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Contents

[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.

RECOMMENDATIONS

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2020/1737

of 14 July 2020

amending Regulation (EC) No 273/2004 of the European Parliament and of the Council and Council Regulation (EC) No 111/2005 as regards the inclusion of certain drug precursors in the list of scheduled substances

(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 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors ([1]), and in particular Article 15 thereof,

Having regard to Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Union and third countries in drug precursors ([2]), and in particular Article 30a thereof,

Whereas:

(1) Annex I to Regulation (EC) No 273/2004 and the Annex to Regulation (EC) No 111/2005 each contain a list of scheduled substances, which are subject to a number of harmonised control and monitoring measures provided for by those Regulations.

(2) By means of Decisions 62/10, 62/11 and 62/12 of the Commission on Narcotic Drugs of the United Nations (CND), taken at its sixty-second session on 19 March 2019, the three substances methyl 3-(1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylate (PMK methyl glycidate), 3-(1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylic acid (PMK glycidic acid) and alpha-phenylacetoacetamide (APAA) have been added to Table I of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 19 December 1988 ([3]) ('the 1988 UN Convention'). Additionally, by means of Decision 63/1 of the CND, taken at its sixty-third session on 4 March 2020, the substance methyl alpha-phenylacetoacetate (MAPA) has been added to Table I of the 1988 UN Convention.

(3) One of the purposes of Regulations (EC) No 273/2004 and (EC) No 111/2005 is to implement Article 12 of the 1988 UN Convention in the Union. PMK methyl glycidate, PMK glycidic acid, APAA and MAPA should consequently be included in Annex I to Regulation (EC) No 273/2004 and in the Annex to Regulation (EC) No 111/2005.

(4) The scheduled substances listed in Annex I to Regulation (EC) No 273/2004 and in the Annex to Regulation (EC) No 111/2005 are divided into categories for which different measures apply, so as to achieve a proportionate balance between the level of threat posed by each specific substance and the burden on licit trade. The strictest control and monitoring measures apply to substances of category 1. For example, substances of category 1 need to be stored in secured premises and each operator dealing with such substances needs a licence.

([1]) OJ L 47, 18.2.2004, p. 1.
([2]) OJ L 22, 26.1.2005, p. 1.
([3]) OJ L 326, 24.11.1990, p. 57.

(5) PMK methyl glycidate and PMK glycidic acid are immediate precursors of 3,4-methylenedioxymethamphetamine (MDMA), commonly known as 'ecstasy'. APAA and MAPA are immediate precursors of amphetamines. In other words, those substances can be easily transformed into MDMA or amphetamines.

(6) The misuse and abuse of MDMA and amphetamines are causing serious social and public health problems in some regions of the Union. Additionally, organised crime groups in the Union produce vast amounts of MDMA and amphetamines. Large quantities of MDMA and amphetamines are also exported to third countries.

(7) There is no known licit production, trade or use of PMK methyl glycidate, PMK glycidic acid, APAA and MAPA in the Union. Including those substances under category 1 in Annex I to Regulation (EC) No 273/2004 and in the Annex to Regulation (EC) No 111/2005 would consequently not entail any extra administrative burden for economic operators and competent authorities in the Union.

(8) In the light of the threat that PMK methyl glycidate, PMK glycidic acid, APAA and MAPA pose to the social and public health in the Union, and considering that their scheduling will have no impact on their licit trade, production and use in the Union, those substances should be listed under category 1 in Annex I to Regulation (EC) No 273/2004 and in the Annex to Regulation (EC) No 111/2005.

(9) Methyl 2-methyl-3-phenyloxirane-2-carboxylate (BMK methyl glycidate) and 2-methyl-3-phenyloxirane-2-carboxylic acid (BMK glycidic acid) are also substances that are immediate precursors of amphetamines and that are frequently used for the illicit manufacture of amphetamines. Those substances should therefore be included in Annex I to Regulation (EC) No 273/2004 and in the Annex to Regulation (EC) No 111/2005.

(10) There is no significant licit production, trade or use of BMK methyl glycidate and BMK glycidic acid in the Union. Including those substances under category 1 in Annex I to Regulation (EC) No 273/2004 and in the Annex to Regulation (EC) No 111/2005 would consequently not entail any significant extra administrative burden for economic operators and competent authorities in the Union.

(11) In the light of the threat that BMK methyl glycidate and BMK glycidic acid pose to the social and public health in the Union and considering that their scheduling will only have marginal impact on their licit trade, production and use in the Union, they should be listed under category 1 in Annex I to Regulation (EC) No 273/2004 and in the Annex to Regulation (EC) No 111/2005.

(12) Red phosphorus is frequently diverted from trade in the internal market and used in the Union for the illicit manufacture of methamphetamine. It is used as a catalyst to drive the chemical conversion to methamphetamine of ephedrine or pseudoephedrine, which are already listed under category 1 in Annex I to Regulation (EC) No 273/2004 and in the Annex to Regulation (EC) No 111/2005). Consequently, red phosphorus should be included in Annex I to Regulation (EC) No 273/2004.

(13) Methamphetamine is a very addictive drug which is causing serious social and public health problems in some regions of the Union.

(14) Red phosphorus has however important and diversified legal uses, such as the manufacture of flame-retardants for plastics, pyrotechnics and striker plates for safety matches and flares.

(15) In order to achieve a proportionate balance between the threat that red phosphorus poses to the social and public health in the Union and the burden on licit trade in that substance on the internal market, red phosphorus should be included under category 2A in Annex I to Regulation (EC) No 273/2004.

(16) Although it is currently not known whether red phosphorus is also being diverted from the trade between the Union and third countries it is very likely that once the trade in that substance on the internal market is placed under control in the context of Regulation (EC) No 273/2004, illicit drug manufactures will try to source it through the diversion from such extra-Union trade. Consequently, red phosphorus poses a high risk of diversion with regard to trade between the Union and third countries and it should therefore also be included under category 2 in the Annex to Regulation (EC) No 111/2005. This also ensures that the parallelism between the substances included in Regulations (EC) No 273/2004 and (EC) No 111/2005 remains and simplifies the implementation of those Regulations by operators and competent authorities.

(17) Annex II to Regulation (EC) No 273/2004 sets quantitative thresholds on transactions involving certain substances carried out over a period of one year. The purpose of that Annex is to avoid unduly hampering legitimate trade in those substances in cases where it is possible to reduce or eliminate the risk of diversion into illicit channels by limiting the restrictions on trade to quantities over a certain threshold. Based on available evidence and consultations with the competent authorities of the Member States, that threshold for red phosphorus should be set at 0,1 kg.

(18) It is also appropriate in this context to update the combined nomenclature codes (CN codes) in Regulations (EC) No 273/2004 and EC (No) 111/2005 on the basis of the latest version of the Combined Nomenclature adopted by Commission Implementing Regulation (EU) 2019/1776 ([4]) and applicable as of 1 January 2020, to ensure the correct classification of the scheduled substances.

(19) As the substance alpha-phenylacetoacetonitrile is commonly referred to as APAAN by competent authorities in the Member States, that abbreviation should be added in Annex I to Regulation (EC) No 273/2004 and in the Annex to Regulation (EC) No 111/2005.

(20) Regulations (EC) No 273/2004 and (EC) No 111/2005 should therefore be amended accordingly.

(21) Given that there is important lawful production, trade and use of red phosphorus in the Union, economic operators and competent authorities should be given sufficient time to adapt to the new restrictions concerning that substance introduced by this Regulation.

(22) Regulations (EC) No 273/2004 and (EC) No 111/2005 jointly implement certain provisions of the 1988 UN Convention. In view of the close material link between those two Regulations, it is justified to adopt the amendments by way of one single delegated act,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 273/2004

Annexes I and II to Regulation (EC) No 273/2004 are amended in accordance with Annex I to this Regulation.

Article 2

Amendments to Regulation (EC) No 111/2005

The Annex to Regulation (EC) No 111/2005 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and application

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

Point (1)(b) and point (2) of Annex I and point (2)(b) of Annex II shall apply from 13 January 2021.

([4]) Commission Implementing Regulation (EU) 2019/1776 of 9 October 2019 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 280, 31.10.2019, p. 1).

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

Done at Brussels, 14 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Annexes I and II to Regulation (EC) No 273/2004 are amended as follows:

(1) Annex I is amended as follows:

(a) the table 'CATEGORY 1' is amended as follows:

(i) the entry for Alpha-phenylacetoacetonitrile is replaced by the following:

Substance	CN designation (if different)	CN Code	CAS No
'*Alpha*-phenylacetoacetonitrile (APAAN)		2926 40 00	4468-48-8'

(ii) in the entry for (1R,2S)-(-)-chloroephedrine, the CN code '2939 99 00' is replaced by '2939 79 90';

(iii) in the entry for (1S,2R)-(+)-chloroephedrine, the CN code '2939 99 00' is replaced by '2939 79 90';

(iv) in the entry for (1S,2S)-(+)-chloropseudoephedrine, the CN code '2939 99 00' is replaced by '2939 79 90';

(v) in the entry for (1R,2R)-(-)-chloropseudoephedrine, the CN code '2939 99 00' is replaced by '2939 79 90';

(vi) the following entries are inserted in the appropriate place sequentially according to the CN Code:

Substance	CN designation (if different)	CN Code	CAS No
'Methyl 3-(1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylate (PMK methyl glycidate)		2932 99 00	13605-48-6
3-(1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylic acid (PMK glycidic acid)		2932 99 00	2167189-50-4
Alpha-phenylacetoacetamide (APAA)		2924 29 70	4433-77-6
Methyl 2-methyl-3-phenyloxirane-2-carboxylate (BMK methyl glycidate)		2918 99 90	80532-66-7
2-methyl-3-phenyloxirane-2-carboxylic acid (BMK glycidic acid)		2918 99 90	25547-51-7
Methyl *alpha*-phenylacetoacetate (MAPA)		2918 30 00	16648-44-5'

(b) in the table 'SUBCATEGORY 2A', the following entry is inserted in the appropriate place sequentially according to the CN Code:

Substance	CN designation (if different)	CN Code	CAS No.
'Red phosphorus		2804 70 00	7723-14-0'

(c) in the entry for Anthranilic acid in the table 'SUBCATEGORY 2B', the CN code '2922 43 00' is replaced by 'ex 2922 43 00';

(d) in the entry for Sulphuric acid in the table 'CATEGORY 3', the CN code '2807 00 10' is replaced by '2807 00 00';

(2) in the table in Annex II, the following entry is added:

Substance	Threshold
'Red phosphorus	0,1 kg'

ANNEX II

The Annex to Regulation (EC) No 111/2005 is amended as follows:

(1) the table 'CATEGORY 1' is amended as follows:

(a) the entry for Alpha-phenylacetoacetonitrile is replaced by the following:

Substance	CN designation (if different)	CN Code	CAS No
'*Alpha*-phenylacetoacetonitrile (APAAN)		2926 40 00	4468-48-8'

(b) in the entry for (1R,2S)-(-)-chloroephedrine, the CN code '2939 99 00' is replaced by '2939 79 90';

(c) in the entry for (1S,2R)-(+)-chloroephedrine, the CN code '2939 99 00' is replaced by '2939 79 90';

(d) in the entry for (1S,2S)-(+)-chloropseudoephedrine, the CN code '2939 99 00' is replaced by '2939 79 90';

(e) in the entry for (1R,2R)-(-)-chloropseudoephedrine, the CN code '2939 99 00' is replaced by '2939 79 90';

(f) the following entries are inserted in the appropriate place sequentially according to the CN Code:

Substance	CN designation (if different)	CN Code	CAS No
'Methyl 3-(1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylate (PMK methyl glycidate)		2932 99 00	13605-48-6
3-(1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylic acid (PMK glycidic acid)		2932 99 00	2167189-50-4
Alpha-phenylacetoacetamide (APAA)		2924 29 70	4433-77-6
Methyl 2-methyl-3-phenyloxirane-2-carboxylate (BMK methyl glycidate)		2918 99 90	80532-66-7
2-methyl-3-phenyloxirane-2-carboxylic acid (BMK glycidic acid)		2918 99 90	25547-51-7
Methyl *alpha*-phenylacetoacetate (MAPA)		2918 30 00	16648-44-5'

(2) the table 'Category 2' is amended as follows:

(a) in the entry for Anthranilic acid in, the CN code '2922 43 00' is replaced by 'ex 2922 43 00';

(b) the following entry is inserted in the appropriate place sequentially according to the CN Code:

Substance	CN designation (if different)	CN Code	CAS No.
'Red phosphorus		2804 70 00	7723-14-0'

(3) in the entry for Sulphuric acid in the table 'Category 3', the CN code '2807 00 10' is replaced by '2807 00 00';

(4) the table 'Category 4' is amended as follows:

(a) in the entry for medicinal products and veterinary medicinal products containing ephedrine or its salts, the CN code '3003 40 20' is replaced by '3003 41 00' and the CN code '3004 40 20' is replaced by '3004 41 00';

(b) in the entry for medicinal products and veterinary medicinal products containing pseudoephedrine or its salts, the CN code '3003 40 30' is replaced by '3003 42 00' and the CN code '3004 40 30' is replaced by '3004 42 00'.

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1738

of 16 November 2020

approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications ('Asparago verde di Altedo' (PGI))

THE EUROPEAN COMMISSION,

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

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

Whereas:

(1) Pursuant to the first subparagraph of Article 53(1) of Regulation (EU) No 1151/2012, the Commission has examined Italy's application for the approval of amendments to the specification for the protected geographical indication 'Asparago verde di Altedo', registered under Commission Regulation (EC) No 492/2003 ([2]).

(2) Since the amendments in question are not minor within the meaning of Article 53(2) of Regulation (EU) No 1151/2012, the Commission published the amendment application in the *Official Journal of the European Union* ([3]) as required by Article 50(2)(a) of that Regulation.

(3) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the amendments to the specification should be approved,

HAS ADOPTED THIS REGULATION:

Article 1

The amendments to the specification published in the *Official Journal of the European Union* regarding the name 'Asparago verde di Altedo' (PGI) are hereby approved.

Article 2

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

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

Done at Brussels, 16 November 2020.

For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission

([1]) OJ L 343, 14.12.2012, p. 1.

([2]) Commission Regulation (EC) No 492/2003 of 18 March 2003 supplementing the Annex to Regulation (EC) No 2400/96 on the entry of certain names in the "Register of protected designations of origin and protected geographical indications" provided for in Council Regulation (EEC) No 2081/92 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs (Soprèssa Vicentina, Asparago verde di Altedo, Pêra Rocha do Oeste) (OJ L 73, 19.3.2003, p. 3).

([3]) OJ C 221, 6.7.2020, p. 7.

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1739

of 20 November 2020

amending and correcting Implementing Regulation (EU) 2020/761 as regards the quantities available for tariff rate quotas for certain agricultural products included in the WTO schedule of the Union following the withdrawal of the United Kingdom from the Union, a tariff quota for poultrymeat originating in Ukraine and a tariff quota for meat of bovine animals originating in Canada

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]), and in particular point (a) of the first paragraph of Article 187 thereof,

Whereas:

(1) Commission Delegated Regulation (EU) 2020/760 ([2]) and Commission Implementing Regulation (EU) 2020/761 ([3]) lay down the rules for the management of import and export tariff quotas for agricultural products managed by a system of import and export licences and replace and repeal a certain number of acts that have opened those quotas and provide for specific rules.

(2) Commission Implementing Regulation (EU) 2019/386 ([4]), which lays down rules on the allocation of tariff rate quotas for certain agricultural products included in the WTO schedule of the Union following the withdrawal of the United Kingdom from the Union, establishes that, from the day from which Article 1(2) of Regulation (EU) 2019/216 of the European Parliament and of the Council ([5]) applies, the tariff rate quota quantities set out in the Regulations opening the respective tariff rate quotas for certain agricultural products are replaced by the new quantities resulting from the apportionment, as set out in the third column of Annexes I and II to Implementing Regulation (EU) 2019/386. In order to ensure that the quantities of the tariff rate quotas laid down in Implementing Regulation (EU) 2020/761 are consistent with the new quantities of the tariff rate quotas resulting from the apportionment as laid down in the third column of Annex I to Implementing Regulation (EU) 2019/386, the relevant tariff rate quota quantities set out in Annexes II, III, IV, VI, VIII, IX, X and XII to Implementing Regulation (EU) 2020/761 should be amended accordingly.

(3) Following discussions between the Union and the United Kingdom, an agreement on new quantities for four tariff quotas in the rice sector was reached. It is therefore also appropriate to amend the quantities for tariff quotas under order numbers 09.4127, 09.4128, 09.4129 and 09.4130 set out in Annex III to Implementing Regulation (EU) 2020/761.

([1]) OJ L 347, 20.12.2013, p. 671.

([2]) Commission Delegated Regulation (EU) 2020/760 of 17 December 2019 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards the rules for the administration of import and export tariff quotas subject to licences and supplementing Regulation (EU) No 1306/2013 of the European Parliament and of the Council as regards the lodging of securities in the administration of tariff quotas (OJ L 185, 12.6.2020, p. 1).

([3]) Commission Implementing Regulation (EU) 2020/761 of 17 December 2019 laying down rules for the application of Regulations (EU) No 1306/2013, (EU) No 1308/2013 and (EU) No 510/2014 of the European Parliament and of the Council as regards the management system of tariff quotas with licences (OJ L 185, 12.6.2020, p. 24).

([4]) Commission Implementing Regulation (EU) 2019/386 of 11 March 2019 laying down rules with regard to the apportionment of tariff rate quotas for certain agricultural products included in the WTO schedule of the Union following the withdrawal of the United Kingdom from the Union and with regard to import licences issued and import rights allocated under those tariff rate quotas (OJ L 70, 12.3.2019, p. 4).

([5]) Regulation (EU) 2019/216 of the European Parliament and of the Council of 30 January 2019 on the apportionment of tariff rate quotas included in the WTO schedule of the Union following the withdrawal of the United Kingdom from the Union and amending Council Regulation (EC) No 32/2000 (OJ L 38, 8.2.2019, p. 1).

(4) Commission Implementing Regulation (EU) 2020/94 ([6]) amends Implementing Regulation (EU) 2015/2078 ([7]) that provides for the opening and administration of Union import tariff quotas for poultry meat originating in Ukraine, in order to take account of the tariff rate quota quantities and CN codes made available pursuant to an Agreement in the form of an Exchange of Letters between the European Union and Ukraine amending the trade preferences for poultry meat and poultry meat preparations provided for by the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Ukraine, of the other part, approved by Council Decision (EU) 2019/2145 ([8]) ('the Agreement'). It is therefore appropriate to amend the quantity and CN codes of the tariff rate quota under order number 09.4273 set out in Annex XII to Implementing Regulation (EU) 2020/761 in order to take account of the tariff rate quota quantities and CN codes made available pursuant to the Agreement.

(5) It is necessary to correct an editorial error in Annex VIII to Implementing Regulation (EU) 2020/761 as regards the product description for a tariff quota on meat of bovine animals originating in Canada.

(6) Implementing Regulation (EU) 2020/761 should therefore be amended and corrected accordingly.

(7) To ensure legal certainty and in order for the revised quantities of the tariff rate quotas to apply to the licence applications that may be submitted for tariff quotas with a tariff quota period starting on 1 January 2021, this Regulation should enter into force as a matter of urgency on the day following that of its publication in the *Official Journal of the European Union*.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Implementing Regulation (EU) 2020/761

Implementing Regulation (EU) 2020/761 is amended as follows:

(1) Annexes II, III, IV, VI, VIII, IX and X are amended as set out in Annex I to this Regulation;

(2) Annex XII is amended as set out in Annex II to this Regulation.

Article 2

Correction to Implementing Regulation (EU) 2020/761

In Annex VIII to Implementing Regulation (EU) 2020/761, for order number 09.4281, the product description 'Meat of bovine animals, excluding bison, fresh or chilled' is replaced by 'Meat of bovine animals, excluding bison, frozen or other'.

Article 3

Entry into force

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

([6]) Commission Implementing Regulation (EU) 2020/94 of 22 January 2020 amending Implementing Regulation (EU) 2015/2078 as regards tariff quotas for poultrymeat originating in Ukraine and derogating from that Implementing Regulation for the quota year 2020 (OJ L 18, 23.1.2020, p. 1).

([7]) Commission Implementing Regulation (EU) 2015/2078 of 18 November 2015 opening and providing for the administration of Union import tariff quotas for poultrymeat originating in Ukraine (OJ L 302, 19.11.2015, p. 63).

([8]) Council Decision (EU) 2019/2145 of 5 December 2019 on the conclusion, on behalf of the Union, of the Agreement in the form of an Exchange of Letters between the European Union and Ukraine amending the trade preferences for poultry meat and poultry meat preparations provided for by the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Ukraine, of the other part (OJ L 325, 16.12.2019, p. 41).

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

Done at Brussels, 20 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Annexes II, III, IV, VI, VIII, IX and X to Implementing Regulation (EU) 2020/761 are amended as follows:

(1) in Annex II, for the order numbers listed in the left column, the quantities are replaced by the quantities set out in the right column:

Order number	New quantity
09.4123	'571 943 000 kg'
09.4125	'2 285 665 000 kg, divided as follows: 50 % for each sub-period'
09.4131	'269 214 000 kg, divided as follows: 50 % for each sub-period'

(2) in Annex III, for the order numbers listed in the left column, the quantities are replaced by the quantities set out in the right column:

Order number	New quantity
09.4112	'4 682 000 kg, divided as follows: 4 682 000 kg for sub-period 1 January to 30 June Carry over from previous sub-periods, for sub-period 1 July to 31 August Carry over from previous sub-periods, for sub-period 1 September to 31 December'
09.4116	'990 000 kg, divided as follows: 990 000 kg for sub-period 1 January to 30 June Carry over from previous sub-periods, for sub-period 1 July to 31 August Carry over from previous sub-periods, for sub-period 1 September to 31 December'
09.4117	'1 458 000 kg, divided as follows: 1 458 000 kg for sub-period 1 January to 30 June Carry over from previous sub-periods, for sub-period 1 July to 31 August Carry over from previous sub-periods, for sub-period 1 September to 31 December'
09.4118	'1 370 000 kg, divided as follows: 1 370 000 kg for sub-period 1 January to 30 June Carry over from previous sub-periods, for sub-period 1 July to 31 August Carry over from previous sub-periods, for sub-period 1 September to 31 December'
09.4119	'3 041 000 kg, divided as follows: 3 041 000 kg for sub-period 1 January to 30 June Carry over from previous sub-periods, for sub-period 1 July to 31 August Carry over from previous sub-periods, for sub-period 1 September to 31 December'
09.4127	'17 251 000 kg, divided as follows: 4 313 000 kg for sub-period 1 January to 31 March 8 626 000 kg for sub-period 1 April to 30 June 4 312 000 kg for sub-period 1 July to 31 August Carry over from previous sub-periods, for sub-period 1 September to 30 September'
09.4128	'17 728 000 kg, divided as follows: 8 864 000 kg for sub-period 1 January to 31 March 4 432 000 kg for sub-period 1 April to 30 June 4 432 000 kg for sub-period 1 July to 31 August Carry over from previous sub-periods, for sub-period 1 September to 30 September'
09.4129	'220 000 kg, divided as follows: 0 kg for sub-period 1 January to 31 March 220 000 kg for sub-period 1 April to 30 June Carry over from previous sub-periods, for sub-period 1 July to 31 August Carry over from previous sub-periods, for sub-period 1 September to 30 September'

09.4130	'1 532 000 kg, divided as follows: 0 kg for sub-period 1 January to 31 March 1 532 000 kg for sub-period 1 April to 30 June Carry over from previous sub-periods, for sub-period 1 July to 31 August Carry over from previous sub-periods, for sub-period 1 September to 30 September'
09.4148	'1 416 000 kg, divided as follows: 1 416 000 kg for sub-period 1 January to 30 June Carry over from previous sub-periods, for sub-period 1 July to 30 September Carry over from previous sub-periods, for sub-period 1 October to 31 December'
09.4149	'48 729 000 kg, divided as follows: 34 110 000 kg for sub-period 1 January to 30 June 14 619 000 kg for sub-period 1 July to 31 December'
09.4150	'14 993 000 kg, divided as follows: 50 % for each sub-period'
09.4153	'8 434 000 kg, divided as follows: 50 % for each sub-period'
09.4154	'11 245 000 kg, divided as follows: 50 % for each sub-period'
09.4166	'22 442 000 kg, divided as follows: 7 480 000 kg for sub-period 1 January to 30 June 14 962 000 kg for sub-period 1 July to 31 August Carry over for sub-period 1 September to 31 December'
09.4168	'26 581 000 kg, divided as follows: 26 581 000 kg for sub-period 1 September to 30 September Carry over from previous sub-period, for sub-period 1 October to 31 December'

(3) in Annex IV, for the order numbers listed in the left column, the quantities are replaced by the quantities set out in the right column:

Order number	New quantity
09.4317	'4 961 000 kg'
09.4318	'TRQ periods until 2023/2024: 308 518 000 kg TRQ periods from 2024/2025: 380 555 000 kg'
09.4320	'260 390 000 kg'
09.4321	'5 841 000 kg'
09.4329	'TRQ periods until 2021/2022: 72 037 000 kg TRQ period 2022/2023: 54 028 000 kg'
09.4330	'TRQ period 2022/2023: 18 009 000 kg TRQ period 2023/2024: 54 028 000 kg'

(4) in Annex VI, for the order numbers listed in the left column, the quantities are replaced by the quantities set out in the right column:

Order number	New quantity
09.4285	'40 556 000 kg, divided as follows: 10 423 000 kg for sub-period 1 June to 31 August 10 423 000 kg for sub-period 1 September to 30 November 9 044 000 kg for sub-period 1 December to 28/29 February 10 666 000 kg for sub-period 1 March to 31 May'
09.4287	'3 711 000 kg, divided as follows: 822 000 kg for sub-period 1 June to 31 August 1 726 000 kg for sub-period 1 September to 30 November 822 000 kg for sub-period 1 December to 28/29 February 341 000 kg for sub-period 1 March to 31 May'

(5) in Annex VIII, for the order numbers listed in the left column, the quantities are replaced by the quantities set out in the right column:

Order number	New quantity
09.4001	'1 405 000 kg expressed in weight of boneless meat'
09.4002	'11 481 000 kg product weight, divided as follows: the quantity available for each sub-period shall correspond to one twelfth of the total quantity'
09.4003	'43 732 000 kg, boneless equivalent'
09.4450	'29 389 000 kg boneless meat'
09.4451	'2 481 000 kg product weight'
09.4452	'5 606 000 kg boneless meat'
09.4453	'8 951 000 kg boneless meat'
09.4454	'846 000 kg product weight'
09.4455	'711 000 kg boneless meat'

(6) in Annex IX, for the order numbers listed in the left column, the quantities are replaced by the quantities set out in the right column:

Order number	New quantity
09.4182	'21 230 000 kg, divided as follows: 50 % for each sub-period'
09.4195	'25 947 000 kg, divided as follows: 50 % for each sub-period'
09.4514	'4 361 000 kg'
09.4515	'1 670 000 kg'
09.4595	'14 941 000 kg, divided as follows: 50 % for each sub-period'

(7) in Annex X, for the order numbers listed in the left column, the quantities are replaced by the quantities set out in the right column:

Order number	New quantity
09.4038	'12 680 000 kg, divided as follows: 25 % for each sub-period'
09.4170	'1 770 000 kg net weight, divided as follows: 25 % for each sub-period'
09.4282	'TRQ period 2021: 68 048 000 kg, divided as follows: 25 % for each sub-period TRQ periods from 2022: 80 548 000 kg, divided as follows: 25 % for each sub-period'

ANNEX II

Annex XII to Implementing Regulation (EU) 2020/761 is amended as follows:

(1) for the order numbers listed in the left column, the quantities are replaced by the quantities set out in the right column:

Order number	New quantity
09.4067	'4 054 000 kg, divided as follows: 25 % for each sub-period'
09.4068	'8 253 000 kg, divided as follows: 25 % for each sub-period'
09.4069	'2 427 000 kg, divided as follows: 25 % for each sub-period'
09.4211	'129 930 000 kg, divided as follows: 30 % for sub-period 1 July to 30 September 30 % for sub-period 1 October to 31 December 20 % for sub-period 1 January to 31 March 20 % for sub-period 1 April to 30 June'
09.4212	'68 385 000 kg, divided as follows: 30 % for sub-period 1 July to 30 September 30 % for sub-period 1 October to 31 December 20 % for sub-period 1 January to 31 March 20 % for sub-period 1 April to 30 June'
09.4213	'824 000 kg'
09.4214	'52 665 000 kg, divided as follows: 30 % for sub-period 1 July to 30 September 30 % for sub-period 1 October to 31 December 20 % for sub-period 1 January to 31 March 20 % for sub-period 1 April to 30 June'
09.4215	'109 441 000 kg, divided as follows: 30 % for sub-period 1 July to 30 September 30 % for sub-period 1 October to 31 December 20 % for sub-period 1 January to 31 March 20 % for sub-period 1 April to 30 June'
09.4216	'8 471 000 kg, divided as follows: 30 % for sub-period 1 July to 30 September 30 % for sub-period 1 October to 31 December 20 % for sub-period 1 January to 31 March 20 % for sub-period 1 April to 30 June'
09.4217	'89 950 000 kg, divided as follows: 30 % for sub-period 1 July to 30 September 30 % for sub-period 1 October to 31 December 20 % for sub-period 1 January to 31 March 20 % for sub-period 1 April to 30 June'
09.4218	'11 301 000 kg, divided as follows: 30 % for sub-period 1 July to 30 September 30 % for sub-period 1 October to 31 December 20 % for sub-period 1 January to 31 March 20 % for sub-period 1 April to 30 June'
09.4251	'10 969 000 kg, divided as follows: 30 % for sub-period 1 July to 30 September 30 % for sub-period 1 October to 31 December 20 % for sub-period 1 January to 31 March 20 % for sub-period 1 April to 30 June'
09.4252	'59 699 000 kg, divided as follows: 30 % for sub-period 1 July to 30 September 30 % for sub-period 1 October to 31 December 20 % for sub-period 1 January to 31 March 20 % for sub-period 1 April to 30 June'

09.4253	'163 000 kg'
09.4254	'8 019 000 kg, divided as follows: 30 % for sub-period 1 July to 30 September 30 % for sub-period 1 October to 31 December 20 % for sub-period 1 January to 31 March 20 % for sub-period 1 April to 30 June'
09.4255	'1 162 000 kg, divided as follows: 30 % for sub-period 1 July to 30 September 30 % for sub-period 1 October to 31 December 20 % for sub-period 1 January to 31 March 20 % for sub-period 1 April to 30 June'
09.4256	'8 572 000 kg, divided as follows: 30 % for sub-period 1 July to 30 September 30 % for sub-period 1 October to 31 December 20 % for sub-period 1 January to 31 March 20 % for sub-period 1 April to 30 June'
09.4257	'0 kg'
09.4258	'300 000 kg'
09.4259	'278 000 kg'
09.4260	'1 669 000 kg, divided as follows: 30 % for sub-period 1 July to 30 September 30 % for sub-period 1 October to 31 December 20 % for sub-period 1 January to 31 March 20 % for sub-period 1 April to 30 June'
09.4263	'159 000 kg'
09.4264	'0 kg'
09.4265	'58 000 kg'
09.4410	'14 479 000 kg, divided as follows: 25 % for each sub-period'
09.4411	'4 432 000 kg, divided as follows: 25 % for each sub-period'
09.4412	'2 868 000 kg, divided as follows: 25 % for each sub-period'
09.4420	'4 227 000 kg, divided as follows: 25 % for each sub-period'
09.4422	'2 121 000 kg, divided as follows: 25 % for each sub-period'

(2) the table concerning order number 09.4273 is replaced by the following:

'**Order number**	**09.4273**
International agreement or other act	**Council Decision (EU) 2017/1247** of 11 July 2017 on the conclusion, on behalf of the European Union, of the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Ukraine, of the other part, with the exception of the provisions relating to the treatment of third-country nationals legally employed as workers in the territory of the other party **Council Decision (EU) 2019/2145** of 5 December 2019 on the conclusion, on behalf of the Union, of the Agreement in the form of an Exchange of Letters between the European Union and Ukraine amending the trade preferences for poultry meat and poultry meat preparations provided for by the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Ukraine, of the other part

Tariff quota period	1 January to 31 December
Tariff quota sub-periods	1 January to 31 March 1 April to 30 June 1 July to 30 September 1 October to 31 December
Licence application	In accordance with Articles 6, 7 and 8 of this Regulation
Product description	Meat and edible offal of poultry, fresh, chilled or frozen; other prepared or preserved meat of turkeys and of fowls of the species *Gallus domesticus*
Origin	Ukraine
Proof of origin at licence application. If yes, body authorised to issue it	No
Proof of origin for release into free circulation	Yes. In accordance with Title V of Protocol 1 to the Association Agreement between the European Union and its Member States, of the one part, and Ukraine, of the other part
Quantity in kilograms	TRQ period as from 2021: 70 000 000 kg net weight, divided as follows: 25 % for each sub-period
CN codes	0207 11 30 0207 11 90 0207 12 0207 13 10 0207 13 20 0207 13 30 0207 13 50 0207 13 60 0207 13 70 0207 13 99 0207 14 10 0207 14 20 0207 14 30 0207 14 50 0207 14 60 0207 14 70 0207 14 99 0207 24 0207 25 0207 26 10 0207 26 20 0207 26 30 0207 26 50 0207 26 60 0207 26 70 0207 26 80 0207 26 99 0207 27 10 0207 27 20 0207 27 30 0207 27 50 0207 27 60 0207 27 70 0207 27 80 0207 27 99 0207 41 30 0207 41 80 0207 42

	0207 44 10 0207 44 21 0207 44 31 0207 44 41 0207 44 51 0207 44 61 0207 44 71 0207 44 81 0207 44 99 0207 45 10 0207 45 21 0207 45 31 0207 45 41 0207 45 51 0207 45 61 0207 45 81 0207 45 99 0207 51 10 0207 51 90 0207 52 90 0207 54 10 0207 54 21 0207 54 31 0207 54 41 0207 54 51 0207 54 61 0207 54 71 0207 54 81 0207 54 99 0207 55 10 0207 55 21 0207 55 31 0207 55 41 0207 55 51 0207 55 61 0207 55 81 0207 55 99 0207 60 05 0207 60 10 ex 0207 60 21 (fresh or chilled, halves or quarters of guinea fowls) 0207 60 31 0207 60 41 0207 60 51 0207 60 61 0207 60 81 0207 60 99 0210 99 39 1602 31 1602 32 1602 39 21
In-quota customs duty	EUR 0
Proof of trade	Yes. Proof of trade required only when Article 9(9) of Delegated Regulation (EU) 2020/760 applies. 25 tonnes
Security for import licence	EUR 75 per 100 kg
Specific entries to be made on the licence application and on the licence	Section 8 of the import licence application and of the import licence shall indicate the country of origin; box 'yes' in that section shall be crossed

Period of validity of a licence	In accordance with Article 13 of this Regulation
Transferability of licence	Yes
Reference quantity	Yes
Operator registered in LORI database	Yes
Specific conditions	No’

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1740

of 20 November 2020

setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012

(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 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ([1]), and in particular Article 39f thereof,

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 ([2]), and in particular Article 19 thereof,

Whereas:

(1) Article 14(1) of Regulation (EC) No 1107/2009 provides that on application the approval of an active substance may be renewed if it is established that the approval criteria in Article 4 of that Regulation are fulfilled.

(2) Commission Implementing Regulation (EU) No 844/2012 ([3]) sets out the provisions necessary for the implementation of the procedure for the renewal of approval of active substances. In particular, it sets out rules for the different steps of the renewal procedure from the preparation to the submission of the application for the renewal of the approval of an active substance ('the application for renewal'), its content and format, on confidentiality and public disclosure of the application for renewal, and on the adoption of a regulation on the renewal or non-renewal of the approval of active substances.

(3) Implementing Regulation (EU) No 844/2012 has been substantially amended three times ([4]). Further amendments are to be made to it following the adoption of Regulation (EU) 2019/1381 of the European Parliament and the Council ([5]).

(4) Therefore, Implementing Regulation (EU) No 844/2012 should be repealed and replaced by this Regulation for the sake of clarity.

(5) It is appropriate to set out new provisions necessary for the implementation of the renewal procedure, in particular the periods for the different steps of the renewal procedure.

([1]) OJ L 31, 1.2.2002, p. 1.

([2]) OJ L 309, 24.11.2009, p. 1.

([3]) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

([4]) Commission Implementing Regulation (EU) 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605 (OJ L 278, 8.11.2018, p. 3); Commission Implementing Regulation (EU) 2019/724 of 10 May 2019 amending Implementing Regulation (EU) No 686/2012 as regards the nomination of rapporteur Member States and co-rapporteur Member States for the active substances glyphosate, lambda-cyhalothrin, imazamox and pendimethalin and amending Implementing Regulation (EU) No 844/2012 as regards the possibility that a group of Member States assumes jointly the role of the rapporteur Member (OJ L 124, 13.5.2019, p. 32) and Commission Implementing Regulation (EU) 2020/103 of 17 January 2020 amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances (OJ L 19, 24.1.2020, p. 1).

([5]) Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and the sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (OJ L 231, 6.9.2019, p. 1).

(6) Regulation (EU) 2019/1381 amended, among others, Regulations (EC) No 178/2002 and (EC) No 1107/2009. Those amendments strengthen the transparency and the sustainability of the Union risk assessment in all areas of the food chain where the European Food Safety Authority ('the Authority') conducts a scientific risk assessment.

(7) Regulation (EU) 2019/1381 introduced provisions that are pertinent for the renewal procedure for active substances provided for in Regulation (EC) No 1107/2009. Those include, amongst others, the provision of pre-submission advice on intended tests and studies for the purposes of a renewal, preceded by a specific notification by the potential applicant and consultation of third parties, the provision of general pre-submission advice on the rules applicable to the application for renewal, and its content, a notification obligation imposed on business operators, laboratories and testing facilities when studies are commissioned or carried out by them to support an application, the public disclosure of all scientific data, studies and other information supporting an admissible application by the Authority, and a consultation of third parties on the submitted scientific data, studies and other information supporting an admissible application. To ensure proper implementation of those provisions in the context of the procedure for the renewal of approval of active substances, detailed rules should be set out.

(8) An application for renewal should include the necessary data and risk assessments and demonstrate why any new data and risk assessments are necessary.

(9) In order to implement the requirement set out in point (c) of Article 38(1) of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381, its Article 39f(2) provides for the adoption of standard data formats to allow documents to be submitted, searched, copied and printed, while ensuring compliance with regulatory requirements set out in Union law. Consequently, it is necessary to adopt a standard data format.

(10) Rules should be set out as regards the establishment of the admissibility of the application for renewal by the rapporteur Member State.

(11) Where all applications for renewal submitted are inadmissible, the Commission should adopt a Regulation on the non-renewal of the active substance concerned to provide clarity on the status of the active substance.

(12) Regulation (EU) 2019/1381 also introduced additional requirements relating to transparency and confidentiality as well as specific procedural requirements for the submission of confidentiality requests in relation to information submitted by an applicant. To ensure a proper implementation of those requirements, the conditions for the assessment of confidentiality requests in the context of applications for renewal should be set out. That assessment should be performed by the Authority in accordance with Regulation (EU) 2019/1381 once the relevant application for renewal has been considered admissible by the rapporteur Member State.

(13) The applicant, the Member States, with the exception of the rapporteur Member State, and the public should be given the opportunity to submit comments on the draft renewal assessment report prepared by the rapporteur Member States and co-rapporteur Member State, or by Member States acting jointly as rapporteur.

(14) In accordance with Article 36(2) of Regulation (EC) No 1272/2008 of the European Parliament and of the Council [6], active substances within the meaning of Regulation (EC) No 1107/2009 are normally to be subject to harmonised classification and labelling. It is therefore appropriate to set detailed rules of procedure regarding the submission of proposals to the European Chemicals Agency in accordance with Article 37(1) of Regulation (EC) No 1272/2008 by the rapporteur Member State during the renewal of approval of active substances pursuant to Article 14 of Regulation (EC) No 1107/2009.

(15) The Authority should organise consultations of experts and provide conclusions, except where the Commission informs it that a conclusion is not necessary.

(16) Rules should be set out as regards the renewal report and the adoption of a regulation on the renewal or non-renewal of the approval of the active substance.

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[6] 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).

(17) Given that this Regulation implements certain provisions of Regulation (EU) 2019/1381, which applies from 27 March 2021 , this Regulation should apply from the same date. Since applications for renewal pursuant to this Regulation are to be submitted at least three years before the expiry of the approval period of an active substance, this Regulation should apply with respect to the renewal of the approval of active substances for which the approval period ends on or after 27 March 2024, even if an application for renewal has already been submitted in accordance with Implementing Regulation (EU) No 844/2012.

(18) Transitional measures should be provided for active substances for which the approval period ends before 27 March 2024 to ensure that the renewal procedure for those substances can continue. Implementing Regulation (EU) No 844/2012 should continue to apply to active substances whose approval period on the date of application of this Regulation expires before 27 March 2024 or for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

(19) 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:

CHAPTER 1

SUBJECT MATTER AND SCOPE

Article 1

Subject matter

This Regulation establishes rules on the procedure for the renewal of the approval of active substances within the meaning of Regulation (EC) No 1107/2009.

Article 2

Scope

This Regulation shall apply to the renewal of the approval of active substances whose approval period ends on or after 27 March 2024.

However, it shall not apply to the renewal of the approval of the active substances for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

CHAPTER 2

NOTIFICATION AND ADVICE PRIOR TO THE SUBMISSION OF THE APPLICATION FOR RENEWAL

Article 3

Notification of intended studies and advice on intended studies

1. Notifications of studies intended to be conducted to support a future application for renewal in accordance with Article 32c(1) of Regulation (EC) No 178/2002 shall be submitted sufficiently ahead of the date for submission of the application for renewal in accordance with Article 5(1) of this Regulation in order to allow public consultation to be performed and comprehensive advice to be provided by the Authority and the studies required in support of a future application for renewal to be carried out in a timely and proper manner.

2. The pre-submission advice by the Authority pursuant to Article 32c(1) of Regulation (EC) No 178/2002 shall be provided with the participation of the rapporteur Member State and the co-rapporteur Member State, taking into account any existing experience and knowledge relevant for the active substance, including, where appropriate, available studies from the earlier approval or renewal of approval.

Article 4

General pre-submission advice

1. A potential applicant may request from the staff of the Authority general pre-submission advice at any time before the submission of the application for renewal. The Authority shall inform the rapporteur Member State of the request and together they shall decide if the co-rapporteur Member State is required to participate in providing the general pre-submission advice.

2. Where several potential applicants request general pre-submission advice, the Authority shall suggest that they submit a joint application for renewal and disclose their contact details to each other for that purpose.

CHAPTER 3

SUBMISSION AND ADMISSIBILITY OF THE APPLICATION FOR RENEWAL

Article 5

Submission of the application for renewal

1. An application for renewal shall be submitted electronically via a central submission system using the format as set out in Article 7 by a producer of the active substance no later than three years before the expiry of the approval.

The rapporteur Member State as set out in the second column of the Annex to Commission Implementing Regulation (EU) No 686/2012 ([7]) or each of the Member States in a group of Member States acting jointly as rapporteur Member State as set out in the fourth column of that Annex, the co-rapporteur Member State as set out in the third column of that Annex, the other Member States, the Authority and the Commission shall be informed via the central submission system referred to in Article 7.

Where a group of Member States jointly assumes the role of the rapporteur Member State, as set out in the fourth column of the tables in Part B and Part C of the Annex to Implementing Regulation (EU) No 686/2012, no co-rapporteur Member State shall be appointed. In this case, all references to 'the rapporteur Member State' in this Regulation shall be deemed to be references to 'the group of Member States acting jointly as rapporteur Member State'.

Prior to the expiry of the deadline for submission of the application for renewal, the Member States acting jointly as rapporteur Member State shall agree on the repartition of all tasks and workload.

Member States forming part of the group of Member States acting jointly as rapporteur Member State shall endeavour to reach consensus during the evaluation.

2. A joint application for renewal may be submitted by an association of producers designated by the producers.

Where there is more than one applicant requesting the renewal of the approval of the same active substance, those applicants shall take all reasonable steps to submit their dossiers jointly. Where contrary to the advice of the Authority as referred to in Article 4 such dossiers are not submitted jointly by all the applicants concerned, the reasons for that shall be set out in the dossiers.

Article 6

Content of the application for renewal

1. An application for renewal shall consist of a renewal dossier in the format as set out in Article 7.

2. The renewal dossier shall include the following:

(a) the name and address of the applicant responsible for the application for renewal and for the obligations under this Regulation;

([7]) Commission Implementing Regulation (EU) No 686/2012 of 26 July 2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances (OJ L 200, 27.7.2012, p. 5).

(b) where the applicant is joined by one or more other applicants, the name and address of that or those other applicants and, if applicable, the name of the association of producers mentioned in Article 5(2);

(c) information with respect to one or more representative uses on a widely grown crop in each zone of at least one plant protection product containing the active substance, demonstrating that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are fulfilled;

(d) data and risk assessments which are necessary:

(i) to reflect changes in legal requirements since the approval or last renewal of the approval of the active substance concerned;

(ii) to reflect changes in scientific and technical knowledge since the approval or last renewal of the approval of the active substance concerned;

(iii) to reflect changes to representative uses; or

(iv) because the application is for an amended renewal;

(e) for each of the data requirements for the active substance, as set out in Commission Regulation (EU) No 283/2013 ([8]), the full text of each test or study report and summaries thereof, including those that were part of the approval dossier or subsequent renewal dossiers;

(f) for each of the data requirements for the plant protection product, as set out in Commission Regulation (EU) No 284/2013 ([9]), the full text of each test or study report and summaries thereof, including where relevant, those that were part of the approval dossier or subsequent renewal dossiers;

(g) where relevant, documented evidence as referred to in Article 4(7) of Regulation (EC) No 1107/2009;

(h) for each test or study involving vertebrate animals, a description of the steps taken to avoid animal testing on vertebrate animals;

(i) where relevant, a copy of an application for maximum residue levels as referred to in Article 7 of Regulation (EC) No 396/2005 of the European Parliament and of the Council ([10]);

(j) a proposal for classification where it is considered that the substance has to be classified or reclassified in accordance with Regulation (EC) No 1272/2008;

(k) a checklist demonstrating that the renewal dossier is complete in view of the uses applied for and indicating which data are new;

(l) the summaries and results of scientific peer-reviewed open literature, as referred in Article 8(5) of Regulation (EC) No 1107/2009;

(m) an assessment according to the current scientific and technical knowledge of all information submitted, including, where relevant, a reassessment of studies and information that were part of the approval dossier or subsequent renewal dossiers;

(n) a consideration and proposal for any necessary and appropriate risk mitigation measures;

(o) all relevant information related to the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002.

The information referred to in point (o) of the first subparagraph shall be clearly identifiable.

The renewal dossier shall not contain any reports of tests or studies involving the deliberate administration of the active substance or the plant protection product containing it to humans.

3. Applicants shall make their best efforts to obtain access to and provide the studies which were part of the approval dossier or subsequent renewal dossiers as required under points (e) and (f) of paragraph 2.

([8]) Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, 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 (OJ L 93, 3.4.2013, p. 1).

([9]) Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, 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 (OJ L 93, 3.4.2013, p. 85).

([10]) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

The Member State that acted as rapporteur for the previous approval and/or subsequent renewal dossiers or the Authority shall endeavour to make available such studies where the applicant provides evidence that its attempts to obtain access from the study owner have failed.

4. If the information submitted in accordance with point (c) of paragraph 2 does not cover all zones or does not concern a widely grown crop, a justification shall be submitted.

5. The uses referred to in point (c) of paragraph 2 shall, where appropriate, include the uses evaluated for the approval or subsequent renewals. At least one plant protection product referred to in point (c) of paragraph 2 shall contain no other active substance, where such a product exists for a representative use.

6. The applicant shall identify and list the new data it submits, including any new studies involving vertebrate animals in a separate list. It shall demonstrate that the new data is necessary in accordance with the first subparagraph of Article 15(2) of Regulation (EC) No 1107/2009 and, where applicable, refer to advice received during the pre-submission phase in accordance with Articles 32a and 32c of Regulation (EC) No 178/2002.

7. When requesting certain information to be kept confidential in accordance with Article 63(1), (2) and (2a) of Regulation (EC) No 1107/2009, the applicant shall identify the confidential and a non-confidential versions of the information submitted.

8. The applicant may submit any data protection claims pursuant to Article 59 of Regulation (EC) No 1107/2009.

Article 7

Format and software for the submission of the application for renewal

1. The Authority shall establish and make available online a central submission system. The Authority shall ensure that the central submission system facilitates the verification of admissibility performed by Member States in accordance with Article 8.

2. The standard data formats proposed by the Authority as part of the IUCLID software package pursuant to Article 39f of Regulation (EC) No 178/2002 are hereby adopted.

3. The application for renewal shall be submitted via the central submission system using the IUCLID software package.

4. The applicant, when requesting certain information to be kept confidential in accordance with Article 63(1), (2) and (2a) of Regulation (EC) No 1107/2009, shall indicate such information using the relevant IUCLID functionality.

The Authority shall assess such a request only if the application is considered admissible in accordance with Article 8 of this Regulation.

Article 8

Admissibility of the application for renewal

1. The rapporteur Member State shall consider an application for renewal admissible, provided that all the following requirements are met:

(a) the application for renewal has been submitted within the period provided for in Article 5(1) and in accordance with the format and using the software provided for in Article 7;

(b) the application for renewal contains all the elements provided for in Article 6;

(c) the application for renewal contains all studies, in full, that have been previously notified in accordance with Article 32b of Regulation (EC) No 178/2002 and no additional ones apart from those contained in the approval dossier or subsequent renewal dossiers or conducted before the obligation under Article 32b of Regulation (EC) No 178/2002 applied, unless a valid justification is provided;

(d) the relevant fee has been paid.

2. The rapporteur Member State shall, within a period of one month from the date provided for in Article 5(1), inform the applicant, the co-rapporteur Member State, the Commission and the Authority of the date of receipt of the application for renewal and of its admissibility.

3. Where an application for renewal has been submitted in accordance with point (a) of paragraph 1, but one or more elements provided for in point (b) or (d) of paragraph 1 are missing, the rapporteur Member State shall, within a period of one month from the date of receipt of the application for renewal, inform the applicant which elements are missing and set a period of 14 days for the submission of those elements via the central submission system referred to in Article 7. Upon expiry of that period, the rapporteur Member State shall, without delay, proceed in accordance with either paragraph 4 or paragraph 5.

4. Where the application for renewal does not comply with point (c) of paragraph 1, the rapporteur Member State shall, in coordination with the Authority, within a period of one month from date of receipt of the application for renewal, inform the applicant accordingly and set a period of 14 days for providing a valid justification for this non-compliance. Upon expiry of that period and where a valid justification has not been provided, the application for renewal shall be considered inadmissible and Article 32b(4) or Article 32b(5) of Regulation (EC) No 178/2002 shall apply. The assessment of the admissibility of a resubmitted application for renewal shall only commence after the expiry of the six-month period mentioned in Article 32b(4) or Article 32b(5) of Regulation (EC) No 178/2002 following the notification of the relevant studies and/or submission of studies as necessary and provided that that point in time is no later than three years before the expiry of the approval of the active substance. If that point in time is later than three years before the expiry of the approval of the active substance, the resubmitted application for renewal shall be considered inadmissible.

5. Where the application for renewal has not been submitted within the period referred to in point (a) of paragraph 1, or where at the end of the 14-day period set for the submission of the missing elements in accordance with paragraphs 3 and 4 the application for renewal still does not contain all the elements provided for in Article 6, the rapporteur Member State shall, without delay, inform the applicant, the co-rapporteur Member State, the Commission, the other Member States and the Authority that the application for renewal is inadmissible and of the reasons for inadmissibility.

Article 9

Adoption of a non-renewal Regulation

Where all applications for renewal submitted for an active substance are inadmissible in accordance with Article 8, a Regulation on the non-renewal of the approval of that active substance shall be adopted in accordance with point (b) of Article 20(1) of Regulation (EC) No 1107/2009.

Article 10

Public access to the information in the application for renewal and consultation of third parties

The Authority shall allow a period of 60 days from the date the application for renewal is made public in accordance with point (c) of Article 38(1) of Regulation (EC) No 178/2002 for the submission of written comments on that information and on whether other relevant scientific data or studies are available on the subject matter concerned by the application for renewal. This paragraph does not apply to the submission of any supplementary information submitted by the applicant during the evaluation process.

CHAPTER 4

ASSESSMENT AND RENEWAL REPORT AND REGULATION

Article 11

Assessment by the rapporteur Member State and the co-rapporteur Member State

1. Where the application is admissible in accordance with Article 8, the rapporteur Member State shall, after consulting the co-rapporteur Member State, at the latest 13 months after the date of submission of the application for renewal in accordance with Article 5(1), submit to the Commission and to the Authority, a report assessing whether the active substance can still be expected to meet the approval criteria, as provided for in Article 4 of Regulation (EC) No 1107/2009 ('the draft renewal assessment report').

2. The draft renewal assessment report shall include the following:

(a) a recommendation with regard to the renewal of the approval, including any necessary conditions and restrictions;

(b) a recommendation on whether the substance is to be considered a 'low-risk' substance;

(c) a recommendation on whether the substance is to be considered a candidate for substitution;

(d) a proposal to set maximum residue levels or a justification in case such proposal is not relevant;

(e) a suggestion for the classification, or its confirmation, where applicable or reclassification of the active substance in accordance with the criteria of Regulation (EC) No 1272/2008, as specified in and consistent with the dossier to be submitted pursuant to paragraph 9 of this Article;

(f) a conclusion on which of the studies included in the renewal dossier are relevant for the assessment;

(g) a recommendation as to the parts of the report on which a consultation of experts is to be organised in accordance with Article 13(1);

(h) where relevant, the points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur Member State or, where applicable, the points where there is no agreement between Member States forming a group of Member States acting jointly as rapporteur Member State; and

(i) the results of the public consultation performed pursuant to Article 10 and how they have been taken into account.

3. The rapporteur Member State shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents applicable at the date of the submission of the application for renewal. It shall take into account all the information submitted as part of the application for renewal, including the dossiers submitted for the approval and subsequent renewals of approval. The rapporteur Member State shall also identify and consider, where appropriate, risk mitigation measures and take into account the written comments received during the public consultation pursuant to Article 10). Where despite the best efforts made the applicant could not submit the full text and summary of each test and study report which were part of the approval dossier or subsequent renewal dossiers and required in accordance with points (e) and (f) of Article 6(2), the rapporteur Member State shall ensure that the respective studies are evaluated and taken into account in their overall assessment.

4. In its assessment, the rapporteur Member State shall first establish whether the approval criteria set out in points 3.6.2, 3.6.3, 3.6.4 and 3.7 of Annex II to Regulation (EC) No 1107/2009 are satisfied.

Where those criteria are not satisfied, the draft renewal assessment report shall be limited to the parts of the assessment corresponding to them, unless Article 4(7) of Regulation (EC) No 1107/2009 applies.

5. Where the rapporteur Member State requires additional information, it shall set a period for the applicant to supply that information. That period shall not lead to an extension of the period of 13 months provided for in paragraph 1. Any confidentiality request pursuant to Article 63 of Regulation (EC) No 1107/2009 shall be addressed to the Authority in accordance with Article 6(7) of this Regulation.

6. The rapporteur Member State may consult the Authority and request additional technical or scientific information from other Member States. Such consultations and requests shall not lead to an extension of the period of 13 months provided for in paragraph 1.

7. Information submitted by the applicant without having been requested, or provided after the expiry of the period set for its submission in accordance with paragraph 5 of this Article, shall not be taken into account, unless it is submitted in accordance with Article 56 of Regulation (EC) No 1107/2009.

8. When submitting the draft renewal assessment report to the Commission and the Authority, the rapporteur Member State shall request the applicant to submit the renewal dossier, updated to include the additional information requested by the rapporteur Member State in accordance with paragraph 5 of this Article or submitted in accordance with Article 56 of Regulation (EC) No 1107/2009, without delay, via the central submission system referred to in Article 7 of this Regulation.

Any confidentiality requests pursuant to Article 63 of Regulation (EC) No 1107/2009 shall be addressed to the Authority in accordance with Article 6(7) of this Regulation.

9. The rapporteur Member State shall at the latest at the time of submission of the draft renewal assessment report submit a proposal to the European Chemicals Agency pursuant to Article 37(1) of Regulation (EC) No 1272/2008 and in accordance with the Agency's requirements to obtain an opinion on a harmonised classification of the active substance at least for the following hazard classes:

(a) explosives;

(b) acute toxicity;

(c) skin corrosion/irritation;

(d) serious eye damage/eye irritation;

(e) respiratory or skin sensitisation;

(f) germ cell mutagenicity;

(g) carcinogenicity;

(h) reproductive toxicity;

(i) specific target organ toxicity – single exposure;

(j) specific target organ toxicity – repeated exposure;

(k) hazardous to the aquatic environment.

The rapporteur Member State shall duly justify its view that the criteria for classification for one or more of these hazard classes are not fulfilled.

Where a proposal for classification of an active substance has already been submitted to the Agency and its assessment is ongoing, the rapporteur Member State shall submit an additional proposal for classification, limited to any hazard classes listed in the first subparagraph that are not covered by the pending proposal unless new information has become available that was not part of the pending dossier as regards those listed hazard classes.

For the hazard classes, which are already covered by an existing opinion of the Committee for Risk Assessment of the Agency set up pursuant to point (c) of Article 76(1) of Regulation (EC) No 1907/2006, whether or not this opinion has formed the basis of a decision concerning an entry for harmonised classification and labelling of a substance in Annex VI to Regulation (EC) No 1272/2008, it is sufficient that the rapporteur Member State duly justifies in its submission to the Agency that the existing opinion, or where it has already formed the basis of a decision concerning the inclusion in Annex VI, the existing classification remains valid as regards the hazard classes listed in the first subparagraph of this paragraph. The Agency may provide its views regarding the rapporteur Member State's submission.

10. The Committee for Risk Assessment shall endeavour to adopt the opinion referred to in Article 37(4) of Regulation (EC) No 1272/2008 within 13 months from the submission referred to in the first subparagraph of paragraph 9 of this Article.

Article 12

Comments on the draft renewal assessment report

1. The Authority shall examine whether the draft renewal assessment report received from the rapporteur Member State contains all the relevant information in the agreed format and circulate it to the applicant and to the other Member States at the latest three months after its receipt.

2. Upon receipt of the draft renewal assessment report pursuant to paragraph 1 of this Article, the applicant may, within a period of two weeks, submit a request to the Authority for certain information in the draft renewal assessment report originating from its application to be kept confidential pursuant to Article 63 of Regulation (EC) No 1107/2009 and in accordance with Article 6(7) of this Regulation.

The Authority shall make the draft renewal assessment report publicly available with the exception of the information for which the confidentiality request has been accepted as justified.

3. The Authority shall allow a period of 60 days from the date the draft report is made available to the public for the submission of written comments. Such comments shall be communicated to the Authority, which shall collate and forward those comments, together with its own comments, to the rapporteur Member States or group of Member States acting jointly as rapporteur Member State and where relevant the co-rapporteur Member State. The Authority shall provide its view to the Commission on whether it is not necessary in the light of the comments received to continue the procedure in accordance with Article 13.

4. The Authority shall make the updated renewal dossier available to the public at the same time as making the draft renewal assessment report available in accordance with Article 10.

Article 13

Conclusion by the Authority

1. The Authority shall establish a conclusion in the light of current scientific and technical knowledge using guidance documents applicable at the date of the submission of the application for renewal and in the light of the opinion of the Committee for Risk Assessment on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority shall, where appropriate, organise a consultation of experts, including experts from the rapporteur Member State and co-rapporteur Member State.

The Authority shall draft the conclusion provided for in the first subparagraph within five months from the expiry of the period referred to in Article 12(3) of this Regulation, or within two weeks from the adoption of the opinion of the Committee for Risk Assessment referred to in Article 37(4) of Regulation (EC) No 1272/2008, if any adopted, whichever occurs later.

Where appropriate, the Authority shall address in its draft conclusion the risk mitigation options identified in the draft renewal assessment report or during the peer review.

The Commission may inform the Authority without delay after the period referred to in Article 12(3) has expired that a conclusion is not necessary.

2. Where the Authority considers that additional information from the applicant is necessary, it shall, in consultation with the rapporteur Member State, set a period not exceeding one month for the applicant to supply such information to the Member States, the Commission and the Authority. The rapporteur Member State shall, within 60 days from the date of receipt of the additional information evaluate the information received and send its evaluation to the Authority.

Where the first subparagraph applies, the period referred to in paragraph 1 shall be extended by the two periods referred to in that subparagraph.

3. The Authority may ask the Commission to consult a European Union reference laboratory designated, pursuant to Regulation (EU) 2017/625 of the European Parliament and of the Council ([11]) for the purposes of verifying whether the analytical method for the determination of the residues proposed by the applicant is satisfactory and complies with the requirements provided for in point (g) of Article 29(1) of Regulation (EC) No 1107/2009. The applicant shall, if requested by the European Union reference laboratory, provide samples and analytical standards.

4. The Authority shall communicate the draft conclusion to the applicant, the Member States and the Commission and give the applicant a possibility to submit comments within a period of two weeks.

Where in its draft conclusion the Authority identifies critical issues and/or critical data gaps such that it is expected that there is no representative use of at least one plant protection product containing the active substance for which the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 would be fulfilled, and which the applicant

([11]) 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) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (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 (OJ L 95, 7.4.2017, p. 1).

could not have known about at the time of submission of the application and did not have the possibility to address following a request for additional information in accordance with Article 13(2), the applicant may also submit additional information on those issues to the Member States, the Commission and the Authority within the two-week period.

Comments and new information shall be considered by the Authority in cooperation with the rapporteur Member State and the co-rapporteur Member State. The Authority shall finalise the conclusion within 75 days from the expiry of the two-week period referred to in the first subparagraph.

In cases where the Authority drafted the conclusion before the expiry of the five months period referred to in the first paragraph of this Article the remaining time may be added to the 75 days mentioned in the previous subparagraph.

5. The Authority shall communicate its final conclusion to the applicant, the Member States and the Commission.

6. After giving the applicant two weeks to request certain information in the conclusion originating from its application to be kept confidential, pursuant to Article 63 of Regulation (EC) No 1107/2009, and in accordance with Article 6(7) of this Regulation, the Authority shall make its conclusion available to the public, excluding any information in respect of which confidentiality has been granted by the Authority.

7. Information submitted by the applicant without having been requested, or provided after the expiry of the period set for its submission in accordance with the first subparagraph of paragraph 2 and the second subparagraph of paragraph 4 of this Article shall not be taken into account, unless it is submitted in accordance with Article 56 of Regulation (EC) No 1107/2009.

Article 14

Renewal report and renewal Regulation

1. The Commission shall present to the Committee referred to in Article 79(1) of Regulation (EC) No 1107/2009 a draft renewal report and a draft Regulation within six months from the date of receipt of the conclusion of the Authority or in cases where there is no such conclusion of the Authority, from the expiry of the period referred to in Article 12(3) of this Regulation.

The draft renewal report and the draft Regulation shall take into account the draft renewal assessment report, the comments referred to in Article 12(3) of this Regulation and the conclusion of the Authority, where such a conclusion has been submitted, and the opinion of the Committee for Risk Assessment, if any, referred to in Article 37(4) of Regulation (EC) No 1272/2008.

The applicant shall be given the possibility to submit comments on the draft renewal report within a period of 14 days.

2. On the basis of the renewal report and taking into account comments submitted by the applicant within the period referred to in the third subparagraph of paragraph 1 of this Article as well as other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) of Regulation (EC) No 178/2002 are relevant, the Commission shall adopt a Regulation in accordance with Article 20(1) of Regulation (EC) No 1107/2009.

CHAPTER 5

REPLACEMENT OF THE APPLICANT, FEES AND CHARGES

Article 15

Replacement of the applicant

An applicant may be replaced by another producer in respect of all of its rights and obligations under this Regulation by informing the rapporteur Member State, by a joint declaration made by both of them. In that case, both shall, at the same time, inform of the replacement the co-rapporteur Member State, the Commission, the other Member States, the Authority and any other applicants that have submitted an application for renewal for the same active substance.

Article 16

Fees and charges

1. Member States may require payment of fees and charges in accordance with Article 74 of Regulation (EC) No 1107/2009 to recover the costs associated with any work they carry out within the scope of this Regulation.

2. In case of simultaneous applications for renewal for more than one active substance, for which at least part of the risk assessment can be considered applicable to all of the active substance applications for renewal, fees shall be proportionate and applied taking into consideration that a common risk assessment might be performed.

The first subparagraph shall in particular apply to such simultaneous applications for renewal concerning strains of microorganisms with genetic, biological and/or ecological similarity, or to pheromones with similar chemical structures acting on the same taxonomic group of target organisms.

CHAPTER 6

FINAL PROVISIONS

Article 17

Repeal

Implementing Regulation (EU) No 844/2012 is repealed.

However, it shall continue to apply to the procedure for the renewal of the approval of the active substances:

(1) whose approval period ends before 27 March 2024;

(2) for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

Article 18

Entry into force and application

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 27 March 2021.

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

Done at Brussels, 20 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2020/1741

of 20 November 2020

amending the Annex to Implementing Decision 2014/709/EU concerning animal health control measures relating to African swine fever in certain Member States

(notified under document C(2020) 8266)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market ([1]), and in particular Article 9(4) thereof,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary checks applicable in intra-Union trade in certain live animals and products with a view to the completion of the internal market ([2]), and in particular Article 10(4) thereof,

Having regard to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption ([3]), and in particular Article 4(3) thereof,

Whereas:

(1) Commission Implementing Decision 2014/709/EU ([4]) lays down animal health control measures in relation to African swine fever in certain Member States, where there have been confirmed cases of that disease in domestic or feral pigs (the Member States concerned). The Annex to that Implementing Decision demarcates and lists certain areas of the Member States concerned in Parts I to IV thereof, differentiated by the level of risk based on the epidemiological situation as regards that disease. The Annex to Implementing Decision 2014/709/EU has been amended several times to take account of changes in the epidemiological situation in the Union as regards African swine fever that need to be reflected in that Annex. The Annex to Implementing Decision 2014/709/EU was last amended by Commission Implementing Decision (EU) 2020/1644 ([5]), following changes in the epidemiological situation as regards that disease in Slovakia.

(2) Council Directive 2002/60/EC ([6]) lays down the minimum Union measures to be taken for the control of African swine fever. In particular, Article 9 of Directive 2002/60/EC provides for the establishment of a protection zone and a surveillance zone when African swine fever has been officially confirmed in pigs on a holding, and Articles 10 and 11 of that Directive lay down the measures to be taken in the protection and surveillance zones in order to prevent the spread of that disease. In addition, Article 15 of Directive 2002/60/EC lays down the measures to be taken where African swine fever has been confirmed in feral pigs. Recent experience has shown that the measures laid down in Directive 2002/60/EC are effective in controlling the spread of that disease, and in particular, the measures providing for the cleaning and disinfecting of infected holdings and the other measures related to the eradication of that disease in domestic and feral pig populations.

(3) In addition, the epidemiological situation in Belgium and in certain areas of Poland has improved as regards domestic and feral pigs, due to the measures being applied by these Member States in accordance with Directive 2002/60/EC.

([1]) OJ L 395, 30.12.1989, p. 13.
([2]) OJ L 224, 18.8.1990, p. 29.
([3]) OJ L 18, 23.1.2003, p. 11.
([4]) 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).
([5]) Commission Implementing Decision (EU) 2020/1644 of 5 November 2020 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 370, 6.11.2020, p. 21).
([6]) 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 (OJ L 192, 20.7.2002, p. 27).

(4) Taking into account the effectiveness of the overall measures being applied in Belgium in accordance with Directive 2002/60/EC, and in particular those laid down in Article 15 thereof, and in line with the risk mitigation measures for African swine fever set out in the Terrestrial Animal Health Code of the World Organization for Animal Health (the OIE Code), all areas in Belgium currently listed in Parts I and II of the Annex to Implementing Decision 2014/709/EU, should now be deleted from the lists in Parts I and II of that Annex, in view of favourable epidemiological situation of the disease in that Member State.

(5) In addition, taking into account the effectiveness of the measures being applied in Poland in accordance with Directive 2002/60/EC, and in particular those laid down in Article 10(4)(b) and Article 10(5) thereof, and in line with the risk mitigation measures for African swine fever set out in the OIE Code, certain areas of the Voivodeships of Podlaskie, Wielkopolskie, Lubelskie and Warmińsko-Mazurskie in Poland, currently listed in Part III of the Annex to Implementing Decision 2014/709/EU should now be listed instead in Part II of that Annex, in view of the expiry of the period of three months from the date of the final cleaning and disinfection of the infected holdings and due to the absence of African swine fever outbreaks in domestic pigs in those areas for the past three months in accordance with the provisions of the OIE Code.

(6) Also, taking into account the effectiveness of the measures being applied in Poland in accordance with Directive 2002/60/EC, and in particular those laid down in Article 10(4)(b) and Article 10(5) thereof, and in line with the risk mitigation measures for African swine fever set out in the OIE Code, certain areas of the Voivodeship of Wielkopolskie in Poland, currently listed in Part III of the Annex to Implementing Decision 2014/709/EU should now be listed instead in Part I of that Annex, in view of the expiry of the period of three months from the date of the final cleaning and disinfection of the infected holdings and due to the absence of African swine fever occurrences in feral pigs and outbreaks in domestic pigs in those areas for the past three months in accordance with the provisions of the OIE Code.

(7) Also, taking into account the effectiveness of the measures being applied in Poland in accordance with Directive 2002/60/EC, and in particular those laid down in Article 15 thereof, and in line with the risk mitigation measures for African swine fever set out in the OIE Code, certain areas of the Voivodeship of Mazowieckie in Poland currently listed in Part II of the Annex to Implementing Decision 2014/709/EU, should now be listed in Part I of that Annex, due to the absence of occurrences of African swine fever in feral pigs in those areas for the past twelve months in accordance with the provisions of the OIE Code.

(8) In September 2020, a case of African swine fever in wild boar was observed in Germany in the state of Brandenburg of that federal Member State. Commission Implementing Decisions (EU) 2020/1270 ([7]) and (EU) 2020/1513 ([8]) were adopted in response to this case. Implementing Decision (EU) 2020/1513 repealed and replaced Implementing Decision (EU) 2020/1270 and it applies until 30 November 2020. Implementing Decision (EU) 2020/1513 provides that the infected area established by Germany, where the measures provided for in Article 15 of Directive 2002/60/EC apply, are to comprise at least the areas listed in the Annex to that Implementing Decision.

(9) Subsequently, in late September 2020, a further case of African swine fever in wild boar was observed in Germany, again in the state of Brandenburg, but in an area not covered by Implementing Decision (EU) 2020/1513. Commission Implementing Decision (EU) 2020/1391 ([9]) was adopted in response to this case and it applies until 30 November 2020. Implementing Decision (EU) 2020/1391 provides that the infected area established by Germany, where the measures provided for in Article 15 of Directive 2002/60/EC apply, are to comprise at least the areas listed in the Annex to that Implementing Decision.

(10) In November 2020, Germany informed the Commission of a new case of African swine fever in a wild boar in the state of Saxony of that federal Member State. Commission Implementing Decisions (EU) 2020/1645 ([10]) was adopted in response to that new case and it applies until 31 January 2021. It provides that the infected area established by Germany, where the measures provided for in Article 15 of Directive 2002/60/EC apply, are to comprise at least the areas listed in the Annex to that Implementing Decision.

([7]) Commission Implementing Decision (EU) 2020/1270 of 11 September 2020 concerning certain interim protective measures relating to African swine fever in Germany (OJ L 297I, 11.9.2020, p. 1).

([8]) Commission Implementing Decision (EU) 2020/1513 of 15 October 2020 concerning certain protective measures relating to African swine fever in Germany (OJ L 344, 19.10.2020, p. 29).

([9]) Commission Implementing Decision (EU) 2020/1391 of 2 October 2020 concerning certain protective measures relating to African swine fever in Germany (OJ L 321, 5.10.2020, p. 5).

([10]) Commission Implementing Decision (EU) 2020/1645 of 5 November 2020 concerning certain interim protective measures relating to African swine fever in Germany (OJ L 370, 6.11.2020, p. 47).

(11) These recent cases of African swine fever in Germany constitute an increased level of risk which should be reflected in the Annex to Implementing Decision 2014/709/EU. Accordingly, these areas of Germany in the states of Brandenburg and Saxony of that federal Member State affected by these recent cases of African swine fever should now be listed in Parts I and II of that Annex.

(12) Following the recent cases of African swine fever in feral pigs in Germany and taking into account the current epidemiological situation in the Union, regionalisation in this Member State has been reassessed and updated. In addition, the risk management measures in place have also been reassessed and updated. These changes need to be reflected in the Annex to Implementing Decision 2014/709/EU.

(13) Since the date of adoption of Implementing Decision (EU) 2020/1644, there have also been new occurrences of African swine fever in feral pigs in Poland.

(14) In November 2020, several cases of African swine fever in feral pigs were observed in the districts of słubicki and swiebodziński in Poland in areas listed in Part II of the Annex to Implementing Decision 2014/709/EU, located in close proximity to areas currently listed in Part I thereof. These cases of African swine fever in feral pigs constitute an increased level of risk, which should be reflected in that Annex. Accordingly, these areas of Poland currently listed in Part I of that Annex, that are in close proximity to areas listed in Part II affected by these recent cases of African swine fever, should now be listed in Part II of that Annex instead of in Part I thereof.

(15) In addition, in November 2020, two cases of African swine fever in feral pigs were observed in the districts of sulęciński and międzyrzecki in Poland in areas currently listed in Part I of the Annex to Implementing Decision 2014/709/EU. These cases of African swine fever in feral pigs constitute an increased level of risk, which should be reflected in that Annex. Accordingly, these areas of Poland currently listed in Part I of the Annex to Implementing Decision 2014/709/EU, affected by these recent cases of African swine fever, should now be listed in Part II of that Annex instead of in Part I thereof, and the current boundaries of Part I also need to be redefined and enlarged to take account of these recent cases.

(16) In order to take account of recent developments in the epidemiological situation of African swine fever in the Union, and in order to combat the risks associated with the spread of that disease in a proactive manner, new high-risk areas of a sufficient size should be demarcated for Poland and duly listed in Parts I and II of the Annex to Implementing Decision 2014/709/EU.

(17) Given the urgency of the epidemiological situation in the Union as regards the spread of African swine fever, it is important that the amendments made to the Annex to Implementing Decision 2014/709/EU by this Decision take effect as soon as possible.

(18) 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 Annex to Implementing Decision 2014/709/EU is replaced by the text set out in the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 20 November 2020.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

The Annex to Implementing Decision 2014/709/EU is replaced by the following:

'*ANNEX*

PART I

1. **Estonia**

The following areas in Estonia:

— Hiiu maakond.

2. **Hungary**

The following areas in Hungary:

— Békés megye 950950, 950960, 950970, 951950, 952050, 952750, 952850, 952950, 953050, 953150, 953650, 953660, 953750, 953850, 953960, 954250, 954260, 954350, 954450, 954550, 954650, 954750, 954850, 954860, 954950, 955050, 955150, 955250, 955260, 955270, 955350, 955450, 955510, 955650, 955750, 955760, 955850, 955950, 956050, 956060, 956150 és 956160 kódszámú vadgazdálkodási egységeinek teljes területe,

— Bács-Kiskun megye 600150, 600850, 601550, 601650, 601660, 601750, 601850, 601950, 602050, 603250, 603750 és 603850 kódszámú vadgazdálkodási egységeinek teljes területe,

— Budapest 1 kódszámú, vadgazdálkodási tevékenységre nem alkalmas területe,

— Csongrád-Csanád megye 800150, 800160, 800250, 802220, 802260, 802310 és 802450 kódszámú vadgazdálkodási egységeinek teljes területe,

— Fejér megye 400150, 400250, 400351, 400352, 400450, 400550, 401150, 401250, 401350, 402050, 402350, 402360, 402850, 402950, 403050, 403250, 403350, 403450, 403550, 403650, 403750, 403950, 403960, 403970, 404570, 404650, 404750, 404850, 404950, 404960, 405050, 405750, 405850, 405950, 406050, 406150, 406550, 406650 és 406750 kódszámú vadgazdálkodási egységeinek teljes területe,

— Jász-Nagykun-Szolnok megye 750150, 750160, 750260, 750350, 750450, 750460, 754450, 754550, 754560, 754570, 754650, 754750, 754950, 755050, 755150, 755250, 755350 és 755450 kódszámú vadgazdálkodási egységeinek teljes területe,

— Komárom-Esztergom megye 250150, 250250, 250350, 250450, 250460, 250550, 250650, 250750, 250850, 250950, 251050, 251150, 251250, 251350, 251360, 251450, 251550, 251650, 251750, 251850, 252150 és 252250, kódszámú vadgazdálkodási egységeinek teljes területe,

— Pest megye 571550, 572150, 572250, 572350, 572550, 572650, 572750, 572850, 572950, 573150, 573250, 573260, 573350, 573360, 573450, 573850, 573950, 573960, 574050, 574150, 574350, 574360, 574550, 574650, 574750, 574850, 574860, 574950, 575 050,575150, 575250, 575350, 575550, 575650, 575750, 575850, 575950, 576050, 576150, 576250, 576350, 576450, 576650, 576750, 576850, 576950, 577050, 577150, 577350, 577450, 577650, 577850, 577950, 578050, 578150, 578250, 578350, 578360, 578450, 578550, 578560, 578650, 578850, 578950, 579050, 579150, 579250, 579350, 579450, 579460, 579550, 579650, 579750, 580250 és 580450 kódszámú vadgazdálkodási egységeinek teljes területe.

3. **Latvia**

The following areas in Latvia:

— Pāvilostas novada Vērgales pagasts,

— Stopiņu novada daļa, kas atrodas uz rietumiem no autoceļa V36, P4 un P5, Acones ielas, Dauguļupes ielas un Dauguļupītes,

— Grobiņas novads,

— Rucavas novada Dunikas pagasts.

4. **Lithuania**

The following areas in Lithuania:

— Klaipėdos rajono savivaldybės: Agluonėnų, Priekulės, Veiviržėnų, Judrėnų, Endriejavo ir Vėžaičių seniūnijos,

— Kretingos rajono savivaldybės: Darbėnų, Kretingos ir Žalgirio seniūnijos,

— Plungės rajono savivaldybės: Nausodžio sen dalis nuo kelio 166 į pietryčius ir Kulių seniūnija,

— Skuodo rajono savivaldybės: Lenkimų, Mosėdžio, Skuodo, Skuodo miesto seniūnijos.

5. **Poland**

The following areas in Poland:

w województwie warmińsko-mazurskim:

— gminy Wielbark i Rozogi w powiecie szczycieńskim,

— gminy Janowiec Kościelny, Janowo i część gminy Kozłowo położona na południe od linii wyznaczonej przez drogę łączącą miejscowości Rączki – Kownatki – Gardyny w powiecie nidzickim,

— powiat działdowski,

— gmina Dąbrówno w powiecie ostródzkim,

— gminy Kisielice, Susz, Iława z miastem Iława, Lubawa z miastem Lubawa, w powiecie iławskim,

— gmina Grodziczno w powiecie nowomiejskim,

w województwie podlaskim:

— gminy Wysokie Mazowieckie z miastem Wysokie Mazowieckie, Czyżew i część gminy Kulesze Kościelne położona na południe od linii wyznaczonej przez linię koleją w powiecie wysokomazowieckim,

— gminy Miastkowo, Nowogród, Śniadowo i Zbójna w powiecie łomżyńskim,

— gminy Szumowo, Zambrów z miastem Zambrów i część gminy Kołaki Kościelne położona na południe od linii wyznaczonej przez linię kolejową w powiecie zambrowskim,

w województwie mazowieckim:

— powiat ostrołęcki,

— powiat miejski Ostrołęka,

— gminy Bielsk, Brudzeń Duży, Drobin, Gąbin, Łąck, Nowy Duninów, Radzanowo, Słupno i Stara Biała w powiecie płockim,

— powiat miejski Płock,

— powiat sierpecki,

— powiat żuromiński,

— gminy Andrzejewo, Brok, Stary Lubotyń, Szulborze Wielkie, Wąsewo, Ostrów Mazowiecka z miastem Ostrów Mazowiecka, część gminy Małkinia Górna położona na północ od rzeki Brok w powiecie ostrowskim,

— gminy Dzierzgowo, Lipowiec Kościelny, miasto Mława, Radzanów, Szreńsk, Szydłowo i Wieczfnia Kościelna, w powiecie mławskim,

— powiat przasnyski,

— powiat makowski,

— gminy Gzy, Obryte, Zatory, Pułtusk i część gminy Winnica położona na wschód od linii wyznaczonej przez drogę łączącą miejscowości Bielany, Winnica i Pokrzywnica w powiecie pułtuskim,

— gminy wyszkowski,

— gminy Jadów, Strachówka i Tłuszcz w powiecie wołomińskim,

— gminy Korytnica, Liw, Łochów, Miedzna, Sadowne, Stoczek i miasto Węgrów w powiecie węgrowskim,

— gminy Kowala, Wierzbica, część gminy Wolanów położona na południe od linii wyznaczonej przez drogę nr 12 w powiecie radomskim,

— powiat miejski Radom,

— powiat szydłowiecki,

— powiat gostyniński,

w województwie podkarpackim:

— gminy Pruchnik, Rokietnica, Roźwienica, w powiecie jarosławskim,

— gminy Fredropol, Krasiczyn, Krzywcza, Medyka, Orły, Żurawica, Przemyśl w powiecie przemyskim,

— powiat miejski Przemyśl,

— gminy Gać, Jawornik Polski, Kańczuga, część gminy wiejskiej Przeworsk położona na zachód od miasta Przeworsk i na zachód od linii wyznaczonej przez autostradę A4 biegnącą od granicy z gminą Tryńcza do granicy miasta Przeworsk, część gminy Zarzecze położona na zachód od linii wyznaczonej przez drogę nr 1594R biegnącą od północnej granicy gminy do miejscowości Zarzecze oraz na południe od linii wyznaczonej przez drogi nr 1617R oraz 1619R biegnącą do południowej granicy gminy w powiecie przeworskim,

— powiat łańcucki,

— gminy Trzebownisko, Głogów Małopolski i część gminy Sokołów Małopolski położona na południe od linii wyznaczonej przez drogę nr 875 w powiecie rzeszowskim,

— gminy Dzikowiec, Kolbuszowa, Niwiska i Raniżów w powiecie kolbuszowskim,

— gminy Borowa, Czermin, Gawłuszowice, Mielec z miastem Mielec, Padew Narodowa, Przecław, Tuszów Narodowy w powiecie mieleckim,

w województwie świętokrzyskim:

— powiat opatowski,

— powiat sandomierski,

— gminy Bogoria, Łubnice, Oleśnica, Osiek, Połaniec, Rytwiany i Staszów w powiecie staszowskim,

— gmina Skarżysko Kościelne w powiecie skarżyskim,

— gmina Wąchock, część gminy Brody położona na zachód od linii wyznaczonej przez drogę nr 9 oraz na południowy - zachód od linii wyznaczonej przez drogi: nr 0618T biegnącą od północnej granicy gminy do skrzyżowania w miejscowości Lipie, drogę biegnącą od miejscowości Lipie do wschodniej granicy gminy oraz na północ od drogi nr 42 i część gminy Mirzec położona na zachód od linii wyznaczonej przez drogę nr 744 biegnącą od południowej granicy gminy do miejscowości Tychów Stary a następnie przez drogę nr 0566T biegnącą od miejscowości Tychów Stary w kierunku północno - wschodnim do granicy gminy w powiecie starachowickim,

— powiat ostrowiecki,

— gminy Gowarczów, Końskie i Stąporków w powiecie koneckim,

w województwie łódzkim:

— gminy Łyszkowice, Kocierzew Południowy, Kiernozia, Chąśno, Nieborów, część gminy wiejskiej Łowicz położona na północ od linii wyznaczonej przez drogę nr 92 biegnącej od granicy miasta Łowicz do zachodniej granicy gminy oraz część gminy wiejskiej Łowicz położona na wschód od granicy miasta Łowicz i na północ od granicy gminy Nieborów w powiecie łowickim,

— gminy Biała Rawska, Cielądz, Rawa Mazowiecka z miastem Rawa Mazowiecka i Regnów w powiecie rawskim,

— powiat skierniewicki,

— powiat miejski Skierniewice,

— gminy Białaczów, Mniszków, Paradyż, Sławno i Żarnów w powiecie opoczyńskim,

— gminy Czerniewice, Inowłódz, Lubochnia, Rzeczyca, Tomaszów Mazowiecki z miastem Tomaszów Mazowiecki i Żelechlinek w powiecie tomaszowskim,

w województwie pomorskim:

— gminy Ostaszewo, miasto Krynica Morska oraz część gminy Nowy Dwór Gdański położona na południowy - zachód od linii wyznaczonej przez drogę nr 55 biegnącą od południowej granicy gminy do skrzyżowania z drogą nr 7, następnie przez drogę nr 7 i S7 biegnącą do zachodniej granicy gminy w powiecie nowodworskim,

— gminy Lichnowy, Miłoradz, Nowy Staw, Malbork z miastem Malbork w powiecie malborskim,

— gminy Mikołajki Pomorskie, Stary Targ i Sztum w powiecie sztumskim,

— powiat gdański,

— Miasto Gdańsk,

— powiat tczewski,

— powiat kwidzyński,

w województwie lubuskim:

— gminy Przytoczna, Pszczew, Skwierzyna i część gminy Trzciel położona na północ od linii wyznaczonej przez drogę nr 92 w powiecie międzyrzeckim,

— gminy Lubniewice i Krzeszyce w powiecie sulęcińskim,

— gminy Bogdaniec, Deszczno, Lubiszyn i część gminy Witnica położona na północny - wschód od drogi biegnącej od zachodniej granicy gminy od miejscowości Krześnica, przez miejscowości Kamień Wielki - Mościce -Witnica - Kłopotowo do południowej granicy gminy w powiecie gorzowskim,

w województwie dolnośląskim:

— gminy Bolesławiec z miastem Bolesławiec, Gromadka i Osiecznica w powiecie bolesławieckim,

— gmina Węgliniec w powiecie zgorzeleckim,

— gmina Chocianów i część gminy Przemków położona na południe od linii wyznaczonej przez drogę nr 12 w powiecie polkowickim,

— gmina Jemielno, Niechlów i Góra w powiecie górowskim,

— gmina Rudna i Lubin z miastem Lubin w powiecie lubińskim,

w województwie wielkopolskim:

— gminy Krzemieniewo, Rydzyna, część gminy Święciechowa położona na południe od linii wyznaczonej przez drogę nr 12w powiecie leszczyńskim,

— część gminy Kwilcz położona na południe od linii wyznaczonej przez drogę nr 24, część gminy Międzychód położona na południe od linii wyznaczonej przez drogę nr 24 w powiecie międzychodzkim,

— gminy Lwówek, Kuślin, Opalenica, część gminy Miedzichowo położona na północ od linii wyznaczonej przez drogę nr 92, część gminy Nowy Tomyśl położona na wschód od linii wyznaczonej przez drogę nr 305 w powiecie nowotomyskim,

— gminy Granowo, Grodzisk Wielkopolski i część gminy Kamieniec położona na wschód od linii wyznaczonej przez drogę nr 308 w powiecie grodziskim,

— gmina Czempiń, miasto Kościan, część gminy wiejskiej Kościan położona na północny – zachód od linii wyznaczonej przez drogę nr 5 oraz na wschód od linii wyznaczonej przez kanał Obry, część gminy Krzywiń położona na wschód od linii wyznaczonej przez kanał Obry w powiecie kościańskim,

— powiat miejski Poznań,

— gminy Buk, Dopiewo, Komorniki, Tarnowo Podgórne, Stęszew, Swarzędz, Pobiedziska, Czerwonak, Mosina, miasto Luboń, miasto Puszczykowo i część gminy Kórnik położona na zachód od linii wyznaczonych przez drogi: nr S11 biegnącą od północnej granicy gminy do skrzyżowania z drogą nr 434 i drogę nr 434 biegnącą od tego skrzyżowania do południowej granicy gminy, część gminy Rokietnica położona na południowy zachód od linii kolejowej biegnącej od północnej granicy gminy w miejscowości Krzyszkowo do południowej granicy gminy w miejscowości Kiekrz oraz część gminy wiejskiej Murowana Goślina położona na południe od linii kolejowej biegnącej od północnej granicy miasta Murowana Goślina do północno-wschodniej granicy gminy w powiecie poznańskim,

— gmina Kiszkowo i część gminy Kłecko położona na zachód od rzeki Mała Wełna w powiecie gnieźnieńskim,

— gminy Lubasz, Czarnków z miastem Czarnków, część gminy Połajewo na położona na północ od drogi łączącej miejscowości Chraplewo, Tarnówko-Boruszyn, Krosin, Jakubowo, Połajewo - ul. Ryczywolska do północno-wschodniej granicy gminy oraz część gminy Wieleń położona na południe od linii kolejowej biegnącej od wschodniej granicy gminy przez miasto Wieleń i miejscowość Herburtowo do zachodniej granicy gminy w powiecie czarnkowsko-trzcianeckim,

— gminy Duszniki, Kaźmierz, Pniewy, Ostroróg, Wronki, miasto Szamotuły i część gminy Szamotuły położona na zachód od zachodniej granicy miasta Szamotuły i na południe od linii kolejowej biegnącej od południowej granicy miasta Szamotuły, do południowo-wschodniej granicy gminy oraz część gminy Obrzycko położona na zachód od drogi nr 185 łączącej miejscowości Gaj Mały, Słopanowo i Obrzycko do północnej granicy miasta Obrzycko, a następnie na zachód od drogi przebiegającej przez miejscowość Chraplewo w powiecie szamotulskim,

— gmina Budzyń w powiecie chodzieskim,

— gminy Mieścisko, Skoki i Wągrowiec z miastem Wągrowiec w powiecie wągrowieckim,

— gmina Dobrzyca i część gminy Gizałki położona na północ od linii wyznaczonej przez drogę nr 443 w powiecie pleszewskim,

— gmina Zagórów w powiecie słupeckim,

— gmina Pyzdry w powiecie wrzesińskim,

— gminy Kotlin, Żerków i część gminy Jarocin położona na wschód od linii wyznaczonej przez drogi nr S11 i 15 w powiecie jarocińskim,

— gmina Rozdrażew, część gminy Koźmin Wielkopolski położona na wschód od linii wyznaczonej przez drogę nr 15, część gminy Krotoszyn położona na wschód od linii wyznaczonej przez drogę nr 15 oraz na wschód od granic miasta Krotoszyn w powiecie krotoszyńskim,

— gminy Nowe Skalmierzyce, Raszków, Ostrów Wielkopolski z miastem Ostrów Wielkopolski w powiecie ostrowskim,

— powiat miejski Kalisz,

— gminy Ceków – Kolonia, Godziesze Wielkie, Koźminek, Lisków, Mycielin, Opatówek, Szczytniki w powiecie kaliskim,

— gmina Malanów i część gminy Tuliszków położona na zachód od linii wyznaczonej przez drogę nr 72 w powiecie tureckim,

— gminy Rychwał, Rzgów, część gminy Grodziec położona na północ od linii wyznaczonej przez drogę nr 443, część gminy Stare Miasto położona na południe od linii wyznaczonej przez autostradę nr A2 w powiecie konińskim,

w województwie zachodniopomorskim:

— część gminy Boleszkowice położona na północny wschód od linii wyznaczonej przez drogę nr 31 i część gminy Dębno położona na północ od linii wyznaczonej przez drogę nr 31 biegnącą od zachodniej granicy gminy do miejscowości Sarbinowo, a następnie na północ od linii wyznaczonej przez drogę biegnącą od miejscowości Sarbinowo przez miejscowość Krześnica do wschodniej granicy gminy w powiecie myśliborskim,

— gmina Mieszkowice w powiecie gryfińskim.

6. **Slovakia**

The following areas in Slovakia:

— the whole district of Vranov nad Topľou, except municipalities included in part II,

— the whole district of Humenné,

— the whole district of Snina,

— the whole district of Medzilaborce,

— the whole district of Stropkov,

— the whole district of Svidník, except municipalities included in part II,

— the whole district of Bardejov, except municipalities included in part II,

— the whole district of Sobrance, except municipalities included in part III,

— in the district of Michalovce municipality Strážske,

— in the district of Gelnica, the whole municipalities of Uhorná, Smolnícka Huta, Mníšek nad Hnilcom, Prakovce, Helcmanovce, Gelnica, Kojšov, Veľký Folkmár, Jaklovce, Žakarovce, Margecany, Henclová and Stará Voda,

— in the district of Prešov, the whole municipalities of Klenov, Miklušovce, Sedlice, Suchá Dolina, Janov, Radatice, Ľubovec, Ličartovce, Drienovská Nová Ves, Kendice, Petrovany, Drienov, Lemešany, Janovík, Bretejovce, Seniakovce, Šarišské Bohdanovce, Varhaňovce, Brestov Mirkovce, Žehňa, Dulova Ves, Záborské, Kokošovce, Abranovce, Lesíček, Zlatá Baňa, Bajerov, Bertotovce, Brežany, Bzenov, Fričovce, Haniska, Hendrichovce, Hermanovce, Hrabkov, Chmiňany, Kojatice, Krížovany, Kvačany, Lipovce, Ondrašovce, Ovčie, Rokycany, Šindliar, Široké, Štefanovce, Víťaz, Žipov, Chminianske Jakubovany, Chminianska Nová Ves,

— in the district of Sabinov , the whole municipalities of Ďačov, Dubovica, Kamenica, Krivany, Lipany, Lúčka, Milpoš, Oľšov, Renčišov, Šarišské Dravce, Torysa, Vysoká, Hanigovce,

— in the district of Rožňava, the whole municipalities of Brzotín, Gočaltovo, Honce, Jovice, Kružná, Kunová Teplica, Pača, Pašková, Pašková, Rakovnica,

— Rozložná, Rožňavské Bystré, Rožňava, Rudná, Štítnik, Vidová, Čučma and Betliar,

— in the district of Revúca, the whole municipalities of Držkovce, Chvalová, Gemerské Teplice, Gemerský Sad, Hucín, Jelšava, Leváre, Licince, Nadraž, Prihradzany, Sekerešovo, Šivetice, Kameňany, Višňové, Rybník and Sása,

— in the district of Michalovce, the whole municipality of Strážske,

— in the district of Rimavská Sobota, municipalities located south of the road No.526 not included in Part II,

— in the district of Lučenec, the whole municipalities of Trenč, Veľká nad Ipľom, Jelšovec, Panické Dravce, Lučenec, Kalonda, Rapovce, Trebeľovce, Mučín, Lipovany, Pleš, Fiľakovské Kováče, Ratka, Fiľakovo, Biskupice, Belina, Radzovce, Čakanovce, Šiatorská Bukovinka, Čamovce, Šurice, Halič, Mašková, Ľuboreč, Šíd and Prša,

— in the district of Veľký Krtíš, the whole municipalities of Ipeľské Predmostie, Veľká Ves nad Ipľom, Sečianky, Kleňany, Hrušov, Vinica, Balog nad Ipľom, Dolinka, Kosihy nad Ipľom, Ďurkovce, Širákov, Kamenné Kosihy, Seľany, Veľká Čalomija, Malá Čalomija, Koláre, Trebušovce, Chrastince, Lesenice, Slovenské Ďarmoty, Opatovská Nová Ves, Bátorová, Nenince, Záhorce, Želovce, Sklabiná, Nová Ves, Obeckov, Vrbovka, Kiarov, Kováčovce, Zombor, Olováry, Čeláre, Glabušovce, Veľké Straciny, Malé Straciny, Malý Krtíš, Veľký Krtíš, Pôtor, Veľké Zlievce, Malé Zlievce, Bušince, Muľa, Ľuboriečka, Dolná Strehová, Vieska, Slovenské Kľačany, Horná Strehová, Chrťany and Závada.

7. **Greece**

The following areas in Greece:

— in the regional unit of Drama:

  — the community departments of Sidironero and Skaloti and the municipal departments of Livadero and Ksiropotamo (in Drama municipality),

  — the municipal department of Paranesti (in Paranesti municipality),

  — the municipal departments of Kokkinogeia, Mikropoli, Panorama, Pyrgoi (in Prosotsani municipality),

  — the municipal departments of Kato Nevrokopi, Chrysokefalo, Achladea, Vathytopos, Volakas, Granitis, Dasotos, Eksohi, Katafyto, Lefkogeia, Mikrokleisoura, Mikromilea, Ochyro, Pagoneri, Perithorio, Kato Vrontou and Potamoi (in Kato Nevrokopi municipality),

— in the regional unit of Xanthi:

  — the municipal departments of Kimmerion, Stavroupoli, Gerakas, Dafnonas, Komnina, Kariofyto and Neochori (in Xanthi municipality),

  — the community departments of Satres, Thermes, Kotyli, and the municipal departments of Myki, Echinos and Oraio and (in Myki municipality),

  — the community department of Selero and the municipal department of Sounio (in Avdira municipality),

— in the regional unit of Rodopi:

  — the municipal departments of Komotini, Anthochorio, Gratini, Thrylorio, Kalhas, Karydia, Kikidio, Kosmio, Pandrosos, Aigeiros, Kallisti, Meleti, Neo Sidirochori and Mega Doukato (in Komotini municipality),

  — the municipal departments of Ipio, Arriana, Darmeni, Archontika, Fillyra, Ano Drosini, Aratos and the Community Departments Kehros and Organi (in Arriana municipality),

  — the municipal departments of Iasmos, Sostis, Asomatoi, Polyanthos and Amvrosia and the community department of Amaxades (in Iasmos municipality),

  — the municipal department of Amaranta (in Maroneia Sapon municipality),

— in the regional unit of Evros:

  — the municipal departments of Kyriaki, Mandra, Mavrokklisi, Mikro Dereio, Protokklisi, Roussa, Goniko, Geriko, Sidirochori, Megalo Derio, Sidiro, Giannouli, Agriani and Petrolofos (in Soufli municipality),

  — the municipal departments of Dikaia, Arzos, Elaia, Therapio, Komara, Marasia, Ormenio, Pentalofos, Petrota, Plati, Ptelea, Kyprinos, Zoni, Fulakio, Spilaio, Nea Vyssa, Kavili, Kastanies, Rizia, Sterna, Ampelakia, Valtos, Megali Doxipara, Neochori and Chandras (in Orestiada municipality),

  — the municipal departments of Asvestades, Ellinochori, Karoti, Koufovouno, Kiani, Mani, Sitochori, Alepochori, Asproneri, Metaxades, Vrysika, Doksa, Elafoxori, Ladi, Paliouri and Poimeniko (in Didymoteixo municipality),

— in the regional unit of Serres:

  — the municipal departments of Kerkini, Livadia, Makrynitsa, Neochori, Platanakia, Petritsi, Akritochori, Vyroneia, Gonimo, Mandraki, Megalochori, Rodopoli, Ano Poroia, Katw Poroia, Sidirokastro, Vamvakophyto, Promahonas, Kamaroto, Strymonochori, Charopo, Kastanousi and Chortero and the community departments of Achladochori, Agkistro and Kapnophyto (in Sintiki municipality),

— the municipal departments of Serres, Elaionas and Oinoussa and the community departments of Orini and Ano Vrontou (in Serres municipality),

— the municipal departments of Dasochoriou, Irakleia, Valtero, Karperi, Koimisi, Lithotopos, Limnochori, Podismeno and Chrysochorafa (in Irakleia municipality).

8. **Germany**

The following areas in Germany:

Bundesland Brandenburg:

— Landkreis Dahme-Spreewald:

— Gemeinde Alt Zauche-Wußwerk,

— Gemeinde Byhleguhre-Byhlen,

— Gemeinde Märkische Heide,

— Gemeinde Neu Zauche,

— Gemeinde Schwielochsee mit den Gemarkungen Groß Liebitz, Guhlen, Mochow und Siegadel,

— Gemeinde Spreewaldheide,

— Gemeinde Straupitz mit der Gemarkung Straupitz,

— Landkreis Märkisch-Oderland:

— Gemeinde Neuhardenberg,

— Gemeinde Gusow-Platkow,

— Gemeinde Lietzen,

— Gemeinde Falkenhagen (Mark),

— Gemeinde Zeschdorf,

— Gemeinde Treplin,

— Gemeinde Lebus mit den Gemarkungen Wüste-Kunersdorf, Wulkow bei Booßen, Schönfließ, Mallnow – westlich der Bahnstrecke RB 60,

— Gemeinde Fichtenhöhe mit den Gemarkungen Niederjesar, Alt Mahlisch, Carzig – westlich der Bahnstrecke RB 60,

— Gemeinde Lindendorf mit den Gemarkungen Neu Mahlisch, Libbenichen – westlich der Bahnstrecke RB 60 und Dolgelin – westlich der Bahnstrecke RB 60,

— Gemeinde Vierlinden mit den Gemarkungen Marxdorf, Neuentempel, Diedersdorf, Worin, Görlsdorf, Alt Rosenthal, Friedersdorf – westlich der Bahnstrecke RB 60,

— Gemeinde Müncheberg mit den Gemarkungen Trebnitz und Jahnsfelde,

— Gemeinde Letschin mit den Gemarkungen Steintoch, Neu Rosenthal, Letschin, Kiehnwerder, Sietzing, Kienitz, Wilhelmsaue, Posedin, Solikante, Klein Neuendorf, Neubarnim, Ortwig, Groß Neuendorf, Ortwig Graben, Mehrin-Graben und Zelliner Loose,

— Gemeinde Seelow mit den Gemarkungen Seelow – westlich der Bahnstrecke RB 60, Werbig – westlich der Bahnstrecke RB 60 und Langsow – westlich der Bahnstrecke RB 60,

— Landkreis Oder-Spree:

— Gemeinde Storkow (Mark),

— Gemeinde Wendisch Rietz,

— Gemeinde Reichenwalde,

— Gemeinde Diensdorf-Radlow,

— Gemeinde Bad Saarow,

— Gemeinde Rietz-Neuendorf mit den Gemarkungen Buckow, Glienicke, Behrensdorf, Ahrensdorf, Herzberg, Görzig, Pfaffendorf, Sauen, Wilmersdorf (G), Neubrück, Drahendorf, Alt Golm,

- Gemeinde Tauche mit den Gemarkungen Briescht, Kossenblatt, Werder, Görsdorf (B), Wiesendorf, Wulfersdorf, Falkenberg (T), Lindenberg,
- Gemeinde Steinhöfel mit den Gemarkungen Dunnitz, Steinhöfel, Hasenfelde, Ahrensdorf, Heinersdorf, Tempelberg,
- Gemeinde Langewahl,
- Gemeinde Berkenbrück,
- Gemeinde Briesen (Mark),
- Gemeinde Jacobsdorf,

— Landkreis Spree-Neiße:

- Gemeinde Jänschwalde,
- Gemeinde Peitz,
- Gemeinde Tauer,
- Gemeinde Turnow-Preilack,
- Gemeinde Drachhausen,
- Gemeinde Schmogrow-Fehrow,
- Gemeinde Drehnow,
- Gemeinde Guben mit der Gemarkung Schlagsdorf,
- Gemeinde Schenkendöbern mit den Gemarkungen Grabko, Kerrkwitz, Groß Gastrose,

— kreisfreie Stadt Frankfurt (Oder),

Bundesland Sachsen:

— Landkreis Görlitz:

- Gemeinde Gablenz,
- Gemeinde Bad Muskau,
- Gemeinde Krauschwitz sofern nicht bereits Teil des Gefährdeten Gebietes,
- Gemeinde Weißkeißel sofern nicht bereits Teil des Gefährdeten Gebietes,
- Gemeinde Rietschen sofern nicht bereits Teil des Gefährdeten Gebietes,
- Gemeinde Hähnichen,
- Gemeinde Rothenburg/ O. L.,
- Gemeinde Neiße-Aue,
- Gemeinde Görlitz nördlich der Bundesautobahn 4.

PART II

1. **Bulgaria**

The following areas in Bulgaria:

- the whole region of Haskovo,
- the whole region of Yambol,
- the whole region of Stara Zagora,
- the whole region of Pernik,
- the whole region of Kyustendil,
- the whole region of Plovdiv,
- the whole region of Pazardzhik,
- the whole region of Smolyan,
- the whole region of Burgas excluding the areas in Part III.

2. **Estonia**

The following areas in Estonia:

— Eesti Vabariik (välja arvatud Hiiu maakond).

3. **Hungary**

The following areas in Hungary:

— Békés megye 950150, 950250, 950350, 950450, 950550, 950650, 950660, 950750, 950850, 950860, 951050, 951150, 951250, 951260, 951350, 951450, 951460, 951550, 951650, 951750, 952150, 952250, 952350, 952450, 952550, 952650, 953250, 953260, 953270, 953350, 953450, 953550, 953560, 953950, 954050, 954060, 954150, 956250, 956350, 956450, 956550, 956650 és 956750 kódszámú vadgazdálkodási egységeinek teljes területe,

— Borsod-Abaúj-Zemplén megye valamennyi vadgazdálkodási egységének teljes területe,

— Fejér megye 403150, 403160, 403260, 404250, 404550, 404560, 405450, 405550, 405650, 406450 és 407050 kódszámú vadgazdálkodási egységeinek teljes területe,

— Hajdú-Bihar megye valamennyi vadgazdálkodási egységének teljes területe,

— Heves megye valamennyi vadgazdálkodási egységének teljes területe,

— Jász-Nagykun-Szolnok megye 750250, 750550, 750650, 750750, 750850, 750970, 750980, 751050, 751150, 751160, 751250, 751260, 751350, 751360, 751450, 751460, 751470, 751550, 751650, 751750, 751850, 751950, 752150, 752250, 752350, 752450, 752460, 752550, 752560, 752650, 752750, 752850, 752950, 753060, 753070, 753150, 753250, 753310, 753450, 753550, 753650, 753660, 753750, 753850, 753950, 753960, 754050, 754150, 754250, 754360, 754370, 754850, 755550, 755650 és 755750 kódszámú vadgazdálkodási egységeinek teljes területe,

— Komárom-Esztergom megye: 251950, 252050, 252350, 252450, 252460, 252550, 252650, 252750, 252850, 252860, 252950, 252960, 253050, 253150, 253250, 253350, 253450 és 253550 kódszámú vadgazdálkodási egységeinek teljes területe,

— Nógrád megye valamennyi vadgazdálkodási egységeinek teljes területe,

— Pest megye 570150, 570250, 570350, 570450, 570550, 570650, 570750, 570850, 570950, 571050, 571150, 571250, 571350, 571650, 571750, 571760, 571850, 571950, 572050, 573550, 573650, 574250, 577250, 580050 és 580150 kódszámú vadgazdálkodási egységeinek teljes területe,

— Szabolcs-Szatmár-Bereg megye valamennyi vadgazdálkodási egységének teljes területe.

4. **Latvia**

The following areas in Latvia:

— Ādažu novads,

— Aizputes novada Aizputes, Cīravas un Lažas pagasts, Kalvenes pagasta daļa uz rietumiem no ceļa pie Vārtājas upes līdz autoceļam A9, uz dienvidiem no autoceļa A9, uz rietumiem no autoceļa V1200, Kazdangas pagasta daļa uz rietumiem no ceļa V1200, P115, P117, V1296, Aizputes pilsēta,

— Aglonas novads,

— Aizkraukles novads,

— Aknīstes novads,

— Alojas novads,

— Alsungas novads,

— Alūksnes novads,

— Amatas novads,

— Apes novads,

— Auces novads,

— Babītes novads,

— Baldones novads,

— Baltinavas novads,

— Balvu novads,

— Bauskas novads,

— Beverīnas novads,

— Brocēnu novads,

— Burtnieku novads,

— Carnikavas novads,

— Cēsu novads,

— Cesvaines novads,

— Ciblas novads,

— Dagdas novads,

— Daugavpils novads,

— Dobeles novads,

— Dundagas novads,

— Durbes novads,

— Engures novads,

— Ērgļu novads,

— Garkalnes novads,

— Gulbenes novads,

— Iecavas novads,

— Ikšķiles novads,

— Ilūkstes novads,

— Inčukalna novads,

— Jaunjelgavas novads,

— Jaunpiebalgas novads,

— Jaunpils novads,

— Jēkabpils novads,

— Jelgavas novads,

— Kandavas novads,

— Kārsavas novads,

— Ķeguma novads,

— Ķekavas novads,

— Kocēnu novads,

— Kokneses novads,

— Krāslavas novads,

— Krimuldas novads,

— Krustpils novads,

— Kuldīgas novada, Laidu pagasta daļa uz ziemeļiem no autoceļa V1296, Padures, Rumbas, Rendas, Kabiles, Vārmes, Pelču, Ēdoles, Īvandes, Kurmāles, Turlavas, Gudenieku un Snēpeles pagasts, Kuldīgas pilsēta,

— Lielvārdes novads,

— Līgatnes novads,

— Limbažu novads,

— Līvānu novads,
— Lubānas novads,
— Ludzas novads,
— Madonas novads,
— Mālpils novads,
— Mārupes novads,
— Mazsalacas novads,
— Mērsraga novads,
— Naukšēnu novads,
— Neretas novads,
— Ogres novads,
— Olaines novads,
— Ozolnieku novads,
— Pārgaujas novads,
— Pāvilostas novada Sakas pagasts, Pāvilostas pilsēta,
— Pļaviņu novads,
— Preiļu novads,
— Priekules novads,
— Priekuļu novads,
— Raunas novads,
— republikas pilsēta Daugavpils,
— republikas pilsēta Jelgava,
— republikas pilsēta Jēkabpils,
— republikas pilsēta Jūrmala,
— republikas pilsēta Rēzekne,
— republikas pilsēta Valmiera,
— Rēzeknes novads,
— Riebiņu novads,
— Rojas novads,
— Ropažu novads,
— Rugāju novads,
— Rundāles novads,
— Rūjienas novads,
— Salacgrīvas novads,
— Salas novads,
— Salaspils novads,
— Saldus novads,
— Saulkrastu novads,
— Sējas novads,
— Siguldas novads,
— Skrīveru novads,

— Skrundas novada Raņķu pagasta daļa uz ziemeļiem no autoceļa V1272 līdz robežai ar Ventas upi, Skrundas pagasta daļa no Skrundas uz ziemeļiem no autoceļa A9 un austrumiem no Ventas upes,

— Smiltenes novads,

— Stopiņu novada daļa, kas atrodas uz austrumiem no autoceļa V36, P4 un P5, Acones ielas, Dauguļupes ielas un Dauguļupītes,

— Strenču novads,

— Talsu novads,

— Tērvetes novads,

— Tukuma novads,

— Vaiņodes novada Vaiņodes pagasts un Embūtes pagasta daļa uz dienvidiem autoceļa P116, P106,

— Valkas novads,

— Varakļānu novads,

— Vārkavas novads,

— Vecpiebalgas novads,

— Vecumnieku novads,

— Ventspils novads,

— Viesītes novads,

— Viļakas novads,

— Viļānu novads,

— Zilupes novads.

5. **Lithuania**

The following areas in Lithuania:

— Alytaus miesto savivaldybė,

— Alytaus rajono savivaldybė,

— Anykščių rajono savivaldybė,

— Akmenės rajono savivaldybė,

— Birštono savivaldybė,

— Biržų miesto savivaldybė,

— Biržų rajono savivaldybė,

— Druskininkų savivaldybė,

— Elektrėnų savivaldybė,

— Ignalinos rajono savivaldybė,

— Jonavos rajono savivaldybė,

— Joniškio rajono savivaldybė,

— Jurbarko rajono savivaldybė: Eržvilko, Girdžių, Jurbarko miesto, Jurbarkų, Raudonės, Šimkaičių, Skirsnemunės, Smalininkų, Veliuonos ir Viešvilės seniūnijos,

— Kaišiadorių rajono savivaldybė,

— Kalvarijos savivaldybė,

— Kauno miesto savivaldybė,

— Kauno rajono savivaldybė: Akademijos, Alšėnų, Batniavos, Ežerėlio, Domeikavos, Garliavos, Garliavos apylinkių, Karmėlavos, Kulautuvos, Lapių, Linksmakalnio, Neveronių, Raudondvario, Ringaudų, Rokų, Samylų, Taurakiemio, Vandžiogalos, Užliedžių, Vilkijos, ir Zapyškio seniūnijos, Babtų seniūnijos dalis į rytus nuo kelio A1, ir Vilkijos apylinkių seniūnijos dalis į vakarus nuo kelio Nr. 1907,

— Kazlų rūdos savivaldybė,

— Kelmės rajono savivaldybė,

— Kėdainių rajono savivaldybė: Dotnuvos, Gudžiūnų, Kėdainių miesto, Krakių, Pelėdnagių, Surviliškio, Šėtos, Truskavos, Vilainių ir Josvainių seniūnijos dalis į šiaurę ir rytus nuo kelio Nr. 229 ir Nr. 2032,

— Kupiškio rajono savivaldybė,

— Kretingos rajono savivaldybė: Imbarės, Kūlupėnų ir Kartenos seniūnijos,

— Lazdijų rajono savivaldybė,

— Marijampolės savivaldybė,

— Mažeikių rajono savivaldybė,

— Molėtų rajono savivaldybė: Alantos seniūnijos dalis į vakarus nuo kelio 119 ir į šiaurę nuo kelio Nr. 2828, Balninkų, Dubingių, Giedraičių, Joniškio ir Videniškių seniūnijos,

— Pagėgių savivaldybė,

— Pakruojo rajono savivaldybė,

— Panevėžio rajono savivaldybė,

— Panevėžio miesto savivaldybė,

— Pasvalio rajono savivaldybė,

— Radviliškio rajono savivaldybė,

— Rietavo savivaldybė,

— Prienų rajono savivaldybė,

— Plungės rajono savivaldybė: Žlibinų, Stalgėnų, Nausodžio sen dalis nuo kelio Nr. 166 į šiaurės vakarus, Plungės miesto ir Šateikių seniūnijos,

— Raseinių rajono savivaldybė: Betygalos, Girkalnio, Kalnujų, Nemakščių, Pagojukų, Paliepių, Raseinių miesto, Raseinių, Šiluvos, Viduklės seniūnijos,

— Rokiškio rajono savivaldybė,

— Skuodo rajono savivaldybės: Aleksandrijos ir Ylakių seniūnijos,

— Šakių rajono savivaldybė,

— Šalčininkų rajono savivaldybė,

— Šiaulių miesto savivaldybė,

— Šiaulių rajono savivaldybė,

— Šilutės rajono savivaldybė,

— Širvintų rajono savivaldybė,

— Šilalės rajono savivaldybė,

— Švenčionių rajono savivaldybė,

— Tauragės rajono savivaldybė,

— Telšių rajono savivaldybė,

— Trakų rajono savivaldybė,

— Ukmergės rajono savivaldybė,

— Utenos rajono savivaldybė,

— Varėnos rajono savivaldybė,

— Vilniaus miesto savivaldybė,

— Vilniaus rajono savivaldybė,

— Vilkaviškio rajono savivaldybė,

— Visagino savivaldybė,

— Zarasų rajono savivaldybė.

6. **Poland**

The following areas in Poland:

w województwie warmińsko-mazurskim:

— gminy Kalinowo, Stare Juchy, Prostki oraz gmina wiejska Ełk w powiecie ełckim,

— powiat elbląski,

— powiat miejski Elbląg,

— powiat gołdapski,

— powiat piski,

— gminy Górowo Iławeckie z miastem Górowo Iławeckie i Sępopol w powiecie bartoszyckim,

— gminy Biskupiec, Kolno, część gminy Olsztynek położona na południe od linii wyznaczonej przez drogę nr S51 biegnącą od wschodniej granicy gminy do miejscowości Ameryka oraz na zachód od linii wyznaczonej przez drogę biegnącą od skrzyżowania z drogą S51 do północnej granicy gminy, łączącej miejscowości Mańki – Mycyny – Ameryka w powiecie olsztyńskim,

— gmina Grunwald, część gminy Małdyty położona na zachód od linii wyznaczonej przez drogę nr S7, część gminy Miłomłyn położona na zachód od linii wyznaczonej przez drogę nr S7, część gminy wiejskiej Ostróda położona na zachód od linii wyznaczonej przez drogę nr S7 oraz na południe od drogi nr 16, część miasta Ostróda położona na zachód od linii wyznaczonej przez drogę nr S7 w powiecie ostródzkim,

— powiat giżycki,

— powiat braniewski,

— powiat kętrzyński,

— gminy Lubomino i Orneta w powiecie lidzbarskim,

— gmina Nidzica i część gminy Kozłowo położona na północ od linii wyznaczonej przez drogę łączącą miejscowości Rączki – Kownatki – Gardyny w powiecie nidzickim,

— gminy Dźwierzuty, Jedwabno, Pasym, Szczytno i miasto Szczytno i Świętajno w powiecie szczycieńskim,

— powiat mrągowski,

— gmina Zalewo w powiecie iławskim,

— powiat węgorzewski,

w województwie podlaskim:

— powiat bielski,

— powiat grajewski,

— powiat moniecki,

— powiat sejneński,

— gminy Łomża, Piątnica, Jedwabne, Przytuły i Wizna w powiecie łomżyńskim,

— powiat miejski Łomża,

— powiat siemiatycki,

— powiat hajnowski,

— gminy Ciechanowiec, Klukowo, Szepietowo, Kobylin-Borzymy, Nowe Piekuty, Sokoły i część gminy Kulesze Kościelne położona na północ od linii wyznaczonej przez linię kolejową w powiecie wysokomazowieckim,

— gmina Rutki i część gminy Kołaki Kościelne położona na północ od linii wyznaczonej przez linię kolejową w powiecie zambrowskim,

— powiat kolneński z miastem Kolno,

— powiat białostocki,

— gminy Filipów, Jeleniewo, Przerośl, Raczki, Rutka-Tartak, Suwałki, Szypliszki Wiżajny oraz część gminy Bakałarzewo położona na północ od linii wyznaczonej przez drogę 653 biegnącej od zachodniej granicy gminy do skrzyżowania z drogą 1122B oraz na wschód od linii wyznaczonej przez drogę nr 1122B biegnącą od drogi 653 w kierunku południowym do skrzyżowania z drogą 1124B i następnie na północny - wschód od drogi nr 1124B biegnącej od skrzyżowania z drogą 1122B do granicy z gminą Raczki w powiecie suwalskim,

— powiat miejski Suwałki,

— powiat augustowski,

— powiat sokólski,

— powiat miejski Białystok,

w województwie mazowieckim:

— powiat siedlecki,

— powiat miejski Siedlce,

— gminy Bielany, Ceranów, Jabłonna Lacka, Kosów Lacki, Repki, Sabnie, Sterdyń i gmina wiejska Sokołów Podlaski w powiecie sokołowskim,

— gminy Grębków i Wierzbno w powiecie węgrowskim,

— powiat łosicki,

— powiat ciechanowski,

— powiat sochaczewski,

— gminy Policzna, Przyłęk, Tczów i Zwoleń w powiecie zwoleńskim,

— powiat kozienicki,

— gminy Chotcza i Solec nad Wisłą w powiecie lipskim,

— gminy Gózd, Jastrzębia, Jedlnia Letnisko, Pionki z miastem Pionki, Skaryszew, Jedlińsk, Przytyk, Zakrzew, część gminy Iłża położona na zachód od linii wyznaczonej przez drogę nr 9, część gminy Wolanów położona na północ od drogi nr 12 w powiecie radomskim,

— gminy Bodzanów, Bulkowo, Staroźreby, Słubice, Wyszogród i Mała Wieś w powiecie płockim,

— powiat nowodworski,

— powiat płoński,

— gminy Pokrzywnica, Świercze i część gminy Winnica położona na zachód od linii wyznaczonej przez drogę łączącą miejscowości Bielany, Winnica i Pokrzywnica w powiecie pułtuskim,

— gminy Dębówka, Klembów, Poświętne, Radzymin, Wołomin, miasto Kobyłka, miasto Marki, miasto Ząbki, miasto Zielonka w powiecie wołomińskim,

— gminy Borowie, Garwolin z miastem Garwolin, Miastków Kościelny, Parysów, Pilawa, część gminy Wilga położona na północ od linii wyznaczonej przez rzekę Wilga biegnącą od wschodniej granicy gminy do ujścia do rzeki Wisły, część gminy Górzno położona na północ od linii wyznaczonej przez drogę łączącą miejscowości Łąki i Górzno biegnącą od wschodniej granicy gminy, następnie od miejscowości Górzno na północ od drogi nr 1328W biegnącej do drogi nr 17, a następnie na północ od linii wyznaczonej przez drogę biegnącą od drogi nr 17 do zachodniej granicy gminy przez miejscowości Józefów i Kobyla Wola w powiecie garwolińskim,

— gminy Boguty – Pianki, Zaręby Kościelne, Nur i część gminy Małkinia Górna położona na południe od rzeki Brok w powiecie ostrowskim,

— gminy Stupsk, Wiśniewo i Strzegowo w powiecie mławskim,

— powiat miński,

— powiat otwocki,

— powiat warszawski zachodni,

— powiat legionowski,

— powiat piaseczyński,

— powiat pruszkowski,

— powiat grójecki,

— powiat grodziski,

— powiat żyrardowski,

— powiat białobrzeski,

— powiat przysuski,

— powiat miejski Warszawa,

w województwie lubelskim:

— powiat bialski,

— powiat miejski Biała Podlaska,

— gminy Batorz, Godziszów, Janów Lubelski, Modliborzyce i Potok Wielki w powiecie janowskim,

— gminy Janowiec, Kazimierz Dolny, Końskowola, Kurów, Markuszów, Nałęczów, Puławy z miastem Puławy, Wąwolnica i Żyrzyn w powiecie puławskim,

— gminy Nowodwór, miasto Dęblin i część gminy Ryki położona na południe od linii wyznaczonej przez linię kolejową powiecie ryckim,

— gminy Adamów, Krzywda, Stoczek Łukowski z miastem Stoczek Łukowski, Wola Mysłowska, Trzebieszów, Stanin, Wojcieszków, gmina wiejska Łuków i miasto Łuków w powiecie łukowskim,

— powiat lubelski,

— powiat miejski Lublin,

— gminy Niedźwiada, Ostrów Lubelski, Serniki i Uścimów w powiecie lubartowskim,

— powiat łęczyński,

— powiat świdnicki,

— gminy Fajsławice, Gorzków, Izbica, Krasnystaw z miastem Krasnystaw, Kraśniczyn, Łopiennik Górny, Siennica Różana i część gminy Żółkiewka położona na północ od linii wyznaczonej przez drogę nr 842 w powiecie krasnostawskim,

— gminy Chełm, Ruda – Huta, Sawin, Rejowiec, Rejowiec Fabryczny z miastem Rejowiec Fabryczny, Siedliszcze, Wierzbica, część gminy Dorohusk położona na północ od linii wyznaczonej przez linię kolejową, część gminy Wojsławice położona na zachód od linii wyznaczonej przez drogę 1839L, część gminy Leśniowice położona na zachód od linii wyznaczonej przez drogę 1839L w powiecie chełmskim,

— powiat miejski Chełm,

— powiat kraśnicki,

— powiat opolski,

— powiat parczewski,

— powiat włodawski,

— powiat radzyński,

w województwie podkarpackim:

— powiat stalowowolski,

— gminy Oleszyce, Lubaczów z miastem Lubaczów, Wielkie Oczy w powiecie lubaczowskim,

— część gminy Kamień położona na zachód od linii wyznaczonej przez drogę nr 19, część gminy Sokołów Małopolski położona na północ od linii wyznaczonej przez drogę nr 875 w powiecie rzeszowskim,

— gminy Cmolas i Majdan Królewski w powiecie kolbuszowskim,

— gminy Grodzisko Dolne, część gminy wiejskiej Leżajsk położona na południe od miasta Leżajsk oraz na zachód od linii wyznaczonej przez rzekę San, w powiecie leżajskim,

— gmina Jarocin, część gminy Harasiuki położona na północ od linii wyznaczona przez drogę nr 1048 R, część gminy Ulanów położona na północ od linii wyznaczonej przez rzekę Tanew, część gminy Nisko położona na zachód od linii wyznaczonej przez drogę nr 19 oraz na północ od linii wyznaczonej przez linię kolejową biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 19, część gminy Jeżowe położona na zachód od linii wyznaczonej przez drogę nr 19 w powiecie niżańskim,

— powiat tarnobrzeski,

w województwie pomorskim:

— gminy Dzierzgoń i Stary Dzierzgoń w powiecie sztumskim,

— gmina Stare Pole w powiecie malborskim,

— gminy Stegny, Sztutowo i część gminy Nowy Dwór Gdański położona na północny - wschód od linii wyznaczonej przez drogę nr 55 biegnącą od południowej granicy gminy do skrzyżowania z drogą nr 7, następnie przez drogę nr 7 i S7 biegnącą do zachodniej granicy gminy w powiecie nowodworskim,

w województwie świętokrzyskim:

— gmina Tarłów i część gminy Ożarów położona na północ od linii wyznaczonej przez drogę nr 74 w powiecie opatowskim,

— część gminy Brody położona na zachód od linii kolejowej biegnącej od miejscowości Marcule i od północnej granicy gminy przez miejscowości Klepacze i Karczma Kunowska do południowej granicy gminy oraz na wschód od linii wyznaczonej przez drogę nr 9 i na północny - wschód od linii wyznaczonej przez drogę nr 0618T biegnącą od północnej granicy gminy do skrzyżowania w miejscowości Lipie oraz przez drogę biegnącą od miejscowości Lipie do wschodniej granicy gminy i część gminy Mirzec położona na wschód od linii wyznaczonej przez drogę nr 744 biegnącą od południowej granicy gminy do miejscowości Tychów Stary a następnie przez drogę nr 0566T biegnącą od miejscowości Tychów Stary w kierunku północno – wschodnim do granicy gminy w powiecie starachowickim,

w województwie lubuskim:

— powiat wschowski,

— gmina Kostrzyn nad Odrą i część gminy Witnica położona na południowy zachód od drogi biegnącej od zachodniej granicy gminy od miejscowości Krześnica, przez miejscowości Kamień Wielki - Mościce -Witnica - Kłopotowo do południowej granicy gminy w powiecie gorzowskim,

— gminy Gubin z miastem Gubin, Maszewo i część gminy Bytnica położona na zachód od linii wyznaczonej przez drogę nr 1157F w powiecie krośnieńskim,

— powiat słubicki,

— gminy Słońsk, Sulęcin i Torzym w powiecie sulęcińskim,

— gminy Bledzew i Międzyrzecz w powiecie międzyrzeckim,

— gminy Kolsko, część gminy Kożuchów położona na południe od linii wyznaczonej przez drogę nr 283 biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 290 i na południe od linii wyznaczonej przez drogę nr 290 biegnącej od miasta Mirocin Dolny do zachodniej granicy gminy, część gminy Bytom Odrzański położona na północny zachód od linii wyznaczonej przez drogi nr 293 i 326, część gminy Nowe Miasteczko położona na zachód od linii wyznaczonych przez drogi 293 i 328, część gminy Siedlisko położona na północny zachód od linii wyznaczonej przez drogę biegnącą od rzeki Odry przy południowe granicy gminy do drogi nr 326 łączącej się z drogą nr 325 biegnącą w kierunku miejscowości Różanówka do skrzyżowania z drogą nr 321 biegnącą od tego skrzyżowania w kierunku miejscowości Bielawy, a następnie przedłużoną przez drogę przeciwpożarową biegnącą od drogi nr 321 w miejscowości Bielawy do granicy gminy w powiecie nowosolskim,

— gminy Nowogród Bobrzański, Trzebiechów część gminy Bojadła położona na północ od linii wyznaczonej przez drogę nr 278 biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 282 i na północ od linii wyznaczonej przez drogę nr 282 biegnącej od miasta Bojadła do zachodniej granicy gminy i część gminy Sulechów położona na wschód od linii wyznaczonej przez drogę nr S3 w powiecie zielonogórskim,

— powiat żarski,

— gminy Brzeźnica, Iłowa, Małomice, Szprotawa, Wymiarki, Żagań, miasto Żagań, miasto Gozdnica, część gminy Niegosławice położona na zachód od linii wyznaczonej przez drogę nr 328 w powiecie żagańskim,

— gminy Lubrza, Łagów i Świebodzin w powiecie świebodzińskim,

w województwie dolnośląskim:

— gmina Pęcław, część gminy Kotla położona na północ od linii wyznaczonej przez rzekę Krzycki Rów, część gminy wiejskiej Głogów położona na wschód od linii wyznaczonej przez drogi nr 12, 319 oraz 329, część miasta Głogów położona na wschód od linii wyznaczonej przez drogę nr 12 w powiecie głogowskim,

— gminy Grębocice i Polkowice w powiecie polkowickim,

w województwie wielkopolskim:

— gminy Przemęt i Wolsztyn w powiecie wolsztyńskim,

— gmina Wielichowo część gminy Kamieniec położona na zachód od linii wyznaczonej przez drogę nr 308 i część gminy Rakoniewice położona na zachód od linii wyznaczonej przez drogę nr 305 w powiecie grodziskim,

— gminy Lipno, Osieczna, Wijewo, Włoszakowice i część gminy Święciechowa położona na północ od linii wyznaczonej przez drogę nr 12 w powiecie leszczyńskim,

— gmina Śmigiel, część gminy wiejskiej Kościan położona na południowy – wschód od linii wyznaczonej przez drogę nr 5 oraz na zachód od linii wyznaczonej przez kanał Obry, część gminy Krzywiń położona na zachód od linii wyznaczonej przez kanał Obry w powiecie kościańskim,

— powiat miejski Leszno,

— powiat obornicki,

— część gminy Połajewo na położona na południe od drogi łączącej miejscowości Chraplewo, Tarnówko-Boruszyn, Krosin, Jakubowo, Połajewo - ul. Ryczywolska do północno-wschodniej granicy gminy w powiecie czarnkowsko-trzcianeckim,

— gmina Suchy Las, część gminy wiejskiej Murowana Goślina położona na północ od linii kolejowej biegnącej od północnej granicy miasta Murowana Goślina do północno-wschodniej granicy gminy oraz część gminy Rokietnica położona na północ i na wschód od linii kolejowej biegnącej od północnej granicy gminy w miejscowości Krzyszkowo do południowej granicy gminy w miejscowości Kiekrz w powiecie poznańskim,

— część gminy Szamotuły położona na wschód od wschodniej granicy miasta Szamotuły i na północ od linii kolejowej biegnącej od południowej granicy miasta Szamotuły do południowo-wschodniej granicy gminy oraz część gminy Obrzycko położona na wschód od drogi nr 185 łączącej miejscowości Gaj Mały, Słopanowo i Obrzycko do północnej granicy miasta Obrzycko, a następnie na wschód od drogi przebiegającej przez miejscowość Chraplewo w powiecie szamotulskim,

w województwie łódzkim:

— gminy Drzewica, Opoczno i Poświętne w powiecie opoczyńskim,

— gmina Sadkowice w powiecie rawskim,

w województwie zachodniopomorskim:

— część gminy Boleszkowice położona na południowy - zachód od linii wyznaczonej przez drogę nr 31 i część gminy Dębno położona na południe od linii wyznaczonej przez drogę nr 31 biegnącą od zachodniej granicy gminy do miejscowości Sarbinowo, a następnie na południe od linii wyznaczonej przez drogę biegnącą od miejscowości Sarbinowo przez miejscowość Krześnica do wschodniej granicy gminy w powiecie myśliborskim.

7. **Slovakia**

The following areas in Slovakia:

— in the district of Gelnica, the whole municipality of Smolník,

— In the district of Košice-okolie the municipalities of Opátka, Košická Belá, Malá Lodina, Veľká Lodina, Kysak, Sokoľ, Trebejov, Obišovce, Družstevná pri Hornáde, Kostoľany nad Hornádom, Budimír, Vajkovce, Chrastné, Čižatice, Kráľovce, Ploské, Nová Polhora, Boliarov, Kecerovce, Vtáčkovce, Herľany, Rankovce, Mudrovce, Kecerovský Lipovec, Opiná, Bunetice,

— the whole city of Košice,

— in the district of Michalovce, the whole municipalities of Tušice, Moravany, Pozdišovce, Michalovce, Zalužice, Lúčky, Závadka, Hnojné, Poruba pod Vihorlatom, Jovsa, Kusín, Klokočov, Kaluža, Vinné, Trnava pri Laborci, Oreské, Staré, Zbudza, Petrovce nad Laborcom, Lesné, Suché, Rakovec nad Ondavou, Nacina Ves, Voľa, and Pusté Čemerné,

— in the district of Vranov nad Topľou, the whole municipalities of Zámutov, Rudlov, Jusková Voľa, Banské, Cabov, Davidov, Kamenná Poruba, Vechec, Čaklov, Soľ, Komárany, Čičava, Nižný Kručov, Vranov nad Topľou, Sačurov, Sečovská Polianka, Dlhé Klčovo, Nižný Hrušov, Poša, Nižný Hrabovec, Hencovce, Kučín, Majerovce, Sedliská, Kladzany and Tovarnianska Polianka,

— in the district of Prešov, the whole municipalities of Tuhrina, Lúčina, Podhradík, Okružná, Ruská Nová Ves, Teriakovce, Ľubotice, Vyšná Šebastová, Lipníky, Chmeľov, Čelovce, Pušovce, Proč, Šarišská Trstená, Chmeľovec, Podhorany, Nemcovce, Lada, Kapušany, Fulianka, Prešov, Fintice, Tulčík, Demjata, Veľký Slivník, Záhradné, Malý Slivník, Mošurov, Terňa, Gregorovce, Medzany, Malý Šariš, Župčany, Svinia, Veľký Šariš, Geraltov, Trnkov, Šarišská Poruba, Lažany, Červenica,

— in the district of Sabinov, the whole municipalities Ostrovany, Daletice, Jarovnice, Šarišské Michaľany, Ražňany, Uzovce, Hubošovce, Ratvaj, Bodovce, Šarišské Sokolovce, Sabinov, Jakubovany, Uzovský Šalgov, Uzovské Pekľany, Pečovská Nová Ves, Rožkovany, Jakubova Voľa, Drienica, Červená Voda, Jakovany, Červenica pri Sabinove, Ľutina, Olejníkov,

— in the district of Svidník, the whole municipalities of Dukovce, Želmanovce, Kuková, Kalnište, Lužany pri Ondave, Lúčka, Giraltovce, Kračúnovce, Železník, Kobylince, Mičakovce,

— in the district of Bardejov, the whole municipalities of Kríže, Hervartov, Richvald, Šiba, Kľušov, Hertník, Fričkovce, Bartošovce, Kobyly, Osikov, Vaniškovce, Janovce, Tročany, Abrahámovce, Raslavice, Buclovany, Lopúchov, Stuľany, Koprivnica, Kochanovce, Harhaj, Vyšný Kručov, Brezov, Lascov, Marhaň, Kučín, Kožany, Kurima, Nemcovce, Porúbka, Hankovce, Oľšavce, Nižná Voľa, Rešov, Vyšná Voľa, Poliakovce, Dubinné, Hrabovec, Komárov, Lukavica,

— in the district of Revúca, the whole municipalities of Gemer, Tornaľa, Žiar, Gemerská Ves, Levkuška, Otročok, Polina, Rašice,

— in the district of Rimavská Sobota, the whole municipalities of Abovce, Barca, Bátka, Cakov, Chanava, Dulovo, Figa, Gemerské Michalovce, Hubovo, Ivanice, Kaloša, Kesovce, Kráľ, Lenartovce, Lenka, Neporadza, Orávka, Radnovce, Rakytník, Riečka, Rimavská Seč, Rumince, Stránska, Uzovská Panica, Valice, Vieska nad Blhom, Vlkyňa, Vyšné Valice, Včelince, Zádor, Číž, Štrkovec Tomášovce and Žíp,

— in the district of Prešov, the whole municipalities of Tuhrina and Lúčina.

8. **Romania**

The following areas in Romania:

— Județul Bistrița-Năsăud, without localities mentioned in Part III:

  — Locality Dealu Ștefăniței,

  — Locality Romuli.

9. **Germany**

The following areas in Germany:

Bundesland Brandenburg:

— Landkreis Oder-Spree:

  — Gemeinde Grunow-Dammendorf,

  — Gemeinde Mixdorf,

  — Gemeinde Schlaubetal,

  — Gemeinde Neuzelle,

  — Gemeinde Neißemünde,

  — Gemeinde Lawitz,

  — Gemeinde Eisenhüttenstadt,

  — Gemeinde Vogelsang,

  — Gemeinde Ziltendorf,

  — Gemeinde Wiesenau,

  — Gemeinde Friedland,

  — Gemeinde Müllrose,

  — Gemeinde Groß Lindow,

  — Gemeinde Brieskow-Finkenheerd,

  — Gemeinde Ragow-Merz,

  — Gemeinde Beeskow,

  — Gemeinde Rietz-Neuendorf mit den Gemarkungen Groß Rietz und Birkholz,

  — Gemeinde Tauche mit den Gemarkungen Stremmen, Ranzig, Trebatsch, Sabrodt, Sawall, Mitwalde und Tauche,

— Landkreis Dahme-Spreewald:

  — Gemeinde Jamlitz,

  — Gemeinde Lieberose,

  — Gemeinde Schwielochsee mit den Gemarkungen Goyatz, Jessern, Lamsfeld, Ressen, Speichrow und Zaue,

— Landkreis Spree-Neiße:

  — Gemeinde Schenkendöbern mit den Gemarkungen Stakow, Reicherskreuz, Groß Drewitz, Sembten, Meuselwitz, Kreyne, Lübbinchen, Bärenklau, Schenkendöbern und Atterwasch,

  — Gemeinde Guben mit den Gemarkungen Bresinchen, Guben und Deulowitz,

— Landkreis Märkisch-Oderland:
  — Gemeinde Zechin,
  — Gemeinde Bleyen-Genschmar,
  — Gemeinde Golzow,
  — Gemeinde Küstriner Vorland,
  — Gemeinde Alt Tucheband,
  — Gemeinde Reitwein,
  — Gemeinde Podelzig,
  — Gemeinde Letschin mit der Gemarkung Sophienthal,
  — Gemeinde Seelow – östlich der Bahnstrecke RB 60,
  — Gemeinde Vierlinden – östlich der Bahnstrecke RB 60,
  — Gemeinde Lindendorf – östlich der Bahnstrecke RB 60,
  — Gemeinde Fichtenhöhe – östlich der Bahnstrecke RB 60,
  — Gemeinde Lebus mit den Gemarkungen Lebus und Mallnow – östlich der Bahnstrecke RB 60,

Bundesland Sachsen:

— Landkreis Görlitz:
  — Gemeinde Krauschwitz östlich der B115,
  — Gemeinde Weißkeißel östlich der B115,
  — Gemeinde Rietschen östlich der B115 und nördlich der Südgrenze Truppenübungsplatz Oberlausitz.

PART III

1. **Bulgaria**

The following areas in Bulgaria:

— the whole region of Blagoevgrad,
— the whole region of Dobrich,
— the whole region of Gabrovo,
— the whole region of Kardzhali,
— the whole region of Lovech,
— the whole region of Montana,
— the whole region of Pleven,
— the whole region of Razgrad,
— the whole region of Ruse,
— the whole region of Shumen,
— the whole region of Silistra,
— the whole region of Sliven,
— the whole region of Sofia city,
— the whole region of Sofia Province,
— the whole region of Targovishte,
— the whole region of Vidin,
— the whole region of Varna,
— the whole region of Veliko Tarnovo,
— the whole region of Vratza,

— in Burgas region:

  — the whole municipality of Burgas,

  — the whole municipality of Kameno,

  — the whole municipality of Malko Tarnovo,

  — the whole municipality of Primorsko,

  — the whole municipality of Sozopol,

  — the whole municipality of Sredets,

  — the whole municipality of Tsarevo,

  — the whole municipality of Sungurlare,

  — the whole municipality of Ruen,

  — the whole municipality of Aytos.

2. **Latvia**

The following areas in Latvia:

— Aizputes novada Kalvenes pagasta daļa uz austrumiem no ceļa pie Vārtājas upes līdz autoceļam A9, uz ziemeļiem no autoceļa A9, uz austrumiem no autoceļa V1200, Kazdangas pagasta daļa uz austrumiem no ceļa V1200, P115, P117, V1296,

— Kuldīgas novada, Laidu pagasta daļa uz dienvidiem no autoceļa V1296,

— Skrundas novada Rudbāržu, Nīkrāces pagasts, Raņķu pagasta daļa uz dienvidiem no autoceļa V1272 līdz robežai ar Ventas upi, Skrundas pagasts (izņemot pagasta daļa no Skrundas uz ziemeļiem no autoceļa A9 un austrumiem no Ventas upes), Skrundas pilsēta,

— Vaiņodes novada Embūtes pagasta daļa uz ziemeļiem autoceļa P116, P106.

3. **Lithuania**

The following areas in Lithuania:

— Jurbarko rajono savivaldybė: Seredžiaus ir Juodaičių seniūnijos,

— Kauno rajono savivaldybė, Čekiškės seniūnija, Babtų seniūnijos dalis į vakarus nuo kelio A1ir Vilkijos apylinkių seniūnijos dalis į rytus nuo kelio Nr. 1907,

— Kėdainių rajono savivaldybė: Pernaravos seniūnija ir Josvainių seniūnijos pietvakarinė dalis tarp kelio Nr. 229 ir Nr. 2032,

— Molėtų rajono savivaldybė: Alantos seniūnijos dalis į rytus nuo kelio Nr. 119 ir į pietus nuo kelio Nr. 2828, Čiulėnų, Inturkės, Luokesos, Mindūnų ir Suginčių seniūnijos,

— Plungės rajono savivaldybė: Alsėdžių, Babrungo, Paukštakių, Platelių ir Žemaičių Kalvarijos seniūnijos,

— Raseinių rajono savivaldybė: Ariogalos ir Ariogalos miesto seniūnijos,

— Skuodo rajono savivaldybės: Barstyčių, Notėnų ir Šačių seniūnijos.

4. **Poland**

The following areas in Poland:

w województwie warmińsko-mazurskim:

— gminy Bisztynek i Bartoszyce z miastem Bartoszyce w powiecie bartoszyckim,

— gminy Kiwity i Lidzbark Warmiński z miastem Lidzbark Warmiński w powiecie lidzbarskim,

— gminy Łukta, Morąg, Miłakowo, część gminy Małdyty położona na wschód od linii wyznaczonej przez drogę nr S7, część gminy Miłomłyn położona na wschód od linii wyznaczonej przez drogę nr S7, część gminy wiejskiej Ostróda położona na wschód od linii wyznaczonej przez drogę nr S7 oraz na północ od drogi nr 16, część miasta Ostróda położona na wschód od linii wyznaczonej przez drogę nr w powiecie ostródzkim,

— powiat olecki,

— gminy Barczewo, Gietrzwałd, Jeziorany, Jonkowo, Dywity, Dobre Miasto, Purda, Stawiguda, Świątki, część gminy Olsztynek położona na północ od linii wyznaczonej przez drogę nr S51 biegnącą od wschodniej granicy gminy do miejscowości Ameryka oraz na wschód od linii wyznaczonej przez drogę biegnącą od skrzyżowania z drogą S51 do północnej granicy gminy, łączącej miejscowości Mańki – Mycyny – Ameryka w powiecie olsztyńskim,

— powiat miejski Olsztyn,

w województwie podlaskim:

— część gminy Bakałarzewo położona na południe od linii wyznaczonej przez drogę 653 biegnącej od zachodniej granicy gminy do skrzyżowania z drogą 1122B oraz na zachód od linii wyznaczonej przez drogę nr 1122B biegnącą od drogi 653 w kierunku południowym do skrzyżowania z drogą 1124B i następnie na południowy-zachód od drogi nr 1124B biegnącej od skrzyżowania z drogą 1122B do granicy z gminą Raczki w powiecie suwalskim,

w województwie mazowieckim:

— gminy Łaskarzew z miastem Łaskarzew, Maciejowice, Sobolew, Trojanów, Żelechów, część gminy Wilga położona na południe od linii wyznaczonej przez rzekę Wilga biegnącą od wschodniej granicy gminy do ujścia do rzeki Wisły, część gminy Górzno położona na południe od linii wyznaczonej przez drogę łączącą miejscowości Łąki i Górzno biegnącą od wschodniej granicy gminy, następnie od miejscowości Górzno na południe od drogi nr 1328W biegnącej do drogi nr 17, a następnie na południe od linii wyznaczonej przez drogę biegnącą od drogi nr 17 do zachodniej granicy gminy przez miejscowości Józefów i Kobyla Wola w powiecie garwolińskim,

— część gminy Iłża położona na wschód od linii wyznaczonej przez drogę nr 9 w powiecie radomskim,

— gmina Kazanów w powiecie zwoleńskim,

— gminy Ciepielów, Lipsko, Rzeczniów i Sienno w powiecie lipskim,

w województwie lubelskim:

— powiat tomaszowski,

— gminy Białopole, Dubienka, Kamień, Żmudź, część gminy Dorohusk położona na południe od linii wyznaczonej przez linię kolejową, część gminy Wojsławice położona na wschód od linii wyznaczonej przez drogę 1839L, część gminy Leśniowice położona na wschód od linii wyznaczonej przez drogę 1839L w powiecie chełmskim,

— gmina Rudnik i część gminy Żółkiewka położona na południe od linii wyznaczonej przez drogę nr 842 w powiecie krasnostawskim,

— powiat zamojski,

— powiat miejski Zamość,

— powiat biłgorajski,

— powiat hrubieszowski,

— gminy Dzwola i Chrzanów w powiecie janowskim,

— gmina Serokomla w powiecie łukowskim,

— gminy Abramów, Kamionka, Michów, Lubartów z miastem Lubartów, Firlej, Jeziorzany, Kock, Ostrówek w powiecie lubartowskim,

— gminy Kłoczew, Stężyca, Ułęż i część gminy Ryki położona na północ od linii wyznaczonej przez linię kolejową w powiecie ryckim,

— gmina Baranów w powiecie puławskim,

w województwie podkarpackim:

— gminy Cieszanów, Horyniec – Zdrój, Narol i Stary Dzików w powiecie lubaczowskim,

— gminy Kuryłówka, Nowa Sarzyna, miasto Leżajsk, część gminy wiejskiej Leżajsk położona na północ od miasta Leżajsk oraz część gminy wiejskiej Leżajsk położona na wschód od linii wyznaczonej przez rzekę San, w powiecie leżajskim,

— gminy Krzeszów, Rudnik nad Sanem, część gminy Harasiuki położona na południe od linii wyznaczona przez drogę nr 1048 R, część gminy Ulanów położona na południe od linii wyznaczonej przez rzekę Tanew, część gminy Nisko położona na wschód od linii wyznaczonej przez drogę nr 19 oraz na południe od linii wyznaczonej przez linię kolejową biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 19, część gminy Jeżowe położona na wschód od linii wyznaczonej przez drogę nr 19 w powiecie niżańskim,

— gminy Chłopice, Jarosław z miastem Jarosław, Laszki, Wiązownica, Pawłosiów, Radymno z miastem Radymno, w powiecie jarosławskim,

— gmina Stubno w powiecie przemyskim,

— część gminy Kamień położona na wschód od linii wyznaczonej przez drogę nr 19 w powiecie rzeszowskim,

— gminy Adamówka, Sieniawa, Tryńcza, miasto Przeworsk, część gminy wiejskiej Przeworsk położona na wschód od miasta Przeworsk i na wschód od linii wyznaczonej przez autostradę A4 biegnącą od granicy z gminą Tryńcza do granicy miasta Przeworsk, część gminy Zarzecze położona na wschód od linii wyznaczonej przez drogę nr 1594R biegnącą od północnej granicy gminy do miejscowości Zarzecze oraz na północ od linii wyznaczonej przez drogi nr 1617R oraz 1619R biegnącą do południowej granicy gminy w powiecie przeworskim,

w województwie lubuskim:

— gminy Nowa Sól i miasto Nowa Sól, Otyń oraz część gminy Kożuchów położona na północ od linii wyznaczonej przez drogę nr 283 biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 290 i na północ od linii wyznaczonej przez drogę nr 290 biegnącej od miasta Mirocin Dolny do zachodniej granicy gminy, część gminy Bytom Odrzański położona na południowy wschód od linii wyznaczonej przez drogi nr 293 i 326, część gminy Nowe Miasteczko położona na wschód od linii wyznaczonych przez drogi 293 i 328, część gminy Siedlisko położona na południowy wschód od linii wyznaczonej przez drogę biegnącą od rzeki Odry przy południowe granicy gminy do drogi nr 326 łączącej się z drogą nr 325 biegnącą w kierunku miejscowości Różanówka do skrzyżowania z drogą nr 321 biegnącą od tego skrzyżowania w kierunku miejscowości Bielawy, a następnie przedłużoną przez drogę przeciwpożarową biegnącą od drogi nr 321 w miejscowości Bielawy do granicy gminy w powiecie nowosolskim,

— gminy Babimost, Czerwieńsk, Kargowa, Świdnica, Zabór, część gminy Bojadła położona na południe od linii wyznaczonej przez drogę nr 278 biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 282 i na południe od linii wyznaczonej przez drogę nr 282 biegnącej od miasta Bojadła do zachodniej granicy gminy i część gminy Sulechów położona na zachód od linii wyznaczonej przez drogę nr S3 w powiecie zielonogórskim,

— część gminy Niegosławice położona na wschód od linii wyznaczonej przez drogę nr 328 w powiecie żagańskim,

— powiat miejski Zielona Góra,

— gminy Skąpe, Szczaniec i Zbąszynek w powiecie świebodzińskim,

— gminy Bobrowice, Dąbie, Krosno Odrzańskie i część gminy Bytnica położona na wschód od linii wyznaczonej przez drogę nr 1157F w powiecie krośnieńskim,

— część gminy Trzciel położona na południe od linii wyznaczonej przez drogę nr 92 w powiecie międzyrzeckim,

w województwie wielkopolskim:

— gmina Zbąszyń, część gminy Miedzichowo położona na południe od linii wyznaczonej przez drogę nr 92, część gminy Nowy Tomyśl położona na zachód od linii wyznaczonej przez drogę nr 305 w powiecie nowotomyskim,

— gmina Siedlec w powiecie wolsztyńskim,

— część gminy Rakoniewice położona na wschód od linii wyznaczonej przez drogę nr 305 w powiecie grodziskim,

— gminy Chocz, Czermin, Gołuchów, Pleszew i część gminy Gizałki położona na południe od linii wyznaczonej przez drogę nr 443 w powiecie pleszewskim,

— część gminy Grodziec położona na południe od linii wyznaczonej przez drogę nr 443 w powiecie konińskim,

— gminy Blizanów, Stawiszyn, Żelazków w powiecie kaliskim,

w województwie dolnośląskim:

— gminy Jerzmanowa, Żukowice, część gminy Kotla położona na południe od linii wyznaczonej przez rzekę Krzycki Rów, część gminy wiejskiej Głogów położona na zachód od linii wyznaczonej przez drogi nr 12, 319 oraz 329, część miasta Głogów położona na zachód od linii wyznaczonej przez drogę nr 12 w powiecie głogowskim,

— gminy Gaworzyce, Radwanice i część gminy Przemków położona na północ od linii wyznaczonej prze drogę nr 12 w powiecie polkowickim,

w województwie świętokrzyskim:

— część gminy Brody położona na wschód od linii kolejowej biegnącej od miejscowości Marcule i od północnej granicy gminy przez miejscowości Klepacze i Karczma Kunowska do południowej granicy gminy w powiecie starachowickim.

5. **Romania**

The following areas in Romania:

— Zona orașului București,

— Județul Constanța,
— Județul Satu Mare,
— Județul Tulcea,
— Județul Bacău,
— Județul Bihor,
— The following localities from Județul Bistrița Năsăud:
  — Dealu Ștefăniței,
  — Romuli,
— Județul Brăila,
— Județul Buzău,
— Județul Călărași,
— Județul Dâmbovița,
— Județul Galați,
— Județul Giurgiu,
— Județul Ialomița,
— Județul Ilfov,
— Județul Prahova,
— Județul Sălaj,
— Județul Suceava,
— Județul Vaslui,
— Județul Vrancea,
— Județul Teleorman,
— Județul Mehedinți,
— Județul Gorj,
— Județul Argeș,
— Județul Olt,
— Județul Dolj,
— Județul Arad,
— Județul Timiș,
— Județul Covasna,
— Județul Brașov,
— Județul Botoșani,
— Județul Vâlcea,
— Județul Iași,
— Județul Hunedoara,
— Județul Alba,
— Județul Sibiu,
— Județul Caraș-Severin,
— Județul Neamț,
— Județul Harghita,
— Județul Mureș,
— Județul Cluj,
— Județul Maramureş.

6. **Slovakia**

— the whole district of Trebišov,

— in the district of Michalovce, the whole municipalities of the district not included in Part I and Part II,

— Region Sobrance – municipalities Lekárovce, Pinkovce, Záhor, Bežovce,

— the whole district of Košice – okolie, except municipalities included in part II,

— In the district Rožnava, the municipalities of Bôrka, Lúčka, Jablonov nad Turňou, Drnava, Kováčová, Hrhov, Ardovo, Bohúňovo, Bretka, Čoltovo, Dlhá Ves, Gemerská Hôrka, Gemerská Panica, Kečovo, Meliata, Plešivec, Silica, Silická Brezová, Slavec, Hrušov, Krásnohorská Dlhá Lúka, Krásnohorské podhradie, Lipovník, Silická Jablonica, Brzotín, Jovice, Kružná, Pača, Rožňava, Rudná, Vidová and Čučma,

— in the district of Gelnica, the whole municipality of Smolník and Úhorná.

PART IV

Italy

The following areas in Italy:

— tutto il territorio della Sardegna.’

COMMISSION IMPLEMENTING DECISION (EU) 2020/1742

of 20 November 2020

concerning certain protective measures in relation to highly pathogenic avian influenza of subtype H5N8 in the United Kingdom

(notified under document C(2020) 8265)

(Only the English 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 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market ([1]), and in particular Article 9(4) thereof, in conjunction with Article 131 of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community ('Withdrawal Agreement'),

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary checks applicable in intra-Union trade in certain live animals and products with a view to the completion of the internal market ([2]), and in particular Article 10(4) thereof, in conjunction with Article 131 of the Withdrawal Agreement,

Whereas:

(1) Avian influenza is an infectious viral disease in birds, including poultry. Infections with avian influenza viruses in domestic poultry cause two main forms of that disease that are distinguished by their virulence. The low pathogenic form generally only causes mild symptoms, while the highly pathogenic form results in very high mortality rates in most poultry species. The disease may have a severe impact on the profitability of poultry farming causing disturbance to trade within the Union and exports to third countries.

(2) Since 2005, highly pathogenic avian influenza (HPAI) viruses of the H5 subtype have shown to be able to infect migratory birds, which can then spread these viruses over long distances during their autumn and spring migrations.

(3) The presence of HPAI viruses in wild birds poses a continuous threat for the direct and indirect introduction of these viruses into holdings where poultry or other captive birds are kept.

(4) In the event of an outbreak of HPAI, there is a risk that the disease agent may spread to other holdings where poultry or other captive birds are kept.

(5) Council Directive 2005/94/EC ([3]) sets out certain preventive measures relating to the surveillance and the early detection of avian influenza and the minimum control measures to be applied in the event of an outbreak of that disease in poultry or other captive birds. That Directive provides for the establishment of protection and surveillance zones in the event of an outbreak of HPAI. This regionalisation is applied in particular to preserve the health status of birds in the remainder of the territory of the country by preventing the introduction of the pathogenic agent and ensuring the early detection of the disease.

([1]) OJ L 395, 30.12.1989, p. 13.
([2]) OJ L 224, 18.8.1990, p. 29.
([3]) Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC (OJ L 10, 14.1.2006, p. 16).

(6) In November 2020, the United Kingdom notified the Commission of outbreaks of HPAI of subtype H5N8 on its territory, in holdings where poultry or other captive birds are kept in the counties of Cheshire and Herefordshire, and it immediately took the measures required pursuant to Directive 2005/94/EC, including the establishment of protection and surveillance zones.

(7) The Commission has examined those measures in collaboration with the United Kingdom, and it is satisfied that the borders of the protection and surveillance zones, established by the competent authority of the United Kingdom, are at a sufficient distance to the holdings where the outbreaks were confirmed.

(8) In order to prevent any unnecessary disturbance to trade within the Union and to avoid unjustified barriers to trade being imposed by third countries, it is necessary to rapidly describe the protection and surveillance zones established in relation to HPAI in the United Kingdom at Union level.

(9) Accordingly, the protection and surveillance zones in the United Kingdom, where the animal health control measures as laid down in Directive 2005/94/EC are applied, should be defined in the Annex to this Decision and the duration of that regionalisation fixed.

(10) In addition, Commission Implementing Decision (EU) 2020/1654 ([4]), which was adopted following the notification by the United Kingdom in November 2020 of the outbreak in the county of Cheshire, and later amended following the notification of the outbreak in the county of Herefordshire, should be repealed and replaced by this Decision.

(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

The United Kingdom shall ensure that the protection and surveillance zones established in accordance with Article 16(1) of Directive 2005/94/EC comprise at least the areas listed in Parts A and B of the Annex to this Decision.

Article 2

Implementing Decision (EU) 2020/1654 is repealed.

Article 3

This Decision shall apply until 31 December 2020.

Article 4

This Decision is addressed to the United Kingdom of Great Britain and Northern Ireland.

Done at Brussels, 20 November 2020.

For the Commission
Stella KYRIAKIDES
Member of the Commission

([4]) Commission Implementing Decision (EU) 2020/1654 of 6 November 2020 concerning certain interim protective measures in relation to highly pathogenic avian influenza of subtype H5N8 in the United Kingdom (OJ L 372, 9.11.2020, p. 52).

ANNEX

PART A

Protection zone as referred to in Article 1:

United Kingdom

Area comprising:	Date until applicable in accordance with Article 29(1) of Directive 2005/94/EC
Those parts of the county of Cheshire (ADNS code 00140) contained within a circle of a radius of three kilometres, centred on WGS84 dec. coordinates N53.25 and W2.81	27.11.2020
Those parts of the county of Herefordshire (ADNS code 00051) contained within a circle of a radius of three kilometres, centred on WGS84 dec. coordinates N52.17 and W2.81	8.12.2020

PART B

Surveillance zone as referred to in Article 1:

United Kingdom

Area comprising:	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
Those parts of the county of Cheshire (ADNS code 00140) extending beyond the area described in the protection zone and within the circle of a radius of ten kilometres, centred on WGS84 dec. coordinates N53.25 and W2.81	6.12.2020
Those parts of the county of Cheshire (ADNS code 00140) contained within a circle of a radius of three kilometres, centred on WGS84 dec. coordinates N53.25 and W2.81	From 28.11.2020 until 6.12.2020
Those parts of the county of Herefordshire (ADNS code 00051) extending beyond the area described in the protection zone and within the circle of a radius of ten kilometres, centred on WGS84 dec. coordinates N52.17 and W2.81	17.12.2020
Those parts of the county of Herefordshire (ADNS code 00051) contained within a circle of a radius of three kilometres, centred on WGS84 dec. coordinates N52.17 and W2.81	From 9.12.2020 until 17.12.2020

RECOMMENDATIONS

COMMISSION RECOMMENDATION (EU) 2020/1743

of 18 November 2020

on the use of rapid antigen tests for the diagnosis of SARS-CoV-2 infection

THE EUROPEAN COMMISSION,

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

Whereas:

(1) In line with Article 168(7) of the Treaty on the Functioning of the European Union ([1]), the definition of health policy as well as the organisation and delivery of health measures remain a national competence. EU Member States are thus responsible for deciding on the development and implementation of COVID-19 testing strategies, including the use of rapid antigen tests, taking into consideration countries' epidemiological and social situations as well as the target population for testing.

(2) The number of SARS-CoV-2 infection continues to rise and is putting pressure on healthcare workers involved in sampling as well as laboratories performing the COVID-19 tests, resulting in increasing turn-around times between the test request and result. Moreover, improved access to COVID-19 test sites and services compared to earlier in 2020 when Europe experienced its first pandemic wave, has resulted in high peaks in testing demands, often exceeding available testing capacities.

(3) Scientific and technical developments continue to evolve, offering new insights on the characteristics of the virus and the possibilities for using different methodologies and approaches for COVID-19 diagnosis. Currently, the 'gold standard' for COVID-19 diagnostics is the RT-PCR test, which is considered the most reliable methodology for testing of cases and contacts by both the World Health Organisation (WHO) and the European Centre for Disease Prevention and Control (ECDC) ([2]).

(4) A new generation of faster and cheaper tests is increasingly available on the European market: the so-called rapid antigen tests, which detect the presence of viral proteins (antigens), can be used to detect an ongoing infection. In the COVID-19 'In Vitro Diagnostic Devices and Test Methods Database' of the European Commission, 72 CE-marked rapid antigen tests are included ([3]).

(5) The currently applicable regulatory framework for placing rapid antigen tests on the market is Directive 98/79/EC of the European Parliament and of the Council ([4]). According to the Directive, for SARS-CoV-2 rapid antigen tests, the manufacturer must draw up a technical file which explicitly shows that the test is safe and performs as intended by the manufacturer, by demonstrating compliance with the requirements laid down in Annex I to the Directive. Following this, the manufacturer may issue an EU declaration of conformity and affix CE-marking to their device. From 26 May 2022, the Directive will be replaced by Regulation (EU) 2017/746 of the European Parliament and of the Council ([5]) on *in vitro* diagnostic medical devices. Under the Regulation, rapid antigen tests will be subject to reinforced requirements on device performance and a thorough assessment by a notified body.

([1]) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012E/TXT&from=EN

([2]) https://www.ecdc.europa.eu/sites/default/files/documents/TestingStrategy_Objective-Sept-2020.pdf

([3]) Value as of 12.11.2020, https://covid-19-diagnostics.jrc.ec.europa.eu/devices?marking=Yes&principle=ImmunoAssay-Antigen&format=Rapid+diagnostic+test&manufacturer=&text_name=#form_content

([4]) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

([5]) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176). The Regulation provides for a transition period starting on the date of its entry into force (May 2017) during which the conformity of *in vitro* diagnostic medical devices can be assessed either under the Regulation or under Directive 98/79/EC.

(6) In line with the Commission Guidelines on COVID-19 *in vitro* diagnostic tests ([6]), work is ongoing in the Medical Device Coordination Group (MDCG) of Member States' competent authorities to facilitate coherent application of the legal framework for placing the tests on the market, including guidance to manufacturers under Directive 98/79/EC. In addition, the Commission, with contribution from the MDCG, intends to develop and adopt common specifications according to Regulation (EU) 2017/746 for COVID-19 tests including rapid antigen tests ([7]).

(7) On 15 April 2020, the Commission adopted Guidelines on COVID-19 *in vitro* diagnostic tests and their performance ([8]), providing an overview of COVID-19 testing and considerations regarding test performance. It underlines that, in line with Directive 98/79/EC, the manufacturer must state the intended purpose of the device, and that the device must be designed and manufactured so that it is suitable for that intended purpose, including the intended user and clinical aspects such as the target population. The manufacturer must also state the levels of analytical performance of the device, which must correspond to the intended purpose. The information accompanying the device must take account of the training and knowledge of the potential users.

(8) The WHO published on 11 September 2020 interim guidance on the use of rapid antigen tests for COVID-19 detection ([9]), offering countries with advice on the potential role played by these tests and the need for careful test selection. As stressed by WHO, while the rapid antigen tests may offer helpful solutions for the diagnosis of SARS-CoV-2 infection in a range of settings and scenarios, their clinical performance is not yet optimal and caution should be exercised.

(9) Among existing models, WHO recommends the use of rapid antigen tests that meet the minimum performance requirements of ≥ 80 % sensitivity and ≥ 97 % specificity, and that these tests should in particular be used when the availability of RT-PCR tests is temporarily limited or where prolonged turn-around-times preclude clinical utility. The use of rapid antigen tests offers the potential for rapid identification of those individuals at greatest risk of spreading the infection, particularly in circumstances of high community transmission.

(10) ECDC has provided guidance on suitable SARS-CoV-2 testing strategies to achieve specific public health objectives in various epidemiological situations ([10]). This guidance provides the framework within which testing for SARS-CoV-2 critically contributes to generating reliable surveillance data, achieving control of transmission in the community, preventing transmission in high-risk settings, and limiting virus reintroduction in communities that have achieved sustained transmission control.

(11) Most of the currently available rapid antigen tests show a lower sensitivity compared to RT-PCR tests. The ECDC guidance ([11]) on the use of rapid antigen tests defines the suitability of various testing strategies in different epidemiological contexts, settings, and expected clinical performance, based on currently available evidence. Until now, clinical evaluation studies of rapid antigen tests show a 29 % to 93,9 % sensitivity and a 80,2 % to 100 % test specificity, compared to the gold standard RT-PCR test. Sensitivity of rapid antigen tests increases if they are applied to populations up to 5 days of symptom onset and tested in specimens with high viral load.

(12) However, rapid antigen tests can offer a significant advantage over RT-PCR tests in terms of simplicity of equipment needed, lower demands of highly skilled operators, price and timeliness of results, by providing health services with easy to use and rapid results which will also help to relieve the pressure on healthcare systems. For instance, when used in targeted population-wide testing approaches, the risk of not detecting all cases or risk of false negative results is counter-balanced by the timeliness of results and the possibility of recurred testing of initially negative individuals. The predictive value of a positive or negative test result depends on the test performance and infection prevalence in the population tested. Interpretation of the results of rapid antigen tests should therefore duly consider these elements.

([6]) Communication from the Commission – Guidelines on COVID-19 *in vitro* diagnostic tests and their performance (2020/C 122 I/01) (OJ C 122 I, 15.4.2020, p. 1).

([7]) These common specifications may be applied on a voluntary basis before the date of application of Regulation (EU) 2017/746 which is 26 May 2022.

([8]) Communication from the Commission – Guidelines on COVID-19 *in vitro* diagnostic tests and their performance (2020/C 122 I/01) (OJ C 122 I, 15.4.2020, p. 1).

([9]) https://apps.who.int/iris/bitstream/handle/10665/334253/WHO-2019-nCoV-Antigen_Detection-2020.1-eng.pdf?sequence=1&isAllowed=y

([10]) ECDC. COVID-19 testing strategies and objectives. Published on 17.9.2020. Available at: https://www.ecdc.europa.eu/en/publications-data/covid-19-testing-strategies-and-objectives

([11]) Guidance on a common validation protocol for rapid antigen tests, from ECDC, to be published on 18.11.2020.

(13) Regarding the possibility to use of antigen tests in asymptomatic persons, it should be noted that, until now, very limited data is available regarding the performance of rapid antigen tests in this context. Moreover, for the currently available rapid antigen tests, manufacturers' instructions do not mention asymptomatic persons as a target population.

(14) The possibility to use rapid antigen tests for travellers might be further considered, taking into account the latest scientific and technological developments in light of the epidemiological situation. For example, as announced in the Commission Recommendation on COVID-19 testing strategies of 28 October 2020, ECDC and the European Union Aviation Safety Agency (EASA) are jointly developing a protocol for safer air travel, including for a common testing approach at airports.

(15) A key body in the coordination of public health crises of Union relevance is the Health Security Committee (HSC). Its role is to reinforce the coordination and sharing of best practice and information on national preparedness and response planning. The use of rapid antigen tests has been discussed since early September 2020. Several Member States have started to use rapid antigen tests in practice and have included their use in their national COVID-19 testing strategies. Additionally, the majority of Member States are currently carrying out validation studies or pilots to assess the clinical performance of rapid antigen tests in specific settings and for the diagnosis of SARS-CoV-2 infection among certain target populations.

(16) The Commission Recommendation on COVID-19 testing, including the use of rapid antigen tests ([12]) of 28 October 2020 sets out guidance for countries regarding key elements to be considered for national, regional or local testing strategies. It provides recommendations focused on the scope of COVID-19 testing strategies, groups to be prioritised, and specific situations to be considered, and addresses key points linked to testing capacities and resources.

(17) It also recommends that Member States should agree on criteria to be used for the selection of rapid antigen tests, particularly those related to their clinical performance such as sensitivity and specificity, as well as to reach agreement on the scenarios and settings during which rapid antigen tests are appropriate to be used, such as for example in circumstances of high community transmission.

(18) The Recommendation also included a commitment by the Commission to work with Member States towards creating a framework for evaluation, approval and mutual recognition of rapid tests, as well as for mutual recognition of test results, which this Recommendation contributes towards.

(19) Economic operators must comply with the requirements set out in the applicable EU law. By fulfilling these requirements and affixing the CE marking to a product, a manufacturer declares that the product meets all the legal requirements for CE marking and that its product can be sold throughout the EEA. Member States have the possibility to restrict the availability of certain devices if they believe this is in the interest of protection of health and safety or in the interest of public health ([13]). The choice of tests at national level depends on the availability of the tests as well as national testing strategies in place, including, for example, the purposes for which the tests are intended to be used, in what combinations, and the accepted levels of performance, taking into consideration the epidemiological and clinical situation of the concerned Member State, region, particular health institution or patient group. Cooperation at EU level in assessing the evidence gathered from the use of these tests in clinical practice, including through the Joint Action EUnetHTA, can provide important benefit to inform national strategies.

(20) Effective testing plays a key role in the smooth functioning of the Internal Market as it allows for targeted isolation or quarantine measures. Mutual recognition of rapid antigen tests would allow limiting restrictions of free movement in line with Council Recommendation (EU) 2020/1475 ([14]) on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic.

(21) Member States health services should mutually recognise results of rapid antigen tests following the guidance set out in this Recommendation. To support mutual recognition, joint discussions of national testing strategies among Member States should continue, notably in the Health Security Committee and taking into account input received from ECDC and other relevant cooperation efforts, such as the EUnetHTA Joint Action.

([12]) C(2020) 7502.

([13]) Articles 8 and 13 of Directive 98/79/EC.

([14]) Council Recommendation (EU) 2020/1475 of 13 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic (OJ L 337, 14.10.2020, p. 3).

(22) EU cooperation in the area of Health Technology Assessment (HTA) has proven useful to HTA national authorities by providing guidance related to SARS-CoV-2, including on the use of antigen tests. The Commission has proposed to further strengthen cooperation at EU level on HTA ([15]). The implementation of an EU HTA framework would provide an important instrument to work jointly, pool resources, share expertise and provide evidence necessary to inform decisions including on the use of antigen tests.

(23) Furthermore, in order to provide additional support to Member States for introducing the use of rapid antigen tests, the Commission has identified EUR 100 million from the European Support Instrument (ESI) for the purchase and distribution of rapid antigen tests to Member States. In addition, the Commission has launched a joint procurement with Member States to facilitate the fair and equitable access to rapid antigen tests.

(24) This Recommendation is based on the latest guidance from ECDC and WHO. It may be updated in the light of new scientific evidence, the latest technological developments and evolving epidemiological situation,

HAS ADOPTED THIS RECOMMENDATION:

1. PURPOSE OF THE RECOMMENDATION

(1) This Recommendation sets out guidance for Member States regarding the use of rapid antigen tests to detect SARS-CoV-2 infection, drawing on the Recommendation of 28 October on COVID-19 testing strategies.

(2) It recommends Member States to conduct rapid antigen tests in addition to RT-PCR tests in clearly defined settings where the deployment of antigen tests is appropriate, and with the aim to contain the spread of the coronavirus, to detect SARS-CoV-2 infections and to limit isolation and quarantine measures.

(3) This Recommendation also contributes to ensuring the free movement of persons and the smooth functioning of the internal market, in times of limited testing capacities.

(4) In particular, the present Recommendation focuses on criteria to be used for the selection of rapid antigen tests, the settings during which rapid antigen tests are appropriate to be used, test operators, and validation and mutual recognition of rapid antigen tests and their results.

2. SELECTION CRITERIA OF RAPID ANTIGEN TESTS

(5) Member States should aim to use rapid antigen tests with acceptable test performance, i.e. ≥ 80 % sensitivity and ≥ 97 % specificity, to avoid as many false negative and false positive test results as possible.

(6) Rapid antigen testing should be conducted by trained healthcare personnel or trained operators where appropriate, and in accordance with manufacturer's instructions. A critical point, often neglected, is the collection of the sample. Protocols for an efficient sample acquisition and handing should also be available.

(7) Rapid antigen tests should be used within five days after the onset of symptoms or within seven days after exposure to a confirmed COVID-19 case.

(8) Before rapid antigen tests are adopted for use, Member States should ensure that such tests carry a CE-marking ([16]) and, before they are introduced into clinical practice, that those tests have been validated, as described in this Recommendation, against the standard RT-PCR tests and within the target population and setting intended for use.

([15]) Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU (COM(2018) 51 final).

([16]) All rapid antigen tests used by Member States should carry a CE-marking with the exception of devices referred to in Article 1(5) of Directive 98/79/EC.

3. RECOMMENDED SETTINGS FOR THE USE OF ANTIGEN TESTS

(9) When the availability of RT-PCR tests is temporarily limited, the use of rapid antigen tests can be considered for individuals with COVID-19 compatible symptoms in areas where the proportion of test positivity is high or very high, e.g. ≥ 10 %.

(10) The use of rapid antigen tests can be recommended to test individuals, regardless of symptoms, in settings where the proportion of test positivity is expected to be ≥ 10 %, e.g. in the context of contact tracing and outbreak investigations.

(11) In order to mitigate the impact of COVID-19 in healthcare and social-care settings, rapid antigen tests use should be considered at admission to healthcare facilities, as well as for triage of symptomatic patients or residents (up to 5 days since symptom onset), including for assigning patients to isolation facilities.

(12) Rapid antigen tests use should also be considered for a targeted population-wide testing approach, e.g. in a local community as well as in other high prevalence situations, and in the context of restrictive measures, in order to detect individuals with high transmission potential in the community and to lower the pressure on health-care settings. In such situations, the risk of not detecting all cases or the risk of false negative results is counter-balanced by the timeliness of results and the possibility of recurred testing of initially negative individuals. A confirmatory test will allow further informing the diagnosis, as stated in this Recommendation.

(13) In high prevalence situations and/or with limited RT-PCR testing capacity to detect the individuals with high transmission potential, rapid antigen tests use should be considered for recurring testing (e.g. every 2-3 days) of staff of health-care, home and social care, other long-term care facilities, closed settings (e.g. prisons or administrative detention centres, other reception infrastructures for asylum seekers and migrants), other relevant frontline workers in relevant sectors (meat processing plants, slaughterhouses, etc.) and other similar settings.

(14) In low prevalence situations, the use of rapid antigen tests should be focused on settings and situations where a fast identification of infected individuals is supporting the management of outbreaks and the regular monitoring of (high) risk groups, such as medical personnel or other long-term care facilities. The risk related to missing positive cases and the risk related to implementing isolation and quarantine measures due to falsely identified positive cases need to be assessed in such situations. This could be addressed by a confirmatory test.

(15) If a rapid antigen test is used in a population with high infection prevalence, negative results should be confirmed either by RT-PCR or by a repeated rapid antigen test. If a rapid antigen test is used in a population with low infection prevalence, positive results should be confirmed either by RT-PCR or by a repeated rapid antigen test. In both situations, the use and choice of the confirmatory test depends on the tolerability of the risk associated with missing positive cases or with detecting falsely positive cases.

4. TESTING CAPACITIES AND RESOURCES

(16) In addition to the considerations above, the choice of a given diagnostic test depends on existing testing capacities. If there are shortages of RT-PCR assays or if the result turn-around-time of these is beyond 24 hours, the choice of a rapid antigen tests can be justified, depending on the intended use and the tolerability of the risk associated with its performance limitations.

(17) Trained healthcare and laboratory staff are needed to carry out sampling, testing, test analysis and reporting of test results to clinical staff and public health authorities at local, regional, national and international level. Manufacturer instructions for sample collection, safe handling, use and disposal need to be strictly followed, including specimen type and intended use. Appropriate biosafety measures must be in place when sampling, handling and processing specimens. Member States need to ensure sufficient capacities and resources for sampling, testing and reporting. To ensure these capacities, it might be necessary to train additional test operators other than healthcare personnel.

(18) Medical laboratories, notably the laboratories being part of the EU network accredited by national bodies of the Member States on the basis of harmonised standard EN ISO 15189 'Medical laboratories – Requirements for quality and competence' and possibly additional standards and requirements, fulfil high quality requirements and could play an active role in rapid antigen testing. Accreditation also ensures that these laboratories are controlled on a regular basis and comply with the necessary quality and competence requirements.

(19) Capacity for confirmatory RT-PCR testing needs to be in place when applying rapid antigen tests as appropriate.

5. VALIDATION AND MUTUAL RECOGNITION

(20) Member States should use technical guidance developed by ECDC ([17]) on the use of rapid antigen tests for COVID-19, particularly as regards the clinical validation of these tests, to ensure reliability and comparability of results, when performing independent validations of rapid antigen tests.

(21) Considerations for rapid antigen test validations, as described in the technical guidance by ECDC, will include elements on validation of tests under similar settings as its intended use, respect of the manufacturer's instructions, comparison to the current RT-PCR gold standard, elements on retrospective approaches and categorisation of samples.

(22) Member States should share with ECDC and the Commission, as soon as they become available, their validation results and corresponding testing strategies by intended use, with the aim of aligning them as much as possible with other Member States, and share any other information on results of validation studies carried out on rapid antigen tests independently of studies conducted by test developers and manufacturers. Testing strategies should consider continuously the new information coming from these validation studies and be adapted accordingly, if necessary.

(23) The Commission will extend the existing COVID-19 diagnostic test database ('COVID-19 In Vitro Diagnostic Devices and Test Methods Database') with information on rapid antigen tests and validation studies results and keep the database updated with the latest information.

(24) ECDC, in cooperation with Commission services and Member States, will prioritise and coordinate the validation of existing and upcoming types of rapid tests (e.g. with different measurement techniques or sample specimen such as saliva) to facilitate an efficient entry of new tests, which meet the required performance criteria, into practice and alleviate pressures on testing and healthcare systems.

(25) The Commission will facilitate joint work and exchange of information on nationally conducted health technology assessments on rapid antigen tests between Member States.

(26) Mutual recognition of test results, as provided for in point 18 of Recommendation (EU) 2020/1475, is essential in order to facilitate cross-border movement, cross-border contact tracing and treatment. Results performed with tests that have been validated at national level by one Member State and that meet the criteria of sensitivity and specificity of this Recommendation, should be recognised by other Member States.

Done at Brussels, 18 November 2020.

For the Commission
Stella KYRIAKIDES
Member of the Commission

([17]) ECDC technical guidance, Options for the use of rapid antigen tests for COVID-19, published on 18.11.2020.

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