EEC and 76/211/EEC, as amended by Directive 78/891/EEC. Swiss producers whose prepackages conform to Community legislation and have been checked according to the Swiss method shall affix the "e" mark on their products exported to the EC.

CHAPTER 12

MOTOR VEHICLES

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

Provisions covered by Article 1 paragraph 2

European Community	Council Directive of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers (70/156/EEC), as last amended by Commission Directive 98/14/EC of 6 February 1998 (OJ L 91,25/03/1998, p.1) Council Directive of 6 February 1970 on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles (70/157/EEC), as last amended by Commission Directive 96/20/EC of 27 March 1996 (OJ L 92, 13/4/1996, p. 23) Council Directive of 20 March 1970 on the approximation of the laws of the Member States relating to measures to be taken against air pollution by gases from positive-ignition engines of motor vehicles (70/220/EEC), as last amended by Directive 96/69/EC of the European Parliament and of the Council of 8 October 1996 (OJ L 282, 1/11/1996, p. 64) Council Directive of 20 March 1970 on the approximation of the laws of the Member States relating to liquid fuel tanks and rear protective devices for motor vehicles and their trailers (70/221/EEC), as last amended by Commission Directive 97/19/EC of 18 April 1997 (OJ L 125, 16/05/1997, p.1) Council Directive of 20 March 1970 on the approximation of the laws of the Member States relating to the space for mounting and the fixing of rear registration plates on motor vehicles and their trailers (70/222/EEC) (OJ L 76, 6/4/1970, p. 25) Council Directive of 8 June 1970 on the approximation of the laws of the Member States relating to the steering equipment for motor vehicles and their trailers (70/311/EEC), as last amended by Commission Directive 92/62/EEC of 2 July 1992 (OJ L 199, 18/7/1992, p. 33)

Council Directive of 27 July 1970 on the approximation of the laws of the Member States relating to the doors of motor vehicles and their trailers (70/387/EEC) (OJ L 176, 10/8/1970, p. 5)
Council Directive of 27 July 1970 on the approximation of the laws of the Member States relating to audible warning devices for motor vehicles (70/388/EEC) (OJ L 176, 10/8/1970, p. 12)
Council Directive of 1 March 1971 on the approximation of the laws of the Member States relating to the rear-view mirrors of motor vehicles (71/127/EEC), as last amended by Commission Directive 88/321/EEC of 16 May 1988 (OJ L 147, 14/6/1988, p. 77)
Council Directive of 26 July 1971 on the approximation of the laws of the Member States relating to the braking devices of certain categories of motor vehicles and of their trailers (71/320/EEC), as last amended by Commission Directive 98/12/EC of 27 January 1998 (OJ L 081, 18/03/1998, p. 1)
Council Directive of 20 June 1972 on the approximation of the laws of the Member States relating to the suppression of radio interference produced by spark-ignition engines fitted to motor vehicles (72/245/EEC), as last amended by Commission Directive 95/54/EC of 31 October 1995 (OJ L 266, 8/11/1995, p. 1)
Council Directive of 2 August 1972 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of pollutants from diesel engines for use in vehicles (72/306/EEC), as last amended by Commission Directive 97/20/EC of 18 April 1997 (OJ L 125, 16/05/1997, p.21)
Council Directive of 17 December 1973 on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles (interior parts of the passenger compartment other than the interior rear-view mirrors, layout of controls, the roof or sliding roof, the backrest and rear part of the seats) (74/60/EEC), as last amended by Commission Directive 78/632/EEC of 19 May 1978 (OJ L 206, 29/7/1978, p. 26)

Council Directive of 17 December 1973 on the approximation of the laws of the Member States relating to devices to prevent the unauthorised use of motor vehicles (74/61/EEC), as last amended by Commission Directive 95/56/EC of 8 November 1995 (OJ L 286, 29/11/1995, p. 1)

Council Directive of 4 June 1974 on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles (the behaviour of the steering mechanism in the event of an impact) (74/297/EEC), as last amended by Commission Directive 91/662/EEC of 6 December 1991 (OJ L 366, 31/12/1991, p. 1)

Council Directive of 22 July 1974 on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles (strength of seats and of their anchorages) (74/408/EEC), as last amended by Commission Directive 96/37/EC of 17 June 1996 (OJ L 186, 25/7/1996, p. 71)

Council Directive of 17 September 1974 on the approximation of the laws of the Member States relating to the external projections of motor vehicles (74/483/EEC), as last amended by Council Directive 87/354/EEC of 25 June 1987 (OJ L 192, 11/7/1987, p. 43)

Council Directive of 26 June 1975 on the approximation of the laws of the Member States relating to the reverse and speedometer equipment of motor vehicles (75/443/EEC), as last amended by Commission Directive 97/39/EC of 24 June 1997 (OJ L 177,05/07/1997, p.15)

Council Directive of 18 December 1975 on the approximation of the laws of the Member States relating to statutory plates and inscriptions for motor vehicles and their trailers, and their location and method of attachment (76/114/EEC), as last amended by Council Directive 87/354/EEC of 25 June1987 (OJ L 192, 11/7/1987, p.43.)

Council Directive of 18 December 1975 on the approximation of the laws of the Member States relating to anchorages for motor-vehicle safety belts (76/115/EEC), as last amended by Commission Directive 96/38/EC of 17 June 1996 (OJ L 187, 26/7/1996, p. 95)

Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to the installation of lighting and light-signalling devices on motor vehicles and their trailers (76/756/EEC), as last amended by Commission Directive 97/28/EC of 11 June 1997 (OJ L 171, 30/6/1997, p. 1)

Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to reflex reflectors for motor vehicles and their trailers (76/757/EEC), as last amended by Commission Directive 97/29/EC of 11 June 1997 (OJ L 171, 30/6/1997, p. 11)

Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to rear position (side) lamps and stop lamps for motor vehicles and their trailers (76/758/EEC), as last amended by Commission Directive 97/30/EC of 11 June 1997 (OJ L 171, 30/6/1997, p. 25)

Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to direction indicator lamps for motor vehicles and their trailers (76/759/EEC), as last amended by Commission Directive 89/277/EEC of 28 March 1989 (OJ L 109, 20/4/1989, p. 25)

Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to the rear registration plate lamps for motor vehicles and their trailers (76/760/EEC), as last amended by Council Directive 87/354/EEC of 25 June1987 (OJ L 192, 11/7/1987, p. 43)

Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to motor-vehicle headlamps which function as main-beam and/or dipped-beam headlamps and to incandescent electric filament lamps for such headlamps (76/761/EEC), as last amended by Commission Directive 89/517/EEC of 1 August 1989 (OJ L 265, 12/9/1989, p. 15)

Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to front fog lamps for motor vehicles and filament lamps for such lamps (76/762/EEC), as last amended by Council Directive 87/354/EEC of 25 June 1987 (OJ L 192, 11/7/1987, p. 43)

Council Directive of 17 May 1977 on the approximation of the laws of the Member States relating to motor-vehicle towing-devices (77/389/EEC), as last amended by Commission Directive 96/64/EC of 2 October 1996 (OJ L 258, 11/10/1996, p. 26)
Council Directive of 28 June 1977 on the approximation of the laws of the Member States relating to rear fog lamps for motor vehicles and their trailers (77/538/EEC), as last amended by Commission Directive 89/518/EEC of 1 August 1989 (OJ L 265, 12/9/1989, p. 24)
Council Directive of 28 June 1977 on the approximation of the laws of the Member States relating to reversing lamps for motor vehicles and their trailers (77/539/EEC), as last amended by Commission Directive 97/32/EC (OJ L 177, 30/06/1997, p. 63)
Council Directive of 28 June 1977 on the approximation of the laws of the Member States relating to parking lamps for motor vehicles (77/540/EEC), as last amended by Council Directive 87/354/EEC of 25 June1987 (OJ L 192, 11/7/1987, p. 43)
Council Directive of 28 June 1977 on the approximation of the laws of the Member States relating to safety belts and restraint systems of motor vehicles (77/541/EEC), as last amended by Commission Directive 96/36/EC of 17 June 1996 (OJ L 178, 17/7/1996, p. 15)
Council Directive of 27 September 1977 on the approximation of the laws of the Member States relating to the field of vision of motor vehicle drivers (77/649/EEC), as last amended by Commission Directive 90/630/EEC of 30 October 1990 (OJ L 341, 6/12/1990, p. 20)
Council Directive of 21 December 1977 on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles (identification of controls, tell-tales and indicators) (78/316/EEC), as last amended by Commission Directive 94/53/EC of 15 November 1994 (OJ L 299, 22/11/1994, p. 26)

Council Directive of 21 December 1977 on the approximation of the laws of the Member States relating to the defrosting and demisting systems of glazed surfaces of motor vehicles (78/317/EEC) (OJ L 81, 28/3/1978, p. 27)
Council Directive of 21 December 1977 on the approximation of the laws of the Member States relating to the wiper and washer systems of motor vehicles (78/318/EEC), as last amended by Commission Directive 94/68/EC of 16 December 1994 (OJ L 354, 31/12/1994, p. 1)
Council Directive of 12 June 1978 on the approximation of the laws of the Member States relating to heating systems for the passenger compartment of motor vehicles (78/548/EEC) (OJ L 168, 26/6/1978, p. 40)
Council Directive of 12 June 1978 on the approximation of the laws of the Member States relating to the wheel guards of motor vehicles (78/549/EEC), as last amended by Commission Directive 94/78/EC of 21 December 1994 (OJ L 354, 31/12/1994, p. 10)
Council Directive of 16 October 1978 on the approximation of the laws of the Member States relating to head restraints of seats of motor vehicles (78/932/EEC), as last amended by Council Directive 87/354/EEC of 25 June1987 (OJ L 192, 11/7/1987, p. 43)
Council Directive of 16 December 1980 on the approximation of the laws of the Member States relating to the fuel consumption of motor vehicles (80/1268/EEC), as last amended by Commission Directive 93/116/EC of 17 December 1993 (OJ L 329, 30/12/1993, p. 39)
Council Directive of 16 December 1980 on the approximation of the laws of the Member States relating to the engine power of motor vehicles (80/1269/EEC), as last amended by Commission Directive 97/21/EC of 18 April 1997 (OJ L 125,16/05/1997, p. 31)
Council Directive of 25 July 1996 laying down for certain road vehicles circulating within the Community the maximum authorised dimensions in national and international traffic and the maximum authorised weights in international traffic (96/53/EC) (OJ L 235, 17/09/1996, p. 59)

Council Directive of 3 December 1987 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous pollutants from diesel engines for use in vehicles (88/77/EEC), as last amended by Council Directive 96/1/EC of 22 January 1996 (OJ L 40, 17/2/1996, p. 1)

Council Directive of 13 April 1989 on the approximation of the laws of the Member States relating to the lateral protection (side guards) of certain motor vehicles and their trailers (89/297/EEC) (OJ L 124, 5/5/1989, p. 1)

Council Directive of 18 July 1989 on the approximation of the laws of the Member States relating to the tread depth of tyres of certain categories of motor vehicles and their trailers (89/459/EEC) (OJ L 226, 3/8/1989, p. 4)

Council Directive of 27 March 1991 on the approximation of the laws of the Member States relating to the spray-suppression systems of certain categories of motor vehicles and their trailers (91/226/EEC) (OJ L 103, 23/4/1991, p. 5)

Council Directive of 10 February 1992 on the installation and use of speed limitation devices for certain categories of motor vehicles in the Community (92/6/EEC) (OJ L 57, 2/3/1992, p. 27)

Council Directive of 31 March 1992 on the masses and dimensions of motor vehicles of category M1 (92/21/EEC), as last amended by Commission Directive 95/48/EC of 20 September 1995 (OJ L 233, 30/9/1995, p. 73)

Council Directive of 31 March 1992 on safety glazing and glazing materials on motor vehicles and their trailers (92/22/EEC) (OJ L 129, 14/5/1992, p. 11)

Council Directive of 31 March 1992 relating to tyres for motor vehicles and their trailers and to their fitting (92/23/EEC) (OJ L 129, 14/5/1992, p. 95)

Council Directive of 31 March 1992 relating to speed limitation devices or similar speed limitation on-board systems of certain categories of motor vehicles (92/24/EEC) (OJ L 129, 14/5/1992, p. 154)

	Council Directive of 17 December 1992 relating to the external projections forward of the cab's rear panel of motor vehicles of category N (92/114/EEC) (OJ L 409, 31/12/1992, p. 17) Directive of the European Parliament and of the Council of 30 May 1994 relating to the mechanical coupling devices of motor vehicles and their trailers and their attachment to those vehicles (94/20/EC) (OJ L 195, 29/7/1994, p. 1) Directive of the European Parliament and of the Council of 24 October 1995 relating to the burning behaviour of materials used in the interior construction of certain categories of motor vehicle (95/28/EC) (OJ L 281, 23/11/1995, p. 1) Directive 96/27/EC of the European Parliament and of the Council of 20 May 1996 on the protection of occupants of motor vehicles in the event of a side impact and amending Directive 70/156/EEC (OJ L 169, 8/7/1996, p. 1) Directive 96/79/EC of the European Parliament and of the Council of 16 December 1996 on the protection of occupants of motor vehicles in the event of a frontal impact and amending Directive 70/156/EEC (OJ L 018 , 21/01/1997 p. 7) Directive 97/27/EC of the European Parliament and of the Council of 22 July 1997 relating to the masses and dimensions of certain categories of motor vehicles and their trailers and amending Directive 70/156/EEC (OJ L 233, 25/08/1997, p. 1 and OJ L 263, 25/09/1997, p. 30)
Switzerland	*Ordonnance du 19 juin 1995 concernant les exigences techniques requises pour les voitures automobiles de transport et leurs remorques* (RO 1995 4145)*, as last amended on 21 April 1997* (RO 1997 1280) *Ordonnance du 19 juin 1995 sur la réception par type des véhicules routiers* (RO 1995 3997)

SECTION II

CONFORMITY ASSESSMENT BODIES

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the authorities responsible for type-approval, technical services and testing bodies.

European Community:

Switzerland:
Authority responsible for type-approval
Swiss Federal Roads Office
Section des homologations
CH-3003 Berne

SECTION III
DESIGNATING AUTHORITIES

European Community

- Austria: Bundesministerium für öffentliche Wirtschaft und Verkehr
- Belgium: Ministère des Communications et de l'Infrastructure
  Ministerie van Verkeer en Infrastructuur
- Denmark: Road safety and Transport Agency
- Finland: Liikenneministeriö/Trafikministeriet
- France: Ministère des Transports
- Germany: Bundesministerium für Verkehr, Bau- und Wohnungswesen
- Greece: Ministry of Transport
- Ireland: Department of Enterprise and Employment
- Italy: Ministero dei Trasporti
- Luxembourg: Ministère des Transports

- Netherlands: Rijksdienst voor het Wegverkeer
- Portugal: Direcção-Geral de Viação
- Spain: Ministerio de Industría y Energía
- Sweden: Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC)
  Vägverket Statens Naturvardsverk (for emissions aspects: Directives 70/220/EEC, 72/306/EEC, 88/77/EEC and 77/537/EEC
- United Kingdom: Vehicle Certification Agency

Switzerland Swiss Federal Roads Office

SECTION IV

SPECIAL RULES RELATING TO THE DESIGNATION OF CONFORMITY ASSESSMENT BODIES

For the designation of conformity assessment bodies, the designating authorities shall refer to their respective legislative, regulatory and administrative provisions as listed in section I.

SECTION V

SUPPLEMENTARY PROVISIONS

The provisions of this section shall apply exclusively to relations between Switzerland and the Community.

1. Information exchange

The competent type-approval authorities in Switzerland and the Member States shall in particular exchange the information referred to in Article 4(5) and (6) of Directive 70/156/EEC, as amended by Directive 92/53/EEC and as last adapted to technical progress by Commission Directive 98/14/EC.

In the event of refusal by Switzerland or the Member States to grant type-approval in accordance with Article 4(2) of Directive 70/156/EEC, as amended by Directive 92/53/EEC, and as last adapted to technical progress by Commission Directive 98/14/EC, their competent authorities shall notify each other of their decision and give the reasons for it. The competent Swiss authority shall likewise inform the Commission thereof.

2. Recognition of vehicle type-approval

Switzerland shall also recognise vehicle type-approval granted before the entry into force of this Agreement in accordance with Directive 70/156/EEC, as amended by Directive 92/53/EEC, and as last adapted to technical progress by Commission Directive 98/14/EC, by the authorities responsible for type-approval listed in section II of this Chapter where that approval is still valid in the EC.

The European Community shall recognise Swiss type-approval where Switzerland's requirements are deemed to be equivalent to those of Directive 70/156/EEC, as amended by Directive 92/53/EEC, and as last adapted to technical progress by Commission Directive 98/14/EC.

Recognition of Swiss-issued type-approval shall be suspended should Switzerland fail to adapt its legislation to all the Community type-approval legislation in force.

3. Vehicle type-approval safeguard clauses

Registration and entry into service

1. Each Member State and Switzerland shall register, permit the sale or entry into service of new vehicles on grounds relating to their construction and functioning if, and only if, they are accompanied by a valid certificate of conformity. In the case of incomplete vehicles, each Member State and Switzerland may not prohibit the sale of such vehicles but may refuse their permanent registration and entry into service so long as they are not completed.

2. Each Member State and Switzerland shall permit the sale or entry into service of components or separate technical units if, and only if, they comply with the requirements of the relevant separate Directive or the requirements of the Swiss legislation equivalent to the relevant separate Directive.

3. If a Member State or Switzerland finds that vehicles, components or separate technical units of a particular type are a serious risk to road safety although they are accompanied by a valid certificate of conformity or are properly marked, it may, for a maximum period of six months, refuse to register such vehicles or may prohibit the sale or entry into service in its territory of such vehicles, components or separate technical units. It shall forthwith notify the other Member States, Switzerland and the Commission thereof, stating the reasons on which its decision is based. If the Member State or Switzerland which granted type-approval disputes the risk to road safety notified to it, the Member States or Switzerland concerned shall endeavour to settle the dispute. The Commission and the Committee shall be kept informed and shall, where necessary, hold appropriate consultations for the purpose of reaching a settlement.

Measures related to the conformity of production

1. When a Member State or Switzerland grants type-approval, it shall take the necessary measures in accordance with Annex X to Framework Directive 70/156/EEC, as amended by Directive 92/53/EEC, and as last adapted to technical progress by Commission Directive 98/14/EC, in relation to that approval to verify, if need be in cooperation with the approval authorities of the other Member States or Switzerland, that adequate arrangements have been made to ensure that vehicles, systems, components or separate technical units produced, conform to the approved type.

2. When a Member State or Switzerland has granted a type approval, it shall take the necessary measures in accordance with Annex X to Framework Directive 70/156/EEC, as amended by Directive 92/53/EEC, and as last adapted to technical progress by Commission Directive 98/14/EC, in relation to that approval to verify, if need be in cooperation with the approval authorities of the other Member States or Switzerland, that the arrangements referred to in paragraph 1 continue to be adequate and that vehicles, systems, components or separate technical units produced, continue to conform to the approved type. Verification to ensure that products conform to the approved type shall be limited to the procedures set out in section 2 of Annex X to Framework Directive 70/156/EEC, as amended by Directive 92/53/EEC, and as last adapted to technical progress by Commission Directive 98/14/EC, and in those separate Directives that contain specific requirements.

Nonconformity with the approved type

1. There shall be failure to conform to the approved type where deviations from the particulars in the type-approval certificate and/or the information package are found to exist and where these deviations have not been authorised under Article 5 (3) or (4), by the Member States or Switzerland which granted the type-approval. A vehicle shall not be considered to deviate from the approved type where tolerances are permitted by separate Directives and these tolerances are respected.

2. Where a Member State or Switzerland has granted type-approval and finds that vehicles, components or separate technical units accompanied by a certificate of conformity or bearing an approval mark do not conform to the type it has approved, it shall take the necessary measures to ensure that vehicles, components or separate technical units produced again conform to the approved type. The approval authorities of that Member State or Switzerland shall notify those of the other Member States and/or Switzerland of the measures taken which may extend to withdrawal of type-approval.

3. If a Member State or Switzerland demonstrates that vehicles, components or separate technical units accompanied by a certificate of conformity or bearing an approval mark do not conform to the approved type, it may request the Member State or Switzerland which granted the type-approval to verify that vehicles, components or separate technical units produced conform to the approved type. Such action shall be taken as soon as possible and in any case within six months of the date of the request.

4. In the case of:

- a vehicle type-approval where the nonconformity of a vehicle arises exclusively from the nonconformity of a system, component or separate technical unit,

or

- a multi-stage type-approval where the nonconformity of a completed vehicle arises exclusively from the nonconformity of a system, component or separate technical unit being part of the incomplete vehicle, or of the incomplete vehicle itself,

the vehicle-approval authority shall request the Member State(s) or Switzerland which granted any relevant system, component, separate technical unit or incomplete vehicle type-approval(s) to take the necessary action to ensure that vehicles produced again conform to the approved type. Such action shall be taken as soon as possible and in any case within six months of the date of the request, if necessary in conjunction with the Member State or Switzerland making the request.

Where a failure to conform is established, the approval authorities of the Member State or Switzerland which granted the system, component or separate technical unit type-approval or the approval of the incomplete vehicle shall take the measures set out in paragraph 2 of Directive 70/156/EEC, as amended by Directive 92/53/EEC, and as last adapted to technical progress by Commission Directive 98/14/EC.

5. The approval authorities of the Member States or Switzerland shall inform each other within one month of any withdrawal of type-approval and of the reasons for such a measure.

6. If the Member State or Switzerland which granted type-approval disputes the failure to conform notified to it, the Member States concerned and Switzerland shall endeavour to settle the dispute. The Commission and the Committee shall be kept informed and shall, where necessary, hold appropriate consultations for the purpose of reaching a settlement.

CHAPTER 13

AGRICULTURAL OR FORESTRY TRACTORS

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

Provisions covered by Article 1 paragraph 2

European Community	Council Directive of 4 March 1974 on the approximation of the laws of the Member States relating to the type-approval of wheeled agricultural or forestry tractors (74/150/EEC), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24) Council Directive of 4 March 1974 on the approximation of the laws of the Member States relating to certain parts and characteristics of wheeled agricultural or forestry tractors (74/151/EEC), as last amended by Commission Directive 98/38/EC of 3 June 1998, (OJ L 170, 16/06/1998, p. 13) Council Directive of 4 March 1974 on the approximation of the laws of the Member States relating to the maximum design speed of and load platforms for wheeled agricultural or forestry tractors (74/152/EEC), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24) Council Directive of 25 June 1974 on the approximation of the laws of the Member States relating to rear-view mirrors for wheeled agricultural or forestry tractors (74/346/EEC), as last amended by Commission Directive 98/40/EC of 6 June 1998, (OJ L 171, 16/06/1998, p. 28) Council Directive of 25 June 1974 on the approximation of the laws of the Member States relating to the field of vision and windscreen wipers for wheeled agricultural or forestry tractors (74/347/EEC), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24) Council Directive of 20 May 1975 on the approximation of the laws of the Member States relating to the steering equipment of wheeled agricultural or forestry tractors (75/321/EEC), as last amended by Commission Directive 98/39/EC of 5 June 1998 (OJ L 170, 16/06/1998, p. 15)

Council Directive of 20 May 1975 on the approximation of the laws of the Member States relating to the suppression of radio interference produced by spark-ignition engines fitted to wheeled agricultural or forestry tractors (75/322/EEC), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24)

Council Directive of 6 April 1976 on the approximation of the laws of the Member States relating to the braking devices of wheeled agricultural or forestry tractors (76/432/EEC), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24)

Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to passenger seats for wheeled agricultural or forestry tractors (76/763/EEC), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24)

Council Directive of 29 March 1977 on the approximation of the laws of the Member States relating to the driver-perceived noise level of wheeled agricultural or forestry tractors (77/311/EEC), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24)

Council Directive of 28 June 1977 on the approximation of the laws of the Member States relating to the roll-over protection structures of wheeled agricultural or forestry tractors (77/536/EEC), as last amended by Council Directive 89/680/EEC of 21 December 1989 (OJ L 398, 30/12/1989, p. 26)

Council Directive of 28 June 1977 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of pollutants from diesel engines for use in wheeled agricultural or forestry tractors (77/537/EEC), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24)

Council Directive of 25 July 1978 on the approximation of the laws of the Member States relating to the driver's seat on wheeled agricultural or forestry tractors (78/764/EEC), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24)

Council Directive of 17 October 1978 on the approximation of the laws of the Member States relating to the installation of lighting and light-signalling devices on wheeled agricultural and forestry tractors (78/933/EEC), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24)

Council Directive of 17 May 1979 on the approximation of the laws of the Member States relating to the component type-approval of lighting and light-signalling devices on wheeled agricultural or forestry tractors (79/532/EEC), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24)

Council Directive of 17 May 1979 on the approximation of the laws of the Member States relating to the coupling device and the reverse of wheeled agricultural or forestry tractors (79/533/EEC), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24)

Council Directive of 25 June 1979 on the approximation of the laws of the Member States relating to the roll-over protection structures of wheeled agricultural or forestry tractors (static testing) (79/622/EEC), as last amended by Commission Directive 88/413/EEC of 22 June 1988 (OJ L 200, 26/7/1988, p. 32)

Council Directive of 24 June 1980 on the approximation of the laws of the Member States relating to the operating space, access to the driving position and the doors and windows of wheeled agricultural or forestry tractors (80/720/EEC), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24)

Council Directive of 26 May 1986 on the approximation of the laws of the Member States relating to the power take-offs of wheeled agricultural and forestry tractors and their protection (86/297/EEC), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24)

Council Directive of 26 May 1986 on rear-mounted roll-over protection structures of narrow-track wheeled agricultural and forestry tractors (86/298/EEC), as last amended by Council Directive 89/682/EEC of 21 December 1989 (OJ L 398, 30/12/1989, p. 29)

	Council Directive of 24 July 1986 on the installation, location, operation and identification of the controls of wheeled agricultural or forestry tractors (86/415/EEC), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24) Council Directive of 25 June 1987 on roll-over protection structures mounted in front of the driver's seat on narrow-track wheeled agricultural and forestry tractors (87/402/EEC), as last amended by Council Directive 89/681/EEC of 21 December 1989 (OJ L 398, 30/12/1989, p. 27) Council Directive of 21 December 1988 on the approximation of the laws of the Member States relating to certain components and characteristics of wheeled agricultural or forestry tractors (89/173/EEC), as last amended by Directive 97/54/EC of the European Parliament and the Council of 23 September 1997 (OJ L 277, 10/10/1997, p. 24)
Switzerland	*Ordonnance du 19 juin 1995 concernant les exigences techniques requises pour les tracteurs agricoles* (RO 1995 4171) *Ordonnance du 19 juin 1995 sur la réception par type des véhicules routiers* (RO 1995 3997)

SECTION II

CONFORMITY ASSESSMENT BODIES

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the authorities responsible for type-approval, technical services and testing bodies.

European Community

Switzerland

Authority responsible for type approval
Swiss Federal Roads Office
CH-3003 Berne

SECTION III

DESIGNATING AUTHORITIES

European Community

-
- Austria: Bundesministerium für offentliche Wirtschaft und Verkehr
- Belgium: Ministère des Communications et de l'Infrastructure
  Ministerie van Verkeer en Infrastructuur
- Denmark: Road safety and Transport Agency
- Finland: Liikenneministeriö/Trafikministeriet
- France: Ministère des Transports
- Germany: Kraftfahrt-Bundesamt
- Greece: Ministry of Transport
- Ireland: Department of Enterprise and Employment
- Italy: Ministero dei Trasporti
- Luxembourg: Ministère des Transports

- Netherlands: Rijksdienst voor het Wegverkeer
- Portugal: Direcção-Geral de Viação
- Spain: Ministerio de Industría y Energía
- Sweden: Under the authority of the Government of Sweden;
  Styrelsen för ackreditering och teknisk kontroll (SWEDAC)
  Vägverket
  Statens Naturvardsverk (for emission aspects: directives 70/220/EEC, 72/306/EEC, 88/77/EEC and 77/537/EEC)
- United Kingdom: Vehicle Certification Agency

Switzerland Swiss Federal Roads Office

SECTION IV

SPECIAL RULES RELATING TO THE DESIGNATION OF CONFORMITY ASSESSMENT BODIES

For the designation of conformity assessment bodies, the designating authorities shall refer to their respective legislative, regulatory and administrative provisions as listed in section I.

SECTION V

SUPPLEMENTARY PROVISIONS

Information exchange

The competent Member State's and Swiss authorities shall notify each other of conforming (Art. 5 and 6, Directive 74/150/EEC) or non-conforming (Art. 8, Directive 74/150/EEC) vehicles, devices and systems placed on the market.

CHAPTER 14

GOOD LABORATORY PRACTICE (GLP)

SCOPE AND COVERAGE

The provisions of this Chapter shall apply to the testing of chemicals according to GLP, being either substances or preparations, covered by the legislative, regulatory and administrative provisions listed in section I**.** For the purposes of this Chapter the provisions of Article 4 of this Agreement concerning origin do not apply.

Unless specific definitions are given, the definition of terms in the "OECD Principles of Good Laboratory Practice" [Appendix II to OECD Council Decision of 12 May 1981 C(81)30(Final)], the "Guides for Compliance Monitoring Procedures for Good Laboratory Practice" [Appendix I to Council Decision-Recommendation of 2 October 1989 C(89)87(Final)] and GLP Consensus documents, OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, and all amendments made thereto, shall apply.

The Parties recognise the equivalence of each other's compliance monitoring programmes on Good Laboratory Practice that are in accordance with the OECD decisions and recommendations mentioned above and the legislative, regulatory and administrative procedures and principles listed in section IV.

The Parties mutually accept studies and data generated therefrom, produced by the test facilities of the other Party listed in section II provided they participate in the Good Laboratory Practice compliance monitoring programme of that Party in accordance with the principles and provisions stated above.

The Parties mutually accept the conclusions of study audits and test facility inspections performed by the monitoring authorities referred to in section III.

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

With regard to the testing of chemicals according to GLP, the relevant parts of the legislative, regulatory and administrative provisions listed below shall apply.

Provisions covered by Article 1 paragraph 1

European Community	<u>Feed additives</u> Council Directive of 18.4.83 on the fixing of guidelines for the assessment of certain products used in animal nutrition (83/228/EEC) (OJ L 126, 13/05/1983, p. 23), as subsequently amended Council Directive of 16.2.87 fixing guidelines for the assessment of additives in animal nutrition (87/153/EEC) (OJ L 64, 07/02/1987, p. 19), as subsequently amended

Foodstuff:
Council Directive of 14.6.89 on the official control of foodstuffs (89/397/EEC) (OJ L 186 of 30.06.1989, p. 23), as subsequently amended

Council Directive of 29.10.93 on the subject of additional measures concerning the official control of foodstuffs (93/99/EEC) (OJ L 290 of 24.11.1993, p. 14) as subsequently amended

Cosmetics:
Council Directive of 14.6.93 amending for the sixth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (93/35/EEC) (OJ L 151, 23.06.1993, p. 32) as subsequently amended

Switzerland No GLP-relevant legislation

Provisions covered by Article 1 paragraph 2

European Community

New and Existing Chemicals:
Council Directive of 18.12.86 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 (87/18/EEC) (OJ L 15, 17.01.1987, p. 29)

Council Directive of 30.4.92 amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (92/32/EEC) (OJ L 154, 5/6/1992, p. 1)

Council Directive of 7.6.88 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (88/379/EEC) (OJ L 187, 16/7/1988, p. 14)

Council Regulation of 23.3.93 on the evaluation and control of the risks of existing substances (No 793/93/EEC) (OJ L 84, 5/4/1993, p. 1)

Medicinal products:
Council Directive of 22.12.86 amending Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products (87/19/EEC) (OJ L 15, 17/1/1987, p. 31)

Council Directive of 22.12.86 amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (87/21/CEE) (OJ L 15 of 17/1/1987, p. 36)

Commission Directive of 19.7.91 modifying the Appendix to Council Directive 75/318/EEC on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products (91/507/EEC) (OJ L 270 of 26/9/1991, p. 32)

Veterinary Drugs:
Council Directive of 22.12.86 amending Directive 81/852/CEE on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products (87/20/EEC) (OJ L 15 of 17/1/1987, p. 34)

Commission Directive of 20 March 1992 modifying the Annex to Council Directive 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products (92/18/EEC) (OJ L 97 of 10/04/92, p.1)

Plant Protection Products:
Council Directive of 15.7.91 concerning the placing of plant protection products on the market (91/414/EEC) (OJ L 230 of 19/8/1991, p. 1)

Commission Directive of 27.7.93 amending Council Directive 91/414 concerning the placing of plant protection products on the market (93/71/EEC) (OJ L 221 of 31/8/1993, p. 27)

Commission Directive of 14.7.95 amending Council Directive 91/414/EEC concerning the placing on the market of plant protection products (95/35/EC) (OJ L 172 of 22/7/1995, p. 6)

Switzerland:

Federal law of 7 October 1983 on the protection of the environment (RO 1984 1122) as last amended on 21 December 1995 (RO 1997 1155)
Ordinance of 9 June 1986 relating to dangerous substances for the environment (RO 1986 1254) as last amended on 4 November 1998 (RO 1999 39)

Federal law of 21 March 1969 on trade in toxic substances (RO 1972 430) as last amended on 21 December 1995 (RO 1997 1155)
Ordinance of 19 September 1983 relating to toxic substances (RO 1983 1387) as last amended on 4 November 1998 (RO 1999 56)
Regulations of 25 May 1972 for the implementation of the intercantonal convention on the control of medicines, as last amended on 23 November 1995

SECTION II

CONFORMITY ASSESSMENT BODIES

For the purpose of this Sectoral Chapter, "Conformity Assessment Bodies" means the test facilities recognised under each Party's GLP monitoring programme.

On the basis of information provided by the Parties according to Section V of this Chapter, the Committee referred to in Article 10 of this Agreement shall establish and keep up to date, according to the procedure described in Article 11 of this Agreement, a list of the test facilities that have been found to be in conformity with the GLP principles.

SECTION III

DESIGNATING AUTHORITIES

For the purpose of this Sectoral Chapter, "Designating Authorities" means the official GLP Monitoring Authorities of the Parties.

European Community:

- Austria
  Bundesministerium für Umwelt, Jugend und Familie
  Department II/2
  Stubenbastei 5 — All products
  A-1010 WIEN

- Belgium
  Ministère de la santé publique, de l'environnement et de l'intégration sociale. Inspection pharmaceutique
  Ministerie van Volksgezondheid, Leemilieu en Sociale Integratie. Farmaceutishce Inspectie
  Rue Juliette Wytsmanstraat 14 — All products
  1050 Bruxelles

- Denmark

Danish Agency of Industry and Trade Tagensvej 137 DK-220 Copenhagen N	Industrial chemicals and pesticides
Danish Medicines Agency 378, Frederikssundsvej DK-2700 Bronshoj	Pharmaceuticals

- Finland

Sossiali-ja terveydenhuollon tuotevalvontakeskus/kemikaaliosasto social-och hälsovårdens produuttillsynscentral/kemikalieavdelning	
PL 267 Box 00531 Helsinki	All products

- France

Groupe Interministériel des produits chimiques (GIPC)	
3/5 Rue Barbet de Jouy 75353 Paris 07 SP	Industrial chemicals, pesticides and products other than veterinary products
Agence du Médicament 143/147 Boulevard Anatole France 93200 Saint Denis	Pharmaceuticals other than veterinary products
Ministère de la Santé, Direction Générale de la Santé, Sous-direction pharmacie 1, place de Fontenoy 75350 Paris 07 SP	Cosmetics

CNEVA, Agence de médicament vétérinaire,
service inspections et contrôles
BP 203 — Veterinary products
35302 Fougères Cedex

- Germany
  Bundesministerium für Umwelt, Naturschutz
  und Reaktorsicherheit
  Kennedyallee 5 — All products
  DE-53175 Bonn

- Greece
  General Chemical State Laboratory
  An Tsoha Street 16 — All products
  11521 Athens

- Ireland
  Irish Laboratory Accreditation Board
  (ILAB)
  Wilton Park House — All products
  Wilton Place
  Dublin 2

- Italy
  Ministero della Sanita
  Dipartimento della Prevenzione
  GLP Compliance Monitoring Unit
  Via della Sierra Nevada 60 — All products
  I-00144 Roma

- Netherlands
  Ministry of Health, Welfare and Sports.
  Inspectorate for Health Protection,
  Commodities and Veterinary Public Health.
  GLP Department — All products
  P.O. Box 16.108
  NL-2500 BC's Gravenahage

- Portugal
  Instituto Português da Qualidade
  Ministério da Indústria e Comércio
  Rua C à Av. dos Três Vales — Industrial chemicals and pesticides
  2825 Monte da Caparica

  Instituto Nacional de Farmacia e do Medicamento.
  Parque de Saúde de Lisboa
  Avenida do Brasil 53 — Pharmaceuticals and veterinary drugs
  1700 Lisboa

- Spain
  Ministerio de Sanidad y Consumo
  Agencia Española de Medicamento
  Subdirección General de Seguridad
  de los Medicamentos
  Paseo del Prado, 18-20 — Pharmaceuticals and cosmetics
  28014 Madrid

- Sweden
  Läkemedelsverket (Medical Products Agency)
  Box 26 — Pharmaceuticals and hygiene and
  751 03 Uppsala — cosmetic products

Styrelsen för ackreditering och teknisk kontroll (SWEDAC) Box 2231 103 15 Stockholm	For all other products

- United Kingdom

Department of Health GLP Monitoring Authority Hannibal House Market Towers 1, Nine Elms Lane London SW8 5NQ	All products

- **Switzerland** :

Federal Office of Environment, Forests and Landscape CH-3003 Berne	Environmental studies on all products
Intercantonal Office for the Control of Medicines Erlachstrasse 8 P.O. Box CH-3000 Berne 9	Health studies on pharmaceutical products
Federal Office of Public Health Chemicals division CH-3003 Berne	Health studies on all products except pharmaceuticals

SECTION IV

SPECIAL PRINCIPLES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

For the purpose of this Sectoral Chapter, "designation of conformity assessment bodies" means the procedure by which the GLP Monitoring Authorities recognise that test facilities comply with the GLP principles. To this end they shall apply the principles and procedures of their provisions listed below, that are recognised to be equivalent and in conformity with the aforementioned OECD Council Acts C(81)30 Final and C(89)87 (Final):

European Community:	Council Directive of 18.12.86 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 (87/18/EEC) (OJ L 15, 17/1/1987, p. 29) Council Directive of 9.6.88 on the inspection and verification of Good Laboratory Practice (GLP) (88/320/EEC) (OJ L 145, 11/6/1988, p. 35) Commission Directive of 18.12.89 adapting to technical progress the Appendix of Council Directive 88/320/EEC on the inspection and verification of good laboratory practice (GLP) (90/18/EEC) (OJ L 11, 13/1/1990, p. 37)
Switzerland:	Federal law of 7 October 1983 on the protection of the environment (RO 1984 1122) as last amended on 21 December 1995 (RO 1197 1155) Ordinance of 9 June 1986 relating to dangerous substances for the environment (RO 1986 1254) as last amended on 4 November 1998 (RO 1999 39) Federal law of 21 March 1969 on trade in toxic substances (1972 435) as last amended on 21 December 1995 (RO 1197 1155) Ordinance of 19 September 1983 relating to toxic substances (RO 1983 1387) as last amended on 4 November 1998 (RO 1999 56) Regulations of 25 May 1972 for the implementation of the intercantonal convention on the control of medicines, as last amended on 23 November 1995 Good Laboratory Practice (GLP) in Switzerland, Procedures and Principles, DFI/IKS, March 1986

SECTION V

ADDITIONAL PROVISIONS

1. Information exchange

In accordance with Article 12 of this Agreement, the Parties in particular provide each other at least annually with a list of the test facilities which, in the light of the results of the inspections and study audits, conform to Good Laboratory Practice, as well as of the dates of inspection or audit and their compliance status.

In accordance with Article 6 of the Agreement, the Parties shall inform each other in a timely manner when a test facility coming under the terms of section II of this sectoral Chapter which states that it applies Good Laboratory Practice fails to conform to such practice to an extent which may jeopardise the integrity or authenticity of any such studies it conducts.

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

2. Test Facility Inspections

Each Party may request further test facility inspection or study audits if there is a documented doubt as to whether a test was conducted in accordance with Good Laboratory Practice.

If, in exceptional cases, doubts persist and the requesting Party can justify special concern, it may, in accordance with Article 8 of the Agreement, designate one or more experts of its authorities listed in section III to participate in a laboratory inspection or the audit of a study conducted by the authorities of the other Party.

3. Confidentiality

In conformity with Article 13 of the Agreement, the Parties shall keep confidential any information brought to their knowledge pursuant to this Sectoral Chapter or that came to their knowledge in the framework of participation in an inspection or study audit and which falls within the definition of a trade secret or confidential commercial or financial information. They shall treat such information with at least the same confidentiality as that accorded to it by the providing Party and ensure that any authority to whom the information is transmitted treats it in the same way.

4. Cooperation

Based on Article 9 of the Agreement, each Party may, on request, participate as an observer in an inspection of a test facility conducted by the authorities of the other Party with the consent of the test facility concerned in order to maintain a continuing understanding of the other Party's inspection procedures.

CHAPTER 15

MEDICINAL PRODUCTS GMP INSPECTION AND BATCH CERTIFICATION

SCOPE AND COVERAGE

The provisions of this Sectoral Chapter cover all medicinal products which are industrially manufactured in Switzerland or the European Community, and to which Good Manufacturing Practice (GMP) requirements apply.

For medicinal products covered by this Chapter, each party shall recognise the conclusions of inspections of manufacturers carried out by the relevant inspection services of the other Party and the relevant manufacturing authorisations granted by the competent authorities of the other Party.

The manufacturer's certification of the conformity of each batch to its specifications shall be recognised by the other Party without recontrol at import.

In addition, official batch releases carried out by an authority of the exporting Party will be recognised by the other Party.

"Medicinal products" means all products regulated by pharmaceutical legislation in the European Community and Switzerland as listed in Section I of this Chapter. The definition of medicinal products includes all human and veterinary products, such as chemical and biological pharmaceuticals, immunologicals, radio-pharmaceuticals, stable medicinal products derived from human blood or human plasma, pre-mixes for the preparation of veterinary medicated feedingstuffs and, where appropriate, vitamins, minerals, herbal remedies and homeopathic medicinal products.

"GMP" is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation and products specifications. For the purpose of this Chapter it includes the system whereby the manufacturer receives the specification of the product and the process from the marketing authorisation holder or applicant and ensures that the medicinal product is made in compliance with this specification (Equivalent to "Qualified Person" for certification in the EC).

With respect to medicinal products covered by the legislation of one Party but not the other, the manufacturing company can request, for the purpose of this Agreement, an inspection be made by the locally competent inspection service. This provision shall apply i.a. to the manufacture of active pharmaceutical ingredients, intermediate products and investigational medicinal products, as well as to pre-marketing inspections. Operational arrangements are detailed under section III, paragraph 3.

Certification of manufacturers

At the request of an exporter, importer or the competent authority of the other Party, the authorities responsible for granting manufacturing authorisations and for supervision of the manufacture of medicinal products shall certify that the manufacturer:

– is appropriately authorised to manufacture the relevant medicinal product, or to carry out the relevant specified manufacturing operation

– is regularly inspected by the authorities

– complies with the national GMP requirements recognised as equivalent by the two parties, and which are listed in Section I of this Chapter. Should different GMP requirements be used as reference, this is to be mentioned in the certificate.

The certificates shall also identify the site(s) of manufacture (and contract quality control laboratories, if any).

Certificates shall be issued expeditiously, and the time taken should not exceed thirty calendar days. In exceptional cases, i.a. when a new inspection has to be carried out, this period may be extended to sixty days.

Batch certification

Each batch exported shall be accompanied by a batch certificate established by the manufacturer (self-certification) after a full qualitative analysis, a quantitative analysis of all the active ingredients and all the other tests or checks necessary to ensure the quality of the product in accordance with the requirements of the marketing authorisation. This certificate shall attest that the batch meets its specifications and shall be kept by the importer of the batch. It will be made available upon request of the competent authority.

When issuing a certificate, the manufacturer shall take account of the provisions of the current WHO certification scheme on the quality of pharmaceutical products moving in international commerce. The certificate shall detail the agreed specifications of the product, the reference of the analytical methods and the analytical results. It shall contain a statement that the batch processing and packaging records were reviewed and found in conformity with GMP. The batch certificate shall be signed by the person responsible for releasing the batch for sale or supply, i.e. in the European Community the "qualified person" referred to in Article 21 of Directive 75/319/EEC, and in Switzerland the responsible person referred to in Articles 4 and 5 of the Ordinance on immunobiological products, Articles 4 and 5 of the Ordinance on immunobiological products for veterinary use and Article 10 of the Directives of the IOCM on the manufacture of medicinal products.

Official Batch Release

When an official batch release procedure applies, official batch releases carried out by an authority of the exporting Party (listed in section II) will be recognised by the other Party. The manufacturer shall provide the certificate of the official batch release.

For the Community, the official batch release procedure is specified in document "Control/Authority Batch Release of Vaccination and Blood Products of 24 September 1998" and different specific batch release procedures. For Switzerland, the official batch release procedure is specified in Articles 22-27 of the Ordinance on immunobiological products, Articles 20-25 of the Ordinance on immunobiological products for veterinary use and Articles 4-6 of the Directives of the IOCM on the Authority Batch Release.

SECTION I

With regard to GMP, the relevant parts of the legislative, regulatory and administrative provisions listed below apply. However, the reference quality requirements of products to be exported, including their manufacturing method and product specifications, shall be those of the relevant marketing authorisation granted by the competent authority of the importing Party.

Provisions covered by Article 1 paragraph 2

European Community	Council Directive of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (65/65/EEC) as last amended by Council Directive 93/39/EEC of June 14, 1993 (OJ L 214, 24.8.1993, p.22)

Council Directive of 20 May 1975 on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products (76/319/EEC) as last amended by Council Directive 89/341/EEC of May 3, 1989 (OJ L 142, 25.5.1989, p.11)

Council Directive of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products (81/851/EEC) as last amended by Council Directive 90/676/EEC of December 13, 1990 (OJ L 373, 31.12.1990, p.15)

Commission Directive of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use (91/356/EEC) (OJ L 193, 17.7.1991, p.30)

Commission Directive of July 23, 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (91/412/EEC) (OJ L 228, 17.8.1991, p.70)

Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, as last amended by Commission Regulation (EC) No 649/98 of 23 March 1998 (OJ L 88, 24.3.1998, p.7)

Council Directive of March 31, 1992 on the wholesale distribution of medicinal products for human use (92/25/EEC) (OJ L 113, 30.4.1992. p.1) and Guide to Good Distribution Practice

Guide to Good Manufacturing Practice Volume IV of Rules Governing Medicinal Products in the European Community.

Switzerland	Federal law of October 6, 1989 on the pharmacopoeia (RO 1990 570) Ordinance of August 23, 1989 on immunobiological products (RO 1989 1797), as last amended on 24 February 1993 (RO 1993 963) Ordinance of June 22, 1994 on radioprotection (RO 1994 1947) Federal Decree of 22 March 1996 on the control of blood, blood products and transplants (RO 1996 2296) Ordinance of 26 June 1996 on the control of blood, blood products and transplants (RO 1996 2309) Federal Law of 1 July 1966 on epizootics (RO 1966 1621) Ordinance of June 27, 1995 on immunobiological products for veterinary use (RO 1995 3805) Intercantonal Convention of June 3, 1971 on the control of medicines (RO 1972 1026), as last amended on 1 January 1979 (RO 1979 252) Regulations of 25 May 1972 for the implementation of the intercantonal convention on the control of medicines, as last amended on on May 14, 1998 Directives of May 18, 1995 of the Intercantonal Office for the Control of Medicines (IOCM) on the manufacture of medicinal products IOCM Directives of May 23, 1985 on the manufacture of active pharmaceutical ingredients IOCM Directives of May 20, 1976 for the wholesale of medicines IOCM Directives of November 24, 1994 on the Authority Batch Release IOCM Directives of May 19, 1988 on the manufacture and distribution of medicated feeding stuff IOCM Directives of November 19, 1998 for the Inspection of Manufacturers of Medicinal Products (Inspection Directives)

SECTION II

CONFORMITY ASSESSMENT BODIES

For the purpose of this Chapter "Conformity Assessment Bodies" means the official GMP inspection services of each Party.

European Community

Germany
Bundesministerium für Gesundheit
Am Propsthof 78a
D-53108 Bonn
Tel.: 49-228-941 2340
Fax.: 49-228-941 4923

for immunologicals:
Paul-Ehrlich-Institut, Federal Agency for Sera & Vaccines
Postfach/P.O. Box
D-63207 Langen
Tel.: 49-6103-77 1010
Fax.: 49-6103-77 12 34

Austria
Bundesministerium für Gesundheit und Konsumentenschuzt
Radetzkystrasse 2
A-1031 Wien
Tel.: 43-1-711 724 642
Fax.: 43-1-714 92 22

Belgium
Inspection générale de la Pharmacie/Algemene Farmaceutische Inspectie
Cité administrative de l'Etat/Rijksadministratief Centrum
Quartier Vésale/Vesalius Gebouw
B-1010 BrusselTel.: 32-2-210 4924
Fax.: 32-2-210 4880

Denmark
Sundhedsstyrelsen Medicines Division
Frederikssundsvej 378
DK-2700 Bronshoj
Tel.: 45-44-889 320
Fax.: 45-42-847 077

Spain
Ministerio de Sanidad y Consumo
Subdirección General de Control Farmaceutico
Paseo del Prado 18-20
E-28014 Madrid
Tel. :34-1-596 4068
Fax. :34-1-596 4069

Finland
National Agency for Medicines
P.O. Box 278
FIN-00531 Helsinki Tel.: 358-0-396 72 112
Fax.: 358-0-714 469

France
for medicinal products for human use
Agence du Médicament
143-145 boulevard Anatole France
F-93200 Saint-Denis
Tel.: standard 4813 2000
Fax.: 33-1-4813 2478

for veterinary medicinal products
Agence Nationale du Médicament Véterinaire la haute Marche - Javené
F-35133 Fougères
Tel.:+33-9994 7878
Fax.:+33-9994 7899

Greece
National Drug Organization (E.O.F.)
Mesogion 284
GR-Athens 15562
Tel.: 30-1-654 5530
Fax.: 30-1-654 9591

Ireland
National Drugs Advisory Board
63-64 Adelaide Road
IRL-Dublin 2
Tel.: 353-1-676 4971-7
Fax.: 353-1-676 7836

Italy
Ministero della Sanità
Direzione Generale del Servicio Farmaceutico
Viale della Civiltà Romana 7
I-00144 Roma
Tel.: 39-6-5994 3676
Fax.: 39-6-5994 3365

Luxembourg
Division de la Pharmacie et des Médicaments
10 rue C.M. Spoo
L-2546 Luxembourg
Tel.: 352-478 5590 / 93
Fax.: 352-22 44 58

Netherlands
Ministerie van Volksgezondheid, Welzijn, en Sport
Inspectie voor de Gezondheidszorg
Postbus 5406
NL-2280 HK Rijswijk
Tel.: 31-70-3407911
Fax.: 31-70-3405177

Portugal
Instituto Nacional da Farmácia e do Medicamento -
INFARMED
Av. do Brasil, 53
P-1700 Lisboa
Tel.: 351-1-795
Fax.: 351-1-795 9116

United Kingdom
for human and veterinary (non immunologicals):
Medicines Control Agency
1 Nine Elms Lane
GB-London SW8 5NQ
Tel.: 44-171-273 0500
Fax.: 44-171-273 0676

for veterinary immunologicals
Veterinary Medicines Directorate
Woodham Lane
New Haw, Addlestone
GB-Surrey KT15 3NB
Tel.: 44-1932-336911
Fax.: 44-1932-336618

Sweden
Läkemedelsverket - Medical Products Agency
Husargatan 8,
P.O. Box 26
S-751 03 Uppsala
Tel.: 46-18-174 600
Fax.: 46-18-548 566

Switzerland

Swiss Federal Office of Public Health, Division of Biologicals, Berne (for immunobiological products for human use)

Institute for Virology and Immunoprophylaxis, Research Station of the Swiss Federal Veterinary Office, 3147 Mittelhäusern (for immunobiological products for veterinary use)

Intercantonal Office for the Control of Medicines, 3000 Berne 9 (for all other medicinal products for human and veterinary use)

SECTION III

ADDITIONAL PROVISIONS

1. Transmission of inspection reports

Upon reasoned request, the relevant inspection services shall forward a copy of the last inspection report of the manufacturing site or, in case analytical operations are contracted out, of the control site. The request may concern a "full inspection report" or a "detailed report" (see item 2 below). Each party shall deal with these inspection reports with the degree of confidentiality requested by the providing Party.

Parties will ensure that inspection reports are forwarded in no more than thirty calendar days, this period being extended to sixty days should a new inspection be carried out.

2. Inspection reports

A "full inspection report" comprises a Site Master File (compiled by the manufacturer or by the inspectorate) and a narrative report by the inspectorate. A "detailed report" responds to specific queries about a firm by the other Party.

3. GMP Reference

(a) Manufacturers shall be inspected against the applicable GMP of the exporting party (see section I).

(b) With respect to medicinal products covered by the pharmaceutical legislation of the importing Party but not the exporting one, the locally competent inspection service willing to carry out an inspection of the relevant manufacturing operations shall inspect against its own GMP or, in the absence of specific GMP requirements, against the applicable GMP of the importing Party.

For specific products or classes of products (e.g. investigational medicinal products, starting materials not limited to active pharmaceutical ingredients), equivalence of GMP requirements shall be determined according to a procedure established by the Committee.

4. Nature of inspections

(a) Inspections shall routinely assess the compliance of the manufacturer with GMP. These are called general GMP inspections (also regular, periodic, or routine inspections).

(b) "Product- or process-oriented" inspections (which may be "pre-marketing" inspections as relevant) focus on the manufacture of one or a series of product(s) or process(es) and include an assessment of the validation of and compliance with specific process or control aspects as described in the marketing authorisation. Where necessary, relevant product information (the quality dossier of an application/authorisation dossier) shall be provided in confidence to the inspectorate.

5. Fees

The regime of inspection/establishment fees is determined by the manufacturer's location. Inspection/establishment fees shall not be charged to manufacturers located on the territory of the other Party.

6. Safeguard clause for inspections

Each Party reserves the right to have its own inspection conducted for reasons identified to the other Party. Such inspections are to be notified in advance to the other Party and shall, in accordance with Article 8 of the Agreement, be carried out jointly by the competent authorities of the two Parties. Recourse to this safeguard clause should be an exception.

7. Exchange of information between authorities and approximation of quality requirements

In accordance with the general provisions of the Agreement, the parties shall exchange any information necessary for the mutual recognition of inspections.

The relevant authorities in Switzerland and in the Community shall also keep each other informed of any new technical guidance or inspection procedure. Each party shall consult the other before their adoption and shall endeavour to proceed towards their approximation.

8. Inspectors training

In accordance with Article 9 of the Agreement, training sessions for inspectors, organised by the authorities, shall be accessible to inspectors of the other Party. The Parties to the Agreement shall keep each other informed on these sessions.

9. Joint Inspections

In accordance with Article 12 of the Agreement, and by mutual agreement between the Parties, joint inspections may be organised. These inspections are intended to develop common understanding and interpretation of practice and requirements. The setting up of these inspections and their form shall be agreed through procedures approved by the Committee established under Article 10 of the Agreement.

10. Alert system

Contact points shall be agreed between both Parties to permit authorities and manufacturers to inform the authorities of the other Party with the appropriate speed in case of quality defect, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the batch. A detailed alert procedure shall be agreed.

The Parties shall ensure that any suspension or withdrawal (total or partial) of a manufacturing authorisation, based on non-compliance with GMP and which could have public health implications, are communicated to each other with the appropriate degree of urgency.

11. Contact points

For the purpose of this Agreement, the contact points for any technical question, such as exchanges of inspection reports, inspectors training sessions, technical requirements, are:

for the EC

the Director of the European Agency for the Evaluation of Medicinal Products and

for Switzerland

the official GMP inspection services listed in Section II above.

12. Divergence of views

Both Parties shall use their best endeavours to resolve any divergence of views concerning *inter alia* compliance of manufacturers and conclusions of inspection reports. Unresolved divergences of view will be referred to the Committee as established under Article 10 of the Agreement.

Annex 2

General rules regarding the designation of conformity assessment bodies

A. General terms and conditions

1. Under this Agreement, the designating authorities shall remain solely responsible for the competence and the capacity of the bodies they have designated and shall designate only legally identifiable bodies under their jurisdiction.

2. Designating authorities shall designate conformity assessment bodies able to demonstrate by objective means that they understand and have the requisite experience and competence to apply the requirements and certification procedures laid down in the legislative, regulatory and administrative provisions referred to in Annex I, that are applicable to the specific product, product category or sector for which they are designated.

3. Demonstration of technical competence shall cover:

   – the conformity assessment body's technical knowledge of the relevant products, processes or services which it is willing to treat;

   – the understanding of the technical standards and/or legislative, regulatory and administrative provisions for which designation is sought;

   – the physical capability to perform a given conformity assessment activity;

   – the adequate management of the activity concerned; and

   – any other circumstance necessary to give assurance that the conformity assessment activity will be adequately performed at all times.

4. The technical competence criteria shall be based as far as possible on internationally accepted documents, such as the EN 45000 series of standards or equivalents as well as on supplemented interpretative documents as appropriate. However these documents clearly need to be interpreted in such a way as to take account of the different types of requirements laid down in the applicable legislative, regulatory and administrative provisions.

5. The Parties shall encourage harmonisation of designation procedures and coordination of conformity assessment procedures through cooperation between designating authorities and conformity assessment bodies based on coordination meetings, participation in mutual recognition arrangements, and *ad hoc* working party meetings. The Parties shall also encourage accreditation bodies to participate in mutual recognition arrangements.

B. System for verification of conformity assessment bodies' competence

6. In order to verify the technical competence of conformity assessment bodies, the authorities concerned may use various procedures ensuring an appropriate level of trust between the Parties. If necessary, a Party shall indicate to the designating authority possible ways of demonstrating competence.

(a) Accreditation

Accreditation shall constitute a presumption of the technical competence of conformity assessment bodies in relation to the application of the requirements of the other Party provided that the competent accreditation body:

- complies with the relevant international provisions in force (EN 45000 standards or ISO/IEC guides); and
- is signatory to multilateral arrangements under which it is subject to peer evaluation, or
- takes part, under the authority of a Designating Authority, and in accordance with whatever conditions are decided on, in programmes to conduct comparisons and exchange technical experience, in the interests of ensuring continued trust in the technical competence of the accreditation and conformity-assessment bodies. Such programmes could include joint evaluations, special cooperation exercises or conformity assessment.

Where the criteria applicable to conformity assessment bodies require the latter to assess the conformity of products, processes or services directly to standards or technical specifications, the designating authorities may use accreditation as a presumption of the conformity assessment body's technical competence provided that it enables assessment of those bodies' ability to apply such standards or technical specifications. Designation shall be limited to those activities of the conformity assessment body.

Where the criteria applicable to conformity assessment bodies require the latter to assess the conformity of products, processes or services not directly to standards or technical specifications, but to general (essential) requirements, the designating authorities may use accreditation as a presumption of the conformity assessment body's technical competence provided that it incorporates elements which will enable assessment of the capacity of the conformity assessment body (technical knowledge of the product, of its use, etc.) to assess the conformity of the product to those essential requirements. Designation shall be limited to those activities of the conformity assessment body.

(b) Other means

If there is no accreditation scheme, or on other grounds, the authorities concerned shall require the conformity assessment bodies to demonstrate their competence by other means, e.g.:

- participation in regional or international mutual recognition arrangements or certification systems;
- regular peer evaluation, based on clear criteria and conducted with the appropriate expertise;
- aptitude tests; or
- comparison of conformity assessment bodies.

C. Evaluation of the verification system

7. Once a verification system to evaluate the competence of conformity assessment bodies has been defined, the other Party will be invited to check that the system guarantees the conformity of the designation process to its own legal requirements. Such checks shall focus on the appropriateness and effectiveness of the verification system rather than on the conformity assessment bodies themselves.

D. Formal designation

8. When the Parties submit their proposals to the Committee on the inclusion of conformity assessment bodies in the Annexes, they shall provide the following details in respect of each body:

(a) its name;

(b) its postal address;

(c) its fax number;

(d) the Sectoral Chapter, product categories or products, processes and services covered by the designation;

(e) the conformity assessment procedures covered by the designation;

(f) the methods used to establish the body's competence.

FINAL ACT

The plenipotentiaries

of the "EUROPEAN COMMUNITY",

and

of the SWISS CONFEDERATION,

meeting on the twenty-first day of June in the year one thousand nine hundred and ninety-nine in Luxembourg for the signature of the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment have adopted the Joint Declarations mentioned below and attached to this Final Act:

Joint Declaration by the Contracting Parties on the revision of Article 4,

Joint Declaration on the mutual recognition of good clinical practice and inspections relating thereto,

Joint Declaration by the Contracting Parties on updating the Annexes,

Joint Declaration on further negotiations.

They also took note of the following Declaration annexed to this Final Act:

Declaration on Swiss attendance of Committees,

Done at Luxembourg, on the twenty-first day of June in the year one thousand nine hundred and ninety-nine.

JOINT DECLARATION BY THE CONTRACTING PARTIES ON THE REVISION OF ARTICLE 4

The Contracting Parties undertake to revise Article 4 of the Agreement on mutual recognition in relation to conformity assessment to include in particular products originating in other countries with which the Parties conclude agreements on mutual recognition in relation to conformity assessment, once such agreements have been concluded.

At that point the provisions of Chapter 12 in Section V of this Agreement will be revised.

JOINT DECLARATION ON THE MUTUAL RECOGNITION OF GOOD CLINICAL PRACTICE AND INSPECTIONS RELATING THERETO

For medicinal products, the results of clinical trials carried out on the territory of the Parties to this Agreement are currently accepted for inclusion in applications for marketing authorisations and their variations or extensions. In principle, the Parties agree to continue to accept these clinical trials for the purpose of marketing authorisations applications. They agree to work towards an approximation of Good Clinical Practice, namely by implementing the current Declarations of Helsinki and Tokyo and all guidance relevant to clinical trials adopted in the framework of the International Conference on Harmonisation. However, due to legislative developments concerning inspections and authorisations of clinical trials in the European Community, detailed arrangements for the mutual recognition of the official supervision of these trials will have to be considered in the near future and laid down in a specific Chapter.

JOINT DECLARATION BY THE CONTRACTING PARTIES ON UPDATING THE ANNEXES

The Contracting Parties undertake to update the Annexes to the Agreement on mutual recognition in relation to conformity assessment not later than one month after its entry into force.

JOINT DECLARATION ON FURTHER NEGOTIATIONS

The European Community and the Swiss Confederation declare their intention of undertaking negotiations to conclude agreements in areas of common interest such as the updating of Protocol 2 to the 1972 Free Trade Agreement and Swiss participation in certain Community training, youth, media, statistical and environmental programmes. Preparatory work for these negotiations should proceed rapidly once the current bilateral negotiations have been concluded.

DECLARATION ON SWISS ATTENDANCE OF COMMITTEES

The Council agrees that Switzerland's representatives may, in so far as the items concern them, attend meetings of the following committees and expert working parties as observers:

- Committees of research programmes, including the Scientific and Technical Research Committee (CREST)
- Administrative Commission on Social Security for Migrant Workers
- Coordinating Group on the mutual recognition of higher-education diplomas
- Advisory committees on air routes and the application of competition rules in the field of air transport.

Switzerland's representatives shall not be present when these committees vote.

In the case of other committees dealing with areas covered by these agreements in which Switzerland has adopted either the *acquis communautaire* or equivalent measures, the Commission will consult Swiss experts by the method specified in Article 100 of the EEA Agreement.