

Official Journal of the European Union

L 128



English edition

Legislation

Volume 66

15 May 2023

Contents

I *Legislative acts*

DIRECTIVES

- ★ **Directive (EU) 2023/946 of the European Parliament and of the Council of 10 May 2023 amending Directive 2003/25/EC as regards the inclusion of improved stability requirements and the alignment of that Directive with the stability requirements defined by the International Maritime Organization ⁽¹⁾ 1**

II *Non-legislative acts*

REGULATIONS

- ★ **Commission Implementing Regulation (EU) 2023/947 of 11 May 2023 amending Annex I to Implementing Regulation (EU) 2023/594 laying down special control measures for African swine fever ⁽¹⁾ 11**
- ★ **Commission Implementing Regulation (EU) 2023/948 of 12 May 2023 authorising the placing on the market of 6'-Sialyllactose sodium salt produced by derivative strains of *Escherichia coli* BL21(DE3) as a novel food and amending Implementing Regulation (EU) 2017/2470 ⁽¹⁾ 52**
- ★ **Commission Implementing Regulation (EU) 2023/949 of 12 May 2023 authorising the placing on the market of iron milk caseinate as a novel food and amending Implementing Regulation (EU) 2017/2470 ⁽¹⁾ 60**
- ★ **Commission Implementing Regulation (EU) 2023/950 of 12 May 2023 amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food 2'-Fucosyllactose ⁽¹⁾ 68**

⁽¹⁾ Text with EEA relevance.

EN

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

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

★ Commission Implementing Regulation (EU) 2023/951 of 12 May 2023 amending Implementing Regulation (EU) 2017/2470 as regards the specifications of the novel food protein extract from pig kidneys ⁽¹⁾	73
★ Commission Implementing Regulation (EU) 2023/952 of 12 May 2023 amending Implementing Regulation (EU) No 1321/2013 as regards the name of the holder of the authorisation for the smoke flavouring primary product ‘Tradismoke™ A MAX’ (unique code SF-007) ⁽¹⁾	79
★ Commission Implementing Regulation (EU) 2023/953 of 12 May 2023 amending Implementing Regulation (EU) 2020/761 as regards the rules governing the tariff rate quota for export of milk powder to the Dominican Republic	81
★ Commission Implementing Regulation (EU) 2023/954 of 12 May 2023 correcting Annexes XIII, XIV and XXII to Implementing Regulation (EU) 2021/404 as regards the lists of third countries, territories or zones thereof authorised for the entry into the Union of consignments of fresh meat of ungulates, poultry and game birds, and certain species and categories of animals, germinal products and products of animal origin for which the Union is not the final destination ⁽¹⁾	84

⁽¹⁾ Text with EEA relevance.

I

(Legislative acts)

DIRECTIVES

DIRECTIVE (EU) 2023/946 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 10 May 2023****amending Directive 2003/25/EC as regards the inclusion of improved stability requirements and the alignment of that Directive with the stability requirements defined by the International Maritime Organization****(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 100(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) Directive 2003/25/EC of the European Parliament and of the Council ⁽³⁾ establishes a uniform level of specific stability requirements for ro-ro passenger ships improving the survivability of this type of vessel in the case of collision damage and providing a high level of safety for the passengers and the crew in conjunction with the requirements set out in the International Convention for the Safety of Life at Sea (the 'SOLAS Convention') in force at the date of adoption of that Directive ('SOLAS 90').
- (2) On 15 June 2017, the International Maritime Organization ('IMO') adopted Resolution MSC.421(98) amending the SOLAS Convention and setting out revised stability requirements for passenger ships in damaged condition. Those requirements also apply to ro-ro passenger ships. It is necessary to take into account that development at international level and to align the Union rules and requirements with those established in the SOLAS Convention for ro-ro passenger ships engaged in international voyages.
- (3) IMO Resolution 14 of the 1995 SOLAS Conference allows IMO members to conclude regional agreements if they consider that prevailing sea conditions and other local conditions require specific stability requirements in a designated area.

⁽¹⁾ OJ C 323, 26.8.2022, p. 119.

⁽²⁾ Position of the European Parliament of 14 March 2023 (not yet published in the Official Journal) and decision of the Council of 24 April 2023.

⁽³⁾ Directive 2003/25/EC of the European Parliament and of the Council of 14 April 2003 on specific stability requirements for ro-ro passenger ships (OJ L 123, 17.5.2003, p. 22).

- (4) The damage stability requirements for ro-ro passenger ships set out in Annex I to Directive 2003/25/EC are deterministic in nature. As such, they differ from the new international probabilistic regime set out in Chapter II-1 of the SOLAS Convention, and in particular from new requirements that measure the safety of a ro-ro passenger ship on the basis of the probability of survival after a collision. In order to bring the Union's requirements into line with those new international requirements, Directive 2003/25/EC should be amended accordingly.
- (5) Requirements laid down in Directive 2009/45/EC of the European Parliament and of the Council ⁽⁴⁾ remain applicable to ro-ro passenger ships. The assessment for different sizes of ro-ro passenger ships of the safety level ensured by the requirements of the SOLAS Convention as last amended by Resolution MSC.421(98) ('SOLAS 2020') led to the conclusion that the application of the SOLAS 2020 stability requirements would result in a significant reduction in risk for ro-ro passenger ships certified to carry more than 1 350 persons on board, as compared with the safety level resulting from the application of requirements set out in Directive 2003/25/EC.
- (6) Stability requirements laid down in this Directive for ro-ro passenger ships certified to carry 1 350 or fewer persons on board would be difficult to implement in respect of certain ship designs. Therefore, companies owning or operating those ships in a regular service in the Union should have the option to apply the stability requirements applicable before the entry into force of this Directive. The use of that option should be notified by Member States to the Commission together with the data related to the ships concerned. 10 years after the date of entry into force of this Directive, the Commission should assess the use of the option in order to decide whether a further revision of this Directive is necessary.
- (7) For ro-ro passenger ships certified to carry 1 350 or fewer persons on board, the optional application of the SOLAS 2020 requirements should be conditional on a higher level of R-index than the one defined in SOLAS 2020, in order to achieve the appropriate level of safety.
- (8) In order to ensure the necessary level of safety, specific damage stability requirements should apply also to existing ro-ro passenger ships that have never been certified in accordance with Directive 2003/25/EC and are entering into regular service in the Union.
- (9) Port States should cooperate to the fullest extent possible in order to establish the list of sea areas referred to in this Directive, taking into account the sovereignty of States over sea areas under their jurisdiction and the general principles of the law of the sea.
- (10) The European Maritime Safety Agency (EMSA) has been assisting the Commission in the effective implementation of Directive 2003/25/EC and should endeavour to continue such assistance in line with Regulation (EC) No 1406/2002 of the European Parliament and of the Council ⁽⁵⁾.
- (11) In order to enable the Commission to evaluate and report to the European Parliament and the Council on the implementation of this Directive, Member States should provide data on every new ro-ro passenger ship that is certified to carry 1 350 or fewer persons on board for regular service in compliance with the stability requirements contained in this Directive. This data should be provided in accordance with the structure set out in Annex II. This data should be available for all new ro-ro passenger ships, as they are required to comply with the probabilistic stability requirements set out in SOLAS 2020.

⁽⁴⁾ Directive 2009/45/EC of the European Parliament and of the Council of 6 May 2009 on safety rules and standards for passenger ships (OJ L 163, 25.6.2009, p. 1).

⁽⁵⁾ Regulation (EC) No 1406/2002 of the European Parliament and of the Council of 27 June 2002 establishing a European Maritime Safety Agency (OJ L 208, 5.8.2002, p. 1).

- (12) As Directive 2009/16/EC of the European Parliament and of the Council ⁽⁶⁾ was amended, and Council Directive 1999/35/EC ⁽⁷⁾ was repealed by Directive (EU) 2017/2110 of the European Parliament and of the Council ⁽⁸⁾, the concept of ‘host State’ is no longer relevant and should therefore be replaced by that of ‘port State’.
- (13) In order not to impose a disproportionate administrative burden on landlocked Member States which have no seaports, and which have no ro-ro passenger ships flying their flag falling within the scope of Directive 2003/25/EC, such Member States should be allowed to derogate from the provisions of Directive 2003/25/EC. This means that as long as those conditions are fulfilled, they are not obliged to transpose that Directive.
- (14) Directive 2003/25/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendments to Directive 2003/25/EC

Directive 2003/25/EC is amended as follows:

- (1) Article 2 is amended as follows:

- (a) points (b) and (c) are replaced by the following:

‘(b) “existing ro-ro passenger ship” means a ro-ro passenger ship the keel of which is laid or which is at a similar stage of construction before 5 December 2024; a similar stage of construction means the stage at which:

- (i) construction identifiable with a specific ship begins; and
- (ii) assembly of that ship has commenced comprising at least 50 tonnes or 1 % of the estimated mass of structural material, whichever is less;

(c) “new ro-ro passenger ship” means a ro-ro passenger ship which is not an existing ro-ro passenger ship;’;

- (b) point (e) is replaced by the following:

‘(e) “SOLAS Convention” means the 1974 International Convention for the Safety of Life at Sea and amendments thereto in force;’;

- (c) the following points are inserted:

‘(ea) “SOLAS 90” means the 1974 International Convention for the Safety of Life at Sea, as last amended by Resolution MSC.117(74);

(eb) “SOLAS 2009” means the 1974 International Convention for the Safety of Life at Sea, as last amended by Resolution MSC.216(82);

(ec) “SOLAS 2020” means the 1974 International Convention for the Safety of Life at Sea, as last amended by Resolution MSC.421(98);’;

- (d) point (f) is replaced by the following:

‘(f) “regular service” means a series of ro-ro passenger ship crossings operated so as to serve traffic between the same two or more ports, or a series of voyages from and to the same port without intermediate calls, either:

- (i) according to a published timetable; or
- (ii) with crossings so regular or frequent that they constitute a recognisable systematic series;’;

⁽⁶⁾ Directive 2009/16/EC of the European Parliament and of the Council of 23 April 2009 on port State control (OJ L 131, 28.5.2009, p. 57).

⁽⁷⁾ Council Directive 1999/35/EC of 29 April 1999 on a system of mandatory surveys for the safe operation of regular ro-ro ferry and high-speed passenger craft services (OJ L 138, 1.6.1999, p. 1).

⁽⁸⁾ Directive (EU) 2017/2110 of the European Parliament and of the Council of 15 November 2017 on a system of inspections for the safe operation of ro-ro passenger ships and high-speed passenger craft in regular service and amending Directive 2009/16/EC and repealing Council Directive 1999/35/EC (OJ L 315, 30.11.2017, p. 61).

(e) point (i) is replaced by the following:

‘(i) “Port State” means a Member State to or from whose ports a ro-ro passenger ship is engaged on a regular service;’;

(f) point (k) is replaced by the following:

‘(k) “specific stability requirements” means, when used as a collective term, the stability requirements referred to in Article 6;’;

(g) the following point is added:

‘(n) “company” means the owner of a ro-ro passenger ship or any other organisation or person, such as the manager or the bareboat charterer, who has assumed responsibility for operating the passenger ship from the owner.’;

(2) in Article 3, paragraph 2 is replaced by the following:

‘2. Each Member State, in its capacity as Port State, shall ensure that ro-ro passenger ships flying the flag of a State which is not a Member State comply fully with the requirements of this Directive before they may be engaged on voyages in regular service from or to ports of that Member State in accordance with Directive (EU) 2017/2110 of the European Parliament and of the Council (*).

(*) Directive (EU) 2017/2110 of the European Parliament and of the Council of 15 November 2017 on a system of inspections for the safe operation of ro-ro passenger ships and high-speed passenger craft in regular service and amending Directive 2009/16/EC and repealing Council Directive 1999/35/EC (OJ L 315, 30.11.2017, p. 61).’;

(3) in Article 3, the following paragraph is added:

‘3. Member States which do not have seaports and which have no ro-ro passenger ships flying their flag that fall within the scope of this Directive may derogate from the provisions of this Directive with the exception of the obligation set out in the second subparagraph.

Those Member States which intend to avail themselves of such derogation shall communicate to the Commission by 5 December 2024 if the conditions have been met, and shall inform the Commission of any subsequent change. Such Member States may not allow ro-ro passenger ships that fall within the scope of this Directive to fly their flag until they have transposed and implemented this Directive.’;

(4) Article 4 is replaced by the following:

‘Article 4

Significant wave heights

The significant wave heights (hS) shall be used for determining the height of water on the car deck when applying the specific stability requirements contained in section A of Annex I. The figures of significant wave heights shall be those which are not exceeded by a probability of more than 10 % on a yearly basis.’;

(5) Article 5 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Port States shall establish and keep updated a list of sea areas crossed by ro-ro passenger ships operating on regular service to or from their ports as well as the corresponding values of significant wave heights in these areas.’;

(b) paragraph 3 is replaced by the following:

‘3. The list shall be published in a public database available on the internet site of the competent maritime authority. The location of such information as well as any updates to the list and the reasons for such updates shall be notified to the Commission.’;

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

'Article 6

Specific stability requirements

1. Without prejudice to the application of Directive 2009/45/EC of the European Parliament and of the Council (*), new ro-ro passenger ships certified to carry more than 1 350 persons on board shall comply with the specific stability requirements set out in Chapter II-1, Part B of SOLAS 2020.

2. At the company's choice, new ro-ro passenger ships certified to carry 1 350 or fewer persons on board shall comply with:

- (a) the specific stability requirements set out in Annex I, section A, to this Directive, or
- (b) the specific stability requirements set out in Annex I, section B, to this Directive.

For each such ship, the administration of the Flag State shall, within a period of two months from the date of issuance of the certificate referred to in Article 8, notify the Commission of the choice made of the option referred to in the first subparagraph and include with such notification the details referred to in Annex III.

3. In applying the requirements set out in Annex I, section A, Member States shall use the guidelines set out in Annex II, in so far as this is practicable and compatible with the design of the ship in question.

4. At the company's choice, existing ro-ro passenger ships certified to carry more than 1 350 persons on board which the company introduces to the regular service operation to or from a port of a Member State after 5 December 2024 and which have never been certified in accordance with this Directive, shall comply with:

- (a) the specific stability requirements set out in Chapter II-1, Part B of SOLAS 2020; or
- (b) the specific stability requirements set out in Annex I, section A to this Directive, in addition to those set out in Chapter II-1, Part B of SOLAS 2009.

The stability requirements that are applied shall be noted in the ship's certificate required under Article 8.

5. At the company's choice, existing ro-ro passenger ships certified to carry 1 350 or fewer persons on board which the company introduces to the regular service operation to or from a port of a Member State after 5 December 2024 and which have never been certified in accordance with this Directive, shall comply with:

- (a) the specific stability requirements set out in Annex I, section A to this Directive, or
- (b) the specific stability requirements set out in Annex I, section B to this Directive.

The stability requirements that are applied shall be noted in the ship's certificate referred to in Article 8.

6. Existing ro-ro passenger ships that were engaged in regular service operation to or from a port of a Member State by 5 December 2024 shall continue to comply with the specific stability requirements set out in Annex I in the version that applied before the entry into force of Directive (EU) 2023/946 of the European Parliament and of the Council (**).

(*) Directive 2009/45/EC of the European Parliament and of the Council of 6 May 2009 on safety rules and standards for passenger ships (OJ L 163, 25.6.2009, p. 1).

(**) Directive (EU) 2023/946 of the European Parliament and of the Council of 10 May 2023 amending Directive 2003/25/EC as regards the inclusion of improved stability requirements and the alignment of that Directive with the stability requirements defined by the International Maritime Organization (OJ L 128, 15.5.2023, p. 1).;

- (7) Article 7 is deleted.

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

'Article 8

Certificates

1. All new and existing ro-ro passenger ships flying the flag of a Member State shall carry a certificate confirming compliance with the specific stability requirements referred to in Article 6.

The certificates shall be issued by the administration of the flag State and may be combined with other related certificates. For ro-ro passenger ships complying with the specific stability requirements set out in Annex I, section A, the certificate shall indicate the significant wave height up to which the ship can satisfy the specific stability requirements.

The certificate shall remain valid as long as the ro-ro passenger ship operates in an area with the same or a lower value of significant wave height.

2. Each Member State acting in its capacity as Port State shall recognise certificates issued by another Member State in compliance with this Directive.

3. Each Member State acting in its capacity as Port State shall accept certificates issued by a third country certifying that a ro-ro passenger ship complies with the specific stability requirements laid down in this Directive.;

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

'Article 9

Seasonal and other short-time period operations

1. If a company operating a regular service on a year-round basis wishes to introduce additional ro-ro passenger ships to operate for a shorter period on that service, it shall notify the competent authority of the Port State or States not later than one month before said ships are operated on that service.

2. However, in cases where, following unforeseen circumstances, a replacement ro-ro passenger ship must be introduced rapidly to ensure continuity of service, Article 4(4) of Directive (EU) 2017/2110 and point 1.3 of Annex XVII to Directive 2009/16/EC of the European Parliament and of the Council (*) shall apply instead of the notification requirement of paragraph 1.

3. If a company wishes to operate a regular service seasonally for a shorter period not exceeding six months a year, it shall notify the competent authority of the Port State or States no later than three months before that operation takes place.

4. For ro-ro passenger ships that comply with the specific requirements in Annex I, section A, where operations within the meaning of paragraphs 1, 2 and 3 of this Article take place under conditions of lower significant wave height than those established for the same sea area for all-year-round operation, the significant wave height value applicable for the shorter period may be used by the competent authority for determining the height of water on the deck when applying the specific stability requirements contained in Annex I, section A. The value of the significant wave height applicable for this shorter time period shall be agreed between the Member States or, wherever applicable and possible, between Member States and third countries at both ends of the route.

5. Following agreement of the competent authority of the Port State or States for operations within the meaning of paragraphs 1, 2 and 3, the ro-ro passenger ship which undertakes such operations shall be required to carry a certificate confirming compliance with the provisions of this Directive, as provided for in Article 8(1).

(*) Directive 2009/16/EC of the European Parliament and of the Council of 23 April 2009 on port State control (OJ L 131, 28.5.2009, p. 57).;

(10) The following Article is inserted:

'Article 13a

Review

The Commission shall evaluate the implementation of this Directive and submit the results of the evaluation to the European Parliament and the Council by 5 June 2033. Information based on the notifications referred to in Article 6(2) shall be made available in anonymised form.;

(11) Annexes I and II to Directive 2003/25/EC are amended in accordance with Annex I to this Directive;

(12) The text set out in Annex II to this Directive is added as Annex III to Directive 2003/25/EC.

Article 2

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 5 December 2024. They shall immediately inform the Commission thereof.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main measures of national law which they adopt in the field covered by this Directive.

Article 3

Entry into force

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

Article 4

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 10 May 2023.

For the European Parliament
The President
R. METSOLA

For the Council
The President
J. ROSWALL

ANNEX I

1. Annex I is amended as follows:

(a) after the title, the following heading is inserted:

‘Section A’;

(b) after that new heading, the following introductory sentence is inserted:

‘For the purposes of Section A, references to the SOLAS Convention regulations shall be construed as references to those regulations as they applied under SOLAS 90.’;

(c) in point 1, the paragraph before points 1.1 to 1.6 is replaced by the following:

‘1. In addition to the requirements of Regulation II-1/B/8 of the SOLAS Convention relating to watertight subdivision and stability in damaged condition, the requirements of this section shall be complied with.’;

(d) point 3.1 is replaced by the following:

‘3.1. For ships, which are to be operated only for a shorter period within the meaning of Article 9, the Port States included in the route shall agree on the applicable significant wave height.’;

(e) the following section is added:

‘Section B

The requirements of Chapter II-1, Part B of SOLAS 2020 shall be complied with. However, by way of derogation from Regulation II-1/B/6.2.3 of SOLAS 2020, the required subdivision index R shall be determined as follows:

Persons on board (N)	Subdivision Index (R)
$N < 1\,000$	$R = 0,000088 * N + 0,7488$
$1\,000 \leq N \leq 1\,350$	$R = 0,0369 * \ln (N + 89,048) + 0,579$

Where:

N = total number of persons on board.’.

2. Annex II is amended as follows:

The introductory paragraph in ‘Application’ is replaced by the following:

‘In line with the provisions of Article 6(3) of this Directive, these guidelines shall be used by the national administrations of Member States in the application of the specific stability requirements set out in Annex I, section A, in so far as this is practicable and compatible with the design of the ship in question. The paragraph numbers appearing below correspond to those in Annex I, section A.’.

ANNEX II

ANNEX III

NOTIFICATION DETAILS

Data to be notified in accordance with Article 6(2):

I. General data

- (1) Applicable stability requirements: section A or section B of Annex I
- (2) Ship's identification number (IMO number, Call sign)
- (3) Main particulars
- (4) General arrangement plan
- (5) Number of persons on board
- (6) GT
- (7) Is the ship double ended: Yes/No
- (8) Does the ship have long lower holds: Yes/No

II. Specific data – for ro-ro passenger ships subject to the probabilistic requirements set out in the SOLAS Convention

- (1) d_l , d_p , d_s ;
- (2) R – required index;
- (3) layout plan (watertight integrity plan) for the sub-compartments with all internal and external opening points including their connected sub-compartments, and particulars used in measuring the spaces, such as general arrangement plan and tank plan; the subdivision limits, longitudinal, transverse and vertical, must be included ⁽¹⁾;
- (4) attained subdivision index A with a summary table for all contributions for all damaged zones ⁽²⁾ with a separate column with the attainable subdivision index ($w \cdot p \cdot v$);
- (5) for 1 and 2 Zone damage cases, the percentage of damage cases that were not investigated (i.e. cases not included in the factor ($w \cdot p \cdot v$)), that $s = 0$, $s = 1$ and $0 < s < 1$;
- (6) for 1 and 2 Zone damage cases, the percentage of damage cases involving ro-ro spaces that were not investigated (i.e. cases not included in the factor ($w \cdot p \cdot v$)), that $s = 0$, $s = 1$ and $0 < s < 1$;
- (7) for each damage which contributes to the attained subdivision index A, identification of flooded spaces, contribution value and factor «S» ⁽³⁾;
- (8) particulars of non-contributing damages ($s = 0$ and $p > 0$) for ro-ro passenger ships fitted with long lower hold, including full details of the calculated factors ⁽⁴⁾.

III. Specific data – for ro-ro passenger ships applying Annex I, section A

- (1) Method of compliance:
 - Model Tests
 - Calculations

Please indicate whether the water on deck calculations have been avoided due to, for example, the residual freeboard being higher than 2.0 m in all damage cases: Yes/No

(2) Significant wave height pursuant to Directive 2003/25/EC.

-
- (¹) This documentation is to be submitted to Administrations in accordance with point 2.2 of the Appendix to IMO Resolution MSC.429(98).
 - (²) This documentation is to be submitted to Administrations in accordance with point 2.3.1 of the Appendix to IMO Resolution MSC.429(98).
 - (³) This documentation is to be submitted to Administrations in accordance with point 2.3.1 of the Appendix to IMO Resolution MSC.429(98).
 - (⁴) This documentation is to be submitted to Administrations in accordance with point 2.3.1 of the Appendix to IMO Resolution MSC.429(98).'
-

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2023/947**of 11 May 2023****amending Annex I to Implementing Regulation (EU) 2023/594 laying down special control measures for African swine fever****(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 71(3) thereof,

Whereas:

- (1) African swine fever is an infectious viral disease affecting kept and wild porcine animals and can have a severe impact on the concerned animal population and the profitability of farming causing disturbance to movements of the consignments of those animals and products thereof within the Union and their exports to third countries.
- (2) Commission Implementing Regulation (EU) 2023/594 ⁽²⁾ lays down special disease control measures regarding African swine fever to be applied for a limited period of time by the Member States ⁽³⁾, which are listed or whose areas are listed in Annexes I and II.
- (3) The areas listed as restricted zones I, II and III in Annex I to Implementing Regulation (EU) 2023/594 are based on the epidemiological situation of African swine fever in the Union. Annex I to Implementing Regulation (EU) 2023/594 was last amended by Commission Implementing Regulation (EU) ⁽⁴⁾ amending Annex I to Implementing Regulation (EU) 2023/594, following changes in the epidemiological situation as regards that disease in Greece. The epidemiological situation as regards that disease in certain Member States concerned has evolved.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2023/594 of 16 March 2023 laying down special disease control measures for African swine fever and repealing Implementing Regulation (EU) 2021/605 (OJ L 79, 17.3.2023, p. 65).

⁽³⁾ In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Regulation references to Member States include the United Kingdom in respect of Northern Ireland.

⁽⁴⁾ Notified under number C(2023) 3174.

- (4) Any amendments to restricted zones I, II and III in Annex I to Implementing Regulation (EU) 2023/594 should be based on the epidemiological situation as regards African swine fever in the areas affected by that disease and the overall epidemiological situation of African swine fever in the Member State concerned, the level of risk for the further spread of that disease, as well as scientifically based principles and criteria for geographically defining zoning due to African swine fever and the Union's guidelines agreed with the Member States at the Standing Committee on Plants, Animals, Food and Feed and publicly available on the Commission's website ⁽⁵⁾. Such amendments should also take account of international standards, such as the Terrestrial Animal Health Code ⁽⁶⁾ of the World Organisation for Animal Health (WOAH) and justifications for zoning provided by the competent authorities of the Member States concerned.
- (5) There have been new outbreaks of African swine fever in wild porcine animals in the Czech Republic and in Italy.
- (6) In May 2023, one outbreak of African swine fever in a wild porcine animal was observed in the Liberec Region in the Czech Republic, in an area currently not listed as a restricted zone in Annex I to Implementing Regulation (EU) 2023/594. This new outbreak of African swine fever in a wild porcine animal constitutes an increased level of risk, which should be reflected in Annex I to Implementing Regulation (EU) 2023/594. Accordingly, this area of the Czech Republic currently not listed as a restricted zone in Annex I to Implementing Regulation (EU) 2023/594, affected by this recent outbreak, due to its proximity to areas currently listed as restricted zones I and II and in order to ensure territorial continuity should be listed as a restricted zone II in Annex I to Implementing Regulation (EU) 2023/594 and the current boundaries of restricted zone I need to be redefined to take account of this outbreak.
- (7) In May 2023, several outbreaks of African swine fever in wild porcine animals were observed in the Piedmont and Liguria Regions in Italy, in areas currently listed as restricted zones II in Annex I to Implementing Regulation (EU) 2023/594 located in close proximity to areas currently listed as restricted zones I in that Annex. Those new outbreaks of African swine fever in wild porcine animals constitute an increased level of risk, which should be reflected in Annex I to Implementing Regulation (EU) 2023/594. Accordingly, those areas of Italy currently listed as restricted zones I in Annex I to Implementing Regulation (EU) 2023/594, that are in close proximity to the areas listed as restricted zones II affected by those recent outbreaks, should be listed as restricted zones II in Annex I to Implementing Regulation (EU) 2023/594 and the current boundaries of restricted zones I need to be redefined to take account of those outbreaks.
- (8) Following those recent outbreaks of African swine fever in wild porcine animals in the Czech Republic and in Italy and taking into account the current epidemiological situation as regards African swine fever in the Union, zoning in those Member States has been reassessed and updated in accordance with Articles 5, 6 and 7 of Implementing Regulation (EU) 2023/594. In addition, the risk management measures in place have been reassessed and updated. These changes should be reflected in Annex I to Implementing Regulation (EU) 2023/594.
- (9) In order to take account of the recent developments in the epidemiological situation of African swine fever in the Union, and in order to combat the risks associated with the spread of that disease in a proactive manner new restricted zones of a sufficient size should be demarcated for the Czech Republic and for Italy and listed as restricted zones I and II in Annex I to Implementing Regulation (EU) 2023/594. As the situation as regards African swine fever is very dynamic in the Union, when demarcating those new restricted zones, account has been taken of the epidemiological situation in the surrounding areas.
- (10) Given the urgency of the epidemiological situation in the Union as regards the spread of African swine fever, it is important that the amendments to be made to Annex I to Implementing Regulation (EU) 2023/594 by this Implementing Regulation take effect as soon as possible.
- (11) 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

Annex I to Implementing Regulation (EU) 2023/594 is replaced by the text set out in the Annex to this Regulation.

⁽⁵⁾ Working Document SANTE/7112/2015/Rev. 3 "Principles and criteria for geographically defining ASF regionalisation". https://ec.europa.eu/food/animals/animal-diseases/control-measures/asf_en

⁽⁶⁾ OIE Terrestrial Animal Health Code, 29th Edition, 2021. Volumes I and II ISBN 978-92-95115-40-8; <https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/>

Article 2

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

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

Done at Brussels, 11 May 2023

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

ANNEX I

RESTRICTED ZONES

PART I

1. Germany

The following restricted zones I in Germany:

Bundesland Brandenburg:

— Landkreis Dahme-Spreewald:

- Gemeinde Alt Zauche-Wußwerk,
- Gemeinde Byhleguhre-Byhlen,
- Gemeinde Märkische Heide, mit den Gemarkungen Alt Schadow, Neu Schadow, Pretschen, Plattkow, Wittmannsdorf, Schuhlen-Wiese, Bückchen, Kuschkow, Gröditsch, Groß Leuthen, Leibchel, Glietz, Groß Leine, Dollgen, Krugau, Dürrenhofe, Biebersdorf und Klein Leine,
- Gemeinde Neu Zauche,
- Gemeinde Schwielochsee mit den Gemarkungen Groß Liebitz, Gühlen, Mochow und Siegadel,
- Gemeinde Spreewaldheide,
- Gemeinde Straupitz,

— Landkreis Märkisch-Oderland:

- Gemeinde Müncheberg mit den Gemarkungen Müncheberg, Eggersdorf bei Müncheberg und Hoppegarten bei Müncheberg,
- Gemeinde Bliesdorf mit den Gemarkungen Kunersdorf - westlich der B167 und Bliesdorf - westlich der B167
- Gemeinde Märkische Höhe mit den Gemarkungen Reichenberg und Batzlow,
- Gemeinde Wriezen mit den Gemarkungen Haselberg, Frankenfelde, Schulzendorf, Lüdersdorf Biesdorf, Rathsdorf - westlich der B 167 und Wriezen - westlich der B167
- Gemeinde Buckow (Märkische Schweiz),
- Gemeinde Strausberg mit den Gemarkungen Hohenstein und Ruhlsdorf,
- Gemeine Garzau-Garzin,
- Gemeinde Waldsiedersdorf,
- Gemeinde Rehfelde mit der Gemarkung Werder,
- Gemeinde Reichenow-Mögelin,
- Gemeinde Prötzel mit den Gemarkungen Harnekop, Sternebeck und Prötzel östlich der B 168 und der L35,
- Gemeinde Oberbarnim,
- Gemeinde Bad Freienwalde mit der Gemarkung Sonnenburg,
- Gemeinde Falkenberg mit den Gemarkungen Dannenberg, Falkenberg westlich der L 35, Gersdorf und Krüge,
- Gemeinde Höhenland mit den Gemarkungen Steinbeck, Wollenberg und Wölsickendorf,

— Landkreis Barnim:

- Gemeinde Joachimsthal östlich der L220 (Eberswalder Straße), östlich der L23 (Töpferstraße und Templiner Straße), östlich der L239 (Glambecker Straße) und Schorfheide (JO) östlich der L238,

- Gemeinde Friedrichswalde mit der Gemarkung Glambeck östlich der L 239,
- Gemeinde Althüttendorf,
- Gemeinde Ziethen mit den Gemarkungen Groß Ziethen und Klein Ziethen westlich der B198,
- Gemeinde Chorin mit den Gemarkungen Golzow, Senftenhütte, Buchholz, Schorfheide (Ch), Chorin westlich der L200 und Sandkrug nördlich der L200,
- Gemeinde Britz,
- Gemeinde Schorfheide mit den Gemarkungen Altenhof, Werbellin, Lichterfelde und Finowfurt,
- Gemeinde (Stadt) Eberswalde mit den Gemarkungen Finow und Spechthausen und der Gemarkung Eberswalde südlich der B167 und westlich der L200,
- Gemeinde Breydin,
- Gemeinde Melchow,
- Gemeinde Sydower Fließ mit der Gemarkung Grüntal nördlich der K6006 (Landstraße nach Tuchen), östlich der Schönholzer Straße und östlich Am Postweg,
- Hohenfinow südlich der B167,
- Landkreis Uckermark:
 - Gemeinde Passow mit den Gemarkungen Briest, Passow und Schönow,
 - Gemeinde Mark Landin mit den Gemarkungen Landin nördlich der B2, Grünow und Schönermark,
 - Gemeinde Angermünde mit den Gemarkungen Frauenhagen, Mürow, Angermünde nördlich und nordwestlich der B2, Dobberzin nördlich der B2, Kerkow, Welsow, Bruchhagen, Greiffenberg, Günterberg, Biesenbrow, Görlsdorf, Wolletz und Altkünkendorf,
 - Gemeinde Zichow,
 - Gemeinde Casekow mit den Gemarkungen Blumberg, Wartin, Luckow-Petershagen und den Gemarkungen Biesendahlshof und Casekow westlich der L272 und nördlich der L27,
 - Gemeinde Hohenselchow-Groß Pinnow mit der Gemarkung Hohenselchow nördlich der L27,
 - Gemeinde Tantow,
 - Gemeinde Mescherin mit der Gemarkung Radekow, der Gemarkung Rosow südlich der K 7311 und der Gemarkung Neurochlitz westlich der B2,
 - Gemeinde Gartz (Oder) mit der Gemarkung Geesow westlich der B2 sowie den Gemarkungen Gartz und Hohenreinkendorf nördlich der L27 und der B2 bis zur Kastanienallee, dort links abbiegend dem Schülerweg folgend bis Höhe Bahnhof, von hier in östlicher Richtung den Salveybach kreuzend bis zum Tantower Weg, diesen in nördlicher Richtung bis zu Stettiner Straße, diese weiter folgend bis zur B2, dieser in nördlicher Richtung folgend,
 - Gemeinde Pinnow nördlich und westlich der B2,
- Landkreis Oder-Spree:
 - Gemeinde Storkow (Mark),
 - Gemeinde Spreehagen mit den Gemarkungen Braunsdorf, Markgrafpieske, Lebbin und Spreehagen,
 - Gemeinde Grünheide (Mark) mit den Gemarkungen Kagel, Kienbaum und Hangelsberg,
 - Gemeinde Fürstenwalde westlich der B 168 und nördlich der L 36,
 - Gemeinde Rauen,
 - Gemeinde Wendisch Rietz bis zur östlichen Uferzone des Scharmützelsees und von der südlichen Spitze des Scharmützelsees südlich der B246,

- Gemeinde Reichenwalde,
- Gemeinde Bad Saarow mit der Gemarkung Petersdorf und der Gemarkung Bad Saarow-Pieskow westlich der östlichen Uferzone des Scharmützelsees und ab nördlicher Spitze westlich der L35,
- Gemeinde Tauche mit der Gemarkung Werder,
- Gemeinde Steinhöfel mit den Gemarkungen Jänickendorf, Schönfelde, Beerfelde, Gölsdorf, Buchholz, Tempelberg und den Gemarkungen Steinhöfel, Hasenfelde und Heinersdorf westlich der L36 und der Gemarkung Neuendorf im Sande nördlich der L36,
- Landkreis Spree-Neiße:
 - Gemeinde Turnow-Preilack mit der Gemarkung Turnow,
 - Gemeinde Drachhausen,
 - Gemeinde Schmogrow-Fehrow,
 - Gemeinde Drehnöw,
 - Gemeinde Guhrow,
 - Gemeinde Werben,
 - Gemeinde Dissen-Striesow,
 - Gemeinde Briesen,
 - Gemeinde Kolkwitz mit den Gemarkungen Babow, Eichow und Milkersdorf,
 - Gemeinde Burg (Spreewald),
- Landkreis Oberspreewald-Lausitz:
 - Gemeinde Lauchhammer,
 - Gemeinde Schwarzheide,
 - Gemeinde Schipkau,
 - Gemeinde Senftenberg mit den Gemarkungen Brieske, Niemtsch, Senftenberg und Reppist,
 - die Gemeinde Schwarzbach mit der Gemarkung Biehlen,
 - Gemeinde Großräschen mit den Gemarkungen Wormlage, Saalhausen, Barzig, Freienhufen, Großräschen,
 - Gemeinde Vetschau/Spreewald mit den Gemarkungen: Naundorf, Fleißdorf, Suschow, Stradow, Göritz, Koßwig, Vetschau, Repten, Tornitz, Missen und Orgosen,
 - Gemeinde Calau mit den Gemarkungen: Kalkwitz, Mlode, Saßleben, Reuden, Bolschwitz, Säritz, Calau, Kemmen, Werchow und Gollnitz,
 - Gemeinde Luckaitztal,
 - Gemeinde Bronkow,
 - Gemeinde Altdöbern mit der Gemarkung Altdöbern westlich der Bahnlinie,
 - Gemeinde Tettau,
- Landkreis Elbe-Elster:
 - Gemeinde Großthiemig,
 - Gemeinde Hirschfeld,
 - Gemeinde Gröden,
 - Gemeinde Schraden,
 - Gemeinde Merzdorf,
 - Gemeinde Röderland mit der Gemarkung Wainsdorf, Präsen, Stolzenhain a.d. Röder,
 - Gemeinde Plessa mit der Gemarkung Plessa,

— Landkreis Prignitz:

- Gemeinde Groß Pankow mit den Gemarkungen Baek, Tangendorf, Tacken, Hohenvier, Strigleben, Steinberg und Gulow,
- Gemeinde Perleberg mit der Gemarkung Schönfeld,
- Gemeinde Karstädt mit den Gemarkungen Postlin, Strehlen, Blüten, Klockow, Premslin, Glövin, Waterloo, Karstädt, Dargardt, Garlin und die Gemarkungen Groß Warnow, Klein Warnow, Reckenzin, Streesow und Dallmin westlich der Bahnstrecke Berlin/Spandau-Hamburg/Altona,
- Gemeinde Gültz-Reetz,
- Gemeinde Putlitz mit den Gemarkungen Lockstädt, Mansfeld und Laaske,
- Gemeinde Triglitz,
- Gemeinde Marienfließ mit der Gemarkung Frehne,
- Gemeinde Küssernitztal mit der Gemarkungen Buckow, Preddöhl und Grabow,
- Gemeinde Gerdshagen mit der Gemarkung Gerdshagen,
- Gemeinde Meyenburg,
- Gemeinde Pritzwalk mit der Gemarkung Steffenshagen,

Bundesland Sachsen:

— Stadt Dresden:

- Stadtgebiet, sofern nicht bereits Teil der Sperrzone II,

— Landkreis Meißen:

- Gemeinde Diera-Zehren, sofern nicht bereits Teil der Sperrzone II,
- Gemeinde Glaubitz, sofern nicht bereits Teil der Sperrzone II,
- Gemeinde Hirschstein,
- Gemeinde Käbschütztal,
- Gemeinde Klipphausen, sofern nicht bereits Teil der Sperrzone II,
- Gemeinde Niederau, sofern nicht bereits Teil der Sperrzone II,
- Gemeinde Nünchritz, sofern nicht bereits Teil der Sperrzone II,
- Gemeinde Röderaue, sofern nicht bereits Teil der Sperrzone II,
- Gemeinde Stadt Gröditz, sofern nicht bereits Teil der Sperrzone II,
- Gemeinde Stadt Lommatzsch,
- Gemeinde Stadt Meißen, sofern nicht bereits Teil der Sperrzone II,
- Gemeinde Stadt Nossen,
- Gemeinde Stadt Riesa,
- Gemeinde Stadt Strehla,
- Gemeinde Stauchitz,
- Gemeinde Wülknitz, sofern nicht bereits Teil der Sperrzone II,
- Gemeinde Zeithain,

— Landkreis Mittelsachsen:

- Gemeinde Großweitzschen mit den Ortsteilen Dörschütz, Gadewitz, Niederranschütz, Redemitz,
- Gemeinde Ostrau mit den Ortsteilen Auerschütz, Beutig, Binnewitz, Clanzschwitz, Delmschütz, Döhlen, Jahna, Kattnitz, Kiebitz, Merschütz, Münchhof, Niederlützschera, Noschkowitz, Oberlützschera, Obersteina, Ostrau, Pulsitz, Rittnitz, Schlagwitz, Schmorren, Schrebitz, Sömnitz, Trebanitz, Zschochau,

- Gemeinde Reinsberg,
- Gemeinde Stadt Döbeln mit den Ortsteilen Beicha, Bormitz, Choren, Döbeln, Dreißig, Geleitshäuser, Gertitzsch, Gödelitz, Großsteinbach, Juchhöh, Kleinmockritz, Leschen, Lüttewitz, Maltitz, Markritz, Meila, Mochau, Nelkanitz, Oberranschütz, Petersberg, Präbschütz, Prüfern, Schallhausen, Schweimnitz, Simselwitz, Theeschütz, Zschackwitz, Zschäschtz,
- Gemeinde Stadt Großschirma mit den Ortsteilen Obergruna, Siebenlehn,
- Gemeinde Stadt Roßwein mit den Ortsteilen Gleisberg, Haßlau, Klinge, Naußlitz, Neuseifersdorf, Niederforst, Ossig, Roßwein, Seifersdorf, Wettersdorf, Wetterwitz,
- Gemeinde Striegistal mit den Ortsteilen Gersdorf, Kammersheim, Marbach,
- Gemeinde Zschaitz-Ottewig,
- Landkreis Nordsachsen:
 - Gemeinde Arzberg mit den Ortsteilen Stehla, Tauschwitz,
 - Gemeinde Cavertitz mit den Ortsteilen Außig, Cavertitz, Klingenhain, Schirmenitz, Treptitz,
 - Gemeinde Liebschützberg mit den Ortsteilen Borna, Bornitz, Clanzschwitz, Ganzig, Kleinragewitz, Laas, Leckwitz, Liebschütz, Sahlassan, Schönnewitz, Terpitz östlich der Querung am Käferberg, Wadewitz, Zaußwitz,
 - Gemeinde Naundorf mit den Ortsteilen Casabra, Gastewitz, Haage, Hof, Hohenwussen, Kreina, Nasenberg, Raitzen, Reppen, Salbitz, Stennschütz, Zeicha,
 - Gemeinde Stadt Belgern-Schildau mit den Ortsteilen Ammelgoßwitz, Dröschkau, Liebersee östlich der B182, Oelzschau, Seydewitz, Staritz, Wohrlau,
 - Gemeinde Stadt Mügeln mit den Ortsteilen Mahris, Schweta südlich der K8908, Zschannewitz,
 - Gemeinde Stadt Oschatz mit den Ortsteilen Lonnewitz östlich des Sandbaches und nördlich der B6, Oschatz östlich des Schmorkauer Wegs und nördlich der S28, Rechau, Schmorkau, Zöschau,
- Landkreis Sächsische Schweiz-Osterzgebirge:
 - Gemeinde Bannewitz,
 - Gemeinde Dürrröhrsdorf-Dittersbach,
 - Gemeinde Kreischa,
 - Gemeinde Lohmen,
 - Gemeinde Müglitztal,
 - Gemeinde Stadt Dohna,
 - Gemeinde Stadt Freital,
 - Gemeinde Stadt Heidenau,
 - Gemeinde Stadt Hohnstein,
 - Gemeinde Stadt Neustadt i. Sa.,
 - Gemeinde Stadt Pirna,
 - Gemeinde Stadt Rabenau mit den Ortsteilen Lübau, Obernaundorf, Oelsa, Rabenau und Spechtritz,
 - Gemeinde Stadt Stolpen,
 - Gemeinde Stadt Tharandt mit den Ortsteilen Fördergersdorf, Großpitz, Kurort Hartha, Pohrsdorf und Spechtshausen,
 - Gemeinde Stadt Wilsdruff, sofern nicht bereits Teil der Sperrzone II,
- Bundesland Mecklenburg-Vorpommern:
 - Landkreis Vorpommern Greifswald
 - Gemeinde Penkun,

- Gemeinde Nadrensee,
- Gemeinde Krackow,
- Gemeinde Glasow,
- Gemeinde Grambow,
- Landkreis Ludwigslust-Parchim:
 - Gemeinde Barkhagen mit den Ortsteilen und Ortschaften: Altenlinden, Kolonie Lalchow, Plauerhagen, Zarchlin, Barkow-Ausbau, Barkow,
 - Gemeinde Blievenstorf mit dem Ortsteil: Blievenstorf,
 - Gemeinde Brenz mit den Ortsteilen und Ortschaften: Neu Brenz, Alt Brenz,
 - Gemeinde Domsühl mit den Ortsteilen und Ortschaften: Severin, Bergrade Hof, Bergrade Dorf, Zieslütbe, Alt Dammerow, Schlieven, Domsühl, Domsühl-Ausbau, Neu Schlieven,
 - Gemeinde Gallin-Kuppentin mit den Ortsteilen und Ortschaften: Kuppentin, Kuppentin-Ausbau, Daschow, Zahren, Gallin, Penzlin,
 - Gemeinde Ganzlin mit den Ortsteilen und Ortschaften: Dresenow, Dresenower Mühle, Twietfort, Ganzlin, Tönchow, Wendisch Priborn, Liebhof, Gnevsdorf,
 - Gemeinde Granzin mit den Ortsteilen und Ortschaften: Lindenbeck, Greven, Beckendorf, Bahlenrade, Granzin,
 - Gemeinde Grabow mit den Ortsteilen und Ortschaften: Fresenbrügge, Grabow, Griemoor, Heidehof, Kaltehof, Winkelmoor,
 - Gemeinde Groß Laasch mit den Ortsteilen und Ortschaften: Groß Laasch,
 - Gemeinde Kremmin mit den Ortsteilen und Ortschaften: Beckentin, Kremmin,
 - Gemeinde Kritzow mit den Ortsteilen und Ortschaften: Schlemmin, Kritzow,
 - Gemeinde Lewitzrand mit dem Ortsteil und Ortschaft: Matzlow-Garwitz (teilweise),
Gemeinde Lübz mit den Ortsteilen und Ortschaften: Bobzin, Broock, Broock Ausbau, Hof Gischow, Lübz, Lutheran, Lutheran Ausbau, Riederfelde, Ruthen, Wessentin, Wessentin Ausbau,
 - Gemeinde Neustadt-Glewe mit den Ortsteilen und Ortschaften: Hohes Feld, Kiez, Klein Laasch, Liebs Siedlung, Neustadt-Glewe, Tuckhude, Wabel,
 - Gemeinde Obere Warnow mit den Ortsteilen und Ortschaften: Grebbin und Wozinkel, Gemarkung Kossebade teilweise, Gemarkung Herzberg mit dem Waldgebiet Bahlenholz bis an die östliche Gemeindegrenze, Gemarkung Woeten unmittelbar östlich und westlich der L16,
 - Gemeinde Parchim mit den Ortsteilen und Ortschaften: Dargelütz, Neuhoof, Kiekindemark, Neu Klockow, Möderitz, Malchow, Damm, Parchim, Voigtsdorf, Neu Matzlow,
 - Gemeinde Passow mit den Ortsteilen und Ortschaften: Unterbrüz, Brüz, Welzin, Neu Brüz, Weisin, Charlottenhof, Passow,
 - Gemeinde Plau am See mit den Ortsteilen und Ortschaften: Reppentin, Gaarz, Silbermühle, Appelburg, Seelust, Plau-Am See, Plötzenhöhe, Klebe, Lalchow, Quetzin, Heidekrug,
 - Gemeinde Rom mit den Ortsteilen und Ortschaften: Lancken, Stralendorf, Rom, Darze, Paarsch,
 - Gemeinde Spornitz mit den Ortsteilen und Ortschaften: Dütschow, Primark, Steinbeck, Spornitz,
 - Gemeinde Werder mit den Ortsteilen und Ortschaften: Neu Benthén, Benthén, Tannenhof, Werder.

2. Estonia

The following restricted zones I in Estonia:

- Hiiu maakond.

3. Latvia

The following restricted zones I in Latvia:

- Dienvidkurzemes novads, Nīcas pagasta daļa uz ziemeļiem no apdzīvotas vietas Bernāti, autoceļā V1232, A11, V1222, Bārtas upes, Otaņķu pagasts,
- Ropažu novads Stopiņu pagasta daļa, kas atrodas uz rietumiem no autoceļā V36, P4 un P5, Acones ielas, Daugulupes ielas un Daugulupītes.

4. Lithuania

The following restricted zones I in Lithuania:

- Klaipėdos rajono savivaldybė: Agluonėnų, Dovilų, Gargždų, Priekulės, Vėžaičių, Kretingalės ir Dauparų-Kvietinių seniūnijos,
- Palangos miesto savivaldybė.

5. Hungary

The following restricted zones I in Hungary:

- Békés megye 950950, 950960, 950970, 951950, 952050, 952750, 952850, 952950, 953050, 953150, 953650, 953660, 953750, 953850, 953960, 954250, 954260, 954350, 954450, 954550, 954650, 954750, 954850, 954860, 954950, 955050, 955150, 955250, 955260, 955270, 955350, 955450, 955510, 955650, 955750, 955760, 955850, 955950, 956050, 956060, 956150 és 956160 kódszámú vadgazdálkodási egységeinek teljes területe,
- Bács-Kiskun megye 600150, 600850, 601550, 601650, 601660, 601750, 601850, 601950, 602050, 603250, 603750 és 603850 kódszámú vadgazdálkodási egységeinek teljes területe,
- Budapest 1 kódszámú, vadgazdálkodási tevékenységre nem alkalmas területe,
- Csongrád-Csanád megye 800150, 800160, 800250, 802220, 802260, 802310 és 802450 kódszámú vadgazdálkodási egységeinek teljes területe,
- Fejér megye 400150, 400250, 400351, 400352, 400450, 400550, 401150, 401250, 401350, 402050, 402350, 402360, 402850, 402950, 403050, 403450, 403550, 403650, 403750, 403950, 403960, 403970, 404650, 404750, 404850, 404950, 404960, 405050, 405750, 405850, 405950,
- 406050, 406150, 406550, 406650 és 406750 kódszámú vadgazdálkodási egységeinek teljes területe,
- Győr-Moson-Sopron megye 100550, 100650, 100950, 101050, 101350, 101450, 101550, 101560 és 102150 kódszámú vadgazdálkodási egységeinek teljes területe,
- Jász-Nagykun-Szolnok megye 750150, 750160, 750260, 750350, 750450, 750460, 754450, 754550, 754560, 754570, 754650, 754750, 754950, 755050, 755150, 755250, 755350 és 755450 kódszámú vadgazdálkodási egységeinek teljes területe,
- Komárom-Esztergom megye 250150, 250250, 250450, 250460, 250550, 250650, 250750, 251050, 251150, 251250, 251350, 251360, 251650, 251750, 251850, 252250, kódszámú vadgazdálkodási egységeinek teljes területe,
- Pest megye 571550, 572150, 572250, 572350, 572550, 572650, 572750, 572850, 572950, 573150, 573250, 573260, 573350, 573360, 573450, 573850, 573950, 573960, 574050, 574150, 574350, 574360, 574550, 574650, 574750, 574850, 574860, 574950, 575050, 575150, 575250, 575350, 575550, 575650, 575750, 575850, 575950, 576050, 576150, 576250, 576350, 576450, 576650, 576750, 576850, 576950, 577050, 577150, 577350, 577450, 577650, 577850, 577950, 578050, 578150, 578250, 578350, 578360, 578450, 578550, 578560, 578650, 578850, 578950, 579050, 579150, 579250, 579350, 579450, 579460, 579550, 579650, 579750, 580250 és 580450 kódszámú vadgazdálkodási egységeinek teljes területe.

6. Poland

The following restricted zones I in Poland:

w województwie kujawsko - pomorskim:

- powiat rypiński,
- powiat brodnicki,
- powiat grudziądzki,

- powiat miejski Grudziądz,
 - powiat wąbrzeski,
- w województwie warmińsko-mazurskim:
- gmina Rozogi w powiecie szczycieńskim,
- w województwie podlaskim:
- gminy Wysokie Mazowieckie z miastem Wysokie Mazowieckie, Czyżew i część gminy Kulesze Kościelne położona na południe od linii wyznaczonej przez linię kolejową w powiecie wysokomazowieckim,
 - powiat łomżyński,
 - gminy Turośl, Mały Płock w powiecie kolneńskim,
 - powiat zambrowski,
 - powiat miejski Łomża,
- w województwie mazowieckim:
- powiat ostrołęcki,
 - powiat miejski Ostrołęka,
 - powiat płocki,
 - powiat miejski Płock,
 - powiat ciechanowski,
 - powiat płoński,
 - powiat sierpecki,
 - gmina Biezuń, Lutocin, Siemiątkowo i Żuromin w powiecie żuromińskim,
 - część powiatu ostrowskiego niewymieniona w części II załącznika I,
 - gminy Dzieżgowo, Lipowiec Kościelny, Mława, Radzanów, Strzegowo, Stupsk, Szreńsk, Szydłowo, Wiśniewo w powiecie mławskim,
 - powiat przasnyski,
 - powiat makowski,
 - powiat pułtuski,
 - część powiatu wyszkowskiego niewymieniona w części II załącznika I,
 - część powiatu węgrowskiego niewymieniona w części II załącznika I,
 - część powiatu wołomińskiego niewymieniona w części II załącznika I,
 - gminy Mokobody i Suchożebry w powiecie siedleckim,
 - gminy Ceglów, Dębe Wielkie, Dobrze, Halinów, Jakubów, Mińsk Mazowiecki z miastem Mińsk Mazowiecki, Kałuszyn, Mrozy, Stanisławów w powiecie mińskim,
 - gminy Bielany i gmina wiejska Sokołów Podlaski w powiecie sokołowskim,
 - powiat gostyniński,
 - gminy Gózd, Iłża, Skaryszew w powiecie radomskim,
 - gminy Ciepeliów, Lipsko, Rzecznów, Sienno w powiecie lipskim,
 - gminy Kazanów, Policzna, Tczów, Zwolen w powiecie zwoleńskim,
- w województwie podkarpackim:
- część gminy Dębowiec położona na północ od linii wyznaczonej przez drogę nr 993, część gminy Osiek Jasielski położona na północ od linii wyznaczonej przez drogę nr 993, część gminy Nowy Żmigród położona na północ od linii wyznaczonej przez drogę nr 993 w powiecie jasielskim,
 - gmina Grodzisko Dolne w powiecie leżajskim,
 - część powiatu ropczycko – sędziszowskiego niewymieniona w części II załącznika I,

- gminy Chłopice, Pawłosiów, Jarosław z miastem Jarosław w powiecie jarosławskim,
- gminy Fredropol, Krasieczyn, Krzywca, Przemyśl, część gminy Orły położona na zachód od linii wyznaczonej przez drogę nr 77, część gminy Żurawica na zachód od linii wyznaczonej przez drogę nr 77 w powiecie przemyskim,
- powiat miejski Przemyśl,
- gminy Adamówka, Sieniawa, Tryńcza, Przeworsk z miastem Przeworsk, część gminy Zarzecze położona na północ od linii wyznaczonej przez rzekę Mleczka w powiecie przeworskim,
- gminy Rakszawa, Żółnia w powiecie łańcuckim,
- gminy Trzebownik, Głogów Małopolski, część gminy Świlcza położona na północ od linii wyznaczonej przez drogę nr 94 i część gminy Sokołów Małopolski położona na południe od linii wyznaczonej przez drogę nr 875 w powiecie rzeszowskim,
- gmina Raniżów w powiecie kolbuszowskim,
- część powiatu dębickiego niewymieniona w części II załącznika I,
- gminy Chorkówka, Dukla, Jaślika w powiecie krośnieńskim,
- gmina Komańcza w powiecie sanockim,
- gmina Cisna w powiecie leskim,
- gminy Lutowska, Czarna, Ustrzyki Dolne w powiecie bieszczadzkim,

w województwie świętokrzyskim:

- powiat buski,
- powiat skarżyski,
- część powiatu opatowskiego niewymieniona w części II załącznika I,
- część powiatu sandomierskiego niewymieniona w części II załącznika I,
- powiat staszowski,
- gminy Mirzec, Brody, część gminy Wąchock położona na północ od linii wyznaczonej przez drogę nr 42 w powiecie starachowckim,
- powiat ostrowiecki,
- gminy Gowarczów, Końskie, Stąporków w powiecie koneckim,

w województwie łódzkim:

- gminy Łyszkowice, Kocierzew Południowy, Kiernoza, Chąsno, Nieborów, część gminy wiejskiej Łowicz położona na północ od linii wyznaczonej przez drogę nr 92 biegnącej od granicy miasta Łowicz do zachodniej granicy gminy oraz część gminy wiejskiej Łowicz położona na wschód od granicy miasta Łowicz i na północ od granicy gminy Nieborów w powiecie łowickim,
- gminy Cieladz, Rawa Mazowiecka z miastem Rawa Mazowiecka w powiecie rawskim,
- gminy Bolimów, Głuchów, Godzianów, Lipce Reymontowskie, Maków, Nowy Kawęczyn, Skierniewice, Słupia w powiecie skierniewickim,
- powiat miejski Skierniewice,
- gminy Mniszków, Paradyż, Sławno i Żarnów w powiecie opoczyńskim,
- gminy Czerniewice, Inowłódz, Lubochnia, Rzeczyca, Tomaszów Mazowiecki z miastem Tomaszów Mazowiecki, Zelechlinek w powiecie tomaszowskim,

w województwie pomorskim:

- gminy Ostaszewo, miasto Krynica Morska oraz część gminy Nowy Dwór Gdański położona na południowy - zachód od linii wyznaczonej przez drogę nr 55 biegnącą od południowej granicy gminy do skrzyżowania z drogą nr 7, następnie przez drogę nr 7 i S7 biegnącą do zachodniej granicy gminy w powiecie nowodworskim,
- gminy Lichnowy, Miłoradz, Malbork z miastem Malbork, część gminy Nowy Staw położona na zachód od linii wyznaczonej przez drogę nr 55 w powiecie malborskim,
- gminy Stary Targ i Sztum w powiecie sztumskim,

- gminy Cedry Wielkie, Suchy Dąb, Pszczółki, miasto Pruszcz Gdański, część gminy wiejskiej Pruszcz Gdański położona na wschód od linii wyznaczonej przez drogę A1 w powiecie gdańskim,
 - Miasto Gdańsk,
 - powiat tczewski,
 - część powiatu kwidzyńskiego niewymieniona w części II załącznika I,
- w województwie lubuskim:
- gmina Lubiszyn w powiecie gorzowskim,
 - powiat strzelecko – drezdenecki,
- w województwie dolnośląskim:
- gminy Międzybórz, Syców, Twardogóra, część gminy wiejskiej Oleśnica położona na północ od linii wyznaczonej przez drogę nr S8, część gminy Dobroszyce położona na wschód od linii wyznaczonej przez linię kolejową biegnącą od północnej do południowej granicy gminy w powiecie oleśnickim,
 - gminy Jordanów Śląski, Kobierzyce, Mietków, Sobótka, część gminy Żórawina położona na zachód od linii wyznaczonej przez autostradę A4, część gminy Kąty Wrocławskie położona na południe od linii wyznaczonej przez autostradę A4 w powiecie wrocławskim,
 - część gminy Domaniów położona na południowy zachód od linii wyznaczonej przez autostradę A4 w powiecie oławskim,
 - gmina Wiązów w powiecie strzelińskim,
 - część powiatu średzkiego niewymieniona w części II załącznika I,
 - gminy Pielgrzymka, miasto Złotoryja, część gminy wiejskiej Złotoryja położona na zachód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy w miejscowości Nowa Wieś Złotoryjska do granicy miasta Złotoryja oraz na południe od linii wyznaczonej przez drogę nr 382 biegnącą od granicy miasta Złotoryja do wschodniej granicy gminy w powiecie złotoryjskim,
 - gminy Janowice Wielkie, Mysłakowice, Stara Kamienica, Szklarska Poręba w powiecie karkonoskim,
 - część powiatu miejskiego Jelenia Góra położona na północ od linii wyznaczonej przez drogę nr 366,
 - gminy Bolków, Mściwojów, Paszowice, miasto Jawor, część gminy Męcinka położona na południe od drogi nr 363 w powiecie jaworskim,
 - gminy Dobromierz, Jaworzyna Śląska, Marcinowice, Strzegom, Żarów w powiecie świdnickim,
 - gminy Dzierżoniów, Pieszyce, miasto Bielawa, miasto Dzierżoniów w powiecie dzierżoniowskim,
 - gminy Głuszycza, Mieroszów w powiecie wałbrzyskim,
 - gmina Nowa Ruda i miasto Nowa Ruda w powiecie kłodzkim,
 - gminy Kamienna Góra, Marciszów i miasto Kamienna Góra w powiecie kamiennogórskim,
- w województwie wielkopolskim:
- gminy Koźmin Wielkopolski, Rozdrażew w powiecie krotoszyńskim,
 - gminy Brodnica, część gminy Dolsk położona na wschód od linii wyznaczonej przez drogę nr 434 biegnącą od północnej granicy gminy do skrzyżowania z drogą nr 437, a następnie na wschód od drogi nr 437 biegnącej od skrzyżowania z drogą nr 434 do południowej granicy gminy, część gminy Śrem położona na wschód od linii wyznaczonej przez drogę nr 310 biegnącą od zachodniej granicy gminy do miejscowości Śrem, następnie na wschód od drogi nr 432 w miejscowości Śrem oraz na wschód od drogi nr 434 biegnącej od skrzyżowania z drogą nr 432 do południowej granicy gminy w powiecie śremskim,

- gminy Borek Wielkopolski, Piaski, Pogorzela, w powiecie gostyńskim,
- gmina Grodzisk Wielkopolski i część gminy Kamieniec położona na wschód od linii wyznaczonej przez drogę nr 308 w powiecie grodziskim,
- gmina Czempiń w powiecie kościańskim,
- gminy Kleszczewo, Kostrzyn, Kórnik, Pobiedziska, Mosina, miasto Puszczykowo w powiecie poznańskim,
- gmina Kiszkowo i część gminy Klecko położona na zachód od rzeki Mała Wełna w powiecie gnieźnieńskim,
- powiat czarnkowsko-trzcianecki,
- część gminy Wronki położona na północ od linii wyznaczonej przez rzekę Wartę biegnącą od zachodniej granicy gminy do przecięcia z drogą nr 182, a następnie na wschód od linii wyznaczonej przez drogi nr 182 oraz 184 biegnącą od skrzyżowania z drogą nr 182 do południowej granicy gminy w powiecie szamotulskim,
- gmina Budzyń w powiecie chodzieskim,
- gminy Mieścisko, Skoki i Wągrowiec z miastem Wągrowiec w powiecie wągrowieckim,
- gmina Dobrzyca w powiecie pleszewskim,
- gminy Odolanów, Przygodzice, Raszków, Sośnie, miasto Ostrów Wielkopolski, część gminy wiejskiej Ostrów Wielkopolski położona na wschód od linii wyznaczonej przez drogę łączącą miejscowości Sulisław – Łakociny – Wierzбно i na zachód od miasta Ostrów Wielkopolski oraz część gminy wiejskiej Ostrów Wielkopolski położona na wschód od miasta Ostrów Wielkopolski w powiecie ostrowskim,
- gmina Kobyla Góra w powiecie ostrzeszowskim,
- gminy Baranów, Bralin, Perzów, Rychtal, Trzcinica, Łęka Opatowska w powiecie kępińskim,

w województwie opolskim:

- gmina Byczyna, część gminy Kluczbork położona na północ od linii wyznaczonej przez drogę nr 42 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą nr 45, a następnie od tego skrzyżowania na wschód od linii wyznaczonej przez drogę nr 45 do skrzyżowania z ulicą Fabryczną w miejscowości Kluczbork i dalej na północ od linii wyznaczonej przez ulicę Fabryczna -Dzierżonia – Strzelecka w miejscowości Kluczbork do wschodniej granicy gminy, część gminy Wołczyn położona na północ od linii wyznaczonej przez drogę nr 42 w powiecie kluczborskim,
- gminy Praszka, Gorzów Śląski, Radłów, Olesno, Zębówice, część gminy Rudniki położona na północ od linii wyznaczonej przez drogę nr 42 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą nr 43 i na zachód od linii wyznaczonej przez drogę nr 43 biegnącą od północnej granicy gminy do skrzyżowania z drogą nr 42 w powiecie oleskim,
- część gminy Grodków położona na zachód od linii wyznaczonej przez linię kolejową w powiecie brzeskim,
- gminy Łambinowice, Pakosławice, Skoroszyce, część gminy Korfantów położona na północ od linii wyznaczonej przez drogę nr 407 w powiecie nyskim,
- część gminy Biała położona na północ od linii wyznaczonej przez drogę nr 407 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą nr 414 i dalej na wschód od linii wyznaczonej przez drogę nr 414 biegnącą od tego skrzyżowania do skrzyżowania z drogą nr 409, a następnie na północ od linii wyznaczonej przez drogę nr 409 biegnącą od tego skrzyżowania do wschodniej granicy gminy w powiecie prudnickim,
- gminy Chrzastowice, Ozimek, Komprachcice, Prószków, część gminy Łubniany położona na południe od linii wyznaczonej przez drogę łączącą miejscowości Świerkle – Masów, ulicę Leśną w miejscowości Masów oraz na południe od ulicy Kolanowskiej biegnącej do wschodniej granicy gminy, część gminy Turawa położona na południe od linii wyznaczonej przez ulicę Powstańców Śląskich -Kolanowską -Opolską – Kotorską w miejscowości Węgry i dalej na południe od drogi łączącej miejscowości Węgry- Kotórz Mały – Turawa – Rzędów – Kadłub Turawski – Zakrzów Turawski biegnącą do wschodniej granicy gminy w powiecie opolskim,

— powiat miejski Opole,

w województwie zachodniopomorskim:

- gminy Nowogródek Pomorski, Barlinek, część gminy Myślibórz położona na wschód od linii wyznaczonej przez drogę nr 23 biegnącej od południowej granicy gminy do skrzyżowania z drogą nr 26, następnie na wschód od drogi nr 26 biegnącej od tego skrzyżowania do skrzyżowania z drogą nr 119 i dalej na wschód od drogi nr 119 biegnącej od skrzyżowania z drogą nr 26 do północnej granicy gminy, część gminy Dębno położona na wschód od linii wyznaczonej przez drogę nr 126 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą nr 23 w miejscowości Dębno, następnie na wschód od linii wyznaczonej przez drogę nr 23 do skrzyżowania z ul. Jana Pawła II w miejscowości Cychry, następnie na północ od ul. Jana Pawła II do skrzyżowania z ul. Ogrodową i dalej na północ od linii wyznaczonej przez ul. Ogrodową, której przedłużenie biegnie do wschodniej granicy gminy w powiecie myśliborskim,
- gmina Stare Czarnowo w powiecie gryfińskim,
- gminy Bielice, Lipiany, Przelewice, Pyrzyce w powiecie pyrzyckim,
- gminy Bierzwnik, Krzęcin, Pełczyce w powiecie choszczeńskim,
- część powiatu miejskiego Szczecin położona na zachód od linii wyznaczonej przez rzekę Odra Zachodnia biegnącą od północnej granicy gminy do przecięcia z drogą nr 10, następnie na południe od linii wyznaczonej przez drogę nr 10 biegnącą od przecięcia z linią wyznaczoną przez rzekę Odra Zachodnia do wschodniej granicy gminy,
- gminy Dobra (Szczecińska), Police w powiecie polickim,

w województwie małopolskim:

- gmina Biecz, Bobowa, Moszczenica, Lipinki, Łużna, Ropa, Gorlice, miasto Gorlice w powiecie gorlickim,
- powiat nowosądecki,
- gminy Czorsztyn, Krościenko nad Dunajcem, Ochotnica Dolna, Szczawnica w powiecie nowotarskim,
- powiat miejski Nowy Sącz,
- gminy Skrzyszów, Lisia Góra, Radłów, Wietrzychowice, Żabno, część gminy wiejskiej Tarnów położona na wschód od miasta Tarnów w powiecie tarnowskim,
- powiat dąbrowski,
- gminy Klucze, Bolesław, Bukowno w powiecie olkuskim,

w województwie śląskim:

- gmina Sławków w powiecie będzińskim,
- powiat miejski Jaworzno,
- powiat miejski Mysłowice,
- powiat miejski Katowice,
- powiat miejski Siemianowice Śląskie,
- powiat miejski Chorzów,
- powiat miejski Piekary Śląskie,
- powiat miejski Bytom,
- gminy Kalety, Ożarowice, Świerklaniec, Miasteczko Śląskie, Radzionków w powiecie tarnogórskim,
- gmina Woźniki w powiecie lublinieckim,
- gminy Myszków i Koziegłowy w powiecie myszkowskim,
- gminy Ogrodzieniec, Zawiercie, Włodowice w powiecie zawierciańskim.

7. Slovakia

The following restricted zones I in Slovakia:

- in the district of Nové Zámky, Sikenička, Pavlová, Bíňa, Kamenín, Kamenný Most, Malá nad Hronom, Belá, Ľubá, Šarkan, Gbelce, Bruty, Mužla, Obid, Štúrovo, Nána, Kamenica nad Hronom, Chľaba, Leľa, Bajtava, Salka, Malé Kosihy,
- in the district of Veľký Krtíš, the municipalities of Ipel'ské Predmostie, Veľká nad Ipľom, Hrušov, Kleňany, Sečianky,
- in the district of Levice, the municipalities of Keť, Čata, Pohronský Ruskov, Hronovce, Želiezovce, Zalaba, Malé Ludince, Šalov, Sikenica, Pastovce, Bielovce, Ipel'ský Sokolec, Lontov, Kubáňovo, Szdice, Demandice, Dolné Semerovce, Vyškovce nad Ipľom, Preseľany nad Ipľom, Hrkovce, Tupá, Horné Semerovce, Hokovce, Slatina, Horné Turovce, Veľké Turovce, Šahy, Tešmak, Plášťovce, Ipel'ské Uľany, Bátorovce, Pečenice, Jabloňovce, Bohunice, Pukanec, Uhliská, Kalná nad Hronom, Nový Tekov, Malé Kozmálovce, Veľké Kozmálovce, Tlmače, Rybník, Hronské Kosihy, Čajkov, Nová Dedina, Devičany,
- in the district of Krupina, the municipalities of Dudince, Terany, Hontianske Moravce, Sudince, Súdovce, Lišov,
- the whole district of Ružomberok,
- the whole district of Turčianske Teplice, except municipalities included in zone II,
- in the district of Martin, municipalities of Blatnica, Folkušová, Necpaly, Belá-Dulice, Ďanová, Karlová, Laskár, Rakovo, Pribovce, Košťany nad Turcom, Socovce, Turčiansky Ďur, Kláštor pod Znievom, Slovany, Ležiachov, Benice,
- in the district of Dolný Kubín, the municipalities of Kraľovany, Žaškov, Jasenová, Vyšný Kubín, Oravská Poruba, Leštiny, Osádka, Malatiná, Chlebnice, Krivá,
- in the district of Tvrdošín, the municipalities of Oravský Biely Potok, Habovka, Zuberec,
- in the district of Prievidza, the municipalities of Handlová, Cígelf, Podhradie, Lehota pod Vtáčnikom, Kamenec pod Vtáčnikom, Bystričany, Čereňany, Oslany, Horná Ves, Radobica, Ráztočno,
- in the district of Partizánske, the municipalities of Veľké Uherce, Pažiť, Kolačno, Veľký Klíž, Ješkova Ves, Klátová Nová Ves,
- in the district of Topoľčany, the municipalities of Krnča, Prázdnovce, Solčany, Nitrianska Streda, Čeladince, Kovarce, Súlovce,
- in the district of Zlaté Moravce, the municipalities of Zlatno, Mankovce, Veľčice, Kostol'any pod Trábečom, Ladice, Sľažany, Neverice, Beladice, Choča, Vieska nad Žitavou, Slepčany, Červený Hrádok, Nevidzany, Malé Vozokany,
- the whole district of Žiar nad Hronom, except municipalities included in zone II.

8. Italy

The following restricted zones I in Italy:

Piedmont Region:

- in the province of Alessandria, the municipalities of Casale Monferrato, Oviglio, Viguzzolo, Bergamasco, Castellar Guidobono, Berzano Di Tortona, Carentino, Frascaro, Borgoratto Alessandrino, Volpigliano, Gamalero, Volpedo, Sarezzano, Pontecurone, Castelnuovo Scrivia, Alluvione Piovera, Sale, Bassignana, Pecetto di Valenza, Rivarone, Montecastello, Valenza, San Salvatore Monferrato, Castelletto Monferrato, Quargnento, Solero, Pietra Marazzi,
- in the province of Asti, the municipalities of Nizza Monferrato, Incisa Scapaccino, Mombaruzzo, Maranzana, Castelletto Molina, Castelnuovo Belbo, Quaranti, Fontanile, Calamandrana, Bruno, Canelli, San Marzano Oliveto,
- in the province of Cuneo, the municipalities of Bergolo, Pezzolo Valle Uzzone, Cortemilia, Levice, Castelletto Uzzone, Perletto, Castino, Cossano Belbo, Rocchetta Belbo, Santo Stefano Belbo, Gottasecca, Monesiglio, Sale delle Langhe, Camerana, Castelnuovo di Ceva, Piero, Brunetto, Montezemolo, Perlo,

Liguria Region:

- in the province of Genova, the Municipalities of Rovegno, Portofino, Santa Margherita Ligure, Camogli, Fontanigorda, Rezzoaglio, Orero, Coreglia Ligure, San Colombano Certenoli, Zoagli, Leivi, Chiavari, Borzonasca,
- in the province of Savona, the municipalities of Bergeggi, Spotorno, Vezzi Portio, Noli, Orco Feglino, Bormida, Calice Ligure, Rialto, Osiglia, Murialdo,

Emilia-Romagna Region:

- in the province of Piacenza, the municipalities of Cerignale, Ottone (est fiume Trebbia),

Lombardia Region:

- in the province of Pavia, the municipalities of Rocca Susella, Montesegale, Menconico, Val Di Nizza, Bagnaria, Santa Margherita Di Staffora, Ponte Nizza, Brallo Di Pregola, Varzi, Godiasco, Cecima,

Lazio Region:

- in the province of Rome,

north: the municipalities of Riano, Castelnuovo di Porto, Capena, Fiano Romano, Morlupo, Sacrofano, Magliano Romano, Formello, Campagnano di Roma, Anguillara,

West: the municipality of Fiumicino,

south: the municipality of Rome between the boundaries of the municipality of Fiumicino (West), the limits of Zone 3 (North), the Tiber River up to the intersection with the Grande Raccordo Anulare GRA Highway, the Grande Raccordo Anulare GRA Highway up to the intersection with A24 Highway, A24 Highway up to the intersection with Viale del Tecnopolo, viale del Tecnopolo up to the intersection with the boundaries of the municipality of Guidonia Montecelio,

east: the municipalities of Guidonia Montecelio, Montelibretti, Palombara Sabina, Monterotondo, Mentana, Sant'Angelo Romano, Fonte Nuova.

Sardinia Region

- in South Sardinia Province the Municipalities of Ballao, Barumini, Escalaplano, Escolca Isola Amministrativa, Genuri, Gergei, Gesico, Guamaggiore, Las Plassas, Mandas, Orroli, Pauli Arbarei, Selegas, Setzu, Siddi, Siurgus Donigala, Suelli, Tuili, Turri, Ussaramanna, Villanovafranca, Villaputzu,
- in Nuoro Province the Municipalities of Arzana Isola Amministrativa, Birori, Borore, Bortigali a ovest della Strada Statale 131, Dualchi, Gairo Isola Amministrativa, Galtelli, Irgoli, Jerzu Isola Amministrativa, Lanusei Isola Amministrativa, Loceri Isola Amministrativa, Loculi, Macomer at ovest della Strada Statale 131, Noragugume, Onifai, Orosei, Ortueri, Osini Isola Amministrativa, Perdasdefogu, Posada, Sindia Isola Amministrativa, Siniscola, Tertenia Isola Amministrativa,
- in Oristano Province the Municipalities of Aidomaggiore, Albagiara, Ardauli, Assolo, Asuni, Baradili, Baressa, Bidoni, Boroneddu, Busachi, Ghilarza, Gonnosnò, Mogorella, Neoneli, Nureci, Ruinas, Samugheo, Sedilo, Senis, Sini, Soddi, Sorradile Isola Amministrativa, Tadasuni, Ulà Tirso, Usellus, Villa Sant'antonio,
- in Sassari Province the Municipalities of Ardara, Berchidda, Bonnanaro, Bonorva a ovest della Strada Statale 131, Borutta, Cheremule, Cossoine, Giave, Loiri Porto San Paolo, Monti, Mores a nord della Strada Statale 128bis – Strada Provinciale 63, Olbia a sud della Strada Statale 127, Oschiri a nord della E 840, Ozieri a nord della Strada Provinciale 63 – Strada Provinciale 1 – Strada Statale 199, Semestene, Telti, Torralba, Tula.

9. Czechia

The following restricted zones I in Czechia:

Liberecký kraj:

- v okrese Liberec katastrální území obcí Hrádek nad Nisou, Oldřichov v Hájích, Grabštejn, Václavice u Hrádku nad Nisou, Horní Vítkov, Dolní Vítkov, Bílý Kostel nad Nisou, Dolní Chrastava, Horní Chrastava, Chrastava I, Nová Ves u Chrastavy, Mlýnice, Albrechtice u Frýdlantu, Kristiánov, Heřmanice u Frýdlantu, Dětrichov u Frýdlantu, Mníšek u Liberce, Oldřichov na Hranicích, Machnín, Svárov u Liberce, Desná I, Krásná Studánka, Stráž nad Nisou, Fojtka, Radčice u Krásné Studánky, Kateřinky u Liberce, Staré Pavlovice, Nové Pavlovice, Růžodol I, Františkov u Liberce,

Liberec, Ruprechtice, Rudolfovo, Horní Růžodol, Rochlice u Liberce, Starý Harcov, Vratislavice nad Nisou, Kunratice u Liberce, Proseč nad Nisou, Lukášov, Rýnovice, Jablonec nad Nisou, Jablonecké Paseky, Jindřichov nad Nisou, Mšeno nad Nisou, Lučany nad Nisou, Smržovka, Tanvald, Jiřetín pod Bukovou, Dolní Maxov, Antonínov, Horní Maxov, Karlov u Josefova Dolu, Loučná nad Nisou, Hraničná nad Nisou, Janov nad Nisou, Bedřichov u Jablonce nad Nisou, Josefův Důl u Jablonce nad Nisou, Albrechtice v Jizerských horách, Desná III, Polubný, Harrachov, Jizerka, Hejnice, Bílý Potok pod Smrkem, Andělská Hora u Chrástavy, Benešovice u Všelibic, Cetenov, Česká Ves v Podještědí, Dolní Sedlo, Dolní Suchá u Chotyně, Donín u Hrádku nad Nisou, Družcov, Hlavičky, Hrubý Lesnov, Chotyně, Chrástava II, Chrástná, Jablonné v Podještědí, Janovice v Podještědí, Janův Důl, Jítrava, Kněžice v Lužických horách, Kotel, Kryštofovo Údolí, Křižany, Lázně Kundratice, Loučná, Lvová, Malčice u Všelibic, Markvartice v Podještědí, Nesvačily u Všelibic, Novina u Liberce, Osečná, Panenská Hůrka, Polesí u Rynoltic, Postřelná, Přibyslavice, Rynoltice, Smržov u Českého Dubu, Vápno, Všelibice, Zábrdí u Osečné, Zdislava, Žibřidice,

- v okrese Česká Lípa katastrální území obcí Bezděz, Blatce, Brniště, Břevniště pod Ralskem, Česká Lípa, Deštná u Dubé, Dobranov, Dražejov u Dubé, Drchlava, Dřevčice, Dubá, Dubice u České Lípy, Dubnice pod Ralskem, Hamr na Jezeře, Heřmaničky u Dobranova, Hlemýžď, Holany, Horky u Dubé, Horní Krupá, Houska, Chlum u Dubé, Jabloneček, Jestřebí u České Lípy, Kamenice u Zákup, Korce, Kruh v Podbezdězí, Kvítkov u České Lípy, Lasvice, Loubí pod Vlhostí, Luhov u Mimoně, Luka, Maršovice u Dubé, Náhlov, Nedamov, Noviny pod Ralskem, Obora v Podbezdězí, Okna v Podbezdězí, Okřešice u České Lípy, Pavlovice u Jestřebí, Písečná u Dobranova, Skalka u Doks, Sosnová u České Lípy, Srní u České Lípy, Stará Lípa, Starý Šidlov, Stráž pod Ralskem, Šváby, Tachov u Doks, Tubož, Újezd u Jestřebí, Velenice u Zákup, Velký Grunov, Velký Valtinov, Vítkov u Dobranova, Vlčí Důl, Vojetín, Vrchovany, Zahrádky u České Lípy, Zákupy, Zbýny, Žďár v Podbezdězí, Ždírec v Podbezdězí, Žizníkov,

Středočeský kraj

- v okrese Mladá Boleslav katastrální území obcí Bezdědice, Březovice pod Bezdězem, Víška u Březovic, Dolní Krupá u Mnichova Hradiště, Mukařov u Jiviny, Neveklovice, Strážiště u Jiviny, Vicmanov, Vrchbělá, Březinka pod Bezdězem, Bělá pod Bezdězem, Dolní Rokytá, Horní Rokytá, Rostkov, Kozmice u Jiviny.

10. Greece

The following restricted zones I in Greece:

- in the regional unit of Drama:
 - the community departments of Sidironero and Skaloti and the municipal departments of Livadero and Ksiropotamo (in Drama municipality),
 - the municipal department of Paranesti (in Paranesti municipality),
 - the municipal departments of Prosotsani, Kokkinogeia, Mikropoli, Panorama, Pyrgoi (in Prosotsani municipality),
 - the municipal departments of Kato Nevrokopi, Chrysokéfalo, Achladea, Vathytopos, Volakas, Granitis, Dasotos, Eksoti, Katafyto, Lefkogeia, Mikrokleisoura, Mikromilea, Ochyro, Pagoneri, Perithorio, Kato Vrontou and Potamoi (in Kato Nevrokopi municipality),
- in the regional unit of Xanthi:
 - the municipal departments of Kimmerion, Stavroupoli, Gerakas, Dafnonas, Komnina, Kariofyto and Neochori (in Xanthi municipality),
 - the community departments of Satres, Thermes, Kotyli, and the municipal departments of Myki, Echinis and Oraio (in Myki municipality),
 - the community department of Selero and the municipal department of Sounio (in Avdira municipality),
- in the regional unit of Rodopi:
 - the municipal departments of Komotini, Anthochorio, Gratini, Thrylorio, Kalhas, Karydia, Kikidio, Kosmio, Pandrosos, Aigeiros, Kallisti, Meleti, Neo Sidirochori and Mega Doukato (in Komotini municipality),

- the municipal departments of Ipio, Arriana, Darmeni, Archontika, Fillyra, Ano Drosini, Aratos and the Community Departments Kehros and Organi (in Arriana municipality),
- the municipal departments of Iasmos, Sostis, Asomatoi, Polyanthos and Amvrosia and the community department of Amaxades (in Iasmos municipality),
- the municipal department of Amaranta (in Maroneia Sapon municipality),
- in the regional unit of Evros:
 - the municipal departments of Kyriaki, Mandra, Mavroklisi, Mikro Dereio, Protokklisi, Roussa, Goniko, Geriko, Sidirochori, Megalo Derio, Sidiro, Giannouli, Agriani and Petrolofos (in Soufli municipality),
 - the municipal departments of Dikaia, Arzos, Elaia, Therapio, Komara, Marasia, Ormenio, Pentalofos, Petrola, Plati, Ptelea, Kyprinos, Zoni, Fulakio, Spilaio, Nea Vyssa, Kavili, Kastanies, Rizia, Sterna, Ampelakia, Valtos, Megali Doxipara, Neochori and Chandras (in Orestiada municipality),
 - the municipal departments of Asvestades, Ellinochori, Karoti, Koufovouno, Kiani, Mani, Sitochori, Alepochori, Asproneri, Metaxades, Vrysika, Doksa, Elafoxori, Ladi, Paliouri and Poimeniko (in Didymoteixo municipality).
- in the regional unit of Serres:
 - the municipal departments of Irakleia, Valtero, Dasochori, Karperi, Koimisi, Pontismeno, Chrysochorafa, Ammoudia, Gefyroudi, Strymoniko, Zevgolatio, Triados and Cheimaros (Irakleia Municipality).
 - the municipal departments of Gonimo, Megalochori, Kamaroto, Sidirokastro, Strymonochori, Chortero, Charopo, the Community Departments of Agkistro, Achladochori, Kapnofyto, part of the Community Department of Promachonas, and part of the Municipal Departments of Kastanousi, Vyroneia, Neo Petritsi (Sintiki Municipality).
 - The municipal departments of Serres, Elaionas, Anagennisi, Vamvakia and Oinoussa and the community departments of Orini and Ano Vrontou (Serres Municipality).
- in the regional unit of Kilikis:
 - the municipal departments of Drosato, Amarantos, Terpyllo, Agios Markos, Anavrytou, Antigoneia, Gerakari, Helliniko, Efkarpi, Isoma, Kentriko, Koiladi, Kokkinia, Pontokerasea, Tripotamos, Fyska, Myriofyto and Plagia and part of the Municipal Departments of Mouries, Agia Paraskevi, Stathmos Mourion (Kilkis Municipality).

PART II

1. Bulgaria

The following restricted zones II in Bulgaria:

- the whole region of Haskovo,
- the whole region of Yambol,
- the whole region of Stara Zagora,
- the whole region of Pernik,
- the whole region of Kyustendil,
- the whole region of Plovdiv,
- the whole region of Pazardzhik, excluding the areas in Part III,
- the whole region of Smolyan,
- the whole region of Dobrich,
- the whole region of Sofia city,
- the whole region of Sofia Province,
- the whole region of Blagoevgrad,

- the whole region of Razgrad,
- the whole region of Kardzhali,
- the whole region of Burgas,
- the whole region of Varna,
- the whole region of Silistra,
- the whole region of Ruse,
- the whole region of Veliko Tarnovo,
- the whole region of Pleven,
- the whole region of Targovishte,
- the whole region of Shumen,
- the whole region of Sliven,
- the whole region of Vidin,
- the whole region of Gabrovo,
- the whole region of Lovech,
- the whole region of Montana,
- the whole region of Vratza.

2. Germany

The following restricted zones II in Germany:

Bundesland Brandenburg:

- Landkreis Oder-Spree:
 - Gemeinde Grunow-Dammendorf,
 - Gemeinde Mixdorf
 - Gemeinde Schlaubetal,
 - Gemeinde Neuzelle,
 - Gemeinde Neißemünde,
 - Gemeinde Lawitz,
 - Gemeinde Eisenhüttenstadt,
 - Gemeinde Vogelsang,
 - Gemeinde Ziltendorf,
 - Gemeinde Wiesenau,
 - Gemeinde Friedland,
 - Gemeinde Siehdichum,
 - Gemeinde Müllrose,
 - Gemeinde Briesen,
 - Gemeinde Jacobsdorf
 - Gemeinde Groß Lindow,
 - Gemeinde Brieskow-Finkenheerd,
 - Gemeinde Ragow-Merz,
 - Gemeinde Beeskow,
 - Gemeinde Rietz-Neuendorf,
 - Gemeinde Tauche mit den Gemarkungen Stremmen, Ranzig, Trebatsch, Sabrodt, Sawall, Mitweide, Lindenberg, Falkenberg (T), Görsdorf (B), Wulfersdorf, Giesensdorf, Briescht, Kossenblatt und Tauche,

- Gemeinde Langewahl,
- Gemeinde Berkenbrück,
- Gemeinde Steinhöfel mit den Gemarkungen Arensdorf und Demitz und den Gemarkungen Steinhöfel, Hasenfelde und Heinersdorf östlich der L 36 und der Gemarkung Neuendorf im Sande südlich der L 36,
- Gemeinde Fürstenwalde östlich der B 168 und südlich der L 36,
- Gemeinde Diensdorf-Radlow,
- Gemeinde Wendisch Rietz östlich des Scharmützelsees und nördlich der B 246,
- Gemeinde Bad Saarow mit der Gemarkung Neu Golm und der Gemarkung Bad Saarow-Pieskow östlich des Scharmützelsees und ab nördlicher Spitze östlich der L 35,
- Landkreis Dahme-Spreewald:
 - Gemeinde Jamlitz,
 - Gemeinde Lieberose,
 - Gemeinde Schwielochsee mit den Gemarkungen Goyatz, Jessern, Lamsfeld, Ressen, Speichrow und Zaue,
- Landkreis Spree-Neiße:
 - Gemeinde Schenkendöbern,
 - Gemeinde Guben,
 - Gemeinde Jänschwalde,
 - Gemeinde Tauer,
 - Gemeinde Peitz,
 - Gemeinde Turnow-Preilack mit der Gemarkung Preilack,
 - Gemeinde Teichland,
 - Gemeinde Heinersbrück,
 - Gemeinde Forst,
 - Gemeinde Groß Schacksdorf-Simmersdorf,
 - Gemeinde Neiße-Malxetal,
 - Gemeinde Jämlitz-Klein Düben,
 - Gemeinde Tschernitz,
 - Gemeinde Döbern,
 - Gemeinde Felixsee,
 - Gemeinde Wiesengrund,
 - Gemeinde Spremberg mit den Gemarkungen Wolkenberg, Stradow, Jessen, Pulsberg und Perpe,
 - Gemeinde Welzow,
 - Gemeinde Neuhausen/Spree mit der Gemarkung Gablenz,
 - Gemeinde Drebkau mit den Gemarkungen Greifenhain und Kausche,
- Landkreis Märkisch-Oderland:
 - Gemeinde Bleyen-Genschmar,
 - Gemeinde Neuhardenberg
 - Gemeinde Golzow,
 - Gemeinde Küstriner Vorland,
 - Gemeinde Alt Tuchebrand,
 - Gemeinde Reitwein,

- Gemeinde Podelzig,
- Gemeinde Gusow-Platkow,
- Gemeinde Seelow,
- Gemeinde Vierlinden,
- Gemeinde Lindendorf,
- Gemeinde Fichtenhöhe,
- Gemeinde Lietzen,
- Gemeinde Falkenhagen (Mark),
- Gemeinde Zeschdorf,
- Gemeinde Treplin,
- Gemeinde Lebus,
- Gemeinde Müncheberg mit den Gemarkungen Jahnsfelde, Trebnitz, Obersdorf, Münchehofe und Hermersdorf,
- Gemeinde Märkische Höhe mit der Gemarkung Ringenwalde,
- Gemeinde Bliesdorf mit der Gemarkung Metzdorf und Gemeinde Bliesdorf – östlich der B167 bis östlicher Teil, begrenzt aus Richtung Gemarkungsgrenze Neutrebbin südlich der Bahnlinie bis Straße „Sophienhof“ dieser westlich folgend bis „Rueterchegraben“ weiter entlang Feldweg an den Windrädern Richtung „Herrnhof“, weiter entlang „Letschiner Hauptgraben“ nord-östlich bis Gemarkungsgrenze Alttrebbin und Kunersdorf – östlich der B167,
- Gemeinde Bad Freienwalde mit den Gemarkungen Altglietzen, Altranft, Bad Freienwalde, Bralitz, Hohenwutzen, Schiffmühle, Hohensaaten und Neuenhagen,
- Gemeinde Falkenberg mit der Gemarkung Falkenberg östlich der L35,
- Gemeinde Oderaue,
- Gemeinde Wriezen mit den Gemarkungen Altwriezen, Jäckelsbruch, Neugaul, Beauregard, Eichwerder, Rathsdorf – östlich der B167 und Wriezen – östlich der B167,
- Gemeinde Neulewin,
- Gemeinde Neutrebbin,
- Gemeinde Letschin,
- Gemeinde Zechin,
- Landkreis Barnim:
 - Gemeinde Lunow-Stolzenhagen,
 - Gemeinde Parsteinsee,
 - Gemeinde Oderberg,
 - Gemeinde Liepe,
 - Gemeinde Hohenfinow (nördlich der B167),
 - Gemeinde Niederfinow,
 - Gemeinde (Stadt) Eberswalde mit den Gemarkungen Eberswalde nördlich der B167 und östlich der L200, Sommerfelde und Tornow nördlich der B167,
 - Gemeinde Chorin mit den Gemarkungen Brodowin, Chorin östlich der L200, Serwest, Neuhütte, Sandkrug östlich der L200,
 - Gemeinde Ziethen mit der Gemarkung Klein Ziethen östlich der Serwester Dorfstraße und östlich der B198,
- Landkreis Uckermark:
 - Gemeinde Angermünde mit den Gemarkungen Crussow, Stolpe, Gellmersdorf, Neukünkendorf, Bölkendorf, Herzprung, Schmargendorf und den Gemarkungen Angermünde südlich und südöstlich der B2 und Dobberzin südlich der B2,

- Gemeinde Schwedt mit den Gemarkungen Criewen, Zützen, Schwedt, Stendell, Kummerow, Kunow, Vierraden, Blumenhagen, Oderbruchwiesen, Enkelsee, Gatow, Hohenfelde, Schöneberg, Flemisdorf und der Gemarkung Felchow östlich der B2,
- Gemeinde Pinnow südlich und östlich der B2,
- Gemeinde Berkholz-Meyenburg,
- Gemeinde Mark Landin mit der Gemarkung Landin südlich der B2,
- Gemeinde Casekow mit der Gemarkung Woltersdorf und den Gemarkungen Biesendahlshof und Casekow östlich der L272 und südlich der L27,
- Gemeinde Hohenselchow-Groß Pinnow mit der Gemarkung Groß Pinnow und der Gemarkung Hohenselchow südlich der L27,
- Gemeinde Gartz (Oder) mit der Gemarkung Friedrichsthal und den Gemarkungen Gartz und Hohenreinkendorf südlich der L27 und der B2 bis Kastanienallee, dort links abbiegend dem Schülerweg folgend bis Höhe Bahnhof, von hier in östlicher Richtung den Salveybach kreuzend bis zum Tantower Weg, diesen in nördlicher Richtung bis zu Stettiner Straße, diese weiter folgend bis zur B2, dieser in nördlicher Richtung folgend,
- Gemeinde Mescherin mit der Gemarkung Mescherin, der Gemarkung Neurochlitz östlich der B2 und der Gemarkung Rosow nördlich der K 7311,
- Gemeinde Passow mit der Gemarkung Jamikow,
- Kreisfreie Stadt Frankfurt (Oder),
- Landkreis Prignitz:
 - Gemeinde Karstädt mit den Gemarkungen Neuhoof und Kribbe und den Gemarkungen Groß Warnow, Klein Warnow, Reckenzin, Streesow und Dallmin östlich der Bahnstrecke Berlin/Spandau-Hamburg/Altona,
 - Gemeinde Berge,
 - Gemeinde Pirow mit den Gemarkungen Hülsebeck, Pirow, Bresch und Burow,
 - Gemeinde Putlitz mit den Gemarkungen Sagast, Nettelbeck, Porep, Lütkenhof, Putlitz, Weitendorf und Telschow,
 - Gemeinde Marienfließ mit den Gemarkungen Jännersdorf, Stepenitz und Krependorf,
- Landkreis Oberspreewald-Lausitz:
 - Gemeinde Vetschau mit den Gemarkungen Wüstenhain und Laasow,
 - Gemeinde Altdöbern mit den Gemarkungen Reddern, Ranzow, Pritzen, Altdöbern östlich der Bahnstrecke Altdöbern –Großräschen,
 - Gemeinde Großräschen mit den Gemarkungen Woschkow, Dörrwalde, Allmosen,
 - Gemeinde Neu-Seeland,
 - Gemeinde Neupetershain,
 - Gemeinde Senftenberg mit den Gemarkungen Peickwitz, Sedlitz, Kleinkoschen, Großkoschen und Hosena,
 - Gemeinde Hohenbocka,
 - Gemeinde Grünwald,
 - Gemeinde Hermsdorf,
 - Gemeinde Kroppen,
 - Gemeinde Ortrand,
 - Gemeinde Großmehlen,
 - Gemeinde Lindenau,
 - Gemeinde Frauendorf,

- Gemeinde Ruhland,
- Gemeinde Guteborn,
- Gemeinde Schwarzbach mit der Gemarkung Schwarzbach,

Bundesland Sachsen:

- Landkreis Bautzen,
- Stadt Dresden:
 - Stadtgebiet nördlich der BAB4 bis zum Verlauf westlich der Elbe, dann nördlich der B6,
- Landkreis Görlitz,
- Landkreis Meißen:
 - Gemeinde Diera-Zehren östlich der Elbe,
 - Gemeinde Ebersbach,
 - Gemeinde Glaubitz östlich des Grödel-Elsterwerdaer-Floßkanals,
 - Gemeinde Klipphausen östlich der S177,
 - Gemeinde Lampertswalde,
 - Gemeinde Moritzburg,
 - Gemeinde Niederau östlich der B101,
 - Gemeinde Nünchritz östlich der Elbe und südlich des Grödel-Elsterwerdaer-Floßkanals,
 - Gemeinde Priestewitz,
 - Gemeinde Röderaue östlich des Grödel-Elsterwerdaer-Floßkanals,
 - Gemeinde Schönhof,
 - Gemeinde Stadt Coswig,
 - Gemeinde Stadt Gröditz östlich des Grödel-Elsterwerdaer-Floßkanals,
 - Gemeinde Stadt Großenhain,
 - Gemeinde Stadt Meißen östlich des Straßenverlaufs der S177 bis zur B6, dann B6 bis zur B101, ab der B101 Elbtalbrücke Richtung Norden östlich der Elbe,
 - Gemeinde Stadt Radebeul,
 - Gemeinde Stadt Radeburg,
 - Gemeinde Thiendorf,
 - Gemeinde Weinböhla,
 - Gemeinde Wülknitz östlich des Grödel-Elsterwerdaer-Floßkanals,
- Landkreis Sächsische Schweiz-Osterzgebirge:
 - Gemeinde Stadt Wilsdruff nördlich der BAB4 zwischen den Abfahren Wilsdruff und Dreieck Dresden-West,

Bundesland Mecklenburg-Vorpommern:

- Landkreis Ludwigslust-Parchim:
 - Gemeinde Balow mit dem Ortsteil: Balow,
 - Gemeinde Brunow mit den Ortsteilen und Ortslagen: Bauerkuhl, Brunow (bei Ludwigslust), Klüß, Löcknitz (bei Parchim),
 - Gemeinde Dambeck mit dem Ortsteil und der Ortslage: Dambeck (bei Ludwigslust),
 - Gemeinde Ganzlin mit den Ortsteilen und Ortslagen: Barackendorf, Hof Retzow, Klein Damerow, Retzow, Wangelin,

- Gemeinde Gehlsbach mit den Ortsteilen und Ortschaften: Ausbau Darß, Darß, Hof Karbow, Karbow, Karbow-Ausbau, Quaßlin, Quaßlin Hof, Quaßliner Mühle, Vietlütbe, Wahlstorf
- Gemeinde Groß Godems mit den Ortsteilen und Ortschaften: Groß Godems, Klein Godems,
- Gemeinde Karrenzin mit den Ortsteilen und Ortschaften: Herzfeld, Karrenzin, Karrenzin-Ausbau, Neu Herzfeld, Repzin, Wulfsahl,
- Gemeinde Kreien mit den Ortsteilen und Ortschaften: Ausbau Kreien, Hof Kreien, Kolonie Kreien, Kreien, Wilsen,
- Gemeinde Kritzow mit dem Ortsteil und der Ortschaft: Benzin,
- Gemeinde Lübz mit den Ortsteilen und Ortschaften: Burow, Gischow, Meyerberg,
- Gemeinde Möllenbeck mit den Ortsteilen und Ortschaften: Carlshof, Horst, Menzendorf, Möllenbeck,
- Gemeinde Muchow mit dem Ortsteil und Ortschaft: Muchow,
- Gemeinde Parchim mit dem Ortsteil und Ortschaft: Slate,
- Gemeinde Prislich mit den Ortsteilen und Ortschaften: Marienhof, Neese, Prislich, Werle,
- Gemeinde Rom mit dem Ortsteil und Ortschaft: Klein Niendorf,
- Gemeinde Ruhner Berge mit den Ortsteilen und Ortschaften: Dorf Polnitz, Drenkow, Griebow, Jarchow, Leppin, Malow, Malower Mühle, Marnitz, Mentin, Mooster, Poitendorf, Polnitz, Suckow, Tessenow, Zachow,
- Gemeinde Siggelkow mit den Ortsteilen und Ortschaften: Groß Pankow, Klein Pankow, Neuburg, Redlin, Siggelkow,
- Gemeinde Stolpe mit den Ortsteilen und Ortschaften: Barkow, Granzin, Stolpe Ausbau, Stolpe,
- Gemeinde Ziegendorf mit den Ortsteilen und Ortschaften: Drefahl, Meierstorf, Neu Drefahl, Pampin, Platschow, Stresendorf, Ziegendorf,
- Gemeinde Zierzow mit den Ortsteilen und Ortschaften: Kolbow, Zierzow.

3. Estonia

The following restricted zones II in Estonia:

- Eesti Vabariik (välja arvatud Hiiu maakond).

4. Latvia

The following restricted zones II in Latvia:

- Aizkraukles novads,
- Alūksnes novads,
- Augšdaugavas novads,
- Ādažu novads,
- Balvu novads,
- Bauskas novads,
- Cēsu novads,
- Dienvidkurzemes novada Aizputes, Cīravas, Lažas, Durbes, Dunalkas, Tadaikū, Vecpils, Bārtas, Sakas, Bunkas, Priekules, Gramzdas, Kalētu, Virgas, Dunikas, Vainodes, Gaviezes, Grobiņas, Rucavas, Vērgales, Medzes pagasts, Nīcas pagasta daļa uz dienvidiem no apdzīvotas vietas Bernāti, autoceļš V1232, A11, V1222, Bārtas upes, Embūtes pagasta daļa uz dienvidiem no autoceļš P116, P106, autoceļš no apdzīvotas vietas Dinsdurbe, Kalvenes pagasta daļa uz rietumiem no ceļa pie Vārtājas upes līdz autoceļam A9, uz dienvidiem no autoceļš A9, uz rietumiem no autoceļš V1200, Kazdangas pagasta daļa uz rietumiem no ceļa V1200, P115, P117, V1296, Aizputes, Durbes, Pāvilostas, Priekules pilsēta, Grobiņas,

- Dobeles novads,
- Gulbenes novads,
- Jelgavas novads,
- Jēkabpils novads,
- Krāslavas novads,
- Kuldīgas novada Alsungas, Gudenieku, Kurmāles, Rendas, Kabiles, Vārmes, Pelču, Snēpeles, Turlavas, Ēdoles, Īvandes, Rumbas, Padures pagasts, Laidu pagasta daļa uz ziemeļiem no autoceļa V1296, Kuldīgas pilsēta,
- Ķekavas novads,
- Limbažu novads,
- Līvānu novads,
- Ludzas novads,
- Madonas novads,
- Mārupes novads,
- Ogres novads,
- Olaines novads,
- Preiļu novads,
- Rēzeknes novads,
- Ropažu novada Garkalnes, Ropažu pagasts, Stopiņu pagasta daļa, kas atrodas uz austrumiem no autoceļa V36, P4 un P5, Acones ielas, Daugulupes ielas un Daugulupītes, Vangažu pilsēta,
- Salaspils novads,
- Saldus novads,
- Saulkrastu novads,
- Siguldas novads,
- Smiltenes novads,
- Talsu novads,
- Tukuma novads,
- Valkas novads,
- Valmieras novads,
- Varakļānu novads,
- Ventspils novads,
- Daugavpils valstspilsētas pašvaldība,
- Jelgavas valstspilsētas pašvaldība,
- Jūrmalas valstspilsētas pašvaldība,
- Rēzeknes valstspilsētas pašvaldība.

5. Lithuania

The following restricted zones II in Lithuania:

- Alytaus miesto savivaldybė,
- Alytaus rajono savivaldybė,
- Anykščių rajono savivaldybė,
- Akmenės rajono savivaldybė,
- Birštono savivaldybė,
- Biržų miesto savivaldybė,

- Biržų rajono savivaldybė,
- Druskininkų savivaldybė,
- Elektrėnų savivaldybė,
- Ignalinos rajono savivaldybė,
- Jonavos rajono savivaldybė,
- Joniškio rajono savivaldybė,
- Jurbarko rajono savivaldybė: Eržvilko, Juodaičių, Seredžiaus, Smalininkų ir Viešvilės seniūnijos,
- Kaišiadorių rajono savivaldybė,
- Kauno miesto savivaldybė,
- Kauno rajono savivaldybė,
- Kalvarijos savivaldybė,
- Kazlų rūdų savivaldybė: Kazlų Rūdų seniūnija, išskyrus vakarinę dalį iki kelio 2602 ir 183, Plutiškių seniūnija,
- Kelmės rajono savivaldybė: Kelmės, Kražių, Liolių, Tytuvėnų, Tytuvėnų apylinkių, Pakražančio ir Vaiguvos seniūnijos,
- Kėdainių rajono savivaldybė,
- Klaipėdos rajono savivaldybė: Jutrėnų, Endriejavo ir Veiviržėnų seniūnijos,
- Kupiškio rajono savivaldybė,
- Kretingos rajono savivaldybė,
- Lazdijų rajono savivaldybė,
- Mažeikių rajono savivaldybė,
- Marijampolės savivaldybė, išskyrus Šumskų ir Sasnavos seniūnijos,
- Molėtų rajono savivaldybė: Alantos, Balninkų, Čiulėnų, Inturkės, Joniškio, Luokesos, Mindūnų, Suginčių ir Videniškių seniūnijos,
- Pagėgių savivaldybė,
- Pakruojo rajono savivaldybė,
- Panevėžio rajono savivaldybė,
- Panevėžio miesto savivaldybė,
- Pasvalio rajono savivaldybė,
- Radviliškio rajono savivaldybė,
- Rietavo savivaldybė,
- Prienų rajono savivaldybė,
- Plungės rajono savivaldybė,
- Raseinių rajono savivaldybė,
- Rokiškio rajono savivaldybė,
- Skuodo rajono savivaldybė,
- Šakių rajono savivaldybė: Kriūkų, Lekėčių ir Lukšių seniūnijos,
- Šalčininkų rajono savivaldybė,
- Šiaulių miesto savivaldybė,
- Šiaulių rajono savivaldybė: Ginkūnų, Gruzdžių, Kairių, Kužių, Meškuičių, Raudėnų, Šakynos ir Šiaulių kaimiškosios seniūnijos,
- Šilutės rajono savivaldybė,
- Širvintų rajono savivaldybė: Čiobiškio, Gelvonų, Jauniūnų, Kernavės, Musninkų ir Širvintų seniūnijos,

- Šilalės rajono savivaldybė,
- Švenčionių rajono savivaldybė,
- Tauragės rajono savivaldybė,
- Telšių rajono savivaldybė,
- Trakų rajono savivaldybė,
- Ukmergės rajono savivaldybė: Deltuvos, Lyduokių, Pabaisko, Pivonijos, Siesikų, Šešuolių, Taujėnų, Ukmergės miesto, Veprių, Vidiškių ir Žemaitkiemo seniūnijos,
- Utenos rajono savivaldybė,
- Varėnos rajono savivaldybė,
- Vilkaviškio rajono savivaldybė: Bartninkų, Gražiškių, Keturvalakių, Pajevonio, Virbalio ir Vištyčio seniūnijos,
- Vilniaus miesto savivaldybė,
- Vilniaus rajono savivaldybė: Avižienių, Bezdonių, Buivydžių, Dūkštų, Juodšilių, Kalvelių, Lavoriškių, Maišiagalos, Marijampolio, Medininkų, Mickūnų, Nemenčinės, Nemenčinės miesto, Nemėžio, Pagirių, Riešės, Rudaminos, Rukainių, Sudervės, Sužionių, Šatrininkų ir Zujūnų seniūnijos,
- Visagino savivaldybė,
- Zarasų rajono savivaldybė.

6. Hungary

The following restricted zones II in Hungary:

- Békés megye 950150, 950250, 950350, 950450, 950550, 950650, 950660, 950750, 950850, 950860, 951050, 951150, 951250, 951260, 951350, 951450, 951460, 951550, 951650, 951750, 952150, 952250, 952350, 952450, 952550, 952650, 953250, 953260, 953270, 953350, 953450, 953550, 953560, 953950, 954050, 954060, 954150, 956250, 956350, 956450, 956550, 956650 és 956750 kódszámú vadgazdálkodási egységeinek teljes területe,
- Borsod-Abaúj-Zemplén megye valamennyi vadgazdálkodási egységének teljes területe,
- Fejér megye 403150, 403160, 403250, 403260, 403350, 404250, 404550, 404560, 404570, 405450, 405550, 405650, 406450 és 407050 kódszámú vadgazdálkodási egységeinek teljes területe,
- Hajdú-Bihar megye valamennyi vadgazdálkodási egységének teljes területe,
- Heves megye valamennyi vadgazdálkodási egységének teljes területe,
- Jász-Nagykun-Szolnok megye 750250, 750550, 750650, 750750, 750850, 750970, 750980, 751050, 751150, 751160, 751250, 751260, 751350, 751360, 751450, 751460, 751470, 751550, 751650, 751750, 751850, 751950, 752150, 752250, 752350, 752450, 752460, 752550, 752560, 752650, 752750, 752850, 752950, 753060, 753070, 753150, 753250, 753310, 753450, 753550, 753650, 753660, 753750, 753850, 753950, 753960, 754050, 754150, 754250, 754360, 754370, 754850, 755550, 755650 és 755750 kódszámú vadgazdálkodási egységeinek teljes területe,
- Komárom-Esztergom megye: 250350, 250850, 250950, 251450, 251550, 251950, 252050, 252150, 252350, 252450, 252460, 252550, 252650, 252750, 252850, 252860, 252950, 252960, 253050, 253150, 253250, 253350, 253450 és 253550 kódszámú vadgazdálkodási egységeinek teljes területe,
- Nógrád megye valamennyi vadgazdálkodási egységének teljes területe,
- Pest megye 570150, 570250, 570350, 570450, 570550, 570650, 570750, 570850, 570950, 571050, 571150, 571250, 571350, 571650, 571750, 571760, 571850, 571950, 572050, 573550, 573650, 574250, 577250, 580050 és 580150 kódszámú vadgazdálkodási egységeinek teljes területe,
- Szabolcs-Szatmár-Bereg megye valamennyi vadgazdálkodási egységének teljes területe.

7. Poland

The following restricted zones II in Poland:

w województwie warmińsko-mazurskim:

- gminy Kalinowo, Stare Juchy, Prostki oraz gmina wiejska Elk w powiecie elckim,

- powiat elbląski,
 - powiat miejski Elbląg,
 - powiat gołdapski,
 - powiat piski,
 - powiat bartoszycki,
 - powiat olecki,
 - powiat giżycki,
 - powiat braniewski,
 - powiat kętrzyński,
 - powiat lidzbarski,
 - gminy Dźwierzuty Jedwabno, Pasym, Świętajno, Wielbark, Szczytno i miasto Szczytno w powiecie szczycieńskim,
 - powiat mrągowski,
 - powiat węgorzewski,
 - powiat olsztyński,
 - powiat miejski Olsztyn,
 - powiat nidzicki,
 - część powiatu ostródzkiego niewymieniona w części III załącznika I,
 - część powiatu nowomiejskiego niewymieniona w części III załącznika I,
 - część powiatu iławskiego niewymieniona w części III załącznika I,
 - część powiatu działdowskiego niewymieniona w części III załącznika I,
- w województwie podlaskim:
- powiat bielski,
 - powiat grajewski,
 - powiat moniecki,
 - powiat sejneński,
 - powiat siemiatycki,
 - powiat hajnowski,
 - gminy Ciechanowiec, Klukowo, Szepietowo, Kobylin-Borzymy, Nowe Piekuty, Sokoły i część gminy Kulesze Kościelne położona na północ od linii wyznaczonej przez linię kolejową w powiecie wysokomazowieckim,
 - powiat białostocki,
 - powiat suwalski,
 - powiat miejski Suwałki,
 - powiat augustowski,
 - powiat sokółski,
 - powiat miejski Białystok,
 - gminy Grabowo, Stawiski, Kolno z miastem Kolno w powiecie kolneńskim,
- w województwie mazowieckim:
- gminy Domanice, Korczew, Kotuń, Mordy, Paprotnia, Przesmyki, Siedlce, Skórzec, Wiśniew, Wodynie, Zbuczyn w powiecie siedleckim,
 - powiat miejski Siedlce,
 - gminy Czeranów, Jabłonna Lacka, Kosów Lacki, Repki, Sabnie, Sterdyń w powiecie sokołowskim,
 - powiat łosicki,
 - powiat sochaczewski,

- gmina Przyłęk w powiecie zwoleńskim,
- powiat kozienicki,
- gminy Chotcza i Solec nad Wisłą w powiecie lipskim,
- gminy Jastrzębia, Jedlińsk, Jedlnia – Letnisko, Kowala, Pionki z miastem Pionki, Przytyk, Wierzbica, Wolanów, Zakrzew w powiecie radomskim,
- powiat miejski Radom,
- powiat szydłowiecki,
- gminy Lubowidz i Kuczbork Osada w powiecie żuromińskim,
- gmina Wieczfnia Kościelna w powiecie mławskim,
- powiat nowodworski,
- gminy Radzymin, Wołomin, miasto Kobyłka, miasto Marki, miasto Ząbki, miasto Zielonka, część gminy Tłuszcz ograniczona liniami kolejowymi: na północ od linii kolejowej biegnącej od wschodniej granicy gminy do miasta Tłuszcz oraz na wschód od linii kolejowej biegnącej od północnej granicy gminy do miasta Tłuszcz, część gminy Jadów położona na północ od linii kolejowej biegnącej od wschodniej do zachodniej granicy gminy w powiecie wołomińskim,
- powiat garwoliński,
- gminy Boguty – Pianki, Brok, Zaręby Kościelne, Nur, Małkinia Górna, część gminy Wąsewo położona na południe od linii wyznaczonej przez drogę nr 60, część gminy wiejskiej Ostrów Mazowiecka położona na południe od miasta Ostrów Mazowiecka i na południe od linii wyznaczonej przez drogę 60 biegnącą od zachodniej granicy miasta Ostrów Mazowiecka do zachodniej granicy gminy w powiecie ostrowskim,
- część gminy Sadowne położona na północny- zachód od linii wyznaczonej przez linię kolejową, część gminy Łochów położona na północny – zachód od linii wyznaczonej przez linię kolejową w powiecie węgrowskim,
- gminy Brańszczyk, Długosiodło, Rząśnik, Wyszaków, część gminy Zabrodzie położona na wschód od linii wyznaczonej przez drogę nr S8 w powiecie wyszkowskim,
- gminy Latowicz, Siennica, Sulejówek w powiecie mińskim,
- powiat otwocki,
- powiat warszawski zachodni,
- powiat legionowski,
- powiat piaseczyński,
- powiat pruszkowski,
- powiat grójecki,
- powiat grodziski,
- powiat żyrardowski,
- powiat białobrzeski,
- powiat przysuski,
- powiat miejski Warszawa,
- w województwie lubelskim:
 - powiat bialski,
 - powiat miejski Biała Podlaska,
 - powiat janowski,
 - powiat puławski,
 - powiat rycki,
 - powiat łukowski,

- powiat lubelski,
- powiat miejski Lublin,
- powiat lubartowski,
- powiat łęczyński,
- powiat świdnicki,
- powiat biłgorajski,
- powiat hrubieszowski,
- powiat krasnostawski,
- powiat chełmski,
- powiat miejski Chełm,
- powiat tomaszowski,
- powiat kraśnicki,
- powiat opolski,
- powiat parczewski,
- powiat włodawski,
- powiat radzyński,
- powiat miejski Zamość,
- powiat zamojski,

w województwie podkarpackim:

- powiat stalowowolski,
- powiat lubaczowski,
- gminy Medyka, Stubno, część gminy Orły położona na wschód od linii wyznaczonej przez drogę nr 77, część gminy Żurawica na wschód od linii wyznaczonej przez drogę nr 77 w powiecie przemyskim,
- gmina Laszki, Wiązownica, Radymno z miastem Radymno w powiecie jarosławskim,
- gmina Kamień, część gminy Sokołów Małopolski położona na północ od linii wyznaczonej przez drogę nr 875 w powiecie rzeszowskim,
- gminy Cmolas, Dzikowiec, Kolbuszowa, Majdan Królewski i Niwiska powiecie kolbuszowskim,
- część powiatu leżajskiego niewymieniona w części I załącznika I,
- powiat niżański,
- powiat tarnobrzeski,
- powiat miejski Tarnobrzeg,
- gmina Ostrów, część gminy Sędziszów Małopolski położona na północ od linii wyznaczonej przez drogę nr A4 w powiecie ropczycko – sędziszowskim,
- część gminy Czarna położona na północ od linii wyznaczonej przez drogę nr A4, część gminy Żyraków położona na północ od linii wyznaczonej przez drogę nr A4, część gminy wiejskiej Dębica położona na północ od linii wyznaczonej przez drogę nr A4 w powiecie dębickim,
- powiat mielecki,
- gmina Krempna, część gminy Dębowiec położona na południe od linii wyznaczonej przez drogę nr 993, część gminy Osiek Jasielski położona na południe od linii wyznaczonej przez drogę nr 993, część gminy Nowy Żmigród położona na południe od linii wyznaczonej przez drogę nr 993 w powiecie jasielskim,

w województwie małopolskim:

- gminy Sękowa, Uście Gorlickie w powiecie gorlickim,

w województwie pomorskim:

- gminy Mikołajki Pomorskie, Dzierżoń i Stary Dzierżoń w powiecie sztumskim,
- gmina Stare Pole, część gminy Nowy Staw położona na wschód od linii wyznaczonej przez drogę nr 55 w powiecie malborskim,
- gminy Stegny, Sztutowo i część gminy Nowy Dwór Gdański położona na północny - wschód od linii wyznaczonej przez drogę nr 55 biegnącą od południowej granicy gminy do skrzyżowania z drogą nr 7, następnie przez drogę nr 7 i S7 biegnącą do zachodniej granicy gminy w powiecie nowodworskim,
- gmina Prabuty w powiecie kwidzińskim,

w województwie świętokrzyskim:

- gmina Tarłów i część gminy Ożarów położona na północ od linii wyznaczonej przez drogę nr 74 biegnącą od miejscowości Honorów do zachodniej granicy gminy w powiecie opatowskim,
- gminy Dwikozy i Zawichost w powiecie sandomierskim,

w województwie lubuskim:

- gminy Bogdaniec, Deszczno, Kłodawa, Kostrzyn nad Odrą, Santok, Witnica w powiecie gorzowskim,
- powiat miejski Gorzów Wielkopolski,
- powiat żarski,
- powiat słubicki,
- powiat żagański,
- powiat krośnieński,
- powiat zielonogórski
- powiat miejski Zielona Góra,
- powiat nowosolski,
- powiat sulęciński,
- powiat międzyrzecki,
- powiat świebodziński,
- powiat wschowski,

w województwie dolnośląskim:

- część powiatu zgorzeleckiego niewymieniona w części III załącznika I,
- część powiatu polkowickiego niewymieniona w części III załącznika I,
- część powiatu wołowskiego niewymieniona w części III załącznika I,
- gmina Jeżów Sudecki w powiecie karkonoskim,
- gminy Rudna, Ścinawa, miasto Lubin i część gminy Lubin niewymieniona w części III załącznika I w powiecie lubińskim,
- gmina Malczyce, Miękinia, Środa Śląska, część gminy Kostomłoty położona na północ od linii wyznaczonej przez drogę nr A4, część gminy Udanin położona na północ od linii wyznaczonej przez drogę nr A4 w powiecie średzkim,
- gmina Wądroże Wielkie, część gminy Męcinka położona na północ od drogi nr 363 w powiecie jaworskim,
- gminy Kunice, Legnickie Pole, Prochowice, Ruja w powiecie legnickim,
- gminy Wisznia Mała, Trzebnica, Zawonia, część gminy Oborniki Śląskie położona na południe od linii wyznaczonej przez drogę nr 340 w powiecie trzebnickim,
- miasto Świeradów Zdrój w powiecie lubańskim,
- powiat miejski Wrocław,

- gminy Czernica, Długołęka, Siechnice, część gminy Żórawina położona na wschód od linii wyznaczonej przez autostradę A4, część gminy Kąty Wrocławskie położona na północ od linii wyznaczonej przez autostradę A4 w powiecie wrocławskim,
- gminy Jelcz - Laskowice, Oława z miastem Oława i część gminy Domaniów położona na północny wschód od linii wyznaczonej przez autostradę A4 w powiecie oławskim,
- gmina Bierutów, Dziadowa Kłoda, miasto Oleśnica, część gminy wiejskiej Oleśnica położona na południe od linii wyznaczonej przez drogę nr S8, część gminy Dobroszyce położona na zachód od linii wyznaczonej przez linię kolejową biegnącą od północnej do południowej granicy gminy w powiecie oleśnickim,
- część powiatu bolesławieckiego niewymieniona w części III załącznika I,
- powiat milicki,
- powiat górowski,
- powiat głogowski,
- gmina Świerzawa, Wojcieszków, część gminy Zagrodno położona na zachód od linii wyznaczonej przez drogę łączącą miejscowości Jadwisin – Modlikowice Zagrodno oraz na zachód od linii wyznaczonej przez drogę nr 382 biegnącą od miejscowości Zagrodno do południowej granicy gminy w powiecie złotoryjskim,
- część powiatu lwóweckiego niewymieniona w części III załącznika I,
- gminy Czarny Bór, Stare Bogaczowice, Walim, miasto Boguszów - Gorce, miasto Jedlina – Zdrój, miasto Szczawno – Zdrój w powiecie wałbrzyskim,
- powiat miejski Wałbrzych,
- gmina Świdnica, miasto Świdnica, miasto Świebodzice w powiecie świdnickim,

w województwie wielkopolskim:

- gminy Siedlec, Wolsztyn, część gminy Przemęt położona na zachód od linii wyznaczonej przez drogę łączącą miejscowości Borek – Kluczewo – Sączkowo – Przemęt – Błotnica – Starkowo – Boszkowo – Letnisko w powiecie wolsztyńskim,
 - gmina Wielichowo, Rakoniewice, Granowo, część gminy Kamieniec położona na zachód od linii wyznaczonej przez drogę nr 308 w powiecie grodziskim,
 - powiat międzychodzki,
 - powiat nowotomyski,
 - powiat obornicki,
 - część gminy Połajewo na położona na południe od drogi łączącej miejscowości Chraplewo, Tarnówko-Boruszyn, Krosin, Jakubowo, Połajewo - ul. Ryczywolska do północno-wschodniej granicy gminy w powiecie czarnkowsko-trzcianeckim,
 - powiat miejski Poznań,
 - gminy Buk, Czerwonak, Dopiewo, Komorniki, Rokietnica, Stęszew, Swarzędz, Suchy Las, Tarnowo Podgórne, Murowana Goślina w powiecie poznańskim,
 - powiat rawicki,
 - część powiatu szamotulskiego niewymieniona w części I załącznika I,
 - część powiatu gostyńskiego niewymieniona w części I i III załącznika I,
 - gminy Kobylin, Zduny, Krotoszyn, miasto Sulmierzyce w powiecie krotoszyńskim,
 - część gminy wiejskiej Ostrów Wielkopolski położona na zachód od linii wyznaczonej przez drogę łączącą miejscowości Sulisław – Łąkociny – Wierzbno w powiecie ostrowskim,
 - gmina Wijewo w powiecie leszczyńskim,
- w województwie łódzkim:
- gminy Białaczów, Drzewica, Opoczno i Poświętne w powiecie opoczyńskim,
 - gminy Biała Rawska, Regnów i Sadkowiec w powiecie rawskim,
 - gmina Kowiesy w powiecie skierniewickim,

w województwie zachodniopomorskim:

- gmina Boleszkowice, część gminy Myślibórz położona na zachód od linii wyznaczonej przez drogę nr 23 biegnącej od południowej granicy gminy do skrzyżowania z drogą nr 26, następnie na zachód od drogi nr 26 biegnącej od tego skrzyżowania do skrzyżowania z drogą nr 119 i dalej na zachód od drogi nr 119 biegnącej od skrzyżowania z drogą nr 26 do północnej granicy gminy, część gminy Dębno położona na zachód od linii wyznaczonej przez drogę nr 126 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą nr 23 w miejscowości Dębno, następnie na zachód od linii wyznaczonej przez drogę nr 23 do skrzyżowania z ul. Jana Pawła II w miejscowości Cychry, następnie na południe od ul. Jana Pawła II do skrzyżowania z ul. Ogrodową i dalej na południe od linii wyznaczonej przez ul. Ogrodową, której przedłużenie biegnie do wschodniej granicy gminy w powiecie myśliborskim,
- gmina Kozielice w powiecie pyrzyckim,
- gminy Banie, Cedynia, Gryfino, Mieszkowice, Moryń, Chojna, Widuchowa, Trzcińsko-Zdrój w powiecie gryfińskim,
- gmina Kołbaskowo w powiecie polickim,

w województwie opolskim:

- gminy Brzeg, Lubsza, Lewin Brzeski, Olszanka, Skarbimierz, część gminy Grodków położona na wschód od linii wyznaczonej przez linię kolejową w powiecie brzeskim,
- gminy Dąbrowa, Dobrzeń Wielki, Popielów, Murów, Niemodlin, Tułowice, część gminy Łubniany położona na północ od linii wyznaczonej przez drogę łączącą miejscowości Świerkle – Masów, ulicę Leśną w miejscowości Masów oraz na północ od ulicy Kolanowskiej biegnącej do wschodniej granicy gminy, część gminy Turawa położona na północ od linii wyznaczonej przez ulice Powstańców Śląskich -Kolanowską -Opolską -Kotorską w miejscowości Węgry i dalej na północ od drogi łączącej miejscowości Węgry- Kotórz Mały – Turawa – Rzędów – Kadłub Turawski – Zakrzów Turawski biegnącą do wschodniej granicy gminy w powiecie opolskim,
- gmina Lasowice Wielkie, część gminy Kluczbork położona na południe od linii wyznaczonej przez drogę nr 42 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą nr 45, a następnie od tego skrzyżowania na zachód od linii wyznaczonej przez drogę nr 45 do skrzyżowania z ulicą Fabryczną w miejscowości Kluczbork i dalej na południe od linii wyznaczonej przez ulicę Fabryczną -Dzierżonia – Strzelecka w miejscowości Kluczbork do wschodniej granicy gminy, część gminy Wołczyn położona na południe od linii wyznaczonej przez drogę nr 42 w powiecie kluczborskim,
- powiat namysłowski,

w województwie śląskim:

- powiat miejski Sosnowiec,
- powiat miejski Dąbrowa Górnicza,
- gminy Bobrowniki, Mierzęcice, Psary, Siewierz, miasto Będzin, miasto Czeladź, miasto Wojkowice w powiecie będzińskim,
- gminy Łazy i Poręba w powiecie zawierciańskim.

8. Slovakia

The following restricted zones II in Slovakia:

- the whole district of Gelnica,
- the whole district of Poprad
- the whole district of Spišská Nová Ves,
- the whole district of Levoča,
- the whole district of Kežmarok,
- the whole district of Michalovce, except municipalities included in zone III,
- the whole district of Medzilaborce
- the whole district of Košice-okolie,
- the whole district of Rožnava,

- the whole city of Košice,
- the whole district of Sobrance, except municipalities included in zone III,
- the whole district of Vranov nad Topľou,
- the whole district of Humenné,
- the whole district of Snina,
- the whole district of Prešov,
- the whole district of Sabinov,
- the whole district of Svidník,
- the whole district of Stropkov,
- the whole district of Bardejov,
- the whole district of Stará Ľubovňa,
- the whole district of Revúca,
- the whole district of Rimavská Sobota,
- in the district of Veľký Krtíš, the whole municipalities not included in part I,
- the whole district of Lučenec,
- the whole district of Poltár,
- the whole district of Zvolen,
- the whole district of Detva,
- the whole district of Krupina, except municipalities included in zone I,
- the whole district of Banská Stiavnica,
- the whole district of Žarnovica,
- in the district of Žiar nad Hronom the municipalities of Hronská Dúbrava, Trnavá Hora, Ihráč, Nevoľné, Kremnica, Kremnické Bane, Krahule,
- the whole district of Banská Bystrica,
- the whole district of Brezno,
- the whole district of Liptovský Mikuláš,
- the whole district of Trebišov,
- in the district of Zlaté Moravce, the whole municipalities not included in part I,
- in the district of Levice the municipality of Kozárovce,
- in the district of Turčianske Teplice, municipalities of Turček, Horná Štubňa, Čremošné, Háj, Rakša, Mošovce.

9. Italy

The following restricted zones II in Italy:

Piedmont Region:

- in the Province of Alessandria, the municipalities of Alessandria, Tortona, Carbonara Scrivia, Frugarolo, Paderna, Spineto Scrivia, Castellazzo Bormida, Bosco Marengo, Castelspana, Casal Cermelli, Alice Bel Colle, Terzo, Bistagno, Cavatore, Castelnovo Bormida, Cabella Ligure, Carrega Ligure, Francavilla Bisio, Carpeneto, Costa Vescovato, Grogna, Orsara Bormida, Pasturana, Melazzo, Mornese, Ovada, Predosa, Lerma, Fraconalto, Rivalta Bormida, Fresonara, Malvicino, Ponzzone, San Cristoforo, Sezzadio, Rocca Grimalda, Garbagna, Tassarolo, Mongiardino Ligure, Morsasco, Montaldo Bormida, Prasco, Montaldeo, Belforte Monferrato, Albera Ligure, Bosio, Cantalupo Ligure, Castelletto D'orba, Cartosio, Acqui Terme, Arquata Scrivia, Parodi Ligure, Ricaldone, Gavi, Cremolino, Brignano-Frascata, Novi Ligure, Molare, Cassinelle, Morbello, Avolasca, Carezzano, Basaluzzo, Dernice, Trisobbio, Strevi, Sant'Agata Fossili, Pareto, Visone, Voltaggio, Tagliolo Monferrato, Casaleggio Boiro, Capriata D'orba, Castellania, Carrosio, Cassine, Vignole Borbera, Serravalle Scrivia, Silvano D'orba, Villalvernia, Roccaforte Ligure, Rocchetta Ligure, Sardigliano, Stazzano, Borghetto Di Borbera, Grondona, Cassano Spinola, Montacuto,

Gremiasco, San Sebastiano Curone, Fabbrica Curone, Spigno Monferrato, Montechiaro d'Acqui, Castelletto d'Erro, Ponti, Denice, Pozzolo Formigaro, Cerreto Grue, Casasco, Montegioco, Montemarzino, Momperone, Merana, Pozzol Groppo, Villaromagnano, Sarezzano, Monleale,

- in the province of Asti, the municipalities of Mombaldone, Castel Rocchero, Montabone, Sessame, Monatero Bormida, Roccaverano, Vesime, Cessole, Loazzolo, San Giorgio Scarampi, Olmo Gentile, Bubbio, Rocchetta Palafea, Cassinasco, Castel Boglione, Serole,
- In the Province of Cuneo, the municipality of Saliceto,

Liguria Region:

- in the province of Genova, the municipalities of Bogliasco, Arenzano, Ceranesi, Ronco Scrivia, Mele, Isola Del Cantone, Lumarzo, Genova, Masone, Serra Riccò, Campo Ligure, Mignanego, Busalla, Bargagli, Savignone, Torriglia, Rossiglione, Sant'Olcese, Valbrevenna, Sori, Tiglieto, Campomorone, Cogoleto, Pieve Ligure, Davagna, Casella, Montoggio, Crocefieschi, Vobbia, Fascia, Gorreto, Propata, Rondanina, Neirone, Lorsica (only Barbagelata exclave), Montebruno, Moconesi (only Santa Brilla exclave), Uscio, Avegno, Recco, Tribogna, Moconesi, Favale Di Malvaro, Cicagna, Lorsica, Rapallo,

in the province of Savona, the municipalities of Savona, Cairo Montenotte, Quiliano, Altare, Albisola Superiore, Celle Ligure, Stella, Pontinvrea, Varazze, Urbe, Sassello, Mioglia, Giusvalla, Dego, Vado Ligure, Albissola Marina, Carcare, Plodio, Cosseria, Piana Crixia, Mallare, Pallare, Roccavignale, Millesimo, Cengio,

Emilia-Romagna Region:

- in the province of Piacenza, the municipalities of Ottone (ovest fiume Trebbia), Zerba,

Lazio Region:

- the Area of the Municipality of Rome within the administrative boundaries of the Local Health Unit "ASL RM1",

Sardinia Region:

- in South Sardinia Province the Municipalities of Escolca, Esterzili, Genoni, Gesturi, Isili, Nuragus, Nurallao, Nurri, Sadali, Serri, Seui, Seulo, Villanova Tulo,
- in Nuoro Province the Municipalities of Atzara, Austis, Bari Sardo, Bitti, Bolotana, Bortigali a East della Strada Statale 131, Cardedu, Dorgali, Elini, Fonni, Gadoni, Gairo, Girasole, Ilbono, Jerzu, Lanusei, Lei, Loceri, Lodè, Lodine, Lotzorai, Lula, Macomer a East della Strada Statale 131, Meana Sardo, Oliena, Onani, Orune, Osidda, Osini, Ovodda, Silanus, Sorgono, Teti, Tiana, Torpè, Tortoli, Ulassai, Ussassai,
- in Oristano Province the Municipalities of Laconi, Nughedu Santa Vittoria, Sorradile,
- in Sassari Province the Municipalities of Alà dei Sardi, Anela, Benetutti, Bono, Bonorva East of SS 131, Bottidda, Buddusò, Budoni, Bultei, Burgos, Esporlatu, Illorai, Ittireddu, Mores a sud della Strada Statale 128bis – Strada Provinciale 63, Nughedu di San Nicolò, Nule, Olbia Isola Amministrativa (Berchiddeddu), Oschiri a sud della E 840, Ozieri a sud della Strada Provinciale 63 – Strada Provinciale 1 – Strada Statale 199, Padru, Pattada, San Teodoro.

10. Czechia

The following restricted zones II in the Czechia:

Liberecký kraj:

- v okrese Liberec katastrální území obcí Arnoltice u Bulovky, Hajniště pod Smrkem, Nové Město pod Smrkem, Dětrichovec, Bulovka, Horní Řasnice, Dolní Pertoltice, Krásný Les u Frýdlantu, Jindřichovice pod Smrkem, Horní Pertoltice, Dolní Řasnice, Raspenava, Dolní Oldřiš, Ludvíkov pod Smrkem, Lázně Libverda, Háj u Habartic, Habartice u Frýdlantu, Kunratice u Frýdlantu, Víška u Frýdlantu, Poustka u Frýdlantu, Višňová u Frýdlantu, Předláneč, Černousy, Boleslav, Ves, Andělka, Frýdlant, Srbská.

- v okrese Česká Lípa katastrální území obcí Bohatice u Zákup, Boreček, Božíkov, Brenná, Doksy u Máchova jezera, Hradčany nad Ploučnicí, Kuřívody, Mimoň, Pertoltice pod Ralskem, Plouznice pod Ralskem, Provodín, Svěbořice, Veselí nad Ploučnicí, Vranov pod Ralskem.

11. Greece

The following restricted zones II in Greece:

- in the regional unit of Serres:
 - part of the municipal departments of Kastanousi, Neo Petritsi, Vyroneia, and Promahonas Community Department (Sintiki Municipality),
- in the regional unit of Kilikis:
 - part of the municipal departments of Mouries, Agia Paraskevi, Stathmos Mourion (Kilikis Municipality).

PART III

1. Bulgaria

The following restricted zones III in Bulgaria:

the Pazardzhik region:

- in municipality of Pazardzhik the villages of Apriltsi, Sbor, Tsar Asen, Rosen, Ovtchepoltsi, Gelemenovo, Saraya, Yunatsite, Velitchkovo,
- in municipality of Panagyurishte the villages of Popintsi, Levski, Elshitsa,
- in municipality of Lesitchovo the villages of Pamidovo, Dinkata, Shtarkovo, Kalugeroovo,
- in municipality of Septemvri the village of Karabunar,
- in municipality of Streltcha the village of Svoboda.

2. Italy

The following restricted zones III in Italy:

Sardinia Region:

- in Nuoro Province the Municipalities of Aritzo, Arzana, Baunei, Belvi, Desulo, Gavoi, Mamoiada, Nuoro, Ollolai, Olzai, Oniferi, Orani, Orgosolo, Orotelli, Ottana, Sarule, Talana, Tonara, Triei, Urzulei, Villagrande Strisaili.

3. Latvia

The following restricted zones III in Latvia:

- Dienvidkurzemes novada Embūtes pagasta daļa uz ziemeļiem autoceļa P116, P106, autoceļa no apdzīvotas vietas Dinsdurbe, Kalvenes pagasta daļa uz austrumiem no ceļa pie Vārtājas upes līdz autoceļam A9, uz ziemeļiem no autoceļa A9, uz austrumiem no autoceļa V1200, Kazdangas pagasta daļa uz austrumiem no ceļa V1200, P115, P117, V1296,
- Kuldīgas novada Rudbāržu, Nīkrāces, Raņķu, Skrundas pagasts, Laidu pagasta daļa uz dienvidiem no autoceļa V1296, Skrundas pilsēta.

4. Lithuania

The following restricted zones III in Lithuania:

- Jurbarko rajono savivaldybė: Jurbarko miesto seniūnija, Girdžių, Jurbarkų Raudonės, Skirsnemunės, Veliuonos ir Šimkaičių seniūnijos,
- Molėtų rajono savivaldybė: Dubingių ir Giedraičių seniūnijos,
- Marijampolės savivaldybė: Sasnavos ir Šunskų seniūnijos,
- Šakių rajono savivaldybė: Barzdų, Gelgaudiškio, Griškabūdžio, Kidulių, Kudirkos Naumiesčio, Sintautų, Slavikų, Sudargo, Šakių, Plokščių ir Žvirgždaičių seniūnijos.
- Kazlų rūdų savivaldybė: Antanavos, Jankų ir Kazlų Rūdų seniūnijos: vakarinė dalis iki kelio 2602 ir 183,

- Kelmės rajono savivaldybė: Kelmės apylinkių, Kukečių, Šaukėnų ir Užvenčio seniūnijos,
- Vilkaviškio rajono savivaldybė: Gižų, Kybartų, Klausučių, Pilviškių, Šeimenos ir Vilkaviškio miesto seniūnijos.
- Širvintų rajono savivaldybė: Alionių ir Zibalų seniūnijos,
- Šiaulių rajono savivaldybė: Bubių, Kuršėnų kaimiškoji ir Kuršėnų miesto seniūnijos,
- Ukmergės rajono savivaldybė: Želvos seniūnija,
- Vilniaus rajono savivaldybė: Paberžės seniūnija.

5. Poland

The following restricted zones III in Poland:

w województwie warmińsko-mazurskim:

- gmina Rybno, część gminy Działdowo położona na północ od linii wyznaczonej przez drogę nr 538, część gminy Płońska położona na północ od linii wyznaczonej przez drogę łączącą miejscowości Burkat – Skurpie – Rutkowice – Płońska – Turza Mała – Koty, część gminy Lidzbark położona na północ od linii wyznaczonej przez drogę nr 544 biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 541 oraz na wschód od linii wyznaczonej przez drogę nr 541 biegnącą od północnej granicy gminy do skrzyżowania z drogą nr 544 w powiecie działdowskim,
- część gminy Grodziczno położona na wschód od linii wyznaczonej przez drogę nr 541 w powiecie nowomiejskim,
- część gminy Lubawa położona na południe od linii wyznaczonej przez drogę nr 537 biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 541, a następnie na wschód od linii wyznaczonej przez drogę nr 541 biegnącą od skrzyżowania z drogą nr 537 do południowej granicy gminy w powiecie iławskim,
- gmina Dąbrówno, część gminy Grunwald położona na południe od linii wyznaczonej przez drogę nr 537 biegnącej od zachodniej granicy gminy do miejscowości Stębark, a następnie na zachód od linii wyznaczonej przez drogę biegnącą od miejscowości Stębark do południowej granicy gminy i łączącej miejscowości Stębark – Łodwigowo w powiecie ostródzkim,

w województwie wielkopolskim:

- gminy Krzemieniewo, Lipno, Osieczna, Rydzyna, Świąciechowa, Włoszakowice w powiecie leszczyńskim,
- powiat miejski Leszno,
- gminy Kościan i miasto Kościan, Krzywiń, Śmigiel w powiecie kościańskim,
- część gminy Dolsk położona na zachód od linii wyznaczonej przez drogę nr 434 biegnącą od północnej granicy gminy do skrzyżowania z drogą nr 437, a następnie na zachód od drogi nr 437 biegnącej od skrzyżowania z drogą nr 434 do południowej granicy gminy, część gminy Śrem położona na zachód od linii wyznaczonej przez drogę nr 310 biegnącą od zachodniej granicy gminy do miejscowości Śrem, następnie na zachód od drogi nr 432 w miejscowości Śrem oraz na zachód od drogi nr 434 biegnącej od skrzyżowania z drogą nr 432 do południowej granicy gminy w powiecie śremskim,
- część gminy Gostyń położona na północ od linii wyznaczonej przez drogę nr 12 w powiecie gostyńskim,
- część gminy Przemęt położona na wschód od linii wyznaczonej przez drogę łączącą miejscowości Borek – Kluczewo – Sączkowo – Przemęt – Błotnica – Starkowo – Boszkowo – Letnisko w powiecie wolsztyńskim,

w województwie dolnośląskim:

- część gminy Lubin położona na południe od linii wyznaczonej przez drogę nr 335 biegnącą od zachodniej granicy gminy do granicy miasta Lubin oraz na zachód od linii wyznaczonej przez drogę nr 333 biegnącą od granicy miasta Lubin do południowej granicy gminy w powiecie lubińskim
- gminy Prusice, Żmigród, część gminy Oborniki Śląskie położona na północ od linii wyznaczonej przez drogę nr 340 w powiecie trzebnickim,

- część gminy Zagrodno położona na wschód od linii wyznaczonej przez drogę łączącą miejscowości Jadwisin – Modlikowice - Zagrodno oraz na wschód od linii wyznaczonej przez drogę nr 382 biegnącą od miejscowości Zagrodno do południowej granicy gminy, część gminy wiejskiej Złotoryja położona na wschód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy w miejscowości Nowa Wieś Złotoryjska do granicy miasta Złotoryja oraz na północ od linii wyznaczonej przez drogę nr 382 biegnącą od granicy miasta Złotoryja do wschodniej granicy gminy w powiecie złotoryjskim,
- część gminy Chocianów położona na południe od linii wyznaczonej przez drogę nr 335 biegnącą od wschodniej granicy gminy do miejscowości Żabice, a następnie na południe od linii wyznaczonej przez drogę łączącą miejscowości Żabice – Trzebnice – Chocianowice - Chocianów – Pasternik biegnącą do zachodniej granicy gminy w powiecie polkowickim,
- gminy Chojnów i miasto Chojnów, Krotoszyce, Miłkowice w powiecie legnickim,
- powiat miejski Legnica,
- część gminy Wołów położona na wschód od linii wyznaczonej przez linię kolejową biegnącą od północnej do południowej granicy gminy, część gminy Wińsko położona na południe od linii wyznaczonej przez drogę nr 36 biegnącą od północnej do zachodniej granicy gminy, część gminy Brzeg Dolny położona na wschód od linii wyznaczonej przez linię kolejową od północnej do południowej granicy gminy w powiecie wołowskim
- gminy Leśna, Lubań z miastem Lubań, Olszyna, Platerówka, Siekierczyn w powiecie lubańskim,
- część gminy Zgorzelec położona na wschód od linii wyznaczonej przez drogę łączącą miejscowości Dłużyna Górna – Przesieczany – Gronów – Sławnikowice – Wyręba, biegnąca od północnej do południowej granicy gminy w powiecie zgorzeleckim,
- część gminy Nowogrodziec położona na południe od linii wyznaczonej przez drogę nr 94 biegnącą od zachodniej granicy gminy do skrzyżowania z linią kolejową w miejscowości Zebrzydowa, następnie na zachód od linii wyznaczonej przez linię kolejową biegnącą na południe od miejscowości Zebrzydowa do wschodniej granicy gminy w powiecie bolesławieckim,
- gmina Gryfów Śląski w powiecie lwóweckim.

6. Romania

The following restricted zones III in Romania:

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

- Județul Sălaj,
- Județul Suceava
- Județul Vaslui,
- Județul Vrancea,
- Județul Teleorman,
- Județul Mehedinți,
- Județul Gorj,
- Județul Argeș,
- Județul Olt,
- Județul Dolj,
- Județul Arad,
- Județul Timiș,
- Județul Covasna,
- Județul Brașov,
- Județul Botoșani,
- Județul Vâlcea,
- Județul Iași,
- Județul Hunedoara,
- Județul Alba,
- Județul Sibiu,
- Județul Caraș-Severin,
- Județul Neamț,
- Județul Harghita,
- Județul Mureș,
- Județul Cluj,
- Județul Maramureș.

7. Slovakia

The following restricted zones III in Slovakia:

- In the district of Michalovce: Iňačovce, Čechov, Hažín, Hnojné, Lastomír, Lúčky, Michalovce, Palín, Pavlovce nad Uhom, Senné, Sliepkovce, Stretava, Stretavka, Vysoká nad Uhom, Zálužice, Závadka, Zemplínska Široká, Budkovce, Žbince, Jastrabie pri Michalovciach, Hatalov,
- In the district of Sobrance: Blatné Remety, Blatné Revištia, Blatná Polianka, Bunkovce, Fekišovce, Ostrov, Porostov, Svätuš, Veľké Revištia, Bežovce, Tašúľa, Kristy, Nižná Rybnica.

8. Germany

The following restricted zones III in Germany:

Bundesland Brandenburg:

- Kreisfreie Stadt Cottbus,
- Landkreis Spree-Neiße:
 - Gemeinde Kolkwitz mit den Gemarkungen Hänchen, Klein Gaglow, Kolkwitz, Gulben, Papitz, Glinzig, Limberg und Krieschow,
 - Gemeinde Drebkau mit den Gemarkungen Jehserig, Domsdorf, Drebkau, Laubst, Leuthen, Siewisch, Casel und der Gemarkung Schorbus bis zur L521,

- Gemeinde Neuhausen/Spree mit den Gemarkungen Groß Oßnig, Klein Döbbern, Groß Döbbern, Haasow, Kathlow, Frauendorf, Koppatz, Roggosen, Sergen, Komptendorf, Laubsdorf, Neuhausen, Drieschnitz, Kahsel und Bagenz,
- Gemeinde Spremberg mit den Gemarkungen Sellessen, Bühlow, Groß Buckow, Klein Buckow, Spremberg, Radeweise und Straußdorf.

9. **Greece**

The following restricted zones III in Greece:

- in the regional unit of Serres:
 - the municipal departments of Lithotopos and Limnochori (Irakleia Municipality),
the municipal departments of Kerkini, Livadia, Makrynitsa, Neochori Syntikis, Platanakion, Rodopolis, Ano Poroia, Kato Poroia, Akritochori and Mandraki (Sintiki Municipality),
 - in the regional unit of Kilis:
 - the municipal departments of Vathis and Kato Theodorakiou (Kilkis Municipality).'
-

COMMISSION IMPLEMENTING REGULATION (EU) 2023/948**of 12 May 2023****authorising the placing on the market of 6'-Sialyllactose sodium salt produced by derivative strains of *Escherichia coli* BL21(DE3) as a novel food and amending 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(1) thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods 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⁾ has established a Union list of novel foods.
- (3) Commission Implementing Regulation (EU) 2021/82 ⁽³⁾ authorised the placing on the Union market of 6'-Sialyllactose sodium salt obtained by microbial fermentation using the genetically modified *Escherichia coli* strain K12 DH1 as a novel food under Regulation (EU) 2015/2283.
- (4) On 15 May 2020, the company Chr. Hansen A/S ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place 6'-Sialyllactose ('6'-SL') sodium salt, obtained by microbial fermentation using two genetically modified strains (a production strain and an optional degradation strain) derived from the host strain *Escherichia coli* BL21(DE3), on the Union market as a novel food. The applicant requested for 6'-SL sodium salt so produced to be used in infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ⁽⁴⁾, processed cereal-based food for infants and young children and baby food for infants and young children as defined in Regulation

⁽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⁾ Commission Implementing Regulation (EU) 2021/82 of 27 January 2021 authorising the placing on the market of 6'-sialyllactose sodium salt 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 (OJ L 29, 28.1.2021, p. 16).

⁽⁴⁾ 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).

(EU) No 609/2013, foods for infants and young children for special medical purposes as defined in Regulation (EU) No 609/2013, foods for special medical purposes as defined in Regulation (EU) No 609/2013 excluding foods for infants and young children, in milk-based drinks and similar products intended for young children, and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ⁽⁵⁾ intended for the general population. Subsequently, on 9 December 2022, the applicant modified the initial request in the application on the use of 6'-SL sodium salt produced with the derivative strains of *Escherichia coli* BL21(DE3) in food supplements to exclude infants and young children. The applicant also proposed that food supplements containing 6'-SL sodium salt produced with the derivative strains of *Escherichia coli* BL21(DE3) should not be consumed if other foods with added 6'-SL sodium salt are consumed the same day.

- (5) On 15 May 2020, the applicant also made a request to the Commission for the protection of proprietary scientific studies and data, namely, mass spectrometry ('MS'), nuclear magnetic resonance ('NMR') and a high-performance anion-exchange chromatography with pulsed amperometric detection ('HPAEC-PAD') method validation and the results for the determination of the identity of 6'-SL and of the carbohydrate by-products present in the novel food ⁽⁶⁾; a description ⁽⁷⁾ and certificates of deposition ⁽⁸⁾ of the genetically modified 6'-SL sodium salt production and optional degradation strains; real time quantitative polymerase chain reaction ('qPCR') system and method validation reports for the genetically modified 6'-SL sodium salt production and optional degradation strains ⁽⁹⁾; a bacterial reverse mutation test with 6'-SL sodium salt ⁽¹⁰⁾; an *in vitro* mammalian cell micronucleus test with 6'-SL sodium salt ⁽¹¹⁾; a 7-day dose range finding oral toxicity study in rats with 6'-SL sodium salt ⁽¹²⁾; and, a 90-day oral toxicity study in rats with 6'-SL sodium salt ⁽¹³⁾, submitted in support of the application.
- (6) In accordance with Article 10(3) of Regulation (EU) 2015/2283, on 11 December 2020, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of 6'-SL sodium salt obtained by microbial fermentation using two genetically modified strains (a production strain and an optional degradation strain) derived from the host strain *Escherichia coli* BL21(DE3), as a novel food.
- (7) On 26 October 2022, the Authority adopted its scientific opinion on the 'Safety of 6'-sialyllactose sodium salt produced by derivative strains of *Escherichia coli* BL21 (DE3) as a novel food pursuant to Regulation (EU) 2015/2283' ⁽¹⁴⁾ in accordance with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (8) In its scientific opinion, the Authority concluded that 6'-SL sodium salt is safe under the proposed conditions of use and for the proposed target populations. Therefore, that scientific opinion gives sufficient grounds to establish that 6'-SL sodium salt produced with the derivative strains of *Escherichia coli* BL21 (DE3), when used in infant formula and follow-on formula as defined in Regulation (EU) No 609/2013, processed cereal-based food for infants and young children and baby food for infants and young children as defined in Regulation (EU) No 609/2013, foods for infants and young children for special medical purposes as defined in Regulation (EU) No 609/2013, foods for special medical purposes as defined in Regulation (EU) No 609/2013 excluding foods for infants and young

⁽⁵⁾ 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).

⁽⁶⁾ Chr. Hansen 2018 and 2021 (unpublished).

⁽⁷⁾ Chr. Hansen 2021 (unpublished).

⁽⁸⁾ Chr. Hansen 2020 and 2021 (unpublished).

⁽⁹⁾ Chr. Hansen 2014 and 2021 (unpublished).

⁽¹⁰⁾ Chr. Hansen 2018 (unpublished) and Parschat K., Oehme A., Leuschner J., Jennewein S., and Parkot J. 2020. A safety evaluation of mixed human milk oligosaccharides in rats. Food and Chemical Toxicology, 136, 111118.

⁽¹¹⁾ Chr. Hansen 2018 (unpublished) and Parschat K., Oehme A., Leuschner J., Jennewein S., and Parkot J. 2020. A safety evaluation of mixed human milk oligosaccharides in rats. Food and Chemical Toxicology, 136, 111118.

⁽¹²⁾ Chr. Hansen 2018 and 2021 (unpublished) and Parschat K., Oehme A., Leuschner J., Jennewein S., and Parkot J. 2020. A safety evaluation of mixed human milk oligosaccharides in rats. Food and Chemical Toxicology, 136, 111118.

⁽¹³⁾ Chr. Hansen 2019 and 2021 (unpublished) and Parschat K., Oehme A., Leuschner J., Jennewein S., and Parkot J. 2020. A safety evaluation of mixed human milk oligosaccharides in rats. Food and Chemical Toxicology, 136, 111118.

⁽¹⁴⁾ EFSA Journal 2022;20(12):7645.

children, in milk-based drinks and similar products intended for young children, and in food supplements as defined in Directive 2002/46/EC, complies with the authorisation requirements of Article 12(1) of Regulation (EU) 2015/2283.

- (9) In its scientific opinion, the Authority noted that its conclusion on the safety of the novel food was based on scientific studies and data from the mass spectrometry ('MS'), nuclear magnetic resonance ('NMR') and a high-performance anion-exchange chromatography with pulsed amperometric detection ('HPAEC-PAD') method validation and the results for the determination of the identity of 6'-SL and of the carbohydrate by-products present in the novel food; the description and certificates of deposition of the genetically modified 6'-SL sodium salt production and optional degradation strains; the real time quantitative polymerase chain reaction ('qPCR') system and method validation reports for the genetically modified 6'-SL sodium salt production and optional degradation strains; the bacterial reverse mutation test with 6'-SL sodium salt; the *in vitro* mammalian cell micronucleus test with 6'-SL sodium salt; the 7-day dose range finding oral toxicity study in rats with 6'-SL sodium salt; and, the 90-day oral toxicity study in rats with 6'-SL sodium salt, contained in the applicant's file, without which it could not have assessed the novel food and reached its conclusion.
- (10) The Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over those scientific studies and data, and to clarify their claim to an exclusive right of reference to them in accordance with Article 26(2)(b) of Regulation (EU) 2015/2283.
- (11) The applicant declared that they held proprietary and exclusive rights of reference to the scientific studies and data submitted in support of the application, namely, mass spectrometry ('MS'), nuclear magnetic resonance ('NMR') and a high-performance anion-exchange chromatography with pulsed amperometric detection ('HPAEC-PAD') method validation and the results for the determination of the identity of 6'-SL and of the carbohydrate by-products present in the novel food; the description and certificates of deposition of the genetically modified 6'-SL sodium salt production and optional degradation strains; the real time quantitative polymerase chain reaction ('qPCR') system and method validation reports for the genetically modified 6'-SL sodium salt production and optional degradation strains; the bacterial reverse mutation test with 6'-SL sodium salt; the *in vitro* mammalian cell micronucleus test with 6'-SL sodium salt; the 7-day dose range finding oral toxicity study in rats with 6'-SL sodium salt; and, the 90-day oral toxicity study in rats with 6'-SL sodium salt, under national law at the time they submitted the application and that third parties cannot lawfully access, use or refer to those data and studies.
- (12) 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. Therefore, the scientific studies and data submitted in support of the application, namely, mass spectrometry ('MS'), nuclear magnetic resonance ('NMR') and a high-performance anion-exchange chromatography with pulsed amperometric detection ('HPAEC-PAD') method validation and the results for the determination of the identity of 6'-SL and of the carbohydrate by-products present in the novel food; the description and certificates of deposition of the genetically modified 6'-SL sodium salt production and optional degradation strains; the real time quantitative polymerase chain reaction ('qPCR') system and method validation reports for the genetically modified 6'-SL sodium salt production and optional degradation strains; the bacterial reverse mutation test with 6'-SL sodium salt; the *in vitro* mammalian cell micronucleus test with 6'-SL sodium salt; the 7-day dose range finding oral toxicity study in rats with 6'-SL sodium salt; and, the 90-day oral toxicity study in rats with 6'-SL sodium salt, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place 6'-SL sodium salt produced with derivative strains of *Escherichia coli* BL21(DE3) on the market within the Union during a period of five years from the entry into force of this Regulation.

- (13) However, restricting the authorisation of 6'-SL sodium salt produced with derivative strains of *Escherichia coli* BL21(DE3) and the reference to the scientific studies and data contained in the applicant's file for the sole use by them does not prevent subsequent 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 such an authorisation.
- (14) In line with the conditions of use of food supplements containing 6'-SL sodium salt produced with derivative strains of *Escherichia coli* BL21(DE3), as proposed by the applicant, it is necessary to inform consumers by appropriate labelling that food supplements containing 6'-SL sodium salt should not be consumed by infants and children under 3 years of age and should not be used if other foods with added 6'-SL sodium salt are consumed the same day.
- (15) It is appropriate that the inclusion of 6'-SL sodium salt produced with derivative strains of *Escherichia coli* BL21(DE3) as a novel food in the Union list of novel foods contains also the required conditions of use, specifications and other information related to its authorisation, as referred to in Article 9(3) of Regulation (EU) 2015/2283.
- (16) 6'-SL sodium salt produced with derivative strains of *Escherichia coli* BL21(DE3) should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (17) 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. 6'-Sialyllactose sodium salt produced with derivative strains of *Escherichia coli* BL21(DE3) is authorised to be placed on the market within the Union.

6'-Sialyllactose sodium salt produced with derivative strains of *Escherichia coli* BL21(DE3) shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

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

Article 2

Only the company Chr. Hansen A/S ⁽¹⁵⁾ is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of five years from 4 June 2023, unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of Chr. Hansen A/S.

Article 3

The scientific data contained in the application file and fulfilling the conditions 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 Chr. Hansen A/S.

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*.

⁽¹⁵⁾ Address: Bøge Allé 10-12, 2970 Hørsholm, Denmark.

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

Done at Brussels, 12 May 2023.

For the Commission
The President
Ursula VON DER LEYEN

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

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

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
'6'-Sialyllactose ('6'-SL) sodium salt (produced by derivative strains of <i>E. coli</i> BL21(DE3))	<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 '6'-Sialyllactose sodium salt'. The labelling of food supplements containing 6'-Sialyllactose (6'-SL) sodium salt shall bear a statement that (a) they should not be consumed by children under 3 years of age; (b) they should not be consumed if other foods containing added 6'-sialyllactose sodium salt are consumed the same day.		Authorised on 4 June 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: "Chr. Hansen A/S", Bøge Allé 10-12, 2970 Hoersholm, Denmark. During the period of data protection, the novel food 6'-Sialyllactose sodium salt is authorised for placing on the market within the Union only by Chr. Hansen 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 "Chr. Hansen A/S". End date of the data protection: 4 June 2028.'
	Infant formula as defined under Regulation (EU) No 609/2013	0,70 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Follow-on formula as defined under Regulation (EU) No 609/2013	0,70 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Processed cereal-based foods for infants and young children and baby foods for infants and young children as defined under Regulation (EU) No 609/2013	0,70 g/L or 0,70 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Milk based drinks and similar products intended for young children	0,70 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Foods for special medical purposes for infants and young children as defined under Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the infants and young children for whom the products are intended but in any case not higher than 0,70 g/L or 0,70 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.			

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
	Foods for special medical purposes as defined under Regulation (EU) No 609/2013 excluding foods for infants and young children	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
	Food Supplements as defined in Directive 2002/46/EC, for the general population, excluding infants and young children	1,8 g/day			

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

Authorised novel food	Specification
‘6’-Sialyllactose (‘6’-SL’) sodium salt (produced by derivative strains of <i>E. coli</i> BL21(DE3))	Description: 6’-Sialyllactose (6’-SL) sodium salt is a purified, white to off-white powder or agglomerate produced by a microbial process and contains limited levels of lactose, 6’-sialyl-lactulose, and sialic acid. Definition: Chemical name: N-Acetyl-α-D-neuraminy-(2 → 6)-β-D-galactopyranosyl-(1 → 4)-D-glucose, sodium salt Chemical formula: C₂₃H₃₈NO₁₉Na Molecular mass: 655,53 Da CAS No: 157574-76-0 Source: Two genetically modified strains (a production strain and an optional degradation strain) of <i>Escherichia coli</i> BL21(DE3) Characteristics/Composition: 6’-Sialyllactose sodium salt (% of dry matter): ≥ 90,0 % (w/w) 6’-Sialyl-lactulose (% of dry matter): ≤ 3,0 % (w/w) D-Lactose (% of dry matter): ≤ 5,0 % (w/w) Sialic acid (% of dry matter): ≤ 2,0 % (w/w) N-acetyl-D-glucosamine (% of dry matter): ≤ 3,0 % (w/w) Sum of other carbohydrates (% of dry matter)^a: ≤ 5,0 % (w/w) Moisture: ≤ 9,0 % (w/w) Ash: ≤ 8,5 % (w/w) Residual protein: ≤ 0,01 % (w/w)

Authorised novel food	Specification
	Sodium: ≤ 4,2 % (w/w) Contaminants: Arsenic: ≤ 0,2 (mg/kg) Aflatoxin M1: ≤ 0,025 (µg/kg) Microbiological criteria: Standard plate count: ≤ 1 000 CFU/g Enterobacteriaceae: ≤ 10 CFU/g <i>Salmonella</i> spp.: Absence in 25 g Yeast and mould: ≤ 100 CFU/g <i>Cronobacter</i> spp.: Absence in 10 g Residual endotoxins: ≤ 10 EU/mg ^a Sum of other carbohydrates = 100 (% (w/w) of dry matter) – 6'-Sialyllactose sodium salt (% (w/w) of dry matter) – quantified carbohydrates (% (w/w) of dry matter) – Ash (% (w/w) of dry matter); CFU: Colony Forming Units; EU: Endotoxin Units'

COMMISSION IMPLEMENTING REGULATION (EU) 2023/949**of 12 May 2023****authorising the placing on the market of iron milk caseinate as a novel food and amending
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(1) thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods 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⁾ has established a Union list of novel foods.
- (3) On 16 June 2020, the company Société des Produits Nestlé S.A. ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place iron milk proteinate, a complex of iron with casein obtained from bovine milk stabilised by phosphate, on the Union market as a novel food. The applicant requested for iron milk proteinate to be used as a source of iron in milk and dairy powder products, soft-drinks marketed in relation to physical exercise, powder cocoa beverage preparations, powder or liquid malt-based coffee substitutes, cereal bars, noodles other than glass noodles, stock cubes or granulates (bouillon bases), single meal replacements for weight control, total diet replacement for weight control as defined in Article 2 of Regulation (EU) No 609/2013 of the European Parliament and of the Council ⁽³⁾, foods for special medical purposes as defined in Article 2 of Regulation (EU) No 609/2013 excluding foods for infants and young children, and in food supplements as defined in Article 2 of Directive 2002/46/EC of the European Parliament and of the Council ⁽⁴⁾ intended for the general population excluding infants and young children. The proposed use levels in food supplements indicated in the application were up to 700 mg/day corresponding to up to 14 mg iron per day. The applicant also proposed that food supplements containing iron milk proteinate should not be used if other foods with added iron milk proteinate are consumed the same day.

⁽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 (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).

⁽⁴⁾ 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).

- (4) On 16 June 2020, the applicant also made a request to the Commission for the protection of proprietary data for an *in vitro* study on the digestibility of iron milk proteinate under simulated gastric conditions ⁽⁵⁾; the certificates of the compositional analyses of the production batches of iron proteinate ⁽⁶⁾; an *in vitro* study on the impact of ascorbic acid on the iron bioavailability of iron milk proteinate ⁽⁷⁾; a randomised human study with a cross over design on the bioavailability of iron from whole milk containing iron milk proteinate as compared to ferrous sulfate ⁽⁸⁾; an acute oral toxicity study in rodents ⁽⁹⁾; a report on the intake assessment of iron milk proteinate resulting from the proposed uses ⁽¹⁰⁾; a literature search study strategy and results conducted by the applicant ⁽¹¹⁾; and an iron bioaccessibility study from iron casein complexes produced with milk ⁽¹²⁾, submitted in support of the application.
- (5) On 9 October 2020, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of iron milk proteinate as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283, and an assessment on the bioavailability of iron in the context of Directive 2002/46/EC.
- (6) On 4 August 2022, the Authority adopted its scientific opinion on the 'Safety of iron milk proteinate as a Novel food pursuant to Regulation (EU) 2015/2283 and bioavailability of iron from this source in the context of Directive 2002/46/EC' ⁽¹³⁾ in accordance with Article 11 of Regulation (EU) 2015/2283.
- (7) The Commission considered that the term 'iron milk proteinate' used to describe the identity of the novel food is rather wide as it would encompass any bovine milk protein which could be used whereas the novel food is made using specifically casein. Consequently the term 'iron milk caseinate' would be a more accurate term to describe it. The Commission therefore requested the applicant to accept the designation 'iron milk caseinate' for the novel food instead of 'iron milk proteinate'. In response to the Commission's request, the applicant agreed to the designation of the novel food as 'iron milk caseinate.'
- (8) In its scientific opinion, the Authority concluded that iron milk caseinate is safe under the proposed conditions of use for the proposed target populations, and that it is a source from which iron is bioavailable. In that opinion however, the Authority noted that, since it had not set a tolerable Upper intake Limit ('UL'), the intake of iron from some foods and food supplements containing the novel food could exceed population guidance levels that have been set by Member States, and that the combined intake of iron from foods and food supplements containing the novel food and the background diet would be high. In light of the Authority's considerations and of the pivotal role of iron in human physiology, growth and development, particularly in the early stages of life, and the rather fine line between beneficial and adverse health effects of iron depending on intakes, the Commission considers that a precautionary approach is needed.
- (9) The Commission therefore requested the applicant to reconsider the levels of iron milk caseinate proposed in their application for some of the foods most likely to contribute the most to the iron daily intake, namely, milk and dairy products (levels up to 950 mg/100 gr or ml that would correspond to up to 19 mg iron/100 gr or ml of food), cocoa beverage preparations (levels up to 800 mg/100 gr or ml that would correspond to up to 16 mg iron/100 gr or ml of food), cereal bars (levels up to 700 mg/100 gr or ml that would correspond to up to 14 mg iron/100gr or ml of food), and for food supplements (levels up to 700 mg/day that would correspond to up to 14 mg iron per day). In response to the Commission's request, the applicant modified its request and proposed the use of iron milk caseinate in milk and dairy products at levels not exceeding 500 mg/100 gr or ml of food corresponding to up to 10 mg of iron/100 gr or ml of food, in cocoa beverage preparations at levels not exceeding 400 mg/100 gr or ml of

⁽⁵⁾ Société des Produits Nestlé S.A. (2020, unpublished).

⁽⁶⁾ Société des Produits Nestlé S.A. (2020, unpublished).

⁽⁷⁾ Sabatier M, Rytz A, Husny J, Dubascoux S, Nicolas M, Dave A, Singh H, Bodis M and Glahn RP, 2020 Impact of ascorbic acid on the *in vitro* iron bioavailability of a casein-based ironfortificant. *Nutrients*, 12, 2776.<https://doi.org/10.3390/nu12092776>

⁽⁸⁾ Henare SJ, Singh NN, Ellis AM, Moughan PJ, Thompson AK and Walczyk T, 2019. Iron bioavailability of a casein-based iron fortificant compared with that of ferrous sulfate in whole milk: a randomized trial with a crossover design in adult women. *The American Journal of Clinical Nutrition*, 110, 1362–1369.

⁽⁹⁾ Société des Produits Nestlé S.A. (2019, unpublished).

⁽¹⁰⁾ Société des Produits Nestlé S.A. (2020, unpublished).

⁽¹¹⁾ Société des Produits Nestlé S.A. (2020, unpublished).

⁽¹²⁾ Société des Produits Nestlé S.A. (2021, unpublished).

⁽¹³⁾ *EFSA Journal* 2022;20(9):7549.

food corresponding to up to 8 mg of iron/100 gr or ml of food, and in cereal bars at levels not exceeding 350 mg/100 gr or ml of food correspond to up to 7 mg of iron/100 gr or ml of food. The applicant also modified its request as regards the use of iron milk caseinate in food supplements, and proposed its use at levels not exceeding 700 mg/day corresponding to up to 14 mg iron/day in food supplements intended for the adult population, and at levels not exceeding 350 mg/day corresponding to up to 7 mg iron/day in food supplements intended for children and adolescents under 18 years of age, excluding infants and young children. In addition, the applicant indicated that it will adjust the levels of iron milk caseinate in foods and in food supplements placed on the market of a Member State to limit the corresponding maximum levels of iron to the guidance values set by that Member State for each age group of the population. The Commission considers that the revised uses would fulfil the conditions for the placing on the market of iron milk caseinate in accordance with Article 12(1) of Regulation (EU) 2015/2283.

- (10) Therefore that scientific opinion gives sufficient grounds to establish that iron milk caseinate, when used as a source of iron in milk and dairy powder products, soft-drinks marketed in relation to physical exercise, powder cocoa beverage preparations, powder or liquid malt-based coffee substitutes, cereal bars, noodles other than glass noodles, stock cubes or granulates (bouillon bases), single meal replacements for weight control, total diet replacement for weight control as defined in Article 2 of Regulation (EU) No 609/2013, foods for special medical purposes as defined in Article 2 of Regulation (EU) No 609/2013 excluding foods for infants and young children, and in food supplements as defined in Article 2 of Directive 2002/46/EC at levels not exceeding 700 mg/day (14 mg iron/day) in food supplements intended for the adult population, and at levels not exceeding 350 mg/day (7 mg iron/day) in food supplements intended for children and adolescents under 18 years of age, excluding infants and young children, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.
- (11) In its scientific opinion, the Authority noted that its conclusion on the safety of the novel food was based on scientific data from the *in vitro* study on the digestibility of iron milk caseinate under simulated gastric conditions; the certificates of the compositional analyses of the production batches of iron milk caseinate; the *in vitro* study on the impact of ascorbic acid on the iron bioavailability of iron milk caseinate; and, the randomised human study with a cross over design on the bioavailability of iron from whole milk containing iron milk caseinate as compared to ferrous sulfate, contained in the applicant's file, without which it could not have assessed the novel food and reached its conclusion.
- (12) The Commission requested the applicant to further clarify the justification provided with regard to its proprietary claim over those scientific studies and data, and to clarify its claim to an exclusive right of reference to them in accordance with Article 26(2)(b) of Regulation (EU) 2015/2283.
- (13) The applicant declared that it held proprietary and exclusive rights of reference to the scientific studies and data submitted in support of the application, namely, the *in vitro* study on the digestibility of iron milk caseinate under simulated gastric conditions; the certificates of the compositional analyses of the production batches of iron milk caseinate; the *in vitro* study on the impact of ascorbic acid on the iron bioavailability of iron milk caseinate; and, the randomised human study with a cross over design on the bioavailability of iron from whole milk containing iron milk caseinate as compared to ferrous sulfate, and that third parties cannot lawfully access, use or refer to those data.
- (14) 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. Therefore, the scientific studies and data from the *in vitro* study on the digestibility of iron milk caseinate under simulated gastric conditions; the certificates of the compositional analyses of the production batches of iron milk caseinate; the *in vitro* study on the impact of ascorbic acid on the iron bioavailability of iron milk caseinate; and the randomised human study with a cross over design on the bioavailability of iron from whole milk containing iron milk caseinate as compared to ferrous sulfate, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place iron milk caseinate on the market within the Union during a period of five years from the entry into force of this Regulation.

- (15) However, restricting the authorisation of iron milk caseinate and the reference to the scientific data contained in the applicant's file for its sole use by them does not prevent subsequent 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 such an authorisation.
- (16) In line with the conditions of use of food supplements containing iron milk caseinate as proposed by the applicant, and the Authority's opinion as regards the rather high intake of iron from the combined intake of iron from foods and food supplements containing the novel food and the background diet, it is necessary to inform consumers by appropriate labelling that food supplements containing iron milk caseinate should not be consumed by infants and children under 3 years of age and should not be consumed if other foods with added iron milk caseinate or other foods with added iron containing compounds are consumed the same day.
- (17) As the source of the novel food comes from bovine milk, which is listed in Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council ⁽¹⁴⁾ as one of a number of substances or products which cause allergies or intolerances, foods containing iron milk caseinate, should be appropriately labelled following the requirements of Article 21 of that Regulation.
- (18) Iron milk caseinate should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (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) Iron milk caseinate is authorised to be placed on the market within the Union.

Iron milk caseinate shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

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

Article 2

Only the company 'Société des Produits Nestlé S.A.' ⁽¹⁵⁾ is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of five years from 4 June 2023, unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of 'Société des Produits Nestlé S.A.'.

Article 3

The scientific data contained in the application file and fulfilling the conditions 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 'Société des Produits Nestlé S.A.'.

⁽¹⁴⁾ 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).

⁽¹⁵⁾ Address: Avenue Nestlé 55, 1800 Vevey, Switzerland.

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, 12 May 2023.

For the Commission
The President
Ursula VON DER LEYEN

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

(1) in Table 1 (Authorised novel foods), the following entry is inserted:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
'Iron milk caseinate	Specified food category	Maximum levels	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'iron milk caseinate'. The labelling of food supplements containing iron milk caseinate shall bear a statement that (a) they should not be consumed by children under 3 years of age; (b) they should not be consumed if other foods containing iron milk caseinate and/or if other foods with added iron are consumed the same day.		Authorised on 4 June 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: "Société des Produits Nestlé S.A.", Avenue Nestlé 55, 1800 Vevey, Switzerland. During the period of data protection, the iron milk caseinate is authorised for placing on the market within the Union only by "Société des Produits Nestlé S.A." 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 "Société des Produits Nestlé S.A.". End date of the data protection: 4 June 2028.'
	Milk and dairy powder products	500 mg/100 g ($\leq$ 10 mg Fe/100 g)			
	Soft-drinks marketed in relation to physical exercise	85 mg/100 g ($\leq$ 1,7 mg Fe/100 g)			
	Powder cocoa beverage preparations	400 mg/100 g ($\leq$ 8 mg Fe/100 g)			
	Powder or liquid malt-based coffee substitutes	1 050 mg/100 g ($\leq$ 21 mg Fe/100 g)			
	Cereal bars	350 mg/100 g ($\leq$ 7 mg Fe/100 g)			
	Noodles other than glass noodles	75 mg/100 g ($\leq$ 1,5 mg Fe/100 g)			
	Stock cubes or granulates (bouillon base)	4 750 mg/100 g ($\leq$ 95 mg Fe/100 g)			
	Single meal replacements for weight control	120 mg/100 g ($\leq$ 2,4 mg Fe/100 g)			
	Total diet replacement for weight control as defined under Regulation (EU) No 609/2013	235 mg/meal ($\leq$ 4,7 mg Fe/meal) or 700 mg/day ($\leq$ 14,0 mg Fe/day)			
	Foods for special medical purposes as defined under Regulation (EU) No 609/2013 excluding foods for infants and young children	In accordance with the particular nutritional requirements of the persons for whom the products are intended			

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
	Food supplements as defined in Directive 2002/46/EC, for the adult population	700 mg/day ($\leq$ 14 mg Fe/day)			
	Food supplements as defined in Directive 2002/46/EC, for children and adolescents under 18 years of age, excluding infants and young children	350 mg/day ($\leq$ 7 mg Fe/day)			

(2) in Table 2 (Specifications), the following entry is inserted:

Authorised novel food	Specification
Iron milk caseinate	Description: Iron milk caseinate is an iron-casein-phosphate complex in the form of a creamy or beige powder produced by the dissolution of ferric iron salts (ferric sulfate or ferric chloride) in a casein solution obtained from bovine milk in the presence of potassium orthophosphate following a series of steps involving pasteurisation, concentration, and drying. Characteristics/Composition: Protein (%): 50,0 – 65,0 Ash (%): 20,0 – 40,0 Moisture (%): < 8,0 Fat (%): < 1,0 Iron (%): 2,0 – 4,0 Potassium (%): 5,0 – 15,0 Phosphorus (%): 2,0 – 6,0 Sodium (%): < 4,0 Heavy metals: Lead: < 0,5 mg/kg Arsenic: $\leq$ 1,0 mg/kg Cadmium: < 0,5 mg/kg Mercury: < 0,1 mg/kg Mycotoxins: Aflatoxin M1: $\leq$ 0,02 mg/kg Microbiological criteria: Aerobic plate count: $\leq$ 1 000 CFU/g Coliforms: $\leq$ 10 CFU/g <i>Salmonella</i> spp.: Absence in 25 g Yeast and mould: $\leq$ 10 CFU/g

Authorised novel food	Specification
	<i>Escherichia coli</i> : ≤ 10 CFU/g <i>Staphylococcus aureus</i> : Absence in 1 g CFU: Colony Forming Units'

COMMISSION IMPLEMENTING REGULATION (EU) 2023/950**of 12 May 2023****amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food 2'-Fucosyllactose****(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 of novel foods 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⁾ has established a Union list of novel foods.
- (3) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 includes 2'-Fucosyllactose of synthetic and microbial source as an authorised novel food.
- (4) Commission Implementing Decision (EU) 2016/376 ⁽³⁾ authorised, in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽⁴⁾, the placing on the market of synthetic 2'-Fucosyllactose as a novel food ingredient.
- (5) On 23 June 2016, the company Glycom A/S ('the applicant'), notified the Commission, pursuant to Article 5 of Regulation (EC) No 258/97, of its intention to place on the market 2'-Fucosyllactose produced by bacterial fermentation with *Escherichia coli* strain K-12. 2'-Fucosyllactose of microbial origin produced with *Escherichia coli* strain K-12 was included in the Union list of novel foods on the basis of that notification when the Union list was established.
- (6) Commission Implementing Decision (EU) 2017/2201 ⁽⁵⁾ authorised, in accordance with Regulation (EC) No 258/97, the placing on the market of 2'-Fucosyllactose produced with *Escherichia coli* strain BL21 as a novel food ingredient.

⁽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⁾ Commission Implementing Decision (EU) 2016/376 of 11 March 2016 authorising the placing on the market of 2'-O-fucosyllactose as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 70, 16.3.2016, p. 27).

⁽⁴⁾ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel food and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

⁽⁵⁾ Commission Implementing Decision (EU) 2017/2201 of 27 November 2017 authorising the placing on the market of 2'-fucosyllactose produced with *Escherichia coli* strain BL21 as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 313, 29.11.2017, p. 5).

- (7) On 13 October 2022, the applicant submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for a change in the conditions of use of 2'-Fucosyllactose. The applicant requested the removal of the obligatory condition that, when 2'-Fucosyllactose is used in combination with Lacto-N-neotetraose in infant formula and follow-on formula as defined in Article 2 of Regulation (EU) No 609/2013 of the European Parliament and of the Council ⁽⁶⁾, and in milk-based drinks and similar products intended for young children, at the currently authorised levels of up to 1,2 g/l, they should be used only at a 2:1 ratio (two parts 2'-Fucosyllactose to one part Lacto-N-neotetraose).
- (8) In the application for the proposed modification in the conditions of use of 2'-Fucosyllactose, the applicant considered that the 2:1 obligatory ratio of 2'-Fucosyllactose to Lacto-N-neotetraose when they are used together in infant formula and follow on formula as defined in Article 2 of Regulation (EU) No 609/2013, and in milk-based drinks and similar products intended for young children, unnecessarily limits the ability of food business operators to place on the market these foods with different ratios of those two oligosaccharides
- (9) The Commission considers that the requested update of the Union list of novel foods is not liable to have an effect on human health and that a safety evaluation by the European Food Safety Authority ('the Authority') in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. In this regard the Authority in the recent opinion ⁽⁷⁾, concluded that the use of 2'-Fucosyllactose alone or Lacto-N-neotetraose alone in food supplements as defined in Article 2 of Directive 2002/46/EC of the European Parliament and of the Council ⁽⁸⁾ at the currently maximum authorised levels of up to 1,2 g/day or up to 0,6 mg/day respectively, is safe and the resulting intakes of each of these oligosaccharides from these uses would be lower than the intakes of Lacto-N-neotetraose or 2'-Fucosyllactose from human milk which naturally contains them.
- (10) The information provided in the application and the Authority's opinion give sufficient grounds to establish that the changes in the conditions of use of the novel food 2'-Fucosyllactose are in accordance with the conditions of Article 12 of Regulation (EU) 2015/2283 and should be approved.
- (11) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (12) 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

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

Article 2

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

⁽⁶⁾ 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).

⁽⁷⁾ EFSA Journal 2022;20(5):7257.

⁽⁸⁾ 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).

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

Done at Brussels, 12 May 2023.

For the Commission
The President
Ursula VON DER LEYEN

In Table 1 (Authorised novel foods) of the Annex to Implementing Regulation (EU) 2017/2470, the entry for 2'-Fucosyllactose is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
2'-Fucosyllactose	<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 "2'-fucosyllactose". - The labelling of food supplements containing 2'-fucosyllactose shall bear a statement that the supplements should not be used if other foods with added 2'-fucosyllactose are consumed the same day. - The labelling of food supplements containing 2'-fucosyllactose intended for young children shall bear a statement that the supplements should not be used if breast milk or other foods with added 2'-fucosyllactose are consumed the same day.'	
	Unflavoured pasteurised and sterilised (including UHT) milk-based products	1,2 g/l		
	Unflavoured fermented milk-based products	1,2 g/l for beverages		
		19,2 g/kg for products other than beverages		
	Flavoured fermented milk-based products including heat-treated products	1,2 g/l for beverages		
		19,2 g/kg for products other than beverages		
	Dairy analogues, including beverage whiteners	1,2 g/l for beverages		
		12 g/kg for products other than beverages		
		400 g/kg for whitener		
	Cereal bars	12 g/kg		
	Table-top sweeteners	200 g/kg		
	Infant formula as defined under Regulation (EU) No 609/2013	1,2 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	Follow-on formula as defined under Regulation (EU) No 609/2013	1,2 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	Processed cereal-based foods and baby foods for infants and young children as defined under Regulation (EU) No 609/2013	12 g/kg for products other than beverages		
		1,2 g/l for liquid food ready for use, marketed as such or reconstituted as instructed by the manufacturer		

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Milk based drinks and similar products intended for young children	1,2 g/l for milk-based drinks and similar products in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	Foods for special medical purposes as defined under Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended		
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	4,8 g/l for drinks		
		40 g/kg for bars		
	Bread and pasta products bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Implementing Regulation (EU) No 828/2014	60 g/kg		
	Flavoured drinks	1,2 g/l		
	Coffee, tea (excluding black tea), herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products	9,6 g/l – the maximum level refers to the products ready to use		
	Food supplements as defined in Directive 2002/46/EC, for the general population, excluding infants	3,0 g/day for general population		
		1,2 g/day for young children		

COMMISSION IMPLEMENTING REGULATION (EU) 2023/951**of 12 May 2023****amending Implementing Regulation (EU) 2017/2470 as regards the specifications of the novel food protein extract from pig kidneys****(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 of novel foods 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⁾ has established a Union list of novel foods.
- (3) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 includes protein extract from pig kidneys as an authorised novel food.
- (4) Pursuant to Article 5 of Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽³⁾, on 29 February 2012, the company Sciotec Diagnostic Technologies, GmbH notified the Commission of its intention to place on the market protein extract from pig kidneys as a novel food ingredient to be used in foods for special medical purposes as defined in Article 2 of Regulation (EU) No 609/2013 of the European Parliament and of the Council ⁽⁴⁾, and in food supplements as defined in Article 2 of Directive 2002/46/EC of the European Parliament and of the Council ⁽⁵⁾. On the basis of that notification, the protein extract from pig kidneys was included in the Union list of novel foods, when that list was established.
- (5) Commission Implementing Regulation (EU) 2020/973 ⁽⁶⁾ amended the specifications of the novel food protein extract from pig kidneys to include enteric coated tablets as an allowed form of protein extract from pig kidneys to be used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council and in foods for special medical purposes as defined in Regulation (EU) No 609/2013, in addition to the authorised enteric coated encapsulated pellets.

⁽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 foods ingredients (OJ L 43, 14.2.1997, p. 1).

⁽⁴⁾ 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).

⁽⁵⁾ 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).

⁽⁶⁾ Commission Implementing Regulation (EU) 2020/973 of 6 July 2020 authorising a change of the conditions of use of the novel food 'protein extract from pig kidneys' and amending Implementing Regulation (EU) 2017/2470 (OJ L 215, 7.7.2020, p. 7).

- (6) On 11 July 2022, the company Bioiberica, S.A.U ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for a change of the specifications of the novel food protein extract from pig kidneys to include a production process involving the use of a series of acetone wash steps of the pig kidneys, followed by heat-drying steps, milling and sieving, to result in a pale brown powder final form of the novel food which is formulated either in enteric coated capsules or as encapsulated enteric coated pellets or enteric coated tablets to reach the active sites of digestion. The applicant also requested the use of Ultra High Performance Liquid Chromatography linked with Fluorescent Detection ('UHPLC-FLD') as an additional method to the currently authorised one for the determination of the enzymatic activity of Diamine Oxidase ('DAO') contained in the protein extracted from the pig kidneys. This method results in the activity of DAO being expressed in measurement units ('MU') that are different from the currently authorised ones. The applicant justified their request for the addition of a new production process on the fact that their production process besides being robust and consistent in producing the novel food in line with the authorised specifications, it is not protected by third party patents as the currently authorised novel food production process is thereby preventing the applicant and other food business operators from making use of it. The applicant justified their request for the use UHPLC-FLD method to measure the DAO activity as being a well-known method that is easy to validate and implement while being equally reliable to the currently authorised Radio Extraction Assay ('REA') method.
- (7) The Commission considers that the requested update of the Union list is not liable to have an effect on human health, and that a safety evaluation by the European Food Safety Authority ('the Authority') in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. The production process using the acetone wash method followed by heat-drying steps, milling and sieving results in the production of a novel food that complies with all the authorised specifications and only differs in its form (powder) and colour (pale brown). The changes in the physical form and appearance of the novel food obtained by the acetone wash method are not expected to impact the safety of the novel food if the authorised conditions of use and specifications are respected. The use of capsules is currently authorised for the enteric coated pellet form of the novel food and their use for the powder form of the novel food is also not liable to change the safety profile of this authorised novel food.
- (8) Acetone as a solvent used in the preparation of foods is authorised by Directive 2009/32/EC of the European Parliament and of the Council ⁽⁷⁾, and levels up to 5 000 mg/kg of acetone have been assessed by the Authority in the context of the safety assessment of the application for the authorisation of nicotinamide riboside chloride as a novel food ⁽⁸⁾ that involved identical proposed uses and resulting anticipated intakes to the uses and intakes of the protein extract from pig kidneys. The Commission however considers that, as an additional safety reassurance element, acetone should be added as a parameter in the specifications of the protein extract from pig kidneys produced by the acetone wash production process, at the same levels ($\leq$ 5 000 mg/kg) that have been assessed by the Authority and are included in the specifications of the novel food nicotinamide riboside chloride authorised by Commission Implementing Regulation (EU) 2020/16 ⁽⁹⁾.
- (9) The Commission also considers that the inclusion in the Union list of the UHPLC-FLD method for the determination of the enzymatic activity of DAO, and the expression of its resulting activity in different measurement units in addition to the currently authorised method and measurement units, will offer food business operators and Member State enforcement authorities another method to verify the performance and quality of the novel food placed on the market.

⁽⁷⁾ Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3).

⁽⁸⁾ EFSA Journal 2019; 17(8):5775.

⁽⁹⁾ Commission Implementing Regulation (EU) 2020/16 of 10 January 2020 authorising the placing on the market of nicotinamide riboside chloride 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 (OJ L 7, 13.1.2020, p. 6).

- (10) The information provided in the application gives sufficient grounds to establish that the changes to the specifications of the novel food protein extract from pig kidneys are in accordance with the conditions of Article 12 of Regulation (EU) 2015/2283 and should be approved.
- (11) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (12) 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

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

Article 2

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

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

Done at Brussels, 12 May 2023.

For the Commission
The President
Ursula VON DER LEYEN

In Table 2 (Specifications) of the Annex to Implementing Regulation (EU) 2017/2470, the entry for 'Protein extract from pig kidneys' is replaced by the following:

Authorised Novel Food	Specification	
Protein extract from pig kidneys	Description/Definition: The protein extract is obtained from homogenised pig kidneys through a combination of salt precipitation and high speed centrifugation. The obtained precipitate contains essentially proteins with 7 % of the enzyme diamine oxidase (enzyme nomenclature E.C. 1.4.3.22) and is resuspended in a physiologic buffer system. The obtained pig kidney extract is formulated as encapsulated enteric coated pellets or enteric coated tablets to reach the active sites of digestion. Basic Product: Specification: pig kidney protein extract with natural content of Diamine oxidase (DAO): Physical condition: liquid Colour: brownish Appearance: slightly turbid solution pH value: 6,4–6,8 Enzymatic activity: > 2 677 kH DU DAO/ml (DAO REA (DAO Radioextraction assay)) Microbiological criteria: Brachyspira spp.: negative (Real Time PCR) Listeria monocytogenes: negative (Real Time PCR) Staphylococcus aureus: < 100 CFU/g	Description/Definition: The protein extract is obtained from homogenised pig kidneys through a series of steps involving a number of acetone washes to defat and dehydrate the homogenized pig kidneys, followed by draining, drying, milling, and sieving to produce a powder containing essentially proteins with a 7-9 % (on average) content of the enzyme diamine oxidase (enzyme nomenclature E.C. 1.4.3.22). The pig kidney extract powder is formulated either in enteric coated capsules or as encapsulated enteric coated pellets or enteric coated tablets to reach the active sites of digestion. Basic Product: Specification: pig kidney protein extract with natural content of Diamine oxidase (DAO): Physical condition: powder Colour: pale brown Enzymatic activity: ≥ 0,10 mU/mg (UHPLC-FLD (Ultra High Performance Liquid Chromatography linked with Fluorescent Detection)). Humidity: < 10 % Residual Solvents: Acetone: < 5 000 mg/kg Microbiological criteria: <i>Staphylococcus aureus</i>: < 100 CFU/g

Influenza A: negative (Reverse Transcription Real Time PCR) Escherichia coli: < 10 CFU/g Total aerobic microbiological count: < 10⁵ CFU/g Yeasts/moulds count: < 10⁵ CFU/g Salmonella: Absence/10g Bile salt resistant enterobacteriaceae: < 10⁴ CFU/g Final product: Specification pig kidney protein extract with natural content of DAO (E.C. 1.4.3.22) in an enteric coated formulation: Physical condition: solid Colour: yellow grey Appearance: micropellets or tablets Enzymatic activity: 110-220 kHDU DAO/g pellet or g tablet (DAO REA (DAO Radio Extraction Assay)) Acid stability 15 min 0,1M HCl followed by 60 min Borat pH = 9,0: > 68 kHDU DAO/g pellet or g tablet (DAO REA (DAO Radio Extraction Assay)) Humidity: < 10 % Microbiological criteria: <i>Staphylococcus aureus</i>: < 100 CFU/g <i>Escherichia coli</i>: < 10 CFU/g	<i>Escherichia coli</i>: < 10 CFU/g Total aerobic microbiological count: < 10⁴ CFU/g Total combined yeasts/moulds count: < 10³ CFU/g <i>Salmonella</i>: Absence/10g Bile salt resistant enterobacteriaceae: < 10² CFU/g <i>Listeria monocytogenes</i>: absence in 25 g Final product: Specification pig kidney protein extract with natural content of DAO (E.C. 1.4.3.22) in an enteric coated formulation: Physical condition: solid Colour: pale brown Appearance: micropellets, capsules, or tablets Enzymatic activity (micropellets, capsules or tablets): 2,29 – 4,6 mU/g pellet or g tablet or g capsule (UHPLC-FLD (Ultra High Performance Liquid Chromatography linked with Fluorescent Detection)). Acid stability 15 min 0,1M HCl followed by 60 min Borat pH = 9,0: > 1,4 mU DAO/g pellet or g tablet or g capsule (UHPLC-FLD (Ultra High Performance Liquid Chromatography linked with Fluorescent Detection)) Humidity: < 10 % Microbiological criteria: <i>Staphylococcus aureus</i>: < 100 CFU/g
--	---

	Total aerobic microbiological count: < 10⁴ CFU/g Total combined yeasts/moulds count: < 10³ CFU/g <i>Salmonella</i>: Absence/10g Bile salt resistant enterobacteriaceae: < 10² CFU/g PCR: Polymerase Chain Reaction; HDU (Histamine Degrading Units);	<i>Escherichia coli</i>: < 10 CFU/g Total aerobic microbiological count: < 10⁴ CFU/g Total combined yeasts/moulds count: < 10³ CFU/g <i>Salmonella</i>: Absence/10g Bile salt resistant enterobacteriaceae: < 10² CFU/g <i>Listeria monocytogenes</i>: absence in 25 g mU: milliUnit (expressed in mU/mg) measures nanomols (nmol) of histamine degraded by the DAO per minute using Ultra High Performance Liquid Chromatography linked with Fluorescent Detection (UHPLC-FLD) (O. Comas-Basté et al. Analytical and Bioanalytical Chemistry 411:7595-7602 (2019)). 1 mU corresponds to 48 000 HDU of the DAO Radio Extraction Assay (REA) method.'
--	---	--

COMMISSION IMPLEMENTING REGULATION (EU) 2023/952**of 12 May 2023****amending Implementing Regulation (EU) No 1321/2013 as regards the name of the holder of the authorisation for the smoke flavouring primary product ‘Tradismoke™ A MAX’ (unique code SF-007)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended to be used in or on foods ⁽¹⁾, and in particular Article 11 thereof,

Whereas:

- (1) On 17 March 2022, an application was submitted on behalf of Nactis (‘the applicant’) in accordance with Article 11(1) of Regulation (EC) No 2065/2003, requesting a change to the name of the holder of the authorisation for the smoke flavouring primary product ‘Tradismoke™ A MAX’ listed in the table in the Annex to Commission Implementing Regulation (EU) No 1321/2013 ⁽²⁾.
- (2) In the application, the applicant stated that the authorisation for the smoke flavouring primary product ‘Tradismoke™ A MAX’ was to be transferred to JRS, J. Rettenmaier & Söhne GmbH & Co. KG. In support of its statement, the applicant provided evidence of the parties’ consent to the transfer in respect of the smoke flavouring primary product ‘Tradismoke™ A MAX’.
- (3) The proposed change of the holder of the authorisation is purely administrative in nature and therefore does not entail a new assessment of the product concerned.
- (4) Implementing Regulation (EU) No 1321/2013 should therefore be amended accordingly.
- (5) In order to ensure a smooth transition, it is appropriate to provide that the smoke flavouring primary product ‘Tradismoke™ A MAX’, smoke flavourings derived therefrom and foods containing the smoke flavouring primary product or smoke flavourings derived therefrom, which comply with the rules applying before the date of entry into force of this Regulation, may continue to be placed on the market and used until the existing stocks are exhausted.
- (6) 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***Amendment to Implementing Regulation (EU) No 1321/2013**

In the table in the Annex to Implementing Regulation (EU) No 1321/2013, the entry on the smoke flavouring primary product ‘Tradismoke™ A MAX’ (unique code SF-007) is amended as follows:

- (1) in the third row ‘name of the authorisation holder’, the word ‘Nactis’ is replaced by the words ‘JRS, J. Rettenmaier & Söhne GmbH & Co. KG’;

⁽¹⁾ OJ L 309, 26.11.2003, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) No 1321/2013 of 10 December 2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings (OJ L 333, 12.12.2013, p. 54).

- (2) in the fourth row 'address of the authorisation holder', the words '36, rue Gutenberg – ZI La Marinière, 91070 Bondoufle, FRANCE' are replaced by the words 'Holzmühle 1, 73494 Rosenberg, GERMANY'.

Article 2

Transitional measures

The smoke flavouring primary product 'Tradismoke™ A MAX' listed in the table in the Annex to Implementing Regulation (EU) No 1321/2013, smoke flavourings derived therefrom and foods containing the smoke flavouring primary product or smoke flavourings derived therefrom, which are produced and labelled before 4 June 2023 in accordance with the rules applicable before 4 June 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 3

Entry into force

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

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

Done at Brussels, 12 May 2023.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2023/953**of 12 May 2023****amending Implementing Regulation (EU) 2020/761 as regards the rules governing the tariff rate quota for export of milk powder to the Dominican Republic**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Commission Implementing Regulation (EU) 2020/761 ⁽²⁾ lays down the rules for the management of import and export tariff quotas for agricultural products managed by a system of import and export licences and provides for specific rules for the administration of those quotas.
- (2) As of 1 July 2023, according to the Economic Partnership Agreement between the CARIFORUM States and the European Community and its Member States ⁽³⁾, the Dominican Republic may import milk powder from the Union at zero duty for an unlimited quantity. As a consequence and for the reason of clarity, the provisions on the tariff rate quota for exports of milk powder from the Union to the Dominican Republic should be removed from Implementing Regulation (EU) 2020/761 with the application as of the next licence application period.
- (3) Implementing Regulation (EU) 2020/761 should therefore be amended accordingly.
- (4) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

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

- (1) Articles 55, 56 and 57 are deleted;
- (2) Annex I and Annex XIII, Part B – Sector: Milk are amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply as of the first licence application period for the tariff quota period starting on 1 July 2023.

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ Commission Implementing Regulation (EU) 2020/761 of 17 December 2019 laying down rules for the application of Regulations (EU) No 1306/2013, (EU) No 1308/2013 and (EU) No 510/2014 of the European Parliament and of the Council as regards the management system of tariff quotas with licences (OJ L 185, 12.6.2020, p. 24).

⁽³⁾ Council Decision 2008/805/EC of 15 July 2008 on the signature and provisional application of the Economic Partnership Agreement between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part (OJ L 289, 30.10.2008, p. 1).

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

Done at Brussels, 12 May 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annex I and Annex XIII, Part B – Sector: Milk to Commission Implementing Regulation (EU) 2020/761 are amended as follows:

(1) in Annex I, the following row is deleted:

Milk powder quota opened by the Dominican Republic	Milk and milk products	Export	EU: simultaneous examination	No	Yes		No'
--	------------------------	--------	------------------------------	----	-----	--	-----

(2) in Annex XIII, Part B – Sector: Milk, the following table is deleted:

Order number	Not applicable
International agreement or other act	The Economic Partnership Agreement between the Cariforum States, of the one part, and the European Community and its Member States, of the other part
Tariff quota period	1 July to 30 June
Tariff quota sub-periods	No
Licence application	In accordance with Articles 6, 7 and 8 of this Regulation
Product description	Milk powders, sweetened or not
Destination	Dominican Republic
Proof of origin at licence application. If yes, body authorised to issue it	No
Proof of origin for release into free circulation	Yes, in accordance with Article 55(4) of this Regulation
Quantity in kilograms	22 400 000 kg
CN codes	0402 10, 0402 21 and 0402 29
Proof of trade	In accordance with Article 8(2)(c) of Delegated Regulation (EU) 2020/760 25 tonnes
Security for export licence	EUR 3 per 100 kg
Specific entries to be made on the licence application and on the licence	In accordance with Article 56(3) of this Regulation
Period of validity of a licence	In accordance with Article 13 of this Regulation
Transferability of licence	No
Reference quantity	No
Operator registered in LORI database	No
Specific conditions	In accordance with Articles 55, 56 and 57 of this Regulation'

COMMISSION IMPLEMENTING REGULATION (EU) 2023/954**of 12 May 2023****correcting Annexes XIII, XIV and XXII to Implementing Regulation (EU) 2021/404 as regards the lists of third countries, territories or zones thereof authorised for the entry into the Union of consignments of fresh meat of ungulates, poultry and game birds, and certain species and categories of animals, germinal products and products of animal origin for which the Union is not the final destination****(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 230(1) thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down, inter alia, the animal health requirements for the entry into the Union of consignments of animals, germinal products and products of animal origin, and it applies from 21 April 2021. One of those animal health requirements is that those consignments must come from a third country or territory, or zone or compartment thereof, listed in accordance with Article 230(1) of that Regulation.
- (2) Commission Delegated Regulation (EU) 2020/692 ⁽²⁾ supplements Regulation (EU) 2016/429 as regards the animal health requirements for the entry into the Union of consignments of certain species and categories of animals, germinal products and products of animal origin from third countries or territories, or zones or compartments thereof. Delegated Regulation (EU) 2020/692 provides that consignments of animals, germinal products and products of animal origin falling within its scope may only be permitted to enter into the Union if they come from a third country or territory, or zone or compartment thereof, listed for the particular species and categories of animals, germinal products and products of animal origin, in accordance with the animal health requirements laid down in that Delegated Regulation.
- (3) Commission Implementing Regulation (EU) 2021/404 ⁽³⁾ establishes the lists of third countries or territories, or zones or compartments thereof, from which the entry into the Union of consignments of those species and categories of animals, germinal products and products of animal origin, that fall within the scope of Delegated Regulation (EU) 2020/692, is permitted. The lists and certain general rules concerning the lists are set out in Annexes I to XXII to that Delegated Regulation. At the time of adoption of Implementing Regulation

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).

⁽³⁾ Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council (OJ L 114, 31.3.2021, p. 1).

(EU) 2021/404, similar lists were set out in several Commission acts, including in Commission Regulation (EC) No 798/2008 ⁽⁴⁾ for consignments of poultry and poultry products, and in Commission Regulation (EU) No 206/2010 ⁽⁵⁾ for consignments of certain animals and fresh meat. Regulations (EC) No 798/2008 and (EU) No 206/2010 were repealed by Delegated Regulation (EU) 2020/692 with effect from 21 April 2021.

- (4) The table in Part 1 of Annex XIII to Implementing Regulation (EU) 2021/404 sets out the list of third countries, territories or zones thereof authorised for the entry into the Union of consignments of fresh meat of ungulates. In the title of column 7 of that table, a footnote should be inserted to reflect the footnote set out in the title of column 7 of the table in Part 1 of Annex II to Regulation (EU) No 206/2010 providing that fresh meat obtained from ungulates slaughtered and certified before the closing date shall be permitted entry into the Union only for a limited period.
- (5) In addition, in column 5 of the table in Part 1 of Annex XIII to Implementing Regulation (EU) 2021/404, in the entry for the zone BR-2 in Brazil, the specific condition 'No vaccination carried out' should be inserted to reflect the supplementary guarantee 'H' in Part 2 of Annex II to Regulation (EU) No 206/2010 as in that zone in Brazil no vaccination against foot and mouth is carried out and the competent authority of Brazil must therefore implement a regular serological surveillance to demonstrate the absence of foot and mouth disease virus circulation therein. The table in Part 1 of Annex XIII to Implementing Regulation (EU) 2021/404 should therefore be corrected accordingly.
- (6) The table in Part 1 of Annex XIV to Implementing Regulation (EU) 2021/404 sets out the list of third countries, territories or zones thereof authorised for the entry into the Union of consignments of fresh meat of poultry and game birds. In the title of column 6 of that table, a footnote should be inserted to reflect the footnote set out in the title of column 6A of the table in Part 1 of Annex I to Regulation (EC) No 798/2008 providing that fresh meat obtained from poultry and game birds slaughtered and certified before the closing date shall be permitted entry into the Union only for a limited period. The table in Part 1 of Annex XIV to Implementing Regulation (EU) 2021/404 should therefore be corrected accordingly.
- (7) The table in Part 1 of Annex XXII to Implementing Regulation (EU) 2021/404 sets out, inter alia, a list of third countries, territories or zones thereof authorised for the entry into the Union of consignments of certain species and categories of animals, germinal products and products of animal origin for which the Union is not the final destination. In column 5 of that table, in the entry for the zone RU-2 in Russia a clerical mistake as regards the name of the animal health certificate 'BOV-X' indicated for that zone should be corrected so as to indicate 'BOV-X-TRANSIT-RU' in line with the model animal health certificate for the entry into the Union of bovine animals intended for transit from the region of Kaliningrad to other regions of Russia via the territory of Lithuania set out in Chapter 3 of Annex II to Commission Implementing Regulation (EU) 2021/403 ⁽⁶⁾. The table in Part 1 of Annex XXII to Implementing Regulation (EU) 2021/404 should therefore be amended accordingly.
- (8) Annexes XIII, XIV and XXII to Implementing Regulation (EU) 2021/404 should therefore be corrected accordingly.
- (9) As Implementing Regulation (EU) 2021/404 applies from 21 April 2021, in the interest of legal certainty and to facilitate trade, the corrections to be made to Implementing Regulation (EU) 2021/404 by this Regulation should take effect as a matter of urgency.

⁽⁴⁾ Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements (OJ L 226, 23.8.2008, p. 1).

⁽⁵⁾ Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements (OJ L 73, 20.3.2010, p. 1).

⁽⁶⁾ Commission Implementing Regulation (EU) 2021/403 of 24 March 2021 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates and model animal health/official certificates, for the entry into the Union and movements between Member States of consignments of certain categories of terrestrial animals and germinal products thereof, official certification regarding such certificates and repealing Decision 2010/470/EU (OJ L 113, 31.3.2021, p. 1).

- (10) 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

Annexes XIII, XIV and XXII to Implementing Regulation (EU) 2021/404 are corrected in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 12 May 2023.

For the Commission
The President
Ursula VON DER LEYEN

(1) Annex XIII to Implementing Regulation (EU) 2021/404 is corrected as follows:

(a) in Part 1, the table is corrected as follows:

(i) the titles of the columns of the table are replaced by the following:

'ISO code and name of the third country or territory	Code of the zone as set out in Part 2	Species of origin of the meat permitted to enter the Union	Animal health certificates	Specific conditions as set out in Part 3	Animal health guarantees as set out in Part 4	Closing date ⁽¹⁾	Opening date
1	2	3	4	5	6	7	8

⁽¹⁾ Consignments of fresh meat of ungulates slaughtered and certified before the date set out in column 7 shall be permitted entry into the Union during the period of 90 days from that date.;

(ii) the entry for the zone BR-2 in Brazil is replaced by the following:

'BR Brazil	BR-2	Bovine animals	BOV	Maturation, pH and de-boning No vaccination carried out No offal Additional traceability			1.12.2008'
----------------------	------	----------------	-----	---	--	--	------------

(2) in Annex XIV, in Part 1, in Section B, the titles of the columns of the table are replaced by the following:

'ISO code and name of the third country or territory	Code of the zone as set out in Part 2	Animal health certificate of the categories permitted to enter the Union	Specific conditions as set out in Part 3	Additional guarantees as set out in Part 4	Closing date ⁽¹⁾	Opening date
1	2	3	4	5	6	7

⁽¹⁾ Consignments of fresh meat of poultry and game birds slaughtered and certified before the date set out in column 6 shall be permitted entry into the Union during the period of 90 days from that date.'

(3) in Annex XXII, in Part 1, in the table, the entry for the zone RU-2 in Russia is replaced by the following:

'RU Russia	RU-2	Bovine animals		BOV-X-TRANSIT-RU	From Kaliningrad to mainland Russia via Lithuania'		
---------------	------	----------------	--	------------------	--	--	--

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



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

EN