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⁽¹⁾ Text with EEA relevance.

EN

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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2023/1149

of 5 April 2023

correcting the Polish language version of Delegated Regulation (EU) 2022/2292 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of food-producing animals and certain goods intended for human consumption

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ⁽¹⁾, and in particular Article 126(1) thereof,

Whereas:

- (1) The Polish language version of Commission Delegated Regulation (EU) 2022/2292 ⁽²⁾ contains an error in the introductory sentence of Article 5(2) that changes the scope of requirements set out in Articles 6-12.
- (2) The Polish language version of Delegated Regulation (EU) 2022/2292 should therefore be corrected accordingly. The other language versions are not affected,

⁽¹⁾ OJ L 95, 7.4.2017, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) 2022/2292 of 6 September 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of food-producing animals and certain goods intended for human consumption (OJ L 304, 24.11.2022, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

(Does not concern the English language)

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, 5 April 2023.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1150

of 6 June 2023

approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications ('Pimentón de Murcia' (PDO))

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Pursuant to the first subparagraph of Article 53(1) of Regulation (EU) No 1151/2012, the Commission has examined Spain's application for the approval of amendments to the specification for the protected designation of origin 'Pimentón de Murcia', registered under Commission Regulation (EC) No 464/2001 ⁽²⁾.
- (2) Since the amendments in question are not minor within the meaning of Article 53(2) of Regulation (EU) No 1151/2012, the Commission published the amendment application in the *Official Journal of the European Union* ⁽³⁾ as required by Article 50(2)(a) of that Regulation.
- (3) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the amendments to the specification should be approved,

HAS ADOPTED THIS REGULATION:

Article 1

The amendments to the specification published in the *Official Journal of the European Union* regarding the name 'Pimentón de Murcia' (PDO) are hereby approved.

Article 2

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

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

Done at Brussels, 6 June 2023.

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

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

⁽²⁾ Commission Regulation (EC) No 464/2001 of 7 March 2001 supplementing the Annex to Regulation (EC) No 2400/96 on the entry of certain names in the 'Register of protected designations of origin and protected geographical indications' provided for in Council Regulation (EEC) No 2081/92 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs (OJ L 66, 8.3.2001, p. 29).

⁽³⁾ OJ C 68, 24.2.2023, p. 44.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1151**of 6 June 2023****entering a name in the register of protected designations of origin and protected geographical indications ('Çağlayancerit Cevizi' (PDO))**

THE EUROPEAN COMMISSION,

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

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

Whereas:

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

HAS ADOPTED THIS REGULATION:

Article 1

The name 'Çağlayancerit Cevizi' (PDO) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 1.6. Fruit, vegetables and cereals, fresh or processed, as listed in Annex XI to Commission Implementing Regulation (EU) No 668/2014 ⁽³⁾.*Article 2*This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 6 June 2023.

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

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

⁽²⁾ OJ C 65, 22.2.2023, p. 12.

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

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1152**of 12 June 2023****correcting certain language versions of Regulation (EU) No 1321/2014 on the continuing airworthiness of aircraft and aeronautical products, parts and appliances, and on the approval of organisations and personnel involved in these tasks****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 ⁽¹⁾, and in particular Article 17(1) and Article 62(14) and (15) thereof,

Whereas:

- (1) The French and German language versions of Commission Regulation (EU) No 1321/2014 ⁽²⁾ contain errors. The French language version contains a terminological error in Section A, Subpart B, point M.A.201(b), of Annex I (Part-M), in point ML.1(c)(3)(ii), of Annex Vb (Part-ML), in Section A, Subpart B, point ML.A.201(b), of Annex Vb (Part-ML), in Appendix I, point (c)(2), of Annex Vb (Part-ML) and in point CAO.1(2)(ii), of Annex Vd (Part-CAO). It contains another terminological error in Appendix I, point 2, Module 12, in the table, first column, point 12.9(b), first line, of Annex III (Part-66), in Appendix III, point 3.1(e), in the table, column 'Level Chapters', under the title 'Helicopters', in the line concerning Chapter 25, of Annex III (Part-66) and in Appendix III, point 3.2(b), in the table, column 'Chapters', under the title 'Helicopters', in the line concerning chapter 25, of Annex III (Part-66). These errors affect the substance of the provisions. The German language version contains an omission in Section A, Subpart C, point ML.A.305(d)(1), of Annex Vb (Part-ML) that affects the substance of the provision.
- (2) The French and German language versions of Regulation (EU) No 1321/2014 should therefore be corrected accordingly. The other language versions are not affected.
- (3) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 65(1) of Regulation (EC) No 216/2008 of the European Parliament and of the Council ⁽³⁾, delivered prior to the adoption of Regulation (EU) No 1321/2014. Those measures are also in accordance with the opinion of the Committee established by Article 127(1) of Regulation (EU) 2018/1139, delivered prior to the adoption of Commission Implementing Regulation (EU) 2019/1383 ⁽⁴⁾,

⁽¹⁾ OJ L 212, 22.8.2018, p. 1.

⁽²⁾ Commission Regulation (EU) No 1321/2014 of 26 November 2014 on the continuing airworthiness of aircraft and aeronautical products, parts and appliances, and on the approval of organisations and personnel involved in these tasks (OJ L 362, 17.12.2014, p. 1).

⁽³⁾ Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79, 19.3.2008, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) 2019/1383 of 8 July 2019 amending and correcting Regulation (EU) No 1321/2014 as regards safety management systems in continuing airworthiness management organisations and alleviations for general aviation aircraft concerning maintenance and continuing airworthiness management (OJ L 228, 4.9.2019, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

(Does not concern the English language)

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 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1153**of 12 June 2023****amending Annex IV to Implementing Regulation (EU) 2021/404 as regards the entry for China in the list of third countries, territories or zones thereof authorised for the entry into the Union of consignments of certain equine animals****(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 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.
- (4) Annex IV 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 equine animals.
- (5) In order to host the equestrian events of the 19th Asian Games, China has requested the recognition of an equine disease-free zone established at the Tonglu Equestrian Center in the part of Yaolin town in the north-western part of Tonglu County, Fuyang District, Hangzhou Municipality, Zhejiang Province in China, connected with the Hangzhou Xiaoshan International Airport. A number of registered horses originating from the Union will take part in the 19th Asian Games.

⁽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).

- (6) In view of the temporary nature of those equestrian events, it is appropriate to foresee only a temporary approval of that equine disease-free zone from 15 September 2023 to 13 November 2023 to provide enough time for the registered horses originating from the Union to enter and leave that zone.
- (7) China has provided guarantees, in particular as regards the notifiability in their country of the listed diseases referred to in point 1 of Annex I to Delegated Regulation (EU) 2020/692 relevant for equine animals, and guarantees regarding compliance or equivalence with the relevant animal health requirements applicable in the Union. In addition, China has informed the Commission that the entire group of registered horses originating from the Union and competing in those events, will be kept separated from any equidae not of the same origin and health status.
- (8) At the same time, the self-declaration by China for the establishment of the equine disease-free zone for the 19th Asian Games has been published at the World Organisation for Animal Health webpage ⁽⁴⁾.
- (9) In the light of those guarantees and information provided by China, the re-entry of registered horses from a designated equine disease-free zone in that third country after the temporary export in accordance with the requirements of Delegated Regulation (EU) 2020/692 and accompanied by an animal health certificate issued in accordance with a model set out in Chapters 16 and 17 of Annex II to Commission Implementing Regulation (EU) 2021/403 ⁽⁵⁾ should be permitted for a limited period. This period should be limited to maximum of 60 days in line with point II.3.2, second option, of the model animal health certificate set out in Chapter 17 of Annex II to Implementing Regulation (EU) 2021/403.
- (10) Annex IV to Implementing Regulation (EU) 2021/404 should therefore be amended accordingly.
- (11) As Implementing Regulation (EU) 2021/404 applies from 21 April 2021, in the interest of legal certainty and to facilitate trade, the amendments to be made to Implementing Regulation (EU) 2021/404 by this Regulation should take effect as a matter of urgency.
- (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

Annex IV to Implementing Regulation (EU) 2021/404 is amended 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*.

⁽⁴⁾ <https://www.woah.org/en/what-we-offer/self-declared-disease-status/>

⁽⁵⁾ 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).

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

Done at Brussels, 12 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

Annex IV to Implementing Regulation (EU) 2021/404 is amended as follows:

(1) in Part 1, in the entry for China, the following zone CN-3 is added after the zone CN-2:

'CN China	CN-3	G	Registered horses	EQUI-RE-ENTRY-30, EQUI-RE-ENTRY-90-COMP			13.11.2023	15.9.2023'
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(2) in Part 2, in the entry for China, the following description of the zone CN-3 is added after the zone CN-2:

'China	CN-3	The 19th Asian Games equine disease-free zone established in the part of Yaolin town north of the Fenshui River in the north-western part of Tonglu County, Fuyang District, Hangzhou Municipality, Zhejiang Province, and including the Biosecurity Highway Passage (see details below): Core zone: The area of 1 300 km² in the north-western part of Tonglu County comprising the Tonglu Equestrian Center (29°54' 40.66"N, 119°32' 15.33"E) in the part of Yaolin town north of Fenshui River (a contributor to the Fuchun River) with the following delimitation: — Western boundary: Chun'an County, — Northern boundary: Lin'an District, — Eastern boundary: Fuyang District, — South-eastern boundary: Fuchun River in Fuchunjiang Town, Tonglu County South Street, Fengchuan Street, — South-western boundary: Jiande City. Protection zone: The area of 12 300 km² surrounding the core zone with the following delimitation: — the districts of Fuyang and Lin'an to the north and the Chun'an County and the City of Jiande to the south; — the part of Tonglu County east of Fuchun River, including the Chengnan and Fengchuan Subdistricts, Jiangnan Town, Xinhe Township and the part of Fuchunjiang Town east of the Fuchun River. Biosecurity Highway Passage: Highway network connecting the equine disease-free zone with the Hangzhou Xiaoshan International Airport (including Airport Expressway, Hangzhou Bay Ring Expressway, Shanghai-Kunming Expressway, Caihong Expressway, G25 Hangzhou Xinjing Expressway) and areas within 1 km on both sides of those highways.'						
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DECISIONS

COUNCIL DECISION (EU) 2023/1154

of 8 June 2023

appointing a member and three alternate members, proposed by the Republic of Latvia, of the Committee of the Regions

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to Council Decision (EU) 2019/852 of 21 May 2019 determining the composition of the Committee of the Regions ⁽¹⁾,

Having regard to the proposals of the Latvian Government,

Whereas:

- (1) Pursuant to Article 300(3) of the Treaty, the Committee of the Regions is to consist of representatives of regional and local bodies who either hold a regional or local authority electoral mandate or are politically accountable to an elected assembly.
- (2) On 10 December 2019, the Council adopted Decision (EU) 2019/2157 ⁽²⁾, appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025.
- (3) A member's seat on the Committee of the Regions has become vacant following the end of the national mandate on the basis of which Ms Inga BĒRZIŅA was proposed for appointment.
- (4) Two alternate members' seats on the Committee of the Regions have become vacant following the end of the national mandate on the basis of which Mr Raimonds ČUDARS and Mr Māris SPRINDŽUKS were proposed for appointment.
- (5) An alternate member's seat will become vacant following the appointment of Mr Māris ZUSTS as a member of the Committee of the Regions.
- (6) The Latvian Government has proposed Mr Māris ZUSTS, representative of a local body who holds a local authority electoral mandate, *Deputāts, Saldus novada dome* (Council Member, Saldus municipality council), as a member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025.
- (7) The Latvian Government has proposed the following representatives of local bodies who hold a local authority electoral mandate as alternate members of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025: Ms Karīna MIKELSONE, *Deputāte, Ādažu novada dome* (Council Member, Ādaži municipality council), Ms Vita PAULĀNE, *Deputāte, Ropažu novada dome* (Council Member, Ropaži municipality council), and Mr Aivars PRIEDOLS, *Deputāts, Dienvidkurzemes novada dome* (Council Member, Dienvidkurzeme municipality council),

⁽¹⁾ OJ L 139, 27.5.2019, p. 13.

⁽²⁾ Council Decision (EU) 2019/2157 of 10 December 2019 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025 (OJ L 327, 17.12.2019, p. 78).

HAS ADOPTED THIS DECISION:

Article 1

The following representatives of local bodies who hold an electoral mandate are hereby appointed to the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025:

(a) as a member:

— Mr Māris ZUSTS, *Deputāts, Saldus novada dome* (Council Member, Saldus municipality council);
and

(b) as alternate members:

— Ms Karīna MIKELSONE, *Deputāte, Ādažu novada dome* (Council Member, Ādaži municipality council),
— Ms Vita PAULĀNE, *Deputāte, Ropažu novada dome* (Council Member, Ropaži municipality council),
— Mr Aivars PRIEDOLS, *Deputāts, Dienvidkurzemes novada dome* (Council Member, Dienvidkurzeme municipality council).

Article 2

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

Done at Luxembourg, 8 June 2023.

For the Council
The President
M. MALMER STENERGARD

COMMISSION IMPLEMENTING DECISION (EU) 2023/1155**of 9 June 2023****on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Rapid Pro referred by France in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council***(notified under document C(2023) 3666)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 36(3) thereof,

Whereas:

- (1) On 7 October 2016, the biocidal product Rapid Pro ('the biocidal product') was authorised in France by mutual recognition in parallel of an authorisation granted by Belgium in accordance with Article 34 of Regulation (EU) No 528/2012. The biocidal product is a rodenticide, falling under product-type 14 and is placed on the market in pre-filled tamper-resistant bait boxes used for indoor control of mice by professionals. The biocidal product contains the approved active substance alphachloralose. The authorisation holder of the biocidal product is Rentokil Initial.
- (2) In 2019, France was informed by the Netherlands and Finland that in 2018 a significant increase of cases of primary and secondary poisonings of cats and dogs with symptoms of alphachloralose poisoning had been reported by poison centres, pet owners and veterinary clinics. In France, the French veterinary poisoning centres had also reported an increase of alphachloralose poisoning of companion animals, mainly primary poisoning of dogs, in 2017 and 2018.
- (3) On 9 December 2019, France amended the authorisation of the biocidal product in accordance with Article 48(1), point (a), of Regulation (EU) No 528/2012 to address the primary poisoning incidents involving dogs and secondary poisoning incidents involving cats.
- (4) France amended the authorisation by requiring additional labelling on the biocidal product to indicate the risk for humans and non-target organisms and on the packaging to indicate the obligation to use the biocidal product only in bait boxes.
- (5) Pursuant to Article 48(3), third subparagraph, read in conjunction with Article 35(2) of Regulation (EU) No 528/2012, on 15 April 2020, Germany referred to the coordination group objections to the amendment of the authorisation of the biocidal product made by France.
- (6) The objection from Germany related to the legal basis under which the product can be authorised, as according to Germany, the product does not fully meet the conditions of Article 19(1) of Regulation (EU) No 528/2012 due to the risk of primary and secondary poisoning of animals and may therefore be authorised only under Article 19(5). France considered that the biocidal product complies with Article 19(1) of Regulation (EU) No 528/2012 and that therefore Article 19(1) is the correct legal basis for the amended authorisation.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

- (7) On 6 June 2020, the secretariat of the coordination group invited the other concerned Member States and the authorisation holder to submit written comments on the referral. The authorisation holder submitted written comments on 30 June 2020, 6 July 2020 and 23 July 2020. The referral was discussed in the coordination group on 6 and 23 July 2020 with the participation of the authorisation holder.
- (8) As no agreement was reached in the coordination group, on 21 October 2020, France, as a reference Member State for the purposes of amending the authorisation under Article 48(1), first subparagraph, of Regulation (EU) No 528/2012, referred the unresolved objections to the Commission pursuant to Article 36(1) of that Regulation and provided the Commission with a detailed statement of the matter on which Member States were unable to reach an agreement and the reasons for their disagreement. That statement was forwarded to the Member States concerned and to the authorisation holder.
- (9) In May 2021, the Finnish Safety and Chemical Agency requested an opinion from the Finnish Food Authority and the Finnish Veterinary Association on the effects of biocidal products containing alphachloralose on pets and the need to restrict the use of such products. That opinion, which Finland shared with the Commission, stated that biocidal products containing alphachloralose cause significant harm and suffering to both pets and wildlife and that the number of pet poisonings reported to the Finnish Safety and Chemical Agency and the Finnish Food Authority is significant.
- (10) In addition, the Swedish Chemical Agency obtained additional information in the form of blood sample analyses from the University Animal Hospital in Uppsala, Sweden, which confirmed the presence of alphachloralose in the blood of poisoned animals.
- (11) According to Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012, it is a condition for granting an authorisation that the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects.
- (12) Article 19(5), first subparagraph, of Regulation (EU) No 528/2012 provides that a biocidal product may be authorised when the conditions laid down in Article 19(1), point (b)(iii), are not fully met, where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation. Furthermore, Article 19(5), second subparagraph, states that the use of a biocidal product authorised pursuant to that provision is to be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised. The use of a biocidal product authorised pursuant to that paragraph is to be restricted to Member States in which the condition set out in Article 19(5), first subparagraph, is met.
- (13) The Commission has carefully examined the information submitted by the Member States and by the authorisation holder of the biocidal product, including the fact that incidents of animal poisoning by products containing alphachloralose were also reported in other Member States and in Norway. The Commission also takes into account the opinion from the Finnish Food Authority and the Finnish Veterinary Association, as well as the reports from the University Animal Hospital in Uppsala and the Swedish Veterinary Association, which strongly indicate that the biocidal product has unacceptable effects on animal health, and which confirm, by analytical tests conducted on the poisoned animals, that a significant number of incidents of secondary poisoning by alphachloralose involving cats had occurred, as well as all the information provided and the discussions held in the context of disagreements for other biocidal products containing alphachloralose that were referred to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012.
- (14) The Commission recognises that it is technically and scientifically impossible to link the reported secondary poisoning cases to a specific biocidal product, as it is not possible to identify which of the specific products was ingested by the mouse that was ingested by the cat. It is only possible to detect the presence of the active substance alphachloralose in the tissue of the animals and sometimes in the carcasses of dead rodents in the stomach of poisoned cats. However, it is clear that those poisoning incidents were linked to biocidal products containing alphachloralose, including the biocidal product.

- (15) Based on similar considerations, the Commission has recently adopted, in respect of similar products containing alphachloralose, Commission Implementing Decisions (EU) 2022/1005 ⁽²⁾, (EU) 2022/1006 ⁽³⁾ and (EU) 2022/1388 ⁽⁴⁾.
- (16) The Commission considers that, while the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 are not fully met due to the unacceptable risks for animal health arising from the use of the biocidal product, no objection was referred to the coordination group on the rest of the conditions laid down in Article 19(1), point (b), and, regarding the risks to animal health identified, the risk mitigation measures applied by Member States are likely to reduce the risk of primary and secondary poisoning.
- (17) The Commission therefore considers that, due to the risk of primary and secondary poisoning of dogs in France and of cats in several Member States, the biocidal product does not fully meet the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012.
- (18) Therefore, in accordance with Article 19(5) of Regulation (EU) No 528/2012, the biocidal product may only be authorised in Member States who consider that not authorising it would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation.
- (19) Also, in accordance with Article 19(5) of Regulation (EU) No 528/2012, the use of the biocidal product is to be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised.
- (20) The active substance alphachloralose was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ⁽⁵⁾ for use in biocidal products of product-type 14, and is therefore, pursuant to Article 86 of Regulation (EU) No 528/2012, deemed to have been approved under that Regulation, subject to the specifications and conditions set out in Annex I to Directive 98/8/EC.
- (21) On 24 December 2019, pursuant to Article 13(1) of Regulation (EU) No 528/2012, an application for renewal of the approval of the active substance alphachloralose was submitted to the European Chemicals Agency. On 15 October 2020, the evaluating competent authority of Poland informed the Commission that it had decided, pursuant to Article 14(1) of that Regulation, that a full evaluation of the application for renewal was necessary.
- (22) For reasons beyond the control of the applicants, the approval of alphachloralose for use in biocidal products of product-type 14, which was to expire on 30 June 2021, would have expired before a decision would have been taken on its renewal. Therefore, the expiry date of the approval of alphachloralose was postponed to 31 December 2023 by Commission Implementing Decision (EU) 2021/333 ⁽⁶⁾, to enable the examination of the application.

⁽²⁾ Commission Implementing Decision (EU) 2022/1005 of 23 June 2022 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product family Alphachloralose Grain referred by France and Sweden in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 168, 27.6.2022, p. 86).

⁽³⁾ Commission Implementing Decision (EU) 2022/1006 of 24 June 2022 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product family Alphachloralose Pasta referred by France and Sweden in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 168, 27.6.2022, p. 90).

⁽⁴⁾ Commission Implementing Decision (EU) 2022/1388 of 23 June 2022 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Pat'Appât Souricide Canadien Foudroyant referred by France and Sweden in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 208, 10.8.2022, p. 7).

⁽⁵⁾ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

⁽⁶⁾ Commission Implementing Decision (EU) 2021/333 of 24 February 2021 postponing the expiry date of approval of alphachloralose for use in biocidal products of product-type 14 (OJ L 65, 25.2.2021, p. 58).

- (23) The risk of primary and secondary poisoning of animals due to the use of biocidal products containing alphachloralose, the differences in the occurrence of primary and secondary poisoning incidents among Member States and the necessary risk mitigation measures to be applied to reduce that risk to an acceptable level should be also assessed in the context of the evaluation of the application for renewal of the approval of alphachloralose and should subsequently be duly taken into account by Member States in the authorisation of biocidal products containing alphachloralose.
- (24) The Commission therefore considers that risk mitigation measures to address the risk of primary and secondary poisoning from the use of the biocidal product should, exceptionally, until the conclusion of the evaluation of the application for renewal of the approval of alphachloralose, take into account the particular circumstances and available scientifically validated evidence of the occurrence of primary and secondary poisoning incidents in the individual Member States.
- (25) On 26 October 2022, the Commission provided the authorisation holder with the opportunity to provide written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012. The authorisation holder provided comments, which have been considered by the Commission.
- (26) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

The biocidal product identified by the asset numbers AT-0016213-0000, BE-0011978-0000, CH-0016234-0000, DE-0015430-0000, DK-0012634-0000, ES-0014035-0000, FR-0012648-0000, IE-0014481-0000, IT-0014977-0000, LU-0012652-0000, LT-0018189-0000, NL-0016288-0000, NO-0015333-0000, PT-0020295-0000 in the Register for Biocidal Products ('the biocidal product') does not fully meet the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012.

The biocidal product may only be authorised in accordance with Article 19(5) of Regulation (EU) No 528/2012 in Member States who consider that not authorising it would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation.

The use of the biocidal product shall be subject to appropriate risk mitigation measures, as referred to in Article 19(5) of Regulation (EU) No 528/2012, which shall be adopted in each Member State based on the particular circumstances and available evidence of the occurrence of primary and secondary poisoning incidents in that Member State.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 9 June 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2023/1156**of 9 June 2023****authorising grading methods for the classification of pig carcasses in Slovakia and repealing
Decision 2009/622/EC***(notified under document C(2023) 3684)***(Only the Slovak text is authentic)**

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 20, first paragraph, point (p), thereof,

Whereas:

- (1) Article 10 of Regulation (EU) No 1308/2013 provides that Union scales for the classification of pig carcasses are to apply in accordance with point B of Annex IV to that Regulation. Section B.IV, point 1, of Annex IV to that Regulation provides that, for the classification of pig carcasses, the lean meat content is to be assessed by means of grading methods authorised by the Commission, that only statistically proven assessment methods based on the physical measurement of one or more anatomical parts of the pig carcass may be authorised and that grading methods are subject to compliance with a maximum tolerance rate for statistical error in assessment. That tolerance is defined in Part A, point 1, paragraph 2, of Annex V to Commission Delegated Regulation (EU) 2017/1182 ⁽²⁾.
- (2) Commission Decision 2009/622/EC ⁽³⁾ authorised the use of three methods for grading pig carcasses in Slovakia.
- (3) Unless explicitly authorised by a Commission implementing decision, modifications of the grading methods or apparatuses thereof should not be allowed.
- (4) Slovakia has requested the Commission to authorise the following new method: 'Fat-O-Meater II (FOM II)'. For that purpose, Slovakia has presented a detailed description of the dissection trial, indicating the principles on which this new method is based, the results of the dissection trial and the equation used for assessing the percentage of lean meat in the protocol referred to in Article 11(3) of Delegated Regulation (EU) 2017/1182.
- (5) Slovakia has also requested the Commission to authorise an updated formula for the 'Two-Point (Zwei Punkte – ZP)' method authorised by Decision 2009/622/EC for grading pig carcasses on its territory.
- (6) The examination of those requests has revealed that the conditions and minimum requirements for authorising the new grading method and updating the equation for the 'Two-Point (Zwei Punkte – ZP)' method as laid down in Part A of Annex V to Delegated Regulation (EU) 2017/1182 are fulfilled. That grading method and the new formula should therefore be authorised in Slovakia.
- (7) For reasons of clarity and legal certainty, Decision 2009/622/EC should be repealed.
- (8) The measures provided for in this Decision are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ Commission Delegated Regulation (EU) 2017/1182 of 20 April 2017 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards the Union scales for the classification of beef, pig and sheep carcasses and as regards the reporting of market prices of certain categories of carcasses and live animals (OJ L 171, 4.7.2017, p. 74).

⁽³⁾ Commission Decision 2009/622/EC of 20 August 2009 authorising methods for grading pig carcasses in Slovakia (OJ L 224, 27.8.2009, p. 11).

HAS ADOPTED THIS DECISION:

Article 1

The use of the following grading methods is authorised for the assessment of the lean meat content of pig carcasses pursuant to Section B.IV, point 1, of Annex IV to Regulation (EU) No 1308/2013 in Slovakia:

- (a) the 'Two-point method (Zwei-punkte, ZP)' and the assessment methods related thereto, the details of which are set out in Part I of the Annex to this Decision;
- (b) the 'Fat-O-Meater (FOM)' apparatus and the assessment methods related thereto, the details of which are set out in Part II of the Annex to this Decision;
- (c) the 'Fat-O-Meater II (FOM II)' apparatus and the assessment methods related thereto, the details of which are set out in Part III of the Annex to this Decision;
- (d) the 'UltraFOM 300 (UFOM)' apparatus and the assessment methods related thereto, the details of which are set out in Part IV of the Annex to this Decision.

Article 2

Modifications of the authorised grading methods or apparatuses thereof referred to in Article 1 shall be authorised by Commission Implementing Decision.

Article 3

Decision 2009/622/EC is repealed.

Article 4

This Decision is addressed to the Slovak Republic.

Done at Brussels, 9 June 2023.

For the Commission
Janusz WOJCIECHOWSKI
Member of the Commission

ANNEX

GRADING METHODS FOR THE CLASSIFICATION OF PIG CARCASSES IN SLOVAKIA

PART I

Two-Point (Zwei Punkte – ZP)

1. The rules provided for in this Part shall apply when the classification of pig carcasses is carried out by use of the 'Two-point method (Zwei-punkte, ZP)' measuring by ruler.
2. This method may be implemented using a ruler, with the grading determined on the basis of the prediction equation. It is based on the manual measurement on the mid-line of the split carcass of the thickness of the muscle and of the thickness of the fat.
3. The lean meat content of carcasses shall be calculated in accordance with the following formula:

$$Y = 60,45 - 0,4 \times F + 0,075 \times M$$

where:

- Y = the estimated percentage of lean meat in the carcass;
- F = the thickness of fat (including rind) in millimeters, measured on the mid-line of the split carcass at the thinnest location above the *musculus gluteus medius*;
- M = the thickness of muscle in millimeters, measured on the mid-line of the split carcass at the shortest connection between the front (cranial) end of the *musculus gluteus medius* and the upper (dorsal) edge of the spinal canal.

This formula shall be valid for carcasses weighing between 60 and 120 kg.

PART II

Fat-O-Meater (FOM)

1. The rules provided for in this Part shall apply when the classification of pig carcasses is carried out by means of the apparatus 'Fat-O-Meater (FOM)'.
2. The apparatus shall be equipped with a probe of 6-millimetre diameter containing a photodiode of the Siemens SFH 950 type and a photodetector (type SFH 960), having an operation distance of between 3 and 103 millimeters. The results of the measurements are converted into estimated lean meat content by means of a computer.
3. The lean meat content of the carcass shall be calculated in accordance with the following formula:

$$Y = 61,213 + 0,152 \times M - 0,624 \times F$$

where:

- Y = the estimated lean meat content in the carcass;
- M = the thickness of muscle in millimeters measured between the second and third last ribs, 70 mm beside the mid-line of the split carcass;
- F = the thickness of fat (including rind) in millimeters, measured between the second and third last ribs, 70 mm beside the mid-line of the split carcass;

This formula shall be valid for carcasses weighing between 60 and 120 kilograms.

PART III

Fat-O-Meater II (FOM II)

1. The rules provided for in this Part shall apply when the classification of pig carcasses is carried out by means of the apparatus 'Fat-O-Meater II (FOM II)'.
2. The apparatus is a Fat-O-Meater type of equipment and it shall be equipped with a probe of six mm diameter containing a photodetector (Siemens, of the type SFH 960 – BP 103 or similar) and having an operating depth up to 125 mm connected with long-term storage of collected data. All legally relevant acquisitions and analyses are contained within the FOM II pistol.
3. The lean meat content of carcasses shall be calculated in accordance with the following formula:

$$Y = 63,21 - 0,643 \times F + 0,089 \times M$$

where:

- Y = the estimated percentage of lean meat in the carcass;
- M = the thickness of the muscle in millimeters, measured between the second and the third last ribs, 70 mm beside the mid-line of the split line;
- F = the thickness of the fat in millimeters, measured between the second and the third last ribs, 70 mm beside the mid-line of the split line;

This formula shall be valid for carcasses weighing between 60 and 120 kg.

PART IV

UltraFOM 300 (UFOM)

1. The rules provided for in this Part shall apply when the classification of pig carcasses is carried out by means of the apparatus 'UltraFOM 300 (UFOM)'.
2. The apparatus shall be equipped with an ultrasonic probe at 4 MHz (Krautkrämer MB 4 SE). The ultrasonic signal is digitised, stored and processed by a microprocessor (type Intel 80 C 32). The results of the measurements shall be converted into estimated lean meat content by means of the Ultrafom apparatus itself.
3. The lean meat content of the carcasses shall be calculated in accordance with the following formula:

$$Y = 64,436 + 0,073 \times M - 0,742 \times F$$

where:

- Y = the estimated lean meat content in the carcass;
- M = the thickness of muscle in millimeters measured between the second and third last ribs, 70 mm beside the mid-line of the split carcass;
- F = the thickness of fat (including rind) in millimeters, measured between the second and third last ribs, 70 mm beside the mid-line of the split carcass;

This formula shall be valid for carcasses weighing between 60 and 120 kilograms.

COMMISSION IMPLEMENTING DECISION (EU) 2023/1157**of 9 June 2023****on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Virazan referred by France in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council***(notified under document C(2023) 3710)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 36(3) thereof,

Whereas:

- (1) On 8 January 2016, the biocidal product Virazan was authorised in France by mutual recognition in sequence of an authorisation granted by United Kingdom in accordance with Article 33 of Regulation (EU) No 528/2012. The biocidal product is a rodenticide, falling under product-type 14 and is placed on the market in pre-filled tamper-resistant bait boxes used for indoor control of mice by professionals. The biocidal product contains the approved active substance alphachloralose. The authorisation holder of the biocidal products is SBM Développement SAS.
- (2) In 2019, France was informed by the Netherlands and Finland that in 2018 a significant increase of cases of primary and secondary poisonings of cats and dogs with symptoms of alphachloralose poisoning had been reported by poison centres, pet owners and veterinary clinics. In France, the French veterinary poisoning centres had also reported an increase of alphachloralose poisoning of companion animals, mainly primary poisoning of dogs, in 2017 and 2018.
- (3) On 9 December 2019, France amended the authorisation of the biocidal product in accordance with Article 48(1), point (a), of Regulation (EU) No 528/2012 to address the primary poisoning incidents involving dogs and secondary poisoning incidents involving cats.
- (4) France amended the authorisation by requiring additional labelling on the biocidal product to indicate the risk for humans and non-target organisms and on the packaging to indicate the obligation to use the biocidal product only in bait boxes.
- (5) Pursuant to Article 48(3), third subparagraph, read in conjunction with Article 35(2) of Regulation (EU) No 528/2012, on 15 April 2020, Germany referred to the coordination group objections to the amendment of the authorisation of the biocidal product made by France.
- (6) The objection from Germany related to the legal basis under which the product can be authorised, as according to Germany, the product does not fully meet the conditions of Article 19(1) of Regulation (EU) No 528/2012 due to the risk of primary and secondary poisoning of animals and may therefore be authorised only under Article 19(5). France considered that the biocidal product complies with Article 19(1) of Regulation (EU) No 528/2012 and that therefore Article 19(1) is the correct legal basis for the amended authorisation.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

- (7) On 6 June 2020, the secretariat of the coordination group invited the other concerned Member States and the authorisation holder to submit written comments on the referral. The authorisation holder submitted written comments on 30 June 2020, 6 July 2020 and 23 July 2020. The referral was discussed in the coordination group on 6 and 23 July 2020 with the participation of the authorisation holder.
- (8) As no agreement was reached in the coordination group, on 21 October 2020, France, as a reference Member State for the purposes of amending the authorisation under Article 48(1), first subparagraph, of Regulation (EU) No 528/2012, referred the unresolved objections to the Commission pursuant to Article 36(1) of that Regulation and provided the Commission with a detailed statement of the matter on which Member States were unable to reach an agreement and the reasons for their disagreement. That statement was forwarded to the Member States concerned and to the authorisation holder.
- (9) In May 2021, the Finnish Safety and Chemical Agency requested an opinion from the Finnish Food Authority and the Finnish Veterinary Association on the effects of biocidal products containing alphachloralose on pets and the need to restrict the use of such products. That opinion, which Finland shared with the Commission, stated that biocidal products containing alphachloralose cause significant harm and suffering to both pets and wildlife and that the number of pet poisonings reported to the Finnish Safety and Chemical Agency and the Finnish Food Authority is significant.
- (10) In addition, the Swedish Chemical Agency obtained additional information in the form of blood sample analyses from the University Animal Hospital in Uppsala, Sweden, which confirmed the presence of alphachloralose in the blood of poisoned animals.
- (11) According to Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012, it is a condition for granting an authorisation that the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects.
- (12) Article 19(5), first subparagraph, of Regulation (EU) No 528/2012 provides that a biocidal product may be authorised when the conditions laid down in Article 19(1), point (b)(iii), are not fully met, where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation. Furthermore, Article 19(5), second subparagraph, states that the use of a biocidal product authorised pursuant to that provision is to be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised. The use of a biocidal product authorised pursuant to that paragraph is to be restricted to Member States in which the condition set out in Article 19(5), first subparagraph, is met.
- (13) The Commission has carefully examined the information submitted by the Member States and by the authorisation holder of the biocidal product, including the fact that incidents of animal poisoning by products containing alphachloralose were also reported in other Member States and in Norway. The Commission also takes into account the opinion from the Finnish Food Authority and the Finnish Veterinary Association, as well as the reports from the University Animal Hospital in Uppsala and the Swedish Veterinary Association, which strongly indicate that the biocidal product has unacceptable effects on animal health, and which confirm, by analytical tests conducted on the poisoned animals, that a significant number of incidents of secondary poisoning by alphachloralose involving cats had occurred, as well as all the information provided and the discussions held in the context of disagreements for other biocidal products containing alphachloralose that were referred to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012.
- (14) The Commission recognises that it is technically and scientifically impossible to link the reported secondary poisoning cases to a specific biocidal product, as it is not possible to identify which of the specific products was ingested by the mouse that was ingested by the cat. It is only possible to detect the presence of the active substance alphachloralose in the tissue of the animals and sometimes in the carcasses of dead rodents in the stomach of poisoned cats. However, it is clear that those poisoning incidents were linked to biocidal products containing alphachloralose, including the biocidal product.

- (15) Based on similar considerations, the Commission has recently adopted, in respect of similar products containing alphachloralose, Commission Implementing Decisions (EU) 2022/1005 ⁽²⁾, (EU) 2022/1006 ⁽³⁾ and (EU) 2022/1388 ⁽⁴⁾.
- (16) The Commission considers that, while the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 are not fully met due to the unacceptable risks for animal health arising from the use of the biocidal product, no objection was referred to the coordination group on the rest of the conditions laid down in Article 19(1), point (b), and, regarding the risks to animal health identified, the risk mitigation measures applied by Member States are likely to reduce the risk of primary and secondary poisoning.
- (17) The Commission therefore considers that, due to the risk of primary and secondary poisoning of dogs in France and of cats in several Member States, the biocidal product does not fully meet the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012.
- (18) Therefore, in accordance with Article 19(5) of Regulation (EU) No 528/2012, the biocidal product may only be authorised in Member States who consider that not authorising it would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation.
- (19) Also, in accordance with Article 19(5) of Regulation (EU) No 528/2012, the use of the biocidal product is to be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised.
- (20) The active substance alphachloralose was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ⁽⁵⁾ for use in biocidal products of product-type 14, and is therefore, pursuant to Article 86 of Regulation (EU) No 528/2012, deemed to have been approved under that Regulation, subject to the specifications and conditions set out in Annex I to Directive 98/8/EC.
- (21) On 24 December 2019, pursuant to Article 13(1) of Regulation (EU) No 528/2012, an application for renewal of the approval of the active substance alphachloralose was submitted to the European Chemicals Agency. On 15 October 2020, the evaluating competent authority of Poland informed the Commission that it had decided, pursuant to Article 14(1) of that Regulation, that a full evaluation of the application for renewal was necessary.
- (22) For reasons beyond the control of the applicants, the approval of alphachloralose for use in biocidal products of product-type 14, which was to expire on 30 June 2021, would have expired before a decision would have been taken on its renewal. Therefore, the expiry date of the approval of alphachloralose was postponed to 31 December 2023 by Commission Implementing Decision (EU) 2021/333 ⁽⁶⁾, to enable the examination of the application.

⁽²⁾ Commission Implementing Decision (EU) 2022/1005 of 23 June 2022 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product family Alphachloralose Grain referred by France and Sweden in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (notified under document C(2022) 4193) (OJ L 168, 27.6.2022, p. 86).

⁽³⁾ Commission Implementing Decision (EU) 2022/1006 of 24 June 2022 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product family Alphachloralose Pasta referred by France and Sweden in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (notified under document C(2022) 4226) (OJ L 168, 27.6.2022, p. 90).

⁽⁴⁾ Commission Implementing Decision (EU) 2022/1388 of 23 June 2022 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Par'Appât Souricide Canadien Foudroyant referred by France and Sweden in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (notified under document C(2022) 4220) (OJ L 208, 10.8.2022, p. 7).

⁽⁵⁾ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

⁽⁶⁾ Commission Implementing Decision (EU) 2021/333 of 24 February 2021 postponing the expiry date of approval of alphachloralose for use in biocidal products of product-type 14 (OJ L 65, 25.2.2021, p. 58).

- (23) The risk of primary and secondary poisoning of animals due to the use of biocidal products containing alphachloralose, the differences in the occurrence of primary and secondary poisoning incidents among Member States and the necessary risk mitigation measures to be applied to reduce that risk to an acceptable level should be also assessed in the context of the evaluation of the application for renewal of the approval of alphachloralose and should subsequently be duly taken into account by Member States in the authorisation of biocidal products containing alphachloralose.
- (24) The Commission therefore considers that risk mitigation measures to address the risk of primary and secondary poisoning from the use of the biocidal product should, exceptionally, until the conclusion of the evaluation of the application for renewal of the approval of alphachloralose, take into account the particular circumstances and available scientifically validated evidence of the occurrence of primary and secondary poisoning incidents in the individual Member States.
- (25) On 26 October 2022, the Commission provided the authorisation holder with the opportunity to provide written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012. The authorisation holder provided comments, which the Commission subsequently considered.
- (26) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

The biocidal product identified by the asset numbers in the Register for Biocidal Products BE-0003002-0000, CH-0009788-0000, DE-0011801-0000, DK-0007141-0000, FR-0005302-0000, IE-0007441-0000, IT-0012826-0000, NL-0005019-0000, PT-0010276-0000 does not fully meet the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012.

The biocidal product may only be authorised in accordance with Article 19(5) of Regulation (EU) No 528/2012 in Member States who consider that not authorising it would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation.

The use of the biocidal product shall be subject to appropriate risk mitigation measures, as referred to in Article 19(5) of Regulation (EU) No 528/2012, which in each Member State shall be adopted based on the particular circumstances and available evidence of the occurrence of secondary poisoning incidents in that Member State.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 9 June 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission

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