

Official Journal of the European Union

L 82



English edition

Legislation

Volume 62

25 March 2019

Contents

II *Non-legislative acts*

INTERNATIONAL AGREEMENTS

- ★ Notice concerning the date of entry into force of the Agreement in the form of an Exchange of Letters between the European Union and the People's Republic of China in connection with DS492 European Union — Measures affecting Tariff Concessions on Certain Poultry Meat Products 1
- ★ Council Decision (EU) 2019/477 of 12 March 2019 on the conclusion of a Protocol to the Euro-Mediterranean Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Hashemite Kingdom of Jordan, of the other part, to take account of the accession of the Republic of Bulgaria and Romania to the European Union 2

REGULATIONS

- ★ Commission Delegated Regulation (EU) 2019/478 of 14 January 2019 amending Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the categories of consignments to be subjected to official controls at border control posts ⁽¹⁾ 4
- ★ Commission Implementing Regulation (EU) 2019/479 of 22 March 2019 operating deductions from fishing quotas available for certain stocks in 2018 on account of overfishing of other stocks in the previous years and amending Implementing Regulation (EU) 2018/1969 6
- ★ Commission Regulation (EU) 2019/480 of 22 March 2019 amending Council Regulation (EC) No 297/95 as regards the adjustment of the fees of the European Medicines Agency to the inflation rate with effect from 1 April 2019 ⁽¹⁾ 15

⁽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.

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

★ Commission Implementing Regulation (EU) 2019/481 of 22 March 2019 approving the active substance flutianil, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽¹⁾	19
★ Commission Implementing Regulation (EU) 2019/482 of 22 March 2019 amending Commission Implementing Regulation (EU) 2016/1368 establishing a list of critical benchmarks used in financial markets pursuant to Regulation (EU) 2016/1011 of the European Parliament and of the Council ⁽¹⁾	26

DECISIONS

★ Council Decision (EU) 2019/483 of 19 March 2019 on the position to be adopted, on behalf of the European Union, within the EEA Joint Committee, concerning the amendment of Annex IX (Financial services) to the EEA Agreement (Capital Requirements Regulation (EU) No 575/2013 (CRR) and Directive 2013/36/EU (CRD IV)) ⁽¹⁾	29
★ Commission Implementing Decision (EU) 2019/484 of 21 March 2019 approving the plan for the eradication of African swine fever in feral pigs in certain areas of Bulgaria (<i>notified under document C(2019) 2133</i>) ⁽¹⁾	38

⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

Notice concerning the date of entry into force of the Agreement in the form of an Exchange of Letters between the European Union and the People's Republic of China in connection with DS492 European Union — Measures affecting Tariff Concessions on Certain Poultry Meat Products

The Agreement in the form of an Exchange of Letters between the European Union and the People's Republic of China in connection with DS492 European Union — Measures affecting Tariff Concessions on Certain Poultry Meat Products ⁽¹⁾, signed in Geneva on 30 November 2018, will enter into force on 1 April 2019.

⁽¹⁾ OJ L 27, 31.1.2019, p. 4.

COUNCIL DECISION (EU) 2019/477**of 12 March 2019**

on the conclusion of a Protocol to the Euro-Mediterranean Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Hashemite Kingdom of Jordan, of the other part, to take account of the accession of the Republic of Bulgaria and Romania to the European Union

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 217 in conjunction with point (i) of Article 218(6)(a) thereof,

Having regard to the 2005 Act of Accession, and in particular Article 6(2) thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament ⁽¹⁾,

Whereas:

- (1) The Protocol to the Euro-Mediterranean Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Hashemite Kingdom of Jordan, of the other part, to take account of the accession of the Republic of Bulgaria and Romania to the European Union (hereinafter 'the Protocol') was signed on behalf of the European Community and its Member States on 30 November 2009 subject to its conclusion.
- (2) In accordance with Article 8(2) of the Protocol, the Protocol has been applied on a provisional basis since 1 January 2007.
- (3) As a consequence of the entry into force of the Treaty of Lisbon on 1 December 2009, the European Union has replaced and succeeded the European Community.
- (4) The Protocol should be approved,

HAS ADOPTED THIS DECISION:

Article 1

The Protocol to the Euro-Mediterranean Association Agreement between the European Communities and their Member States, of the one part, and the Hashemite Kingdom of Jordan, of the other part, to take account of the accession of the Republic of Bulgaria and Romania to the European Union ⁽²⁾ is hereby approved on behalf of the European Union and its Member States.

Article 2

The President of the Council shall give the notifications provided for in Article 7 of the Protocol on behalf of the Union ⁽³⁾ and shall make the following notification to the Hashemite Kingdom of Jordan:

'As a consequence of the entry into force of the Treaty of Lisbon on 1 December 2009, the European Union has replaced and succeeded the European Community and from that date exercises all rights and assumes all obligations of the European Community. Therefore, references to 'the European Community' or to 'the Community' in the text of the Protocol are, where appropriate, to be read as 'the European Union'.'

Article 3

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

⁽¹⁾ Consent given on 18 January 2011 (OJ C 136E, 11.5.2012, p. 105).

⁽²⁾ OJ L 40, 13.2.2010, p. 64.

⁽³⁾ The date of entry into force of the Protocol will be published in the *Official Journal of the European Union* by the General Secretariat of the Council.

Article 4

This Decision shall be published in the *Official Journal of the European Union*.

Done at Brussels, 12 March 2019.

For the Council
The President
E.O. TEODOROVICI

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2019/478

of 14 January 2019

amending Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the categories of consignments to be subjected to official controls at border control posts

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulation (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC ⁽¹⁾, and in particular Article 47(3) thereof,

Whereas:

- (1) Regulation (EU) 2017/625 establishes the framework for official controls and other official activities to verify the correct application of Union food and feed law. That framework includes official controls performed on animals and goods entering the Union from third countries.
- (2) Regulation (EU) 2017/625 requires for certain categories of animals and goods that each consignment is made subject to official controls at designated border control posts of first arrival into the Union, because of the risk those categories of animals and goods may pose to public and animal health.
- (3) In addition to the categories of consignments already listed in Regulation (EU) 2017/625, foodstuffs containing both products of plant origin and processed products of animal origin (composite products), as well as hay and straw should undergo official controls at border control posts as they too may pose a risk to public and animal health.
- (4) Regulation (EU) 2017/625 should therefore be amended accordingly.
- (5) Since Regulation (EU) 2017/625 applies from 14 December 2019, this Regulation should also apply from that date,

HAS ADOPTED THIS REGULATION:

Article 1

In Article 47(1) of Regulation (EU) 2017/625, point (b) is replaced by the following:

‘(b) products of animal origin, germinal products, animal by-products, hay and straw and foodstuffs containing both products of plant origin and processed products of animal origin (“composite products”)’.

⁽¹⁾ OJ L 95, 7.4.2017, p. 1.

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*.

It shall apply from 14 December 2019.

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

Done at Brussels, 14 January 2019.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2019/479**of 22 March 2019****operating deductions from fishing quotas available for certain stocks in 2018 on account of overfishing of other stocks in the previous years and amending Implementing Regulation (EU) 2018/1969**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Union control system for ensuring compliance with the rules of the common fisheries policy, amending Regulations (EC) No 847/96, (EC) No 2371/2002, (EC) No 811/2004, (EC) No 768/2005, (EC) No 2115/2005, (EC) No 2166/2005, (EC) No 388/2006, (EC) No 509/2007, (EC) No 676/2007, (EC) No 1098/2007, (EC) No 1300/2008, (EC) No 1342/2008 and repealing Regulations (EEC) No 2847/93, (EC) No 1627/94 and (EC) No 1966/2006 ⁽¹⁾, and in particular Article 105(1), (2), (3) and (5) thereof,

Whereas:

(1) Fishing quotas for the year 2017 have been established by:

- Council Regulation (EU) 2016/1903 ⁽²⁾,
- Council Regulation (EU) 2016/2285 ⁽³⁾,
- Council Regulation (EU) 2016/2372 ⁽⁴⁾, and
- Council Regulation (EU) 2017/127 ⁽⁵⁾.

(2) Fishing quotas for the year 2018 have been established by:

- Council Regulation (EU) 2016/2285,
- Council Regulation (EU) 2017/1970 ⁽⁶⁾,
- Council Regulation (EU) 2017/2360 ⁽⁷⁾, and
- Council Regulation (EU) 2018/120 ⁽⁸⁾.

(3) Pursuant to Article 105(1) of Regulation (EC) No 1224/2009, when the Commission has established that a Member State has exceeded the fishing quotas which have been allocated to it, the Commission is to operate deductions from future fishing quotas of that Member State.

(4) Commission Implementing Regulation (EU) 2018/1969 ⁽⁹⁾ has established deductions from fishing quotas for certain stocks in 2018 on account of overfishing in the previous years.

⁽¹⁾ OJ L 343, 22.12.2009, p. 1.

⁽²⁾ Council Regulation (EU) 2016/1903 of 28 October 2016 fixing for 2017 the fishing opportunities for certain fish stocks and groups of fish stocks applicable in the Baltic Sea and amending Regulation (EU) 2016/72 (OJ L 295, 29.10.2016, p. 1).

⁽³⁾ Council Regulation (EU) 2016/2285 of 12 December 2016 fixing for 2017 and 2018 the fishing opportunities for Union fishing vessels for certain deep-sea fish stocks and amending Council Regulation (EU) 2016/72 (OJ L 344, 17.12.2016, p. 32).

⁽⁴⁾ Council Regulation (EU) 2016/2372 of 19 December 2016 fixing for 2017 the fishing opportunities for certain fish stocks and groups of fish stocks in the Black Sea (OJ L 352, 23.12.2016, p. 26).

⁽⁵⁾ Council Regulation (EU) 2017/127 of 20 January 2017 fixing for 2017 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in Union waters and, for Union fishing vessels, in certain non-Union waters (OJ L 24, 28.1.2017, p. 1).

⁽⁶⁾ Council Regulation (EU) 2017/1970 of 27 October 2017 fixing for 2018 the fishing opportunities for certain fish stocks and groups of fish stocks applicable in the Baltic Sea and amending Regulation (EU) 2017/127 (OJ L 281, 31.10.2017, p. 1).

⁽⁷⁾ Council Regulation (EU) 2017/2360 of 11 December 2017 fixing for 2018 the fishing opportunities for certain fish stocks and groups of fish stocks in the Black Sea (OJ L 337, 19.12.2017, p. 1).

⁽⁸⁾ Council Regulation (EU) 2018/120 of 23 January 2018 fixing for 2018 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in Union waters and, for Union fishing vessels, in certain non-Union waters, and amending Regulation (EU) 2017/127 (OJ L 27, 31.1.2018, p. 1).

⁽⁹⁾ Commission Implementing Regulation (EU) 2018/1969 of 12 December 2018 operating deductions from fishing quotas available for certain stocks in 2018 on account of overfishing in the previous years (OJ L 316, 13.12.2018, p. 12).

- (5) However, for certain Member States no deductions could be operated by Implementing Regulation (EU) 2018/1969 from quotas allocated for the overfished stocks because such quotas are not available for those Member States in the year 2018.
- (6) Article 105(5) of Regulation (EC) No 1224/2009 provides that, if it is not possible to operate deductions on the overfished stock in the year following the overfishing because the Member State concerned has no available quota, deductions may be operated on other stocks in the same geographical area or with the same commercial value. According to Commission Communication 2012/C 72/07 containing Guidelines for deduction of quotas under Article 105(1), (2) and (5) of Regulation (EC) No 1224/2009 ⁽¹⁰⁾ such deductions should be preferably operated from quotas allocated for stocks fished by the same fleet as the fleet that overfished the quota, taking into account the need to avoid discards in mixed fisheries.
- (7) The Member States concerned have been consulted with regard to the proposed deductions from quotas allocated for stocks other than those which have been overfished.
- (8) In certain cases, exchanges of fishing opportunities concluded in accordance with Article 16(8) of Regulation (EU) No 1380/2013 of the European Parliament and of the Council ⁽¹¹⁾ enable deductions from the same stocks in the framework of Implementing Regulation (EU) 2018/1969.
- (9) On 17 October 2018, Spain informed the Commission that the catches in 2017 of swordfish in the Atlantic Ocean, South of 5° N (SWO/AS05N) had been erroneously reported. Following corrections submitted on 3 December 2018 by Spain in the aggregated catch data reporting system, it appears that the catch uptake for swordfish in the Atlantic Ocean, South of 5° N remains below the allocated quota for 2017. Therefore, the corresponding deductions should be deleted from the Annex to Implementing Regulation (EU) 2018/1969.
- (10) On 23 November 2018, Spain requested to update its catch declarations regarding yellowfin tuna in IOTC area of competence (YFT/IOTC). On the basis of the last updated data transmitted by Spain on 13 December 2018, it appears that the Spanish 2017 quota was exceeded for yellowfin tuna in IOTC area of competence (YFT/IOTC). The corresponding deduction should consequently be added to the Annex to Implementing Regulation (EU) 2018/1969.
- (11) Moreover, certain deductions required by Implementing Regulation (EU) 2018/1969 appear to be larger than the adapted quota available in the year 2018 and, as a consequence, cannot be entirely operated in that year. According to Communication 2012/C 72/07, the remaining amounts should be deducted from the adapted quotas available in subsequent years until the full overfished amount is paid back.
- (12) Implementing Regulation (EU) 2018/1969 should therefore be amended accordingly.
- (13) This Regulation should apply retroactively from the day on which Implementing Regulation (EU) 2018/1969 establishing the deductions from fishing quotas for the same stocks in 2018 entered into force,

HAS ADOPTED THIS REGULATION:

Article 1

The fishing quotas fixed in Regulations (EU) 2016/2285, (EU) 2017/1970, (EU) 2017/2360 and (EU) 2018/120 for the year 2018 referred to in Annex I to this Regulation shall be reduced by applying the deductions on the alternative stocks set out in that Annex.

Article 2

The Annex to Implementing Regulation (EU) 2018/1969 is replaced by the text in Annex II to this Regulation.

⁽¹⁰⁾ Communication from the Commission — Guidelines for deduction of quotas under Article 105(1), (2) and (5) of Regulation (EC) No 1224/2009 (2012/C 72/07) (OJ C 72, 10.3.2012, p. 27).

⁽¹¹⁾ Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC (OJ L 354, 28.12.2013, p. 22).

Article 3

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

It shall apply from 20 December 2018.

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

Done at Brussels, 22 March 2019.

For the Commission

The President

Jean-Claude JUNKER

DEDUCTIONS FROM 2018 FISHING QUOTAS FOR ALTERNATIVE STOCKS

OVERFISHED STOCK						ALTERNATIVE STOCK					
Member State	Species code	Area code	Species name	Area name	Quantity that cannot be deducted from the 2018 fishing quota for the over-fished stock (in kilograms)	Member State	Species code	Area code	Species name	Area name	Quantity to be deducted from the 2018 fishing quota for the alternative stock (in kilograms)
DK	NOP	04-N.	Norway pout	Norwegian waters of IV	24 447	DK	NOP	2A3A4.	Norway pout	3a; Union waters of 2a and 4	24 447
DK	OTH	1N2AB.	Other species	Norwegian waters of I and II	9 979	DK	HER	1/2-	Herring	Union, Faroese, Norwegian and international waters of 1 and 2	9 979
DK	POK	1N2AB.	Saithe	Norwegian waters of I and II	9 508	DK	HER	1/2-	Herring	Union, Faroese, Norwegian and international waters of 1 and 2	9 508
ES	GHL	1N2AB.	Greenland halibut	Norwegian waters of I and II	25 335	ES	RED	1N2AB.	Redfish	Norwegian waters of 1 and 2	25 335
ES	POK	1N2AB.	Saithe	Norwegian waters of I and II	1 650	ES	RED	1N2AB.	Redfish	Norwegian waters of 1 and 2	1 650
FR	GHL	1N2AB.	Greenland halibut	Norwegian waters of I and II	6 868	FR	RED	1N2AB.	Redfish	Norwegian waters of 1 and 2	6 868

OVERFISHED STOCK						ALTERNATIVE STOCK					
Member State	Species code	Area code	Species name	Area name	Quantity that cannot be deducted from the 2018 fishing quota for the over-fished stock (in kilograms)	Member State	Species code	Area code	Species name	Area name	Quantity to be deducted from the 2018 fishing quota for the alternative stock (in kilograms)
IE	HKE	8ABDE.	Hake	VIIIa, VIIIb, VIIIc and VIId	1 300	IE	HKE	571214	Hake	6 and 7; Union and international waters of 5b; international waters of 12 and 14	1 300
NL	WHG	56-14	Whiting	VI; Union and international waters of Vb; international waters of XII and XIV	18 648	NL	WHG	2AC4.	Whiting	4; Union waters of 2a	18 648

ANNEX II

‘ANNEX

DEDUCTIONS FROM 2018 FISHING QUOTAS

Member State	Species code	Area code	Species name	Area name	Initial quota 2017 (in kilograms)	Permitted landings 2017 (Total adapted quantity in kilograms) ⁽¹⁾	Total catches 2017 (quantity in kilograms)	Quota consumption related to permitted landings	Overfishing related to permitted landing (quantity in kilograms)	Multi-plying factor ⁽²⁾	Additional Multiplying factor ⁽³⁾ ⁽⁴⁾	Outstanding deductions from previous year(s) ⁽⁵⁾ (quantity in kilograms)	Deductions from fishing quotas for 2018 ⁽⁶⁾ and subsequent years (quantity in kilograms)	Deductions from 2018 fishing quotas for the over-fished stocks ⁽⁷⁾ (quantity in kilograms)	Deductions from 2018 fishing quotas for alternative stocks in accordance with Annex I to Implementing Regulation (EU) 2019/479 ⁽⁸⁾ (quantity in kilograms)	To be deducted from fishing quotas for 2019 and subsequent year(s) (quantity in kilograms)
BE	RJU	07D.	Undulate ray	Union waters of VIIId	2 000	2 000	5 648	282,40 %	3 648	1,00	/	/	3 648	1 031	/	2 617
BE	SRX	07D.	Skates and rays	Union waters of VIIId	96 000	91 353	95 695	104,75 %	4 342	/	/	/	4 342	4 342	/	/
BE	SRX	67AKXD	Skates and rays	Union waters of VIa, VIb, VIIa-c and VIIe-k	762 000	907 100	919 333	101,35 %	12 233	/	/	/	12 233	12 233	/	/
DK	MAC	2A34.	Mackerel	IIIa and IV; Union waters of IIa, IIIb, IIIc and Subdivisions 22-32	22 031	17 525 756	17 992 741	102,66 %	466 985	/	/	/	466 985	466 985	/	/
DK	MAC	2A4A-N	Mackerel	Norwegian waters of IIa and IVa	16 004	14 538 090	14 801 414	101,81 %	263 324	/	/	/	263 324	263 324	/	/
DK	MAC	2CX14-	Mackerel	VI, VII, VIIa, VIIb, VIIId and VIIIe; Union and international waters of Vb; international waters of IIa, XII and XIV	/	5 341 916	5 342 930	100,02 %	1 014	/	/	/	1 014	1 014 ⁽¹²⁾	/	/
DK	NOP	04-N.	Norway pout and associated by-catches	Norwegian waters of IV	0	0	16 298	N/A	16 298	1,00	A	/	24 447	/	24 447	/
DK	OTH	1N2AB.	Other species	Norwegian waters of I and II	/	0	9 979	N/A	9 979	1,00	/	/	9 979	/	9 979	/

Member State	Species code	Area code	Species name	Area name	Initial quota 2017 (in kilograms)	Permitted landings 2017 (Total adapted quantity in kilograms) ⁽¹⁾	Total catches 2017 (quantity in kilograms)	Quota consumption related to permitted landings	Overfishing related to permitted landing (quantity in kilograms)	Multi-plying factor ⁽²⁾	Additional Multiplying factor ⁽³⁾ ⁽⁴⁾	Outstanding deductions from previous year(s) ⁽⁵⁾ (quantity in kilograms)	Deductions from fishing quotas for 2018 ⁽⁶⁾ and subsequent years (quantity in kilograms)	Deductions from 2018 fishing quotas for the over-fished stocks ⁽⁷⁾ (quantity in kilograms)	Deductions from 2018 fishing quotas for alternative stocks in accordance with Annex I to Implementing Regulation (EU) 2019/479 ⁽⁸⁾ (quantity in kilograms)	To be deducted from fishing quotas for 2019 and subsequent year(s) (quantity in kilograms)
DK	POK	1N2AB.	Saithe	Norwegian waters of I and II	/	0	9 508	N/A	9 508	1,00	/	/	9 508	/	9 508	/
ES	ALB	AN05N	Northern albacore	Atlantic Ocean, north of 5° N	14 981 130	13 961 453	13 940 306	99,85 %	– 21 147 ⁽¹⁰⁾	/	/	189 117 ⁽¹¹⁾	189 117	189 117	/	/
ES	GHL	1N2AB.	Greenland halibut	Norwegian waters of I and II	/	19 200	36 090	187,97 %	16 890	1,00	A	/	25 335	/	25 335	/
ES	GHL	N3LMNO	Greenland halibut	NAFO 3LMNO	4 067 000	4 061 001	4 072 229	100,28 %	11 228	/	C ⁽⁹⁾	/	11 228	11 228	/	/
ES	POK	1N2AB.	Saithe	Norwegian waters of I and II	/	86 500	88 150	101,91 %	1 650	/	/	/	1 650	/	1 650	/
ES	YFT	IOTC	Yellowfin tuna	IOTC Area of Competence	45 682 000	45 682 000	48 147 520	105,40 %	2 465 520	/	/	/	2 465 520	327 060	/	2 138 460
FR	GHL	1N2AB.	Greenland halibut	Norwegian waters of I and II	/	0	6 868	N/A	6 868	1,00	/	/	6 868	/	6 868	/
FR	YFT	IOTC	Yellowfin tuna	IOTC Area of Competence	29 501 000	29 651 000	29 960 730	101,04 %	309 730	/	/	/	309 730	309 730	/	/
IE	HKE	8ABDE.	Hake	VIIIa, VIIIb, VIIIc and VIId	/	0	1 300	N/A	1 300	1,00	C ⁽⁹⁾	/	1 300	/	1 300	/
IE	MAC	2CX14-	Mackerel	VI, VII, VIIIa, VIIIb, VIId and VIIf; Union and international waters of Vb; international waters of IIa, XII and XIV	86 426 000	86 319 537	86 520 982	100,23 %	201 445	/	/	/	201 445	201 445	/	/

Member State	Species code	Area code	Species name	Area name	Initial quota 2017 (in kilograms)	Permitted landings 2017 (Total adapted quantity in kilograms) ⁽¹⁾	Total catches 2017 (quantity in kilograms)	Quota consumption related to permitted landings	Overfishing related to permitted landing (quantity in kilograms)	Multi-plying factor ⁽²⁾	Additional Multiplying factor ⁽³⁾ ⁽⁴⁾	Outstanding deductions from previous year(s) ⁽⁵⁾ (quantity in kilograms)	Deductions from fishing quotas for 2018 ⁽⁶⁾ and subsequent years (quantity in kilograms)	Deductions from 2018 fishing quotas for the over-fished stocks ⁽⁷⁾ (quantity in kilograms)	Deductions from 2018 fishing quotas for alternative stocks in accordance with Annex I to Implementing Regulation (EU) 2019/479 ⁽⁸⁾ (quantity in kilograms)	To be deducted from fishing quotas for 2019 and subsequent year(s) (quantity in kilograms)
NL	WHG	56-14	Whiting	VI; Union and international waters of Vb; international waters of XII and XIV	/	0	18 648	N/A	18 648	1,00	/	/	18 648	/	18 648	/
PL	COD	3BC+24	Cod	Subdivisions 22-24	654 000	915 170	947 501	103,53 %	32 331	/	C ⁽⁹⁾	/	32 331	0	/	32 331
PT	ALB	AN05N	Northern albacore	Atlantic Ocean, north of 5° N	2 413 800	2 332 800	2 564 017	109,91 %	231 217	/	/	/	231 217	231 217	/	/
PT	ALF	3X14-	Alfonsinos	Union and international waters of III, IV, V, VI, VII, VIII, IX, X, XII and XIV	182 000	182 626	185 582	101,62 %	2 956	/	/	/	2 956	2 956	/	/
PT	ANE	9/3411	Anchovy	IX and X; Union waters of CECAF 34.1.1	6 522 000	8 992 936	9 141 377	101,65 %	148 441	/	/	/	148 441	148 441	/	/
PT	BUM	ATLANT	Blue marlin	Atlantic ocean	52 320	51 259	56 271	109,78 %	5 012	/	/	/	5 012	5 012	/	/
PT	LEZ	8C3411	Megrim	VIIIc, IX and X; Union waters of CECAF 34.1.1	36 000	139 400	142 316	102,09 %	2 916	/	/	/	2 916	2 916	/	/
PT	SBR	09-	Red seabream	Union and international waters of IX	37 000	72 027	75 905	105,38 %	3 878	/	/	/	3 878	3 878	/	/
PT	SRX	89-C.	Skates and rays	Union waters of VIII and IX	1 156 000	1 132 824	1 211 808	106,97 %	78 984	/	/	/	78 984	78 984	/	/
PT	SWO	AN05N	Swordfish	Atlantic Ocean, North of 5° N	1 170 830	1 738 532	1 854 956	106,70 %	116 424	/	/	/	116 424	116 424	/	/

Member State	Species code	Area code	Species name	Area name	Initial quota 2017 (in kilograms)	Permitted landings 2017 (Total adapted quantity in kilograms) ⁽¹⁾	Total catches 2017 (quantity in kilograms)	Quota consumption related to permitted landings	Overfishing related to permitted landing (quantity in kilograms)	Multi-plying factor ⁽²⁾	Additional Multiplying factor ⁽³⁾ ⁽⁴⁾	Outstanding deductions from previous year(s) ⁽⁵⁾ (quantity in kilograms)	Deductions from fishing quotas for 2018 ⁽⁶⁾ and subsequent years (quantity in kilograms)	Deductions from 2018 fishing quotas for the overfished stocks ⁽⁷⁾ (quantity in kilograms)	Deductions from 2018 fishing quotas for alternative stocks in accordance with Annex 1 to Implementing Regulation (EU) 2019/479 ⁽⁸⁾ (quantity in kilograms)	To be deducted from fishing quotas for 2019 and subsequent year(s) (quantity in kilograms)
UK	MAC	2CX14-	Mackerel	VI, VII, VIIa, VIIb, VIIId and VIIIe; Union and international waters of Vb; international waters of IIa, XII and XIV	237 677 000	222 116 471	224 288 943	100,98 %	2 172 472	/	A ⁽⁹⁾	/	2 172 472	2 172 472	/	/

⁽¹⁾ Quotas available to a Member State pursuant to the relevant fishing opportunities Regulations after taking into account exchanges of fishing opportunities in accordance with Article 16(8) of Regulation (EU) No 1380/2013 of the European Parliament and of the Council (OJ L 354, 28.12.2013, p. 22), quota transfers from 2016 to 2017 in accordance with Article 4(2) of Council Regulation (EC) No 847/96 (OJ L 115, 9.5.1996, p. 3) and with Article 15(9) of Regulation (EU) No 1380/2013 or reallocation and deduction of fishing opportunities in accordance with Articles 37 and 105 of Regulation (EC) No 1224/2009.

⁽²⁾ As set out in Article 105(2) of Regulation (EC) No 1224/2009. Deduction equal to the overfishing * 1,00 shall apply in all cases of overfishing equal to, or less than, 100 tonnes.

⁽³⁾ As set out in Article 105(3) of Regulation (EC) No 1224/2009 and provided that the extent of overfishing exceeds 10 %.

⁽⁴⁾ Letter 'A' indicates that an additional multiplying factor of 1,5 has been applied due to consecutive overfishing in the years 2015, 2016 and 2017. Letter 'C' indicates that an additional multiplying factor of 1,5 has been applied as the stock is subject to a multiannual plan.

⁽⁵⁾ Remaining quantities from previous year(s).

⁽⁶⁾ Deductions to operate in 2018.

⁽⁷⁾ Deductions to operate in 2018 that could be actually applied considering the available quota on 20 December 2018.

⁽⁸⁾ Commission Implementing Regulation (EU) 2019/479 of 22 March 2019 operating deductions from fishing quotas available for certain stocks in 2018 on account of overfishing of other stocks in the previous years and amending Implementing Regulation (EU) 2018/1969 (OJ L 82, 25.3.2019, p. 6).

⁽⁹⁾ Additional multiplying factor not applicable because the overfishing does not exceed 10 % of the permitted landings.

⁽¹⁰⁾ The deduction cannot be reduced by this unused quantity as article 4 of Regulation (EC) No 847/96 is not applicable to the ALB/AN05N stock.

⁽¹¹⁾ At Spain's request, the deduction of 2 269 354 kilos due in 2017 was equally spread over two years (2017 and 2018) by Implementing Regulation (EU) 2017/2309. Since the 2018 initial quota for Spain as fixed by Regulation (EU) 2018/120 already reflects a deduction of 945 560 kilos, the remaining quantity to deduct amounts to 189 117 kilos.

⁽¹²⁾ Despite not having initial quota for this overfished stock, Denmark concluded exchanges of fishing opportunities in accordance with Article 16(8) of Regulation (EU) No 1380/2013 enabling deductions from the same stock.'

COMMISSION REGULATION (EU) 2019/480**of 22 March 2019****amending Council Regulation (EC) No 297/95 as regards the adjustment of the fees of the European Medicines Agency to the inflation rate with effect from 1 April 2019****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products ⁽¹⁾, and in particular the fifth paragraph of Article 12 thereof,

Whereas:

- (1) In accordance with Article 67(3) of Regulation (EC) No 726/2004 of the European Parliament and of the Council ⁽²⁾, the revenue of the European Medicines Agency consists of a contribution from the Union and fees paid by undertakings to that Agency. Regulation (EC) No 297/95 lays down the categories and levels of such fees.
- (2) Those fees should be updated by reference to the inflation rate of 2018. The inflation rate in the Union, as published by the Statistical Office of the European Union ⁽³⁾, was 1,7 % in 2018.
- (3) For the sake of simplicity, the adjusted levels of the fees should be rounded to the nearest EUR 100.
- (4) Regulation (EC) No 297/95 should therefore be amended accordingly.
- (5) For reasons of legal certainty, this Regulation should not apply to valid applications which are pending on 1 April 2019.
- (6) In accordance with Article 12 of Regulation (EC) No 297/95, the update is to be made with effect from 1 April 2019. It is therefore appropriate that this Regulation enters into force as a matter of urgency and applies from that date,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 297/95 is amended as follows:

(1) Article 3 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) point (a) is amended as follows:

- in the first subparagraph, 'EUR 286 900' is replaced by 'EUR 291 800';
- in the second subparagraph, 'EUR 28 800' is replaced by 'EUR 29 300';
- in the third subparagraph, 'EUR 7 200' is replaced by 'EUR 7 300';

(ii) point (b) is amended as follows:

- in the first subparagraph, 'EUR 111 400' is replaced by 'EUR 113 300';
- in the second subparagraph, 'EUR 185 500' is replaced by 'EUR 188 700';
- in the third subparagraph, 'EUR 11 100' is replaced by 'EUR 11 300';
- in the fourth subparagraph, 'EUR 7 200' is replaced by 'EUR 7 300';

⁽¹⁾ OJ L 35, 15.2.1995, p. 1.

⁽²⁾ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

⁽³⁾ <https://ec.europa.eu/eurostat/documents/2995521/9499950/2-17012019-AP-EN.pdf/4ea467c3-8ff2-4723-bc6e-b0c85fb991e4>

- (iii) point (c) is amended as follows:
 - in the first subparagraph, 'EUR 86 100' is replaced by 'EUR 87 600';
 - in the second subparagraph, 'EUR 21 600 to EUR 64 600' is replaced by 'EUR 22 000 to EUR 65 700';
 - in the third subparagraph, 'EUR 7 200' is replaced by 'EUR 7 300';
- (b) paragraph 2 is amended as follows:
 - (i) the first subparagraph of point (a) is amended as follows:
 - 'EUR 3 100' is replaced by 'EUR 3 200';
 - 'EUR 7 200' is replaced by 'EUR 7 300';
 - (ii) point (b) is amended as follows:
 - in the first subparagraph, 'EUR 86 100' is replaced by 'EUR 87 600';
 - in the second subparagraph, 'EUR 21 600 to EUR 64 600' is replaced by 'EUR 22 000 to EUR 65 700';
- (c) in paragraph 3, 'EUR 14 200' is replaced by 'EUR 14 400';
- (d) in the first subparagraph of paragraph 4, 'EUR 21 600' is replaced by 'EUR 22 000';
- (e) in paragraph 5, 'EUR 7 200' is replaced by 'EUR 7 300';
- (f) paragraph 6 is amended as follows:
 - (i) in the first subparagraph, 'EUR 102 900' is replaced by 'EUR 104 600';
 - (ii) in the second subparagraph, 'EUR 25 600 to EUR 77 100' is replaced by 'EUR 26 000 to EUR 78 400';
- (2) in the first paragraph of Article 4, 'EUR 71 400' is replaced by 'EUR 72 600';
- (3) Article 5 is amended as follows:
 - (a) paragraph 1 is amended as follows:
 - (i) point (a) is amended as follows:
 - in the first subparagraph, 'EUR 143 700' is replaced by 'EUR 146 100';
 - in the second subparagraph, 'EUR 14 200' is replaced by 'EUR 14 400';
 - in the third subparagraph, 'EUR 7 200' is replaced by 'EUR 7 300';
 - the fourth subparagraph is amended as follows:
 - 'EUR 71 400' is replaced by 'EUR 72 600';
 - 'EUR 7 200' is replaced by 'EUR 7 300';
 - (ii) point (b) is amended as follows:
 - in the first subparagraph, 'EUR 71 400' is replaced by 'EUR 72 600';
 - in the second subparagraph, 'EUR 121 200' is replaced by 'EUR 123 300';
 - in the third subparagraph, 'EUR 14 200' is replaced by 'EUR 14 400';
 - in the fourth subparagraph, 'EUR 7 200' is replaced by 'EUR 7 300';
 - the fifth subparagraph is amended as follows:
 - 'EUR 35 900' is replaced by 'EUR 36 500';
 - 'EUR 7 200' is replaced by 'EUR 7 300';

- (iii) point (c) is amended as follows:
 - in the first subparagraph, 'EUR 35 900' is replaced by 'EUR 36 500';
 - in the second subparagraph, 'EUR 8 900 to EUR 27 000' is replaced by 'EUR 9 100 to EUR 27 500';
 - in the third subparagraph, 'EUR 7 200' is replaced by 'EUR 7 300';
- (b) paragraph 2 is amended as follows:
 - (i) the first subparagraph of point (a) is amended as follows:
 - 'EUR 3 100' is replaced by 'EUR 3 200';
 - 'EUR 7 200' is replaced by 'EUR 7 300';
 - (ii) point (b) is amended as follows:
 - in the first subparagraph, 'EUR 43 000' is replaced by 'EUR 43 700';
 - in the second subparagraph, 'EUR 10 800 to EUR 32 400' is replaced by 'EUR 11 000 to EUR 33 000';
 - in the third subparagraph, 'EUR 7 200' is replaced by 'EUR 7 300';
- (c) in paragraph 3, 'EUR 7 200' is replaced by 'EUR 7 300';
- (d) in the first subparagraph of paragraph 4, 'EUR 21 600' is replaced by 'EUR 22 000';
- (e) in paragraph 5, 'EUR 7 200' is replaced by 'EUR 7 300';
- (f) paragraph 6 is amended as follows:
 - (i) in the first subparagraph, 'EUR 34 400' is replaced by 'EUR 35 000';
 - (ii) in the second subparagraph, 'EUR 8 500 to EUR 25 600' is replaced by 'EUR 8 600 to EUR 26 000';
- (4) in the first paragraph of Article 6, 'EUR 43 000' is replaced by 'EUR 43 700';
- (5) Article 7 is amended as follows:
 - (a) in the first paragraph, 'EUR 71 400' is replaced by 'EUR 72 600';
 - (b) in the second paragraph, 'EUR 21 600' is replaced by 'EUR 22 000';
- (6) Article 8 is amended as follows:
 - (a) paragraph 1 is amended as follows:
 - (i) in the second subparagraph, 'EUR 86 100' is replaced by 'EUR 87 600';
 - (ii) in the third subparagraph, 'EUR 43 000' is replaced by 'EUR 43 700';
 - (iii) in the fourth subparagraph, 'EUR 21 600 to EUR 64 600' is replaced by 'EUR 22 000 to EUR 65 700';
 - (iv) in the fifth subparagraph, 'EUR 10 800 to EUR 32 400' is replaced by 'EUR 11 000 to EUR 33 000';
 - (b) paragraph 2 is amended as follows:
 - (i) in the second subparagraph, 'EUR 286 900' is replaced by 'EUR 291 800';
 - (ii) in the third subparagraph, 'EUR 143 700' is replaced by 'EUR 146 100';
 - (iii) in the fifth subparagraph, 'EUR 3 100 to EUR 247 300' is replaced by 'EUR 3 200 to EUR 251 500';
 - (iv) in the sixth subparagraph, 'EUR 3 100 to EUR 123 800' is replaced by 'EUR 3 200 to EUR 125 900';
 - (c) in the first subparagraph of paragraph 3, 'EUR 7 200' is replaced by 'EUR 7 300'.

Article 2

This Regulation shall not apply to valid applications pending on 1 April 2019.

Article 3

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

It shall apply from 1 April 2019.

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

Done at Brussels, 22 March 2019.

For the Commission

The President

Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2019/481**of 22 March 2019****approving the active substance flutianil, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011****(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 13(2) thereof,

Whereas:

- (1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, the United Kingdom received on 23 February 2011 an application from Otsuka AgriTechno Co., Ltd for the approval of the active substance flutianil.
- (2) In accordance with Article 9(3) of that Regulation, the United Kingdom, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') on 21 October 2011 of the admissibility of the application.
- (3) On 19 June 2013, the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (4) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of Regulation (EC) No 1107/2009, it requested that the applicant supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the format of an updated draft assessment report on 2 June 2014.
- (5) On 29 July 2014, the Authority communicated to the applicant, the Member States and the Commission its conclusion ⁽²⁾ on whether the active substance flutianil can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority made its conclusion available to the public.
- (6) The Authority concluded that flutianil should be classified as carcinogen category 2 and reproductive toxicant (for the development) category 2. The active substance was therefore deemed not to fulfil the approval criteria referred to in Article 4(1) of Regulation (EC) No 1107/2009.
- (7) On 4 December 2014, the rapporteur Member State notified its intention to launch a request for harmonised classification under the provisions of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽³⁾. According to that proposal, it was not appropriate to classify flutianil as carcinogen or reproductive toxicant and therefore flutianil was deemed to fulfil the approval criteria referred to in Article 4(1) of Regulation (EC) No 1107/2009. The application was submitted by the United Kingdom to the European Chemicals Agency on 23 February 2015.
- (8) On 10 December 2015, the Commission presented a draft review report for non-approval of flutianil to the Standing Committee on Plants, Animals, Food and Feed. Given the potential implication for decision-making, the Commission decided to await the outcome of the classification process under Regulation (EC) No 1272/2008 before presenting a draft Regulation to the Standing Committee on Plants, Animals, Food and Feed.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.⁽²⁾ EFSA Journal 2014;12(8):3805 [89 pp.]. doi: 10.2903/j.efsa.2014.3805.⁽³⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

- (9) In March 2016, the Risk Assessment Committee of the European Chemicals Agency proposed no classification as carcinogenic or toxic to reproduction for the active substance flutianil⁽⁴⁾. On request of the European Commission, the Authority published on 5 July 2018 a 'Statement on the impact of the harmonised classification on the conclusion on the peer review of the pesticide risk assessment of the active substance flutianil'⁽⁵⁾. In that statement, the Authority acknowledged that the harmonised classification proposed by the Risk Assessment Committee of the European Chemicals Agency was, based on new additional information, different from the provisional classification used in the Authority's conclusion. On 4 October 2018, the active substance flutianil was included in Part 3 of Annex VI to Regulation (EC) No 1272/2008 with no classification as carcinogenic or toxic to reproduction⁽⁶⁾.
- (10) The Commission revised the draft review report in order to align it with the outcome of the classification process and submitted it for comments to the applicant together with a draft Regulation on 20 March 2018. The documents were presented to the Standing Committee on Plants, Animals, Food and Feed on 21 March 2018.
- (11) Following the publication of the Authority's statement, on 24 October 2018 the Commission presented to the Standing Committee on Plants, Animals, Food and Feed a revised review report and a draft Regulation providing that flutianil is approved.
- (12) The applicant was given the possibility to submit comments on the revised review report and on the Authority's statement.
- (13) As regards the new criteria to identify endocrine disrupting properties set in Commission Regulation (EU) 2018/605⁽⁷⁾, which became applicable on 10 November 2018, and the Joint guidance document to identify endocrine disrupting substances⁽⁸⁾, the information contained in the conclusions of the Authority allow to infer that it is highly unlikely that flutianil is an endocrine disruptor via the estrogenic, androgenic, thyroidogenic and steroidogenic modalities. Although effects on the thyroid (weight increase) were observed, these occurred only at the top doses exceeding the maximum recommended doses for the type of study where the effects were observed. Testicular, prostate and uterus effects observed (histopathological changes) were within the historical control values or they were not replicated in the two-generation reproductive toxicity study, nor affected fertility parameters. The two-generation reproductive toxicity study was performed following the test protocol according to the latest OECD Guidelines⁽⁹⁾, as prescribed by the Joint guidance document to identify endocrine disrupting substances and did not detect any endocrine sensitive reproductive and developmental parameters such as oestrous cycle length, mating index, mean number of implantation sites, preputial separation and vaginal opening.
- (14) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, and in particular the uses which were examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (15) It is therefore appropriate to approve flutianil.
- (16) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions. It is, in particular, appropriate to require further confirmatory information, amongst others to confirm that flutianil is not an endocrine disruptor in accordance with Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, in order to increase the confidence, in accordance with Point 2(2)(b) of Annex II to Regulation (EC) No 1107/2009, in the conclusion drawn by the Commission in recital 13.

⁽⁴⁾ Committee for Risk Assessment (RAC) Opinion proposing harmonised classification and labelling at EU level of Flutianil (ISO);(2Z)-[2-fluoro-5-(trifluoromethyl)phenyl]thio[3-(2-methoxyphenyl)-1,3-thiazolidin-2-ylidene] acetonitrile, EC Number: -, CAS Number: 958647-10-4 CLH-O-0000001412-86-101/F. Adopted 10 March 2016.
<https://echa.europa.eu/documents/10162/efc05a0b-a819-51d6-6f43-5396ee76e29f>.

⁽⁵⁾ EFSA Journal 2018;16(7):5383 [19 pp.]. doi: 10.2903/j.efsa.2018.5383.

⁽⁶⁾ Commission Regulation (EU) 2018/1480 of 4 October 2018 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2017/776 (OJ L 251, 5.10.2018, p. 1).

⁽⁷⁾ Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

⁽⁸⁾ Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5311>.

⁽⁹⁾ OECD (Organisation for Economic Cooperation and Development), 2001. Test No 416: Two-Generation Reproduction Toxicity. In: OECD Guidelines for the Testing of Chemicals, Section 4. OECD Publishing, Paris. 13 pp. <https://doi.org/10.1787/9789264070868-en>.

- (17) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽¹⁰⁾ should be amended accordingly.
- (18) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of active substance

The active substance flutianil, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force

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, 22 March 2019.

For the Commission
The President
Jean-Claude JUNKER

⁽¹⁰⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Flutianil CAS No [958647-10-4] CIPAC No 835	(Z)-[3-(2-methoxy-phenyl)-1,3-thiazolidin-2-ylidene]($\alpha,\alpha,\alpha,4$ -tetrafluoro- <i>m</i> -tolylthio)acetonitrile	≥ 985 g/kg	14 April 2019	14 April 2029	<p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flutianil, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators and workers, — the risk to aquatic organisms, — the risk to groundwater from metabolites, if the substance is applied under vulnerable soil or climatic conditions. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ol style="list-style-type: none"> 1. the technical specification of the active substance as manufactured (based on commercial scale production) and the compliance of the toxicity batches with the confirmed technical specification; 2. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or ground water is abstracted for drinking water; 3. an updated assessment of the information submitted and, where relevant further information, confirming that flutianil is not an endocrine disruptor in accordance with Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, applying also the ECHA and EFSA guidance for identification of endocrine disruptors ⁽²⁾. <p>The applicant shall submit the information:</p> <ul style="list-style-type: none"> — referred to in point 1 by 14 April 2020;

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
					<p>— referred to in point 2 within two years from the date of publication, by the Commission, of a guidance document on the evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater; and</p> <p>— referred to in point 3 by 14 April 2021.</p>

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.

⁽²⁾ Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. EFSA Journal 2018;16(6):5311; ECHA-18-G-01-EN.

In Part B of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

'133	<p>Flutianil</p> <p>CAS No [958647-10-4]</p> <p>CIPAC No 835</p>	<p>(Z)-[3-(2-methoxyphenyl)-1,3-thiazolidin-2-ylidene]($\alpha,\alpha,\alpha,4$-tetrafluoro-<i>m</i>-tolylthio)acetonitrile</p>	≥ 985 g/kg	14 April 2019	14 April 2029	<p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flutianil, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators and workers, — the risk to aquatic organisms, — the risk to groundwater from metabolites, if the substance is applied under vulnerable soil or climatic conditions. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ol style="list-style-type: none"> 1. the technical specification of the active substance as manufactured (based on commercial scale production) and the compliance of the toxicity batches with the confirmed technical specification; 2. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or ground water is abstracted for drinking water; 3. an updated assessment of the information submitted and, where relevant further information, confirming that flutianil is not an endocrine disruptor in accordance with Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, applying also the ECHA and EFSA guidance for identification of endocrine disruptors (*). <p>The applicant shall submit the information:</p> <ul style="list-style-type: none"> — referred to in point 1 by 14 April 2020;
------	--	--	-----------------	---------------	---------------	--

						<ul style="list-style-type: none"> — referred to in point 2 within two years from the date of publication, from the Commission, of a guidance document on the evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater; and — referred to in point 3 by 14 April 2021.
(*) Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. EFSA Journal 2018;16(6):5311; ECHA-18-G-01-EN.'						

COMMISSION IMPLEMENTING REGULATION (EU) 2019/482**of 22 March 2019****amending Commission Implementing Regulation (EU) 2016/1368 establishing a list of critical benchmarks used in financial markets pursuant to Regulation (EU) 2016/1011 of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/1011 of the European Parliament and of the Council of 8 June 2016 on indices used as benchmarks in financial instruments and financial contracts or to measure the performance of investment funds and amending Directives 2008/48/EC and 2014/17/EU and Regulation (EU) No 596/2014 ⁽¹⁾, and in particular Article 20(1) thereof,

Whereas:

- (1) Benchmarks play an important role in the determination of the price of many financial instruments and financial contracts and in the measurement of performance for many investment funds. The contribution to and administration of benchmarks are in many cases vulnerable to manipulation and persons involved often face conflicts of interest.
- (2) In order to fulfil their economic role, benchmarks need to be representative of the underlying market or economic reality they intend to measure. Should a benchmark no longer be representative of an underlying market, such as interbank offered rates, there is a risk of negative effects on, inter alia, market integrity, the financing of households (loans and mortgages) and businesses in the Union.
- (3) Risks to users, markets and the economy of the Union generally increase where the total value of financial instruments, financial contracts and investment funds referencing a specific benchmark is high. Regulation (EU) 2016/1011 therefore establishes different categories of benchmarks and provides for additional requirements ensuring the integrity and robustness of certain benchmarks considered as being critical, including the power of competent authorities to mandate, under certain conditions, contributions to or the administration of a critical benchmark.
- (4) Pursuant to Article 20(1) of Regulation (EU) 2016/1011, the Commission is empowered to adopt implementing acts to establish and review at least every two years a list of critical benchmarks.
- (5) Commission Implementing Regulation (EU) 2016/1368 ⁽²⁾ established a list of critical benchmarks used in financial markets pursuant to Regulation (EU) 2016/1011.
- (6) According to point (b) of Article 20(1) of Regulation (EU) 2016/1011, benchmarks may be included in the list of critical benchmarks where those benchmarks are based on input data submitted by contributors the majority of which are located in one Member State and are recognised as being critical in that Member State.
- (7) On 10 October 2018, the Polish competent authority, Komisja Nadzoru Finansowego ('KNF'), notified the European Securities and Markets Authority ('ESMA') of its proposal to recognise the Warsaw Interbank Offered Rate ('WIBOR') as a critical benchmark, under point (b) of Article 20(1) of Regulation (EU) 2016/1011, because it is critical in Poland and it is based on submissions of contributors, all of which are located in Poland.
- (8) WIBOR is a reference rate based on an average of the interest rates at which banks operating in the Polish money market are willing to lend unsecured funds to each other at different maturities. As of 10 October 2018, eleven banks participate in the WIBOR panel, all of which are located in Poland.

⁽¹⁾ OJ L 171, 29.6.2016, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2016/1368 of 11 August 2016 establishing a list of critical benchmarks used in financial markets pursuant to Regulation (EU) 2016/1011 of the European Parliament and of the Council (OJ L 217, 12.8.2016, p. 1).

- (9) In its assessment submitted to ESMA, the KNF concluded that the cessation of WIBOR, or its provision on the basis of input data or of a panel of contributors no longer representative of the underlying market or economic reality, could have a significant adverse impact on the functioning of financial markets in Poland.
- (10) The assessment by the KNF illustrates that WIBOR is used as a reference in 60 % of total loans to households in Poland, and in 70,1 % of outstanding mortgages. In mortgages subscribed since 2013, WIBOR's prevalence has increased to 98,5 %. In addition, WIBOR serves as a reference for the coupon payments for nearly 26 % of the total nominal value of Polish bonds. KNF also presented data showing that WIBOR is used as a reference in OTC interest rate derivatives for an outstanding notional amount of EUR 366 billion. Finally, KNF concluded on the basis of a survey that WIBOR is referenced in investment funds with a total net asset value of EUR 2,6 billion. The total value of financial instruments and financial contracts referencing WIBOR is therefore larger than the gross national product of Poland. The assessment concludes that WIBOR is of vital importance for financial stability and market integrity in Poland, and that WIBOR's discontinuity or unreliability could have a significant adverse impact on the functioning of financial markets in Poland and on companies and consumers as it is used in loans, consumer credit products and investment funds.
- (11) On 8 November 2018, ESMA sent the Commission its opinion setting out that the KNF had taken into consideration all the elements and criteria included in Article 20(3) of Regulation (EU) 2016/1011 and that it had provided quantitative data to support the case for the recognition of WIBOR as a critical benchmark, as well as analytical reasoning highlighting the crucial role of WIBOR in the Polish economy.
- (12) Implementing Regulation (EU) 2016/1368 should therefore be amended accordingly.
- (13) In light of the crucial importance of WIBOR, its widespread use and its role in the allocation of capital in Poland, this Regulation should enter into force as a matter of urgency.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the European Securities Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2016/1368 is replaced by the text in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 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, 22 March 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

‘ANNEX

List of critical benchmarks pursuant to Article 20(1) of Regulation (EU) 2016/1011

No	Benchmark	Administrator	Location
1	Euro Interbank Offered Rate (EURIBOR®)	European Money Markets Institute (EMMI)	Brussels, Belgium
2	Euro Overnight Index Average (EONIA®)	European Money Markets Institute (EMMI)	Brussels, Belgium
3	London Interbank Offered Rate (LIBOR)	ICE Benchmark Administration (IBA)	London, United Kingdom
4	Stockholm Interbank Offered Rate (STIBOR)	Swedish Bankers' Association (Svenska Bankföreningen)	Stockholm, Sweden
5	Warsaw Interbank Offered Rate (WIBOR)	GPW Benchmarks S.A.	Warsaw, Poland'

DECISIONS

COUNCIL DECISION (EU) 2019/483

of 19 March 2019

on the position to be adopted, on behalf of the European Union, within the EEA Joint Committee, concerning the amendment of Annex IX (Financial services) to the EEA Agreement (Capital Requirements Regulation (EU) No 575/2013 (CRR) and Directive 2013/36/EU (CRD IV))

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 in conjunction with Article 218(9) thereof,

Having regard to Council Regulation (EC) No 2894/94 of 28 November 1994 concerning arrangements for implementing the Agreement on the European Economic Area ⁽¹⁾, and in particular Article 1(3) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Agreement on the European Economic Area ⁽²⁾ ('the EEA Agreement') entered into force on 1 January 1994.
- (2) Pursuant to Article 98 of the EEA Agreement, the EEA Joint Committee may decide to amend, inter alia, Annex IX to that Agreement, which contains provisions on financial services.
- (3) Regulation (EU) No 575/2013 of the European Parliament and of the Council ⁽³⁾ and Directive 2013/36/EU of the European Parliament and of the Council ⁽⁴⁾ are to be incorporated into the EEA Agreement.
- (4) Annex IX to the EEA Agreement should therefore be amended accordingly.
- (5) The position of the Union within the EEA Joint Committee should therefore be based on the attached draft decision,

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted, on behalf of the Union, within the EEA Joint Committee on the proposed amendment of Annex IX (Financial services) to the EEA Agreement, shall be based on the draft decision of the EEA Joint Committee attached to this Decision.

⁽¹⁾ OJ L 305, 30.11.1994, p. 6.

⁽²⁾ OJ L 1, 3.1.1994, p. 3.

⁽³⁾ Regulation (EU) No 575/2013 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and investment firms and amending Regulation (EU) No 648/2012 (OJ L 176, 27.6.2013, p. 1).

⁽⁴⁾ Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

Article 2

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

Done at Brussels, 19 March 2019.

For the Council
The President
G. CIAMBA

DRAFT

DECISION OF THE EEA JOINT COMMITTEE No .../2019
of ...
amending Annex IX (Financial services) to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area ('the EEA Agreement'), and in particular Article 98 thereof,

Whereas:

- (1) Regulation (EU) No 575/2013 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and investment firms and amending Regulation (EU) No 648/2012 ⁽¹⁾, as corrected by OJ L 208, 2.8.2013, p. 68, OJ L 321, 30.11.2013, p. 6 and OJ L 20, 25.1.2017, p. 2, is to be incorporated into the EEA Agreement.
- (2) Regulation (EU) 2017/2395 of the European Parliament and of the Council of 12 December 2017 amending Regulation (EU) No 575/2013 as regards transitional arrangements for mitigating the impact of the introduction of IFRS 9 on own funds and for the large exposures treatment of certain public sector exposures denominated in the domestic currency of any Member State ⁽²⁾, is to be incorporated into the EEA Agreement.
- (3) Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC ⁽³⁾, as corrected by OJ L 208, 2.8.2013, p. 73 and OJ L 20, 25.1.2017, p. 1, is to be incorporated into the EEA Agreement.
- (4) Regulation (EU) No 575/2013 and Directive 2013/36/EU refer to 'EU parent institutions', 'EU parent financial holding companies' and 'EU parent mixed financial holding companies', which in the context of the EEA Agreement are understood as referring to entities fulfilling the relevant definitions set out in the Regulation that are established in an EEA Contracting Party and which are not subsidiaries of any other institution set up in any other EEA Contracting Party.
- (5) Directive 2013/36/EU repeals Directives 2006/48/EC ⁽⁴⁾ and 2006/49/EC ⁽⁵⁾ of the European Parliament and of the Council, which are incorporated into the EEA Agreement and which are consequently to be repealed under the EEA Agreement.
- (6) The potential for unwarranted reductions in own funds requirements from the use of internal models has, inter alia, been limited by national legislation implementing Article 152 of Directive 2006/48/EC, which, by the end of 2017 was replaced by Article 500 of Regulation (EU) 575/2013. There are, however, still several other provisions in Regulation (EU) 575/2013 and Directive 2013/36/EU which allow competent authorities to address the same issue, including the possibility for measures to counterbalance unwarranted reductions in the riskweighted exposure amounts, see for instance Article 104 of Directive 2013/36/EU, and to impose prudent margins of conservatism in the calibration of internal models, see for instance Article 144 of Regulation (EU) 575/2013 and Article 101 of Directive 2013/36/EU.
- (7) Annex IX to the EEA Agreement should therefore be amended accordingly,

⁽¹⁾ OJ L 176, 27.6.2013, p. 1.

⁽²⁾ OJ L 345, 27.12.2017, p. 27.

⁽³⁾ OJ L 176, 27.6.2013, p. 338.

⁽⁴⁾ OJ L 177, 30.6.2006, p. 1.

⁽⁵⁾ OJ L 177, 30.6.2006, p. 201.

HAS ADOPTED THIS DECISION:

Article 1

Annex IX to the EEA Agreement shall be amended as follows:

1. The text of point 14 (Directive 2006/48/EC of the European Parliament and of the Council) is replaced by the following:

‘32013 L 0036: Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338), as corrected by OJ L 208, 2.8.2013, p. 73 and OJ L 20, 25.1.2017, p. 1.

The provisions of the Directive shall, for the purposes of this Agreement, be read with the following adaptations:

- (a) Notwithstanding the provisions of Protocol 1 to this Agreement, and unless otherwise provided for in this Agreement, the terms “Member State(s)” and “competent authorities” shall be understood to include, in addition to their meaning in the Directive, the EFTA States and their competent authorities, respectively.
- (b) References to “ESCB central banks” or to “central banks” shall be understood to include, in addition to their meaning in the Directive, the national central banks of the EFTA States.
- (c) References to other acts in the Directive shall apply to the extent and in the form that those acts are incorporated into this Agreement.
- (d) References to the powers of EBA under Article 19 of Regulation (EU) No 1093/2010 of the European Parliament and of the Council in the Directive shall be understood as referring, in the cases provided for in and in accordance with point 31g of this Annex, to the powers of the EFTA Surveillance Authority as regards the EFTA States.
- (e) In Article 2(5), the following point shall be inserted:

“(11a) In Iceland, the “Bygðastofnun”, the “Íbúðalánasjóður” and the “Lánasjóður sveitarfélaga ohf.”;

- (f) In Article 6, the following subparagraph is added to point (a):

“The competent authorities of the EFTA States cooperate with trust and full mutual respect, in particular when ensuring the flow of appropriate and reliable information between them and the parties to the ESFS and with the EFTA Surveillance Authority. Competent authorities of the EU Member States shall cooperate with the competent authorities of the EFTA States in the same manner.”

- (g) Article 47(3) shall not apply as regards the EFTA States. An EFTA State may, through agreements concluded with one or more third countries, agree to apply provisions which accord to branches of a credit institution having its head office in a third country identical treatment on the territory of that EFTA State.

The Contracting Parties shall inform and consult each other prior to concluding agreements with third countries on the basis of Article 47(3) or the first paragraph of this point, as the case may be.

Whenever the European Union negotiates with one or more third countries towards the conclusion of an agreement on the basis of Article 47(3), and such an agreement pertains to obtain national treatment or effective market access for branches of credit institutions having their head office in a Member State of the European Union in the third countries concerned, the European Union shall endeavour to obtain equal treatment for branches of credit institutions having their head office in an EFTA State.

- (h) Article 48 shall not apply. Where an EFTA State concludes an agreement with one or more third countries regarding the means of exercising supervision on a consolidated basis over institutions the parent undertakings of which have their head offices in a third country and institutions situated in third countries the parent undertakings of which, whether institutions, financial holding companies or mixed financial holding companies, have their head offices in that EFTA State, that agreement shall seek to ensure that EBA is able to obtain from the competent authority of that EFTA State the information received from national authorities of third countries in accordance with Article 35 of Regulation (EU) No 1093/2010.
- (i) In Article 53(2), the words “or, as the case may be, the EFTA Surveillance Authority” shall be inserted before the words “in accordance with this Directive”.

- (j) In Article 58(1)(d), the words “or, as the case may be, the EFTA Surveillance Authority” shall be inserted after the word “ESMA”.
- (k) In Article 89(5), the words “future Union legislative acts for disclosure obligations” shall be replaced by the words “future legislative acts applicable pursuant to the EEA Agreement provide for disclosure obligations that”.
- (l) In Article 114(1), as regards Liechtenstein, the words “an ESCB central bank” shall be replaced by the words “the competent authority”.
- (m) In the second subparagraph of Article 117(1), the words “or the EFTA Surveillance Authority, as the case may be,” shall be inserted after the word “EBA”.
- (n) In Article 133(14) and (15), the words “or, as regards the EFTA States, the Standing Committee of the EFTA States” shall be inserted after the words “the Commission”.
- (o) In Article 151(1), as regards the EFTA States, the words “a decision of the EEA Joint Committee containing” shall be inserted after the words “in accordance with”.

2. The following is inserted after point 14 (Directive 2013/36/EU of the European Parliament and of the Council):

‘14a. **32013 R 0575:** Regulation (EU) No 575/2013 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and investment firms and amending Regulation (EU) No 648/2012 (OJ L 176, 27.6.2013, p. 1), as corrected by OJ L 208, 2.8.2013, p. 68, OJ L 321, 30.11.2013, p. 6 and OJ L 20, 25.1.2017, p. 2, as amended by:

— **32017 R 2395:** Regulation (EU) 2017/2395 of the European Parliament and of the Council of 12 December 2017 (OJ L 345, 27.12.2017, p. 27).

The provisions of the Regulation shall, for the purposes of this Agreement, be read with the following adaptations:

- (a) Notwithstanding the provisions of Protocol 1 to this Agreement, and unless otherwise provided for in this Agreement, the terms “Member State(s)” and “competent authorities” shall be understood to include, in addition to their meaning in the Regulation, the EFTA States and their competent authorities, respectively.
- (b) References to “ESCB central banks” or to “central banks” shall be understood to include, in addition to their meaning in the Regulation, the national central banks of the EFTA States
- (c) References to other acts in the Regulation shall apply to the extent and in the form that those acts are incorporated into this Agreement.
- (d) References to the powers of EBA under Article 19 of Regulation (EU) No 1093/2010 of the European Parliament and of the Council in the Regulation shall be understood as referring, in the cases provided for in and in accordance with point 31g of this Annex, to the powers of the EFTA Surveillance Authority as regards the EFTA States.
- (e) In point (75) of Article 4(1), the words “Norway and” shall be inserted before the word “Sweden”.
- (f) In Article 31(1)(b), as regards the EFTA States, the words “the Commission” shall read “the EFTA Surveillance Authority”.
- (g) In paragraphs 1 and 2 of Article 80, the words “or, in case an EFTA State is concerned, the EFTA Surveillance Authority” shall be inserted after the words “the Commission”.
- (h) In Articles 329(4), 344(2), 352(6), 358(4) and 416(5), as regards the EFTA States, the words “the decisions of the EEA Joint Committee containing” shall be inserted after the words “entry into force of”.
- (i) In Article 395:
 - (i) in paragraphs 7 and 8, as regards the EFTA States, the words “the Council,” shall not apply;
 - (ii) as regards the EFTA States, the first subparagraph of paragraph 8 shall read as follows:

“The power to adopt a decision to accept or reject the proposed national measure referred to in paragraph 7 is conferred on the Standing Committee of the EFTA States.”

- (iii) the first sentence of the second subparagraph of paragraph 8 shall be replaced by the following:

“Within one month of receiving the notification referred to in paragraph 7, EBA shall provide its opinion on the points mentioned in that paragraph to the Council, the Commission and the Member State concerned or, where its opinion concerns national measures proposed by an EFTA State, to the Standing Committee of the EFTA States and the EFTA State concerned.”

- (j) In Article 458:

- (i) as regards the EFTA States, the first subparagraph of paragraph 2 shall read as follows:

“Where the authority determined in accordance with paragraph 1 identifies changes in the intensity of macroprudential or systemic risk in the financial system with the potential to have serious negative consequences to the financial system and the real economy in a specific EFTA State and which that authority considers would better be addressed by means of stricter national measures, it shall notify the Standing Committee of the EFTA States, the EFTA Surveillance Authority, the ESRB and EBA of that fact and submit relevant quantitative or qualitative evidence of all of the following:”

- (ii) as regards the EFTA States, the first subparagraph of paragraph 4 shall read as follows:

“The power to adopt an implementing act to reject the draft national measures referred to in point (d) of paragraph 2 is conferred on the Standing Committee of the EFTA States, acting on a proposal from the EFTA Surveillance Authority.”;

- (iii) in the second subparagraph of paragraph 4, the following shall be added:

“Where their opinions concern draft national measures of an EFTA State, the ESRB and EBA shall provide their opinions to the Standing Committee of the EFTA States, the EFTA Surveillance Authority and the EFTA State concerned.”;

- (iv) as regards the EFTA States, the third to eighth subparagraphs of paragraph 4 shall read as follows:

“Taking utmost account of the opinions referred to in the second subparagraph and if there is robust, strong and detailed evidence that the measure will have a negative impact on the internal market that outweighs the financial stability benefits resulting in a reduction of the macroprudential or systemic risk identified, the EFTA Surveillance Authority may, within one month, propose to the Standing Committee of the EFTA States to reject the draft national measures.

In the absence of an EFTA Surveillance Authority proposal within that period of one month, the EFTA State concerned may immediately adopt the draft national measures for a period of up to two years or until the macroprudential or systemic risk ceases to exist if that occurs sooner.

The Standing Committee of the EFTA States shall decide on the proposal by the EFTA Surveillance Authority within one month after receipt of the proposal and state its reasons for rejecting or not rejecting the draft national measures.

The Standing Committee of the EFTA States shall only reject the draft national measures if it considers that one or more of the following conditions are not complied with:

- (a) the changes in the intensity of macroprudential or systemic risk are of such nature as to pose risk to financial stability at national level;
- (b) Articles 124 and 164 of this Regulation and Articles 101, 103, 104, 105, 133, and 136 of Directive 2013/36/EU cannot adequately address the macroprudential or systemic risk identified, taking into account the relative effectiveness of those measures;
- (c) the draft national measures are more suitable to address the identified macroprudential or systemic risk and do not entail disproportionate adverse effects on the whole or parts of the financial system in other Contracting Parties or in the EEA as a whole, thus forming or creating an obstacle to the functioning of the internal market;

- (d) the issue concerns only one EFTA State; and
- (e) the risks have not already been addressed by other measures in this Regulation or in Directive 2013/36/EU.

The assessment of the Standing Committee of the EFTA States shall take into account the opinion of the ESRB and EBA and shall be based on the evidence presented in accordance with paragraph 2 by the authority determined in accordance with paragraph 1.

In the absence of a decision of the Standing Committee of the EFTA States to reject the draft national measures within one month after receipt of the proposal by the EFTA Surveillance Authority, the EFTA State may adopt the measures and apply them for a period of up to two years or until the macroprudential or systemic risk ceases to exist if that occurs sooner.”

- (v) as regards the EFTA States, paragraph 6 shall read as follows:

“Where an EFTA State recognises the measures set in accordance with this Article, it shall notify the Standing Committee of the EFTA States, the EFTA Surveillance Authority, EBA, the ESRB and the Contracting Party to the EEA Agreement authorised to apply the measures.”

- (k) In Article 467(2), as regards the EFTA States, the words “the Commission has adopted a regulation” shall read “the entry into force of a decision of the EEA Joint Committee containing a regulation adopted”.
- (l) In Article 497, as regards the EFTA States:
 - (i) in paragraphs 1 and 2, the words “the decisions of the EEA Joint Committee containing” shall be inserted after the words “entry into force of the latest of”;
 - (ii) in paragraph 1, the words “have been adopted” shall read “apply in the EEA”.

3. In point 31bc (Regulation (EU) No 648/2012 of the European Parliament and of the Council):

- (a) the following indent is added:

‘— **32013 R 0575:** Regulation (EU) No 575/2013 of the European Parliament and of the Council of 26 June 2013 (OJ L 176, 27.6.2013, p. 1), as corrected by OJ L 208, 2.8.2013, p. 68, OJ L 321, 30.11.2013, p. 6 and OJ L 20, 25.1.2017, p. 2.’

- (b) in adaptation (zh), the following is added:

‘(v) in paragraph 5a, as regards the EFTA States, the words “the decisions of the EEA Joint Committee containing” shall be inserted after the words “entry into force of the latest of”.’

4. The following indent is added in point 31ea (Directive 2002/87/EC of the European Parliament and of the Council):

‘— **32013 L 0036:** Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 (OJ L 176, 27.6.2013, p. 338), as corrected by OJ L 208, 2.8.2013, p. 73 and OJ L 20, 25.1.2017, p. 1.’

5. The text of point 31 (Directive 2006/49/EC of the European Parliament and of the Council) is deleted.

Article 2

The texts of Regulations (EU) No 575/2013, as corrected by OJ L 208, 2.8.2013, p. 68, OJ L 321, 30.11.2013, p. 6 and OJ L 20, 25.1.2017, p. 2, and (EU) 2017/2395 and Directive 2013/36/EU, as corrected by OJ L 208, 2.8.2013, p. 73 and OJ L 20, 25.1.2017, p. 1, in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on [...], provided that all the notifications under Article 103(1) of the EEA Agreement have been made (*).

(*) [No constitutional requirements indicated.] [Constitutional requirements indicated.]

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels,

For the EEA Joint Committee

The President

The Secretaries to the EEA Joint Committee

Joint Declaration by the Contracting Parties to Decision No .../2019 incorporating Directive 2013/36/EU into the EEA Agreement

The Contracting Parties share the understanding that the incorporation into the EEA Agreement of Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC is without prejudice to national rules of general application concerning the screening for security or public order of foreign direct investment.

COMMISSION IMPLEMENTING DECISION (EU) 2019/484**of 21 March 2019****approving the plan for the eradication of African swine fever in feral pigs in certain areas of Bulgaria***(notified under document C(2019) 2133)***(Only the Bulgarian text is authentic)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever ⁽¹⁾, and in particular the second subparagraph of Article 16(1) thereof,

Whereas:

- (1) Directive 2002/60/EC lays down the minimum Union measures to be taken for the control of African swine fever, including those to be applied in the event of confirmation of a case of African swine fever in feral pigs.
- (2) In addition, Commission Implementing Decision 2014/709/EU ⁽²⁾ lays down animal health control measures in relation to African swine fever in the Member States or areas thereof as listed in the Annex thereto (the Member States concerned), and in all Member States as regards movements of feral pigs and information obligations. The Annex to Implementing Decision 2014/709/EU demarcates and lists certain areas of the Member States concerned, differentiated by the level of risk based on the epidemiological situation as regards that disease, including a list of high risk areas. That Annex has been amended several times to take account of changes in the epidemiological situation in the Union as regards African swine fever that needed to be reflected in that Annex.
- (3) In 2018 Bulgaria notified the Commission of cases of African swine fever in feral pigs and has duly taken the disease control measures required by Directive 2002/60/EC.
- (4) In light of the current epidemiological situation and in accordance with Article 16 of Directive 2002/60/EC, Bulgaria has submitted to the Commission a plan for the eradication of African swine fever (the eradication plan).
- (5) The Annex to Implementing Decision 2014/709/EU was amended by Commission Implementing Decision (EU) 2018/1635 ⁽³⁾ to take account, inter alia, of the cases of African swine fever in feral pigs in Bulgaria and Parts I and II of that Annex now include the infected areas in Bulgaria.
- (6) The eradication plan submitted by Bulgaria has been examined by the Commission and found to comply with the requirements set out in Article 16 of Directive 2002/60/EC. The plan should therefore be approved accordingly.
- (7) 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

The plan submitted by Bulgaria on 7 December 2018 in accordance with Article 16(1) of Directive 2002/60/EC, concerning the eradication of African swine fever from the feral pig population in the areas referred to in the Annex to Implementing Decision 2014/709/EU is approved.

⁽¹⁾ OJ L 192, 20.7.2002, p. 27.

⁽²⁾ Commission Implementing Decision 2014/709/EU of 9 October 2014 concerning animal health control measures relating to African swine fever in certain Member States and repealing Implementing Decision 2014/178/EU (OJ L 295, 11.10.2014, p. 63).

⁽³⁾ Commission Implementing Decision (EU) 2018/1635 of 30 October 2018 amending the Annex to Implementing Decision 2014/709/EU concerning animal health control measures relating to African swine fever in certain Member States (OJ L 272, 31.10.2018, p. 38).

Article 2

Bulgaria shall bring into force the laws, regulations and administrative provisions required for the implementation of the eradication plan within a period of 30 days from the date of adoption of this Decision.

Article 3

This Decision is addressed to the Republic of Bulgaria.

Done at Brussels, 21 March 2019.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

