

EUROPEAN COMMISSION

> Brussels, 13.6.2025 COM(2025) 308 final

ANNEX 4

ANNEX

to the

Proposal for a Council Decision

on the signing, on behalf of the European Union, of a broad package of agreements to consolidate, deepen and expand the bilateral relations with the Swiss Confederation, and on the provisional application of the Agreement on the terms and conditions for the participation of the Swiss Confederation in the European Union Agency for the Space Programme AMENDING PROTOCOL TO THE AGREEMENT BETWEEN THE EUROPEAN COMMUNITY AND THE SWISS CONFEDERATION ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT

THE EUROPEAN UNION, hereinafter referred to as the "Union"

and

THE SWISS CONFEDERATION, hereinafter referred to as "Switzerland",

hereinafter referred to as the "Contracting Parties";

HAVING REGARD to the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment, done in Luxembourg on 21 June 1999, which entered into force on 1 June 2002 (hereinafter referred to as "the Agreement");

WHEREAS a broad bilateral package, including the Institutional Protocol to this Agreement, has been agreed between the Contracting Parties in order to stabilise and develop mutual relations in the fields related to the internal market in which Switzerland participates;

WHEREAS, in the framework of that broad bilateral package, it is necessary to update certain provisions of the Agreement,

HAVE AGREED AS FOLLOWS:

ARTICLE 1

Amendments to the Agreement

The Agreement is amended as follows:

(1) Article 1 is replaced by the following text:

"ARTICLE 1

Purpose

1. The Community and Switzerland hereby grant mutual acceptance of reports, certificates, authorisations and conformity marks issued by the bodies recognised in accordance with the procedures of this Agreement (hereinafter "recognised conformity assessment bodies") and of the manufacturer's declarations of conformity certifying conformity to the requirements of the other Party with regard to products under Chapter 11, Section I, point A of Annex 1 at the time of entry into force of the amending Protocol to this Agreement.

2. In order to avoid duplication of procedures, the Community and Switzerland shall mutually accept reports, certificates and authorisations issued by recognised conformity assessment bodies 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 indicate conformity with the Community legislation and may refer to the corresponding Swiss provisions adopted or maintained pursuant to Article 5(2) of the Institutional Protocol. Conformity marks required by the legislation of one of the Parties shall be affixed to products placed on the market of that Party.";

(2) Article 3 is replaced by the following text:

"ARTICLE 3

Scope

1. This Agreement covers the obligatory conformity assessment procedures ensuing from the legislative, regulatory and administrative provisions listed in Annex 1 and as regards provisions covered by Article 1(2), the corresponding Swiss provisions adopted or maintained in accordance with Article 5(2) of the Institutional Protocol.

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.";

(3) Article 9 is replaced by the following text:

"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 and as regards provisions covered by Article 1(2), the corresponding Swiss provisions adopted or maintained in accordance with Article 5(2) of the Institutional Protocol.

2. The designating authorities shall ascertain by appropriate means whether the recognised conformity assessment bodies under their jurisdiction 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 recognised conformity assessment bodies 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. The designating authorities shall use their best endeavours to ensure that recognised conformity assessment bodies cooperate in an appropriate way.";

(4) Article 10 is replaced by the following text:

"ARTICLE 10

Joint Committee

1. A Joint Committee (hereinafter referred as "the Committee") is hereby established.

The Committee shall be composed of representatives of the Parties.

2. The Committee shall be co-chaired by a representative of the Union and a representative of Switzerland.

- 3. The Committee shall:
- (a) ensure the proper functioning and the effective administration and application of this Agreement;
- (b) provide a forum for mutual consultation and a continuous exchange of information between the Parties, in particular with a view to finding a solution to any difficulty of interpretation or application of the Agreement or of a legal act of the Union to which reference is made in the Agreement in accordance with Article 10 of the Institutional Protocol to this Agreement;
- (c) make recommendations to the Parties in matters pertaining to this Agreement;
- (d) adopt decisions where provided for in this Agreement and adopt, on the proposal by one of the Parties, a decision to add chapters to Annex 1 of this Agreement; and
- (e) be responsible for:
 - drawing up the procedure for carrying out the verifications provided for in Article 7;
 - drawing up the procedure for carrying out the verifications provided for in Article 8;

- deciding on the recognition of conformity assessment bodies contested under Article 8;
- deciding on the withdrawal of recognition of recognised conformity assessment bodies contested under Article 8; and
- where necessary to ensure coherence, upon proposal by one of the Parties, adopt a decision to modify Annex 2.

4. The Committee shall act by consensus.

Decisions shall be binding on the Parties, which shall take all necessary measures to implement them.

5. The Committee shall meet at least once a year, in Brussels and Bern alternately, unless the co-chairs decide otherwise. It shall also meet at the request of either Party. The co-chairs may agree that a meeting of the Committee be held by videoconference or teleconference.

6. The Committee shall adopt its rules of procedure and update them as necessary.

7. The Committee may decide to set up any working party or group of experts that can assist it in carrying out its duties.";

(5) Article 11 is replaced by the following text:

"ARTICLE 11

Recognition, withdrawal of recognition, modification of the scope, and suspension of conformity assessment bodies

1. The following procedure shall apply for the recognition of conformity assessment bodies in relation to the requirements set out in the relevant Chapters of Annex 1 and as regards provisions covered by Article 1(2), the corresponding Swiss provisions adopted or maintained according to Article 5(2) of the Institutional Protocol:

- (a) A Party wishing to have recognised any conformity assessment body shall notify the other Party in writing of its proposal, 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 conformity assessment body shall be considered to be a recognised conformity assessment body under the terms of Article 5.
- (c) If the other Party raises objections in writing within that 60-day period, Article 8 shall apply.

2. A Party can withdraw or suspend the recognition or remove the suspension of recognition of a conformity assessment body under its jurisdiction. The Party concerned shall immediately notify the other Party of its decision in writing, together with the date of such decision. The withdrawal, suspension, or removal of suspension shall take effect at that date. Such withdrawal or suspension shall be indicated in the common list of recognised conformity assessment bodies referred to in Annex 1.

3. A Party can propose that the scope of activity of a recognised conformity assessment body under its jurisdiction be amended. For scope extensions and scope reductions the procedures provided for in Article 11(1) and (2) respectively shall apply.

4. A Party can, in exceptional circumstances, contest the technical competence of a recognised conformity assessment body under the jurisdiction of the other Party. In this case Article 8 shall apply.

5. Reports, certificates, authorisations and conformity marks issued by a conformity assessment body after the date at which its recognition has been withdrawn or suspended need not be recognised by the Parties. Reports, certificates, authorisations and conformity marks issued by a conformity assessment body before the date its recognition has been withdrawn shall continue to be recognised by the Parties unless the responsible designating authority has limited or cancelled their validity. The Party under whose jurisdiction the responsible designating authority is operating shall notify the other Party in writing of any such changes relating to a limitation or cancellation of validity.";

- (6) Article 12 is repealed;
- (7) Article 13 is amended as follows:
 - (a) the title is replaced by the following:

"Professional Secrecy";

(b) the following text is inserted as second paragraph:

"Technical adaptations of the relevant chapters of Annex 1 may set out specific provision for the protection of information as referred to in the first paragraph.";

(8) a new Article is inserted as follows:

"ARTICLE 13bis

Classified information and sensitive non-classified information

1. Nothing in this Agreement shall be construed as requiring a Party to make available classified information.

2. Classified information or material provided by, or exchanged between, the Parties under this Agreement shall be handled and protected in compliance with the Agreement between the Swiss Confederation and the European Union on the security procedures for the exchange of classified information, done at Brussels on 28 April 2008, and any security arrangement implementing it.

3. The Committee shall adopt, by means of a decision, handling instructions to ensure the protection of sensitive non-classified information exchanged between the Parties.";

(9) Article 17 is replaced by the following text:

"ARTICLE 17

Territorial application

This Agreement shall apply, of the one part, to the territory in which the Treaty on European Union and the Treaty on the Functioning of the European Union apply and under the conditions laid down in those Treaties, and, of the other part, to the territory of Switzerland.".

ARTICLE 2

Amendments to Annex 1

Annex 1 is amended as follows:

(1) the following text is inserted after the list of chapters:

"GENERAL PROVISIONS

ARTICLE 1

Unless otherwise provided for in technical adaptations, rights and obligations provided for in the legal acts of the Union integrated into this Annex for Member States of the Union shall be understood to be provided for for Switzerland. This shall be applied in full respect for the Institutional Protocol to this Agreement. For the purposes of clarity, given the specificities of this Agreement, the foregoing shall only apply where those rights and obligations fall under the scope of this Agreement.

ARTICLE 2

1. Where a Member State of the Union is to submit information to the European Commission (the 'Commission'), Switzerland shall submit such information to the Commission via the Committee. Where the Commission is to submit information to one or more Member States of the Union, where Switzerland is concerned, the Commission shall submit such information to Switzerland via the Committee, unless otherwise provided for in technical adaptations to the specific chapters of this Annex. 2. Where the competent authorities of the Member States of the Union are to submit information to the competent authorities of another Member State of the Union, they shall also submit that information to the competent authorities of Switzerland while informing the Commission unless otherwise provided for in technical adaptations to the specific chapters of this Annex. The competent authorities of Switzerland shall submit information to the competent authorities of the Member States of the Union and inform the Commission.

3. The Committee can, by means of technical adaptations to the specific chapters of this Annex agree on appropriate solutions providing for the direct exchange of information in areas where the rapid transfer of information is called for.

4. Paragraphs 1 and 2 are without prejudice to the sector-specific rules and arrangements applicable to the exchange of information by means of information systems.

ARTICLE 3

Where a legal act of the Union set out in this Annex requires the competent authorities of the Member States of the Union or the economic operators in the Member States of the Union to provide information or data by means of digital tools, and where it is relevant for the implementation of this Agreement, each specific chapter of this Annex shall establish whether the Swiss competent authorities and the economic operators in Switzerland may provide such information and/or data by using the relevant Swiss interface. Where a specific Chapter in this Annex allows for the use of such interface, the extent and conditions of such use shall be agreed and established in the same Chapter.

ARTICLE 4

1. Whenever the legal acts of the Union set out in this Annex, or the corresponding Swiss provisions adopted or maintained in accordance with Article 5(2) of the Institutional Protocol, assign specific obligations to economic operators, persons or entities established in the Union or Switzerland, respectively, the obligations can, when it is relevant for the purposes of the implementation of this Agreement, also be fulfilled by economic operators, persons or entities established in Switzerland or in the Union, respectively, unless otherwise provided for in technical adaptations to the specific chapters of this Annex.

2. Whenever the legal acts of the Union set out in this Annex or the corresponding Swiss provisions adopted or maintained in accordance with Article 5(2) of the Institutional Protocol, provide that a specific item of information is to be made available to the competent authorities of a Party by an economic operator, person or entity as referred to in the first paragraph of this Article, these authorities may contact the competent authorities of the other Party or enter into direct contact with these economic operators, persons or entities in the territory of the other Party, in order to obtain that information.";

(2) in Chapter 4, the following sentence will be inserted in a position to be determined when the technical work is carried out:

"For the purpose of clarity, Switzerland will participate in the Committee on Medical Devices and in the Medical Device Coordination Group as an observer, in accordance with the relevant rules of procedure."; (3) in Chapter 5, the following paragraph is inserted after the title:

"This Chapter covers the appliances burning gaseous fuels as defined in Regulation (EU) 2016/426, listed under point 1 of Section I of this Chapter as well as the energy efficiency and emissions requirements relating to hot-water boilers fired with liquid or gaseous fuels as defined in Directive 92/42 CEE listed under point 2 of Section I of this Chapter.";

(4) in Chapter 5, Section I is replaced by the following text:

"Section I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1 paragraph 2

- European Union 1. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99).
 - Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels (OJ L 167, 22.6.1992, p. 17), as last amended by Commission Regulation (EU) No 813/2013 of 2 August 2013 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for space heaters and combination heaters (OJ L 239, 6.9.2013, p. 136).";

(5) In Chapter 11, Section I is replaced by the following text:

"Section I

Legislative, regulatory and administrative provisions

A. Provisions covered by Article 1 paragraph 1

European Union	1.	Directive 2007/45/EC of the European Parliament and of the Council of 5 September 2007 laying down rules on nominal quantities for prepacked products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC (OJ L 247, 21.9.2007, p. 17) applicable as from 11 April 2009.
Switzerland	100.	Ordinance of 5 September 2012 on the declaration of quantities for unpackaged and prepackaged products (RS 941.204), as subsequently amended.
	101.	Ordinance of the Federal Ministry of Justice and Police of 10 September 2012 on the declaration of quantities for unpackaged and prepackaged products (RS 941.204.1), as subsequently amended.

- B. Provisions covered by Article 1 paragraph 2
 - European Union 1. Directive 2009/34/EC of the European Parliament and of the Council of 23 April 2009 relating to common provisions for both measuring instruments and methods of metrological control (Recast) (OJ L 106, 28.04.2009, p. 7).
 - 2. Council Directive 75/107/EEC of 19 December 1974 on the approximation of the laws of the Member States relating to bottles used as measuring containers (OJ L 42, 15.2.1975, p. 14).
 - 3. Council Directive 76/211/EEC 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 (OJ L 46, 21.2.1976, p. 1).
 - Council Directive 80/181/EEC 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 (OJ L 39, 15.2.1980, p. 40) as last amended by Directive 2009/3/EC of the European Parliament and of the Council of 11 March 2009 (OJ L 114, 7.5.2009, p. 10).
 - 5. Directive 2014/31/UE of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (OJ L 96, 29.3.2014, p. 107).
 - Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Members States relating to the making available on the market of measuring instruments (OJ L 96, 29.3.2014, p. 149).

- Directive 2011/17/EU of the European Parliament and of the Council of 9 March 2011 repealing Council Directives 71/317/EEC, 71/347/EEC, 71/349/EEC, 74/148/EEC, 75/33/EEC, 76/765/EEC, 76/766/EEC and 86/217/EEC regarding metrology (OJ L 71, 18.3.2011, p. 1).";
- (6) In Chapter 15, the following sentence will be inserted in a position to be determined when the technical work is carried out:

"Notwithstanding Article 4 of the Institutional Protocol, Switzerland shall not participate in, and Switzerland's experts shall not be consulted on the preparation of, the proposals and drafts referred to therein relating to the development, manufacture, placing on the market and use of medicinal products including, in the context of procedures related to medicinal products. The application by Switzerland of the relevant provisions of the legal acts of the Union listed in this Section, as per Article 1 of Annex 1, shall not give the right to Switzerland to participate in the European Medicines Agency with the exception of participation as an observer in the meetings of GMDP Inspectors Working Group, in accordance with relevant rules of procedure.".

ARTICLE 3

Entry into force

1. This Protocol shall be ratified or approved by the Contracting Parties in accordance with their own procedures. The Contracting Parties shall notify each other of the completion of the internal procedures necessary to the entry into force of this Protocol.

2. This Protocol shall enter into force on the first day of the second month following the last notification regarding the following instruments:

- (a) Institutional Protocol to the Agreement between the European Community and its Member States, of the one part, and the Swiss Confederation, of the other, on the free movement of persons;
- (b) Amending Protocol to the Agreement between the European Community and its Member States, of the one part, and the Swiss Confederation, of the other, on the free movement of persons;
- Institutional Protocol to the Agreement between the European Community and the Swiss Confederation on air transport;
- (d) Amending Protocol to the Agreement between the European Community and the Swiss Confederation on air transport;
- (e) State Aid Protocol to the Agreement between the European Community and the Swiss Confederation on air transport;
- (f) Institutional Protocol to the Agreement between the European Community and the Swiss Confederation on the carriage of goods and passengers by rail and road;
- (g) Amending Protocol to the Agreement between the European Community and the Swiss Confederation on the carriage of goods and passengers by rail and road;

- (h) State Aid Protocol to the Agreement between the European Community and the Swiss Confederation on the carriage of goods and passengers by rail and road;
- (i) Amending Protocol to the Agreement between the European Community and the Swiss Confederation on trade in agricultural products;
- (j) Institutional Protocol to the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment;
- (k) Agreement between the European Union and the Swiss Confederation on Switzerland's regular financial contribution towards reducing economic and social disparities in the European Union;
- Agreement between the European Union and the European Atomic Energy Community, of the one part, and the Swiss Confederation, of the other part, on the participation of the Swiss Confederation in Union programmes;
- (m) Agreement between the European Union and the Swiss Confederation on the terms and conditions for the participation of the Swiss Confederation in the European Union Agency for the Space Programme.

Done at [...], on [...], in duplicate in the Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Irish, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish languages, each of these texts being equally authentic.

IN WITNESS WHEREOF, the undersigned, duly authorised thereto, have signed this Protocol.

(Signature Block, to the effect of, in all 24 EU languages: "For the European Union" and "For the Swiss Confederation")

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

THE EUROPEAN UNION, hereinafter referred to as the "Union",

and

THE SWISS CONFEDERATION, hereinafter referred to as "Switzerland",

hereinafter referred to as the "Contracting Parties";

WHEREAS the Union and Switzerland are bound by numerous bilateral agreements covering various fields, providing for specific rights and obligations similar, in certain respects, to those provided for within the Union;

RECALLING that the purpose of those bilateral agreements is to increase Europe's competitiveness and to create closer economic ties between the Contracting Parties, based on equality, reciprocity and the general balance of their advantages, rights and obligations;

RESOLVED to strengthen and deepen Switzerland's participation in the internal market of the Union, on the basis of the same rules as those that apply to the internal market, while preserving their independence and that of their institutions and, as regards Switzerland, respect for the principles stemming from direct democracy, federalism and the sectoral nature of its participation in the internal market;

REAFFIRMING that the competence of the Swiss Federal Supreme Court and all other Swiss courts as well as that of the Member States' courts and of the Court of Justice of the European Union to interpret the Agreement in individual cases is preserved;

CONSCIOUS of ensuring uniformity in the fields related to the internal market in which Switzerland participates, both current and future,

HAVE AGREED AS FOLLOWS:

CHAPTER 1

GENERAL PROVISIONS

ARTICLE 1

Objectives

1. The objective of this Protocol is to guarantee for the Contracting Parties, and for economic operators and individuals, greater legal certainty, equal treatment and a level playing field in the field related to the internal market falling under the scope of the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment, done at Luxembourg on 21 June 1999 (hereinafter referred to as the "Agreement").

2. To this end, this Protocol provides new institutional solutions facilitating a continuous and balanced strengthening of economic relations between the Contracting Parties. Taking account of the principles of international law, this Protocol lays down, in particular, institutional solutions for the Agreement which are common to the bilateral agreements concluded or to be concluded in the fields related to the internal market in which Switzerland participates, without changing the scope or the objectives of the Agreement, notably:

 (a) the procedure for aligning the Agreement with legal acts of the Union relevant to the Agreement;

- (b) the uniform interpretation and application of the Agreement and of the legal acts of the Union to which reference is made in the Agreement;
- (c) the surveillance and application of the Agreement; and
- (d) the settlement of disputes in the context of the Agreement.

ARTICLE 2

Relation to the Agreement

- 1. This Protocol, its Annex and its Appendix shall form an integral part of the Agreement.
- 2. The provisions of the Agreement repealed by this Protocol are listed below:
- (a) Article 1(3);
- (b) Article 14;
- (c) Article 19.

3. References to the "European Community" or to the "Community" in the Agreement shall be construed as references to the Union.

ARTICLE 3

Bilateral agreements in the fields related to the internal market in which Switzerland participates

1. Existing and future bilateral agreements between the Union and Switzerland in the fields related to the internal market in which Switzerland participates shall be considered as a coherent whole which ensures a balance of rights and obligations between the Union and Switzerland.

2. The Agreement constitutes a bilateral agreement in a field related to the internal market in which Switzerland participates.

CHAPTER 2

ALIGNMENT OF THE AGREEMENT WITH LEGAL ACTS OF THE UNION

ARTICLE 4

Participation in the drafting of legal acts of the Union ("decision shaping")

1. When drafting a proposal for a legal act of the Union in accordance with the Treaty on the Functioning of the European Union (hereinafter referred to as "TFEU") in the field covered by the Agreement, the European Commission (hereinafter referred to as the "Commission") shall inform Switzerland thereof and shall informally consult Switzerland's experts in the same way that it asks for the views of experts from the Member States of the Union for the drafting of its proposals.

At the request of either Contracting Party, a preliminary exchange of views shall take place within the Joint Committee.

The Contracting Parties shall consult each other again, at the request of either of them, within the Joint Committee at important moments of the phase preceding the adoption of the legal act by the Union, in a continuous process of information and consultation.

2. When preparing, in accordance with the TFEU, delegated acts concerning basic acts of Union law in the field covered by the Agreement, the Commission shall ensure that Switzerland has the widest possible participation in the preparation of the drafts and shall consult Switzerland's experts on the same basis as it consults the experts of the Member States of the Union. 3. When preparing, in accordance with the TFEU, implementing acts concerning basic acts of Union law in the field covered by the Agreement, the Commission shall ensure that Switzerland has the widest possible participation in the preparation of the drafts to be submitted later on to the committees assisting the Commission in the exercise of its implementing powers and shall consult Switzerland's experts on the same basis as it consults the experts from the Member States of the Union.

Switzerland's experts shall be involved in the work of committees not covered by paragraphs
and 3 where this is required for the proper functioning of the Agreement. A list of those
committees and, where appropriate, of other committees with similar characteristics, shall be drawn
up and updated by the Joint Committee.

5. This Article shall not apply with regard to legal acts of the Union or provisions thereof falling within the scope of an exception referred to in Article 5(7).

ARTICLE 5

Integration of legal acts of the Union

1. In order to guarantee legal certainty and the homogeneity of the law in the field related to the internal market in which Switzerland participates by virtue of the Agreement, Switzerland and the Union shall ensure that legal acts of the Union adopted in the field covered by the Agreement are integrated into the Agreement as quickly as possible after their adoption.

2. Switzerland shall adopt or maintain provisions in its legal order with a view to achieving the result to be attained by the legal acts of the Union integrated into the Agreement in accordance with paragraph 4 subject, as the case may be, to the adaptations decided upon by the Joint Committee.

3. When it adopts a legal act in the field covered by the Agreement, the Union shall inform Switzerland thereof as quickly as possible through the Joint Committee. At the request of either of the Contracting Parties, the Joint Committee shall conduct an exchange of views on the subject.

4. The Joint Committee shall act in accordance with paragraph 1 by adopting a decision as quickly as possible to amend the Annex 1 to the Agreement, including the necessary adaptations.

5. Without prejudice to paragraphs 1 and 2, if necessary in order to ensure coherence of the Agreement with Annex 1 as amended pursuant to paragraph 4, the Joint Committee may propose, for approval by the Contracting Parties according to their internal procedures, the revision of the Agreement.

6. References in the Agreement to legal acts of the Union that are no longer in force shall be construed as references to the repealing legal act of the Union as integrated into Annex 1 to the Agreement as from the entry into force of the Joint Committee's decision on the corresponding amendment of Annex 1 to the Agreement pursuant to paragraph 4, unless otherwise provided in that decision.

7. The obligation set out in paragraph 1 shall not apply to legal acts of the Union or provisions thereof falling within the scope of an exception listed below:

– Article 1(1).

8. Subject to Article 6, decisions of the Joint Committee pursuant to paragraph 4 shall enter into force immediately, but under no circumstances before the date on which the corresponding legal act of the Union becomes applicable in the Union.

9. The Contracting Parties shall cooperate in good faith throughout the procedure set out in this Article in order to facilitate decision-making.

ARTICLE 6

Fulfilment of constitutional obligations by Switzerland

1. During the exchange of views referred to in Article 5(3), Switzerland shall inform the Union whether a decision as referred to in Article 5(4) requires the fulfilment of constitutional obligations by Switzerland in order to become binding.

2. Where the decision referred to in Article 5(4) requires Switzerland to fulfil constitutional obligations in order to become binding, Switzerland shall have a time limit of two years maximum from the date of the information provided for in paragraph 1, except where a referendum procedure is launched, in which case this period shall be extended by one year.

3. Pending the information by Switzerland that it has fulfilled its constitutional obligations, the Contracting Parties shall provisionally apply the decision referred to in Article 5(4), unless Switzerland informs the Union that the provisional application of the decision is not possible and provides the reasons for this.

Under no circumstances can the provisional application occur before the date on which the corresponding legal act of the Union becomes applicable in the Union.

4. Switzerland shall notify the Union without delay through the Joint Committee once it has fulfilled the constitutional obligations referred to in paragraph 1.

5. The decision shall enter into force on the day on which the notification provided for in paragraph 4 is delivered, but under no circumstances before the date on which the corresponding legal act of the Union becomes applicable in the Union.

CHAPTER 3

INTERPRETATION AND APPLICATION OF THE AGREEMENT

ARTICLE 7

Uniform interpretation principle

1. For the purpose of achieving the objectives set out in Article 1 and in accordance with the principles of public international law, the bilateral agreements in the fields related to the internal market in which Switzerland participates and the legal acts of the Union to which reference is made in such agreements shall be uniformly interpreted and applied in the fields related to the internal market in which Switzerland participates.

2. The legal acts of the Union to which reference is made in the Agreement and, to the extent that their application involves concepts of Union law, the provisions of the Agreement shall be interpreted and applied in accordance with the case law of the Court of Justice of the European Union, prior or subsequent to the signature of the Agreement.

ARTICLE 8

Effective and harmonious application principle

1. The Commission and the competent Swiss authorities shall cooperate and assist each other in ensuring the surveillance of the application of the Agreement. They may exchange information on the activities of surveillance of the application of the Agreement. They may exchange views and discuss issues of mutual interest.

2. Each Contracting Party shall take appropriate measures to ensure the effective and harmonious application of the Agreement on its territory.

3. The surveillance of the application of the Agreement shall be carried out jointly by the Contracting Parties within the Joint Committee.

If the Commission or the competent Swiss authorities become aware of a case of incorrect application, the matter may be referred to the Joint Committee with a view to finding an acceptable solution.

4. The Commission and the competent Swiss authorities respectively shall monitor the application of the Agreement by the other Contracting Party. The procedure provided for in Article 10 applies.

To the extent that certain surveillance competences of the institutions of the Union as regards one Contracting Party are necessary to ensure the effective and harmonious application of the Agreement, such as investigation and decision powers, the Agreement must foresee them specifically.

ARTICLE 9

Exclusivity principle

The Contracting Parties undertake not to submit a dispute regarding the interpretation or application of the Agreement and of the legal acts of the Union to which reference is made in the Agreement or, where applicable, regarding the conformity with the Agreement of a decision adopted by the Commission on the basis of the Agreement to any method of settlement other than those provided for in this Protocol.

ARTICLE 10

Procedure in the event of difficulty of interpretation or application

1. In the event of difficulty of interpretation or application of the Agreement or of a legal act of the Union to which reference is made in the Agreement, the Contracting Parties shall consult each other within the Joint Committee in order to find a mutually acceptable solution. To this end, all useful elements of information shall be provided to the Joint Committee to enable it to make a detailed examination of the situation. The Joint Committee shall examine all possibilities that allow the proper functioning of the Agreement to be maintained.

2. If the Joint Committee is not able to find a solution to the difficulty referred to in paragraph 1 within three months of the date on which the difficulty was submitted to it, either of the Contracting Parties may request that an arbitral tribunal settle the dispute in accordance with the rules laid down in the Appendix.

3. Where the dispute raises a question concerning the interpretation or application of a provision referred to in Article 7(2), and if the interpretation of that provision is relevant to the settlement of the dispute and necessary to enable it to decide, the arbitral tribunal shall refer that question to the Court of Justice of the European Union.

Where the dispute raises a question concerning the interpretation or application of a provision that falls within the scope of an exception from the dynamic alignment obligation referred to in Article 5(7), and where the dispute does not involve the interpretation or application of concepts of Union law, the arbitral tribunal shall settle the dispute without referral to the Court of Justice of the European Union.

4. Where the arbitral tribunal refers a question to the Court of Justice of the European Union pursuant to paragraph 3:

- (a) the ruling of the Court of Justice of the European Union shall be binding on the arbitral tribunal; and
- (b) Switzerland shall enjoy the same rights as the Member States and the institutions of the Union and shall be subject to the same procedures before the Court of Justice of the European Union, *mutatis mutandis*.

5. Each Contracting Party shall take all measures necessary to comply in good faith with the arbitral tribunal's decision.

The Contracting Party that has been found by the arbitral tribunal not to have complied with the Agreement shall inform the other Contracting Party through the Joint Committee of the measures it has taken to comply with the arbitral tribunal's decision.

ARTICLE 11

Compensatory measures

1. If the Contracting Party that has been found by the arbitral tribunal not to have complied with the Agreement does not inform the other Contracting Party, within a reasonable time period set in accordance with Article IV.2(6) of the Appendix, of the measures it has taken to comply with the arbitral tribunal's decision, or if the other Contracting Party considers that the measures communicated do not comply with the arbitral tribunal's decision, this other Contracting Party may adopt proportionate compensatory measures within the framework of the Agreement or of any other bilateral agreement in the fields related to the internal market in which Switzerland participates (hereinafter referred to as "compensatory measures") in order to remedy a potential imbalance. It shall notify the Contracting Party that has been found by the arbitral tribunal not to have complied with the Agreement of the compensatory measures, which shall be specified in the notification. Those compensatory measures shall take effect three months from the date of this notification.

2. If, within one month from the date of the notification of the intended compensatory measures, the Joint Committee has not taken a decision to suspend, amend or annul those compensatory measures, either Contracting Party may submit to arbitration the question of the proportionality of those compensatory measures, in accordance with the Appendix.

3. The arbitral tribunal shall decide within the time limits laid down in Article III.8(4) of the Appendix.

4. Compensatory measures shall not have retroactive effect. In particular, the rights and obligations already acquired by individuals and economic operators before the compensatory measures take effect shall be preserved.

ARTICLE 12

Cooperation between jurisdictions

1. To promote the homogeneous interpretation, the Swiss Federal Supreme Court and the Court of Justice of the European Union shall agree on a dialogue and the modalities thereof.

2. Switzerland shall have the right to lodge statements of case or written observations with the Court of Justice of the European Union where a court of a Member State of the Union refers to the Court of Justice of the European Union a question concerning the interpretation of the Agreement or of a provision of a legal act of the Union referred to therein for a preliminary ruling.

CHAPTER 4

OTHER PROVISIONS

ARTICLE 13

Financial contribution

1. Switzerland shall contribute to the financing of the activities of the Union agencies, information systems and other activities listed in Article 1 of the Annex to which it has access, in accordance with this Article and the Annex.

The Joint Committee may adopt a decision to amend the Annex.

2. The Union may suspend the participation of Switzerland in the activities referred to in paragraph 1 of this Article at any time if Switzerland fails to meet the payment deadline in accordance with the terms of payment set out in Article 2 of the Annex.

Where Switzerland fails to meet a payment deadline, the Union shall send Switzerland a formal letter of reminder. Where no full payment is made within 30 days of the date of reception of that formal letter of reminder, the Union may suspend the participation of Switzerland in the relevant activity.

3. The financial contribution shall take the form of the sum of:

(a) an operational contribution; and

(b) a participation fee.

4. The financial contribution shall take the form of an annual financial contribution and shall be due at the dates specified in the calls for funds issued by the Commission.

5. The operational contribution shall be based on a contribution key defined as the ratio of the gross domestic product (hereinafter referred to as "GDP") of Switzerland at market prices to the GDP of the Union at market prices.

For that purpose, the figures for GDP at market prices of the Contracting Parties shall be the latest such figures available as of 1 January of the year in which the annual payment is made as provided by the Statistical Office of the European Union (EUROSTAT), with due regard to the Agreement between the European Community and the Swiss Confederation on cooperation in the field of statistics, done at Luxembourg on 26 October 2004. If that agreement ceases to apply, the GDP of Switzerland shall be the one established on the basis of data provided by the Organisation for Economic Co-operation and Development.

6. The operational contribution for each Union agency shall be calculated by applying the contribution key to its annual voted budget inscribed on the relevant Union budget subsidy line(s) of the year in question, taking into account for each agency any adjusted operational contribution as defined in Article 1 of the Annex.

The operational contribution for the information systems and other activities shall be calculated by applying the contribution key to the relevant budget of the year in question as set out in documents implementing the budget, such as work programmes or contracts.

All reference amounts shall be based on commitment appropriations.

7. The annual participation fee shall be 4 % of the annual operational contribution as calculated in accordance with paragraphs 5 and 6.

8. The Commission shall provide Switzerland with adequate information in relation to the calculation of its financial contribution. That information shall be provided having due regard to the Union's confidentiality and data protection rules.

9. All financial contributions by Switzerland or payments from the Union, and the calculation of amounts due or to be received, shall be made in euro.

10. Where the entry into force of this Protocol does not coincide with the beginning of a calendar year, Switzerland's operational contribution for the year in question shall be subject to adjustment, according to the methodology and terms of payment defined in Article 5 of the Annex.

11. Detailed provisions for the application of this Article are set out in the Annex.

12. Three years following the entry into force of this Protocol, and every three years subsequently, the Joint Committee shall review the conditions of Switzerland's participation as defined in Article 1 of the Annex and, where appropriate, adapt them.

ARTICLE 14

References to territories

Whenever the legal acts of the Union integrated into the Agreement contain references to the territory of the "European Union", of the "Union", of the "common market" or of the "internal market", the references shall for the purposes of the Agreement be understood to be references to the territories referred to in Article 17 of the Agreement.

ARTICLE 15

References to nationals of Member States of the Union

Whenever the legal acts of the Union integrated into the Agreement contain references to nationals of Member States of the Union, the references shall, for the purposes of the Agreement, be understood to be references to nationals of the Member States of the Union and of Switzerland.

ARTICLE 16

Entry into force and implementation of the legal acts of the Union

1. Provisions of the legal acts of the Union integrated into the Agreement on their entry into force or implementation are not relevant for the purposes of the Agreement.

2. The time limits and dates for Switzerland for bringing into force and implementing the decisions integrating legal acts of the Union into the Agreement follow from Article 5(8) and Article 6(5), as well as from provisions on transitional arrangements.

ARTICLE 17

Addressees of the legal acts of the Union

Provisions of the legal acts of the Union integrated into the Agreement indicating that they are addressed to the Member States of the Union are not relevant for the purposes of the Agreement.

CHAPTER 5

FINAL PROVISIONS

ARTICLE 18

Implementation

1. The Contracting Parties shall take all appropriate measures, whether general or particular, to ensure the fulfilment of the obligations arising from the Agreement and shall refrain from taking any measure which could jeopardise the achievement of its objectives.

2. The Contracting Parties shall take all measures necessary to guarantee the intended result of the legal acts of the Union to which reference is made in the Agreement and shall refrain from taking any measure that could jeopardise the achievement of their aims.

ARTICLE 19

Entry into force

1. This Protocol shall be ratified or approved by the Contracting Parties in accordance with their own procedures. The Contracting Parties shall notify each other of the completion of the internal procedures necessary to the entry into force of this Protocol.

2. This Protocol shall enter into force on the first day of the second month following the last notification regarding the following instruments:

- (a) Institutional Protocol to the Agreement between the European Community and its Member States, of the one part, and the Swiss Confederation, of the other, on the free movement of persons;
- (b) Amending Protocol to the Agreement between the European Community and its Member States, of the one part, and the Swiss Confederation, of the other, on the free movement of persons;
- c) Institutional Protocol to the Agreement between the European Community and the Swiss Confederation on air transport;
- (d) Amending Protocol to the Agreement between the European Community and the Swiss Confederation on air transport;
- (e) State Aid Protocol to the Agreement between the European Community and the Swiss Confederation on air transport;
- (f) Institutional Protocol to the Agreement between the European Community and the Swiss Confederation on the carriage of goods and passengers by rail and road;
- (g) Amending Protocol to the Agreement between the European Community and the Swiss Confederation on the carriage of goods and passengers by rail and road;

- (h) State Aid Protocol to the Agreement between the European Community and the Swiss Confederation on the carriage of goods and passengers by rail and road;
- (i) Amending Protocol to the Agreement between the European Community and the Swiss Confederation on trade in agricultural products;
- (j) Amending Protocol to the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment;
- (k) Agreement between the European Union and the Swiss Confederation on Switzerland's regular financial contribution towards reducing economic and social disparities in the European Union;
- Agreement between the European Union and the European Atomic Energy Community, of the one part, and the Swiss Confederation, of the other part, on the participation of the Swiss Confederation in Union programmes;
- (m) Agreement between the European Union and the Swiss Confederation on the terms and conditions for the participation of the Swiss Confederation in the European Union Agency for the Space Programme.

ARTICLE 20

Amendment and termination

1. This Protocol may be amended at any time by mutual agreement of the Contracting Parties.

2. Where the Agreement is terminated in accordance with Article 21(3) of the Agreement, this Protocol shall cease to be in force on the date referred to in Article 21(4) of the Agreement.

3. Where the Agreement ceases to be in force, the rights and obligations that individuals and economic operators have already acquired by virtue of the Agreement before the date of the cessation of the Agreement shall be preserved. The Contracting Parties shall settle by mutual agreement what action is to be taken in respect of rights in the process of being acquired.

Done at [...], on [...], in duplicate in the Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Irish, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish languages, each of these texts being equally authentic.

IN WITNESS WHEREOF, the undersigned, duly authorised thereto, have signed this Protocol.

(Signature Block, to the effect of, in all 24 EU languages: "For the European Union" and "For the Swiss Confederation")

ANNEX ON THE APPLICATION OF ARTICLE 13 OF THE PROTOCOL

ARTICLE 1

List of the activities of the Union agencies, information systems and other activities to which Switzerland is to contribute financially

Switzerland shall contribute financially to the following:

(a) agencies:

none.

(b) information systems:

EudraGMDP as established in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.¹

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311 28.11.2001, p. 67).

(c) other activities:

none.

ARTICLE 2

Terms of payment

1. Payments due pursuant to Article 13 of the Protocol shall be made in accordance with this Article.

2. When issuing the call for funds of the financial year, the Commission shall communicate the following information to Switzerland:

(a) the amount of the operational contribution; and

(b) the amount of the participation fee.

3. The Commission shall communicate to Switzerland, as soon as possible and at the latest on 16 April of each financial year, the following information in relation to Switzerland's participation:

- (a) the amounts in commitment appropriations of the annual Union voted budget inscribed on the relevant Union budget subsidy line(s) of the year in question for each Union agency, taking into account for each agency any adjusted operational contribution as defined in Article 1, and the amounts in commitment appropriations in relation to the Union voted budget of the year in question for the relevant budget of the information systems and other activities, covering the participation of Switzerland in accordance with Article 1;
- (b) the amount of the participation fee referred to in Article 13(7) of the Protocol; and
- (c) as regards agencies, in year N+1, the amounts in budgetary commitments made on commitment appropriations authorised in year N on the relevant Union budget subsidy line(s) in relation to the annual Union budget inscribed on the relevant Union budget subsidy line(s) of year N.

4. On the basis of its draft budget, the Commission shall provide an estimate of information under points (a) and (b) of paragraph 3 as soon as possible, and at the latest, by 1 September of the financial year.

5. The Commission shall issue to Switzerland, at the latest on 16 April and, if applicable to the relevant agency, information system or other activity, at the earliest on 22 October and at the latest on 31 October of each financial year, a call for funds that corresponds to the contribution of Switzerland under the Agreement for each of the agencies, information systems and other activities in which Switzerland participates.

- 6. The call(s) for funds referred to in paragraph 5 shall be structured in instalments as follows:
- (a) the first instalment of each year, in relation to the call for funds to be issued by 16 April, shall correspond to an amount up to the equivalent of the estimate of the annual financial contribution of the agency, information system or other activity in question referred to in paragraph 4;

Switzerland shall pay the amount indicated in this call for funds at the latest 60 days after the call for funds is issued.

(b) where applicable, the second instalment of the year, in relation to the call for funds to be issued at the earliest on 22 October and at the latest on 31 October, shall correspond to the difference between the amount referred to in paragraph 4 and the amount referred to in paragraph 5, where the amount referred to in paragraph 5 is higher.

Switzerland shall pay the amount indicated in this call for funds at the latest by 21 December.

For each call for funds, Switzerland may make separate payments for each agency, information system or other activity.

7. For the first year of implementation of the Protocol, the Commission shall issue a single call for funds, within 90 days of the entry into force of the Protocol.

Switzerland shall pay the amount indicated in the call for funds at the latest 60 days after the call for funds is issued.

8. Any delay in the payment of the financial contribution shall give rise to the payment of default interest by Switzerland on the outstanding amount as from the due date until the day on which that outstanding amount is paid in full.

The interest rate for amounts receivable not paid on the due date shall be the rate applied by the European Central Bank to its principal refinancing operations, as published in the C series of the Official Journal of the European Union, in force on the first day of the month in which the due date falls, or 0 %, whichever is higher, plus 3,5 percentage points.

ARTICLE 3

Adjustment of Switzerland's financial contribution to Union agencies in the light of implementation

The adjustment of Switzerland's financial contribution to Union agencies shall be made in year N+1, when the initial operational contribution shall be adjusted upwards or downwards by the difference between the initial operational contribution and an adjusted contribution calculated by applying the contribution key of year N to the amount of budgetary commitments made on commitment appropriations authorised in year N under the relevant Union subsidy budget line(s). Where applicable, the difference shall take into account, for each agency, the percentage-based adjusted operational contribution as defined in Article 1.

ARTICLE 4

Existing arrangements

Article 13 of the Protocol and this Annex shall not apply to specific arrangements between Switzerland and the Union which include financial contributions by Switzerland. The agencies, information systems and other activities covered by such arrangements are the following:

European Chemical Agency, established by Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

ARTICLE 5

Transitional arrangements

In the event that the date of entry into force of the Protocol is not 1 January, this Article shall apply by way of derogation from Article 2.

For the first year of implementation of the Protocol, in relation to the operational contribution due for the year in question applicable to the relevant agency, information system or other activity, as established in accordance with Article 13 of the Protocol and Articles 1 to 3 of this Annex, the operational contribution shall be reduced on a pro rata temporis basis by multiplying the amount of the annual operational contribution due to the ratio of the following:

- (a) the number of calendar days from the date of entry into force of the Protocol until 31 December of the year in question; and
- (b) the total number of calendar days of the year in question.

Appendix

APPENDIX ON THE ARBITRAL TRIBUNAL

CHAPTER I

PRELIMINARY PROVISIONS

ARTICLE I.1

Scope

If one of the Contracting Parties (hereinafter referred to as "parties") submits a dispute for arbitration in accordance with Articles 10(2) or 11(2) of the Protocol, the rules set out in this Appendix shall apply.

ARTICLE I.2

Registry and secretarial services

The International Bureau of the Permanent Court of Arbitration at the Hague (hereinafter referred to as "International Bureau") shall fulfil the functions of registry and provide the necessary secretarial services.

Notices and calculation of time limits

1. Notices, including communications or proposals, may be sent by any means of communication that certifies their transmission, or enables them to be certified.

2. Such notices may be sent electronically only if an address has been designated or authorised by a party specifically for this purpose.

3. Such notices served on the parties shall be sent, for Switzerland, to Switzerland's Europe Division of the Federal Department of Foreign Affairs and, for the Union, to the Commission's Legal Service.

4. Any time limit laid down in this Appendix shall run from the day after an event occurs or an action takes place. If the last day for delivery of a document falls on a non-working day of the institutions of the Union or of the government of Switzerland, the time period for the delivery of the document shall end on the first following working day. Non-working days that fall within the time period shall be counted.

Notice of arbitration

1. The party taking the initiative to use arbitration (hereinafter referred to as "applicant") shall send to the other party (hereinafter referred to as "defendant") and to the International Bureau a notice of arbitration.

2. Arbitration proceedings shall be deemed to commence on the day after that on which the notice of arbitration is received by the defendant.

3. The notice of arbitration shall include the following information:

- (a) the demand that the dispute be referred to arbitration;
- (b) the names and contact details of the parties;
- (c) the name and address of the applicant's agent(s);
- (d) the legal basis of the proceedings (Article 10(2) or Article 11(2) of the Protocol) and:
 - (i) in the cases referred to in Article 10(2) of the Protocol, the question causing the dispute as officially entered, for resolution, on the agenda of the Joint Committee in accordance with Article 10(1) of the Protocol; and

- (ii) in the cases referred to in Article 11(2) of the Protocol, the decision of the arbitral tribunal, any implementation measures mentioned in Article 10(5) of the Protocol and the disputed compensatory measures;
- (e) the designation of any rule causing the dispute or related to it;
- (f) a brief description of the dispute; and
- (g) the designation of an arbitrator or, if five arbitrators are to be appointed, the designation of two arbitrators.

4. In the cases referred to in Article 10(3) of the Protocol, the notice of arbitration may also contain information concerning the need for a referral to the Court of Justice of the European Union.

5. Any claims on the sufficiency of the notice of arbitration shall not prevent the constitution of the arbitral tribunal. The dispute shall be decided definitively by the arbitral tribunal.

Response to the notice of arbitration

1. Within 60 days of receiving the notice of arbitration, the defendant shall send a response to the notice of arbitration to the applicant and the International Bureau, which shall include the following information:

- (a) the names and contact details of the parties;
- (b) the name and address of the defendant's agent(s);
- (c) a response to the information given in the notice of arbitration in accordance with points (d) to (f) of Article I.4(3); and
- (d) the designation of an arbitrator or, if five arbitrators are to be appointed, the designation of two arbitrators.

2. In the cases referred to in Article 10(3) of the Protocol, the response to the notice of arbitration may also contain a response to the information given in the notice of arbitration in accordance with Article I.4(4) of this Appendix and information concerning the need for a referral to the Court of Justice of the European Union.

3. The lack of, or an incomplete or late, response from the defendant to the notice of arbitration shall not prevent the constitution of an arbitral tribunal. The dispute shall be decided definitively by the arbitral tribunal.

4. If the defendant requests that the arbitral tribunal consist of five arbitrators in its response to the notice of arbitration, the applicant shall designate an additional arbitrator within 30 days of receipt of the response to the notice of arbitration.

ARTICLE I.6

Representation and assistance

1. The parties shall be represented before the arbitral tribunal by one or more agents. The agents may be assisted by advisers or lawyers.

2. Any change to the agents or their addresses shall be notified to the other party, the International Bureau and the arbitral tribunal. The arbitral tribunal may, at any time, on its own initiative or at the request of a party, request evidence of the powers conferred on the agents of the parties.

CHAPTER II

COMPOSITION OF THE ARBITRAL TRIBUNAL

ARTICLE II.1

Number of arbitrators

The arbitral tribunal shall be composed of three arbitrators. If the applicant in its notice of arbitration or the defendant in its response to the notice of arbitration so request, the arbitral tribunal shall be composed of five arbitrators.

ARTICLE II.2

Appointment of arbitrators

1. If three arbitrators are to be appointed, each of the parties shall designate one of them. The two arbitrators appointed by the parties shall select the third arbitrator, who shall be the chair of the arbitral tribunal.

2. If five arbitrators are to be appointed, each of the parties shall designate two of them. The four arbitrators appointed by the parties shall select the fifth arbitrator, who shall be the chair of the arbitral tribunal.

3. If, within 30 days of the designation of the last arbitrator appointed by the parties, the arbitrators have not reached agreement on the selection of the chair of the arbitral tribunal, the chair shall be appointed by the Secretary-General of the Permanent Court of Arbitration.

4. To assist in the selection of arbitrators to compose the arbitral tribunal, an indicative list of persons possessing the qualifications referred to in paragraph 6, which shall be common to all bilateral agreements in the fields related to the internal market in which Switzerland participates as well as the Agreement between the European Union and the Swiss Confederation on health, done at [...] on [...] (hereinafter referred to as "Agreement on health"), the Agreement between the European Community and the Swiss Confederation on trade in agricultural products, done at Luxembourg on 21 June 1999 (hereinafter referred to as "Agreement on trade in agricultural products, done at products") and the Agreement between the European Union and the Swiss Confederation on Switzerland's regular financial contribution towards reducing economic and social disparities in the European Union, done at [...] on [...] (hereinafter referred to as "Agreement on Switzerland's regular financial contribution"), shall be established and updated when necessary. The Joint Committee shall adopt and update that list by a decision for the purposes of the Agreement.

5. Where a party fails to designate an arbitrator, the Secretary-General of the Permanent Court of Arbitration shall appoint that arbitrator from the list referred to in paragraph 4. In the absence of such a list, the arbitrator shall be appointed by lot by the Secretary-General of the Permanent Court of Arbitration from the individuals who have been formally proposed by one party or both parties for the purposes of paragraph 4.

6. The persons constituting the arbitral tribunal shall be highly qualified persons, with or without ties to the parties, whose independence and lack of conflicts of interest is guaranteed, along with a wide range of experience. In particular, they shall have demonstrated expertise in law and the matters covered by this Agreement; they shall not take instructions from either party; and they shall serve in their individual capacities and not take instructions from any organisation or government with regard to matters related to the dispute. The chair of the arbitral tribunal shall also have experience in dispute settlement procedures.

ARTICLE II.3

Arbitrators' declarations

1. When a person is being considered for appointment as an arbitrator, that person shall report all circumstances likely to give rise to legitimate doubts as to his or her impartiality or independence. From the appointment and throughout the entire arbitration proceedings, an arbitrator shall report such circumstances to the parties and to the other arbitrators without delay, if the arbitrator has not already done so.

2. Any arbitrator may be dismissed if circumstances exist that could give rise to legitimate doubts about his or her impartiality or independence.

3. A party may only request the dismissal of an arbitrator that it has appointed for a reason that becomes known to it after that appointment.

4. If an arbitrator fails to act or if it is impossible de jure or de facto for an arbitrator to fulfil his or her role, the procedure for the dismissal of arbitrators laid down in Article II.4 shall apply.

ARTICLE II.4

Dismissal of arbitrators

1. Any party wishing to dismiss an arbitrator shall make a request for dismissal within 30 days of the date on which it is notified of the appointment of that arbitrator or within 30 days of the date on which it becomes aware of the circumstances referred to in Article II.3.

2. The request for dismissal shall be sent to the other party, to the dismissed arbitrator, to the other arbitrators and to the International Bureau. It shall set out the reasons for the request for dismissal.

3. When a request for dismissal has been made, the other party may accept the request for dismissal. The arbitrator in question may also step aside. The acceptance or stepping aside does not imply acknowledgement of the reasons for the request for dismissal.

4. If, within 15 days of the date of the notification of the request for dismissal, the other party does not accept the request for dismissal or the arbitrator in question does not step aside, the party requesting the dismissal may ask the Secretary-General of the Permanent Court of Arbitration to take a decision on the dismissal.

5. Unless the parties agree otherwise, the decision referred to in paragraph 4 shall indicate the reasons for that decision.

ARTICLE II.5

Replacement of an arbitrator

1. Subject to paragraph 2 of this Article, if it is necessary to replace an arbitrator during the arbitration proceedings, a replacement shall be appointed or selected in accordance with the procedure laid down in Article II.2 applicable to the appointment or selection of the arbitrator to be replaced. That procedure shall apply even if one party had not exercised its right to appoint or to participate in the appointment of the arbitrator to be replaced.

2. In the event of replacement of an arbitrator, the procedure shall resume at the stage where the replaced arbitrator ceased to perform his or her functions, unless the arbitral tribunal decides otherwise.

ARTICLE II.6

Exclusion of liability

Except in cases of intentional wrongdoing or gross negligence, the parties renounce, to the maximum extent permitted by the applicable law, any action against the arbitrators for any act or omission related to the arbitration.

CHAPTER III

ARBITRATION PROCEEDINGS

ARTICLE III.1

General provisions

1. The date of establishment of the arbitral tribunal shall be the date on which the last arbitrator has accepted his or her appointment.

2. The arbitral tribunal shall ensure that the parties are treated equally and that, at an appropriate stage of the proceedings, each of them has sufficient possibility to assert their rights and present their case. The arbitral tribunal shall conduct the proceedings in such a way as to avoid delays and unnecessary expenditure and to ensure the dispute between the parties is settled.

3. A hearing shall be organised, unless the arbitral tribunal decides otherwise, having heard the parties.

4. When a party sends a communication to the arbitral tribunal, it shall do so through the International Bureau and shall send a copy to the other party at the same time. The International Bureau shall send a copy of that communication to each of the arbitrators.

Place of arbitration

The place of arbitration is The Hague. The arbitral tribunal may, if exceptional circumstances so require, meet at any other place that it considers appropriate for its deliberations.

ARTICLE III.3

Language

1. The languages of the proceedings shall be French and English.

2. The arbitral tribunal may order all documents enclosed with the statement of claim or the statement of defence and all further documents produced during the proceedings, submitted in their original language, to be accompanied by a translation in one of the languages of the proceedings.

Statement of claim

1. The applicant shall send its statement of claim in writing to the defendant and to the arbitral tribunal through the International Bureau, within the time limit set by the arbitral tribunal. The applicant may decide to deem its notice of arbitration referred to in Article I.4 a statement of claim, provided that it also meets the conditions in paragraphs 2 and 3 of this Article.

2. The statement of claim shall include the following information:

(a) the information set out in points (b) to (f) of Article I.4(3);

(b) a statement of facts submitted in support of the claim; and

(c) the legal arguments put forward in support of the claim.

3. The statement of claim shall, as far as possible, be accompanied by any documents and other evidence mentioned by the applicant or should refer to them. In the cases referred to in Article 10(3) of the Protocol, the statement of claim shall also, as far as possible, contain information concerning the need for a referral to the Court of Justice of the European Union.

Statement of defence

1. The defendant shall send the statement of defence in writing to the applicant and to the arbitral tribunal through the International Bureau, within the time limit set by the arbitral tribunal. The defendant may decide to deem the response to the notice of arbitration referred to in Article I.5 a statement of defence, provided that the response to the notice of arbitration also meets the conditions in paragraph 2 of this Article.

2. The statement of defence shall respond to the points in the statement of claim indicated in accordance with points (a) to (c) of Article III.4(2) of this Appendix. It shall, as far as possible, be accompanied by any documents and other evidence mentioned by the defendant or should refer to them. In the cases referred to in Article 10(3) of the Protocol, the statement of defence shall also, as far as possible, contain information concerning the need for a referral to the Court of Justice of the European Union.

3. In the statement of defence, or at a later stage in the arbitration proceedings if the arbitral tribunal decides that a delay is justified by circumstances, the defendant may make a counterclaim provided that the arbitral tribunal has jurisdiction in respect of it.

4. Article III.4(2) and (3) shall apply to a counterclaim.

Arbitral jurisdiction

1. The arbitral tribunal shall rule on whether it has jurisdiction on the basis of Articles 10(2) or 11(2) of the Protocol.

2. In the cases referred to in Article 10(2) of the Protocol, the arbitral tribunal shall have a mandate to examine the question causing the dispute as officially entered, for resolution, on the agenda of the Joint Committee in accordance with Article 10(1) of the Protocol.

3. In the cases referred to in Article 11(2) of the Protocol, the arbitral tribunal that heard the main case shall have a mandate to examine the proportionality of the disputed compensatory measures, including where those measures have in whole or in part been taken in another bilateral agreement in the fields related to the internal market in which Switzerland participates.

4. A preliminary objection of lack of jurisdiction of the arbitral tribunal shall be made at the latest in the statement of defence or, in the case of a counterclaim, in the reply. The fact that a party has appointed an arbitrator or has taken part in their appointment shall not deprive it of the right to make such a preliminary objection. The preliminary objection that the dispute would exceed the arbitral tribunal's powers shall be made as soon as the question alleged to exceed its powers is raised during the arbitration proceedings. In any event, the arbitral tribunal may allow a preliminary objection made after the time limit laid down has elapsed if it believes that the delay was for a valid reason.

5. The arbitral tribunal may rule on the preliminary objection referred to in paragraph 4 either by treating it as a preliminary question or in the decision on the substance of the case.

ARTICLE III.7

Other written submissions

The arbitral tribunal shall, after having consulted the parties, decide what other written submissions, in addition to the statement of claim and statement of defence, the parties shall or may submit and shall set the time limit for their submission.

ARTICLE III.8

Time limits

1. The time limits set by the arbitral tribunal for the communication of the written documents, including the statement of claim and the statement of defence, shall not exceed 90 days, unless the parties agree otherwise.

2. The arbitral tribunal shall take its final decision within 12 months of the date of its establishment. In exceptional circumstances of particular difficulty, the arbitral tribunal may extend that period by up to three additional months.

- 3. The time limits laid down in paragraphs 1 and 2 shall be halved:
- (a) upon request by the applicant or the defendant, if, within 30 days of that request, the arbitral tribunal rules, after hearing the other party, that the case is urgent; or

(b) if the parties so agree.

4. In the cases referred to in Article 11(2) of the Protocol, the arbitral tribunal shall take its final decision within six months of the date on which the compensatory measures have been notified in accordance with Article 11(1) of the Protocol.

ARTICLE III.9

Referrals to the Court of Justice of the European Union

1. In application of Article 7 and Article 10(3) of the Protocol, the arbitral tribunal shall make a referral to the Court of Justice of the European Union.

2. The arbitral tribunal may make a referral to the Court of Justice of the European Union at any time in the proceedings, provided that the arbitral tribunal is able to define precisely enough the legal and factual background of the case, and the legal questions it raises.

The proceedings before the arbitral tribunal shall be suspended until the Court of Justice of the European Union has delivered its ruling.

3. Each party may send a reasoned request to the arbitral tribunal to make a referral to the Court of Justice of the European Union. The arbitral tribunal shall reject such a request if it considers the conditions for a referral to the Court of Justice of the European Union referred to in paragraph 1 not to be met. If the arbitral tribunal rejects a party's request for a referral to the Court of Justice of the European Union, it shall give reasons for its decision in the decision on the substance of the case.

4. The arbitral tribunal shall make a referral to the Court of Justice of the European Union by means of a notice. The notice shall contain at least the following information:

(a) a brief description of the dispute;

(b) the legal act(s) of the Union and/or the provision(s) of the Agreement at issue; and

(c) the concept of Union law to be interpreted in accordance with Article 7(2) of the Protocol.

The arbitral tribunal shall give notice of the referral to the Court of Justice of the European Union to the parties.

5. The Court of Justice of the European Union shall apply, by analogy, the internal rules of procedure applicable to the exercise of its jurisdiction to make a preliminary ruling on the interpretation of the Treaties and acts made by the Union's institutions, bodies, offices and agencies.

6. The agents and lawyers authorised to represent the parties before the arbitral tribunal pursuant to Articles I.4, I.5, III.4 and III.5 shall be authorised to represent the parties before the Court of Justice of the European Union.

ARTICLE III.10

Interim measures

1. In the cases referred to in Article 11(2) of the Protocol, either party may, at any stage of the arbitration procedure, apply for interim measures consisting of the suspension of the compensatory measures.

2. An application pursuant to paragraph 1 shall state the subject matter of the proceedings, the circumstances giving rise to urgency and the pleas of fact and law establishing a prima facie case for the interim measures applied for. It shall contain all the evidence and offers of evidence available to justify the grant of the interim measures.

3. The party requesting the interim measures shall send its application in writing to the other party and to the arbitral tribunal through the International Bureau. The arbitral tribunal shall set a short time limit within which that other party may submit written or oral observations.

4. The arbitral tribunal shall, within one month of the submission of the application referred to in paragraph 1, adopt a decision on the suspension of the contested compensatory measures if the following conditions are met:

- (a) the arbitral tribunal is prima facie satisfied of the merit of the case submitted by the party requesting the interim measures in its application;
- (b) the arbitral tribunal considers that, pending its final decision, the party requesting the interim measures would suffer serious and irreparable harm absent the suspension of the compensatory measures; and

(c) the harm caused to the party requesting the interim measures by the immediate application of the contested compensatory measures outweighs the interest in the immediate and effective application of those measures.

5. The suspension of proceedings referred to in the second subparagraph of Article III.9(2) shall not apply in proceedings pursuant to this Article.

6. A decision taken by the arbitral tribunal in accordance with paragraph 4 shall have only an interim effect and shall be without prejudice to the decision of the arbitral tribunal on the substance of the case.

7. Unless the decision taken by the arbitral tribunal in accordance with paragraph 4 of this Article sets an earlier date for the end of the suspension, the suspension shall lapse when the final decision pursuant to Article 11(2) of the Protocol is taken.

8. For the avoidance of doubt, for the purposes of this Article, it is understood that, in considering the respective interests of the party requesting the interim measures and the other party, the arbitral tribunal shall take into account those of the individuals and economic operators of the parties, but that consideration shall not amount to granting any standing to such individuals or economic operators before the arbitral tribunal.

ARTICLE III.11

Evidence

1. Each party shall provide evidence of the facts forming the grounds of its claim or its defence.

2. On request of a party, or on its own initiative, the arbitral tribunal may seek from the parties relevant information it considers necessary and appropriate. The arbitral tribunal shall set a time limit for the parties to respond to its request.

3. On request of a party, or on its own initiative, the arbitral tribunal may seek from any source any information it considers appropriate. The arbitral tribunal may also seek the opinion of experts as it considers appropriate and subject to any terms and conditions agreed by the parties, where applicable.

4. Any information obtained by the arbitral tribunal under this Article shall be made available to the parties, and the parties may submit comments on that information to the arbitral tribunal.

5. After seeking the views of the other party, the arbitral tribunal shall adopt appropriate measures to address any questions raised by a party with regard to the protection of personal data, professional secrecy and the legitimate interests of confidentiality.

6. The arbitral tribunal shall be the judge of the admissibility, relevance and strength of the evidence submitted.

ARTICLE III.12

Hearings

1. When a hearing must take place, the arbitral tribunal, having consulted the parties, shall notify the parties sufficiently far in advance of the date, time and place of the hearing.

2. The hearing shall be public, unless the arbitral tribunal, of its own motion or on application by the parties, decides otherwise for serious reasons.

3. Minutes of each hearing shall be drawn up and signed by the chair of the arbitral tribunal. Only those minutes shall be authentic.

4. The arbitral tribunal may decide to hold the hearing virtually in accordance with the practice of the International Bureau. The parties shall be informed of this practice in a timely manner. In such cases, paragraph 1, *mutatis mutandis*, and paragraph 3 shall apply.

ARTICLE III.13

Default

1. If, within the time limit set by this Appendix or by the arbitral tribunal, without showing sufficient cause, the applicant has not submitted its statement of claim, the arbitral tribunal shall order the closure of the arbitration proceedings, unless there are outstanding questions on which a ruling may be necessary and if the arbitral tribunal considers it appropriate to do so.

If, within the time limit set by this Appendix or by the arbitral tribunal, without showing sufficient cause, the defendant has not submitted its response to the notice of arbitration or its statement of defence, the arbitral tribunal shall order the continuation of the proceedings, without considering that default of itself to constitute acceptance of the applicant's allegations.

The second subparagraph also applies where the applicant fails to submit a reply to a counterclaim.

2. If a party, duly convened in accordance with Article III.12(1), does not appear at a hearing and does not demonstrate sufficient cause for its failure to do so, the arbitral tribunal may continue the arbitration.

3. If a party, duly invited by the arbitral tribunal to produce further evidence, fails to do so within the time limits set without showing sufficient cause for its failure to do so, the arbitral tribunal may rule on the basis of the evidence it has available.

ARTICLE III.14

Closure of the procedure

1. Where it is demonstrated that the parties have reasonably had the possibility of presenting their arguments, the arbitral tribunal may declare the closure of the proceedings.

2. The arbitral tribunal may, if it considers it necessary because of exceptional circumstances, decide on its own initiative or at the request of a party to reopen the proceedings at any time before it has taken its decision.

CHAPTER IV

DECISION

ARTICLE IV.1

Decisions

The arbitral tribunal shall strive to take its decisions by consensus. If, however, it proves impossible to take a decision by consensus, the arbitral tribunal's decision shall be taken by a majority of the arbitrators.

ARTICLE IV.2

Form and effect of the decision of the arbitral tribunal

1. The arbitral tribunal may take separate decisions on different questions at different times.

2. All decisions shall be issued in writing and shall state the reasons on which they are based. They shall be final and binding on the parties.

3. The decision of the arbitral tribunal shall be signed by the arbitrators, shall contain the date on which it was taken and state the place of arbitration. A copy of the decision signed by the arbitrators shall be communicated to the parties by the International Bureau.

4. The International Bureau shall make the decision of the arbitral tribunal public.

When making the decision of the arbitral tribunal public, the International Bureau shall respect the relevant rules on the protection of personal data, professional secrecy and the legitimate interests of confidentiality.

The rules referred to in the second subparagraph shall be identical for all bilateral agreements in the fields of the internal market in which Switzerland participates as well as for the Agreement on health, the Agreement on trade in agricultural products and the Agreement on Switzerland's regular financial contribution. The Joint Committee shall adopt and update those rules by a decision for the purposes of the Agreement.

5. The parties shall comply with all decisions of the arbitral tribunal without delay.

6. In the cases referred to in Article 10(2) of the Protocol, having obtained the opinion of the parties, the arbitral tribunal shall set a reasonable time limit in the decision on the substance of the case to comply with its decision in accordance with Article 10(5) of the Protocol taking account of the parties' internal procedures.

ARTICLE IV.3

Applicable law, rules of interpretation, mediator

1. The applicable law consists of the Agreement, the legal acts of the Union to which reference is made therein, as well as any other rule of international law relevant to the application of those instruments.

2. The arbitral tribunal shall decide in accordance with the rules of interpretation referred to in Article 7 of the Protocol.

3. Prior decisions taken by a dispute settlement body with regard to the proportionality of compensatory measures under another bilateral agreement among those referred to in Article 11(1) of the Protocol shall be binding upon the arbitral tribunal.

4. The arbitral tribunal shall not be permitted to decide as mediator or ex aequo et bono.

ARTICLE IV.4

Mutually agreed solution or other reasons for closure of the proceedings

1. The parties may, at any time, mutually agree a solution to their dispute. They shall jointly communicate any such solution to the arbitral tribunal. If the solution requires approval pursuant to the relevant domestic procedures of either party, the notification shall refer to that requirement, and the arbitration procedure shall be suspended. If such approval is not required, or upon notification of the completion of any such domestic procedures, the arbitration procedure shall be closed.

2. If, in the course of proceedings, the applicant informs the arbitral tribunal in writing that it does not wish to further pursue the proceedings, and if, at the date on which that communication is received by the arbitral tribunal, the defendant has not yet taken any step in the proceedings, the arbitral tribunal shall issue an order officially recording the closure of the proceedings. The arbitral tribunal shall decide on the costs, which shall be borne by the applicant, if this appears justified by the conduct of that party.

3. If, before the decision of the arbitral tribunal is taken, the arbitral tribunal concludes that the continuation of the proceedings has become pointless or impossible for any reason other than those referred to in paragraphs 1 and 2, the arbitral tribunal shall inform the parties of its intention to issue an order closing the proceedings.

The first subparagraph does not apply where there are outstanding questions on which it may be necessary to rule and if the arbitral tribunal judges it appropriate to do so.

4. The arbitral tribunal shall communicate to the parties a copy of the order closing the arbitration proceedings or of the decision taken by agreement between the parties, signed by the arbitrators. Article IV.2(2) to (5) shall apply to arbitration decisions taken by agreement between the parties.

ARTICLE IV.5

Correction of the decision of the arbitral tribunal

1. Within 30 days of receiving the decision of the arbitral tribunal, a party may, by giving notice to the other party and to the arbitral tribunal through the International Bureau, ask the arbitral tribunal to correct in the text of the decision of the arbitral tribunal any errors in computation, any clerical or typographical errors, or any errors or omissions of a similar nature. If it considers the request to be justified, the arbitral tribunal shall make the correction within 45 days of receiving the request. The request shall not have a suspensive effect on the time limit provided for in Article IV.2(6).

2. The arbitral tribunal may, within 30 days of communicating its decision, make the corrections referred to in paragraph 1 on its own initiative.

3. The corrections referred to in paragraph 1 of this Article shall be done in writing and form an integral part of the decision. Article IV.2(2) to (5) shall apply.

ARTICLE IV.6

Arbitrators' fees

1. The fees referred to in Article IV.7 shall be reasonable, taking account of the complexity of the case, the time spent on it by the arbitrators and all other relevant circumstances.

2. A list of daily compensation and maximum and minimum hours, which shall be common to all bilateral agreements in the fields related to the internal market in which Switzerland participates as well as the Agreement on health, the Agreement on trade in agricultural products and the Agreement on Switzerland's regular financial contribution, shall be established and updated when necessary. The Joint Committee shall adopt and update that list by a decision for the purposes of the Agreement.

ARTICLE IV.7

Costs

1. Each party shall bear its own costs and half of the costs of the arbitral tribunal.

2. The arbitral tribunal shall set its costs in its decision on the substance of the case. Those costs shall include only:

- (a) the arbitrators' fees, to be stated separately for each arbitrator and to be set by the arbitral tribunal itself in accordance with Article IV.6;
- (b) the travel and other expenses incurred by the arbitrators; and
- (c) the fees and expenses of the International Bureau.

3. The costs referred to in paragraph 2 shall be reasonable, taking account of the amount in dispute, the complexity of the dispute, the time that the arbitrators and any experts appointed by the arbitral tribunal have spent on it and any other relevant circumstances.

ARTICLE IV.8

Deposit of costs

1. At the start of the arbitration, the International Bureau may ask the parties to deposit an equal amount as an advance for the costs referred to in Article IV.7(2).

2. During the arbitration proceedings, the International Bureau may request from the parties deposits supplementary to those referred to in paragraph 1.

3. All amounts deposited by the parties in application of this Article shall be paid to the International Bureau and paid out by it to cover the costs actually incurred, including, in particular, the fees paid to the arbitrators and to the International Bureau.

CHAPTER V

FINAL PROVISIONS

ARTICLE V.1

Amendments

The Joint Committee may adopt, by decision, amendments to this Appendix.