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DECISIONS

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⁽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.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1386

of 9 August 2022

extending a derogation from Council Regulation (EC) No 1967/2006 as regards the minimum distance from coast and the minimum sea depth for boat seines fishing for transparent goby (*Aphia minuta*) in certain territorial waters of Italy (Tuscany and Liguria)

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) On 4 October 2011, the Commission adopted Implementing Regulation (EU) No 988/2011 ⁽²⁾ establishing for the first time a derogation from Article 13(1), first subparagraph of Regulation (EC) No 1967/2006 until 31 March 2014 as regards the minimum distance from the coast and the minimum sea depth for boat seines fishing for transparent goby (*Aphia minuta*) in certain territorial waters of Italy (Tuscany and Liguria). An extension of that derogation was granted by Commission Implementing Regulation (EU) 2015/2407 ⁽³⁾, which expired on 31 March 2018. A further extension of that derogation was granted by Commission Implementing Regulation (EU) 2018/1634 ⁽⁴⁾, which expired on 31 March 2021.
- (2) On 10 March 2021, the Commission received from Italy a request for an extension of that derogation, concerning the use of boat seines fishing for transparent goby (*Aphia minuta*), within its territorial waters in the regions of Tuscany and Liguria.
- (3) Italy provided up-to-date scientific and technical justifications for the renewal of that derogation.
- (4) Italy adopted the management plan by Decree ⁽⁵⁾ in accordance with Article 19(2) of Regulation (EC) No 1967/2006 ('Italian management plan') on 14 October 2021.

⁽¹⁾ OJ L 409, 30.12.2006, p. 11.

⁽²⁾ Commission Implementing Regulation (EU) No 988/2011 of 4 October 2011 establishing a derogation from Council Regulation (EC) No 1967/2006 as regards the minimum distance from coast and the minimum sea depth for boat seines fishing for transparent goby (*Aphia minuta*) in certain territorial waters of Italy (OJ L 260, 5.10.2011, p. 15).

⁽³⁾ Commission Implementing Regulation (EU) 2015/2407 of 18 December 2015 renewing the derogation from Council Regulation (EC) No 1967/2006 as regards the minimum distance from coast and the minimum sea depth for boat seines fishing for transparent goby (*Aphia minuta*) in certain territorial waters of Italy (OJ L 333, 19.12.2015, p. 104).

⁽⁴⁾ Commission Implementing Regulation (EU) 2018/1634 of 30 October 2018 renewing the derogation from Council Regulation (EC) No 1967/2006 as regards the minimum distance from coast and the minimum sea depth for boat seines fishing for transparent goby (*Aphia minuta*) in certain territorial waters of Italy (OJ L 272, 31.10.2018, p. 35).

⁽⁵⁾ Gazzetta Ufficiale della Repubblica Italiana 297, 15.12.2021, pag. 46.

- (5) The request concerns fishing activities already authorised by Italy and covers vessels which have a track record of more than 5 years in the fishery and operate under the Italian management plan adopted in accordance with Article 19(2) of Regulation (EC) No 1967/2006 ('management plan') on 14 October 2021.
- (6) The request covers 117 vessels, smaller than 14 m in length overall and with a total effort of 5 886,9 kW for vessels, and the management plan guarantees no future increase in the fishing effort, as required by Article 13(9) of Regulation (EC) No 1967/2006.
- (7) Those vessels are included on a list communicated to the Commission in line with Article 13(9) of Regulation (EC) No 1967/2006.
- (8) The Scientific, Technical and Economic Committee for Fisheries (STECF) assessed the extension of the derogation requested by Italy and the related draft management plan at its plenary session from 22 to 26 March 2021 ⁽⁶⁾.
- (9) The overall assessment by the STECF is positive and the draft management plan contains the main elements supporting the request. Information on its biology and ecology, fleet and effort are well presented. Italy was requested to examine few elements that required further clarification on the position of fishing operations, the level of the safeguards triggers and the timing of management response. In order to address these issues, the Italian authorities agreed to provide the additional data required. The derogation requested by Italy complies with the conditions set out in Article 13(5) and (9) of Regulation (EC) No 1967/2006.
- (10) The extension of the derogation requested by Italy affects a limited number of vessels and there are specific geographical constraints, given both the limited size of the continental shelf and the spatial distribution of the target species which limit the fishing grounds.
- (11) The fishery cannot be undertaken with other gears since only boat seines have the technical characteristics necessary to carry out this type of fishery.
- (12) As mentioned in recital 9, STECF requested additional data on spatial distribution of fishing operations in relation to the distribution of the seagrass habitats. Italy provided these additional data that confirm the fishing location and the absence of overlap with *Posidonia* beds. In addition, with respect to the impact on the seabed, the observations carried out on board during the fishing seasons have shown that the boat seines operate effectively only on the clean seabed, made of sand or mud. Account taken of the above, it is concluded that boat seines fishing has no significant impact on protected habitats and is very selective, since the seines are hauled in the water column and do not touch the seabed because collection of material from the seabed would damage the target species and make the selection of the fished species virtually impossible due to their very small size.
- (13) The fishing activities concerned fulfil the requirements of Article 4 of Regulation (EC) No 1967/2006 since the management plan explicitly prohibits to fish above protected habitats.
- (14) The fishing activities concerned do not interfere with gears other than trawls, seines or similar towed nets.
- (15) Moreover, the fishery has no significant impact on the marine environment, since the boat seines are very selective gears and do not touch the seabed.

⁽⁶⁾ Scientific, Technical and Economic Committee for Fisheries (STECF) - 66th Plenary Report (PLEN-21-01). EUR 28359 EN, Publications Office of the European Union, Luxembourg, 2021, available here: https://stecf.jrc.ec.europa.eu/reports/plenary/-/asset_publisher/os6k/document/id/2851300.

- (16) The requirements of Article 8(1), point (h) of Regulation (EC) No 1967/2006, as replaced by Article 8(1) and Annex IX, Part B, section I to Regulation (EU) 2019/1241 of the European Parliament and of the Council ⁽⁷⁾, are not applicable since they relate to trawlers.
- (17) Italy authorised a derogation from the minimum mesh size established in Article 9 of Regulation (EC) No 1967/2006 on the basis of the fulfilment of the requirements of Article 9(7) of that Regulation given the highly selective nature of the fisheries concerned, its negligible effect on the marine environment and that it is not affected by the provisions in Article 4(5) of Regulation (EC) No 1967/2006.
- (18) Although Article 9 of Regulation (EC) No 1967/2006 was deleted by Regulation (EU) 2019/1241, Annex IX, Part B, point 4 to that Regulation allows derogations from minimum mesh sizes to continue to apply on the basis of certain conditions referred to in Article 15(5) of that Regulation. Such derogations should have been in force on 14 August 2019, do not lead to a deterioration of selectivity standards, in particular in terms of an increase in catches of juveniles, and aim at achieving the objectives and targets set out in Articles 3 and 4 of that Regulation. The requested extension complies with the referred conditions.
- (19) The fishing activities concerned take place at a very short distance from the coast in shallow waters within the 3 nautical miles stripe and therefore do not interfere with the activities of other vessels.
- (20) The activity of boat seines is regulated in the management plan to ensure that catches of species mentioned in Annex IX to Regulation (EU) 2019/1241 are minimal. Moreover, according to paragraph 6 of the Italian management plan, the fishing for *Aphia minuta* is limited to a fishing season from 1 November to 31 March each year and to a maximum of 60 days per boat for every fishing season.
- (21) Boat seines are highly selective and do not target cephalopods.
- (22) The management plan includes measures for the monitoring of fishing activities, as provided for in Article 13(9), third subparagraph of Regulation (EC) No 1967/2006.
- (23) The fishing activities concerned fulfil the requirements of Article 14 of Council Regulation (EC) No 1224/2009 ⁽⁸⁾.
- (24) The requested extension of the derogation should therefore be granted for 3 years.
- (25) Italy should report to the Commission in due time and in accordance with the monitoring plan provided for in the Italian management plan.
- (26) A limitation in duration of the derogation should be introduced, to allow prompt corrective management measures in case the report to the Commission shows a poor conservation status of the exploited stock, while providing scope to enhance the scientific basis for an improved management plan.
- (27) Since the derogation granted by Implementing Regulation (EU) 2018/1634 expired on 31 March 2021 and the fishing season starts on 1 November each year, in order to ensure legal continuity, this Regulation should apply with effect from 1 November 2021.

⁽⁷⁾ Regulation (EU) 2019/1241 of the European Parliament and of the Council of 20 June 2019 on the conservation of fisheries resources and the protection of marine ecosystems through technical measures, amending Council Regulations (EC) No 1967/2006, (EC) No 1224/2009 and Regulations (EU) No 1380/2013, (EU) 2016/1139, (EU) 2018/973, (EU) 2019/472 and (EU) 2019/1022 of the European Parliament and of the Council, and repealing Council Regulations (EC) No 894/97, (EC) No 850/98, (EC) No 2549/2000, (EC) No 254/2002, (EC) No 812/2004 and (EC) No 2187/2005 (OJ L 198, 25.7.2019, p. 105).

⁽⁸⁾ Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy, amending Regulations (EC) No 847/96, (EC) No 2371/2002, (EC) No 811/2004, (EC) No 768/2005, (EC) No 2115/2005, (EC) No 2166/2005, (EC) No 388/2006, (EC) No 509/2007, (EC) No 676/2007, (EC) No 1098/2007, (EC) No 1300/2008, (EC) No 1342/2008 and repealing Regulations (EEC) No 2847/93, (EC) No 1627/94 and (EC) No 1966/2006 (OJ L 343, 22.12.2009, p. 1).

- (28) For reasons of legal certainty, this Regulation should enter into force as a matter of urgency.
- (29) The measures provided for in this Regulation are in accordance with the opinion of the Committee for Fisheries and Aquaculture,

HAS ADOPTED THIS REGULATION:

Article 1

Derogation

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

- (a) are registered in the maritime Directorates (Direzione Marittima) of Genova and Livorno respectively;
- (b) have a track record in the fishery of more than 5 years and do not involve any further increase in the fishing effort deployed; and
- (c) hold a fishing authorisation and operate under the management plan adopted by Italy in accordance with Article 19 of Regulation (EC) No 1967/2006.

Article 2

Monitoring plan and reporting

Italy shall communicate to the Commission, by 1 November 2022, a report drawn up in accordance with the monitoring plan established in the management plan referred to in Article 1(c).

Article 3

Entry into force and period of application

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

It shall apply from 1 November 2021 to 31 March 2024.

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

Done at Brussels, 9 August 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1387**of 9 August 2022**

amending Implementing Regulation (EU) 2022/58 imposing a definitive anti-dumping duty on imports of certain grain-oriented flat-rolled products of silicon-electrical steel originating in the People's Republic of China, Japan, the Republic of Korea, the Russian Federation and the United States of America following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/1036 of the European Parliament and of the Council of 8 June 2016 on protection against dumped imports from countries not members of the European Union ⁽¹⁾, and in particular Article 14(1) thereof,

Whereas:

- (1) Imports of certain grain-oriented flat-rolled products of silicon-electrical steel ('GOES') originating in the People's Republic of China, Japan, the Republic of Korea, the Russian Federation and the United States of America are subject to a definitive anti-dumping duty, imposed by Commission Implementing Regulation (EU) 2022/58 ⁽²⁾.
- (2) On 7 July 2021, AK Steel Corporation ('the applicant'), TARIC ⁽³⁾ additional code C044, a company located in the United States of America ('USA'), whose exports to the Union of GOES are subject to the *ad valorem* anti-dumping duty of 22 %, informed the Commission that it had changed its name to 'Cleveland-Cliffs Steel Corporation' based in Ohio, USA.
- (3) The company requested the Commission to confirm that the change of name does not affect the right of the company to benefit from the individual anti-dumping duty rate applied to it under its previous name.
- (4) The Commission invited the company to provide a questionnaire reply which was submitted on 20 August 2021. Additional clarifications were provided on 3 January 2022.
- (5) The Commission examined the information supplied and concluded that the change of name was properly registered with the relevant authorities, and did not result in any new relationship with other groups of companies, which were not investigated by the Commission.
- (6) The Commission assessed, among others, the following supporting documents provided by the applicant: certificate of amendment, company registration certificates and audited financial statements. The Union industry was consulted on the request but did not provide any comments.
- (7) Accordingly, this change of name does not affect the findings of Implementing Regulation (EU) 2022/58 and in particular the *ad valorem* anti-dumping duty rate applicable to it.
- (8) The name change should take effect as of the date on which the company informed the Commission that it had changed its name (as indicated under recital 2 above).
- (9) Given the considerations in the recitals above, the Commission considered it appropriate to amend Implementing Regulation (EU) 2022/58 to reflect the changed name of the company previously attributed to additional TARIC code C044.

⁽¹⁾ OJ L 176, 30.6.2016, p. 21.

⁽²⁾ Commission Implementing Regulation (EU) 2022/58 of 14 January 2022 imposing a definitive anti-dumping duty on imports of certain grain-oriented flat-rolled products of silicon-electrical steel originating in the People's Republic of China, Japan, the Republic of Korea, the Russian Federation and the United States of America following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council (OJ L 10, 17.1.2022, p. 17).

⁽³⁾ The Integrated Tariff of the European Union.

- (10) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 15(1) of Regulation (EU) 2016/1036,

HAS ADOPTED THIS REGULATION:

Article 1

1. Article 1(4) of Implementing Regulation (EU) 2022/58 is amended as follows:

'AK Steel Corporation, Ohio, United States of America	22,0 %	C044'
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is replaced by

'Cleveland-Cliffs Steel Corporation, Ohio, United States of America	22,0 %	C044'
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2. TARIC additional code C044 previously attributed to AK Steel Corporation, shall apply to Cleveland-Cliffs Steel Corporation as of 7 July 2021. Any definitive duty paid on imports of products manufactured by Cleveland-Cliffs Steel Corporation in excess of the anti-dumping duty established in Article 1(4) of Implementing Regulation (EU) 2022/58 as regards AK Steel Corporation shall be repaid or remitted in accordance with the applicable customs legislation.

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, 9 August 2022.

For the Commission
The President
Ursula VON DER LEYEN

DECISIONS

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

(notified under document C(2022) 4220)

(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 17 June 2013, the biocidal product Physalys Expresse (currently placed on the market under the tradename Protect home express) was nationally authorised by the United Kingdom in accordance with Directive 98/8/EC of the European Parliament and of the Council ⁽²⁾. On 19 November 2015 and 26 February 2019, the biocidal product was mutually recognised in sequence by France (Pat'Appât Souricide Canadien Foudroyant) and by Sweden (Rodicum Express) in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council ('the biocidal product'). The biocidal product is a rodenticide, falling under product-type 14 in accordance with Annex V to Regulation (EU) No 528/2012 to be used for indoor control of mice in pre-filled tamper resistant bait boxes by non-professionals. It contains the approved active substance alphachloralose. Current authorisation holder of the biocidal products is SBM Développement.
- (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 were 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, between 2017 and 2018.
- (3) In 2019 Sweden received information from veterinary clinics indicating that rodenticides containing alphachloralose had caused secondary poisoning in cats. The Swedish University of Agricultural Sciences, Small Animal Hospital stated that, there had, in recent years, been an increased number of reports of suspected cases of alphachloralose poisoning in cats.
- (4) On 9 December 2019 and 17 December 2019 France and Sweden respectively amended the authorisations of the biocidal product Pat'Appât Souricide Canadien Foudroyant and Rodicum Express 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.
- (5) France amended the authorisation to require additional labelling on the biocidal product to clearly indicate the risk for humans and non-target organisms and indicate on the packaging the obligation to use the biocidal product only in bait boxes.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ 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) Based on the information supplied to the Swedish Chemicals Agency, Sweden amended the authorisation of the product to restrict the use to trained professionals and added the conditions that the biocidal product was not to be used in environments where cats are expected to be present and that dead mice must be collected after the use of the biocidal product. The authorisation holder appealed the amendment made by Sweden and the Swedish Land and Environment Court concluded that the Swedish Chemicals Agency's decision to amend the authorisation of products containing alphachloralose and to issue a restriction in respect of those products were well-founded, and the appeal was rejected.
- (7) Pursuant to Article 48(3) of Regulation (EU) No 528/2012, on 15 April 2020, Germany and Denmark referred to the coordination group objections to the amendments of the authorisation of the biocidal product, made by France and Sweden.
- (8) The objection from Germany related to the measures introduced by France, which were in their opinion not sufficient. Germany considered that, in order to address secondary poisoning incidents, the use of the biocidal product should be restricted to trained professionals.
- (9) The objection from Denmark relates to the restriction of the use of the biocidal product to 'trained professionals' by Sweden. According to Denmark, the restriction of use to trained professionals was not justified in their territory. Denmark informed that they were not aware of secondary poisoning happening in Denmark and that there was no definition of 'trained professionals' in relation to chemical control of mice or in their national legislation.
- (10) 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.
- (11) As no agreement was reached in the coordination group, France on 21 October 2020 and Sweden on 7 August 2020, referred the unresolved objections to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012 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.
- (12) After the referrals pursuant to Article 36(1) of Regulation (EU) No 528/2012 by France and Sweden, in May 2021 the Finnish Safety and Chemical Agency (Tukes) requested an opinion from the Finnish Food Authority and the Finnish Veterinary Association on the effects of alphachloralose products on pets and the need to restrict the use of alphachloralose 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, that the number of pet poisonings reported to Tukes and the Finnish Food Authority is significant and that derogations to the authorisations made in accordance with Article 37(1)(a) and (c) of Regulation (EU) No 528/2012 in 2019 consisting of restricting the marketing and use of the biocidal products for non-professionals only to prefilled bait boxes, which Finland had already introduced, had not sufficiently reduced the number of cases. Therefore, the Finnish Food Authority recommended that the use and availability of products containing alphachloralose should be restricted to trained professionals. On 8 December 2021, Finland modified the authorisations of rodenticides containing alphachloralose to restrict the products to professional use in accordance with Article 48(1) of Regulation (EU) No 528/2012.
- (13) 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 the poisoned animals.
- (14) 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 animals, directly or through drinking water, food, feed, air, or through other indirect effects.

- (15) 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. Article 19(5), second subparagraph, furthermore 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 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 of the first subparagraph is met.
- (16) Having carefully examined the information submitted by the Member States and the authorisation holder of the biocidal product, the Commission considers that the biocidal product does not fully meet the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012, taking 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, in which it was indicated that the biocidal product has unacceptable effects on animal health and confirmed, by analytical tests conducted on the poisoned animals, that a significant number of poisoning incidents with alphachloralose involving cats had occurred.
- (17) 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.
- (18) 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 animals and the environment to that biocidal product is minimised.
- (19) The active substance alphachloralose was included in Annex I to Directive 98/8/EC 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 that Directive.
- (20) On 24 December 2019, pursuant to Article 13(1) of Regulation (EU) No 528/2012, an application for renewal of the active substance alphachloralose was submitted to the 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.
- (21) As a result, for reasons beyond the control of the applicant, the approval of alphachloralose for use in biocidal products of product-type 14 was to expire on 30 June 2021, before a decision would have been taken on its renewal. Therefore, the expiry date of approval of alphachloralose was postponed to 31 December 2023, to enable the examination of the application, by Commission Implementing Decision (EU) 2021/333 ^(*).
- (22) The risk of secondary poisoning of animals due to the use of biocidal products containing alphachloralose and the necessary risk mitigation measures to be applied in order to reduce that risk to an acceptable level should be 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.

(*) 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) Having regard to the foregoing considerations, the Commission considers that risk mitigation measures to address the risk of primary and secondary poisoning incidents from the use of biocidal products containing alphachloralose, in the form placed on the market, should, exceptionally, pending the conclusion of the evaluation of the application for renewal of the approval of alphachloralose, depend on the particular circumstances and available scientifically validated evidence of the occurrence of secondary poisoning incidents in the individual Member States. Some Member States might, for example, consider it necessary to restrict use of biocidal products containing alphachloralose to trained professionals while others might consider that additional labelling requirements suffice.
- (24) On 15 February 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 took into account.
- (25) 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 number in the Register for Biocidal Products FR-0005286-0000 does not fully meet the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012.

The biocidal product identified by the asset number in the Register for Biocidal Products FR-0005286-0000 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.

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, 23 June 2022.

For the Commission
Stella KYRIAKIDES
Member of the Commission

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