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⁽¹⁾ Text with EEA relevance.

EN

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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COUNCIL REGULATION (EU) 2018/1628

of 30 October 2018

fixing for 2019 the fishing opportunities for certain fish stocks and groups of fish stocks applicable in the Baltic Sea and amending Regulation (EU) 2018/120 as regards certain fishing opportunities in other waters

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(3) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) Regulation (EU) No 1380/2013 of the European Parliament and of the Council ⁽¹⁾ requires that conservation measures be adopted taking into account available scientific, technical and economic advice, including, where relevant, reports drawn up by the Scientific, Technical and Economic Committee for Fisheries and other advisory bodies, as well as in the light of any advice received from Advisory Councils established for the relevant geographical areas or fields of competence and joint recommendations made by Member States.
- (2) It is incumbent upon the Council to adopt measures on the fixing and allocation of fishing opportunities, including certain conditions functionally linked thereto, as appropriate. Fishing opportunities should be allocated to Member States in such a way as to ensure the relative stability of fishing activities of each Member State for each stock or fishery and having due regard to the objectives of the Common Fisheries Policy (CFP) set out in Regulation (EU) No 1380/2013.
- (3) Regulation (EU) No 1380/2013 provides that the objective of the CFP is to achieve the maximum sustainable yield (MSY) exploitation rate by 2015 where possible and, on a progressive, incremental basis, at the latest by 2020 for all stocks.
- (4) The total allowable catches (TACs) should therefore be established, in accordance with Regulation (EU) No 1380/2013, on the basis of the available scientific advice, taking into account biological and socioeconomic aspects whilst ensuring fair treatment between fishing sectors, as well as having regard to the opinions expressed during the consultation with stakeholders.
- (5) Regulation (EU) 2016/1139 of the European Parliament and of the Council ⁽²⁾ establishes a multiannual plan for the stocks of cod, herring and sprat in the Baltic Sea and for the fisheries exploiting those stocks ('the plan'). The plan aims to ensure that exploitation of living marine biological resources restores and maintains populations of harvested species above levels which can produce the MSY. To that end, the target fishing mortality for the stocks

⁽¹⁾ Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC (OJ L 354, 28.12.2013, p. 22).

⁽²⁾ Regulation (EU) 2016/1139 of the European Parliament and of the Council of 6 July 2016 establishing a multiannual plan for the stocks of cod, herring and sprat in the Baltic Sea and the fisheries exploiting those stocks, amending Council Regulation (EC) No 2187/2005 and repealing Council Regulation (EC) No 1098/2007 (OJ L 191, 15.7.2016, p. 1).

concerned, expressed in ranges, is to be achieved as soon as possible and, on a progressive, incremental basis, by 2020. It is appropriate that the catch limits applicable in 2019 for the cod, herring and sprat stocks in the Baltic Sea are established in line with the objectives of the plan.

- (6) The International Council for the Exploration of the Sea (ICES) has indicated the biomass of Western Baltic herring in ICES subdivisions 20-24 to be below the conservation reference points of the spawning stock biomass as set out in Annex II, column A, to Regulation (EU) 2016/1139. In accordance with Article 5(2) of that Regulation, all appropriate remedial measures should be adopted to ensure a rapid return of the stock concerned to a level capable of producing MSY. To that end, it is necessary to take into account the timeline for the achievement of the objectives of the CFP in general and of the plan in particular in view of the expected effect of the remedial measures adopted, whilst at the same time adhering to the objectives of achieving economic, social and employment benefits as set out in Article 2 of Regulation (EU) No 1380/2013. Accordingly, and in line with Article 4(3) of Regulation (EU) 2016/1139, it is appropriate that fishing opportunities for Western Baltic herring are set below the fishing mortality range in Annex I, column A, of that Regulation, as such a level takes into account the decrease in the biomass.
- (7) As regards the Western Baltic Sea cod stock, scientific advice indicates that recreational fisheries contribute significantly to the overall fishing mortality of that stock and should be limited. It is therefore appropriate to set a daily bag limit per fisherman. This is without prejudice to the principle of relative stability applicable to commercial fishing activities.
- (8) As regards the Eastern Baltic cod stock, ICES has not yet been able to establish biological reference points, following changes in the biology of the stock. It is therefore appropriate, in order to contribute to the achievement of the objectives of the plan, to fix the TAC for Eastern Baltic cod in accordance with the precautionary approach as established in Regulation (EU) No 1380/2013 and to set a closure period.
- (9) In order to guarantee full use of coastal fishing opportunities, it is appropriate to introduce a limited inter-area flexibility for salmon from ICES subdivisions 22-31 to ICES subdivision 32 for the Member State that has requested that flexibility.
- (10) According to ICES advice, 29 % of catches in the salmon fishery is misreported, in particular as sea trout catches. As most of the sea trout in the Baltic Sea is exploited in coastal areas, it is appropriate to prohibit fishing for sea trout beyond four nautical miles and to limit by-catches of sea trout to 3 % of the combined catch of sea trout and salmon in order to contribute to preventing misreporting of salmon catches as sea trout catches.
- (11) The use of the fishing opportunities set out in this Regulation is subject to Council Regulation (EC) No 1224/2009 ⁽¹⁾, and in particular to Articles 33 and 34 thereof concerning the recording of catches and fishing effort, and to the transmission of data on the exhaustion of fishing opportunities to the Commission. This Regulation should therefore specify the codes relating to landings of stocks subject to this Regulation that are to be used by Member States when sending data to the Commission.
- (12) Council Regulation (EC) No 847/96 ⁽²⁾ introduced additional conditions for year-to-year management of TACs including, under Articles 3 and 4, flexibility provisions for precautionary and analytical TACs. Under Article 2 of that Regulation, when fixing the TACs, the Council is to decide to which stocks Articles 3 or 4 shall not apply, in particular on the basis of the biological status of the stocks. More recently, the year-to-year flexibility mechanism was introduced by Article 15(9) of Regulation (EU) No 1380/2013 for all stocks that are subject to the landing obligation. Therefore, in order to avoid excessive flexibility that would undermine the principle of rational and responsible exploitation of living marine biological resources, hinder the achievement of the objectives of the CFP and cause the biological status of the stocks to deteriorate, it should be established that Articles 3 and 4 of Regulation (EC) No 847/96 apply to analytical TACs only where the year-to-year flexibility provided for in Article 15(9) of Regulation (EU) No 1380/2013 is not used.
- (13) Based on new scientific advice, a preliminary TAC for Norway pout in ICES division 3a and Union waters of ICES division 2a and ICES subarea 4 should be established for the period from 1 November 2018 to 31 October 2019.

⁽¹⁾ Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy, amending Regulations (EC) No 847/96, (EC) No 2371/2002, (EC) No 811/2004, (EC) No 768/2005, (EC) No 2115/2005, (EC) No 2166/2005, (EC) No 388/2006, (EC) No 509/2007, (EC) No 676/2007, (EC) No 1098/2007, (EC) No 1300/2008, (EC) No 1342/2008 and repealing Regulations (EEC) No 2847/93, (EC) No 1627/94 and (EC) No 1966/2006 (OJ L 343, 22.12.2009, p. 1).

⁽²⁾ Council Regulation (EC) No 847/96 of 6 May 1996 introducing additional conditions for year-to-year management of TACs and quotas (OJ L 115, 9.5.1996, p. 3).

- (14) In previous years the TACs for anchovy in ICES subareas 9 and 10 and Union waters of CECAF division 34.1.1 have been fixed for a calendar year. In July 2018 ICES issued its advice for the period from 1 July 2018 to 30 June 2019 for that stock. Those periods should be aligned in order to match the TAC period with the period covered by the ICES advice. Exceptionally and only due to the transition, the TAC for anchovy should be amended to cover the period of 18 months, ending on 30 June 2019.
- (15) In order to avoid the interruption of fishing activities and to ensure the livelihoods of Union fishermen, this Regulation should apply from 1 January 2019. However, this Regulation should apply to anchovy in ICES subareas 9 and 10 and Union waters of CECAF division 34.1.1 from 1 January 2018. Such retroactive application is without prejudice to the principles of legal certainty and protection of legitimate expectations as the fishing opportunities for that longer period exceed those initially fixed under Council Regulation (EU) 2018/120 ⁽¹⁾. Furthermore, this Regulation should apply to Norway pout in ICES division 3a and Union waters of ICES division 2a and ICES subarea 4 from 1 November 2018 until 31 October 2019. For reasons of urgency, this Regulation should enter into force immediately after its publication,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation fixes the fishing opportunities for certain fish stocks and groups of fish stocks in the Baltic Sea for 2019 and amends certain fishing opportunities in other waters fixed by Regulation (EU) 2018/120.

Article 2

Scope

1. This Regulation shall apply to Union fishing vessels operating in the Baltic Sea.
2. This Regulation shall also apply to recreational fisheries where they are expressly referred to in the relevant provisions.

Article 3

Definitions

For the purposes of this Regulation, the definitions referred to in Article 4 of Regulation (EU) No 1380/2013 apply.

In addition, the following definitions apply:

- (1) 'subdivision' means an ICES subdivision of the Baltic Sea as defined in Annex I to Council Regulation (EC) No 2187/2005 ⁽²⁾;
- (2) 'total allowable catch' (TAC) means the quantity of each stock that can be caught over the period of a year;
- (3) 'quota' means a proportion of the TAC allocated to the Union, a Member State or a third country;
- (4) 'recreational fisheries' means non-commercial fishing activities exploiting marine biological resources such as for recreation, tourism or sport.

CHAPTER II

FISHING OPPORTUNITIES

Article 4

TACs and allocations

The TACs, the quotas and the conditions functionally linked thereto, where appropriate, are set out in the Annex.

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

⁽²⁾ Council Regulation (EC) No 2187/2005 of 21 December 2005 for the conservation of fishery resources through technical measures in the Baltic Sea, the Belts and the Sound, amending Regulation (EC) No 1434/98 and repealing Regulation (EC) No 88/98 (OJ L 349, 31.12.2005, p. 1).

*Article 5***Special provisions on allocations of fishing opportunities**

The allocation of fishing opportunities among Member States, as set out in this Regulation, shall be without prejudice to:

- (a) exchanges made pursuant to Article 16(8) of Regulation (EU) No 1380/2013;
- (b) deductions and reallocations made pursuant to Article 37 of Regulation (EC) No 1224/2009;
- (c) additional landings allowed under Article 3 of Regulation (EC) No 847/96 or under Article 15(9) of Regulation (EU) No 1380/2013;
- (d) quantities withheld in accordance with Article 4 of Regulation (EC) No 847/96 or transferred under Article 15(9) of Regulation (EU) No 1380/2013;
- (e) deductions made pursuant to Articles 105 and 107 of Regulation (EC) No 1224/2009.

*Article 6***Conditions for landing of catches and by-catches**

The stocks of non-target species within the safe biological limits referred to in Article 15(8) of Regulation (EU) No 1380/2013 which qualify for the derogation from the obligation to count catches against the relevant quota, are identified in the Annex to this Regulation.

*Article 7***Measures on recreational fisheries for cod in subdivisions 22-24**

1. In recreational fisheries, no more than seven specimens of cod may be retained per fisherman per day in subdivisions 22-24.
2. Paragraph 1 is without prejudice to more stringent national measures.

*Article 8***Measures on sea trout fishing in subdivisions 22-32**

1. Fishing for sea trout beyond four nautical miles measured from the baselines in subdivisions 22-32 is prohibited for fishing vessels from 1 January to 31 December 2019. When fishing for salmon in those waters by-catches of sea trout may not exceed 3 % of the total catch of salmon and sea trout at any moment on board or landed after each fishing trip.
2. Paragraph 1 is without prejudice to more stringent national measures.

*Article 9***Flexibility**

1. Except where specified otherwise in the Annex to this Regulation, Article 3 of Regulation (EC) No 847/96 shall apply to stocks subject to precautionary TACs and Article 3(2) and (3) and Article 4 of that Regulation shall apply to stocks subject to an analytical TAC.
2. Article 3(2) and (3) and Article 4 of Regulation (EC) No 847/96 shall not apply where a Member State uses the year-to-year flexibility provided for in Article 15(9) of Regulation (EU) No 1380/2013.

*Article 10***Data transmission**

When, pursuant to Articles 33 and 34 of Regulation (EC) No 1224/2009, Member States send data relating to quantities of stocks caught or landed to the Commission, they shall use the stock codes set out in the Annex to this Regulation.

CHAPTER III

FINAL PROVISIONS

Article 11

Amendments to Regulation (EU) 2018/120

Annex IA to Regulation (EU) 2018/120 is amended as follows:

- (1) the fishing opportunities table for anchovy in ICES subareas 9 and 10 and Union waters of CECAF division 34.1.1 is replaced by the following:

'Species:	Anchovy <i>Engraulis encrasicolus</i>	Zone:	9 and 10; Union waters of CECAF 34.1.1 (ANE/9/3411)
Spain	10 802 ⁽¹⁾		
Portugal	11 784 ⁽¹⁾		
Union	22 586 ⁽¹⁾		
TAC	22 586 ⁽¹⁾		Precautionary TAC

⁽¹⁾ The quota may only be fished from 1 January 2018 to 30 June 2019.'

- (2) the fishing opportunities table for Norway pout and associated by-catches in ICES division 3a and Union waters of ICES division 2a and ICES subarea 4 is replaced by the following:

'Species:	Norway pout and associated by-catches <i>Trisopterus esmarkii</i>		Zone:	3a; Union waters of 2a and 4 (NOP/2A3A4.)
Year	2018	2019		
Denmark	85 186 ⁽¹⁾ ⁽³⁾	49 953 ⁽¹⁾ ⁽⁶⁾		
Germany	16 ⁽¹⁾ ⁽²⁾ ⁽³⁾	10 ⁽¹⁾ ⁽²⁾ ⁽⁶⁾		
The Netherlands	63 ⁽¹⁾ ⁽²⁾ ⁽³⁾	37 ⁽¹⁾ ⁽²⁾ ⁽⁶⁾		
Union	85 265 ⁽¹⁾ ⁽³⁾	50 000 ⁽¹⁾ ⁽⁶⁾		
Norway	15 000 ⁽⁴⁾	0		
Faroe Islands	6 000 ⁽⁵⁾	0		
TAC	not relevant	not relevant		Analytical TAC Article 3 of Regulation (EC) No 847/96 shall not apply Article 4 of Regulation (EC) No 847/96 shall not apply

⁽¹⁾ Up to 5 % of the quota may consist of by-catches of haddock and whiting (OT2/*2A3A4). By-catches of haddock and whiting counted against the quota pursuant to this provision and by-catches of species counted against the quota pursuant to Article 15(8) of Regulation (EU) No 1380/2013 shall, together, not exceed 9 % of the quota.

⁽²⁾ Quota may be fished in Union waters of ICES zones 2a, 3a and 4 only.

⁽³⁾ Union quota may only be fished from 1 November 2017 to 31 October 2018.

⁽⁴⁾ A sorting grid shall be used.

⁽⁵⁾ A sorting grid shall be used. Includes a maximum of 15 % of unavoidable by-catches (NOP/*2A3A4), to be counted against this quota.

⁽⁶⁾ Union quota may be fished from 1 November 2018 to 31 October 2019.'

*Article 12***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*.

It shall apply from 1 January 2019, with the exception of point 2 of Article 11 which shall apply from 1 November 2018 until 31 October 2019 and with the exception of point 1 of Article 11 which shall apply from 1 January 2018.

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

Done at Brussels, 30 October 2018.

For the Council
The President
J. BOGNER-STRAUSS

ANNEX

TACs applicable to Union fishing vessels in areas where TACs exist by species and by area

The following tables set out the TACs and quotas (in tonnes live weight, except where otherwise specified) by stock, and conditions functionally linked thereto.

The references to fishing zones are references to ICES zones, unless otherwise specified.

The fish stocks are referred to using the alphabetical order of the Latin names of the species.

For the purposes of this Regulation, the following comparative table of Latin names and common names is provided:

Scientific name	Alpha-3 code	Common name
<i>Clupea harengus</i>	HER	Herring
<i>Gadus morhua</i>	COD	Cod
<i>Pleuronectes platessa</i>	PLE	Plaice
<i>Salmo salar</i>	SAL	Atlantic salmon
<i>Sprattus sprattus</i>	SPR	Sprat

Species:	Herring <i>Clupea harengus</i>	Zone:	Subdivisions 30-31 (HER/30/31.)
Finland	72 724		
Sweden	15 979		
Union	88 703		
TAC	88 703		Analytical TAC

Species:	Herring <i>Clupea harengus</i>	Zone:	Subdivisions 22-24 (HER/3BC+24)
Denmark	1 262		
Germany	4 966		
Finland	1		
Poland	1 171		
Sweden	1 601		
Union	9 001		
TAC	9 001		Analytical TAC Article 3(2) and (3) of Regulation (EC) No 847/96 shall not apply. Article 4 of Regulation (EC) No 847/96 shall not apply.

Species:	Herring <i>Clupea harengus</i>	Zone:	Union waters of subdivisions 25-27, 28.2, 29 and 32 (HER/3D-R30)
Denmark	3 748		
Germany	994		
Estonia	19 139		
Finland	37 360		
Latvia	4 723		
Lithuania	4 973		
Poland	42 444		
Sweden	56 979		
Union	170 360		
TAC	Not relevant		Analytical TAC Article 6 of this Regulation shall apply.

Species:	Herring <i>Clupea harengus</i>	Zone:	Subdivision 28.1 (HER/03D.RG)
Estonia	14 336		
Latvia	16 708		
Union	31 044		
TAC	31 044		Analytical TAC Article 6 of this Regulation shall apply.

Species:	Cod <i>Gadus morhua</i>	Zone:	Union waters of subdivisions 25-32 (COD/3DX32.)
Denmark	5 539 ⁽¹⁾		
Germany	2 203 ⁽¹⁾		
Estonia	540 ⁽¹⁾		
Finland	424 ⁽¹⁾		
Latvia	2 060 ⁽¹⁾		
Lithuania	1 357 ⁽¹⁾		
Poland	6 377 ⁽¹⁾		
Sweden	5 612 ⁽¹⁾		
Union	24 112 ⁽¹⁾		
TAC	Not relevant		Precautionary TAC Article 3(2) and (3) of Regulation (EC) No 847/96 shall not apply. Article 4 of Regulation (EC) No 847/96 shall not apply.

⁽¹⁾ In subdivisions 25 and 26, it shall be prohibited to fish this quota from 1 July to 31 July for:

- fishing vessels of 12 meters length overall and more fishing with trawls, Danish seines or similar gear of a mesh size equal to or larger than 90 mm; and
- fishing vessels of 12 meters length overall and more, fishing with gillnets, entangling nets or trammel nets of a mesh size equal to or larger than 90 mm, or with bottom set lines, longlines except drifting lines, handlines and jigging equipment.

Species:	Cod <i>Gadus morhua</i>	Zone:	Subdivisions 22-24 (COD/3BC+24)
Denmark	4 152		
Germany	2 031		
Estonia	92		
Finland	82		
Latvia	344		
Lithuania	223		
Poland	1 111		
Sweden	1 480		
Union	9 515		
TAC	9 515		

Analytical TAC
Article 3(2) and (3) of Regulation (EC) No 847/96 shall not apply.
Article 4 of Regulation (EC) No 847/96 shall not apply.

Species:	Plaice <i>Pleuronectes platessa</i>	Zone:	Union waters of subdivisions 22-32 (PLE/3BCD-C)
Denmark	7 251		
Germany	806		
Poland	1 518		
Sweden	547		
Union	10 122		
TAC	10 122		

Analytical TAC
Article 6 of this Regulation shall apply.

Species:	Atlantic salmon <i>Salmo salar</i>	Zone:	Union waters of subdivisions 22-31 (SAL/3BCD-F)
Denmark	18 885 ⁽¹⁾		
Germany	2 101 ⁽¹⁾		
Estonia	1 919 ⁽¹⁾ ⁽²⁾		
Finland	23 548 ⁽¹⁾		
Latvia	12 012 ⁽¹⁾		
Lithuania	1 412 ⁽¹⁾		
Poland	5 729 ⁽¹⁾		
Sweden	25 526 ⁽¹⁾		
Union	91 132 ⁽¹⁾		
TAC	Not relevant		

Analytical TAC
Article 3(2) and (3) of Regulation (EC) No 847/96 shall not apply.
Article 4 of Regulation (EC) No 847/96 shall not apply.

⁽¹⁾ Expressed by number of individual fish.

⁽²⁾ Special condition: up to 20 % and no more than 400 specimens of this quota may be fished in Union waters of subdivision 32 (SAL/*3D32)

Species:	Atlantic salmon <i>Salmo salar</i>	Zone:	Union waters of subdivision 32 (SAL/3D32.)
Estonia	995 ⁽¹⁾		
Finland	8 708 ⁽¹⁾		
Union	9 703 ⁽¹⁾		
TAC	Not relevant		Precautionary TAC

⁽¹⁾ Expressed by number of individual fish.

Species:	Sprat <i>Sprattus sprattus</i>	Zone:	Union waters of subdivisions 22-32 (SPR/3BCD-C)
Denmark	26 710		
Germany	16 921		
Estonia	31 016		
Finland	13 982		
Latvia	37 460		
Lithuania	13 551		
Poland	79 497		
Sweden	51 635		
Union	270 772		
TAC	Not relevant		Analytical TAC Article 6 of this Regulation shall apply.

COMMISSION DELEGATED REGULATION (EU) 2018/1629**of 25 July 2018****amending the list of diseases set out in Annex II to Regulation (EU) 2016/429 of the European Parliament and of the Council on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ⁽¹⁾, and in particular Article 5(2) and (4) thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down rules for the prevention and control of animal diseases which are transmissible to animals or to humans, including rules for the prioritisation and categorisation of diseases of Union concern. Article 5 of Regulation (EU) 2016/429 provides that disease-specific rules for the prevention and control of diseases apply to the diseases listed in that Article and in Annex II to that Regulation. In addition, Article 5(3) of that Regulation lays down certain criteria to be taken into account in amending the list in that Annex, while the assessment parameters to be used in order to determine whether a disease meets the conditions requiring it to be listed in accordance with that Article are laid down in Article 7 of that Regulation.
- (2) In addition, Article 275 of Regulation (EU) 2016/429 provides that the Commission is to review the list of diseases set out in Annex II to that Regulation by 20 April 2019 at the latest.
- (3) The Commission systematically assessed the animal diseases which require Union intervention with the assistance of the European Food Safety Authority (EFSA), drawing on the scientific expertise provided by the EU Animal Health Reference Laboratories and the international standards of the World Organisation for Animal Health (OIE). For the purposes of that assessment, it used the criteria laid down in Article 5(3) of Regulation (EU) 2016/429 and the assessment parameters laid down in Article 7 of that Regulation.
- (4) The assessed diseases consist of 39 diseases that are currently listed in Annex II to Regulation (EU) 2016/429, as well as another 19 diseases of special relevance for disease prevention, control or trade measures, such as enzootic bovine leukosis, infectious bovine rhinotracheitis or infection with Aujeszky's disease virus, and certain other diseases which have been listed by the OIE, such as surra (*Trypanosoma evansi*) or contagious caprine pleuropneumonia.
- (5) For the purposes of the assessments, 29 scientific opinions were requested from EFSA on different animal diseases. In providing them, EFSA followed the method set out in its Scientific Opinion adopted on 5 April 2017 on ad hoc method for the assessment on listing and categorisation of animal diseases within the framework of the Animal Health Law ⁽²⁾. For the remaining diseases, the assessments were based on recent EFSA opinions or on information provided by the EU Animal Health Reference Laboratories. As regards all assessed diseases, the relevant OIE standards were considered.
- (6) The results of the scientific assessments by EFSA were inconclusive for certain diseases such as surra (*Trypanosoma evansi*) ⁽³⁾, enzootic bovine leukosis ⁽⁴⁾, Venezuelan equine encephalomyelitis ⁽⁵⁾, infestation with *Varroa* spp. (Varroosis) ⁽⁶⁾ and Koi herpes virus disease ⁽⁷⁾. Taking into account the discussions held at the meetings of the expert group on animal health ⁽⁸⁾, those five diseases fulfil the requirements laid down in Article 5(3) of Regulation (EU) 2016/429. Therefore those diseases should be included in the list set out in Annex II to that Regulation.
- (7) The results of the scientific assessments carried out showed that swine vesicular disease ⁽⁹⁾, vesicular stomatitis ⁽⁹⁾, epizootic ulcerative syndrome ⁽¹⁰⁾ and Teschen disease do not fulfil the requirements laid down in Article 5(3) of Regulation (EU) 2016/429. Therefore, those diseases should be removed from the list set out in Annex II to that Regulation.

- (8) At the same time, surra (*Trypanosoma evansi*)⁽¹⁾, Ebola virus disease⁽¹¹⁾, paratuberculosis⁽¹²⁾, Japanese encephalitis⁽¹³⁾, West Nile fever⁽¹⁴⁾, Q fever⁽¹⁵⁾, infectious bovine rhinotracheitis/infectious pustular vulvovaginitis⁽¹⁶⁾, bovine viral diarrhoea⁽¹⁷⁾, bovine genital campylobacteriosis⁽¹⁸⁾, trichomonosis⁽¹⁹⁾, enzootic bovine leukosis⁽⁴⁾, contagious caprine pleuropneumonia⁽²⁰⁾, ovine epididymitis (*Brucella ovis*)⁽²¹⁾, infection with *Burkholderia mallei* (Glanders), infection with equine arteritis virus, equine infectious anaemia, dourine, contagious equine metritis, equine encephalomyelitis (Eastern and Western)⁽²²⁾, infection with Aujeszky's disease virus⁽²³⁾, infection with porcine reproductive and respiratory syndrome virus⁽²⁴⁾, avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*)⁽²⁵⁾, infection with low pathogenic avian influenza viruses⁽²⁶⁾, avian chlamydiosis⁽²⁷⁾, infestation with *Varroa* spp. (Varroosis)⁽⁶⁾, infestation with *Aethina tumida* (Small hive beetle)⁽²⁸⁾, American foulbrood, infestation with *Tropilaelaps* spp⁽²⁸⁾ and infection with *Batrachochytrium salamandrivorans*⁽²⁹⁾ do fulfil the requirements laid down in Article 5(3) of Regulation (EU) 2016/429. Therefore those diseases should be included in the list set out in Annex II to that Regulation.
- (9) In addition, Article 2(2) of Regulation (EU) 2016/429 provides that that Regulation is to apply to transmissible diseases, including zoonosis, without prejudice to rules laid down in Decision No 1082/2013/EU of the European Parliament and of the Council⁽³⁰⁾, Regulation (EC) No 999/2001 of the European Parliament and of the Council⁽³¹⁾, Directive 2003/99/EC of the European Parliament and of the Council⁽³²⁾ and Regulation (EC) No 2160/2003 of the European Parliament and of the Council⁽³³⁾. As the diseases covered by the rules laid down in those acts, namely listeriosis, salmonellosis (zoonotic salmonella), trichinellosis, verotoxigenic *E. coli* and transmissible spongiform encephalopathies (TSE) are already covered by sector-specific rules, they should therefore be removed from the list set out in Annex II to Regulation (EU) 2016/429.
- (10) The list of diseases in Annex II to Regulation (EU) 2016/429 should therefore be amended accordingly.
- (11) Regulation (EU) 2016/429 should therefore be amended.
- (12) As Regulation (EU) 2016/429 applies with effect from 21 April 2021, the amendments made to it by this Regulation should also apply from that date,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EU) 2016/429 is replaced by the text set out in the Annex to this Regulation.

Article 2

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

It shall apply from 21 April 2021.

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

Done at Brussels, 25 July 2018.

For the Commission
The President
Jean-Claude JUNCKER

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ EFSA Journal 2017;15(7):4783.

⁽³⁾ EFSA Journal 2017;15(7):4892.

⁽⁴⁾ EFSA Journal 2017;15(8):4956.

⁽⁵⁾ EFSA Journal 2017;15(8):4950.

⁽⁶⁾ EFSA Journal 2017;15(10):4997.

⁽⁷⁾ EFSA Journal 2017;15(7):4907.

⁽⁸⁾ https://ec.europa.eu/food/animals/health/expert_group_en

⁽⁹⁾ EFSA Journal 2012;10(4):2631.

- ⁽¹⁰⁾ EFSA Journal 2011;9(10):2387.
- ⁽¹¹⁾ EFSA Journal 2017;15(7):4890.
- ⁽¹²⁾ EFSA Journal 2017;15(7):4960.
- ⁽¹³⁾ EFSA Journal 2017;15(7):4948.
- ⁽¹⁴⁾ EFSA Journal 2017;15(8):4955.
- ⁽¹⁵⁾ EFSA Journal 2010; 8(5):1595.
- ⁽¹⁶⁾ EFSA Journal 2017;15(7):4947.
- ⁽¹⁷⁾ EFSA Journal 2017;15(8):4952.
- ⁽¹⁸⁾ EFSA Journal 2017;15(10):4990.
- ⁽¹⁹⁾ EFSA Journal 2017;15(10):4992.
- ⁽²⁰⁾ EFSA Journal 2017;15(10):4996.
- ⁽²¹⁾ EFSA Journal 2017;15(10):4994.
- ⁽²²⁾ EFSA Journal 2017;15(7):4946.
- ⁽²³⁾ EFSA Journal 2017;15(7):4888.
- ⁽²⁴⁾ EFSA Journal 2017;15(7):4949.
- ⁽²⁵⁾ EFSA Journal 2017;15(8):4953.
- ⁽²⁶⁾ EFSA Journal 2017;15(7):4891.
- ⁽²⁷⁾ Report of the Scientific Committee on Animal Health and Animal Welfare adopted on 16 April 2002, https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scah_out73_en.pdf
- ⁽²⁸⁾ EFSA Journal 2013;11(3):3128.
- ⁽²⁹⁾ EFSA Journal 2017;15(11):5071.
- ⁽³⁰⁾ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).
- ⁽³¹⁾ Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).
- ⁽³²⁾ Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (OJ L 325, 12.12.2003, p. 31).
- ⁽³³⁾ Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents (OJ L 325, 12.12.2003, p. 1).
-

ANNEX

'ANNEX II

LIST OF ANIMAL DISEASES

- Infection with rinderpest virus
- Infection with Rift Valley fever virus
- Infection with *Brucella abortus*, *B. melitensis* and *B. suis*
- Infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*)
- Infection with rabies virus
- Infection with bluetongue virus (serotypes 1-24)
- Infestation with *Echinococcus multilocularis*
- Infection with epizootic haemorrhagic disease virus
- Anthrax
- Surra (*Trypanosoma evansi*)
- Ebola virus disease
- Paratuberculosis
- Japanese encephalitis
- West Nile fever
- Q fever
- Infection with lumpy skin disease virus
- Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia)
- Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- Bovine viral diarrhoea
- Bovine genital campylobacteriosis
- Trichomonosis
- Enzootic bovine leukosis
- Sheep pox and goat pox
- Infection with peste des petits ruminants virus
- Contagious caprine pleuropneumonia
- Ovine epididymitis (*Brucella ovis*)
- Infection with *Burkholderia mallei* (Glanders)
- Infection with equine arteritis virus
- Equine infectious anaemia
- Dourine
- Venezuelan equine encephalomyelitis
- Contagious equine metritis
- Equine encephalomyelitis (Eastern and Western)
- Infection with Aujeszky's disease virus
- Infection with porcine reproductive and respiratory syndrome virus
- Infection with Newcastle disease virus
- Avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*)
- Infection with *Salmonella Pullorum*, *S. Gallinarum* and *S. arizonae*

- Infection with low pathogenic avian influenza viruses
 - Avian chlamydiosis
 - Infestation with *Varroa* spp. (Varroosis)
 - Infestation with *Aethina tumida* (Small hive beetle)
 - American foulbrood
 - Infestation with *Tropilaelaps* spp.
 - Infection with *Batrachochytrium salamandrivorans*
 - Epizootic haematopoietic necrosis
 - Viral haemorrhagic septicaemia
 - Infectious haematopoietic necrosis
 - Infection with highly polymorphic region (HPR) deleted infectious salmon anaemia virus
 - Koi herpes virus disease
 - Infection with *Mikrocytos mackini*
 - Infection with *Perkinsus marinus*
 - Infection with *Bonamia ostreae*
 - Infection with *Bonamia exitiosa*
 - Infection with *Marteilia refringens*
 - Infection with Taura syndrome virus
 - Infection with yellow head virus
 - Infection with white spot syndrome virus'
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COMMISSION IMPLEMENTING REGULATION (EU) 2018/1630**of 24 October 2018****entering a name in the register of protected designations of origin and protected geographical indications ('Lička janjetina' (PGI))**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Croatia's application to register the name 'Lička janjetina' was published in the *Official Journal of the European Union* ⁽²⁾.
- (2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Lička janjetina' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name 'Lička janjetina' (PGI) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 1.1. — Fresh meat (and offal), as listed in Annex XI to Commission Implementing Regulation (EU) No 668/2014 ⁽³⁾.*Article 2*This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 24 October 2018.

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

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

⁽²⁾ OJ C 153, 2.5.2018, p. 11.

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

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1631**of 30 October 2018****authorising the placing on the market of cranberry extract powder as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 12 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ was adopted, which establishes a Union list of authorised novel foods.
- (3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a novel food and on updating the Union list.
- (4) On 20 September 2011, the company Ocean Spray Cranberries Inc. ('the Applicant') made a request to the competent authority of France to place cranberry extract powder on the Union market as a novel food within the meaning of point (c) of Article 1(2) of Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽³⁾. The application requested for cranberry extract powder to be used in fruit-flavoured beverages, isotonic beverages, tea beverages, vitamin enhanced waters, yogurts and yogurt drinks.
- (5) On 11 December 2014, the competent authority of France issued its initial assessment report. In that report it came to the conclusion that cranberry extract powder meets the criteria for novel food ingredients set out in Article 3(1) of Regulation (EC) No 258/97. In the same report, the competent authority of France also expressed concerns regarding possible nutritional risks associated with the overconsumption of polyphenols for children between one and three years of age resulting from the intake of polyphenols from the novel food, and from other sources of polyphenols in children's diet.
- (6) On 16 January 2015, the Commission forwarded the initial assessment report to the other Member States. Reasoned objections were raised by the other Member States within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97 with regard to insufficient data excluding the risk for young children aged between one and three years, incomplete specification of the novel food, and lack of information on the protein content needed to exclude allergy risk.
- (7) In view of the initial assessment report issued by the competent authority of France and the objections raised by some Member States, the Commission consulted the European Food Safety Authority ('the Authority') on 20 April 2016, asking it to carry out an additional assessment for cranberry extract powder as a novel food in accordance with Regulation (EC) No 258/97.
- (8) In contacts with the Authority the Applicant has declared that the novel food is not intended to be marketed to infants, toddlers and children of below 19 years of age.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

⁽³⁾ Regulation (EC) No 258/97 of the European Parliament and of the Council concerning novel foods and novel foods ingredients (OJ L 43, 14.2.1997, p. 1).

- (9) On 4 April 2017, the Authority adopted a ‘Scientific Opinion on the safety of cranberry extract powder as a novel food ingredient pursuant to Regulation (EC) No 258/97’ in which it concluded that cranberry extract is safe for the uses communicated by the Applicant ⁽¹⁾. That opinion, although elaborated and adopted by the Authority under Regulation (EC) No 258/97, is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (10) On 7 June 2017 the Commission informed the applicant of its and certain Member States’ positions that, in view of the risk that infants, toddlers and children of below 19 years of age could consume the intended products, an authorisation would require an additional safety evaluation for these age groups. Alternatively, the Commission suggested that the risk of consumption by the age groups for which the Authority had not concluded on safety could be sufficiently contained, if cranberry extract would be authorised as a novel food supplement for the adult population. ⁽²⁾
- (11) On 22 December 2017, the Applicant informed the Commission of its decision to, at this stage, pursue the authorisation of cranberry extract for use in food supplements for the general adult population, without prejudice to a subsequent further application for an extension of the conditions of use based on a further safety assessment by the Authority.
- (12) Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 and for which the final decision has not been taken before 1 January 2018 shall be treated as an application submitted under Regulation (EU) 2015/2283. The application also meets the requirements laid down in Regulation (EU) 2015/2283.
- (13) The opinion of the Authority gives sufficient grounds to establish that cranberry extract powder, when used in food supplements for general adult population, complies with Article 12(1) of Regulation (EU) 2015/2283.
- (14) On 2 May 2018, the applicant made a request to the Commission for protection of proprietary data for three studies submitted in support of the application namely, a ten-week clinical study in healthy adults ⁽³⁾, a twelve-week clinical study in adults with low to moderate cardiovascular disease risk ⁽⁴⁾ and a report on the influence on systemic immune functions, urinary and systemic biomarkers of health and faecal characteristics of human subjects during a 10 weeks administration ⁽⁵⁾. The applicant also made a request to the Commission for protection of proprietary data for consumption information of their cranberry juice cocktail product in Europe, as well as consumption information relating to children ⁽⁶⁾. A request to the Commission for protection of proprietary data was also made for the compositional data ⁽⁷⁾ and the intake estimate on cranberry beverage consumption ⁽⁸⁾.
- (15) On 27 June 2018, the Authority considered ⁽⁹⁾ that in elaborating its opinion on cranberry extract powder as a novel food, the compositional information (Table IX.b-1, original application, dated June 2011, page 24) and the intake estimate on cranberry beverage consumption (File: ‘Ocean Spray’s response to Member States’ objections’, dated November 2015) were needed for the characterisation and setting of specifications of the novel food, as well as for hazard identification, and for the assessment whether the potential intake of proanthocyanidins (PAC) from the novel food is comparable to the PAC intake from the consumption of cranberry juice products. Therefore, it is considered that the conclusions on the safety of cranberry extract powder could not have been reached without the aforementioned data.
- (16) Following the receipt of the Authority’s opinion, the Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over the data, and their claim to an exclusive right of reference to that data, as referred to in points (a) and (b) of Article 26(2) of Regulation (EU) 2015/2283.

⁽¹⁾ EFSA Journal 2017; 15(5):4777.

⁽²⁾ Food supplements are subject to specific labelling and marketing requirements pursuant to Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

⁽³⁾ Nantz et al., unpublished manuscript.

⁽⁴⁾ Juturu et al., unpublished manuscript.

⁽⁵⁾ Unpublished Report.

⁽⁶⁾ Original application, dated June 2011.

⁽⁷⁾ Table IX.b-1, Original application, dated June 2011, page 24.

⁽⁸⁾ Ocean Spray’s response to Member States’ objections, dated November 2015.

⁽⁹⁾ EFSA Scientific Panel on Dietetic Products, Nutrition and Allergies, Minutes of XXX. Plenary held on 28-29 June 2018.

- (17) The applicant declared that, at the time the application was submitted, it held proprietary and exclusive rights of reference to the evidence and data under national law and that therefore third parties could not lawfully access or use that scientific evidence or scientific data. The Commission assessed all the information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283.
- (18) Accordingly, as provided for under Article 26(2) of Regulation (EU) 2015/2283, the compositional data and the intake estimate contained in the applicant's file and without which the novel food could not have been assessed by the Authority should not be used by for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation. As a consequence, the placing on the market within the Union of the novel food authorised by this Regulation should be restricted to the applicant for a period of five years.
- (19) However, restricting the authorisation of this novel food and of the reference to the scientific evidence or scientific data contained in the applicant's file for the sole use of the applicant does not prevent other applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting the authorisation under this Regulation.
- (20) Directive 2002/46/EC lays down requirements on food supplements. The use of cranberry extract powder should be authorised without prejudice to the requirements of that Directive.
- (21) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

1. Cranberry extract powder as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.
2. For a period of five years from the date of entry into force of this Regulation only the Applicant:
 - Company: Ocean Spray Cranberries Inc.
 - Address: One Ocean Spray Drive Lakeville-Middleboro, MA, 02349, USA;is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for the same novel food without reference to the data protected pursuant to Article 2 of this Regulation or with the agreement of Ocean Spray Cranberries Inc.
3. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.
4. The authorisation provided for in this Article shall be without prejudice to the provisions of Directive 2002/46/EC.

Article 2

The data contained in the application file on the basis of which the novel food referred to in Article 1 has been assessed by the Authority, claimed by the applicant as fulfilling the requirements laid down in Article 26(2) of Regulation (EC) No 2015/2283, shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of Ocean Spray Cranberries Inc.

Article 3

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 4

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, 30 October 2018.

For the Commission
The President
Jean-Claude JUNCKER

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) The following last column is added in Table 1 (Authorised novel foods):

'Data protection'

(2) The following entry is inserted in Table 1 (Authorised novel foods) in alphabetical order:

'Authorised novel food'	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
	<i>Specified food category</i>	<i>Maximum levels</i>			
Cranberry extract powder	Food Supplements as defined in Directive 2002/46/EC for the adult population	350 mg/day	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'cranberry extract powder'		<p>Authorised on 20 November 2018. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.</p> <p>Applicant: Ocean Spray Cranberries Inc. One Ocean Spray Drive Lakeville-Middleboro, MA, 02349, USA.</p> <p>During the period of data protection the novel food, cranberry extract powder, is authorised for placing on the market within the Union only by Ocean Spray Cranberries Inc. unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Ocean Spray Cranberries Inc.</p> <p>End date of the data protection: 20 November 2023.'</p>

(3) The following entry is inserted in Table 2 (Specifications) in alphabetical order:

'Authorised Novel Food'	Specification
Cranberry extract powder	<p>Description/Definition:</p> <p>Cranberry extract powder is a water-soluble phenolic-rich powder extract prepared through an ethanolic extraction from the juice concentrate of sound, mature berries of the cranberry cultivar <i>Vaccinium macrocarpon</i>.</p> <p>Characteristics/Composition</p> <p>Moisture (% w/w): ≤ 4</p> <p>Proanthocyanidins — PACs (% w/w dry weight)</p> <p>— OSC-DMAC method ⁽¹⁾ ⁽²⁾: 55.0-60.0 or</p> <p>— BL-DMAC method ⁽²⁾ ⁽³⁾: 15.0-18.0</p>

Authorised Novel Food	Specification
	<p>Total phenolics (GAE ⁽⁴⁾, % w/w dry weight) ⁽³⁾ — Folin-Ciocalteu method: > 46.2</p> <p>Solubility (water): 100 %, with no visible insoluble particles</p> <p>Ethanol Content (mg/kg): ≤ 100</p> <p>Screen Analysis: 100 % through 30 mesh screen</p> <p>Appearance and aroma, as powder: Free-flowing, deep red colour. Earthy aroma with no burnt character.</p> <p>Heavy metals:</p> <p>Arsenic (ppm): < 3</p> <p>Microbiological criteria:</p> <p>Yeast: < 100 CFU ⁽⁵⁾/g</p> <p>Mould: < 100 CFU/g</p> <p>Aerobic plate count: < 1 000 CFU/g</p> <p>Coliforms: < 10 CFU/g</p> <p><i>Escherichia coli</i>: < 10 CFU/g</p> <p><i>Salmonella</i>: Absent in 375 g</p>
<p>⁽¹⁾ OSC-DMAC (4-dimethylaminocinnamaldehyde) method (Ocean Spray Cranberries, Inc) Martin MA, Ramos S, Mateos R, Marais JJP, Bravo-Clemente, L, Khoo C and Goya L. Food Res Intl 2015 71: 68-82. Modified from Cunningham DG, Vannozzi S, O'Shea E, Turk R (2002) In: Ho C-T, Zheng QY (eds) Quality Management of Nutraceuticals ACS Symposium series 803, Washington DC. <i>Quantitation of PACs by DMAC Color Reaction</i> pp 151-166.</p> <p>⁽²⁾ BL-DMAC 4-dimethylaminocinnamaldehyde) method (Brunswick Lab) Multi-laboratory validation of a standard method for quantifying proanthocyanidins in cranberry powders. Prior RL, Fan E, Ji H, Howell A, Nio C, Payne MJ, Reed J. <i>J Sci Food Agric</i>. 2010 Jul;90(9):1473-8.</p> <p>⁽³⁾ The different values for these three parameters are due to the different methods used.</p> <p>⁽⁴⁾ GAE: Gallic Acid Equivalents</p> <p>⁽⁵⁾ CFU: Colony Forming Units'</p>	

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1632**of 30 October 2018****authorising the placing on the market of bovine milk basic whey protein isolate as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 12 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ establishing a Union list of authorised novel foods was adopted.
- (3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a novel food and on updating the Union list.
- (4) On 22 August 2016, the company Armor Protéines S.A.S. ('the Applicant') made a request to the competent authority of Ireland to place bovine milk basic whey protein isolate obtained from skimmed bovine milk through a series of purification steps, on the Union market as a novel food ingredient within the meaning of point (e) of Article 1(2) of Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽³⁾. The application seeks to have bovine milk basic whey protein isolate used in infant and follow-on formulae, in total diet replacement foods for weight control and in foods for special medical purposes, and in food supplements.
- (5) Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, and for which the final decision has not been taken before 1 January 2018 shall be treated as an application submitted under Regulation (EU) 2015/2283.
- (6) While the request for placing bovine milk basic whey protein isolate on the market as a novel food within the Union was submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97, the application also meets the requirements laid down in Regulation (EU) 2015/2283.
- (7) On 27 June 2017, the competent authority of Ireland issued its initial assessment report. In that report, it concluded that bovine milk basic whey protein isolate meets the criteria for a novel food ingredient set out in Article 3(1) of Regulation (EC) No 258/97.
- (8) On 4 July 2017, the Commission forwarded the initial assessment report to the other Member States. Reasoned objections were raised by other Member States within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97 with regard to the safety of bovine milk basic whey protein isolate for infants, and the toxicological relevance of the results in a 6-week developmental toxicity study in juvenile rats ⁽⁴⁾.
- (9) In view of the objections raised by the other Member States, the Commission consulted the European Food Safety Authority ('the Authority') on 11 December 2017, asking it to carry out an additional assessment for bovine milk basic whey protein isolate as a novel food ingredient in accordance with Regulation (EC) No 258/97.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, (OJ L 351, 30.12.2017, p. 72).

⁽³⁾ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, (OJ L 43, 14.2.1997, p. 1).

⁽⁴⁾ Spézia (2012).

- (10) In a subsequent application submitted on 3 January 2018, the Applicant made a request to the Commission for protection of proprietary data for a number of studies submitted in support of the application, namely two human clinical studies with a bovine milk basic whey protein isolate ⁽¹⁾ ⁽²⁾, an *in vitro* bacterial reverse mutation assay ⁽³⁾, an *in vitro* mammalian cell micronucleus test ⁽⁴⁾, a 90-day oral toxicity study in rats ⁽⁵⁾, a 6-week developmental toxicity study in juvenile rats, and the electrophoresis analysis of bovine milk basic whey protein isolate ⁽⁶⁾.
- (11) On 27 June 2018, the Authority adopted ‘Scientific Opinion on the safety of bovine milk basic whey protein isolate as a novel food pursuant to Regulation (EU) 2015/2283’ ⁽⁷⁾. That opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (12) That opinion gives sufficient grounds to establish that bovine milk basic whey protein isolate, in the proposed uses and use levels when used as an ingredient in infant and follow-on formulae, in total diet replacement foods for weight control, in foods for special medical purposes, and in food supplements, complies with Article 12(1) of Regulation (EU) 2015/2283.
- (13) In its opinion on bovine milk basic whey protein isolate, the Authority considered that the data from the 90-day oral toxicity study in rats served as a basis to establish a reference point and to assess whether the margin of exposure in relation to the proposed maximum intake of the novel food by humans is sufficient. Therefore, it is considered that the conclusions on the safety of bovine milk basic whey protein isolate could not have been reached without the data from the report of this study.
- (14) Following receipt of the Authority’s opinion, the Commission requested the Applicant to further clarify the justification provided with regard to their proprietary claim over the 90-day oral toxicity in rats study report, and to clarify their claim to an exclusive right of reference to this study, as referred to in points (a) and (b) of Article 26(2) of Regulation (EU) 2015/2283.
- (15) The Applicant also declared to hold proprietary and exclusive rights of reference to the study under national law at the time the application was submitted, and that therefore third parties could not lawfully access or use this study. The Commission has assessed all the information provided by the Applicant and considers that the Applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283.
- (16) Accordingly, as provided for under Article 26(2) of Regulation (EU) 2015/2283, the 90-day oral toxicity study in rats contained in the Applicant’s file, and without which the novel food could not have been assessed by the Authority, should not be used by the Authority for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation. As a consequence, the placing on the market within the Union of the novel food authorised by this Regulation should be restricted to the Applicant for a period of five years.
- (17) However, restricting the authorisation of this novel food and of the reference to the 90-day oral toxicity study in rats contained in the Applicant’s file for the sole use of the Applicant does not prevent other applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting the authorisation under this Regulation.
- (18) As the source of the novel food comes from milk, which is listed in Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council ⁽⁸⁾ as one of a number of substances or products which cause allergies or intolerances, foods and food supplements containing bovine milk basic whey protein isolate should be appropriately labelled following the requirements of Article 21 of that Regulation.

⁽¹⁾ Armor Protéines (2013).

⁽²⁾ Schmitt & Mireaux (2008).

⁽³⁾ Sire, G. (2012a).

⁽⁴⁾ Sire, G. (2012b).

⁽⁵⁾ Silvano (2012).

⁽⁶⁾ Armor Protéines (2017).

⁽⁷⁾ EFSA Journal 2018; 16(7):5360.

⁽⁸⁾ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

- (19) Directive 2002/46/EC of the European Parliament and of the Council ⁽¹⁾ lays down requirements on food supplements. The use of bovine milk basic whey protein isolate should be authorised without prejudice to that Directive.
- (20) Regulation (EU) No 609/2013 of the European Parliament and of the Council ⁽²⁾ lays down requirements on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. The use of bovine milk basic whey protein isolate should be authorised without prejudice to that Regulation.
- (21) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

1. Bovine milk basic whey protein isolate as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.
2. For a period of five years from the date of entry into force of this Regulation only the initial Applicant:
 - Company: Armor Protéines S.A.S.
 - Address: Armor Protéines S.A.S., 19 bis, rue de la Libération 35460 Saint-Brice-en-Coglès, France;is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for the novel food without reference to the data protected pursuant to Article 2 of this Regulation or with the agreement of Armor Protéines S.A.S.
3. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.
4. The authorisation provided for in this Article shall be without prejudice to the provisions of Regulation (EU) No 1169/2011, to the provisions of Directive 2002/46/EC, and to the provisions of Regulation (EU) No 609/2013.

Article 2

The study contained in the application file on the basis of which the novel food referred to in Article 1 has been assessed by the Authority, claimed by the Applicant as fulfilling the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283, shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of Armor Protéines S.A.S.

Article 3

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 4

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

⁽¹⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, (OJ L 183, 12.7.2002, p. 51).

⁽²⁾ Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009, (OJ L 181, 29.6.2013, p. 35).

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

Done at Brussels, 30 October 2018.

For the Commission
The President
Jean-Claude JUNCKER

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) the following last column is added in Table 1 (Authorised novel foods):

'Data Protection'

(2) the following entry is inserted in Table 1 (Authorised novel foods) in alphabetical order:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
	<i>Specified food category</i>	<i>Maximum levels</i>			
'Bovine milk basic whey protein isolate	Infant formulae as defined in Regulation (EU) No 609/2013	30 mg/100 g (powder) 3,9 mg/100 mL (reconstituted)	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Milk whey protein isolate". Food supplements containing bovine milk basic whey protein isolate shall bear the following statement: "This food supplement should not be consumed by children/adolescents under the age of three/eighteen (*) years" (*) Depending on the age group the food supplement is intended for.		Authorised on 20 November 2018. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Armor Protéines S.A.S., 19 bis, rue de la Libération 35460 Saint-Brice-en-Coglès, France. During the period of data protection the novel food bovine milk basic whey protein isolate is authorised for placing on the market within the Union only by Armor Protéines S.A.S. unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Armor Protéines S.A.S.. End date of the data protection: 20 November 2023.'
	Follow-on formulae as defined in Regulation (EU) No 609/2013	30 mg/100 g (powder) 4,2 mg/100 mL (reconstituted)			
	Total diet replacement foods for weight control as defined by Regulation (EU) No 609/2013	300 mg/day			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	58 mg/day for young children 380 mg/day for children and adolescents from 3 to 18 years of age 610 mg/day for adults			
	Food Supplements as defined in Directive 2002/46/EC	58 mg/day for young children 250 mg/day for children and adolescents from 3 to 18 years of age 610 mg/day for adults			

(3) the following entry is inserted in Table 2 (Specifications) in alphabetical order:

Authorised Novel Food	Specification
Bovine milk basic whey protein isolate	<p>Description Bovine milk basic whey protein isolate is a yellowish grey powder obtained from bovine skimmed milk via a series of isolation and purification steps.</p> <p>Characteristics/Composition Total protein (w/weight of product): ≥ 90 % Lactoferrin (w/weight of product): 25-75 % Lactoperoxidase (w/weight of product): 10-40 % Other proteins (w/weight of product): ≤ 30 % TGF-β2: 12-18 mg/100 g Moisture: ≤ 6,0 % pH (5 % solution w/v): 5,5 – 7,6 Lactose: ≤ 3,0 % Fat: ≤ 4,5 % Ash: ≤ 3,5 % Iron: ≤ 25 mg/100 g</p> <p>Heavy Metals Lead: < 0,1 mg/kg Cadmium: < 0,2 mg/kg Mercury: < 0,6 mg/kg Arsenic: < 0,1 mg/kg</p> <p>Microbiological criteria: Aerobic mesophilic count: ≤ 10 000 CFU/g <i>Enterobacteriaceae</i>: ≤ 10 CFU/g <i>Escherichia coli</i>: Negative/g Coagulase positive <i>Staphylococci</i>: Negative/g <i>Salmonella</i>: Negative/25 g <i>Listeria</i>: Negative/25 g <i>Cronobacter</i> spp.: Negative/25 g Moulds: ≤ 50 CFU/g Yeasts: ≤ 50 CFU/g CFU: Colony Forming Units'</p>

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1633**of 30 October 2018****authorising the placing on the market of refined shrimp peptide concentrate as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 12 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ establishing a Union list of authorised novel foods was adopted.
- (3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a novel food and on updating the Union list.
- (4) On 22 December 2016, the company Marealis AS ('the Applicant') made a request to the competent authority of Finland to place refined shrimp peptide concentrate produced from the enzymatic hydrolysis of Northern shrimp (*Pandalus borealis*) shells and heads, on the Union market as a novel food ingredient within the meaning of point (e) of Article 1(2) of Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽³⁾. The application seeks to have refined shrimp peptide concentrate used in food supplements for the general adult population.
- (5) Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, and for which the final decision has not been taken before 1 January 2018 shall be treated as an application submitted under Regulation (EU) 2015/2283.
- (6) While the request for placing refined shrimp peptide concentrate on the market as a novel food within the Union was submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97, the application also meets the requirements laid down in Regulation (EU) 2015/2283.
- (7) On 8 March 2017, the competent authority of Finland issued its initial assessment report. In that report, it concluded that refined shrimp peptide concentrate meets the criteria for a novel food ingredient set out in Article 3(1) of Regulation (EC) No 258/97.
- (8) On 13 March 2017, the Commission forwarded the initial assessment report to the other Member States. Reasoned objections were raised by other Member States within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97 with regard to the safety of refined shrimp peptide concentrate for hypo-, normo-, and hyper-tensive consumers due to its putative antihypertensive effects, its potential side effects related to its postulated inhibition of the angiotensin converting enzyme (ACE) and potential cardiac effects, and its potential interactions with medicines used in the treatment of blood pressure disorders.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

⁽³⁾ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

- (9) In view of the objections raised by the other Member States, the Commission consulted the European Food Safety Authority ('the Authority') on 21 September 2017, asking it to carry out an additional assessment for refined shrimp peptide concentrate as novel food ingredient in accordance with Regulation (EC) No 258/97.
- (10) On 2 February 2018, the Applicant made a request to the Commission for the protection of proprietary data for a number of studies submitted in support of the application namely, a *de novo* peptide synthesis study ⁽¹⁾, the analytical report of the ACE inhibitory effects study ⁽²⁾, an acute oral toxicity study ⁽³⁾, an *in vitro* bacterial reverse mutation assay ⁽⁴⁾, a 90-day oral toxicity study ⁽⁵⁾, an assessment study of the antihypertensive effects and safety of the refined shrimp peptide concentrate in healthy humans with mild or moderate hypertension ⁽⁶⁾, and a double-blind, placebo-controlled, parallel study on the assessment of anti-hypertensive effect and safety of a the refined shrimp peptide concentrate in dietary supplements in healthy humans with mild or moderate hypertension ⁽⁷⁾. This request was reiterated by the Applicant in a subsequent application submitted on 29 March 2018.
- (11) On 18 April 2018, the Authority adopted 'Scientific Opinion on the safety of shrimp peptide concentrate as a novel food pursuant to Regulation (EU) 2015/2283' ⁽⁸⁾. That opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (12) That opinion gives sufficient grounds to establish that refined shrimp peptide concentrate, in the proposed uses and use levels when used as an ingredient in food supplements, complies with Article 12(1) of Regulation (EU) 2015/2283.
- (13) In its opinion, the Authority considered that the data from the 90-day oral toxicity study served as a basis to assess the toxicity profile of refined shrimp peptide concentrate and to establish the related No Observed Adverse Effect Level (NOAEL). The data from the assessment study of the antihypertensive effects and safety of the refined shrimp peptide concentrate in healthy humans with mild or moderate hypertension, and the data from the double-blind, placebo-controlled, parallel study on the assessment of anti-hypertensive effect and safety of a the refined shrimp peptide concentrate dietary supplement in healthy humans with mild or moderate hypertension, served as the basis to establish the safety of the novel food for this category of consumers. Therefore, it is considered that the conclusions on the safety of refined shrimp peptide concentrate, could not have been reached without the data from the unpublished reports of these studies.
- (14) Following receipt of the Authority's opinion, the Commission requested the Applicant to further clarify the justification provided with regard to their proprietary claim over the study reports, and to clarify their claim to an exclusive right of reference to those studies, as referred to in points (a) and (b) of Article 26(2) of Regulation (EU) 2015/2283. The Applicant also declared to hold proprietary and exclusive rights of reference to the studies under national law at the time the application was submitted, and that therefore third parties could not lawfully access or use those studies. The Commission has assessed all the information provided by the Applicant and considers that the Applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283.
- (15) Accordingly, as provided for under Article 26(2) of Regulation (EU) 2015/2283, the 90-day oral toxicity study, the assessment study of the antihypertensive effects and safety of the refined shrimp peptide concentrate in healthy humans with mild or moderate hypertension, and the double-blind, placebo-controlled, parallel study on the assessment of anti-hypertensive effect and safety of a the refined shrimp peptide concentrate dietary supplement in healthy humans with mild or moderate hypertension, contained in the Applicant's file and without which the novel food could not have been assessed by the Authority, should not be used by the Authority for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation. As a consequence, the placing on the market within the Union of the novel food authorised by this Regulation should be restricted to the Applicant for a period of five years.
- (16) However, restricting the authorisation of this novel food and of the reference to the 90-day oral toxicity study, to the assessment study of the antihypertensive effects and safety of the refined shrimp peptide concentrate in healthy humans with mild or moderate hypertension, and to the double-blind, placebo-controlled, parallel study on the assessment of anti-hypertensive effect and safety of a the refined shrimp peptide concentrate dietary supplement in healthy humans with mild or moderate hypertension, contained in the Applicant's file for the sole

⁽¹⁾ Marealis A.S., 2016.

⁽²⁾ Marealis A.S., 2009-2016.

⁽³⁾ Marealis A.S., 2010.

⁽⁴⁾ Marealis A.S., 2011.

⁽⁵⁾ Marealis A.S., 2011.

⁽⁶⁾ Sarkkinen, E., et al. 2013.

⁽⁷⁾ Pelipyagina, T., 2016.

⁽⁸⁾ EFSA Journal 2018; 16(5):5267.

use of the Applicant does not prevent other applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting the authorisation under this Regulation.

- (17) As the source of the novel food comes from crustaceans, and may contain traces of fish, of other crustaceans, and of molluscs, which are listed in Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council ⁽¹⁾ as substances or products which cause allergies or intolerances, food supplements containing refined shrimp peptide concentrate should be appropriately labelled following the requirements of Article 21 of that Regulation.
- (18) Directive 2002/46/EC of the European Parliament and of the Council ⁽²⁾ lays down requirements on food supplements. The use of refined shrimp peptide concentrate should be authorised without prejudice to that Directive.
- (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:

Article 1

1. Refined shrimp peptide concentrate as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.
2. For a period of five years from the date of entry into force of this Regulation only the initial Applicant:
 - Company: Marealis AS;
 - Address: Stortorget 1, Kystens Hus, 2nd floor, N-9008 Tromsø Postal address: P.O. Box 1065, 9261 Tromsø, Norway;is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for the novel food without reference to the data protected pursuant to Article 2 of this Regulation or with the agreement of Marealis AS.
3. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation
4. The authorisation provided for in this Article shall be without prejudice to the provisions of Directive 2002/46/EC and to the provisions of Regulation (EU) No 1169/2011.

Article 2

The studies contained in the application file on the basis of which the novel food referred to in Article 1 has been assessed by the Authority, claimed by the Applicant as fulfilling the requirements laid down in Article 26(2) of Regulation (EC) No 2015/2283, shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of Marealis AS.

Article 3

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

⁽¹⁾ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

⁽²⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

Article 4

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, 30 October 2018.

For the Commission
The President
Jean-Claude JUNCKER

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

- (1) the following last column is added in Table 1 (Authorised novel foods):

'Data Protection'

- (2) The following entry is inserted in Table 1 (Authorised novel foods) in alphabetical order:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
'Refined shrimp peptide concentrate	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'refined shrimp peptide concentrate'.		Authorised on 20 November 2018. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Marealis AS., Stortorget 1, Kystens Hus, 2nd floor, N-9008 Tromsø Postal address: P.O. Box 1065, 9261 Tromsø, Norway. During the period of data protection the novel food refined shrimp peptide concentrate is authorised for placing on the market within the Union only by Marealis AS unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Marealis AS. End date of the data protection: 20 November 2023.'
	Food Supplements as defined in Directive 2002/46/EC for the adult population	1 200 mg/day			

- (3) The following entry is inserted in Table 2 (Specifications) in alphabetical order:

Authorised Novel Food	Specification
'Refined shrimp peptide concentrate	Description Refined shrimp peptide concentrate is a peptide mixture obtained from northern shrimp (<i>Pandalus borealis</i>) shells and heads via a series of purification steps following enzymatic proteolysis using a protease from <i>Bacillus licheniformis</i> and/or <i>Bacillus amyloliquefaciens</i> .

Authorised Novel Food	Specification
	<p>Characteristics/Composition</p> <p>Total Dry matter (%): ≥ 95,0 %</p> <p>Peptides (w/weight dry matter): ≥ 87,0 % of which peptides with molecular weight < 2 kDa: ≥ 99,9 %</p> <p>Fat (w/w): ≤ 1,0 %</p> <p>Carbohydrates (w/w): ≤ 1,0 %</p> <p>Ash (w/w): ≤ 15,0 %</p> <p>Calcium: ≤ 2,0 %</p> <p>Potassium: ≤ 0,15 %</p> <p>Sodium: ≤ 3,5 %</p> <p>Heavy Metals</p> <p>Arsenic (inorganic): ≤ 0,22 mg/kg</p> <p>Arsenic (organic): ≤ 51,0 mg/kg</p> <p>Cadmium: ≤ 0,09 mg/kg</p> <p>Lead: ≤ 0,18 mg/kg</p> <p>Total mercury: ≤ 0,03 mg/kg</p> <p>Microbiological criteria:</p> <p>Total viable cell count: ≤ 20 000 CFU/g</p> <p><i>Salmonella</i>: ND/25g</p> <p><i>Listeria monocytogenes</i>: ND/25g</p> <p><i>Escherichia coli</i>: ≤ 20 CFU/g</p> <p>Coagulase positive <i>Staphylococcus aureus</i>: ≤ 200 CFU/g</p> <p><i>Pseudomonas aeruginosa</i>: ND/25g</p> <p>Mould/yeast: ≤ 20 CFU/g</p> <p>CFU: Colony Forming Units</p> <p>ND: Not Detectable'</p>

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1634**of 30 October 2018****renewing the derogation from Council Regulation (EC) No 1967/2006 as regards the minimum distance from coast and the minimum sea depth for boat seines fishing for transparent goby (*Aphia minuta*) in certain territorial waters of Italy**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1967/2006 of 21 December 2006 concerning management measures for the sustainable exploitation of fishery resources in the Mediterranean Sea, amending Regulation (EEC) No 2847/93 and repealing Regulation (EC) No 1626/94 ⁽¹⁾, and in particular Article 13(5) thereof,

Whereas:

- (1) Article 13(1) of Regulation (EC) No 1967/2006 prohibits the use of towed gears within 3 nautical miles of the coast or within the 50 m isobaths where that depth is reached at a shorter distance from the coast.
- (2) At the request of a Member State, the Commission may allow a derogation from Article 13(1) of Regulation (EC) No 1967/2006, provided that a number of conditions set out in Article 13(5) and (9) are fulfilled.
- (3) A derogation from Article 13(1) of that Regulation for the use of boat seines by vessels fishing for transparent goby (*Aphia minuta*) in the territorial waters of the Geographical Sub-Area 9, as defined in Annex I to Regulation (EU) No 1343/2011 of the European Parliament and of the Council ⁽²⁾ was granted until 31 March 2014 by Commission Implementing Regulation (EU) No 988/2011 ⁽³⁾.
- (4) An extension of the derogation was granted until 31 March 2018 by Commission Implementing Regulation (EU) 2015/2407 ⁽⁴⁾.
- (5) On 23 May 2018, the Commission received from Italy a request to extend the derogation which expired on 31 March 2018. Italy provided up-to-date information justifying the extension of the derogation.
- (6) Italy adopted the management plan by Decree ⁽⁵⁾ in accordance with Article 19(2) of Regulation (EC) No 1967/2006. The management plan adopted is put in place to accompany the entire duration of the derogation.
- (7) The Scientific, Technical and Economic Committee for Fisheries (STECF) assessed the derogation requested by Italy and the related updated management plan in July 2018 ⁽⁶⁾. The overall assessment by the STECF is positive, information on its biology and ecology, fleet and effort are well presented. STECF stated that the objectives proposed by the management plan are consistent with the objectives of Article 2 of Regulation (EU) No 1380/2013 ⁽⁷⁾ of the European Parliament and of the Council and with the relevant provisions of Article 6. The presence of other species in the catches is quite occasional. The boat-seine for transparent goby can be considered as selective gear while for species from the Annex III of Regulation (EC) No 1967/2006 the impact of this boat seine on these species can be considered as very low. STECF stated that the management plan contains a lot of elements for the monitoring and management of the fishing activities. STECF highlighted the need for

⁽¹⁾ OJ L 409, 30.12.2006, p. 11.

⁽²⁾ Regulation (EU) No 1343/2011 of the European Parliament and of the Council of 13 December 2011 on certain provisions for fishing in the GFCM (General Fisheries Commission for the Mediterranean) agreement area and amending Council Regulation (EC) No 1967/2006 concerning management measures for the sustainable exploitation of fishery resources in the Mediterranean Sea (OJ L 347, 30.12.2011, p. 44).

⁽³⁾ Commission Implementing Regulation (EU) No 988/2011 of 4 October 2011 establishing a derogation from Council Regulation (EC) No 1967/2006 as regards the minimum distance from coast and the minimum sea depth for boat seines fishing for transparent goby (*Aphia minuta*) in certain territorial waters of Italy (OJ L 260, 5.10.2011, p. 15).

⁽⁴⁾ Commission Implementing Regulation (EU) 2015/2407 of 18 December 2015 renewing the derogation from Council Regulation (EC) No 1967/2006 as regards the minimum distance from coast and the minimum sea depth for boat seines fishing for transparent goby (*Aphia minuta*) in certain territorial waters of Italy (OJ L 333, 19.12.2015, p. 104).

⁽⁵⁾ *Gazzetta Ufficiale della Repubblica Italiana* 226, 28.9.2018, supplemento ordinario n. 44.

⁽⁶⁾ <https://stecf.jrc.ec.europa.eu/documents/43805/2147402/STECF+PLEN+18-02.pdf>

⁽⁷⁾ Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC (OJ L 354, 28.12.2013, p. 22).

some clarifications on gears interaction on seabed, monitoring and scientific data. Italy was requested to examine these issues. In order to address the issue of improved scientific data, the Italian authorities agreed to update the management plan and re-enforce the compulsory reporting obligations with the commitment to provide preliminary scientific report at the end of the 2019-2020 fishing season.

- (8) The extension of the derogation requested by Italy complies with the conditions laid down in Article 13(5) and (9) of Regulation (EC) No 1967/2006.
- (9) There are specific geographical constraints given both the limited size of the continental shelf and the spatial distribution of the target species, which is exclusively limited to certain zones in the coastal areas at depths smaller than 50 m. Hence, the fishing grounds are limited.
- (10) STECF expressed some concerns on the lack of updated data on spatial distribution of fishing operations in relation to the distribution of the seagrass habitats. However, it should be noted that with respect to the impact on the seabed, the observations carried out on board during the fishing seasons have shown that the boat-seine operates effectively only on the clean seabed, made of sand or mud while fishing is prohibited over *Posidonia* beds. Account taken of the above, it is concluded that boat seines fishing has no significant impact on protected habitats and is very selective, since the seines are hauled in the water column and do not touch the seabed because collection of material from the seabed would damage the target species and make the selection of the fished species virtually impossible due to their very small size.
- (11) Boat seines fishing is carried out close to the shore in shallow depths. The nature of this type of fishery is such that it cannot be undertaken with any other gears.
- (12) The derogation requested by Italy affects 117 vessels.
- (13) The management plan presented by Italy guarantees no future increase of the fishing effort, as fishing authorisations will be issued to specified 117 vessels, involving a total effort of 5 886,9 kW that are already authorised to fish in Italy.
- (14) The request covers vessels with a track record in the fishery of more than five years
- (15) Those vessels are included on a list communicated to the Commission in accordance with the requirements of Article 13(9) of Regulation (EC) No 1967/2006.
- (16) The fishing activities concerned fulfil the requirements of Article 4 of Regulation (EC) No 1967/2006 since the Italian management plan explicitly prohibits to fish above protected habitats.
- (17) The requirements of Article 8(1)(h) of Regulation (EC) No 1967/2006 are not applicable since they relate to trawlers.
- (18) As regards the minimum mesh size requirement laid down in Article 9(3) of Regulation (EC) No 1967/2006, it should be noted that, given the fishing activities concerned are highly selective, have a negligible effect on the marine environment and are not carried out above protected habitats, Italy authorised in the management plan in line with Article 9(7) of Regulation (EC) No 1967/2006 a derogation from that requirement.
- (19) The fishing activities concerned fulfil the recording requirements laid down in Article 14 of Council Regulation (EC) No 1224/2009 ⁽¹⁾.
- (20) The fishing activities concerned take place at a very short distance from the coast and therefore do not interfere with the activities of vessels using gears other than trawls, seines or similar towed nets.
- (21) The activity of the boat seines is regulated in the Italian management plan to ensure that catches of species mentioned in Annex III to Regulation (EC) No 1967/2006 are minimal. Moreover, according to paragraph 5.1.2(a) of the Italian management plan, the fishing for *Aphia minuta* is limited to a fishing season from 1 November to 31 March each year and to a maximum of 60 days per boat for every fishing season.

⁽¹⁾ Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Union control system for ensuring compliance with the rules of the common fisheries policy, amending Regulations (EC) No 847/96, (EC) No 2371/2002, (EC) No 811/2004, (EC) No 768/2005, (EC) No 2115/2005, (EC) No 2166/2005, (EC) No 388/2006, (EC) No 509/2007, (EC) No 676/2007, (EC) No 1098/2007, (EC) No 1300/2008, (EC) No 1342/2008 and repealing Regulations (EEC) No 2847/93, (EC) No 1627/94 and (EC) No 1966/2006 (OJ L 343, 22.12.2009, p. 1).

- (22) Boat seines do not target cephalopods.
- (23) The Italian management plan includes measures for the monitoring of fishing activities, as provided for in the third subparagraph of Article 13(9) of Regulation (EC) No 1967/2006.
- (24) The requested extension of the derogation should therefore be granted.
- (25) Italy should report to the Commission in due time and in accordance with the monitoring plan provided for in the Italian management plan.
- (26) A limitation in duration of the derogation will allow ensuring prompt corrective measures in case the report to the Commission shows a poor conservation status of the exploited stock, while providing scope to enhance the scientific basis for an improved management plan.
- (27) Accordingly, the derogation should apply until 31 March 2021.
- (28) The measures provided for in this Regulation are in accordance with the opinion of the Committee for Fisheries and Aquaculture,

HAS ADOPTED THIS REGULATION:

Article 1

Derogation

Article 13(1) of Regulation (EC) No 1967/2006 shall not apply in territorial waters of Italy adjacent to the coast of Liguria and Tuscany, to fishing for transparent goby (*Aphia minuta*) with boat seines used by vessels:

- (a) registered in the maritime Directorates (Direzione Marittima) of Genova and Livorno respectively;
- (b) having a track record in the fishery of more than five years and not involving any future increase in the fishing effort deployed; and
- (c) having a fishing authorisation and operating under the management plan adopted by Italy in accordance with Article 19(2) of Regulation (EC) No 1967/2006.

Article 2

Monitoring plan and report

Italy shall communicate to the Commission, within one year following the entry into force of this Regulation, a report drawn up in accordance with the monitoring plan established in the management plan referred to in Article 1(c).

Article 3

Entry into force and period of application

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

It shall apply until 31 March 2021.

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

Done at Brussels, 30 October 2018.

For the Commission
The President
Jean-Claude JUNCKER

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2018/1635

of 30 October 2018

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

(notified under document C(2018) 7333)

(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 and zootechnical checks applicable in intra-Community 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) 2018/1576 ⁽⁵⁾, following recent instances of African swine fever in Latvia, Lithuania, Poland and Romania.
- (2) The risk of the spread of African swine fever in wildlife is linked to the natural slow spread of that disease among feral pig populations, and also the risks linked to human activity, as demonstrated by the recent epidemiological evolution of that disease in the Union, and as documented by the European Food Safety Authority (EFSA) in the Scientific Opinion of the Panel on Animal Health and Welfare, published on 14 July 2015; in the Scientific Report of EFSA on Epidemiological analyses on African swine fever in the Baltic countries and Poland, published on 23 March 2017; and in the Scientific Report of EFSA on Epidemiological analyses of African swine fever in the Baltic States and Poland, published on 8 November 2017 ⁽⁶⁾.
- (3) Since the date of adoption of Implementing Decision (EU) 2018/1576, the epidemiological situation in the Union has evolved as regards African swine fever, and there have been further instances of that disease that need to be reflected in the Annex to Implementing Decision 2014/709/EU.

⁽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) 2018/1576 of 18 October 2018 amending the Annex to Implementing Decision 2014/709/EU concerning animal health control measures relating to African swine fever in certain Member States (OJ L 262, 19.10.2018, p. 71).

⁽⁶⁾ EFSA Journal 2015;13(7):4163; EFSA Journal 2017;15(3):4732; EFSA Journal 2017;15(11):5068.

- (4) In October 2018, one case of African swine fever in a feral pig was observed in the province of Silistra in Bulgaria. This case of African swine fever in a feral pig constitutes an increased level of risk which should be reflected in the Annex to Implementing Decision 2014/709/EU. Accordingly, this area of Bulgaria affected by African swine fever should be listed in Part II of that Annex.
- (5) In October 2018, an outbreak of African swine fever in domestic pigs was observed in the county of Maramureş in Romania. This outbreak of African swine fever in domestic pigs constitutes an increased level of risk which should be reflected in the Annex to Implementing Decision 2014/709/EU. Accordingly, this area of Romania affected by African swine fever should now be listed in Part III of that Annex instead of in Part I thereof. Given that Part III of the Annex to Implementing Decision 2014/709/EU lists the areas where the situation is still evolving and dynamic, when any areas are listed in that Part, particular consideration must always be given to the effect on the surrounding areas.
- (6) In order to take account of recent developments in the epidemiological evolution 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 Bulgaria and Romania and duly listed in Parts I, II and III of the Annex to Implementing Decision 2014/709/EU. The Annex to Implementing Decision 2014/709/EU should therefore be amended accordingly.
- (7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

The 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, 30 October 2018.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

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

‘ANNEX

PART I

1. Bulgaria

The following areas in Bulgaria:

in Silistra region:

- within municipality of Alfatar:
 - Bistra,
 - Alekovo,
- within municipality of Dulovo:
 - Kolobar,
 - Varbina,
 - Kozyak,
 - Mezhden,
 - Chukovetz,
 - Tzar Asen,
 - Cherkovna,
 - Dulovo,
 - Chernik,
 - Poroyno,
 - Vodno,
 - Chernolik,
- within municipality of Sitovo:
 - Sitovo,
 - Yastrebno,
 - Slatina,
- within municipality of Silistra:
 - Bradvari,
 - Zlatoklas,
 - Yordanovo,
 - Profesor Ishirkovo,
 - Kazimir,
 - Babuk,
 - Sarpovo,
 - Smiletz,
 - Tzenovich,
 - Polkovnik Lambrinovo,
 - Srebarna,
 - Aydemir,
 - Silistra,
 - Kalipetrovo,

in Dobrich region:

— within municipality of General Toshevo:

- Rosen,
- Krasen,
- Zhiten,
- Snop,
- Gradini,

— within municipality of Krushari:

- Severnyak,
- Abrit,
- Dobrin,
- Alexandria,
- Polkovnik Dyakovo,
- Zagortzi,
- Krushartzi,
- Bistretz,
- Telerig,
- Lozenetz,

— within municipality of Tervel:

- Onogur,
- Balik,
- Angelariy,
- Sarnetz,
- Bozhan,
- Popgruevo,
- Kochmar,
- Guslar,
- Mali Izvor,
- Tervel,
- Bonevo,
- Voynikovo,
- Bezmer,
- Chestimensko,
- Profesor Zlatarski,
- Kableshkovo,
- Glavantzi,
- Nova kamena,
- Kladentzi,
- Gradnitza,

— within municipality of Dobrich:

- Kragulevo,
- Dobrevo,
- Cherna,
- Pchelnik,
- Zhitnitza,

- Polkovnik Ivanovo,
- Hitovo,
- Vodnyantzi,
- Feldfebel Denkovo (Dyankovo),
- Podslon,
- Geshanovo.

2. The Czech Republic

The following areas in the Czech Republic:

- okres Uherské Hradiště,
- okres Kroměříž,
- okres Vsetín,
- katastrální území obcí v okrese Zlín:
 - Bělov,
 - Biskupice u Luhačovic,
 - Bohuslavice nad Vlárí,
 - Brumov,
 - Bylnice,
 - Divnice,
 - Dobrkovice,
 - Dolní Lhota u Luhačovic,
 - Drnovice u Valašských Klobouk,
 - Halenkovice,
 - Haluzice,
 - Hrádek na Vlárské dráze,
 - Hřivínův Újezd,
 - Jestřabí nad Vlárí,
 - Kaňovice u Luhačovic,
 - Kelníky,
 - Kladná-Žilín,
 - Kochavec,
 - Komárov u Napajedel,
 - Křekov,
 - Lipina,
 - Lipová u Slavičína,
 - Ludkovice,
 - Luhačovice,
 - Machová,
 - Mirošov u Valašských Klobouk,
 - Mysločovice,
 - Napajedla,
 - Návojná,
 - Nedašov,
 - Nedašova Lhota,
 - Nevšová,
 - Otrokovice,

- Petrůvka u Slavičina,
- Pohořelice u Napajedel,
- Polichno,
- Popov nad Vlárí,
- Poteč,
- Pozlovice,
- Rokytnice u Slavičina,
- Rudimov,
- Řetechov,
- Sazovice,
- Sidonie,
- Slavičín,
- Smolína,
- Spytihněv,
- Svatý Štěpán,
- Šanov,
- Šarovy,
- Štítná nad Vlárí,
- Tichov,
- Tlumačov na Moravě,
- Valašské Klobouky,
- Velký Ořechov,
- Vlachova Lhota,
- Vlachovice,
- Vrbětice,
- Žlutava.

3. Estonia

The following areas in Estonia:

- Hiiu maakond.

4. Hungary

The following areas in Hungary:

- Borsod-Abaúj-Zemplén megye 650100, 650200, 650300, 650400, 650500, 650600, 650700, 650800, 650900, 651000, 651100, 651200, 651300, 651400, 651500, 651610, 651700, 651801, 651802, 651803, 651900, 652000, 652100, 652200, 652300, 652400, 652500, 652601, 652602, 652603, 652700, 652800, 652900, 653000, 653100, 653200, 653300, 653401, 653403, 653500, 653600, 653700, 653800, 653900, 654000, 654201, 654202, 654301, 654302, 654400, 654501, 654502, 654600, 654700, 654800, 654900, 655000, 655100, 655200, 655300, 655400, 655500, 655600, 655700, 655800, 655901, 655902, 656000, 656100, 656200, 656300, 656400, 656600, 657300, 657400, 657500, 657600, 657700, 657800, 657900, 658000, 658100, 658201, 658202, 658310, 658403, 659100, 659210, 659220, 659300, 659400, 659500, 659601, 659602, 659701, 659800, 659901, 660000, 660100, 660200, 660400, 660501, 660502, 660600 és 660800 kódszámú vadgazdálkodási egységeinek teljes területe,
- Hajdú-Bihar megye 900150, 900250, 900350, 900450, 900550, 900650, 900660, 900670, 900750, 900850, 900860, 900930, 900950, 901050, 901150, 901250, 901260, 901270, 901350, 901560, 901590, 901850, 901950, 902950, 902960, 903050, 903150, 903250, 903350, 903360, 903370, 903450, 904450, 904460, 904550, 904650, 904750, 904760, 905450 és 905550 kódszámú vadgazdálkodási egységeinek teljes területe,
- Heves megye 700150, 700250, 700260, 700350, 700450, 700460, 700550, 700650, 700750, 700850, 702350, 702450, 702550, 702750, 702850, 703350, 703360, 703450, 703550, 703610, 703750, 703850, 703950, 704050, 704150, 704250, 704350, 704450, 704550, 704650, 704750, 704850, 704950, 705050, 705250, 705350, 705510 és 705610 kódszámú vadgazdálkodási egységeinek teljes területe,
- Jász-Nagykun-Szolnok megye 750150, 750160, 750250, 750260, 750350, 750450, 750460, 750550, 750650, 750750, 750850, 750950 és 750960 kódszámú vadgazdálkodási egységeinek teljes területe,

- Nógrád megye 550120, 550130, 550210, 550710, 550810, 551450, 551460, 551550, 551650, 551710, 552010, 552150, 552250, 552350, 552360, 552450, 552460, 552520, 552550, 552610, 552620, 552710, 552850, 552860, 552950, 552960, 552970, 553050, 553110, 553250, 553260, 553350, 553650, 553750, 553850, 553910 és 554050 kódszámú vadgazdálkodási egységeinek teljes területe,
- Pest megye 571250, 571350, 571550, 571610, 571750, 571760, 572250, 572350, 572550, 572850, 572950, 573360, 573450, 580050 és 580450 kódszámú vadgazdálkodási egységeinek teljes területe,
- Szabolcs-Szatmár-Bereg megye 850650, 850850, 851851, 851852, 851950, 852350, 852450, 852550, 852750, 853560, 853650, 853751, 853850, 853950, 853960, 854050, 854150, 854250, 854350, 855250, 855350, 855450, 855460, 855550, 855650, 855660, 855750, 855850, 855950, 855960, 856012, 856050, 856150, 856260, 857050, 857150, 857350 és 857450 kódszámú vadgazdálkodási egységeinek teljes területe.

5. Latvia

The following areas in Latvia:

- Aizputes novads,
- Alsungas novads,
- Kuldīgas novada Gudenieku, Turlavas un Laidu pagasts,
- Pāvilostas novada Sakas pagasts un Pāvilostas pilsēta,
- Priekules novads,
- Skrundas novada Rudbāržu pagasts,
- Stopiņu novada daļa, kas atrodas uz rietumiem no autoceļa V36, P4 un P5, Acones ielas, Dauguļupes ielas un Dauguļupītes,
- Ventpils novada Jūrkalnes pagasts.

6. Lithuania

The following areas in Lithuania:

- Jurbarko rajono savivaldybė: Smalininkų ir Viešvilės seniūnijos,
- Kelmės rajono savivaldybė: Kelmės, Kelmės apylinkių, Kražių, Kukečių, Liolių, Pakražančio seniūnijos, Tytyvėnų seniūnijos dalis į vakarus ir šiaurę nuo kelio Nr. 157 ir į vakarus nuo kelio Nr. 2105 ir Tytuvėnų apylinkių seniūnijos dalis į šiaurę nuo kelio Nr. 157 ir į vakarus nuo kelio Nr. 2105, ir Vaiguvos seniūnijos,
- Mažeikių rajono savivaldybė: Sedos, Šerkšnėnų ir Židikų seniūnijos,
- Pagėgių savivaldybė,
- Plungės rajono savivaldybė,
- Raseinių rajono savivaldybė: Girkalnio ir Kalnųjų seniūnijos dalis į šiaurę nuo kelio Nr A1, Nemakščių, Paliepių, Raseinių, Raseinių miesto ir Viduklės seniūnijos,
- Rietavo savivaldybė,
- Šakių rajono savivaldybė: Barzdų, Griškabūdžio, Kriūkų, Kudirkos Naumiesčio, Lekėčių, Lukšių, Sintautų, Slavikų, Sudargo ir Žvirgždaičių seniūnijos,
- Šilalės rajono savivaldybė,
- Šilutės rajono savivaldybė: Juknaičių, Kintų, Šilutės ir Usėnų seniūnijos,
- Tauragės rajono savivaldybė: Lauksargių, Skaudvilės, Tauragės, Mažonų, Tauragės miesto ir Žygaičių seniūnijos.

7. Poland

The following areas in Poland:

w województwie warmińsko-mazurskim:

- gmina Stare Juchy w powiecie ełckim,
- gminy Dubeninki, Gołdap i część gminy Banie Mazurskie położona na południe od linii wyznaczonej przez drogę nr 650 w powiecie gołdapskim,
- gmina Pozezdrze i część gminy Węgorzewo położona na zachód od linii wyznaczonej przez drogę nr 63 biegnącą od południowo-wschodniej granicy gminy do skrzyżowania z drogą nr 650, a następnie na południe od linii wyznaczonej przez drogę nr 650 biegnącą od skrzyżowania z drogą nr 63 do skrzyżowania z drogą biegnącą do miejscowości Przyszań i na wschód od linii wyznaczonej przez drogę łączącą miejscowości Przyszań, Pniewo, Kamionek Wielki, Radziejewo, Dłużec w powiecie węgorzewskim,

- gmina Ruciane – Nida i część gminy Pisz położona na południe od linii wyznaczonej przez drogę nr 58 oraz miasto Pisz w powiecie piskim,
 - gminy Giżycko z miastem Giżycko, Krukłanki, Miłki, Wydminy i Ryn w powiecie giżyckim,
 - gminy Mikołajki, Piecki, część gminy Sorkwity położona na południe od drogi nr 16 i część gminy wiejskiej Mrągowo położona na południe od linii wyznaczonej przez drogę nr 16 biegnącą od zachodniej granicy gminy do granicy miasta Mrągowo oraz na południe od linii wyznaczonej przez drogę nr 59 biegnącą od wschodniej granicy gminy do granicy miasta Mrągowo w powiecie mrągowskim,
 - gmina Bisztynek w powiecie bartoszyckim,
 - gminy Dźwierzuty i Świętajno w powiecie szczycieńskim.
 - gminy Orneta, Lubomino, część gminy wiejskiej Lidzbark Warmiński położona na południe od linii wyznaczonej przez drogę nr 513 biegnącą od wschodniej granicy gminy do wschodniej granicy miasta Lidzbark Warmiński oraz na południowy wschód od linii wyznaczonej przez drogę nr 51 i część gminy Kiwity położona na południe od linii wyznaczonej przez drogę nr 513 w powiecie lidzbarskim,
 - gminy Elbląg, Godkowo, Gronowo Elbląskie, Markusy, Pasłęk i część gminy Tolkmicko niewymieniona w części II załącznika w powiecie elbląskim oraz strefa wód przybrzeżnych Zalewu Wiślanego i Zatoki Elbląskiej,
 - powiat miejski Elbląg,
 - gminy Biskupiec, Dobre Miasto, Jeziorany i Kolno w powiecie olsztyńskim,
 - gmina Miłakowo w powiecie ostródzkim,
- w województwie podlaskim:
- gminy Brańsk z miastem Brańsk, Rudka i Wyszki w powiecie bielskim,
 - gmina Perlejewo w powiecie siemiatyckim,
 - gminy Kolno z miastem Kolno, Mały Płock i Turośl w powiecie kolneńskim,
 - gmina Poświętne w powiecie białostockim,
 - gminy Kołaki Kościelne, Rutki, Szumowo, część gminy Zambrów położona na południe od linii wyznaczonej przez drogę nr 58 i miasto Zambrów w powiecie zambrowskim,
 - gminy Wiżajny i Przerośl w powiecie suwalskim,
 - gminy Kulesze Kościelne, Nowe Piekuty, Szepietowo, Klukowo, Ciechanowiec, Wysokie Mazowieckie z miastem Wysokie Mazowieckie, Czyżew w powiecie wysokomazowieckim,
 - gminy Miastkowo, Nowogród i Zbójna w powiecie łomżyńskim.
- w województwie mazowieckim:
- gminy Ceranów, Kosów Lacki, Sabnie, Sterdyń, część gminy Bielany położona na zachód od linii wyznaczonej przez drogę nr 63 i część gminy wiejskiej Sokołów Podlaski położona na zachód od linii wyznaczonej przez drogę nr 63 w powiecie sokołowskim,
 - gminy Grębków, Korytnica, Liw, Łochów, Miedzna, Sadowne, Stoczek, Wierzбно i miasto Węgrów w powiecie węgrowskim,
 - część gminy Kotuń położona na zachód od linii wyznaczonej przez drogę łączącą miejscowości Nowa Dąbrówka, Pieróg, Kotuń wzdłuż ulicy Gorzkowskiego i Kolejowej do przejazdu kolejowego łączącego się z ulicą Siedlecką, Broszków, Żuków w powiecie siedleckim,
 - gminy Rzekuń, Troszyn, Lelis, Czerwin i Goworowo w powiecie ostrołęckim,
 - powiat miejski Ostrołęka,
 - powiat ostrowski,
 - gminy Karniewo, Maków Mazowiecki, Rzewnie i Szelków w powiecie makowskim,
 - gmina Krasne w powiecie przasnyskim,
 - gminy Mała Wieś i Wyszogród w powiecie płockim,
 - gminy Ciechanów z miastem Ciechanów, Gliniojeck, Gołymin – Ośrodek, Ojrzeń, Opinogóra Górna i Sońsk w powiecie ciechanowskim,
 - gminy Baboszewo, Czerwińsk nad Wisłą, Naruszewo, Płońsk z miastem Płońsk, Sochocin i Załuski w powiecie płońskim,
 - 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 Brańszczyk, Długosiodło, Rząśnik, Wyszów, Zabrodzie i część gminy Somianka położona na północ od linii wyznaczonej przez drogę nr 62 w powiecie wyszkowskim,
- gminy Jadów, Klembów, Poświętne, Strachówka i Tłuszcz w powiecie wołomińskim,
- gminy Dobre, Jakubów, Mrozy, Kałuszyn, Stanisławów, część gminy Ceglów położona na północ od linii wyznaczonej przez drogę biegnącą od zachodniej granicy gminy łączącą miejscowości Wiciejów, Mienia, Ceglów i na wschód od linii wyznaczonej przez drogę łączącą miejscowości Ceglów, Skwarne i Podskwarne biegnącą do wschodniej granicy gminy i część gminy Mińsk Mazowiecki położona na północ od linii wyznaczonej przez drogę nr 92 biegnącą od zachodniej granicy gminy do granicy miasta Mińsk Mazowiecki i na północ od linii wyznaczonej przez drogę biegnącą od wschodniej granicy miasta Mińsk Mazowiecki łączącą miejscowości Targówka, Budy Barczackie do wschodniej granicy gminy w powiecie mińskim,
- gminy Górzno, Łaskarzew z miastem Łaskarzew, Sobolew, Trojanów, Żelechów i część gminy Miastków Kościelny położona na południe od rzeki Wilga w powiecie garwolińskim,
- gminy Garbatka Letnisko, Gniewoszków, i Sieciechów w powiecie kozienickim,
- gminy Baranów i Jaktorów w powiecie grodziskim,
- powiat żyrardowski,
- gminy Belsk Duży, Błędów, Goszczyn i Mogielnica w powiecie grójeckim,
- gminy Białobrzegi, Promna, Stara Błotnica, Wyśmierzyce i część gminy Stromiec położona na południe od linii wyznaczonej przez drogę nr 48 w powiecie białobrzeskim,
- gminy Jedlińsk, Jastrzębia i Pionki z miastem Pionki w powiecie radomskim,
- gminy Iłów, Młodzieszyn, Nowa Sucha, Rybno, Sochaczew z miastem Sochaczew i Teresin w powiecie sochaczewskim,
- gmina Policzna w powiecie zwoleńskim.

w województwie lubelskim:

- gminy Jabłonna, Krzczonów, Jastków, Konopnica, Wólka, Głusk i Wojciechów w powiecie lubelskim,
- gminy Miączyn, Nielisz, Sitno, Skierbieszów, Stary Zamość, Komarów-Osada w powiecie zamojskim,
- gminy Trzeszczany i Werbkowice w powiecie hrubieszowskim,
- gminy Jeziorzany i Kock, w powiecie lubartowskim,
- gminy Adamów i Serokomla w powiecie łukowskim,
- powiat rycki,
- gminy Janowiec, i część gminy wiejskiej Puławy położona na zachód od rzeki Wisły w powiecie puławskim,
- gminy Karczmiska, Poniatowa i Wilków w powiecie opolskim,
- gminy Mełgiew, Rybczewice, miasto Świdnik i część gminy Piaski położona na południe od linii wyznaczonej przez drogę nr 17 biegnącą od wschodniej granicy gminy Piaski do skrzyżowania z drogą nr S12 i na zachód od linii wyznaczonej przez drogę biegnącą od skrzyżowania dróg nr 17 i nr S12 przez miejscowość Majdan Brzezicki do północnej granicy gminy w powiecie świdnickim;
- gminy Gorzków, Izbica, Rudnik i Żółkiewka w powiecie krasnostawskim,
- gminy Bełzec, Jarczów, Lubycza Królewska, Łaszczów, Susiec, Tyszowce i Ulhówek w powiecie tomaszowskim,
- gminy Łukowa i Obsza w powiecie biłgorajskim,
- powiat miejski Lublin.

w województwie podkarpackim:

- gminy Horyniec-Zdrój, Narol, Stary Dzików i Wielkie Oczy i część gminy Oleszyce położona na południe od linii wyznaczonej przez drogę biegnącą od wschodniej granicy gminy przez miejscowość Borchów do skrzyżowania z drogą nr 865 w miejscowości Oleszyce, a następnie na zachód od linii wyznaczonej przez drogę nr 865 biegnącą w kierunku północno-wschodnim do skrzyżowania z drogą biegnącą w kierunku północno-zachodnim przez miejscowość Lubomierz - na południe od linii wyznaczonej przez tę drogę do skrzyżowania z drogą łączącą miejscowości Uszkowce i Nowy Dzików - na zachód od tej drogi w powiecie lubaczowskim,
- gminy Laszki i Wiązownica w powiecie jarosławskim.

8. Romania

The following areas in Romania:

- Județul Alba cu următoarea delimitare:
 - La nord de drumul național nr. 7,

- Județul Arad cu următoarea delimitare:
 - La nord de linia descrisă de următoarele localități:
 - Macea,
 - Șiria,
 - Bârzava,
 - Toc, care se află la joncțiunea cu drumul național nr. 7,
 - La nord de drumul național nr. 7,
- Județul Argeș,
- Județul Bistrița,
- Județul Brașov,
- Județul Cluj,
- Județul Covasna,
- Județul Dolj,
- Județul Harghita,
- Județul Hunedoara cu următoarea delimitare:
 - La nord de linia descrisă de următoarele localități:
 - Brănișca,
 - Municipiul Deva,
 - Turdaș,
 - Localitățile Zam și Aurel Vlaicu, care se află la joncțiunea cu drumul național nr. 7,
 - La nord de drumul național nr. 7,
- Județul Iași,
- Județul Neamț,
- Județul Vâlcea,
- Județul Bistrița Năsăud,
- Restul județului Maramureș care nu a fost inclus în Partea III cu următoarele comune:
 - Comuna Vișeu de Sus,
 - Comuna Borșa,
 - Comuna Oarța de Jos,
 - Comuna Suceiu de Sus,
 - Comuna Moisei,
 - Comuna Coroieni,
 - Comuna Târgu Lăpuș,
 - Comuna Vima Mică,
 - Comuna Boiu Mare,
 - Comuna Valea Chioarului,
 - Comuna Ulmeni,
 - Comuna Băsești,
 - Comuna Baia Mare,
 - Comuna Tăuții Magherăuș,
 - Comuna Cicărlău,
 - Comuna Seini,
 - Comuna Ardușat,
 - Comuna Farcasa,
 - Comuna Salsig,

- Comuna Asuaju de Sus,
- Comuna Băița de sub Codru,
- Comuna Bicaz,
- Comuna Grosi,
- Comuna Recea,
- Comuna Baia Sprie,
- Comuna Sisesti,
- Comuna Cernesti,
- Copalnic Mănăstur,
- Comuna Dumbrăvița,
- Comuna Cuspeni,
- Comuna Șomcuța Mare,
- Comuna Sacaleșeni,
- Comuna Remetea Chioarului,
- Comuna Mireșu Mare,
- Comuna Ariniș.

PART II

1. Bulgaria

The following areas in Bulgaria:

in Silistra region:

- within municipality of Kaynardzha:
 - Voynovo,
 - Kaynardzha,
 - Kranovo,
 - Zarnik,
 - Dobrudzhanka,
 - Golesh,
 - Svetoslav,
 - Polk. Cholakovo,
 - Kamentzi,
 - Gospodinovo,
 - Sredishte,
 - Strelkovo,
 - Poprusanovo,
 - Posev,
- within municipality of Alfatar:
 - Alfatar,
 - Kutlovitza,
 - Vasil Levski,
- within municipality of Silistra:
 - Glavan,
 - Popkralevo,
 - Bogorovo,
 - Sratzimir,
 - Bulgarka,

in Dobrich region:

- within municipality of Krushari:
 - Kapitan Dimitrovo,
 - Ognyanovo,
 - Zimnitsa,
- within municipality of Tervel:
 - Brestnitsa,
 - Kolartzi.

2. The Czech Republic

The following areas in the Czech Republic:

- katastrální území obcí v okrese Zlín:
 - Bohuslavice u Zlína,
 - Bratřejov u Vizovic,
 - Březnice u Zlína,
 - Březová u Zlína,
 - Březůvky,
 - Dešná u Zlína,
 - Dolní Ves,
 - Doubravy,
 - Držková,
 - Fryšták,
 - Horní Lhota u Luhačovic,
 - Horní Ves u Fryštáku,
 - Hostišová,
 - Hrobice na Moravě,
 - Hvozdná,
 - Chrastěšov,
 - Jaroslavice u Zlína,
 - Jasenná na Moravě,
 - Karlovice u Zlína,
 - Kašava,
 - Klečůvka,
 - Kostelec u Zlína,
 - Kudlov,
 - Kvítkovice u Otrokovic,
 - Lhota u Zlína,
 - Lhotka u Zlína,
 - Lhotsko,
 - Lípa nad Dřevnicí,
 - Loučka I,
 - Loučka II,
 - Louky nad Dřevnicí,
 - Lukov u Zlína,
 - Lukoveček,
 - Lutonina,
 - Lužkovice,

- Malenovice u Zlína,
- Mladcová,
- Neubuz,
- Oldřichovice u Napajedel,
- Ostrata,
- Podhradí u Luhačovic,
- Podkopná Lhota,
- Provodov na Moravě,
- Prštné,
- Příluky u Zlína,
- Racková,
- Raková,
- Salaš u Zlína,
- Sehradice,
- Slopné,
- Slušovice,
- Štípa,
- Tečovice,
- Trnava u Zlína,
- Ublo,
- Újezd u Valašských Klobouk,
- Velíková,
- Veselá u Zlína,
- Vítová,
- Vizovice,
- Vlčková,
- Všemina,
- Vysoké Pole,
- Zádveřice,
- Zlín,
- Želechovice nad Dřevnicí.

3. Estonia

The following areas in Estonia:

- Eesti Vabariik (välja arvatud Hiiu maakond).

4. Hungary

The following areas in Hungary:

- Heves megye 700860, 700950, 701050, 701111, 701150, 701250, 701350, 701550, 701560, 701650, 701750, 701850, 701950, 702050, 702150, 702250, 702260, 702950, 703050, 703150, 703250, 703370, 705150 és 705450 kódszámú vadgazdálkodási egységeinek teljes területe,
- Szabolcs-Szatmár-Bereg megye 850950, 851050, 851150, 851250, 851350, 851450, 851550, 851650, 851660, 851751, 851752, 852850, 852860, 852950, 852960, 853050, 853150, 853160, 853250, 853260, 853350, 853360, 853450, 853550, 854450, 854550, 854560, 854650, 854660, 854750, 854850, 854860, 854870, 854950, 855050, 855150, 856250, 856350, 856360, 856450, 856550, 856650, 856750, 856760, 856850, 856950, 857650, valamint 850150, 850250, 850260, 850350, 850450, 850550, 852050, 852150, 852250 és 857550 kódszámú vadgazdálkodási egységeinek teljes területe,
- Nógrád megye 550110, 550310, 550320, 550450, 550460, 550510, 550610, 550950, 551010, 551150, 551160, 551250, 551350, 551360, 551810 és 551821 kódszámú vadgazdálkodási egységeinek teljes területe,

- Borsod-Abaúj-Zemplén megye 656701, 656702, 656800, 656900, 657010, 657100, 658401, 658402, 658404, 658500, 658600, 658700, 658801, 658802, 658901, 658902 és 659000 kódszámú vadgazdálkodási egységeinek teljes területe.

5. Latvia

The following areas in Latvia:

- Ādažu novads,
- Aglonas novads,
- Aizkraukles novads,
- Aknīstes novads,
- Alojās novads,
- Alūksnes novads,
- Amatas novads,
- Apes novads,
- Auces novads,
- Babītes novads,
- Baldones novads,
- Baltinavas novads,
- Balvu novads,
- Bauskas novads,
- Beverīnas novads,
- Brocēnu novada Blīdenes pagasts, Remtes pagasta daļa uz austrumiem no autoceļa 1154 un P109,
- Burtnieku novads,
- Carnikavas novads,
- Cēsu novads,
- Cesvaines novads,
- Ciblas novads,
- Dagdas novads,
- Daugavpils novads,
- Dobeles novads,
- Dundagas 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 Ēdoles, Īvandes, Padures, Rendas un Kabiles, pagasts, Rumbas pagasta daļa uz ziemeļiem no autoceļa P120, Kurmāles pagasta daļa uz rietumiem no autoceļa 1283 un 1290, un uz ziemeļaustrumiem no autoceļa P118, 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,
- Pļaviņu novads,
- Preiļu novads,
- Priekule 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 novada Novadnieku, Kursišu, Zvārdes, Šķēdes, Nīgrandes, Jaunaucis, Rubas, Vadakstes, un Pampāļu pagasts,
- Saulkrastu novads,
- Sējas novads,
- Siguldas novads,
- Skrīveru novads,
- Skrundas novada Nīkrāces, Skrundas un Raņķu pagasts, Skrundas pilsēta,
- 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 novads,
- Valkas novads,
- Varakļānu novads,
- Vārkavas novads,
- Vecpiebalgas novads,
- Vecumnieku novads,
- Ventspils novada Ances, Tārgales, Popes, Vārves, Užavas, Piltenes, Puzes, Ziru, Ugāles, Usmas un Zlēku pagasts, Piltenes pilsēta,
- Viesītes novads,
- Viļakas novads,
- Viļānu novads,
- Zilupes novads.

6. Lithuania

The following areas in Lithuania:

- Alytaus rajono savivaldybė: Krokialaukio, Miroslavo ir Simno seniūnijos,
- Anykščių rajono savivaldybė,
- Biržų miesto savivaldybė,
- Biržų rajono savivaldybė,
- Druskininkų savivaldybė,
- Elektrėnų savivaldybė,
- Ignalinos rajono savivaldybė,
- Jonavos rajono savivaldybė,
- Jurbarko rajono savivaldybė: Eržvilko, Jurbarko miesto ir Jurbarkų seniūnijos,
- Kaišiadorių miesto savivaldybė,
- Kaišiadorių rajono savivaldybė: Kaišiadorių apylinkės, Kruonio, Nemaitonių, Palomenės, Pravieniškių, Rumšiškių, Žiežmarių ir Žiežmarių apylinkės seniūnijos,
- Kalvarijos savivaldybė,
- Kauno miesto savivaldybė,
- Kauno rajono savivaldybė,
- Kazlų Rūdos savivaldybė,
- Kelmės rajono savivaldybė: Užvenčio ir Šaukėnų seniūnijos,

- Kėdainių rajono savivaldybė,
- Kupiškio rajono savivaldybė,
- Marijampolės savivaldybė: Igliaukos, Gudelių, Liudvinavo, Sasnavos, Šunskų seniūnijos,
- Molėtų rajono savivaldybė: Alantos, Balninkų, Čiulėnų, Inturkės, Joniškio, Luokesos, Mindūnų, Suginčių, Videniškių seniūnijos,
- Pakruojo rajono savivaldybė,
- Panevėžio rajono savivaldybė,
- Pasvalio rajono savivaldybė,
- Radviliškio rajono savivaldybė: Aukštelkų seniūnija, Baisogalos seniūnijos dalis į vakarus nuo kelio Nr. 144, Radviliškio, Radviliškio miesto seniūnija, Šeduvos miesto seniūnijos dalis į pietus nuo kelio Nr. A9 ir į vakarus nuo kelio Nr. 3417 ir Tyrulių seniūnija,
- Prienų miesto savivaldybė,
- Prienų rajono savivaldybė: Ašmintos, Balbieriškio, Išlaužo, Naujosios Ūtos, Pakuonio, Šilavoto ir Veiverių seniūnijos,
- Raseinių rajono savivaldybė: Ariogalos, Betygalos, Pajogukų, Šiluvos, Kalnųjų seniūnijos ir Girkalnio seniūnijos dalis į pietus nuo kelio Nr. A1,
- Rokiškio rajono savivaldybė,
- Šalčininkų rajono savivaldybė,
- Šilutės rajono savivaldybė: Rusnės seniūnija,
- Širvintų rajono savivaldybės: Čiobiškio, Gelvonų, Jauniūnų, Karnavės, Musninkų, Širvintų, Zibalų seniūnijos,
- Švenčionių rajono savivaldybė,
- Tauragės rajono savivaldybė: Batakių ir Gaurės seniūnijos,
- Telšių rajono savivaldybė: Degaičių, Gadūnavo, Luokės, Nevarėnų, Ryškėnų, Telšių miesto, Upynos, Varnių, Viešvėnų ir Žarėnų seniūnijos,
- Trakų rajono savivaldybė,
- Ukmergės rajono savivaldybė,
- Utenos rajono savivaldybė,
- Varėnos rajono savivaldybė,
- Vilniaus miesto savivaldybė,
- Vilniaus rajono savivaldybė: Avižienių, Bezdonių, Buivydžių, Dūkštų, Juodšilių, Kalvelių, Lavoriškių, Maišiagalos, Marijampolio, Medininkų, Mickūnų, Nemenčinės, Nemenčinės miesto, Nemėžio, Pagirių, Riešės, Rudaminos, Rūkainių, Sudervės, Sužionių, Šatrininkų, Žujūnų seniūnijos,
- Vilkaviškio rajono savivaldybė,
- Visagino savivaldybė,
- Zarasų rajono savivaldybė.

7. Poland

The following areas in Poland:

w województwie warmińsko-mazurskim:

- gminy Kalinowo, Prostki i gmina wiejska Elk w powiecie elckim,
- gmina Milejewo i część obszaru ładowego gminy Tolkmicko położona na południe od linii brzegowej Zalewu Wiślanego i Zatoki Elbląskiej do granicy z gminą wiejską Elbląg w powiecie elbląskim,
- powiat olecki,
- gminy Orzysz, Biała Piska i część gminy Pisz położona na północ od linii wyznaczonej przez drogę nr 58 w powiecie piskim,
- gmina Frombork, część gminy wiejskiej Braniewo położona na zachód od linii wyznaczonej przez drogę nr E28 i S22 i miasto Braniewo w powiecie braniewskim,

- gminy Kętrzyn z miastem Kętrzyn, Reszel i część gminy Korsze położona na południe od linii wyznaczonej przez drogę biegnącą od wschodniej granicy łączącą miejscowości Krelikiejmy i Sątoczno i na wschód od linii wyznaczonej przez drogę łączącą miejscowości Sątoczno, Sajna Wielka biegnącą do skrzyżowania z drogą nr 590 w miejscowości Glitajny, a następnie na wschód od drogi nr 590 do skrzyżowania z drogą nr 592 i na południe od linii wyznaczonej przez drogę nr 592 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą nr 590 w powiecie kętrzyńskim,
- część gminy wiejskiej Lidzbark Warmiński położona na zachód od linii wyznaczonej przez drogę nr 511 oraz na północny zachód od linii wyznaczonej przez drogę nr 51 i miasto Lidzbark Warmiński w powiecie lidzbarskim,
- część gminy Sorkwity położona na północ od drogi nr 16 i część gminy wiejskiej Mrągowo położona na północ od linii wyznaczonej przez drogę nr 16 biegnącą od zachodniej granicy gminy do granicy miasta Mrągowo oraz na północ od linii wyznaczonej przez drogę nr 59 biegnącą od wschodniej granicy gminy do granicy miasta Mrągowo;
- w województwie podlaskim:
 - powiat grajewski,
 - powiat moniecki,
 - powiat sejneński,
 - gminy Łomża, Piątnica, Śniadowo, Jedwabne, Przytuły i Wizna w powiecie łomżyńskim,
 - powiat miejski Łomża,
 - gminy Mielnik, Nurzec – Stacja, Grodzisk, Drohiczyn, Dziadkowice, Milejczyce i Siemiatycze z miastem Siemiatycze w powiecie siemiatyckim,
 - powiat hajnowski,
 - gminy Kobylin-Borzymy i Sokoły w powiecie wysokomazowieckim,
 - część gminy Zambrów położona na północ od linii wyznaczonej przez drogę nr S8 w powiecie zambrowskim,
 - gminy Grabowo i Stawiski w powiecie kolneńskim,
 - gminy Czarna Białostocka, Dobrzyniewo Duże, Gródek, Juchnowiec Kościelny, Łapy, Michałowo, Supraśl, Suraż, Turośń Kościelna, Tykocin, Wasilków, Zabłudów, Zawady i Choroszcz w powiecie białostockim,
 - gminy Boćki, Orla i Bielsk Podlaski z miastem Bielsk Podlaski w powiecie bielskim,
 - gmina Puńsk, część gminy Krasnopol położona na północ od linii wyznaczonej przez drogę nr 653, część gminy Sejny położona na północ od linii wyznaczonej przez drogę nr 653 i na wschód od linii wyznaczonej przez drogę nr 663 i miasto Sejny w powiecie sejneńskim,
 - gminy Bakalarzewo, Filipów, Jeleniewo, Raczki, Rutka-Tartak, Suwałki i Szypliszki w powiecie suwalskim,
 - powiat miejski Suwałki,
 - powiat augustowski,
 - powiat sokólski,
 - powiat miejski Białystok.
- w województwie mazowieckim:
 - gminy Przesmyki, Wodynie, Skórzec i część gminy Mordy położona na południe od linii wyznaczonej przez drogę nr 698 biegnącą od zachodniej granicy gminy do północno – wschodniej granicy gminy i część gminy Zbuczyn położona na wschód od linii wyznaczonej przez drogę biegnącą od północno-wschodniej do południowej granicy gminy i łączącą miejscowości Tarcze, Choja, Zbuczyn, Grodzisk, Dziewule i Smolanka w powiecie siedleckim,
 - gminy Repki, Jabłonna Lacka, część gminy Bielany położona na wschód od linii wyznaczonej przez drogę nr 63 i część gminy wiejskiej Sokołów Podlaski położona na wschód od linii wyznaczonej przez drogę nr 63 w powiecie sokołowskim,
 - powiat łosicki,
 - gmina Brochów w powiecie sochaczewskim,
 - powiat nowodworski,
 - gminy Joniec i Nowe Miasto w powiecie płońskim,
 - 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 Dąbrówka, Kobyłka, Marki, Radzymin, Wołomin, Zielonka i Ząbki w powiecie wołomińskim,

- część gminy Somianka położona na południe od linii wyznaczonej przez drogę nr 62 w powiecie wyszkowskim,
 - gminy Dębe Wielkie, Halinów, Sulejówek miasto Mińsk Mazowiecki i części gminy Latowicz położona na wschód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy przez miejscowość Stawek do skrzyżowania z drogą nr 802 i na północ od linii wyznaczonej przez drogę nr 802 biegnącą od tego skrzyżowania do wschodniej granicy gminy w powiecie mińskim,
 - gminy Borowie, Wilga i Garwolin z miastem Garwolin, Maciejowice i część gminy Miastków Kościelny położona na północ od rzeki Wilga w powiecie garwolińskim,
 - gminy Celestynów, Józefów, Karczew, Osieck, Otwock, Sobienie Jeziory i Wiązowna w powiecie otwockim
 - powiat warszawski zachodni,
 - powiat legionowski,
 - powiat piaseczyński,
 - powiat pruszkowski,
 - gminy Chynów, Grójec, Jasieniec, Pniewy i Warka w powiecie grójeckim,
 - gminy Milanówek, Grodzisk Mazowiecki, Podkowa Leśna i Żabia Wola w powiecie grodziskim,
 - gminy Grabów nad Pilicą, Magnuszew, Głowaczów, Kozienice w powiecie kozienickim,
 - część gminy Stromiec położona na północ od linii wyznaczonej przez drogę nr 48 w powiecie białobrzeskim,
 - powiat miejski Warszawa.
- w województwie lubelskim:
- gminy Czemierniki, Kąkolewnica, Komarówka Podlaska, Wołyń, część gminy Borki położona na południowy – wschód od linii wyznaczonej przez drogę nr 19, miasto Radzyń Podlaski, część gminy wiejskiej Radzyń Podlaski położona na wschód od linii wyznaczonej przez drogę biegnącą od północno-zachodniej granicy gminy i łącząca miejscowości Brzostowiec i Radowiec do jej przecięcia z granicą miasta Radzyń Podlaski, następnie na wschód od linii stanowiącej granicę miasta Radzyń Podlaski biegnącej do południowej granicy gminy i na południe od linii wyznaczonej przez drogę nr 19 biegnącą od południowo zachodniej granicy gminy do granicy miasta Radzyń Podlaski oraz na południe od południowej granicy miasta Radzyń Podlaski do granicy gminy w powiecie radzyńskim,
 - gminy Stoczek Łukowski z miastem Stoczek Łukowski, Wola Mysłowska, Trzebieszów, część gminy Krzywda położona na zachód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy w kierunku południowym i łącząca miejscowości Kozuchówka, Krzywda i Adamów, część gminy Stanin położona na zachód od linii wyznaczonej przez drogę nr 807, i część gminy wiejskiej Łuków położona na wschód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy przez miejscowość Wólka Świątkowa do północnej granicy miasta Łuków i na północ od linii wyznaczonej przez drogę nr 806 biegnącą od wschodniej granicy miasta Łuków do wschodniej granicy gminy wiejskiej Łuków i część miasta Łuków położona na wschód od linii wyznaczonej przez drogę nr 63 biegnącą od północnej granicy miasta Łuków do skrzyżowania z drogą nr 806 i na północ od linii wyznaczonej przez drogę nr 806 biegnącą od tego skrzyżowania do wschodniej granicy miasta Łuków w powiecie łukowskim,
 - gminy Janów Podlaski, Kodeń, Tuczna, Leśna Podlaska, Rossosz, Łomazy, Konstantynów, Piszczac, Rokitno, Biała Podlaska, Zalesie, Terespol z miastem Terespol, Drelów, Międzyrzec Podlaski z miastem Międzyrzec Podlaski w powiecie białskim,
 - powiat miejski Biała Podlaska,
 - gmina Łęczna i część gminy Spiczyn położona na zachód od linii wyznaczonej przez drogę nr 829 w powiecie łużyńskim,
 - część gminy Siemień położona na zachód od linii wyznaczonej przez drogę nr 815 i część gminy Milanów położona na zachód od drogi nr 813 w powiecie parczewskim,
 - gminy Niedźwiada, Ostrówek, Abramów, Firlej, Kamionka, Michów i Lubartów z miastem Lubartów, w powiecie lubartowskim,
 - gminy Niemce i Garbów w powiecie lubelskim,
 - część gminy Piaski położona na północ od linii wyznaczonej przez drogę nr 17 biegnącą od wschodniej granicy gminy Piaski do skrzyżowania z drogą nr S12 i na wschód od linii wyznaczonej przez drogę biegnącą od skrzyżowania dróg nr 17 i nr S12 przez miejscowość Majdan Brzezicki do północnej granicy gminy w powiecie świdnickim;
 - gmina Fajslawice, Kraśniczyn, część gminy Krasnystaw położona na zachód od linii wyznaczonej przez drogę nr 17 biegnącą od północno – wschodniej granicy gminy do granicy miasta Krasnystaw, miasto Krasnystaw i część gminy Łopiennik Górny położona na zachód od linii wyznaczonej przez drogę nr 17 w powiecie krasnostawskim,

- gminy Dołhobyczów, Mircze i część gminy wiejskiej Hrubieszów położona na południe od linii wyznaczonej przez drogę nr 844 oraz na południe od linii wyznaczonej przez drogę nr 74 i miasto Hrubieszów w powiecie hrubieszowskim,
- gmina Telatyn w powiecie tomaszowskim,
- część gminy Wojsławice położona na zachód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy przez miejscowość Wojsławice do południowej granicy gminy w powiecie chełmskim,
- gmina Grabowiec w powiecie zamojskim,
- gminy Markuszów, Nałęczów, Kazimierz Dolny, Końskowola, Kurów, Wąwolnica, Żyrzyn, Baranów, część gminy wiejskiej Puławy położona na wschód od rzeki Wisły i miasto Puławy w powiecie puławskim.

PART III

1. Latvia

The following areas in Latvia:

- Brocēnu novada Cieceres un Gaiķu pagasts, Remtes pagasta daļa uz rietumiem no autoceļa 1154 un P109, Brocēnu pilsēta,
- Kuldīgas novada Pelču, Snēpeles un Vārmes pagasts, Rumbas pagasta daļa uz dienvidiem no autoceļa P120, Kurmāles pagasta daļa uz austrumiem no autoceļa 1283 un 1290, un uz dienvidrietumiem no autoceļa P118,
- Saldus novada Saldus, Zirņu, Lutriņu, Zaņas, Ezeres un Jaunlutriņu pagasts, Saldus pilsēta.

2. Lithuania

The following areas in Lithuania:

- Akmenės rajono savivaldybė,
- Alytaus miesto savivaldybė,
- Alytaus rajono savivaldybė: Alytaus, Alovės, Butrimonių, Daugų, Nemunaičio, Pivašiūnų, Punios ir Raitininkų seniūnijos,
- Birštono savivaldybė,
- Jurbarko rajono savivaldybė: Girdžių, Juodaičių, Raudonės, Seredžiaus, Skirsnemunės, Šimkaičių ir Veliuonos seniūnijos,
- Joniškio rajono savivaldybė,
- Kaišiadorių rajono savivaldybė: Paparčių ir Žaslių seniūnijos,
- Kelmės rajono savivaldybė: Tytyvėnų seniūnijos dalis į rytus ir pietus nuo kelio Nr. 157 ir į rytus nuo kelio Nr. 2105 ir Tytuvėnų apylinkių seniūnijos dalis į pietus nuo kelio Nr. 157 ir į rytus nuo kelio Nr. 2105,
- Lazdijų rajono savivaldybė,
- Marijampolės savivaldybė: Degučių, Mokolų, Narto, Marijampolės seniūnijos,
- Mažeikių rajono savivaldybės: Laižuvos, Mažeikių apylinkės, Mažeikių, Reivyčių, Tirkšlių ir Viekšnių seniūnijos,
- Molėtų rajono savivaldybė: Dubingių, Giedraičių seniūnijos,
- Prienų rajono savivaldybė: Jiezno ir Stakliškių seniūnijos,
- Radviliškio rajono savivaldybė: Baisogalos seniūnijos dalis į rytus nuo kelio Nr. 144, Grinkiškio, Pakalniškių, Sidabravo, Skėmių seniūnijos, Šeduvos miesto seniūnijos dalis į šiaurę nuo kelio Nr. A9 ir į rytus nuo kelio Nr. 3417, Šaukoto ir Šiaulėnų seniūnijos,
- Raseinių rajono savivaldybė: Kalnųjų seniūnijos ir Girkalnio seniūnijos dalis į pietus nuo kelio Nr. A1,
- Šakių rajono savivaldybė: Gelgaudiškio, Kidulių, Plokščių ir Šakių seniūnijos,
- Šiaulių miesto savivaldybė,
- Šiaulių rajono savivaldybė,
- Širvintų rajono savivaldybė: Alionių seniūnija,
- Telšių rajono savivaldybė: Tryškių seniūnija,
- Vilniaus rajono savivaldybė: Paberžės sen.

3. Poland

The following areas in Poland:

w województwie warmińsko-mazurskim:

- gminy Lelkowo, Pieniężno, Płoskinia, Wilczęta i część gminy wiejskiej Braniewo położona na wschód od linii wyznaczonej przez drogę nr E28 i S22 w powiecie braniewskim,
- gminy Bartoszyce z miastem Bartoszyce, Górowo Iławeckie z miastem Górowo Iławeckie i Sępopol w powiecie bartoszyckim,
- gmina Młynary w powiecie elbląskim,
- część gminy Kiwity położona na północ od linii wyznaczonej przez drogę nr 513 i część gminy Lidzbark Warmiński położona na północ od linii wyznaczonej przez drogę nr 513 biegnącą od wschodniej granicy gminy do wschodniej granicy miasta Lidzbark Warmiński i na wschód od linii wyznaczonej przez drogę nr 511 w powiecie lidzbarskim,
- gminy Srokowo, Barciany i część gminy Korsze położona na północ od linii wyznaczonej przez drogę biegnącą od wschodniej granicy łączącą miejscowości Krelikiejmy i Sątoczno i na zachód od linii wyznaczonej przez drogę łączącą miejscowości Sątoczno, Sajna Wielka biegnącą do skrzyżowania z drogą nr 590 w miejscowości Glitajny, a następnie na zachód od drogi nr 590 do skrzyżowania z drogą nr 592 i na północ od linii wyznaczonej przez drogę nr 592 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą nr 590 w powiecie kętrzyńskim,
- gmina Budry i część gminy Węgorzewo położona na wschód od linii wyznaczonej przez drogę nr 63 biegnącą od południowo-wschodniej granicy gminy do skrzyżowania z drogą nr 650, a następnie na północ od linii wyznaczonej przez drogę nr 650 biegnącą od skrzyżowania z drogą nr 63 do skrzyżowania z drogą biegnącą do miejscowości Przysań i na zachód od linii wyznaczonej przez drogę łączącą miejscowości Przysań, Pniewo, Kamionek Wielki, Radzieje, Dłużec w powiecie węgorzewskim,
- część gminy Banie Mazurskie położona na północ od linii wyznaczonej przez drogę nr 650 w powiecie gołdapskim,

w województwie mazowieckim:

- gminy Domanice, Korczew, Paprotnia, Wiśniew, Mokobody, Siedlce, Suchożebry, część gminy Kotuń położona na wschód od linii wyznaczonej przez drogę łączącą miejscowości Nowa Dąbrówka, Pieróg, Kotuń wzdłuż ulicy Gorzkowskiego i Kolejowej do przejazdu kolejowego łączącego się z ulicą Siedlecką, Broszków, Żuków, część gminy Mordy położona na północ od linii wyznaczonej przez drogę nr 698 biegnącą od zachodniej granicy gminy do północno – wschodniej granicy gminy w powiecie siedleckim,
- powiat miejski Siedlce,
- gmina Siennica, część gminy Mińsk Mazowiecki położona na południe od linii wyznaczonej przez drogę nr 92 biegnącą od zachodniej granicy gminy do granicy miasta Mińsk Mazowiecki i na południe od linii wyznaczonej przez drogę biegnącą od wschodniej granicy miasta Mińsk Mazowiecki łączącą miejscowości Targówka, Budy Barczackie do wschodniej granicy gminy, część gminy Cegłów położona na południe od linii wyznaczonej przez drogę biegnącą od zachodniej granicy gminy łączącą miejscowości Wiciejów, Mienia, Cegłów i na zachód od linii wyznaczonej przez drogę łączącą miejscowości Cegłów, Skwarne i Podskwarne biegnącą do wschodniej granicy gminy i części gminy Latowicz położona na zachód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy przez miejscowość Stawek do skrzyżowania z drogą nr 802 i na południe od linii wyznaczonej przez drogę nr 802 biegnącą od tego skrzyżowania do wschodniej granicy gminy w powiecie mińskim,
- gmina Kołbiel w powiecie otwockim,
- gminy Parysów i Pilawa w powiecie garwolińskim,

w województwie lubelskim:

- gminy Białopole, Dubienka, Chełm, Leśniowice, Wierzbica, Sawin, Ruda Huta, Dorohusk, Kamień, Rejowiec, Rejowiec Fabryczny z miastem Rejowiec Fabryczny, Siedliszcze, Żmudź i część gminy Wojsławice położona na wschód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy do miejscowości Wojsławice do południowej granicy gminy w powiecie chełmskim,
- powiat miejski Chełm,
- gmina Siennica Różana część gminy Łopiennik Górny położona na wschód od linii wyznaczonej przez drogę nr 17 i część gminy Krasnystaw położona na wschód od linii wyznaczonej przez drogę nr 17 biegnącą od północno – wschodniej granicy gminy do granicy miasta Krasnystaw w powiecie krasnostawskim,

- gminy Hanna, Hańsk, Wola Uhruska, Urszulin, Stary Brus, Wiryki i gmina wiejska Włodawa w powiecie włodawskim,
- gminy Cyców, Ludwin, Puchaczów, Milejów i część gminy Spiczyn położona na wschód od linii wyznaczonej przez drogę nr 829 w powiecie łączyńskim,
- gmina Trawniki w powiecie świdnickim,
- gminy Jabłoń, Podedwórze, Dębowa Kłoda, Parczew, Sosnowica, część gminy Siemień położona na wschód od linii wyznaczonej przez drogę nr 815 i część gminy Milanów położona na wschód od drogi nr 813 w powiecie parczewskim,
- gminy Sławatycze, Sosnówka, i Wisznice w powiecie bialskim,
- gmina Ulan Majorat, część gminy wiejskiej Radzyń Podlaski położona na zachód od linii wyznaczonej przez drogę biegnącą od północno-zachodniej granicy gminy i łączącą miejscowości Brzostówek i Radowiec do jej przecięcia z granicą miasta Radzyń Podlaski, a następnie na zachód od linii stanowiącej granicę miasta Radzyń Podlaski do jej przecięcia z drogą nr 19 i na północ od linii wyznaczonej przez drogę nr 19 biegnącą od południowo zachodniej granicy gminy do granicy miasta Radzyń Podlaski, część gminy Borki położona na północny – zachód od linii wyznaczonej przez drogę nr 19 w powiecie radzyńskim,
- gminy, Ostrów Lubelski, Serniki i Uścimów w powiecie lubartowskim,
- gminy Wojcieszków, część gminy wiejskiej Łuków położona na zachód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy przez miejscowość Wólka Świątkowa do północnej granicy miasta Łuków, a następnie na północ, zachód, południe i wschód od linii stanowiącej północną, zachodnią, południową i wschodnią granicę miasta Łuków do jej przecięcia się z drogą nr 806 i na południe od linii wyznaczonej przez drogę nr 806 biegnącą od wschodniej granicy miasta Łuków do wschodniej granicy gminy wiejskiej Łuków, część miasta Łuków położona na zachód i na południe od linii wyznaczonej przez drogę nr 63 biegnącą od północnej granicy miasta Łuków do skrzyżowania z drogą nr 806 i na południe od linii wyznaczonej przez drogę nr 806 biegnącą do wschodniej granicy miasta Łuków, część gminy Stanin położona na wschód od linii wyznaczonej przez drogę nr 807 i część gminy Krzywda położona na wschód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy w kierunku południowym i łączącą miejscowości Kozuchówka, Krzywda i Adamów w powiecie łukowskim;
- gminy Horodło, Uchanie i część gminy wiejskiej Hrubieszów położona na północ od linii wyznaczonej przez drogę nr 844 biegnącą od zachodniej granicy gminy wiejskiej Hrubieszów do granicy miasta Hrubieszów oraz na północ od linii wyznaczonej przez drogę nr 74 biegnącą od wschodniej granicy miasta Hrubieszów do wschodniej granicy gminy wiejskiej Hrubieszów w powiecie hrubieszowskim,

w województwie podkarpackim:

- gminy Cieszanów, Lubaczów z miastem Lubaczów i część gminy Oleszyce położona na północ od linii wyznaczonej przez drogę biegnącą od wschodniej granicy gminy przez miejscowość Borchów do skrzyżowania z drogą nr 865 w miejscowości Oleszyce, a następnie na wschód od linii wyznaczonej przez drogę nr 865 biegnącą w kierunku północno-wschodnim do skrzyżowania z drogą biegnącą w kierunku północno-zachodnim przez miejscowość Lubomierz - na północ od linii wyznaczonej przez tę drogę do skrzyżowania z drogą łączącą miejscowości Uszkowce i Nowy Dzików – na wschód od tej drogi w powiecie lubaczowskim.

4. Romania

The following areas in Romania:

- Zona oraşului Bucureşti,
- Judeţul Constanţa,
- Judeţul Satu Mare,
- Judeţul Tulcea,
- Judeţul Bacău,
- Judeţul Bihor,
- Judeţul Brăila,
- Judeţul Buzău,
- Judeţul Călăraşi,
- Judeţul Dâmboviţa,
- Judeţul Galaţi,
- Judeţul Giurgiu,
- Judeţul Ialomiţa,

- Județul Ilfov,
- Județul Prahova,
- Județul Sălaj,
- Județul Vaslui,
- Județul Vrancea,
- Județul Teleorman,
- Județul Olt,
- Partea din județul Maramureș cu următoarele delimitări:
 - Comuna Petrova,
 - Comuna Bistra,
 - Comuna Repedea,
 - Comuna Poienile de sub Munte,
 - Comuna Vișeu e Jos,
 - Comuna Ruscova,
 - Comuna Leordina,
 - Comuna Rozavlea,
 - Comuna Strâmtura,
 - Comuna Bârsana,
 - Comuna Rona de Sus,
 - Comuna Rona de Jos,
 - Comuna Bocoiu Mare,
 - Comuna Sighetu Marmației,
 - Comuna Sarasau,
 - Comuna Câmpulung la Tisa,
 - Comuna Săpânța,
 - Comuna Remeti,
 - Comuna Giulești,
 - Comuna Ocna Șugatag,
 - Comuna Desești,
 - Comuna Budești,
 - Comuna Băiuț,
 - Comuna Căvnic,
 - Comuna Lăpuș,
 - Comuna Dragomirești,
 - Comuna Ieud,
 - Comuna Saliștea de Sus,
 - Comuna Săcel,
 - Comuna Călinești,
 - Comuna Vadu Izei,
 - Comuna Botiza,
 - Comuna Bogdan Vodă,
 - Localitatea Groșii Țibileșului, comuna Suciul de Sus,
 - Localitatea Vișeu de Mijloc, comuna Vișeu de Sus,
 - Localitatea Vișeu de Sus, comuna Vișeu de Sus.

PART IV

Italy

The following areas in Italy:

- tutto il territorio della Sardegna.

EUROPEAN SECURITIES AND MARKETS AUTHORITY DECISION (EU) 2018/1636**of 23 October 2018****renewing and amending the temporary restriction in Decision (EU) 2018/796 on the marketing, distribution or sale of contracts for differences to retail clients**

THE EUROPEAN SECURITIES AND MARKETS AUTHORITY BOARD OF SUPERVISORS,

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

Having regard to Regulation (EU) No 1095/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Securities and Markets Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/77/EC ⁽¹⁾, and in particular Articles 9(5), 43(2) and 44(1) thereof,

Having regard to Regulation (EU) No 600/2014 of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Regulation (EU) No 648/2012 ⁽²⁾, and in particular Article 40 thereof,

Having regard to Commission Delegated Regulation (EU) 2017/567 of 18 May 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council with regard to definitions, transparency, portfolio compression and supervisory measures on product intervention and positions ⁽³⁾, and in particular Article 19 thereof,

Whereas:

- (1) By its Decision (EU) 2018/796 ⁽⁴⁾, the European Securities and Markets Authority (ESMA) restricted the marketing, distribution or sale of contracts for differences (CFDs) to retail clients with effect from 1 August 2018 for a period of three months.
- (2) In accordance with Article 40(6) of Regulation (EU) No 600/2014, ESMA must review a temporary product intervention measure at appropriate intervals and at least every three months.
- (3) ESMA's review of the restriction on CFDs has been informed by, inter alia, a survey among national competent authorities ⁽⁵⁾ (NCAs) on the practical application and impact of the product intervention measure as well as additional information provided by NCAs and stakeholders.
- (4) NCAs detected only limited examples of non-compliance with the ESMA product intervention measure, which mainly related to the risk warnings.
- (5) NCAs reported an overall decrease in the number of CFD retail client accounts, trading volume and total retail client equity over the month of August 2018 in comparison with August 2017. The share of profitable retail client accounts decreased slightly, but this appears to be mainly arising from the soaring prices of cryptocurrencies in August 2017 ⁽⁶⁾. Comparing client outcomes over time is not only impacted by the product

⁽¹⁾ OJ L 331, 15.12.2010, p. 84.

⁽²⁾ OJ L 173, 12.6.2014, p. 84.

⁽³⁾ OJ L 87, 31.3.2017, p. 90.

⁽⁴⁾ European Securities and Markets Authority Decision (EU) 2018/796 of 22 May 2018 to temporarily restrict contracts for differences in the Union in accordance with Article 40 of Regulation (EU) No 600/2014 of the European Parliament and of the Council (OJ L 136, 1.6.2018, p. 50).

⁽⁵⁾ 23 NCAs have responded: Financial Services and Markets Authority (BE – FSMA), Czech National Bank (CZ – CNB), Finanstilsynet (DK – Finanstilsynet), Bundesanstalt für Finanzdienstleistungsaufsicht (DE – BaFin), Central Bank of Ireland (IE – CBI), Ελληνική Επιτροπή Κεφαλαιαγοράς (EL – HCMC), Comisión Nacional del Mercado de Valores (ES – CNMV), Autorité des Marchés Financiers (FR – AMF), Commissione Nazionale per le Società e la Borsa (IT – Consob), Cyprus Securities and Exchange Commission (CY – CySEC), Finanšu un kapitāla tirgus komisija (LV – FKTK), Commission de Surveillance du Secteur Financier (LU – CSSF), Magyar Nemzeti Bank (HU – MNB), Malta Financial Services Authority (MT – MFSA), Autoriteit Financiële Markten (NL – AFM), Financial Market Authority (AT – FMA), Komisja Nadzoru Finansowego (PL – KNF), Comissão do Mercado de Valores Mobiliários (PT – CMVM), Romanian Financial Supervisory Authority (RO – FSA), Agencija za trg vrednostnih papirjev (SI – ATVP), Finnish Financial Supervisory Authority (FI – FSA), Financial Conduct Authority (UK – FCA), Fjármálaeftirlitið (IS – FME).

⁽⁶⁾ For example, for Bitcoins the percentage change in price from 31 July 2017 to 31 August 2017 was + 65,8 % in comparison to – 9,3 % over the same period in 2018 (Available at [Coindesk.com](https://www.coindesk.com/) – <https://www.coindesk.com/>).

intervention measures, but also for example by market conditions. Market conditions in August 2017 were bullish in comparison to August 2018. Furthermore, the population of retail clients changed ⁽¹⁾. Finally, NCAs reported a decrease in the number of automatic close-outs and the occurrences that accounts went into negative equity ⁽²⁾.

- (6) NCAs also reported an increase in the number of clients treated as professional clients on request over the month of August 2018 in comparison with August 2017. ESMA is aware that some CFD providers are advertising to retail clients the possibility of becoming professional clients on request. However, a retail client may request to be treated as a professional client when, in particular, the client submits a request in writing in accordance with all the requirements set out in the applicable legislation. Providers should ensure that they comply at all times with those requirements ⁽³⁾. ESMA is also aware that some third-country firms are actively approaching Union clients or that some CFD providers in the Union are marketing the possibility for retail clients to move their accounts to an intra-group third-country entity. However, without authorisation or registration in the Union, third-country firms are only allowed to offer services to clients established or situated in the Union at the client's own exclusive initiative. Finally, ESMA is aware that firms are starting to provide other speculative investment products. ESMA will continue to monitor the offer of these other products to determine whether any other Union measures are appropriate.
- (7) During the review period, ESMA did not obtain evidence contradicting its overall finding of a significant investor protection concern identified in Decision (EU) 2018/796. ESMA has therefore concluded that the significant investor protection concern identified in Decision (EU) 2018/796 would persist if its decision to restrict the marketing, distribution or sale of CFDs to retail clients is not renewed.
- (8) Since the adoption of that Decision, the applicable existing regulatory requirements under Union law have not changed and continue not to address the threat identified by ESMA. Furthermore, NCAs have not taken action to address the threat or the actions taken do not adequately address the threat. In particular, since the adoption of the Decision, no NCA has adopted its own national product intervention measure under Article 42 of Regulation (EU) No 600/2014 ⁽⁴⁾.
- (9) The renewal of the restriction set out in Decision (EU) 2018/796 does not have a detrimental effect on the efficiency of financial markets or on investors that is disproportionate to the benefits of the action and does not create a risk of regulatory arbitrage for the same reasons set out in that Decision.
- (10) If the temporary restriction is not renewed, ESMA considers it is likely that CFDs will again be offered without adequate measures to sufficiently protect retail clients against the risks related to those products that gave rise to the consumer detriment identified in Decision (EU) 2018/796.
- (11) In view of these reasons, taken together with the reasons set out in Decision (EU) 2018/796, ESMA has decided to renew the restriction for a further three-month period to address the significant investor protection concern.
- (12) In renewing the restriction, ESMA has carefully considered any new relevant information that has emerged during the review period. In this respect, ESMA obtained information that, in certain cases, CFD providers experience technical difficulties in using the abbreviated risk warning due to the character limits imposed by third party marketing providers for communications other than through a durable medium or a webpage. Therefore, a reduced character risk warning should be introduced in this renewal.

⁽¹⁾ Also due to the re-categorisation of retail clients as professional clients on request or active retail clients that may have moved their account to third country providers.

⁽²⁾ In August 2018, the negative balance protection was in force. However, market gapping can lead to the client initially being closed out at a price that creates negative equity, with the account then re-credited back to zero equity by the provider to meet the new requirement of negative balance protection. This was also the case for those providers that offered negative balance protection in August 2017.

⁽³⁾ Annex II, Section II of Directive 2014/65/EU of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Directive 2002/92/EC and Directive 2011/61/EU (OJ L 173, 12.6.2014, p. 349). See also Section 11 of ESMA's Questions and Answers on MiFID II and MiFIR investor protection and intermediaries topics (ESMA35-43-349), where ESMA has identified forms of practices that investment firms should not use when applying the legal requirements on the categorisation of clients as professionals on request. Section 11 was last updated on 25 May 2018.

⁽⁴⁾ On 4 June 2018, a competent authority of an EEA EFTA State, NO-Finanstilsynet, adopted national product intervention measures that have the same terms and dates of application of ESMA's measures.

- (13) The reduced character risk warning is not intended to replace the abbreviated risk warning. The new warning is envisaged to be used only for cases where the third party relied on by a CFD provider to market the product imposes a character limit that is not compatible with the number of characters comprising the risk warnings.
- (14) The reduced character risk warning provides retail clients with information on the percentage of CFD retail accounts losing money. However, in order to fully draw clients' attention to whether they can afford the high risk of losing their money when investing in CFDs, this renewal requires that any communication containing the reduced character risk warning also includes a direct link to a webpage of the CFD provider where the warning required for durable media or webpages is shown.
- (15) As the proposed measures may, to a limited extent, relate to agricultural commodities derivatives, ESMA has consulted the public bodies competent for the oversight, administration and regulation of physical agricultural markets under Council Regulation (EC) No 1234/2007 ⁽¹⁾. None of those bodies has raised any objections to the proposed renewal of the measures.
- (16) ESMA has notified NCAs of the proposed renewal Decision,

HAS ADOPTED THIS DECISION:

Article 1

Definitions

For the purposes of this Decision:

- (a) 'contract for differences' or 'CFD' means a derivative other than an option, future, swap or forward rate agreement, the purpose of which is to give the holder a long or short exposure to fluctuations in the price, level or value of an underlying, irrespective of whether it is traded on a trading venue, and that must be settled in cash or may be settled in cash at the option of one of the parties other than by reason of default or other termination event;
- (b) 'excluded non-monetary benefit' means any non-monetary benefit other than, insofar as they relate to CFDs, information and research tools;
- (c) 'initial margin' means any payment for the purpose of entering into a CFD, excluding commission, transaction fees and any other related costs;
- (d) 'initial margin protection' means the initial margin determined by Annex I;
- (e) 'margin close-out protection' means the closure of one or more of a retail client's open CFDs on terms most favourable to the client in accordance with Articles 24 and 27 of Directive 2014/65/EU when the sum of funds in the CFD trading account and the unrealised net profits of all open CFDs connected to that account falls to less than half of the total initial margin protection for all those open CFDs;
- (f) 'negative balance protection' means the limit of a retail client's aggregate liability for all CFDs connected to a CFD trading account with a CFD provider to the funds in that CFD trading account.

Article 2

Temporary restriction on CFDs in respect of retail clients

The marketing, distribution or sale to retail clients of CFDs is restricted to circumstances where at least all of the following conditions are met:

- (a) the CFD provider requires the retail client to pay the initial margin protection;
- (b) the CFD provider provides the retail client with the margin close-out protection;
- (c) the CFD provider provides the retail client with the negative balance protection;

⁽¹⁾ Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) (OJ L 299, 16.11.2007, p. 1).

- (d) the CFD provider does not directly or indirectly provide the retail client with a payment, monetary or excluded non-monetary benefit in relation to the marketing, distribution or sale of a CFD, other than the realised profits on any CFD provided; and
- (e) the CFD provider does not send directly or indirectly a communication to or publish information accessible by a retail client relating to the marketing, distribution or sale of a CFD unless it includes the appropriate risk warning specified by and complying with the conditions in Annex II.

Article 3

Prohibition of participating in circumvention activities

It shall be prohibited to participate, knowingly and intentionally, in activities the object or effect of which is to circumvent the requirements in Article 2, including by acting as a substitute for the CFD provider.

Article 4

Entry into force and application

This Decision enters into force on the day following that of its publication in the *Official Journal of the European Union*.

This Decision shall apply from 1 November 2018 for a period of 3 months.

Done at Paris, 23 October 2018.

For the Board of Supervisors
Steven MAIJOR
The Chair

ANNEX I

INITIAL MARGIN PERCENTAGES BY TYPE OF UNDERLYING

- (a) 3,33 % of the notional value of the CFD when the underlying currency pair is composed of any two of the following currencies: US dollar, Euro, Japanese yen, Pound sterling, Canadian dollar or Swiss franc;
 - (b) 5 % of the notional value of the CFD when the underlying index, currency pair or commodity is:
 - (i) any of the following equity indices: Financial Times Stock Exchange 100 (FTSE 100); Cotation Assistée en Continu 40 (CAC 40); Deutsche Bourse AG German Stock Index 30 (DAX30); Dow Jones Industrial Average (DJIA); Standard & Poors 500 (S&P 500); NASDAQ Composite Index (NASDAQ), NASDAQ 100 Index (NASDAQ 100); Nikkei Index (Nikkei 225); Standard & Poors/Australian Securities Exchange 200 (ASX 200); EURO STOXX 50 Index (EURO STOXX 50);
 - (ii) a currency pair composed of at least one currency that is not listed in point (a) above; or
 - (iii) gold;
 - (c) 10 % of the notional value of the CFD when the underlying commodity or equity index is a commodity or any equity index other than those listed in point (b) above;
 - (d) 50 % of the notional value of the CFD when the underlying is a cryptocurrency; or
 - (e) 20 % of the notional value of the CFD when the underlying is:
 - (i) a share; or
 - (ii) not otherwise listed in this Annex.
-

ANNEX II

RISK WARNINGS

SECTION A

Risk warning conditions

1. The risk warning shall be in a layout ensuring its prominence, in a font size at least equal to the predominant font size and in the same language as that used in the communication or published information.
2. If the communication or published information is in a durable medium or a webpage, the risk warning shall be in the format specified in Section B.
3. If the communication or published information is in a medium other than a durable medium or a webpage, the risk warning shall be in the format specified in Section C.
4. By way of derogation to paragraphs 2 and 3, if the number of characters contained in the risk warning in the format specified in Section B or C exceeds the character limit permitted in the standard terms of a third party marketing provider, the risk warning may instead be in the format specified in Section D.
5. If the risk warning in the format specified in Section D is used, the communication or published information shall also include a direct link to the webpage of the CFD provider containing the risk warning in the format specified in Section B.
6. The risk warning shall include an up-to-date provider-specific loss percentage based on a calculation of the percentage of CFD trading accounts provided to retail clients by the CFD provider that lost money. The calculation shall be performed every three months and cover the 12-month period preceding the date on which it is performed ('12-month calculation period'). For the purposes of the calculation:
 - (a) an individual retail client CFD trading account shall be considered to have lost money if the sum of all realised and unrealised net profits on CFDs connected to the CFD trading account during the 12-month calculation period is negative;
 - (b) any costs relating to the CFDs connected to the CFD trading account shall be included in the calculation, including all charges, fees and commissions;
 - (c) the following items shall be excluded from the calculation:
 - (i) any CFD trading account that did not have an open CFD connected to it within the calculation period;
 - (ii) any profits or losses from products other than CFDs connected to the CFD trading account;
 - (iii) any deposits or withdrawals of funds from the CFD trading account.
7. By way of derogation from paragraphs 2 to 6, if in the last 12-month calculation period a CFD provider has not provided an open CFD connected to a retail client CFD trading account, that CFD provider shall use the standard risk warning in the format specified in Sections E to G, as appropriate.

SECTION B

Durable medium and webpage provider-specific risk warning

CFDs are complex instruments and come with a high risk of losing money rapidly due to leverage.

[insert percentage per provider] % of retail investor accounts lose money when trading CFDs with this provider.

You should consider whether you understand how CFDs work and whether you can afford to take the high risk of losing your money.

SECTION C

Abbreviated provider-specific risk warning

[insert percentage per provider] % of retail investor accounts lose money when trading CFDs with this provider.

You should consider whether you can afford to take the high risk of losing your money.

SECTION D

Reduced character provider-specific risk warning

[insert percentage per provider] % of retail CFD accounts lose money.

SECTION E

Durable medium and webpage standard risk warning

CFDs are complex instruments and come with a high risk of losing money rapidly due to leverage.

Between 74-89 % of retail investor accounts lose money when trading CFDs.

You should consider whether you understand how CFDs work and whether you can afford to take the high risk of losing your money.

SECTION F

Abbreviated standard risk warning

Between 74-89 % of retail investor accounts lose money when trading CFDs.

You should consider whether you can afford to take the high risk of losing your money.

SECTION G

Reduced character standard risk warning

74-89 % of retail CFD accounts lose money.

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