Official Journal of the European Union

L 72

English edition

Legislation

Volume 61

15 March 2018

Contents

[1] Text with EEA relevance.
[2] Text with relevance for the EEA and for Switzerland.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION (EU) 2018/398

of 12 June 2017

on the signing, on behalf of the European Union, and provisional application of the Agreement between the European Union and Iceland on supplementary rules in relation to the instrument for financial support for external borders and visa, as part of the Internal Security Fund, for the period 2014 to 2020

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 77(2) and 218(5) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) Regulation (EU) No 515/2014 of the European Parliament and of the Council ([1]) provides that the countries associated with the implementation, application and development of the Schengen *acquis* are to participate in the instrument for financial support for external borders and visa in accordance with its provisions and that arrangements are to be concluded on their financial contributions and the supplementary rules necessary for such participation, including provisions ensuring the protection of the Union's financial interests and the powers of audit of the Court of Auditors.

(2) On 14 July 2014, the Council authorised the Commission to open negotiations with the Kingdom of Norway, Iceland, the Swiss Confederation and the Principality of Liechtenstein for an Agreement on the modalities of their participation in the Internal Security Fund – Borders and Visa for the period 2014 to 2020. The negotiations with Iceland were successfully concluded by the initialling of the Agreement on 21 September 2016.

(3) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, Denmark is not taking part in the adoption of this Decision and is not bound by it or subject to its application. Given that this Decision builds upon the Schengen *acquis*, Denmark shall, in accordance with Article 4 of that Protocol, decide within a period of six months after the Council has decided on this Decision whether it will implement it in its national law.

(4) This Decision constitutes a development of the provisions of the Schengen *acquis* in which the United Kingdom does not take part, in accordance with Council Decision 2000/365/EC ([2]); the United Kingdom is therefore not taking part in the adoption of this Decision and is not bound by it or subject to its application.

(5) This Decision constitutes a development of the provisions of the Schengen *acquis* in which Ireland does not take part, in accordance with Council Decision 2002/192/EC ([3]); Ireland is therefore not taking part in the adoption of this Decision and is not bound by it or subject to its application.

([1]) Regulation (EU) No 515/2014 of the European Parliament and of the Council of 16 April 2014 establishing, as part of the Internal Security Fund, the instrument for financial support for external borders and visa and repealing Decision No 574/2007/EC (OJ L 150, 20.5.2014, p. 143).

([2]) Council Decision 2000/365/EC of 29 May 2000 concerning the request of the United Kingdom of Great Britain and Northern Ireland to take part in some of the provisions of the Schengen *acquis* (OJ L 131, 1.6.2000, p. 43).

([3]) Council Decision 2002/192/EC of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen *acquis* (OJ L 64, 7.3.2002, p. 20).

(6) The Agreement should be signed on behalf of the Union, subject to its conclusion at a later date.

(7) In order to allow for the prompt application of the measures provided for in the Agreement and not delay the approval and implementation of the national programme, this Decision should enter into force on the day following that of its publication in the *Official Journal of the European Union*.

(8) In accordance with Article 19(4) of the Agreement, the Agreement with the exception of Article 5 thereof should be applied provisionally as from the day following that of its signature,

HAS ADOPTED THIS DECISION:

Article 1

The signing on behalf of the Union of the Agreement between the European Union and Iceland on supplementary rules in relation to the instrument for financial support for external borders and visa, as part of the Internal Security Fund for the period 2014 to 2020 is authorised, subject to the conclusion of the said Agreement.

The text of the Agreement is attached to this Decision.

Article 2

The President of the Council is hereby authorised to designate the person(s) empowered to sign the Agreement on behalf of the Union.

Article 3

The Agreement with the exception of its Article 5, shall be applied on a provisional basis in accordance with Article 19(4) thereof from the day following that of its signature ([1]), pending the completion of the procedures necessary for its entry into force.

Article 4

This Decision shall enter into force on the date following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 12 June 2017.

For the Council
The President
C. CAMILLERI

([1]) The date from which the Agreement will be provisionally applied will be published in the *Official Journal of the European Union* by the General Secretariat of the Council.

AGREEMENT

between the European Union and Iceland on supplementary rules in relation to the instrument for financial support for external borders and visa, as part of the Internal Security Fund, for the period 2014 to 2020

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

and

ICELAND,

hereinafter referred to jointly as 'the Parties'

HAVING REGARD to the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the latters' association with the implementation, application and development of the Schengen *acquis* ([1]) ('Association Agreement with Iceland and Norway'),

Whereas:

(1) The Union established the instrument for financial support for external borders and visa, as part of the Internal Security Fund by means of Regulation (EU) No 515/2014 of the European Parliament and of the Council ([2]).

(2) Regulation (EU) No 515/2014 constitutes a development of the Schengen *acquis* within the meaning of the Association agreement with Iceland and Norway.

(3) As Regulation (EU) No 514/2014 of the European Parliament and of the Council ([3]) has a direct impact on the application of the provisions of Regulation (EU) No 515/2014, thus affecting the latter's legal framework, and as the procedures set out in the Association Agreement with Iceland and Norway have been applied for the adoption of Regulation (EU) No 514/2014 which was notified to Iceland, the Parties acknowledge that Regulation (EU) No 514/2014 constitutes a development of the Schengen *acquis* within the meaning of the Association Agreement with Iceland and Norway insofar as it is necessary for the implementation of Regulation (EU) No 515/2014.

(4) Article 5(7) of Regulation (EU) No 515/2014 provides that the countries associated with the implementation, application and development of the Schengen *acquis*, among which Iceland, participate in the instrument in accordance with its provisions and that arrangements should be concluded to specify financial contributions by those countries and supplementary rules necessary for such participation, including provisions ensuring the protection of the Union's financial interests and the power of audit of the Court of Auditors.

(5) The instrument for financial support for external borders and visa, as part of he Internal Security Fund ('the ISF – Borders and Visa') constitutes a specific instrument in the context of the Schengen *acquis* designed to provide for burden sharing and financial support in the field of external borders and visa policy in Member States and associated States.

(6) Article 60 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council ([4]) provides for rules on indirect management that are applicable where third countries, including associated States, are entrusted with budget implementation tasks.

([1]) OJ L 176, 10.7.1999, p. 36.
([2]) Regulation (EU) No 515/2014 of the European Parliament and of the Council of 16 April 2014 establishing, as part of the Internal Security Fund, the instrument for financial support for external borders and visa and repealing Decision No 574/2007/EC (OJ L 150, 20.5.2014, p. 143).
([3]) Regulation (EU) No 514/2014 of the European Parliament and of the Council of 16 April 2014 laying down general provisions on the Asylum, Migration and Integration Fund and on the instrument for financial support for police cooperation, preventing and combating crime, and crisis management (OJ L 150, 20.5.2014, p. 112).
([4]) Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

(7) Article 17(4) of Regulation (EU) No 514/2014 provides for the eligibility of expenditure incurred in 2014 by a Responsible Authority not yet formally designated, thereby ensuring a smooth transition between the External Borders Fund and the Internal Security Fund. Similarly, it is important that the same concern be reflected in this Agreement. Given that this Agreement did not come into force before the end of 2014, it is essential to ensure the eligibility of expenditure incurred before and until the formal designation of the Responsible Authority, provided that the management and control systems applied before are essentially the same as the ones in force after the formal designation of the Responsible Authority.

(8) To facilitate the calculation and use of the annual contributions due by Iceland to the ISF – Borders and Visa, its contributions for the period 2014-2020 will be paid in five annual instalments from 2016 to 2020. From 2016 to 2018, the annual contributions are set in fixed amounts while the contributions due for the years 2019 and 2020 will be determined in 2019 on the basis of the gross domestic product of all States participating in the ISF – Borders and Visa taking into account the payments effectively made,

HAVE AGREED AS FOLLOWS:

Article 1

Scope

This Agreement sets out the supplementary rules necessary for the participation of Iceland in the ISF – Borders and Visa in accordance with Regulation (EU) No 515/2014.

Article 2

Financial management and control

1. Iceland shall take the necessary measures to ensure compliance with the provisions relevant to the financial management and control which are laid down in the Treaty on the Functioning of the European Union ('TFEU') and in Union law which derives its legal basis from the TFEU.

The provisions of the TFEU and of secondary legislation referred to in the first sub paragraph are the following:

(a) Article 287(1), (2) and (3) TFEU;

(b) Articles 30, 32 and 57, Article point (i) of 58(1)(c), Article 60 and Articles 79(2) and 108(2) of Regulation (EU, Euratom) No 966/2012;

(c) Articles 32, 38, 42, 84, 88, 142 and 144 of Commission Delegated Regulation (EU) No 1268/2012 ([1]);

(d) Council Regulation (Euratom, EC) No 2185/96 ([2]);

(e) Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council ([3]).

The Parties may decide to amend this list by mutual agreement.

2. Iceland shall apply the provisions referred to in paragraph 1 in its territory in accordance with this Agreement.

Article 3

Respect for the principle of sound financial management

The funds allocated to Iceland under the ISF – Borders and Visa shall be used in accordance with the principle of sound financial management.

([1]) Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1).

([2]) Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

([3]) Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

Article 4

Respect for the principle on conflict of interest

All financial actors and any other person involved in budget implementation and management, including acts preparatory thereto, audit or control acting in the territory of Iceland shall be prohibited from taking any action which may bring their own interests into conflict with those of the Union.

Article 5

Enforcement

Decisions taken by the Commission which impose a pecuniary obligation on persons other than states shall be enforceable in the territory of Iceland.

Enforcement shall be governed by the rules of civil procedure in force in Iceland. The order for enforcement of a decision shall be appended to that decision, without any formality other than the verification of the authenticity of the decision, by the national authority which the government of Iceland shall designate for that purpose and shall make known to the Commission.

When those formalities have been completed on application by the Commission, the Commission may proceed to enforcement in accordance with national law by bringing the matter directly before the competent authority.

Enforcement may be suspended only by a decision of the Court of Justice of the European Union. However, the courts of Iceland shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

Article 6

Protection of the financial interests of the Union against fraud

1. Iceland shall:

(a) counter fraud and any other illegal activities affecting the financial interests of the Union through measures which shall act as a deterrent and be such as to afford effective protection in Iceland;

(b) take the same measures to counter fraud affecting the financial interests of the Union as it takes to counter fraud affecting its own financial interests; and

(c) coordinate its action aimed at protecting the financial interests of the Union with the Member States and the Commission.

2. Iceland shall adopt equivalent measures to those adopted by the Union in accordance with Article 325(4) TFEU which are in force at the date of signature of this Agreement.

The Parties may decide by mutual agreement to adopt equivalent measures to any subsequent measures adopted by the Union in accordance with this Article.

Article 7

On-the spot checks and inspections by the Commission (OLAF)

Without prejudice to its rights under Article 5(8) of Regulation (EU) No 514/2014, the Commission (the European Anti-Fraud Office OLAF) shall be authorised to carry out on-the spot checks and inspections in the territory of Iceland as regards the ISF – Borders and Visa in accordance with the terms and conditions laid down in Regulation (Euratom, EC) No 2185/96.

The authorities of Iceland shall facilitate on-the-spot checks and inspections which may, if those authorities so wish, be carried out jointly with them.

Article 8

Court of Auditors

In accordance with Article 287(3) TFEU and with Part One, Title X, chapter 1 of Regulation (EU, Euratom) No 966/2012, the Court of Auditors shall have the possibility to perform audits on the premises of any body which manages revenue or expenditure on behalf of the Union in the territory of Iceland as regards the ISF – Borders and Visa including on the premises of any natural or legal person in receipt of payments from the budget.

In Iceland, audits by the Court of Auditors shall be carried out in liaison with national audit bodies or, if they do not have the necessary powers, with the competent national departments. The Court of Auditors and the national audit bodies of Iceland shall cooperate in a spirit of trust while maintaining their independence. Those bodies or departments shall inform the Court of Auditors whether they intend to take part in the audit.

The Court of Auditors shall have at least the same rights as the Commission as laid down in Article 5(7) of Regulation (EU) No 514/2014 and Article 7 of this Agreement.

Article 9

Public procurement

Iceland shall apply the provisions of their law on public procurement in accordance with Annex XVI to the Agreement on the European Economic Area ([1]).

Article 10

Financial contributions

1. For the years 2016 to 2018, Iceland shall make annual payments to the budget of the ISF – Borders and Visa in accordance with the following table:

(All amounts in EUR)

	2016	2017	2018
Iceland	563 999	563 999	563 999

2. The contributions of Iceland for the years 2019 and 2020 shall be calculated in accordance with its respective Gross Domestic Product (GDP) as a percentage of the GDP of all States participating in the ISF – Borders and Visa in accordance with the formula described in the Annex.

3. The financial contributions referred to in this Article shall be due by Iceland irrespective of the date of adoption of its national programme referred to Article 14 of Regulation (EU) No 514/2014.

Article 11

Use of financial contributions

1. The total of the annual payments for 2016 and 2017 shall be assigned as follows:

(a) 75 % to the mid-term review referred to in Article 8 of Regulation (EU) No 515/2014;

(b) 15 % to the development of IT systems referred to in Article 15 of Regulation (EU) No 515/2014, subject to the adoption of the relevant Union legislative acts by 30 June 2017;

(c) 10 % to Union actions referred to in Article 13 of Regulation (EU) No 515/2014 and emergency assistance referred to in Article 14 of Regulation (EU) No 515/2014.

Where the amount referred to in point (b) is not allocated or spent, the Commission shall, pursuant to the procedure set in the second subparagraph of Article 5(5)(b) of Regulation (EU) No 515/2014, re-allocate it to the specific actions referred to in Article 7 of Regulation (EU) No 515/2014.

If this Agreement does not enter into force or is not applied on a provisional basis by 1 June 2017, the full contribution of Iceland shall be used in accordance with paragraph 2 of this Article.

([1]) OJ L 1, 3.1.1994, p. 461.

2. The total of the annual payments for 2018, 2019 and 2020 shall be assigned as follows:

(a) 40 % to specific actions referred to in Article 7 of Regulation (EU) No 515/2014;

(b) 50 % to the development of IT systems referred to in Article 15 of Regulation (EU) No 515/2014, subject to the adoption of the relevant Union legislative acts by 31 December 2018;

(c) 10 % to Union actions referred to in Article 13 of Regulation (EU) No 515/2014 and emergency assistance referred to in Article 14 of Regulation (EU) No 515/2014.

Where the amount referred to in point (b) is not allocated or spent, the Commission shall, pursuant to the procedure set out in the second subparagraph of Article 5(5)(b) of Regulation (EU) No 515/2014, re-allocate it to the specific actions referred to in Article 7 of Regulation (EU) No 515/2014.

3. The additional amounts assigned to the mid-term review, Union actions, specific actions or the programme on the development of IT systems shall be used in accordance with the relevant procedure laid down in one of the following provisions:

(a) Article 6(2) of Regulation (EU) No 514/2014;

(b) Article 8(7) of Regulation (EU) No 515/2014;

(c) Article 7(3) of Regulation (EU) No 515/2014;

(d) the second subparagraph of Article 15 of Regulation (EU) No 515/2014.

4. Each year, the Commission may use up to 4 076 EUR of the payments made by Iceland to finance the administrative expenditure related to staff or external staff necessary for supporting the implementation by Iceland of Regulation (EU) No 515/2014 and this Agreement.

Article 12

Confidentiality

Information communicated or acquired in any form whatsoever pursuant to this Agreement shall be covered by professional secrecy and protected in the same way as similar information is protected by the provisions applicable to the Union institutions and by the laws of Iceland. Such information shall not be communicated to persons other than those within the Union institutions, in the Member States or in Iceland whose functions require them to know it, nor may it be used for purposes other than to ensure effective protection of the financial interests of the Parties.

Article 13

Designation of Responsible Authority

1. Iceland shall notify the Commission of the formal designation at ministerial level of the Responsible Authority responsible for the management and control of expenditure under the ISF – Borders and Visa, as soon as possible after the approval of the national programme.

2. The designation referred to in paragraph 1 shall be made subject to the body complying with the designation criteria on internal environment, control activities, information and communication, and monitoring laid down in or on the basis of Regulation (EU) No 514/2014.

3. The designation of a Responsible Authority shall be based on an opinion of an audit body, which may be the Audit Authority, which assesses the Responsible Authority's compliance with the designation criteria. That body may be the autonomous public institution responsible for monitoring, evaluating and auditing the administration. The audit body shall function independently of the Responsible Authority and shall carry out its work in accordance with internationally accepted audit standards. Iceland may base its decision on designation on whether the management and control systems are essentially the same as those in place for the previous period and whether they have functioned effectively. If the existing audit and control results show that the designated body no longer complies with the designation criteria, Iceland shall take the necessary measures to ensure that deficiencies in the implementation of the tasks of that body are remedied, including by ending the designation.

Article 14

Definition of financial year

For the purpose of this Agreement, the financial year referred to in Article 60(5) of Regulation (EU, Euratom) No 966/2012 shall cover expenditure paid and revenue received and entered into the accounts of the Responsible Authority in the period commencing on 16 October of the year 'N – 1' and ending on 15 October of year 'N'.

Article 15

Eligibility of expenditure

By way of derogation from Article 17(3)(b) and (4) of Regulation (EU) No 514/2014, expenditure shall be eligible where it has been paid by the Responsible Authority before the Responsible Authority's formal designation in accordance with Article 13 of this Agreement, provided that the management and control systems applied before are essentially the same as the ones in force after the formal designation of the Responsible Authority.

Article 16

Request for payment of the annual balance

1. By 15 February of the year following the financial year, Iceland shall submit to the Commission the documents and information required in points (b) and (c) of the first subparagraph of Article 60(5) of Regulation (EU, Euratom) No 966/2012.

By way of derogation from Article 44(1) of Regulation (EU) No 514/2014 and in accordance with the third subparagraph of Article 60(5) of Regulation (EU, Euratom) No 966/2012, Iceland shall submit to the Commission the opinion referred to in the second subparagraph of Article 60(5) of Regulation (EU, Euratom) No 966/2012 by 15 March of the year following the financial year.

The documents submitted referred to in this paragraph shall serve as the request for payment of the annual balance.

2. The documents referred to in paragraph 1 shall be drawn up according to the models adopted by the Commission on the basis of Article 44(3) of Regulation (EU) No 514/2014.

Article 17

Implementation report

By way of derogation from Article 54(1) of Regulation (EU) No 514/2014 and in accordance with the third subparagraph of Article 60(5) of Regulation (EU, Euratom) No 966/2012, Iceland shall submit to the Commission an annual report on the implementation of the national programme in the previous financial year by 15 February each year until and including 2022 and may, at the appropriate level, publish this information.

The first annual report on the implementation of the national programme shall be submitted on 15 February following the entry into force of this Agreement or the start of its provisional application.

The first report shall cover the financial years from 2014 onwards until the financial year before the first annual report was due in accordance with the second paragraph. Iceland shall submit a final report on the implementation of the national programme by 31 December 2023.

Article 18

Electronic data exchange system

In accordance with Article 24(5) of Regulation (EU) No 514/2014, all official exchanges of information between Iceland and the Commission shall be carried out using an electronic data exchange system provided for by the Commission for that purpose.

Article 19

Entry into force

1. The Secretary-General of the Council of the European Union shall act as depositary of this Agreement.

2. The Parties shall approve this Agreement in accordance with their own procedures. They shall notify each other of the completion of those procedures.

3. This Agreement shall enter into force on the first day of the first month following the day of the last notification referred to in paragraph 2.

4. Except for Article 5, the Parties shall apply this Agreement provisionally as from the day following that of its signature, without prejudice to constitutional requirements.

Article 20

Validity and termination

1. Either the Union or Iceland may terminate this Agreement by notifying the other Party of its decision. The Agreement shall cease to apply three months after the date of such notification. Projects and activities in progress at the time of termination shall continue according to the conditions laid down in this Agreement. The Parties shall settle by mutual agreement any other consequences of termination.

2. This Agreement shall be terminated when the Association Agreement with Iceland and Norway is terminated in accordance with Article 8(4), Article 11(3) or Article 16 of the Association Agreement with Iceland and Norway.

Article 21

Languages

This Agreement shall be drawn up in a single original in the Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish, Swedish and Icelandic languages, each of those texts being equally authentic.

Съставено в Брюксел на втори март две хиляди и осемнадесета година.
Hecho en Bruselas, el dos de marzo de dos mil dieciocho.
V Bruselu dne druhého března dva tisíce osmnáct.
Udfærdiget i Bruxelles den anden marts to tusind og atten.
Geschehen zu Brüssel am zweiten März zweitausendachtzehn.
Kahe tuhande kaheksateistkümnenda aasta märtsikuu teisel päeval Brüsselis.
Έγινε στις Βρυξέλλες, στις δύο Μαρτίου δύο χιλιάδες δεκαοκτώ.
Done at Brussels on the second day of March in the year two thousand and eighteen.
Fait à Bruxelles, le deux mars deux mille dix-huit.
Sastavljeno u Bruxellesu drugog ožujka godine dvije tisuće osamnaeste.
Fatto a Bruxelles, addì due marzo duemiladiciotto.
Briselē, divi tūkstoši astoņpadsmitā gada otrajā martā.
Priimta du tūkstančiai aštuonioliktų metų kovo antrą dieną Briuselyje.
Kelt Brüsszelben, a kétezer-tizennyolcadik év március havának második napján.
Magħmul fi Brussell, fit-tieni jum ta' Marzu fis-sena elfejn u tmintax.
Gedaan te Brussel, twee maart tweeduizend achttien.
Sporządzono w Brukseli dnia drugiego marca roku dwa tysiące osiemnastego.
Feito em Bruxelas, em dois de março de dois mil e dezoito.
Întocmit la Bruxelles la doi martie două mii optsprezece.
V Bruseli druhého marca dvetisícosemnásť.
V Bruslju, dne drugega marca leta dva tisoč osemnajst.
Tehty Brysselissä toisena päivänä maaliskuuta vuonna kaksituhattakahdeksantoista.
Som skedde i Bryssel den andra mars år tjugohundraarton.
Gjört í Brussel hinn annan dag marsmánaðar árið tvö þúsund og átján.

За Европейския съюз
Por la Unión Europea
Za Evropskou unii
For Den Europæiske Union
Für die Europäische Union
Euroopa Liidu nimel
Για την Ευρωπαϊκή Ένωση
For the European Union
Pour l'Union européenne
Za Europsku uniju
Per l'Unione europea
Eiropas Savienības vārdā –
Europos Sąjungos vardu
Az Európai Unió részéről
Għall-Unjoni Ewropea
Voor de Europese Unie
W imieniu Unii Europejskiej
Pela União Europeia
Pentru Uniunea Europeană
Za Európsku úniu
Za Evropsko unijo
Euroopan unionin puolesta
För Europeiska unionen
Fyrir hönd Evrópusambandsins

За Исландия
Por Islandia
Za Island
For Island
Für Island
Islandi nimel
Για την Ισλανδία
For Iceland
Pour l'Islande
Za Island
Per l'Islanda
Islandes vārdā –
Islandijos vardu
Izland részéről
Għall-Iżlanda
Voor IJsland
W imieniu Islandii
Pela Islândia
Pentru Islanda
Za Island
Za Islandijo
Islannin puolesta
För Island
Fyrir hönd Íslands

ANNEX

FORMULA TO CALCULATE THE FINANCIAL CONTRIBUTIONS FOR THE YEARS 2019 AND 2020 AND PAYMENT DETAILS

The financial contribution of Iceland to the ISF – Borders and Visa referred to in the second and third subparagraphs of Article 5(7) of Regulation (EU) No 515/2014 is calculated as follows for the years 2019 and 2020:

For each single year from 2013 to 2017, the final figures of the Gross Domestic Product (GDP) of Iceland available on 31 March of 2019 shall be divided by the sum of the GDP figures of all the States participating in the ISF – Borders and Visa for the respective year. The average of the obtained five percentages for the years 2013 to 2017 shall be applied to the sum of the actual annual appropriations for the ISF – Borders and Visa for the years 2014 to 2019 and the annual commitment appropriation for the ISF – Borders and Visa for the year 2020 as included in the draft General budget of the European Union for the financial year 2020 adopted by the Commission to obtain the total amount to be paid by Iceland over the whole period of implementation of the ISF – Borders and Visa. From this amount, the annual payments effectively made by Iceland in accordance with Article 10(1) of this Agreement shall be subtracted in order to obtain the total amount of its contributions for the years 2019 and 2020. Half of this amount shall be paid in 2019 and the other half in 2020.

The financial contribution shall be paid in Euro.

Iceland shall pay its respective financial contribution no later than 45 days after receiving the debit note. Any delay in payment of the contribution shall give rise to the payment of default interest on the outstanding amount from the due date. The interest rate shall be the rate applied by the European Central Bank to its main refinancing operations, as published in the C series of the *Official Journal of the European Union*, in force on the first calendar day of the month in which the deadline falls, increased by 3,5 percentage points.

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2018/399

of 1 March 2018

entering a name in the register of protected designations of origin and protected geographical indications ('Beelitzer Spargel' (PGI))

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ([1]), and in particular Article 52(2) thereof,

Whereas:

(1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Germany's application to register the name 'Beelitzer Spargel' was published in the *Official Journal of the European Union* ([2]).

(2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Beelitzer Spargel' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name 'Beelitzer Spargel' (PGI) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 1.6. — Fruit, vegetables and cereals, fresh or processed, as listed in Annex XI to Commission Implementing Regulation (EU) No 668/2014 ([3]).

Article 2

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

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

Done at Brussels, 1 March 2018.

For the Commission,
On behalf of the President,
Phil HOGAN
Member of the Commission

([1]) OJ L 343, 14.12.2012, p. 1.
([2]) OJ C 388, 17.11.2017, p. 9.
([3]) Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

COMMISSION REGULATION (EU) 2018/400

of 14 March 2018

amending Regulation (EC) No 1126/2008 adopting certain international accounting standards in accordance with Regulation (EC) No 1606/2002 of the European Parliament and of the Council as regards International Accounting Standard (IAS) 40

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1606/2002 of the European Parliament and of the Council of 19 July 2002 on the application of international accounting standards ([1]), and in particular Article 3(1) thereof,

Whereas:

(1) By Commission Regulation (EC) No 1126/2008 ([2]) certain international standards and interpretations that were in existence at 15 October 2008 were adopted.

(2) On 8 December 2016, the International Accounting Standards Board (IASB) published the amendments to International Accounting Standard (IAS) 40 *Investment Property*. The amendments clarify when a company is allowed to reclassify a property to (or from) the 'investment property' category.

(3) Following the consultations with the European Financial Reporting Advisory Group, the Commission concludes that the amendments to International Accounting Standard (IAS) 40 meet the criteria for adoption set out in Article 3(2) of Regulation (EC) No 1606/2002.

(4) Regulation (EC) No 1126/2008 should therefore be amended accordingly.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Accounting Regulatory Committee,

HAS ADOPTED THIS REGULATION:

Article 1

In the Annex to Regulation (EC) No 1126/2008, International Accounting Standard (IAS) 40 *Investment Property* is amended as set out in the Annex to this Regulation.

Article 2

Each company shall apply the amendments referred to in Article 1, at the latest, as from the commencement date of its first financial year starting on or after 1 January 2018.

Article 3

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

([1]) OJ L 243, 11.9.2002, p. 1.
([2]) Commission Regulation (EC) No 1126/2008 of 3 November 2008 adopting certain international accounting standards in accordance with Regulation (EC) No 1606/2002 of the European Parliament and of the Council (OJ L 320, 29.11.2008, p. 1).

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

Done at Brussels, 14 March 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Transfers of Investment Property

(Amendments to IAS 40)

Amendments to IAS 40 *Investment Property*

Paragraphs 57–58 are amended.

TRANSFERS

57 An entity shall transfer a property to, or from, investment property when, and only when, there is a change in use. A change in use occurs when the property meets, or ceases to meet, the definition of investment property and there is evidence of the change in use. In isolation, a change in management's intentions for the use of a property does not provide evidence of a change in use. Examples of evidence of a change in use include:

(a) commencement of owner-occupation, or of development with a view to owner-occupation, for a transfer from investment property to owner-occupied property;

(b) commencement of development with a view to sale, for a transfer from investment property to inventories;

(c) end of owner-occupation, for a transfer from owner-occupied property to investment property; and

(d) inception of an operating lease to another party, for a transfer from inventories to investment property.

(e) [deleted]

58 When an entity decides to dispose of an investment property without development, it continues to treat the property as an investment property until it is derecognised (eliminated from the statement of financial position) and does not reclassify it as inventory. Similarly, if an entity begins to redevelop an existing investment property for continued future use as investment property, the property remains an investment property and is not reclassified as owner-occupied property during the redevelopment.

…

Paragraphs 84C–84E and their related heading, and paragraph 85G, are added.

TRANSITIONAL PROVISIONS

…

Transfers of investment property

84C *Transfers of Investment Property* (Amendments to IAS 40), issued in December 2016, amended paragraphs 57–58. An entity shall apply those amendments to changes in use that occur on or after the beginning of the annual reporting period in which the entity first applies the amendments (the date of initial application). At the date of initial application, an entity shall reassess the classification of property held at that date and, if applicable, reclassify property applying paragraphs 7–14 to reflect the conditions that exist at that date.

84D Notwithstanding the requirements in paragraph 84C, an entity is permitted to apply the amendments to paragraphs 57–58 retrospectively in accordance with IAS 8 if, and only if, that is possible without the use of hindsight.

84E If, in accordance with paragraph 84C, an entity reclassifies property at the date of initial application, the entity shall:

(a) account for the reclassification applying the requirements in paragraphs 59–64. In applying paragraphs 59–64, an entity shall:

(i) read any reference to the date of change in use as the date of initial application; and

(ii) recognise any amount that, in accordance with paragraphs 59–64, would have been recognised in profit or loss as an adjustment to the opening balance of retained earnings at the date of initial application.

(b) disclose the amounts reclassified to, or from, investment property in accordance with paragraph 84C. The entity shall disclose those amounts reclassified as part of the reconciliation of the carrying amount of investment property at the beginning and end of the period as required by paragraphs 76 and 79.

EFFECTIVE DATE

…

85G *Transfers of Investment Property* (Amendments to IAS 40), issued in December 2016, amended paragraphs 57–58 and added paragraphs 84C–84E. An entity shall apply those amendments for annual periods beginning on or after 1 January 2018. Earlier application is permitted. If an entity applies those amendments for an earlier period, it shall disclose that fact.

COMMISSION REGULATION (EU) 2018/401

of 14 March 2018

amending Regulation (EU) No 139/2014 as regards the classification of runways

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC ([1]), and in particular Article 8a(5) thereof,

Whereas:

(1) Annex I to Commission Regulation (EU) No 139/2014 ([2]) lays down the definition of the term 'instrument runway' for the purposes of that Regulation. The provisions of that Regulation should reflect the state of the art and the best practices in the field of aerodromes and take into account the applicable international standards.

(2) The International Civil Aviation Organization (ICAO), in its State letter AN 41.2.24–13/20, adopted Amendment 11-B to Annex 14, Volume 1 to the Chicago Convention, which has been applicable in ICAO Contracting States as of 13 November 2014. The changes set out therein simplify the existing runway approach classification and more accurately describe the various types of approach and landing operations.

(3) Those changes to Annex 14 of the Chicago Convention should be reflected in Regulation (EU) No 139/2014, in particular in its provisions concerning performance-based navigation (PBN) approach operations with vertical guidance and runway requirements in relation to the approach operations. In addition, the implementation of PBN approach operations with vertical guidance by a significant number of aerodromes, without the need to upgrade their runway infrastructure, should be facilitated.

(4) Regulation (EU) No 139/2014 should therefore be amended accordingly.

(5) The measures provided for in this Regulation are based on Opinion No 03/2016 issued by the European Aviation Safety Agency in accordance with point (b) of Article 17(2) and Article 19(1) of Regulation (EC) No 216/2008.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 65 of Regulation (EC) No 216/2008,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) No 139/2014 is amended in accordance with the Annex to this Regulation.

Article 2

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

([1]) OJ L 79, 19.3.2008, p. 1.

([2]) Commission Regulation (EU) No 139/2014 of 12 February 2014 laying down requirements and administrative procedures related to aerodromes pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 44, 14.2.2014, p. 1).

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

Done at Brussels, 14 March 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Annex I to Regulation (EU) No 139/2014 is amended as follows:

(1) point (22) is replaced by the following:

'(22) "instrument runway" means one of the following types of runways intended for the operation of aircraft using instrument approach procedures:

1. "non-precision approach runway": a runway served by visual aids and at least one non-visual aid, intended for landing operations following a type A instrument approach operation;

2. "precision approach runway, category I": a runway served by visual aids and at least one non-visual aid, intended for landing operations following a type B CAT I instrument approach operation;

3. "precision approach runway, category II": a runway served by visual aids and at least one non-visual aid, intended for landing operations following a type B CAT II instrument approach operation;

4. "precision approach runway, category III": a runway served by visual aids and at least one non-visual aid, intended for landing operations following a type B CAT IIIA, IIIB or IIIC instrument approach operation to and along the surface of the runway;';

(2) the following points (47a) and (47b) are inserted:

'(47a) "type A instrument approach operation" means an instrument approach operation with a minimum descent height or decision height at or above 75 m (250 ft);

(47b) "type B instrument approach operation" means an instrument approach operation with a decision height below 75 m (250 ft). Type B instrument approach operations are categorised as follows:

1. Category I (CAT I): a decision height not lower than 60 m (200 ft) and with either a visibility not less than 800 m or a runway visual range not less than 550 m;

2. Category II (CAT II): a decision height lower than 60 m (200 ft), but not lower than 30 m (100 ft) and a runway visual range not less than 300 m;

3. Category IIIA (CAT IIIA): a decision height lower than 30 m (100 ft) or no decision height and a runway visual range not less than 175 m;

4. Category IIIB (CAT IIIB): a decision height lower than 15 m (50 ft) or no decision height and a runway visual range less than 175 m, but not less than 50 m;

5. Category IIIC (CAT IIIC): no decision height and no runway visual range limitation;'.

DECISIONS

COMMISSION DECISION (EU) 2018/402

of 13 March 2018

setting up the European Advisory Group for the European Labour Authority

(Text with relevance for the EEA and for Switzerland)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 46 and 48, Article 53(1), Article 62, and Article 91(1) thereof,

Whereas:

(1) In his State of the Union address 2017 ([1]), President Juncker proposed the establishment of a 'European Labour Authority' to strengthen fairness in the Internal Market and ensure that EU rules on labour mobility are enforced in a fair, simple and effective way.

(2) On 13 March 2018, the Commission has proposed to set up the European Labour Authority ([2]), in order to support the Member States and the Commission in facilitating access for individuals and employers to information on their rights and obligations as well as to relevant services in cross-border labour mobility situations, to support cooperation between Member States in the cross-border enforcement of relevant Union law, and to mediate and facilitate solutions in case of cross-border disputes or labour market disruptions.

(3) An advisory group should be set up to advise and assist the Commission on the swift establishment and future functioning of the European Labour Authority, which should be called the European Advisory Group for the European Labour Authority (hereafter 'the Group'). While not taking part in the legislative process leading to the adoption of the proposed Regulation establishing the European Labour Authority, the Group should help lay the ground for setting up the European Labour Authority.

(4) The Group should in particular allow exchanging best practices and experiences on cooperation in the areas of cross-border labour mobility and the coordination of social security systems that could be further developed by the European Labour Authority, as well as examining general questions, questions of principle and practical problems arising from the implementation of relevant Union law. The Group should also assist with identifying the means of cooperation and contribution of relevant existing bodies, including EU agencies, towards the establishment and good functioning of the European Labour Authority.

(5) The Group should be chaired by the Commission (DG Employment, Social Affairs and Inclusion) and be composed of representatives at senior level of Member States' authorities, Union-level social partners, the European Foundation for the Improvement of Living and Working Conditions (Eurofound), the European Centre for the Development of Vocational Training (Cedefop), the European Training Foundation (ETD) and the European Agency for Safety and Health at Work (EU-OSHA). Union-level social partners should equally represent trade unions and employers' organisations.

(6) European Free Trade Association (EFTA) States and the European Union Agency for Law Enforcement Cooperation (Europol) should be granted an observer status.

(7) The Group should cooperate with existing bodies in the area of labour mobility and social security coordination.

(8) Rules on disclosure of information by the members and observers of the Group should be laid down.

([1]) The 2017 State of the Union address is available at: https://ec.europa.eu/commission/state-union-2017_en
([2]) COM(2018) 131.

(9) Personal data should be processed in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council ([1]).

(10) This Decision should apply until the European Labour Authority has been set up,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter

The European Advisory Group for the European Labour Authority (hereafter referred to as 'the Group') is set up.

Article 2

Tasks

The Group shall advise and assist the Commission (DG Employment, Social Affairs and Inclusion) on the swift establishment and future functioning of the European Labour Authority.

In particular, the group's tasks shall be:

(a) to facilitate cooperation among national authorities and stakeholders and advise the Commission on the swift establishment and operational future functioning of the European Labour Authority.

(b) to examine general questions, questions of principle and practical problems arising from the implementation of Union legislation on cross border labour mobility and social security coordination and their impact on the activities of the European Labour Authority.

(c) to exchange views on and identify best practices and examples of good cooperation in the area of cross border labour mobility and social security coordination in view of developing the activities of the European Labour Authority.

(d) to identify the means of cooperation and the contribution of existing bodies, including decentralised EU agencies, towards the establishment and good functioning of the European Labour Authority.

Article 3

Membership

1. The Group shall be composed of:

— One representative from each Member State;

— Six representatives from Union-level social partners equally representing trade unions and employers' organisations;

— One representative from each EU Agency in the field of employment and social affairs.

2. Members shall nominate their representatives at senior level and shall be responsible for ensuring that their representatives provide a high level of expertise.

3. Representatives shall be nominated within 30 days of the entry into force of this Decision. Representatives may be accompanied by experts.

4. Members who are no longer capable of contributing effectively to the expert group's deliberations, who, in the opinion of the Commission (DG Employment, Social Affairs and Inclusion), do not comply with the conditions set out in Article 339 of the Treaty on the Functioning of the European Union or who resign, shall no longer be invited to participate in any meetings of the group and may be replaced for the remainder of their term of office.

Article 4

Chair

The Group shall be chaired by a representative of the Commission (DG Employment, Social Affairs and Inclusion).

([1]) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

Article 5

Operation

1. The group shall act at the request of the Commission (DG Employment, Social Affairs and Inclusion), in compliance with the horizontal rules ([1]).

2. The Group shall meet at least three times per year. Meetings of the group shall, in principle, be held on Commission premises.

3. The Commission (DG Employment, Social Affairs and Inclusion) shall provide secretarial services. Commission officials from other departments with an interest in the proceedings may attend meetings of the group.

4. In agreement with the Commission (DG Employment, Social Affairs and Inclusion), the group may, by simple majority of its members, decide that deliberations shall be public.

5. Minutes on the discussion on each point on the agenda and on the opinions delivered by the group shall be meaningful and complete. Minutes shall be drafted by the secretariat under the responsibility of the Chair.

6. The group shall adopt its opinions, recommendations or reports by consensus.

7. Participation of European Parliament's experts in the work of the Group is governed by point 15 and Annex I of the Framework Agreement on relations between the European Parliament and the European Commission ([2]).

Article 6

Invited experts

The Commission (DG Employment, Social Affairs and Inclusion) may invite experts with specific expertise with respect to a subject matter on the agenda to take part in the work of the group on an ad hoc basis.

Article 7

Observers

1. European Free Trade Association (EFTA) States and the European Union Agency for Law Enforcement Cooperation shall be granted an observer status, in compliance with the horizontal rules, by direct invitation.

2. Observers shall nominate their representatives.

3. Observers' representatives may be permitted by the Chair to take part in the discussions of the group and provide expertise. However, they shall not participate in the formulation of recommendations or advice of the group.

Article 8

Rules of procedure

On a proposal by and in agreement with the Commission (DG Employment, Social Affairs and Inclusion) the group shall adopt its rules of procedure by simple majority of its members, on the basis of the standard rules of procedure for expert groups, in compliance with the horizontal rules.

Article 9

Professional secrecy and handling of classified information

The members of the group and their representatives, as well as invited experts and observers, are subject to the obligation of professional secrecy, which by virtue of the Treaties and the rules implementing them applies to all members of the institutions and their staff, as well as to the Commission's rules on security regarding the protection of Union classified information, laid down in Commission Decisions (EU, Euratom) 2015/443 ([3]) and (EU, Euratom) 2015/444 ([4]). Should they fail to respect these obligations, the Commission may take all appropriate measures.

([1]) C(2016) 3301, Article 13 paragraph 1.
([2]) OJ L 304, 20.11.2010, p. 47.
([3]) Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).
([4]) Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

Article 10

Transparency

1. The group shall be registered in the Register of Commission expert groups and other similar entities (the 'Register of expert groups').

2. As concerns the group composition, the following data shall be published on the Register of expert groups:

(a) the name of the Member States;

(b) the name of social partners; the interest represented shall be disclosed;

(c) the name of the agencies in the field of employment and social affairs;

(d) the name of observers, including the name of the third countries.

3. All relevant documents, including the agendas, the minutes and the participants' submissions, shall be made available either on the Register of expert groups or via a link from the Register to a dedicated website, where this information can be found. Access to dedicated websites shall not be submitted to user registration or any other restriction. In particular, the agenda and other relevant background documents shall be published in due time ahead of the meeting, followed by timely publication of minutes. Exceptions to publication shall only be foreseen where it is deemed that disclosure of a document would undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) No 1049/2001 of the European Parliament and of the Council [1].

Article 11

Meeting expenses

1. Participants in the activities of the group shall not be remunerated for the services they offer.

2. Travel and subsistence expenses incurred by participants in the activities of the group shall be reimbursed by the Commission. Reimbursement shall be made in accordance with the provisions in force within the Commission and within the limits of the available appropriations allocated to the Commission departments under the annual procedure for the allocation of resources.

Article 12

Applicability

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply until the European Labour Authority has been set up.

Done at Strasbourg, 13 March 2018.

For the Commission
The President
Jean-Claude JUNCKER

[1] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 2/2017 OF THE COMMITTEE ESTABLISHED UNDER THE AGREEMENT BETWEEN THE EUROPEAN COMMUNITY AND THE SWISS CONFEDERATION ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT

of 22 December 2017

on the amendment of Chapter 2 on Personal protective equipment, Chapter 4 on medical devices, Chapter 5 on gas appliances and boilers and Chapter 19 on Cableway installations [2018/403]

THE COMMITTEE,

Having regard to the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment ('the Agreement') and in particular Articles 10(4), 10(5) and 18(2) thereof;

Whereas:

(1) The European Union has adopted a new Regulation on personal protective equipment ([1]) and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the above mentioned European Union legislation.

(2) Chapter 2, Personal protective equipment, of Annex 1 should be amended to reflect these developments.

(3) The European Union has adopted a new Regulation on medical devices ([2]) whose Chapter IV applies mandatorily from 26 November 2017 and a new Regulation on in vitro diagnostic medical devices ([3]) whose Chapter IV applies mandatorily from 26 November 2017. Furthermore, manufacturers have the possibility to apply these Regulations on a voluntary basis as from this date. Switzerland has amended its regulatory provisions deemed equivalent under Article 1(2) of the Agreement to the abovementioned provisions of European Union legislation mandatorily applicable from 26 November 2017.

(4) Chapter 4, Medical devices, of Annex 1 should be amended to reflect these developments.

(5) The European Union has adopted a new Regulation on appliances burning gaseous fuels ([4]) and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the above mentioned European Union legislation.

(6) Chapter 5, Gas appliances and boilers, of Annex 1 should be amended to reflect these developments.

(7) The European Union has adopted a new Regulation on Cableway installations ([5]) and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the above-mentioned European Union legislation.

(8) Chapter 19, Cableway installations, of Annex 1 should be amended to reflect these developments.

(9) Article 10(5) of the Agreement provides that the Committee may, on a proposal from one of the Parties, modify the Annexes to the Agreement,

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([1]) Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).

([2]) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

([3]) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

([4]) 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).

([5]) Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1).

HAS DECIDED AS FOLLOWS:

1. Chapter 2, Personal protective equipment, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment A annexed to this Decision.

2. Chapter 4, Medical devices, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment B annexed to this Decision.

3. Chapter 5, Gas appliances and boilers, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment C annexed to this Decision.

4. Chapter 19, Cableway installations, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment D to this Decision.

5. This Decision, done in duplicate, shall be signed by representatives of the Committee who are authorised to act on behalf of the Parties. This Decision shall be effective from the date of the later of these signatures.

On behalf of the Swiss Confederation
Christophe PERRITAZ
Signed in Bern on 22 December 2017

On behalf of the European Union
Ignacio IRUARRIZAGA
Signed in Brussels on 21 December 2017

ATTACHMENT A

In Annex 1, Product Sectors, Chapter 2, Personal protective equipment should be deleted and replaced by the following one, which shall be effective from 21 April 2018, when Regulation (EU) 2016/425 and the corresponding Swiss legislation become applicable, except for Section IV, which becomes effective on the same day as the Decision:

'CHAPTER 2

PERSONAL PROTECTIVE EQUIPMENT

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	1.	Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).
Switzerland	100.	Federal Law of 12 June 2009 on product safety (RO 2010 2573)
	101.	Ordinance of 19 May 2010 on product safety (RO 2010 2583) as last amended on 25 October 2017 (RO 2017 5865)
	102.	Ordinance of 25 October 2017 on the safety of personal protective equipment (RO 2017 5859)
	103.	Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 25 November 2015 (RO 2016 261)

SECTION II

Conformity assessment bodies

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

SECTION III

Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

SECTION IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and the assessment criteria set out in Chapter V of Regulation (EU) 2016/425.

SECTION V

Supplementary provisions

1. **Economic operators**

1.1. *Specific obligations of economic operators pursuant to the legislation under Section I*

Pursuant to the legislation under Section I, economic operators established in the EU or Switzerland are subject to equivalent obligations.

In order to avoid unnecessary duplication of obligations:

(a) for the purpose of the obligations in Articles 8(6) and 10(3) of Regulation (EU) 2016/425 and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;

(b) for the purpose of the obligations in Article 8(3) and 10(8) of Regulation (EU) 2016/425 and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keeps the technical documentation and the EU declaration of conformity for 10 years after the PPE has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keeps a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensures that the technical documentation can be made available to those authorities upon request for 10 years after the PPE has been placed on the market in either the European Union or Switzerland;

(c) for the purpose of the obligations in Article 8(4), second subparagraph, and 10(6) of Regulation (EU) 2016/425 and the corresponding Swiss provisions, it shall be sufficient that such obligations be fulfilled by the manufacturer established within the territory of either the European Union or Switzerland, or, in case the manufacturer is not established within the territory of either the European Union or Switzerland, by the importer established within the territory of either the European Union or Switzerland.

1.2. *Authorised representative*

For the purpose of the obligation in Article 9(2) of Regulation (EU) 2016/425 and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 9(1) of Regulation (EU) 2016/425 or the corresponding Swiss provisions.

1.3. *Cooperation with market surveillance authorities*

The competent national market surveillance authority of a Member State of the European Union or Switzerland may, on reasoned request, ask the relevant economic operators in the European Union and in Switzerland to provide all the information and documentation necessary to demonstrate the conformity of a PPE with the legislation in section I.

That authority may contact the economic operator established within the territory of the other Party either directly or with the assistance of the competent national market surveillance authority of the other Party. It may request manufacturers or, where applicable, authorised representatives and importers to provide the documentation in a language easily understood by that authority. It may request the economic operators to cooperate on any action taken to eliminate the risks posed by the PPE.

2. **Exchange of experience**

Swiss designating authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 35 of Regulation (EU) 2016/425.

3. **Coordination of conformity assessment bodies**

Swiss designated conformity assessment bodies may take part in the coordination and cooperation mechanisms provided for in Article 36 of Regulation (EU) 2016/425, directly or by means of designated representatives.

4. **Mutual assistance of market surveillance authorities**

Pursuant to Article 9(1) of the Agreement, the Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of Member States and Switzerland shall cooperate and exchange information. They shall give each other assistance on an adequate scale by supplying information or documentation concerning economic operators based in a Member State or in Switzerland.

5. **Procedure for dealing with PPE presenting a risk not restricted to the national territory**

Pursuant to Article 12(4) of this Agreement, where the market surveillance authorities of a Member State or Switzerland have taken action or have sufficient reason to believe that a PPE covered by this Chapter presents a risk to the health or safety of persons covered by the legislation in Section I of this Chapter, and if they consider that non-compliance is not restricted to their national territory, they shall inform the European Commission, the other Member States and Switzerland without delay of:

— the results of the evaluation and of the actions which they have required the economic operator to take;

— where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the PPE being made available on their national market, to withdraw the PPE from that market or to recall it.

This information shall include all available details, in particular the data necessary for the identification of the non-compliant PPE, their origin, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, it shall be indicated whether the non-compliance is due to either:

— failure of the PPE to meet requirements relating to the health or safety of persons referred to in the legislation in section I, or

— shortcomings in the harmonised standards referred to in the legislation in Section I.

Switzerland or Member States shall without delay inform the European Commission and the other national authorities of any measures adopted and of any additional information at their disposal relating to the non-compliance of the PPE concerned.

Member States and Switzerland shall ensure that appropriate restrictive measures are taken in respect of the PPE concerned, such as withdrawal of the PPE from their market, without delay.

6. **Safeguard procedure in case of objections against national measures**

Should Switzerland or a Member State disagree with the national measure in paragraph 5, it shall inform the European Commission of its objections within three months of the receipt of the information.

Where, on completion of the procedure set out in paragraph 5, objections are raised by a Member State or Switzerland against a measure taken by Switzerland or a Member State or where the Commission considers a national measure to be contrary to the relevant legislation referred to in Section I, the European Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators. It shall evaluate the national measure, in order to determine whether the national measure is justified or not.

If the national measure is considered:

— justified, all Member States and Switzerland shall take the measures necessary to ensure that the non-compliant PPE is withdrawn from their markets, and shall inform the Commission accordingly;

— unjustified, the Member State concerned or Switzerland shall withdraw that measure.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

7. **Compliant PPE which nevertheless present a risk**

Where a Member State or Switzerland finds that, although a PPE that an economic operator has made available on the EU and on the Swiss market is in compliance with the legislation referred to in Section I of this Chapter, it presents a risk for the health or safety of persons, it shall take all appropriate measures and immediately inform the Commission, other Member States and Switzerland. That information shall include all available details, in particular the data necessary for the identification of the PPE concerned, the origin and the supply chain of the PPE, the nature of the risk involved and the nature and duration of the national measures taken.

The Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not, and, where necessary, propose appropriate measures.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

8. **Safeguard clause in case of remaining disagreement between the Parties**

In case of a disagreement between the Parties on measures at stake in paragraphs 6 and 7 above, the issue will be forwarded to the Committee established under Article 10 of this Agreement, which will decide on an appropriate course of action, including the possibility to have an expert study carried out.

Where the Committee considers that the measure is:

(a) justified, the Parties shall take the measures necessary to ensure that the PPE is withdrawn from their market;

(b) unjustified, the national authority of the Member State or Switzerland shall withdraw the measure.'

ATTACHMENT B

In Annex 1, Product Sectors, Chapter 4, Medical Devices should be deleted and replaced by the following one:

'CHAPTER 4

MEDICAL DEVICES

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union

1. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1).

2. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as last amended by Regulation (EC) No 1882/2003 of the European Parliament and the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1)

3. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1), as last amended by Regulation (EC) No 1882/2003 of the European Parliament and the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1) and corrected by Corrigenda (OJ L 22, 29.1.1999, p. 75 and OJ L 6, 10.1.2002, p. 70).

4. Commission Decision 2002/364/EC of 7 May 2002 on common technical specifications for in vitro-diagnostic medical devices (OJ L 131, 16.5.2002, p. 17).

5. Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices (OJ L 28, 4.2.2003, p. 43).

6. Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (OJ L 22, 9.8.2012, p. 3).

7. Commission Directive 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices (OJ L 210, 12.8.2005, p. 41).

8. Commission Regulation (EC) No 2007/2006 of 22 December 2006 implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the importation and transit of certain intermediate products derived from Category 3 material intended for technical uses in medical devices, in vitro diagnostics and laboratory reagents and amending that Regulation (OJ L 379, 28.12.2006, p. 98).

9. Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (OJ L 247, 21.9.2007, p. 21).

10. Commission Decision 2011/869/EU of 20 December 2011 amending Decision 2002/364/EC on common technical specifications for in vitro diagnostic medical devices (OJ L 341, 22.12.2011, p. 63).

11. Commission Directive 2011/100/EU of 20 December 2011 amending Directive 98/79/EC of the European Parliament and the Council on in-vitro diagnostic medical devices (OJ L 341, 22.12.2011, p. 50).

12. Directive 2011/65/EU of the European Parliament and the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88).

13. Commission Decision 2010/227/EU of 19 April 2010 on the European Databank on Medical Devices (Eudamed) (OJ L 102, 23.4.2010, p. 45).

14. Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (OJ L 72, 10.3.2012, p. 28).

15. Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices (OJ L 253, 25.9.2013, p. 8).

16. Chapter IV and Annex VII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

17. Chapter IV and Annex VII of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

Switzerland	100.	Federal Law of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended 1 January 2014 (RO 2013 4137)
	101.	Federal Law of 24 June 1902 concerning the electrical weak and heavy current installations (RO 19 252 et RS 4 798), as last amended on 20 March 2008 (RO 2008 3437)
	102.	Federal Law of 9 June 1977 on metrology (RO 1977 2394), as last amended on 17 June 2011 (RO 2012 6235)
	103.	Federal law of 22 March 1991 on radiation protection (RO 1994 1933), as last amended on 10 December 2004 (RO 2004 5391)
	104.	Ordinance of 17 October 2001 on medical devices (RO 2001 3487), as last amended on 25 October 2017 (RO 2017 5935)
	105.	Ordinance of 18 April 2007 on import, transit and export of animals and animal products (RO 2007 1847), as last amended on 4 September 2013 (RO 2013 3041)
	106.	Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 25 November 2015 (RO 2016 261)
	107.	Federal Act on Data Protection of 19 June 1992 (RO 1992 1945), as last amended on 30 September 2011 (RO 2013 3215)

SECTION II

Conformity assessment bodies

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

SECTION III

Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties

SECTION IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies under this Chapter, the designating authorities shall:

— comply with the general principles contained in Annex 2 to this Agreement,

— as laid down in Regulation (EU) No 920/2013, comply with the assessment criteria set out in Annex XI to Directive 93/42/EEC, in Annex 8 to Directive 90/385/EEC and in Annex IX to Directive 98/79/EC, and

— comply with the assessment criteria set out in Chapter IV and Annex VII of Regulation (EU) 2017/745 and of Regulation (EU) 2017/746.

The Parties shall make available assessors for the pool established under Regulation (EC) No 920/2013, Article 40 of Regulation (EU) 2017/745 and Article 36 of Regulation (EU) 2017/746. The designating authorities of the Parties shall cooperate for the assessment of notified bodies in line with Article 39 of Regulation (EU) 2017/745 and Article 35 of Regulation (EU) 2017/746. They shall participate in peer reviews pursuant to Article 48 of Regulation (EU) 2017/745 and Article 44 of Regulation (EU) 2017/746.

SECTION V

Supplementary provisions

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

Any manufacturer or his authorised representative who places on the market of one of the Parties the medical devices referred to in Article 14 of Directive 93/42/EEC or Article 10 of Directive 98/79/EC shall inform the competent authorities of the Party in which he has his registered place of business of the particulars referred to in those Articles. The Parties shall reciprocally recognise that registration. The manufacturer shall not be obliged to designate a person responsible for placing devices on the market established in the territory of the other Party.

2. **Labelling of medical devices**

Manufacturers of both Parties shall indicate their name or trade name and address on the label of medical devices specified in Annex 1, point 13.3(a) to Directive 93/42/EEC and in vitro diagnostic medical devices specified in Annex 1, point 8.4(a), to Directive 98/79/EC. They shall not be obliged to indicate the name and address of the person responsible for placing the device on the market, of the representative or of the importer established within the territory of the other Party on the label, outer packaging or instructions for use.

For devices imported from third countries, in view of their distribution in the Union and Switzerland, the label, or the outer packaging, or instructions for use, shall contain the name and address of the single authorised representative of the manufacturer established within the Union or Switzerland, as appropriate.

3. **Information exchange and cooperation**

In accordance with Article 9 of the Agreement,

— the Parties shall in particular exchange the information referred to in Article 8 of Directive 90/385/EEC, Article 10 of Directive 93/42/EEC, Article 11 of Directive 98/79/EC and Article 3 of Regulation (EU) No 920/2013,

— the Parties shall in particular cooperate according to Articles 102 and 103 of Regulation (EC) No 2017/745 and Articles 97 and 98 of Regulation (EU) 2017/746.

— Switzerland may submit the application of expert laboratories for designation by the Commission in accordance with Article 106 of Regulation (EU) 2017/745 or the application of reference laboratories for designation by the Commission in accordance with Article 100 of Regulation (EU) 2017/746.

4. **European databases**

The competent Swiss authorities shall have access to the European databases established under Article 12 of Directive 98/79/EC, Article 14a of Directive 93/42/EEC, Article 3 of Regulation (EU) No 920/2013, Article 33 of Regulation (EU) 2017/745 and Article 30 of Regulation (EU) 2017/746. They shall transmit to the Commission and/or body responsible for managing the databases the data provided for in those Articles collected in Switzerland for entry into the European databases.

5. **Transitional provisions**

By way of derogation to the legislation in Section I, devices which comply with Regulation (EU) 2017/745 and Regulation (EU) 2017/746 may be placed on the market of both Parties respectively.

By way of derogation to the legislation in Section I, notified bodies which are designated and notified in accordance with Regulation (EU) 2017/745 and Regulation (EU) 2017/746 may carry out assessment procedures laid down in these regulations and issue certificates in accordance with these Regulations. Such certificates shall be recognized by the Parties.'

ATTACHMENT C

In Annex 1, Product Sectors, Chapter 5, Gas appliances and boilers, should be deleted and replaced by the following one, which shall be effective from 21 April 2018, when Regulation (EU) 2016/426 and the corresponding Swiss legislation become applicable, except for Section IV which becomes effective on the same day as this Decision:

'CHAPTER 5

GAS APPLIANCES AND BOILERS

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(1)

European Union	1.	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 subsequently amended
Switzerland	100.	Ordinance of 16 December 1985 on Air Pollution Control (OAPC) (Annex 3 and 4) (RS 814.318.142.1, as subsequently amended

Provisions covered by Article 1(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).
Switzerland	100.	Federal Law of 12 June 2009 on product safety (RO 2010 2573)
	101.	Ordinance of 19 May 2010 on product safety (RO 2010 2583), as last amended on 25 October 2017 (RO 2017 5865)
	102.	Ordinance of 25 October 2017 on gas appliances (RO 2017 5865)
	103.	Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 25 November 2015 (RO 2016 261)

SECTION II

Conformity assessment bodies

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

SECTION III

Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

SECTION IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and the assessment criteria set out in Chapter IV of Regulation (EU) 2016/426.

SECTION V

Supplementary provisions

1. Economic operators

1.1. *Specific obligations of economic operators pursuant to the legislation under Section I*

Pursuant to the legislation under Section I, economic operators established in the EU or Switzerland are subject to equivalent obligations.

In order to avoid unnecessary duplication of obligations:

(a) for the purpose of the obligations in Articles 7(6) and 9(3) of Regulation (EU) 2016/426 and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark, and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;

(b) for the purpose of the obligations in Article 7(3) and 9(8) of Regulation (EU) 2016/426 and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keeps the technical documentation and the EU declaration of conformity for 10 years after the appliance or the fitting has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keeps a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensures that the technical documentation can be made available to those authorities upon request for 10 years after the appliance or the fitting has been placed on the market in either the European Union or Switzerland;

(c) for the purpose of the obligations in Article 7(4), second subparagraph, and 9(6) of Regulation (EU) 2016/426 and the corresponding Swiss provisions, it shall be sufficient that such obligations be fulfilled by the manufacturer established within the territory of either the European Union or Switzerland, or, in case the manufacturer is not established within the territory of either the European Union or Switzerland, by the importer established within the territory of either the European Union or Switzerland.

1.2. *Authorised representative*

For the purpose of the obligation in Article 8(2) of Regulation (EU) 2016/426 and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 8(1) of Regulation (EU) 2016/426 or the corresponding Swiss provisions.

1.3. *Cooperation with market surveillance authorities*

The competent national market surveillance authority of a Member State of the European Union or Switzerland may, on reasoned request, ask the relevant economic operators in the European Union and in Switzerland to provide all the information and documentation necessary to demonstrate the conformity of an appliance or fitting with the legislation in section I.

That authority may contact the economic operator established within the territory of the other Party either directly or with the assistance of the competent national market surveillance authority of the other Party. It may request manufacturers or, where applicable, authorised representatives and importers to provide the documentation in a language easily understood by that authority. It may request the economic operators to cooperate on any action taken to eliminate the risks posed by the appliance or the fitting.

2. Exchange of experience

Swiss designating authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 34 of Regulation (EU) 2016/426.

3. **Coordination of conformity assessment bodies**

Swiss designated conformity assessment bodies may take part in the coordination and cooperation mechanisms provided for in Article 35 of Regulation (EU) 2016/426, directly or by means of designated representatives.

4. **Mutual assistance of market surveillance authorities**

Pursuant to Article 9(1) of the Agreement, the Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of Member States and Switzerland shall cooperate and exchange information. They shall give each other assistance on an adequate scale by supplying information or documentation concerning economic operators based in a Member State or in Switzerland.

5. **Procedure for dealing with appliances or fittings presenting a risk not restricted to the national territory**

Pursuant to Article 12(4) of this Agreement, where the market surveillance authorities of a Member State or Switzerland have taken action or have sufficient reason to believe that an appliance or fitting covered by this Chapter presents a risk to the health or safety of persons or to domestic animals or property covered by the legislation in Section I of this Chapter, and if they consider that non-compliance is not restricted to their national territory, they shall inform the European Commission, the other Member States and Switzerland without delay of:

— the results of the evaluation and of the actions which they have required the economic operator to take;

— where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the appliances or fittings being made available on their national market, to withdraw the appliance or fitting from that market or to recall it.

This information shall include all available details, in particular the data necessary for the identification of the non-compliant appliance or fitting, their origin, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, it shall be indicated whether the non-compliance is due to either:

— failure of the appliance or fitting to meet requirements relating to the health or safety of persons or to domestic animals or property referred to in the legislation in section I, or

— shortcomings in the harmonised standards referred to in the legislation in Section I.

Switzerland or Member States shall without delay inform the European Commission and the other national authorities of any measures adopted and of any additional information at their disposal relating to the non-compliance of the appliance or fitting concerned.

Member States and Switzerland shall ensure that appropriate restrictive measures are taken in respect of the appliance or fitting concerned, such as withdrawal of appliance or fitting from their market, without delay.

6. **Safeguard procedure in case of objections against national measures**

Should Switzerland or a Member State disagree with the national measure in paragraph 5, it shall inform the European Commission of its objections within three months of the receipt of the information.

Where, on completion of the procedure set out in paragraph 5, objections are raised by a Member State or Switzerland against a measure taken by Switzerland or a Member State or where the Commission considers a national measure to be contrary to the relevant legislation referred to in Section I, the European Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators. It shall evaluate the national measure, in order to determine whether the national measure is justified or not.

If the national measure relating to an appliance or fitting is considered:

— justified, all Member States and Switzerland shall take the measures necessary to ensure that the non-compliant appliance or fitting is withdrawn from their markets, and shall inform the Commission accordingly;

— unjustified, the Member State concerned or Switzerland shall withdraw that measure.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

7. **Compliant appliances or fittings which nevertheless present a risk**

Where a Member State or Switzerland finds that, although an appliance or fitting that an economic operator has made available on the EU and on the Swiss market is in compliance with the legislation referred to in Section I of this Chapter, it presents a risk for the health or safety of persons or to domestic animals or property, it shall take all appropriate measures and immediately inform the Commission, other Member States and Switzerland. That information shall include all available details, in particular the data necessary for the identification of the appliance or fitting concerned, the origin and the supply chain of the appliance or fitting, the nature of the risk involved and the nature and duration of the national measures taken.

The Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not, and, where necessary, propose appropriate measures.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

8. **Safeguard clause in case of remaining disagreement between the Parties**

In case of a disagreement between the Parties on measures at stake in paragraphs 6 and 7 above, the issue will be forwarded to the Committee established under Article 10 of this Agreement, which will decide on an appropriate course of action, including the possibility to have an expert study carried out.

Where the Committee considers that the measure is:

(a) justified, the Parties shall take the measures necessary to ensure that the appliance or fitting is withdrawn from their market;

(b) unjustified, the national authority of the Member State or Switzerland shall withdraw the measure.

9. **Information exchange**

In accordance with Article 12 of this Agreement, the Parties shall exchange information on the types of gas and the corresponding supply pressures of gaseous fuels used on their territory referred to in Annex II of Regulation (EU) 2016/426. Further Switzerland shall inform about the changes thereof within six months after the announcement of the envisaged changes. The European Union shall inform about the changes thereof within six months after it received the notification by a Member State.'

ATTACHMENT D

In Annex 1, Product Sectors, Chapter 19, Cableway installations should be deleted and replaced by the following one, which shall be effective from 21 April 2018, when Regulation (EU) 2016/424 and the corresponding Swiss legislation become applicable, except for Section IV which becomes effective as the same day as this Decision:

'CHAPTER 19

CABLEWAY INSTALLATIONS

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	1.	Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1).
Switzerland	100.	Federal Law of 23 June 2006 on cableway installations transporting people (RO 2006 5753) as last amended on 20 March 2009 (RO 2009 5597)
	101.	Ordinance of 21 December 2006 on cableway installations transporting people (RO 2007 39) as last amended on 11 October 2017 (RO 2017 5831)
	102.	Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 25 November 2015 (RO 2016 261)

SECTION II

Conformity assessment bodies

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

SECTION III

Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

SECTION IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and the assessment criteria set out in Chapter IV of Regulation (EU) 2016/424.

SECTION V

Supplementary provisions

1. **Economic operators**

1.1. *Specific obligations of economic operators pursuant to the legislation under Section I*

Pursuant to the legislation under Section I, economic operators established in the EU or Switzerland are subject to equivalent obligations.

In order to avoid unnecessary duplication of obligations:

(a) for the purpose of the obligations in Articles 11(6) and 13(3) of Regulation (EU) 2016/424 and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;

(b) for the purpose of the obligations in Article 11(3) and 13(8) of Regulation (EU) 2016/424 and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keeps the technical documentation and the EU declaration of conformity for 30 years after the subsystem or the safety component has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keeps a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensures that the technical documentation can be made available to those authorities upon request for 30 years after the subsystem or the safety component has been placed on the market in either the European Union or Switzerland;

(c) for the purpose of the obligations in Article 11(4), second subparagraph, and 13(6) of Regulation (EU) 2016/424 and the corresponding Swiss provisions, it shall be sufficient that such obligations be fulfilled by the manufacturer established within the territory of either the European Union or Switzerland, or, in case the manufacturer is not established within the territory of either the European Union or Switzerland, by the importer established within the territory of either the European Union or Switzerland.

1.2. *Authorised representative*

For the purpose of the obligation in Article 12(2) of Regulation (EU) 2016/424 and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 12(1) of Regulation (EU) 2016/424 or the corresponding Swiss provisions.

1.3. *Cooperation with market surveillance authorities*

The competent national market surveillance authority of a Member State of the European Union or Switzerland may, on reasoned request, ask the relevant economic operators in the European Union and in Switzerland to provide all the information and documentation necessary to demonstrate the conformity of a subsystem or safety component with the legislation in section I.

That authority may contact the economic operator established within the territory of the other Party either directly or with the assistance of the competent national market surveillance authority of the other Party. It may request manufacturers or, where applicable, authorised representatives and importers to provide the documentation in a language easily understood by that authority. It may request the economic operators to cooperate on any action taken to eliminate the risks posed by the subsystem or safety component.

2. **Exchange of experience**

Swiss designating authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 37 of Regulation (EU) 2016/424.

3. **Coordination of conformity assessment bodies**

Swiss designated conformity assessment bodies may take part in the coordination and cooperation mechanisms provided for in Article 38 of Regulation (EU) 2016/424, directly or by means of designated representatives.

4. **Mutual assistance of market surveillance authorities**

Pursuant to Article 9(1) of the Agreement, the Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of Member States and Switzerland shall cooperate and exchange information. They shall give each other assistance on an adequate scale by supplying information or documentation concerning economic operators based in a Member State or in Switzerland.

5. **Procedure for dealing with subsystems or safety components presenting a risk not restricted to the national territory**

Pursuant to Article 12(4) of this Agreement, where the market surveillance authorities of a Member State or Switzerland have taken action or have sufficient reason to believe that a subsystem or safety component covered by this Chapter presents a risk to the health or safety of persons or to property covered by the legislation in Section I of this Chapter, and if they consider that non-compliance is not restricted to their national territory, they shall inform the European Commission, the other Member States and Switzerland without delay of:

— the results of the evaluation and of the actions which they have required the economic operator to take;

— where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the subsystem or safety component being made available on their national market, to withdraw the subsystem or safety component from that market or to recall it.

This information shall include all available details, in particular the data necessary for the identification of the non-compliant subsystem or safety component, its origin, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, it shall be indicated whether the non-compliance is due to either:

— failure of the subsystem or safety component to meet requirements relating to the health or safety of persons or to property referred to in the legislation in section I, or

— shortcomings in the harmonised standards referred to in the legislation in Section I.

Switzerland or Member States shall without delay inform the European Commission and the other national authorities of any measures adopted and of any additional information at their disposal relating to the non-compliance of the subsystem or safety component concerned.

Member States and Switzerland shall ensure that appropriate restrictive measures are taken in respect of the subsystem or safety component concerned, such as withdrawal of subsystems or safety components from their market, without delay.

6. **Safeguard procedure in case of objections against national measures**

Should Switzerland or a Member State disagree with the national measure in paragraph 5, it shall inform the European Commission of its objections within three months of the receipt of the information.

Where, on completion of the procedure set out in paragraph 5, objections are raised by a Member State or Switzerland against a measure taken by Switzerland or a Member State or where the Commission considers a national measure to be contrary to the relevant legislation referred to in Section I, the European Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators. It shall evaluate the national measure, in order to determine whether the national measure is justified or not.

If the national measure relating to a subsystem or safety component is considered:

— justified, all Member States and Switzerland shall take the measures necessary to ensure that the non-compliant subsystem or safety component is withdrawn from their markets, and shall inform the Commission accordingly;

— unjustified, the Member State concerned or Switzerland shall withdraw that measure.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

7. **Compliant subsystems or safety components which nevertheless present a risk**

Where a Member State or Switzerland finds that, although a subsystem or safety component that an economic operator has made available on the EU and on the Swiss market is in compliance with the legislation referred to in Section I of this Chapter, it presents a risk to the health or safety of persons or to property, it shall take all appropriate measures and immediately inform the Commission, other Member States and Switzerland. That information shall include all available details, in particular the data necessary for the identification of the subsystem or safety component concerned, the origin and the supply chain of the subsystem or safety component, the nature of the risk involved and the nature and duration of the national measures taken.

The Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not, and, where necessary, propose appropriate measures.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

8. **Safeguard clause in case of remaining disagreement between the Parties**

In case of a disagreement between the Parties on measures at stake in paragraphs 6 and 7 above, the issue will be forwarded to the Committee established under Article 10 of this Agreement, which will decide on an appropriate course of action, including the possibility to have an expert study carried out.

Where the Committee considers that the measure is:

(a) justified, the Parties shall take the measures necessary to ensure that the subsystem or safety component is withdrawn from their market;

(b) unjustified, the national authority of the Member State or Switzerland shall withdraw the measure.'

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)

Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

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