

Official Journal of the European Union

L 39



English edition

Legislation

Volume 62

11 February 2019

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⁽¹⁾ Text with EEA relevance.

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.

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RECOMMENDATIONS

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II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2019/237

of 8 February 2019

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 28

(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 12 October 2017, the International Accounting Standards Board (IASB) published Long Term Interests in Associates and Joint Ventures (Amendments to IAS 28), in the framework of its regular improvement process which aims at streamlining and clarifying the standards. The objective of the amendments is to clarify that the impairment requirements of International Financial Reporting Standard (IFRS) 9 *Financial Instruments* apply to Long Term Interests in Associates and Joint Ventures.
- (3) Following the consultation with the European Financial Reporting Advisory Group, the Commission concludes that the amendments to International Accounting Standard (IAS) 28 *Investments in Associates and Joint Ventures* 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) 28 *Investments in Associates and Joint Ventures* 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 2019.

⁽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).

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*.

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

Done at Brussels, 8 February 2019.

For the Commission

The President

Jean-Claude JUNKER

ANNEX

Long-term Interests in Associates and Joint Ventures

(Amendments to IAS 28)

Amendments to IAS 28 Investments in Associates and Joint Ventures

Paragraphs 14A and 45G-45K are added and paragraph 41 is deleted.

EQUITY METHOD

- 14A An entity also applies IFRS 9 to other financial instruments in an associate or joint venture to which the equity method is not applied. These include long-term interests that, in substance, form part of the entity's net investment in an associate or joint venture (see paragraph 38). An entity applies IFRS 9 to such long-term interests before it applies paragraph 38 and paragraphs 40-43 of this Standard. In applying IFRS 9, the entity does not take account of any adjustments to the carrying amount of long-term interests that arise from applying this Standard.

APPLICATION OF THE EQUITY METHOD

...

41. [Deleted]

...

EFFECTIVE DATE AND TRANSITION

...

- 45G *Long-term Interests in Associates and Joint Ventures*, issued in October 2017, added paragraph 14A and deleted paragraph 41. An entity shall apply those amendments retrospectively in accordance with IAS 8 for annual reporting periods beginning on or after 1 January 2019, except as specified in paragraphs 45H-45K. Earlier application is permitted. If an entity applies those amendments earlier, it shall disclose that fact.
- 45H An entity that first applies the amendments in paragraph 45G at the same time it first applies IFRS 9 shall apply the transition requirements in IFRS 9 to the long-term interests described in paragraph 14A.
- 45I An entity that first applies the amendments in paragraph 45G after it first applies IFRS 9 shall apply the transition requirements in IFRS 9 necessary for applying the requirements set out in paragraph 14A to long-term interests. For that purpose, references to the date of initial application in IFRS 9 shall be read as referring to the beginning of the annual reporting period in which the entity first applies the amendments (the date of initial application of the amendments). The entity is not required to restate prior periods to reflect the application of the amendments. The entity may restate prior periods only if it is possible without the use of hindsight.
- 45J When first applying the amendments in paragraph 45G, an entity that applies the temporary exemption from IFRS 9 in accordance with IFRS 4 *Insurance Contracts* is not required to restate prior periods to reflect the application of the amendments. The entity may restate prior periods only if it is possible without the use of hindsight.
- 45K If an entity does not restate prior periods applying paragraph 45I or paragraph 45J, at the date of initial application of the amendments it shall recognise in the opening retained earnings (or other component of equity, as appropriate) any difference between:
- (a) the previous carrying amount of long-term interests described in paragraph 14A at that date; and
 - (b) the carrying amount of those long-term interests at that date.

COMMISSION IMPLEMENTING REGULATION (EU) 2019/238**of 8 February 2019****amending Regulation (EU) No 37/2010 to classify the substance ovotransferrin as regards its maximum residue limit****(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 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and the Council ⁽¹⁾, and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated on 19 July 2018 by the Committee for Medicinal Products for Veterinary Use,

Whereas:

- (1) Article 17 of Regulation (EC) No 470/2009 requires that the maximum residue limit (MRL) for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry is established in a Regulation.
- (2) Table 1 of the Annex to Commission Regulation (EU) No 37/2010 ⁽²⁾ sets out the pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin.
- (3) The substance ovotransferrin is not included in that table.
- (4) An application for the establishment of MRLs for ovotransferrin in chicken tissues and eggs has been submitted to the European Medicines Agency ('EMA').
- (5) The EMA, based on the opinion of the Committee for Medicinal Products for Veterinary Use, has recommended that the establishment of an MRL for ovotransferrin in chicken is not necessary for the protection of human health.
- (6) According to Article 5 of Regulation (EC) No 470/2009, the EMA is to consider using MRLs established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or MRLs established for a pharmacologically active substance in one or more species for other species.
- (7) The EMA has considered that the extrapolation of the 'no MRL required' classification for ovotransferrin from chicken tissue to the tissue of other poultry species is appropriate.
- (8) Regulation (EU) No 37/2010 should therefore be amended accordingly.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 37/2010 is amended as set out in 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 152, 16.6.2009, p. 11.

⁽²⁾ Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

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

Done at Brussels, 8 February 2019.

For the Commission

The President

Jean-Claude JUNKER

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, an entry for the following substance is inserted in alphabetical order:

Pharmacologically active substance	Marker residue	Animal Species	MRLs	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic Classification
'Ovotransferrin	NOT APPLICABLE	Chicken	No MRL required	NOT APPLICABLE	For inhalation use only	Anti-infectious agent'
		All poultry except chicken	No MRL required	NOT APPLICABLE	For inhalation use only Not for use in animals from which eggs are produced	

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2019/239

of 6 February 2019

amending Decision 2011/891/EU and Implementing Decisions (EU) 2017/1211, (EU) 2017/1212, (EU) 2017/2449 and (EU) 2017/2450 as regards the representative or the authorisation holder

(notified under document C(2019) 736)

(Only the French and English texts are authentic)

(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 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽¹⁾, and in particular to Article 9(2) and Article 21(2) thereof,

Whereas:

- (1) Dow AgroSciences Europe, based in the United Kingdom, is representative in the Union of Dow AgroSciences LLC, Mycogen Seeds and M.S. Technologies LLC, based in the United States, pursuant to Commission Decision 2011/891/EU ⁽²⁾ and Commission Implementing Decisions (EU) 2017/1211 ⁽³⁾, (EU) 2017/2449 ⁽⁴⁾ and (EU) 2017/2450 ⁽⁵⁾ for genetically modified food and feed in accordance with Regulation (EC) No 1829/2003.
- (2) Dow AgroSciences Europe is also the authorisation holder for genetically modified products authorised pursuant to Commission Implementing Decision (EU) 2017/1212 ⁽⁶⁾.
- (3) By letter dated 13 September 2018, Dow AgroSciences Europe requested the Commission, in the context of the withdrawal of the United Kingdom from the European Union, that the authorisations for genetically modified food and feed for which the company is representative or authorisation holder, should be transferred to Dow AgroSciences Distribution S.A.S., based in France. Dow AgroSciences Distribution S.A.S confirmed its agreement with the transfer by a letter dated 7 September 2018.
- (4) By letter dated 10 October 2018, M.S. Technologies LLC confirmed its agreement with the transfer of the authorisations from the current representative.
- (5) By letter dated 12 October 2018, Dow AgroSciences LLC also confirmed its agreement with the transfer of the representative and clarified that Mycogen Seeds is a subsidiary of Dow AgroSciences LLC.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Decision 2011/891/EU of 22 December 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236x3006-210-23 (DAS-24236-5x DAS-21Ø23-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 344, 28.12.2011, p. 51).

⁽³⁾ Commission Implementing Decision (EU) 2017/1211 of 4 July 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236 × 3006-210-23 × MON 88913 (DAS-24236-5 × DAS-21Ø23-5 × MON-88913-8) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 173, 6.7.2017, p. 38).

⁽⁴⁾ Commission Implementing Decision (EU) 2017/2449 of 21 December 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-68416-4, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (OJ L 346, 28.12.2017, p. 12).

⁽⁵⁾ Commission Implementing Decision (EU) 2017/2450 of 21 December 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-44406-6, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (OJ L 346, 28.12.2017, p. 16).

⁽⁶⁾ Commission Implementing Decision (EU) 2017/1212 of 4 July 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize DAS-40278-9, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (OJ L 173, 6.7.2017, p. 43).

- (6) The proposed amendments concerning the authorisation holders and consequently addressees of the authorisation decisions are purely administrative in nature and therefore do not entail a new assessment of the products concerned.
- (7) Decision 2011/891/EU and Implementing Decisions (EU) 2017/1211, (EU) 2017/1212, (EU) 2017/2449 and (EU) 2017/2450 should therefore be amended accordingly.
- (8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Amendment to Decision 2011/891/EU

Decision 2011/891/EU is amended as follows:

- (1) Article 6 is replaced by the following:

'Article 6

Authorisation holder

The authorisation holder shall be Dow AgroSciences Distribution S.A.S., France, representing Mycogen Seeds, United States.';

- (2) Article 8 is replaced by the following:

'Article 8

Addressee

This Decision is addressed to Dow AgroSciences Distribution S.A.S., 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France.';

- (3) point (a) of the Annex is replaced by the following:

'(a) Applicant and Authorisation holder

Name: Dow AgroSciences Distribution S.A.S.

Address: 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France.'.

Article 2

Amendment to Implementing Decision (EU) 2017/1211

Implementing Decision (EU) 2017/1211 is amended as follows:

- (1) Article 6 is replaced by the following:

'Article 6

Authorisation holder

The authorisation holder shall be Dow AgroSciences Distribution S.A.S., France, representing Mycogen Seeds, United States.';

- (2) Article 8 is replaced by the following:

'Article 8

Addressee

This Decision is addressed to Dow AgroSciences Distribution S.A.S., 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France.';

- (3) point (a) of the Annex is replaced by the following:

'(a) Applicant and Authorisation holder

Name: Dow AgroSciences Distribution S.A.S.

Address: 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France.'.

*Article 3***Amendment to Implementing Decision (EU) 2017/1212**

Implementing Decision (EU) 2017/1212 is amended as follows:

- (1) Article 6 is replaced by the following:

'Article 6

Authorisation holder

The authorisation holder shall be Dow AgroSciences Distribution S.A.S., France.';

- (2) Article 8 is replaced by the following:

'Article 8

Addressee

This Decision is addressed to Dow AgroSciences Distribution S.A.S., 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France.';

- (3) point (a) of the Annex is replaced by the following:

'(a) Authorisation holder

Name: Dow AgroSciences Distribution S.A.S.

Address: 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France.'.

*Article 4***Amendment to Implementing Decision (EU) 2017/2449**

Implementing Decision (EU) 2017/2449 is amended as follows:

- (1) Article 7 is replaced by the following:

'Article 7

Authorisation holder

The authorisation holder shall be Dow AgroSciences Distribution S.A.S., France, on behalf of Dow AgroSciences LLC.';

- (2) Article 9 is replaced by the following:

'Article 9

Addressee

This Decision is addressed to Dow AgroSciences Distribution S.A.S., 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France.';

- (3) in point (a) of the Annex, the name 'Dow AgroSciences Europe' is replaced by 'Dow AgroSciences Distribution S.A.S.'; the address 'European Development Centre, 3 Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom' is replaced by '6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France'.

*Article 5***Amendment to Implementing Decision (EU) 2017/2450**

Implementing Decision (EU) 2017/2450 is amended as follows:

- (1) Article 7 is replaced by the following:

'Article 7

Authorisation holder

The authorisation holder shall be Dow AgroSciences Distribution S.A.S., France, representing Dow AgroSciences LLC, United States, and M.S. Technologies LLC, United States.';

(2) Article 9 is replaced by the following:

'Article 9

Addressee

This Decision is addressed to Dow AgroSciences Distribution S.A.S., 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France.';

(3) in point (a) of the Annex, the name 'Dow AgroSciences Europe' is replaced by 'Dow AgroSciences Distribution S.A.S.'; the address 'European Development Centre, 3 Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom' is replaced by '6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France'.

Article 6

Addressee

This Decision is addressed to Dow AgroSciences Distribution S.A.S., 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France.

Done at Brussels, 6 February 2019.

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2019/240**of 6 February 2019****amending Implementing Decisions 2013/648/EU and 2013/650/EU as regards the representative of the authorisation holders***(notified under document C(2019) 747)***(Only the Dutch, French and English texts are authentic)****(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 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽¹⁾, and in particular to Article 9(2) and Article 21(2) thereof,

Whereas:

- (1) Dow AgroSciences Ltd, based in the United Kingdom, is representative in the Union of Dow AgroSciences LLC, based in the United States, pursuant to Commission Implementing Decisions 2013/648/EU ⁽²⁾ and 2013/650/EU ⁽³⁾ for genetically modified food and feed in accordance with Regulation (EC) No 1829/2003. For the authorisations under those decisions, Monsanto Europe S.A., based in Belgium, is representative in the Union of Monsanto Company, based in the United States.
- (2) By letter dated 13 September 2018, Dow AgroSciences Ltd requested the Commission, in the context of the withdrawal of the United Kingdom from the European Union, that the authorisations for genetically modified food and feed for which Dow AgroSciences Ltd is representative of Dow AgroSciences LLC, should be transferred to Dow AgroSciences Distribution S.A.S., based in France. By letter dated 7 September 2018, Dow AgroSciences Distribution S.A.S confirmed its agreement with the transfer of representative.
- (3) By letter dated 27 August 2018, the representative in the Union of Monsanto Company for those authorisations, Monsanto Europe S.A., informed the Commission that it converted its legal form and changed its name to Bayer Agriculture BVBA, Belgium. By letter dated 4 September 2018 the Commission informed Monsanto Europe S.A. that the authorisations concerned would need to be amended accordingly.
- (4) The requested changes are purely administrative in nature and therefore do not entail a new assessment of the products concerned. The same applies as regards the addressees of the authorisations Decisions concerned, which should also be adapted accordingly.
- (5) Implementing Decisions 2013/648/EU and 2013/650/EU should therefore be amended accordingly.
- (6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Implementing Decision 2013/648/EU of 6 November 2013 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034 × 1507 × NK603 (MON-89034-3 × DAS-01507-1 × MON-00603-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 302, 13.11.2013, p. 38).

⁽³⁾ Commission Implementing Decision 2013/650/EU of 6 November 2013 authorising the placing on the market of products containing, consisting of, or produced from genetically modified (GM) maize MON 89034 × 1507 × MON88017 × 59122 (MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7), four related GM maize combining three different single GM events (MON89034 × 1507 × MON88017 (MON-89034-3 × DAS-01507-1 × MON-88017-3), MON89034 × 1507 × 59122 (MON-89034-3 × DAS-01507-1 × DAS-59122-7), MON89034 × MON88017 × 59122 (MON-89034-3 × MON-88017-3 × DAS-59122-7), 1507 × MON 88017 × 59122 (DAS-01507-1 × MON-88017-3 × DAS-59122-7)) and four related GM maize combining two different single GM events (MON89034 × 1507 (MON-89034-3 × DAS-01507-1), MON89034 × 59122 (MON-89034-3 × DAS-59122-7), 1507 × MON88017 (DAS-01507-1 × MON-88017-3), MON 88017 × 59122 (MON-88017-3 × DAS-59122-7)) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 302, 13.11.2013, p. 47).

HAS ADOPTED THIS DECISION:

Article 1

Amendments to Implementing Decision 2013/648/EU

Implementing Decision 2013/648/EU is amended as follows:

- (1) the text of point (a) of Article 6(1) is replaced by the following: 'Dow AgroSciences Distribution S.A.S., France, representing DowAgroSciences LLC, United States; and';
- (2) the text of point (b) of Article 6(1) is replaced by the following: 'Bayer Agriculture BVBA, Belgium, representing Monsanto Company, United States';
- (3) the text of point (a) of Article 8 is replaced by the following: 'Dow AgroSciences Distribution S.A.S., 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France; and';
- (4) the text of point (b) of Article 8 is replaced by the following: 'Bayer Agriculture BVBA, Scheldelaan 460, 2040 Antwerp, Belgium';
- (5) point (a) of the Annex is amended as follows:
 - (a) the name 'Dow AgroSciences Ltd' is replaced by the terms 'Dow AgroSciences Distribution S.A.S.';
 - (b) the address 'European Development Centre, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom' is replaced by the terms '6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France';
 - (c) the name 'Monsanto Europe S.A.' is replaced by the terms 'Bayer Agriculture BVBA';
 - (d) the address 'Avenue de Tervuren 270-272, 1150 Brussels, Belgium' is replaced by the terms 'Scheldelaan 460, 2040 Antwerp, Belgium'.

Article 2

Amendments to Implementing Decision 2013/650/EU

Implementing Decision 2013/650/EU is amended as follows:

- (1) the text of point (a) of Article 6(1) is replaced by the following: 'Dow AgroSciences Distribution S.A.S., France, representing DowAgroSciences LLC, United States; and';
- (2) the text of point (b) of Article 6(1) is replaced by the following: 'Bayer Agriculture BVBA, Belgium, representing Monsanto Company, United States';
- (3) the text of point (a) of Article 8 is replaced by the following: 'Dow AgroSciences Distribution S.A.S., 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France; and';
- (4) the text of point (b) of Article 8 is replaced by the following: 'Bayer Agriculture BVBA, Scheldelaan 460, 2040 Antwerp, Belgium';
- (5) point (a) of the Annex is amended as follows:
 - (a) the name 'Dow AgroSciences Ltd' is replaced by 'Dow AgroSciences Distribution S.A.S.';
 - (b) the address 'European Development Centre, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom' is replaced by '6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France';
 - (c) the name 'Monsanto Europe S.A.' is replaced by the terms 'Bayer Agriculture BVBA';
 - (d) the address 'Avenue de Tervuren 270-272, 1150 Brussels, Belgium' is replaced by the terms 'Scheldelaan 460, 2040 Antwerp, Belgium'.

*Article 3***Addressee**

This Decision is addressed to:

- (a) Dow AgroSciences Distribution S.A.S., 6, rue Jean Pierre Timbaud, 78180 Montigny le Bretonneux, France; and
- (b) Bayer Agriculture BVBA, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels, 6 February 2019.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2019/241**of 6 February 2019****amending Decision 2007/703/EC and Implementing Decisions (EU) 2017/2452 and (EU) 2018/1109
as regards the representative of the authorisation holder***(notified under document C(2019) 748)***(Only the Dutch, French and English texts are authentic)****(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 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽¹⁾, and in particular to Article 9(2) and Article 21(2) thereof,

Whereas:

- (1) Dow AgroSciences Ltd and Dow AgroSciences Europe Ltd, based in the United Kingdom, are representatives in the Union of respectively Dow AgroSciences LLC and Mycogen Seeds for genetically modified food and feed covered by Commission Decision 2007/703/EC ⁽²⁾ and Commission Implementing Decision (EU) 2017/2452 ⁽³⁾ and (EU) 2018/1109 ⁽⁴⁾. For the authorisations under those decisions, Pioneer Overseas Corporation, based in Belgium, is representative in the Union of Pioneer Hi-Bred International Inc.
- (2) In the context of the withdrawal of the United Kingdom from the European Union, Dow AgroSciences Europe requested the Commission, by letter dated 13 September 2018, to change its representative for the genetically modified food and feed concerned, by having Dow AgroSciences Distribution S.A.S., based in France, as representative, instead of Dow AgroSciences Ltd and Dow AgroSciences Europe Ltd. By letter dated 12 October 2018, Dow AgroSciences LLC clarified that Dow AgroSciences Europe, Dow AgroSciences Ltd and Dow AgroSciences Europe Ltd, are the same legal entity. By letter dated 7 September 2018, Dow AgroSciences Distribution S.A.S confirmed its agreement with the transfer of representative.
- (3) The requested changes are purely administrative in nature and therefore do not entail a new assessment of the products concerned. The same applies as regards the addressees of the authorisation decisions concerned, which should also be adapted accordingly.
- (4) Decision 2007/703/EC and Implementing Decisions (EU) 2017/2452 and (EU) 2018/1109 should therefore be amended accordingly.
- (5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

*Article 1***Amendments to Decision 2007/703/EC**

Decision 2007/703/EC is amended as follows:

- (1) The text of point (b) of Article 6(1) is replaced by the following: 'Dow AgroSciences Distribution S.A.S., France, representing Mycogen Seeds, United States';

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Decision 2007/703/EC of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507xNK603 (DAS-Ø15Ø7-1xMON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 285, 31.10.2007, p. 47).

⁽³⁾ Commission Implementing Decision (EU) 2017/2452 of 21 December 2017 renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 346, 28.12.2017, p. 25).

⁽⁴⁾ Commission Implementing Decision (EU) 2018/1109 of 3 August 2018 renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 203, 10.8.2018, p. 7).

- (2) The text of point (b) of Article 8 is replaced by the following: 'Dow AgroSciences Distribution S.A.S., 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France';
- (3) Point (a) of the Annex is amended as follows:
 - (a) the name 'Dow AgroSciences Europe Ltd' is replaced by the terms 'Dow AgroSciences Distribution S.A.S.';
 - (b) the address 'European Development Centre, 3 Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom' is replaced by '6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France'.

Article 2

Amendments to Implementing Decision (EU) 2017/2452

Implementing Decision (EU) 2017/2452 is amended as follows:

- (1) The text of point (b) of Article 7(1) is replaced by the following: 'Dow AgroSciences Distribution S.A.S., France, representing Dow AgroSciences LLC, United States';
- (2) The text of point (b) of Article 9 is replaced by the following: 'Dow AgroSciences Distribution S.A.S., 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France';
- (3) Point (a) of the Annex is amended as follows:
 - (a) the name 'Dow AgroSciences Europe Ltd' is replaced by the terms 'Dow AgroSciences Distribution S.A.S.';
 - (b) the address 'European Development Center, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom' is replaced by '6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France'.

Article 3

Amendments to Implementing Decision (EU) 2018/1109

Implementing Decision (EU) 2018/1109 is amended as follows:

- (1) The text of point (b) of Article 7(1) is replaced by the following: 'Dow AgroSciences Distribution S.A.S., France, representing Dow AgroSciences LLC, United States';
- (2) The text of point (b) of Article 9 is replaced by the following: 'Dow AgroSciences Distribution S.A.S., 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France';
- (3) Point (a) of the Annex is amended as follows:
 - (a) the name 'Dow AgroSciences Europe Ltd' is replaced by 'Dow AgroSciences Distribution S.A.S.';
 - (b) the address 'European Development Center, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom' is replaced by '6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France'.

Article 4

Addressees

This Decision is addressed to:

- (a) Dow AgroSciences Distribution S.A.S., 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France; and
- (b) Pioneer Overseas Corporation, Avenue des Arts 44, 1040 Brussels, Belgium.

Done at Brussels, 6 February 2019.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2019/242**of 7 February 2019****amending Implementing Decision (EU) 2017/675 with regards to measures preventing the introduction into the Union of the foot-and-mouth disease virus from Algeria, Libya, Morocco and Tunisia***(notified under document C(2019) 768)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION

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

Having regard to Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC ⁽¹⁾, and in particular Article 18(7) thereof,

Having regard to Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries ⁽²⁾, and in particular Article 22(6) thereof,

Whereas:

- (1) Directive 91/496/EEC lays down the principles of veterinary checks on animals entering the European Union from third countries. Directive 97/78/EC lays down the principles of veterinary checks on products entering the Union from third countries. Both these directives provide for measures which can be adopted by the Commission, if a disease liable to present a serious threat to animal or public health manifests itself or spreads in the territory of a third country or if any other serious animal health reason so warrants.
- (2) Commission Implementing Decision (EU) 2017/675 ⁽³⁾, as amended by the Commission Implementing Decisions (EU) 2017/887 ⁽⁴⁾ and (EU) 2018/489 ⁽⁵⁾, was adopted following outbreaks of foot-and-mouth disease in Algeria and Tunisia and established protection measures at Union level which take into account the survival of the foot-and-mouth disease virus in the environment and potential transmission routes of that virus.
- (3) Those measures provided for appropriate cleansing and disinfection of livestock vehicles and vessels from Algeria and Tunisia entering the Union territory either directly or transiting through other countries, as this is the most appropriate way to reduce the risk of rapid virus transmission over large distances.
- (4) There is an unclear situation as regards foot-and-mouth disease in Libya and the initial results of laboratory diagnosis on 19 October 2018 on a suspected case appear to be positive for a SAT serotype. The typing of the serotype is still ongoing. Morocco also notified an outbreak of foot-and-mouth diseases of undetermined serotype.
- (5) As the presence of foot-and-mouth disease in Libya and Morocco is liable to present a serious threat to the livestock population of the Union, the same protective measures applied to Algeria and Tunisia should therefore also be applied to Libya and Morocco.
- (6) Similarly to measures applied with regards to Algeria and Tunisia, any livestock vehicle from Libya and Morocco should be covered by those measures even if they reach the Union territory transiting through any third country
- (7) In addition, Algeria and Tunisia have reported further outbreaks of foot-and-mouth disease.
- (8) Implementing Decision (EU) 2017/675 as amended by Implementing Decision (EU) 2018/489 applies currently until 30 June 2019. The measures provided for by this Decision should however apply for a period of time which allows for a full evaluation of the evolution of the foot-and-mouth disease in the affected areas.

⁽¹⁾ OJ L 268, 24.9.1991, p. 56.

⁽²⁾ OJ L 24, 30.1.1998, p. 9.

⁽³⁾ Commission Implementing Decision (EU) 2017/675 of 7 April 2017 on measures to prevent the introduction into the Union of the foot-and-mouth disease virus from Algeria and Tunisia (OJ L 97, 8.4.2017, p. 31).

⁽⁴⁾ Commission Implementing Decision (EU) 2017/887 of 22 May 2017 on measures to prevent the introduction into the Union of the foot-and-mouth disease virus from Tunisia and amending Implementing Decision (EU) 2017/675 (OJ L 135, 24.5.2017, p. 25).

⁽⁵⁾ Commission Implementing Decision (EU) 2018/489 of 21 March 2018 amending Decision (EU) 2017/675 on measures to prevent the introduction into the Union of the foot-and-mouth disease virus from Algeria and Tunisia (OJ L 81, 23.3.2018, p. 20).

- (9) As the foot-and-mouth disease situation in Algeria, Libya, Morocco and Tunisia still remains uncertain and a significant number of consignments of live bovine animals is exported from EU Member States to those countries, it is also appropriate to extend the measures in place.
- (10) Implementing Decision (EU) 2017/675 should therefore be amended accordingly.
- (11) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Implementing Decision (EU) 2017/675 should be amended as follows:

- (1) the title is replaced by the following:

‘on measures to prevent the introduction into the Union of the foot-and-mouth disease virus from Algeria, Libya, Morocco and Tunisia’;

- (2) in Article 2(1) and Article 3(1), the words:

‘from Algeria and Tunisia either directly or transiting through any other third country’

are replaced by the words:

‘from Algeria, Libya, Morocco and Tunisia either directly or after transiting through any other third country’;

- (3) in Article 3(2) and Article 4, the words ‘Algeria and Tunisia’ are replaced by the words ‘Algeria, Libya, Morocco and Tunisia’;

- (4) the date of application in Article 5 is replaced by ‘31 December 2019’;

- (5) in the title of Annex I and the title of Annex II respectively the words:

‘from Algeria and Tunisia either directly or transiting through any other third country’

are replaced by the the words:

‘from Algeria, Libya, Morocco and Tunisia either directly or after transiting through any other third country’.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 7 February 2019.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

RECOMMENDATIONS

COMMISSION RECOMMENDATION (EU) 2019/243

of 6 February 2019

on a European Electronic Health Record exchange format

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

- (1) Citizens have the right to access their personal data, including their health data as provided for by Regulation (EU) 2016/679 of the European Parliament and of the Council ⁽¹⁾, which lays down the conditions for lawful processing of personal data, including data concerning health, as defined therein ⁽²⁾ (health data). However most citizens cannot yet access (nor securely share) their health data across borders.
- (2) The ability of citizens and healthcare providers to securely access and share electronic health records ('EHR's), that is to say collections of longitudinal medical records or similar documentation of an individual, in digital form, within and across borders has a number of benefits: an improvement in the quality of care for citizens, reduction in the cost of healthcare to households, and it supports the modernisation of health systems in the Union that are under pressure from demographic changes, rising expectations and costs of treatment. For example, sharing the results of blood tests in a digital format among clinical teams prevents repeating invasive and costly tests on the same person. Similarly, where patients need to see different health professionals, sharing electronic health records can avoid a repetition of the same information about their medical history saving time for all parties involved and improving the quality of care.
- (3) Enabling the secure access and sharing of health records across borders in the Union will facilitate citizens' life in a number of cross-border situations, such as citizens, and their families, who are currently living in another Member State for work purposes or retired people living in another country, enabling them to have access to health records between the Member States in which they have been resident. It will also improve the quality of care in situations which require medical treatment while travelling in the Union or as part of a cross border agreement. There are over two million recorded instances a year where a citizen living in one Member State has sought healthcare in another ⁽³⁾. Moreover, in the future, it can be usefully linked to European Union initiatives in the field of social security coordination.
- (4) Healthcare needs are expected to further increase in the future as a result of population ageing, rising prevalence of chronic conditions and a rise in demand for long-term care. This is evidenced by health spending amounting to 9,6 % of Gross Domestic Product in the Union as a whole in 2017, up from 8,8 % in 2008 ⁽⁴⁾. Similarly, evidence from various countries suggest that up to 20 % of healthcare spending is wasteful, for example because patients receive unnecessary tests or treatments, or as a result of avoidable hospital admissions.
- (5) Digital technologies are powerful solutions to address those issues and to adapt health systems to future challenges. For example, digital solutions linked to health apps, or wearable devices, combined with a system that allows a citizen secure access to their own health data, should enable patients with chronic conditions, such as diabetes, or cancer, to monitor their own symptoms at home and share them quickly with their clinical teams. This should reduce the number of visits to a health facility for monitoring. Digital technologies can also

⁽¹⁾ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

⁽²⁾ Article 4(15) of the General Data Protection Regulation.

⁽³⁾ Either using a European Health Insurance Card or under the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

⁽⁴⁾ 'Health at a Glance: Europe 2018 — State of Health in the EU Cycle' https://ec.europa.eu/health/sites/health/files/state/docs/2018_healthatglance_rep_en.pdf

help to detect early a need for a change in treatments, resulting in fewer hospitalisations due to complications. Better management of chronic conditions in the community, alongside reducing duplication of healthcare actions (such as tests) should not only make systems more sustainable but also improve overall quality of life, the quality of healthcare provided to citizens, and reduce the costs associated with healthcare for individuals and households.

- (6) The Council has regularly called for Member States to strengthen the implementation of their digital health strategies. In particular, the Council conclusions on Health in the Digital Society adopted on 8 December 2017 ⁽⁵⁾ stress the need for Member States to make their electronic health systems more interoperable in order to give citizens greater control over their health data.
- (7) To support the digital transformation of health and care, the Commission adopted the Communication on 'enabling the digital transformation of health and care in the Digital Single Market: empowering citizens and building a healthier society' ⁽⁶⁾. That Communication adapts for the health sector, the objectives set out in the Communication 'A Digital Single Market Strategy for Europe' adopted on 6 May 2015 ⁽⁷⁾ and the Communication 'EU eGovernment Action Plan — Accelerating the Digital Transformation of Government', adopted on 19 April 2016 ⁽⁸⁾. It addresses the concerns raised in the Communication on the Mid-Term Review on the implementation of the Digital Single Market Strategy, 'A Connected Digital Single Market for All' ⁽⁹⁾ regarding the fact that the uptake of digital solutions for health and care remains slow and varies significantly across the Member States and regions.
- (8) Digitising health records, and creating systems that enable them to be securely accessed by citizens and securely shared within and between the different actors in the health system (patients, their clinical teams in the community and hospital facilities) is an important step towards integrating digital technologies into health and care approaches. That integration requires electronic health records, to be interoperable across the Union whereas currently many of the formats and standards in electronic health record systems — that are information systems for recording, retrieving and managing electronic health records — used across the Union are incompatible.
- (9) New technologies for health should support citizens to become active agents of their own health journey. To this end, citizens' and patients' needs should be taken into account when designing health information systems including making these systems more accessible to users, in particular to persons with disabilities, according to the accessibility requirements laid down by Directive (EU) 2016/2102 of the European Parliament and of the Council ⁽¹⁰⁾, where applicable
- (10) The aim of interoperability with regard to electronic health records is to allow for the processing of information in a consistent manner between those health information systems, regardless of their technology, application or platform in a way that it can be meaningfully interpreted by the recipient.
- (11) The lack of interoperability with regard to electronic health records leads to fragmentation and a lower quality of cross-border healthcare provision. The Commission has already identified specific 'Integrating the Healthcare Enterprise' (IHE) profiles listed in the Annex to Commission Decision (EU) 2015/1302 ⁽¹¹⁾ ⁽¹²⁾ with the potential to increase interoperability of eHealth services and applications to the benefit of citizens and the healthcare professional community and to be eligible for referencing in public procurement. Those profiles provide detailed specifications for different layers of interoperability. Some of those profiles are already used to address specific business requirements in the eHealth Digital Service Infrastructure ('eHDSI').
- (12) The highest possible standards for security and data protection are central to developing and exchanging electronic health records. The General Data Protection Regulation requires patient data to be protected and

⁽⁵⁾ 2017/C 440/05.

⁽⁶⁾ COM(2018) 233 final.

⁽⁷⁾ COM(2015) 192 final.

⁽⁸⁾ COM(2016) 179 final.

⁽⁹⁾ COM(2017) 228 final.

⁽¹⁰⁾ Directive (EU) 2016/2102 of the European Parliament and of the Council of 26 October 2016 on the accessibility of the websites and mobile applications of public sector bodies (OJ L 327, 2.12.2016, p. 1) (Web Accessibility Directive).

⁽¹¹⁾ Commission Decision (EU) 2015/1302 of 28 July 2015 on the identification of 'Integrating the Healthcare Enterprise' profiles for referencing in public procurement (OJ L 199, 29.7.2015, p. 43).

⁽¹²⁾ <https://www.ihe.net/> and <https://www.ihe-europe.net/>

properly secured so that its confidentiality, integrity and availability are ensured. As a consequence, systems must be secure, safe, trustable and integrate data protection by design and by default. A series of European wide digital solutions and common approaches for government and institutions lay the basis for this.

- (13) The use of secure electronic identification and authentication means provided for in Regulation (EU) No 910/2014 of the European Parliament and of the Council ⁽¹³⁾ (eIDAS) should enhance access, security and trust in electronic health record systems. That Regulation lays down the conditions under which recognised electronic identification means, falling under a notified electronic identification scheme of a Member State, may be used by citizens to gain access to online public services from abroad, including access to health services and health data. It also lays down rules for trust services such as electronic signatures, electronic seals and electronic registered delivery services, to securely manage and exchange health data by minimising the risk of possible tampering and misuse.
- (14) Under Directive (EU) 2016/1148 of the European Parliament and of the Council ⁽¹⁴⁾ healthcare providers, that are identified as operators of essential services by Member States and digital service providers falling in its scope are required to take appropriate and proportionate technical and organisational measures to manage the risks posed to the security of network and information systems they use in their operations of provision of service. They are also required to notify security incidents having a significant or substantial impact on the continuity of the services they provide to the competent national authorities or to the national Computer Security Incident Response Teams (CSIRTs). As regards in particular cybersecurity for electronic health record systems, cybersecurity certification may allow the demonstration that cybersecurity requirements are fulfilled, under the relevant Union cybersecurity framework ⁽¹⁵⁾.
- (15) Member States have taken important steps to foster interoperability with the support of the Commission, through the activities of the eHealth Network established under Article 14 of Directive 2011/24/EU. The eHealth Network's main objective is to support the development of sustainable eHealth systems, services and interoperable applications, facilitate cooperation and the exchange of information among Member States, enhance continuity of care and ensure access to safe and high-quality healthcare. Consequently it plays a crucial role for the interoperability of electronic health records.
- (16) In particular, in order to facilitate the interoperability of European eHealth systems, a number of Member States participating in the eHealth Network have worked together with the Commission to build the eHealth Digital Services Infrastructure, supported by the Connecting Europe Facility (CEF) Programme ⁽¹⁶⁾. In some of those Member States, the exchange of 'ePrescriptions' between health professionals across borders through the eHealth Digital Services Infrastructure has started, while the exchange of 'Patient Summaries' is expected to start soon. Enhancing the interoperability of electronic health records should help expanding the datasets currently being exchanged within the eHealth Digital Services Infrastructure to include valuable information concerning laboratory results, medical imaging and reports, and hospital discharge reports, which would enhance continuity of care. A number of tools developed for the eHealth Digital Services Infrastructure are a resource for Member States for the exchange of electronic health records.
- (17) In the context of exchanging electronic health records, the eHealth Network plays a valuable role in further developing the European electronic health record exchange format, by using it for the eHealth Digital Services Infrastructure and promoting its use for exchanges between healthcare providers at national level.
- (18) Digitising health records and enabling their exchange could also support the creation of large health data structures which combined with the use of new technologies, such as big data analytics and artificial intelligence can support the search for new scientific discoveries.
- (19) Existing national specifications for electronic health record systems may continue to apply in parallel with a European electronic health record exchange format,

⁽¹³⁾ Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (OJ L 257, 28.8.2014, p. 73).

⁽¹⁴⁾ Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union (OJ L 194, 19.7.2016, p. 1).

⁽¹⁵⁾ See Joint Communication on Resilience, Deterrence and Defence: Building strong cybersecurity for the EU, point 2.2 (JOIN(2017) 450 final).

⁽¹⁶⁾ <https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/eHealth+DSI+Operations+Home>

HAS ADOPTED THIS RECOMMENDATION:

OBJECTIVES

- (1) This Recommendation sets out a framework for the development of a European electronic health record exchange format in order to achieve secure, interoperable, cross-border access to, and exchange of, electronic health data in the Union.

The framework includes:

- (a) a set of principles that should govern access to and exchange of electronic health records across borders in the Union;
- (b) a set of common technical specifications for the cross-border exchange of data in certain health information domains, which should constitute the baseline for a European electronic health record exchange format;
- (c) a process to take forward the further elaboration of a European electronic health record exchange format.

It also encourages Member States to ensure secure access to electronic health record systems at national level.

ELECTRONIC HEALTH RECORD SYSTEMS IN MEMBER STATES

Ensuring secure access to electronic health record systems

- (2) Member States should ensure that electronic health record systems meet high standards for the protection of health data, and the security of network and information systems on which such electronic health record systems rely, to avoid data breaches and minimise the risks of security incidents.
- (3) Member States should ensure that citizens and their healthcare professionals have online access to their electronic health records using secure electronic identification means, taking into account the framework for security and trust established by the Regulation (EU) No 910/2014.

Tools and incentives

- (4) Member States should use the tools and building blocks provided by the eHealth Digital Services Infrastructure supported under the Connecting Europe Facility Programme and refer to the Refined eHealth European Interoperability Framework ⁽¹⁷⁾ as the common framework for managing interoperability in the eHealth domain.
- (5) Member States should take appropriate measures to support the use of interoperable electronic health record systems such as leveraging dedicated financial investments, including incentive mechanisms, and adapting legislation where appropriate.

National digital health networks

- (6) To enhance the interoperability and security of national health systems and support the secure exchange of health data across borders, each Member State should set up a national digital health network involving representatives of the relevant competent national authorities and, where appropriate, regional authorities dealing with digital health matters and the interoperability of electronic health records, and security of networks and information systems, and the protection of personal data. In particular national digital health networks should involve the following:
 - (a) the national representative of the eHealth Network;
 - (b) national, or regional, authorities with clinical and technical competence for digital health matters;
 - (c) supervisory authorities established under Article 51 of Regulation (EU) 2016/679;
 - (d) competent authorities designated pursuant to Directive (EU) 2016/1148.
- (7) The results of discussions or consultations of the national digital health networks should be transmitted to the eHealth Network and to the Commission.

⁽¹⁷⁾ https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf

FRAMEWORK FOR CROSS-BORDER EXCHANGE OF ELECTRONIC HEALTH RECORDS**Principles for access to and cross-border exchange of electronic health records**

- (8) Member States should ensure that citizens are able to access and securely share their electronic health data across borders.
- (9) Member States are encouraged to give citizens the ability to choose to whom they provide access to their electronic health data, and which health information details are shared.
- (10) Member States should ensure that the principles set out in the Annex are observed when developing solutions enabling access to, and exchange of electronic health data in the Union.

Baseline for a European electronic health record exchange format

- (11) Member States should take measures to ensure that the following health information domains, as a baseline, are part of a European electronic health record exchange format:
 - (a) Patient Summary;
 - (b) ePrescription/eDispensation;
 - (c) Laboratory results;
 - (d) Medical imaging and reports;
 - (e) Hospital discharge reports.

The cross-border exchange of information should take place in accordance with the baseline standards, interoperability specifications and the profiles depending on the health information domain as set out the Annex.

Further elaboration of a European electronic health record exchange format

- (12) Member States should, in the context of Article 14 of Directive 2011/24/EU and in collaboration with the Commission, support the further elaboration of the recommended baseline of health information domains and specifications for a European electronic health record exchange format, through a joint coordination process.
- (13) Through this process, Member States, supported by the Commission, should engage in discussions and cooperation at Union level with relevant stakeholders, including healthcare professional organisations, national competence centres, industry actors and patient groups, as well as other Union and national authorities with competence in relevant areas to encourage, and contribute to, an iterative process of further elaborating and adopting a European electronic health record exchange format. In particular, clinical and technical experts should be involved in work concerning technical and semantic specifications for cross-border exchange of health data. The results of these discussions and consultations should be transmitted to the eHealth Network.
- (14) The joint coordination process should benefit from knowledge available in national competence centres targeting the identification of the meaningful medical concepts for each given context.
- (15) The joint coordination process should take forward approaches that all Member States can support, while Member States that so wish may progress towards electronic health record interoperability at a faster speed.
- (16) The joint coordination process should build on, and incorporate the results of, existing initiatives of the eHealth Network such as the Common Semantic Strategy task force.

- (17) Member States, in the context of the eHealth Network, should cooperate with the Commission and other relevant stakeholders in establishing practical implementation guidelines, sharing good practice and promoting awareness actions for citizens and healthcare providers on the benefits of access to, and exchange of electronic health record, across borders. Pilot projects including research, innovation or deployment actions, such as those supported under the Horizon 2020 ⁽¹⁸⁾ and Connecting Europe Facility Programmes, where relevant, should be used to advance interoperability and raise awareness.

MONITORING AND FUTURE DEVELOPMENTS

Monitor progress towards interoperability

- (18) Member States, in the context of the eHealth Network and in cooperation with the Commission, should monitor progress towards interoperability on the basis of a shared roadmap revised annually, identifying common priorities, tasks, deliverables and milestones.

For that purpose, Member States should, on a yearly basis:

- (a) share information on the measures they have taken to support the adoption of the specifications of the European electronic health record exchange format;
 - (b) identify common priorities and synergies with national strategies to improve cross-border exchange of electronic health records.
- (19) The elements referred to in points 18(a) and (b) should be taken into account when assessing the next steps for the exchange of electronic health records across the Union.

Future work

- (20) Member States should engage with the Commission and relevant stakeholders to identify and review emerging technological and methodological innovation and identify appropriate steps to achieve progress in the long-term exchange of electronic health records.

Assessment of the effects of the Recommendation

- (21) Member States should cooperate with the Commission to assess the effects of this Recommendation taking into account their experience and any relevant technological developments with a view to determine appropriate ways forward.

Done at Brussels, 6 February 2019.

For the Commission

Mariya GABRIEL

Member of the Commission

⁽¹⁸⁾ <https://ec.europa.eu/programmes/horizon2020/en/>

ANNEX

1. Principles*(a) Citizen-centric by design*

Citizens should be central to the way in which systems are designed. Such systems are to be designed to implement the principles of data protection by design and by default to meet the requirements of the General Data Protection Regulation.

(b) Comprehensiveness and machine-readability

Electronic health records should be as comprehensive as possible in order to support health and care services throughout the Union.

Health data introduced in electronic health records should be machine-readable to the extent required by reasonable intended reuse of those data. Information should be structured and codified in the most practical way possible, with a view to making health data interoperable, including across borders.

(c) Data protection and confidentiality

Electronic Health Record systems and interoperability solutions have to guarantee the confidentiality of personal health data and conform with all aspects of data protection legislation, from their design stage onward.

The fundamental right to the protection of personal data should be fully and effectively implemented, in conformity with Regulation (EU) 2016/679, including the right to transparent information, the right of access and other relevant rights listed in Chapter III. In particular, citizens should be able to exercise their right to access their health data by having access to their electronic health records, including across borders.

(d) Consent or other lawful basis

Any processing ⁽¹⁾ of health data must be based on the explicit consent of the citizen concerned or on any other lawful basis, pursuant to Articles 6 and 9 of Regulation (EU) 2016/679.

(e) Auditability

Any processing of health data should be registered and verified for auditing purposes, using appropriate techniques, such as logging and audit trailing, to keep an accurate record of the access to electronic records, their exchange or any other processing operation.

(f) Security

Pursuant to Regulation (EU) 2016/679 and Directive (EU) 2016/1148 appropriate technical and organisational measures must be implemented to ensure that electronic health record systems are secure. Those measures should include protection against unauthorised or unlawful processing of health data and against accidental loss, destruction or damage. Entities exchanging electronic health records should ensure that personnel dealing with electronic health records systems is properly aware of cybersecurity risks and adequately trained.

(g) Identification and authentication

Strong and reliable identification and authentication of all involved parties is a key element to guarantee trust in exchanges of data between electronic health record systems.

The use of notified national electronic identifications ('eID's) supports citizens' cross-border identification and authentication to access their health data in full security and convenience, as well as the principle of 'non-repudiation' assuring the origin and integrity of such data. Through the mutual recognition of national

⁽¹⁾ As defined in Article 4(2) of the General Data Protection Regulation.

electronic identification schemes, as foreseen in Regulation (EU) No 910/2014, citizens of one Member State may use their national electronic identifications to securely access online services provided to them in another Member State. Pursuant to Article 6 of that Regulation, online public services requiring electronic identification assurance corresponding to a certain level ('substantial' or 'high') must accept the notified electronic identification schemes of other Member States.

(h) *Continuity of service*

Continuity and availability of the electronic health record exchange service is essential to guarantee continuity of care. Any incidents or interruptions that may arise in the course of the use of the service should be promptly addressed in accordance with defined business continuity plans.

2. **Baseline for the European electronic health record exchange format: health information domains and specifications for cross-border exchange of electronic health records**

The baseline for the European electronic health record exchange format should include the health information domains and interoperability specifications (including standards, and profiles ⁽²⁾) mentioned below for representing and exchanging (structured and unstructured) health data.

This baseline should be further refined and extended through a joint coordination process. Additional international standards, specifications and profiles, currently being developed, under revision or in trial implementation phase should be considered in further developing a European electronic health record exchange format.

2.1. *Health information domains for cross-border exchange*

The initial set of health information domains for cross-border exchange should include the following:

- (i) Patient Summaries ⁽³⁾
- (ii) ePrescriptions/eDispensations ⁽⁴⁾
- (iii) Laboratory reports
- (iv) Medical images and reports
- (v) Hospital discharge reports.

These health information domains have been prioritised in alignment with the eHealth Network established priorities, on the basis of current work under the eHealth Digital Services Infrastructure and clinical relevance for cross-border healthcare.

2.2. *Interoperability specifications*

Tables A and B contain a set of recommended interoperability specifications for content structuring and representation.

2.2.1. Table A: Content structuring and representation for health information domains for which the eHealth Network have adopted guidelines

Health information domains	Clinical information for cross-border exchange	Content representation for cross-border exchange
Patient Summary	Structured according to the provisions in the 'GUIDELINE on the electronic exchange of health data under Cross-Border Directive 2011/24/EU Release 2 — Patient Summary for unscheduled care' adopted by the eHealth Network on 21 November 2016 ⁽¹⁾	Health Level Seven (HL7) Clinical Document Architecture (CDA) Release 2 ⁽²⁾ Level 3 and Level 1 (PDF ⁽³⁾)/A

⁽²⁾ The way in which standards can be implemented to meet specific clinical needs.

⁽³⁾ https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co10_en.pdf

⁽⁴⁾ https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co091_en.pdf

Health information domains	Clinical information for cross-border exchange	Content representation for cross-border exchange
ePrescription/ eDispensation	Structured according to the provisions in the 'GUIDELINE on the electronic exchange of health data under Cross-Border Directive 2011/24/EU Release 2 — ePrescriptions and eDispensations' adopted by the eHealth Network on 21 November 2016 ⁽⁴⁾	Health Level Seven (HL7) Clinical Document Architecture (CDA) Release 2 Level 3 and Level 1 (PDF ⁽³⁾)/A

⁽¹⁾ https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co10_en.pdf
⁽²⁾ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
⁽³⁾ Portable Document Format.
⁽⁴⁾ https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co091_en.pdf

2.2.2. Table B: Content structuring and representation for other health information domains

Health information domain	Clinical information for cross-border exchange	Content representation for cross-border exchange
Laboratory results	Enable cross-border exchange according to the clinical information structure currently used by the sender electronic health record system, while common clinical information structures for cross-border exchange are developed and agreed.	For laboratory results, medical imaging reports and hospital discharge reports
Medical imaging and reports		Health Level Seven (HL7) Clinical Document Architecture (CDA) Release 2
Hospital discharge reports		Level 3 or Level 1 (PDF ⁽¹⁾)/A For medical imaging Digital Imaging and Communications in Medicine (DICOM)

⁽¹⁾ Portable Document Format

2.2.3. Cross-border exchange profiles

The use of relevant 'Integrating the Healthcare Enterprise' profiles listed in the Annex to Decision (EU) 2015/1302 should be duly considered to facilitate the exchange of healthcare information domains across borders.

Those 'Integrating the Healthcare Enterprise' profiles could be used, inter alia, for patient identification, document exchange, audit trails and identity claims.

The joint coordination process should also consider other 'Integrating the Healthcare Enterprise' profiles currently at trial stage, or any other standards or specifications needed to address the requirements for secure health data exchange, as well as other types of message exchange patterns.

3. Future work

The aim is to deliver the right data, at the right time — for citizens and healthcare providers — and allow for the secure access, sharing and exchange of electronic health records.

As such, working towards comprehensive cross-border exchange of electronic health records in a fast changing, connected environment requires regular review of the latest technological and methodological innovations to managing data, including those related to accessing and leveraging of advanced technological infrastructures.

The refinement of the exchange format should consider the possibility offered by resource driven information models (such as Health Level Seven Fast Healthcare Interoperability Resources (HL7 FHIR⁽²⁾) ⁽²⁾).

⁽²⁾ <http://hl7.org/fhir/>

In order to make further progress, a review of new approaches to interoperability specifications, such as relevant Application Programming Interfaces ('API's) and developments in digital technologies such as artificial intelligence, cloud computing, interaction technologies, high performance computing and cyber security solutions should be carried out. Evolution in other technologies such as distributed ledger technologies may have the potential to build trust amongst citizens and health care organisations provided that they comply with personal data protection rules.

The above technologies should be considered with a view to supporting innovation in health care service provision, offering new possibilities to address issues such as health data provenance, and automated integrity assurance.

