Reports of Cases

JUDGMENT OF THE GENERAL COURT (Fourth Chamber)

3 July 2024*

(Biocidal products – Authorisation through mutual recognition – Biocidal product Pat'Appât Souricide Canadien Foudroyant – Commission decision on unresolved objections – Articles 35, 36 and 48 of Regulation (EU) No 528/2012 – Cancellation or amendment of marketing authorisations – Action for annulment – Direct concern – Individual concern – Admissibility – Conditions for granting an authorisation – Article 19(1) of Regulation No 528/2012 – Article 19(5) of Regulation No 528/2012 – Competence of the Commission – Concept of 'national authorisation' – Concept of 'reference Member State' – Manifest error of assessment – Proportionality)

In Case T-667/22,

SBM Développement SAS, established in Écully (France), represented by B. Arash and H. Lindström, lawyers,

applicant,

v

European Commission, represented by M. Escobar Gómez and R. Lindenthal, acting as Agents,

defendant,

supported by

Republic of Finland, represented by H. Leppo and A. Laine, acting as Agents,

intervener,

THE GENERAL COURT (Fourth Chamber),

composed of R. da Silva Passos, President, S. Gervasoni and I. Reine (Rapporteur), Judges,

Registrar: V. Di Bucci,

having regard to the written part of the procedure,

* Language of the case: English.

having regard to the fact that no request for a hearing was submitted by the parties within three weeks after service of notification of the close of the written part of the procedure, and having decided to rule on the action without an oral part of the procedure, pursuant to Article 106(3) of the Rules of Procedure of the General Court,

gives the following

Judgment

1 By its action under Article 263 TFEU, the applicant, SBM Développement SAS, seeks the annulment of Commission Implementing Decision (EU) 2022/1388 of 23 June 2022 on 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 2022 L 208, p. 7; 'the contested decision').

Legal background

2 Article 19 of 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 (OJ 2012 L 167, p. 1) sets out the conditions for granting an authorisation for a biocidal product. Paragraph 1 of that article provides, inter alia, as follows:

'A biocidal product other than those eligible for the simplified authorisation procedure in accordance with Article 25 shall be authorised provided the following conditions are met:

(a) the active substances are included in Annex I or approved for the relevant product-type and any conditions specified for those active substances are met;

(b) it is established, according to the common principles for the evaluation of dossiers for biocidal products laid down in Annex VI, that the biocidal product, when used as authorised and having regard to the factors referred to in paragraph 2 of this Article, fulfils the following criteria:

…

(iii) the biocidal product has no immediate or delayed unacceptable effects itself … on the health of … animals, directly or through drinking water, food, feed, air, or through other indirect effects;

…'

3 Under Article 19(5) of Regulation No 528/2012:

'Notwithstanding paragraphs 1 and 4, a biocidal product may be authorised when the conditions laid down in paragraph 1(b)(iii) and (iv) are not fully met, or may be authorised for making available on the market for use by the general public when the criteria referred to in paragraph 4(c) are 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.

The use of a biocidal product authorised pursuant to this paragraph shall 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 this paragraph shall be restricted to Member States in which the condition of the first subparagraph is met.'

4 Chapter VII of Regulation No 528/2012 concerns the procedures for the mutual recognition of authorisations for biocidal products within the European Union. Article 32 of that regulation is worded as follows:

'1. Applications for mutual recognition of a national authorisation shall be made in accordance with the procedures set out in Article 33 (mutual recognition in sequence) or Article 34 (mutual recognition in parallel).

2. Without prejudice to Article 37, all Member States receiving applications for mutual recognition of a national authorisation for a biocidal product shall, in accordance with and subject to the procedures set out in this Chapter, authorise the biocidal product under the same terms and conditions.'

5 As regards mutual recognition in sequence, Article 33(1) of Regulation No 528/2012 provides, inter alia, as follows:

'Applicants wishing to seek the mutual recognition in sequence, in one or more Member States ("the Member States concerned"), of the national authorisation of a biocidal product already granted in another Member State in accordance with Article 17 ("the reference Member State") shall submit an application to each of the competent authorities of the Member States concerned containing, in each case, a translation of the national authorisation granted by the reference Member State into such official languages of the Member State concerned as it may require.

…'

6 In addition, under Article 35 of Regulation No 528/2012:

'1. A coordination group shall be set up to examine any question, other than matters referred to in Article 37, relating to whether a biocidal product for which an application for mutual recognition has been made in accordance with Article 33 or 34 meets the conditions for granting an authorisation laid down in Article 19.

…

2. If any of the Member States concerned considers that a biocidal product assessed by the reference Member State does not meet the conditions laid down in Article 19, it shall send a detailed explanation of the points of disagreement and the reasons for its position to the reference Member State, the other Member States concerned, the applicant, and, where applicable, to the authorisation holder. The points of disagreement shall be referred without delay to the coordination group.

3. Within the coordination group, all Member States referred to in paragraph 2 of this Article shall use their best endeavours to reach agreement on the action to be taken. They shall allow the applicant the opportunity to make its point of view known. Where they reach agreement within 60 days of the referral of the points of disagreement referred to in paragraph 2 of this Article, the reference Member State shall record the agreement in the Register for Biocidal Products. The

procedure shall then be considered to be closed and the reference Member State and each of the Member States concerned shall authorise the biocidal product in accordance with Article 33(3) or 34(6) as appropriate.'

7 In the event that the Member States fail to reach an agreement, Article 36 of Regulation No 528/2012 provides for a mechanism for communicating unresolved objections to the European Commission, in the following terms:

'1. If the Member States referred to in Article 35(2) fail to reach agreement within the 60-day period laid down in Article 35(3), the reference Member State shall immediately inform the Commission, and provide it with a detailed statement of the matters on which Member States have been unable to reach agreement and the reasons for their disagreement. A copy of that statement shall be forwarded to the Member States concerned, the applicant and, where applicable, the authorisation holder.

2. The Commission may ask the [European Chemicals] Agency for an opinion on scientific or technical questions raised by Member States. Where the Commission does not ask the Agency for an opinion it shall provide the applicant and, where applicable, the authorisation holder with the opportunity to provide written comments within 30 days.

3. The Commission shall adopt, by means of implementing acts, a decision on the matter referred to it. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

4. The decision referred to in paragraph 3 shall be addressed to all Member States and reported for information to the applicant and, where applicable, the authorisation holder. The Member States concerned and the reference Member State shall, within 30 days of notification of the decision, either grant, refuse to grant or cancel the authorisation, or vary its terms and conditions as necessary to comply with the decision.'

8 Article 37 of Regulation No 528/2012 sets out the conditions under which, by way of derogation from the mechanism of mutual recognition provided for in Article 32(2) of that regulation, a Member State may refuse to grant an authorisation or adjust the conditions of the authorisation to be granted.

9 Furthermore, Chapter IX of Regulation No 528/2012 contains several provisions relating to the cancellation, review and amendment of authorisations for biocidal products. In particular, Article 48 of that regulation provides as follows:

'1. Without prejudice to Article 23, the competent authority of a Member State or, in the case of a Union authorisation, the Commission shall at any time cancel or amend an authorisation it has granted where it considers that:

(a) the conditions referred to in Article 19 or, where relevant, in Article 25 are not satisfied;

(b) the authorisation was granted on the basis of false or misleading information; …

(c) the authorisation holder has failed to comply with its obligations under the authorisation or this Regulation.

2. Where the competent authority or, in the case of a Union authorisation, the Commission, intends to cancel or amend an authorisation, it shall inform the authorisation holder thereof and give it the opportunity to submit comments or additional information within a specified time limit. The evaluating competent authority or, in the case of a Union authorisation, the Commission, shall take due account of those comments when finalising its decision.

3. Where the competent authority or, in the case of a Union authorisation, the Commission, cancels or amends an authorisation in accordance with paragraph 1, it shall without delay notify the authorisation holder, the competent authorities of other Member States and, where relevant, the Commission.

Competent authorities that have issued authorisations under the mutual recognition procedure for biocidal products for which the authorisation has been cancelled or amended shall, within 120 days of the notification, cancel or amend the authorisations and shall notify the Commission accordingly.

In the case of disagreement between competent authorities of certain Member States concerning national authorisations subject to mutual recognition the procedures laid down in Articles 35 and 36 shall apply *mutatis mutandis*.'

Background to the dispute

10 The applicant is the holder, in several Member States, of a marketing authorisation for a biocidal product containing the active substance alphachloralose, registered under CAS number 15879-93-3 for product-type 14 (namely, rodenticides). That product, which is marketed under various names in the European Union, is intended for use indoors and against mice ('the biocidal product at issue').

11 The active substance alphachloralose was approved by the Commission and included in Annex I to 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 1998 L 123, p. 1) by Commission Directive 2009/93/EC of 31 July 2009 amending Directive 98/8 to include alphachloralose as an active substance in Annex I to that directive (OJ 2009 L 201, p. 46).

12 On 17 June 2013, the biocidal product at issue was approved by the competent authority of the United Kingdom, in accordance with the national authorisation procedure laid down by Directive 98/8. That authorisation was maintained following the entry into force of Regulation No 528/2012.

13 Between 2014 and 2019, the applicant sought the mutual recognition in sequence, in several Member States, of the national authorisation for the biocidal product at issue already granted in the United Kingdom, pursuant to Article 33 of Regulation No 528/2012. On 21 October 2015 and 26 February 2019, respectively, the French Republic and the Kingdom of Sweden thus authorised the biocidal product at issue, known as 'Pat'Appât Souricide Canadien Foudroyant' in France and 'Rodicum Express' in Sweden.

14 On 9 and 17 December 2019, respectively, the French Republic and the Kingdom of Sweden amended the national authorisation for the biocidal product at issue under Article 48 of Regulation No 528/2012, in response to the communication of several primary poisoning incidents involving dogs and secondary poisoning incidents involving cats.

15 The French Republic thus required additional labelling to be affixed to the biocidal product at issue which clearly emphasised the risk for humans and non-target organisms and which indicated in a very legible manner on the packaging the obligation to use the biocidal product at issue only in bait boxes.

16 The Kingdom of Sweden restricted the use of the biocidal product at issue to trained professionals. It also added two conditions, namely that the biocidal product at issue was not to be used in environments where cats were expected to be present and that the dead mice were to be collected after the use of the biocidal product at issue. The applicant brought an action against those amendments before the Swedish national courts, which dismissed it as unfounded.

17 On 24 December 2019, in accordance with Article 13(1) of Regulation No 528/2012, an application for the renewal of the approval of the active substance alphachloralose was submitted. 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.

18 On 15 April 2020, pursuant to Article 48(3) of Regulation No 528/2012, the Kingdom of Denmark and the Federal Republic of Germany referred, to the coordination group set up under Article 35 of that regulation, objections to the amendments made by the French Republic and the Kingdom of Sweden to the authorisation of the biocidal product at issue.

19 As no agreement was reached in the coordination group, the Kingdom of Sweden, on 7 August 2020 and the French Republic, on 21 October 2020, referred the unresolved objections to the Commission pursuant to Article 36(1) of Regulation No 528/2012 and provided it with a detailed statement of the matters on which Member States were unable to reach an agreement and the reasons for their disagreement.

20 On 8 December 2021, following receipt of an opinion from the Ruokavirasto (Finnish Food Authority) and the Finlands Veterinärförbund (Finnish Veterinary Association) on the effects of alphachloralose products on pets, the Republic of Finland also amended the authorisations of rodenticide products containing alphachloralose to restrict them to professional use.

21 On 23 June 2022, the Commission adopted the contested decision on the basis of Article 36(3) of Regulation No 528/2012. According to that decision, after carefully examining the information submitted by the Member States and by the applicant, the Commission considered that the biocidal product at issue did not fully meet the conditions laid down in Article 19(1)(b)(iii) of Regulation No 528/2012.

22 The Commission therefore considered that, in accordance with Article 19(5) of Regulation No 528/2012, the biocidal product at issue may only be authorised in Member States which 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. In addition, the

Commission considered that, if authorised, the use of the biocidal product at issue should be subject to appropriate risk mitigation measures to ensure that the exposure of animals and the environment to that biocidal product is minimised.

Forms of order sought

23 The applicant claims that the Court should:

– annul the contested decision;

– order the Commission to pay the costs of the proceedings.

24 The Commission, supported by the Republic of Finland, contends that the Court should:

– dismiss the application as inadmissible;

– in any event, dismiss the action as unfounded;

– order the applicant to pay the costs.

Law

Admissibility of the action

25 Without formally raising a plea of inadmissibility, the Commission, supported by the Republic of Finland, submits that the action is inadmissible on the ground that the applicant does not fulfil any of the conditions of the fourth paragraph of Article 263 TFEU.

26 According to the Commission, first, the applicant is not the addressee of the contested decision. Second, that decision does not constitute a regulatory act that does not entail implementing measures, since the Member States are required to take a decision cancelling or amending the existing authorisations. Third, the applicant is not directly concerned by the contested decision, since, even though that decision has binding legal effects, it requires implementing measures and leaves a broad discretion to the Member States. The Member States can choose whether or not to maintain the authorisation of the biocidal product at issue, on the basis of their own discretionary proportionality assessments. They can authorise the product under conditions which comply with the provisions of Article 19(5) of Regulation No 528/2012, while retaining a broad discretion as regards the adoption of the risk mitigation measures which they consider to be the most appropriate.

27 Moreover, in the Commission's submission, it does not follow from Article 36(4) of Regulation No 528/2012 that the Member States must automatically cancel the granted authorisations. On the contrary, the contested decision does not prescribe a result. Nor does it disqualify the biocidal product at issue from being marketed and used under Article 17(1) of Regulation No 528/2012, since the Member States have a period of 30 days in which to comply with the contested decision and to review the authorisation at issue, pursuant to Article 36(4) of that regulation.

28 The applicant disputes the arguments of the Commission and the Republic of Finland.

29 It should be borne in mind that, pursuant to fourth paragraph of Article 263 TFEU, any natural or legal person may, under the conditions laid down in the first and second paragraphs of that article, institute proceedings against an act addressed to that person or which is of direct and individual concern to them, and against regulatory acts which are of direct concern to them and do not entail implementing measures.

30 In the present case, in the first place, it is not disputed by the parties that the contested decision is addressed solely to the Member States. The applicant is therefore not an addressee of that decision.

31 In the second place, it is to be recalled that the admissibility of an action brought by a natural or legal person against an act which is not addressed to them, in accordance with the fourth paragraph of Article 263 TFEU, is subject to the condition that they be accorded standing to bring proceedings, which arises in two situations. First, such proceedings may be instituted if the act is of direct and individual concern to them. Second, such persons may bring proceedings against a regulatory act not entailing implementing measures if that act is of direct concern to them (judgment of 17 September 2015, *Mory and Others* v *Commission*, C-33/14 P, EU:C:2015:609, paragraphs 59 and 91).

32 According to the case-law, the condition that a natural or legal person must be directly concerned by the decision against which the action is brought, laid down in the fourth paragraph of Article 263 TFEU, requires two cumulative criteria to be met, namely, first, that the contested measure directly affect the legal situation of the individual and, second, that it leave no discretion to the addressees who are entrusted with the task of implementing it, such implementation being purely automatic and resulting from the EU rules alone without the application of other intermediate rules (judgment of 5 May 1998, *Dreyfus* v *Commission*, C-386/96 P, EU:C:1998:193, paragraph 43; see also judgment of 17 May 2018, *Bayer CropScience and Others* v *Commission*, T-429/13 and T-451/13, EU:T:2018:280, paragraph 57 and the case-law cited).

33 Moreover, as the condition that the applicant must be directly concerned by the act being challenged appears, in identical terms, both in the second limb of the fourth paragraph of Article 263 TFEU and in the third limb of that provision, it must have the same meaning for each of those limbs of that provision. The objective assessment of that condition cannot vary depending on which of the different limbs of that provision is being considered (judgment of 12 July 2022, *Nord Stream 2* v *Parliament and Council*, C-348/20 P, EU:C:2022:548, paragraph 73).

34 Consequently, any act, whether regulatory or another type of act, may, in principle, directly concern an individual and thus directly affect its legal situation, irrespective of whether it entails implementing measures. Accordingly, in a case where the contested act has such effects, the fact that implementing measures have been adopted or have yet to be adopted is not, in itself, relevant since they do not call into question the direct nature of the connection between the contested act and its effects, provided that that act does not leave any discretion to the Member States as to the imposition of those effects on that individual (see, to that effect, judgment of 12 July 2022, *Nord Stream 2* v *Parliament and Council*, C-348/20 P, EU:C:2022:548, paragraph 74).

35 In the present case, according to the first article of the contested decision, the biocidal product at issue does not fully meet the conditions laid down in Article 19(1)(b)(iii) of Regulation No 528/2012. Pursuant to Article 19(5) of that regulation, the contested decision therefore

provides, first, that that product may be authorised only in the Member States which consider that not authorising it would have disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from its use under the conditions laid down in the authorisation, and, second, that the use of that biocidal product must be subject to appropriate risk mitigation measures which are to be adopted in each Member State based on the particular circumstances and available evidence of the occurrence of secondary poisoning incidents in that Member State.

36 In that regard, it should be noted, first, that the authorisations of the biocidal product at issue granted before the adoption of the contested decision were based on the finding that that biocidal product complied with the conditions laid down in Article 19(1) to (4) of Regulation No 528/2012. It is on that basis that the applicant submitted its applications for mutual recognition in sequence in the Member States concerned, within the meaning of Article 33 of that regulation, and that the authorisations of that biocidal product were granted by those States. However, the contested decision invalidates that finding, since it now states that that biocidal product does not fully meet the conditions laid down in Article 19(1)(b)(iii) of Regulation No 528/2012.

37 In addition, it is apparent from Article 36(4) of Regulation No 528/2012, applicable *mutatis mutandis* to the present case, that, within 30 days of notification of the Commission's decision, such as the contested decision, the Member States are required to bring their authorisation into line with that decision. Thus, the contested decision requires all the Member States which have granted an authorisation for the biocidal product at issue to re-examine that authorisation. In that regard, in accordance with Article 19(5) of Regulation No 528/2012, they are required to verify whether not authorising that biocidal product would result in disproportionate negative impacts for society when compared to the risks, in particular, to animal health, arising from its use.

38 Furthermore, before the adoption of the contested decision, under Article 32(2) of Regulation No 528/2012, all Member States which had received an application for mutual recognition of the national authorisation of the biocidal product at issue were required, in principle, to authorise that product under the same terms and conditions.

39 The first article of the contested decision changes the system of mutual recognition applicable until then to the biocidal product at issue, as established by Article 32 of Regulation No 528/2012, since it requires each Member State to review the authorisation granted by weighing up, on the one hand, the disproportionate negative impacts for society of not authorising it and, on the other hand, the risks arising from the use of the product. Such a balancing exercise, which is specific to each Member State, may lead those Member States to withdraw the authorisation of that biocidal product, even though other Member States decide to maintain that authorisation subject, as the case may be, to certain conditions.

40 The contested decision therefore calls into question the authorisations issued by Member States for the biocidal product at issue. By applying Article 19(5) of Regulation No 528/2012, it changes the criteria to which those authorisations are subject and the rules applicable to the mutual recognition of that product. That decision therefore directly affects the applicant's legal situation, within the meaning of the case-law referred to in paragraph 32 above.

41 As to whether the contested decision leaves discretion to the addressees responsible for implementing it, it must be observed that, admittedly, the Member States enjoy a margin of discretion when weighing up, on the one hand, the disproportionate negative impacts for society of not authorising the biocidal product and, on the other hand, the risks arising from the use of that product, under Article 19(5) of Regulation No 528/2012.

42 However, the contested decision has the effect of automatically subjecting the biocidal product at issue to the comparative assessment procedure laid down in Article 19(5) of Regulation No 528/2012, which must be carried out for all existing or future authorisations for that product. The Member States are therefore required to carry out that comparative assessment when re-assessing existing authorisations, as well as any applications for future authorisations, without enjoying any discretion in that regard (see, by analogy, judgment of 19 December 2019, *Probelte* v *Commission*, T-67/18, EU:T:2019:873, paragraph 57).

43 Furthermore, what matters in the context of the assessment of whether the applicant is directly concerned by the contested decision is that that decision now provides for the application of Article 19(5) of Regulation No 528/2012, which automatically changes the legal rules applicable to mutual recognition of authorisations for the biocidal product at issue (see, by analogy, judgment of 19 December 2019, *Probelte* v *Commission*, T-67/18, EU:T:2019:873, paragraph 59).

44 For those reasons, it must be held that the contested decision directly affects the applicant's legal situation, as the holder of the national authorisations for the biocidal product at issue, and leaves no discretion to the Member States responsible for its implementation, since they are required to review existing authorisations and apply the additional condition laid down in Article 19(5) of Regulation No 528/2012, relating to the balancing exercise referred to in paragraph 39 above. The applicant is therefore directly concerned by the contested decision.

45 Since the applicant is directly concerned by the contested decision, it follows that, in order to be acknowledged as having standing to bring proceedings within the meaning of the fourth paragraph of Article 263 TFEU, the applicant must also be individually concerned by that decision.

46 In that regard, it should be recalled that persons other than those to whom an act is addressed may claim to be individually concerned within the meaning of the fourth paragraph of Article 263 TFEU only if that act affects them, by reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons, and by virtue of those factors distinguishes them individually just as in the case of the person addressed (judgment of 15 July 1963, *Plaumann* v *Commission*, 25/62, EU:C:1963:17, p. 107, and judgment of 13 March 2018, *European Union Copper Task Force* v *Commission*, C-384/16 P, EU:C:2018:176, paragraph 93 and the case-law cited).

47 In the present case, first, the contested decision concerns the conditions for the authorisation of the biocidal product at issue held by the applicant in several Member States. In that regard, the applicant is referred to by name in recital 1 of the contested decision, as the current holder of the authorisation of that biocidal product.

48 Second, the referral of the matter to the coordination group established under Article 35(1) of Regulation No 528/2012 follows from the decisions adopted by the French and Swedish authorities to amend the conditions of the authorisation of the biocidal product in question, as is clear from recitals 4 and 5 of the contested decision. On that basis, the applicant participated in

the conciliation procedure within the coordination group, provided for in Article 35 of Regulation No 528/2012, as is apparent from recital 16 of the contested decision. It also provided information which was taken into account by the Commission for the purposes of the adoption of that decision, as is apparent from recital 16 thereof.

49 For those reasons, it must be concluded that the contested decision affects the applicant by reason of certain attributes which are peculiar to it and by reason of circumstances in which it is differentiated from all other persons, so that the applicant is also individually concerned by the contested decision.

50 Therefore, contrary to what is claimed by the Commission, the applicant has standing to bring an action for annulment of the contested decision, since that decision is of direct and individual concern to the applicant, within the meaning of the second limb of the fourth paragraph of Article 263 TFEU.

51 As regards the applicant's arguments relating to the Commission's failure to communicate certain information and the lack of access to the documents containing the data which the Commission allegedly analysed in order to reach the conclusion set out in the contested decision, it will be necessary to examine them in the context of the analysis of the fourth plea below.

Substance

52 In support of its action, the applicant raises, in essence, four pleas in law alleging: (i) infringement of Article 32(2) and of Article 48(1) and (3) of Regulation No 528/2012; (ii) infringement of the third subparagraph of Article 48(3) of Regulation No 528/2012, substantial procedural defects resulting from failure to take full account of Articles 35 and 36 of that regulation and excess of powers of the Commission; (iii) infringement of Article 51 of Regulation No 528/2012, infringement of the principles of legal certainty and protection of legitimate expectations and excess of powers of the Commission; and (iv) a manifest error of assessment in the application of the criteria in Article 19 of Regulation No 528/2012, infringement of the principles of proportionality, protection of legitimate expectations and legal certainty, and of the right to freedom to conduct a business.

Preliminary observations

53 As is apparent from recital 3 thereof, the purpose of Regulation No 528/2012 is to improve the free movement of biocidal products within the European Union, while ensuring a high level of protection of both human and animal health and the environment. With a view to removing, as far as possible, obstacles to trade in biocidal products, that regulation lays down rules on the mutual recognition of authorisations. In that regard, recital 40 of Regulation No 528/2012 states that the mutual recognition of the authorisations of a biocidal product should help to avoid duplication of the evaluation procedures and to ensure the free movement of those products within the European Union.

54 The rules on mutual recognition, which are laid down in Articles 32 to 40 of Regulation No 528/2012, are therefore one of the cornerstones of that regulation.

55 That said, it is also apparent from recital 3 of Regulation No 528/2012 that the improvement of the free movement of biocidal products in the European Union, which the mechanism of mutual recognition provided for in that regulation is intended to implement, must be reconciled with the protection of human and animal health and the environment and with the precautionary principle. As stated in recital 28 of Regulation No 528/2012, only products which comply with the provisions of that regulation, in particular Article 19 thereof, may be made available on the market.

56 For those reasons, the rule of mutual recognition, as set out in Article 32(2) of Regulation No 528/2012, does not constitute an absolute principle. Thus, in that regulation, the legislature provided for exceptions to that rule, in the interest of protecting human and animal health and the environment, which are in the general interest.

57 On the one hand, as is apparent from Article 32(2) of Regulation No 528/2012, the rule of mutual recognition applies 'without prejudice to Article 37' of that regulation, which provides for derogations from that rule on grounds that are exhaustively listed and relate to the general interest.

58 On the other hand, under Article 48(1) of Regulation No 528/2012, the authority of a Member State may cancel or amend an authorisation which it has granted where it considers, inter alia, that the conditions referred to in Article 19 of that regulation are not, or are no longer, met.

59 It is in the light of those factors that the pleas in law raised by the applicant must be examined.

The first plea, alleging infringement of Article 32(2) and Article 48(1) and (3) of Regulation No 528/2012

60 The applicant submits that Article 48(1) and (3) of Regulation No 528/2012 must be interpreted as meaning that only the competent authority of the reference Member State, within the meaning of Article 33 of that regulation, may cancel or amend an authorisation of a biocidal product which has been the subject of a procedure of mutual recognition in sequence. As is apparent from an administrative note addressed to the coordination group concerning the application of Article 48 of that regulation, the Commission took the view that that provision authorised any competent authority, and not only that of the initial reference Member State, to cancel or amend the terms and conditions of the authorisation of a biocidal product which it has granted by way of mutual recognition. In that context, the applicant, without however raising a plea of illegality, complains of the lack of clarity and precision in Article 48 of that regulation.

61 The applicant submits that the term 'authorisation' in Article 48(1) and (3) of Regulation No 528/2012 is defined in Article 3(1)(o) thereof and designates a national authorisation, EU authorisation or authorisation in accordance with Article 26 of that regulation. According to the applicant, that definition excludes authorisations granted by way of mutual recognition under Chapter VII of the same regulation.

62 By extending the scope of Article 48(1) and (3) of Regulation No 528/2012 and by allowing any competent authority of a Member State to cancel or amend the conditions of an authorisation granted by mutual recognition, the Commission also infringed Article 32(2) of that regulation, according to which biocidal products placed on the EU market are expected to be authorised under the same terms and under the same conditions in all Member States. Such an approach would allow any Member State to compel all the other Member States to align themselves with

such amendments, thus leading to a lack of consistency in the application of Regulation No 528/2012 and to numerous disagreements between the Member States. As guardian of the Treaties, the Commission is required, in that regard, to ensure a harmonised application of that regulation which does not undermine the principle of mutual recognition.

63 The Commission, supported by the Republic of Finland, contends that the first plea is inadmissible and, in any case, unfounded.

64 In the present case, the applicant's arguments should be understood as essentially criticising the Commission for having adopted the contested decision even though it was not entitled to do so, since the procedure of discussion within the coordination group, followed by the referral of unresolved objections to the Commission, is based on the cancellation or amendment of existing authorisations for the biocidal product at issue by Member States which were not the initial reference Member State, within the meaning of Article 33 of Regulation No 528/2012.

65 In that regard, while it is true that, in the present case, the decisions adopted by the French Republic and the Kingdom of Sweden in 2019 to amend the authorisation of the biocidal product at issue are not attributable to the Commission, the fact remains that the referral of unresolved objections to the Commission under Article 36 of Regulation No 528/2012 necessarily presupposes that such objections have been identified in accordance with Article 48(3) of that regulation, the third subparagraph of which refers, *mutatis mutandis*, to Articles 35 and 36 of that regulation. There can be no question of disagreement between the competent authorities of the Member States, within the meaning of Article 48(3) of Regulation No 528/2012, unless a Member State has cancelled or amended an existing authorisation as referred to in Article 48(1) of that regulation. In the absence of such a disagreement, the Commission cannot be regarded as duly empowered to resolve the dispute under the procedure laid down in Articles 35 and 36 of that regulation.

66 In that context, the Commission's argument that the applicant's plea alleging infringement of Article 48(1) of Regulation No 528/2012 is inadmissible on the ground that the decisions amending the authorisation of the biocidal product are not attributable to it, must in any event be rejected.

67 As to the substance, it should be noted that Article 48 of Regulation No 528/2012 provides for a mechanism for cancelling or amending existing authorisations. Paragraph 1 of that article thus allows the competent authority of a Member State to cancel or amend at any time an authorisation which it has granted, under the conditions laid down in that provision. In order to respond to the applicant's arguments, it is therefore necessary to interpret the concept of 'competent authority of a Member State'.

68 In that regard, it should be noted that, with respect to with the wording of Article 48 of Regulation No 528/2012, that article allows the competent authority of a Member State to amend 'an authorisation it has granted', without further specification. Thus, it is in no way indicated that that provision only empowers, in addition the Commission, the competent authority of the 'reference Member State' within the meaning of Article 33(1) of the regulation.

69 That said, it should be recalled that, for the purpose of interpreting a provision of EU law, it is necessary to consider not only its wording but also the context in which it occurs and the objectives pursued by the rules of which it is part (see judgment of 25 July 2018, *Confédération paysanne and Others*, C-528/16, EU:C:2018:583, paragraph 42 and the case-law cited).

70 In that regard, it should be noted that the term 'authorisation' in Article 48(1) of Regulation No 528/2012 is defined in Article 3(1)(o) thereof and designates a national authorisation, EU authorisation or authorisation in accordance with Article 26 of that regulation. It is also apparent from Article 3(1)(m) of that regulation that the term 'national authorisation' refers to an administrative act by which the competent authority of a Member State authorises the making available on the market and use of a biocidal product or a biocidal product family in its territory or in a part thereof.

71 Thus, Article 3(1)(m) of Regulation No 528/2012 does not refer either to the reference Member State within the meaning of Article 33(1) of that regulation, or to any initial authorisation or first authorisation in the European Union. Nor does that definition make an exclusive reference to the provisions of Chapter VI of that regulation, relating to national authorisations for biocidal products, to the exclusion of authorisations granted by way of mutual recognition, within the meaning of Chapter VII thereof.

72 On the contrary, it should be noted that Article 32 of Regulation No 528/2012, relating to an 'authorisation through mutual recognition', uses the verb '[to] authorise' in order to designate the act by which a competent authority accepts an application for mutual recognition of a national authorisation.

73 The Commission also rightly stated that the expression 'national authorisation' was used in other articles of Regulation No 528/2012, in a broader sense than only authorisations granted by the reference Member State. That is, inter alia, the case with regard to Article 39 of Regulation No 528/2012, on the application for mutual recognition by official or scientific bodies, which provides for the possibility for those bodies to apply for the national authorisation of a biocidal product 'under the mutual recognition procedure' where no application for a 'national authorisation' has been submitted in a Member State for a biocidal product that is already authorised in another Member State.

74 In addition, Article 48(1) of Regulation No 528/2012 falls within Chapter IX of that regulation, relating to the cancellation, review and amendment of authorisations which have already been granted, including under the mutual recognition mechanism. Thus, unlike Articles 35 and 36 of that regulation, which concern possible objections raised by one or more Member States with a view to the possible grant of an authorisation, Article 48 of that regulation concerns the situation in which the competent authority of a Member State finds, after having authorised a biocidal product, that that authorisation should be cancelled or amended, by way of derogation from the obligations arising from the mutual recognition mechanism provided for in Article 32 of that regulation.

75 None of the other provisions of Chapter IX of Regulation No 528/2012 refer further to the reference Member State. On the contrary, it is apparent from Articles 47 and 49 of that regulation that applications for cancellation or amendment of an authorisation must be addressed to 'the competent authority that granted the national authorisation'.

76 In particular, the second subparagraph of Article 47(3) of Regulation No 528/2012 provides that, in the event of notification of unexpected or adverse effects by the holder of an authorisation, the competent authorities of the Member States that have issued 'a national authorisation for the same biocidal product under the mutual recognition procedure' are to examine whether that authorisation needs to be cancelled in accordance with Article 48 of that regulation.

77 Similarly, it is apparent from Article 49 of Regulation No 528/2012 that, at the reasoned request of an authorisation holder, the competent authority which granted the national authorisation is to cancel that authorisation. That article cannot be interpreted as referring solely to the national authorisation granted by the reference Member State, to the exclusion of any other authorisation granted under the mechanism of mutual recognition provided for by that regulation, as otherwise that holder would be prohibited from seeking the cancellation of an authorisation in the Member State of his choice and that provision would thus be deprived of all practical effect.

78 Regarding the objective of Article 48(1) of Regulation No 528/2012, as the Commission rightly points out, it is apparent from recital 47 of that regulation that Chapter IX thereof, which includes Article 48, specifies the conditions under which authorisations may be cancelled, reviewed or amended in order to take account, inter alia, of scientific and technical progress. That recital states, in addition, that the notification and exchange of information which may affect authorisations is also necessary to enable competent authorities and the Commission to take appropriate action. It follows from paragraph 56 above that the fundamental reason behind those mechanisms is the necessary protection of human and animal health and the environment.

79 In that regard, Article 48(1) of Regulation No 528/2012 lists exhaustively the grounds on which a Member State may cancel or amend an authorisation of a biocidal product which it has granted. It cannot be ruled out that one or more of those grounds may be established in one Member State, for example because of certain local characteristics, without that also being the case in other Member States which have authorised the same product. It would be contrary to the objective recalled in paragraph 78 above if such a Member State which authorised a biocidal product were not in a position to review that authorisation when it became apparent, in particular on account of scientific and technical progress, that the authorisation of that product could not be maintained as it stands.

80 More generally, limiting the application of Article 48(1) of Regulation No 528/2012 to the reference Member State alone would run counter to the precautionary principle, according to which preventive action must be taken in order to avoid risks to human health or the environment, and on which the provisions of the regulation are based, in accordance with Article 1(1) thereof.

81 Thus, contrary to what the applicant claims, the expression ‘national authorisation’ cannot be interpreted as referring solely to authorisations granted by the reference Member State within the meaning of Article 33 of Regulation No 528/2012. On the contrary, it is apparent from the use of that expression in that regulation that the use of the term ‘national’ must be understood as referring to biocidal products authorised at national level, as opposed to biocidal products which are subject to EU authorisation under Chapter VIII of that regulation.

82 As regards the applicant’s arguments alleging that such an interpretation undermines the principle of mutual recognition, it should be borne in mind that, as stated in paragraphs 55 and 56 above, the free movement of biocidal products, which the rules on mutual recognition laid down in Articles 32 to 40 of Regulation No 528/2012 are intended to implement, must be applied in compliance with the protection of human and animal health and the environment as well as the precautionary principle.

83 Thus, the rule on mutual recognition, as set out in Article 32(2) of Regulation No 528/2012, is not absolute, since the mutual recognition procedure does not create an automatic mechanism and leaves a margin of discretion to the Member State to which an application for mutual recognition is made, in the interests of the protection of human and animal health and of the environment, and of the precautionary principle.

84 In that regard, Articles 35 and 36 of Regulation No 528/2012 establish a mechanism for resolving any disagreements which may arise between the Member States when an application for mutual recognition is made concerning compliance by a biocidal product with the conditions laid down in Article 19 of that regulation. That mechanism is based on the search for an agreement between the Member States. In the light of that mechanism, the applicant cannot maintain that, under Article 48(1) of Regulation No 528/2012, any Member State is able to compel all the other Member States to align themselves with its own amendments.

85 Consequently, it is necessary to reject the applicant's argument that, in accordance with the principle of mutual recognition, only the reference Member State which issued the initial national authorisation in the European Union is entitled to cancel or amend the authorisation which it granted on the basis of Article 48(1) of Regulation No 528/2012.

86 Lastly, in support of its application for annulment of the contested decision, the applicant also cannot rely on a lack of clarity and precision in Article 48(1) of Regulation No 528/2012 nor, accordingly, on an infringement of the principles of legal certainty and the protection of legitimate expectations.

87 The principle of legal certainty requires that legal rules be clear and precise and that their application be foreseeable by those subject to them, so that those concerned may know precisely the extent of the obligations which the legislation in question imposes on them and that they may be able to ascertain unequivocally what their rights and obligations are and take steps accordingly (see judgment of 17 November 2022, *Avicarvil Farms*, C-443/21, EU:C:2022:899, paragraph 46 and the case-law cited). However, where a degree of uncertainty regarding the meaning and scope of a rule of law is inherent in that rule, it is necessary to examine whether the rule of law at issue displays such ambiguity as to make it difficult for individuals to resolve with sufficient certainty any doubts as to the scope or meaning of that rule (judgment of 14 April 2005, *Belgium* v *Commission*, C-110/03, EU:C:2005:223, paragraph 31).

88 As is apparent from paragraphs 68 to 81 above, the interpretation of the concept of 'competent authority' used in Article 48(1) of Regulation No 528/2012, namely that which granted the national authorisation, is sufficiently clear not only from the wording of Article 48 of that regulation as a whole, but also from the context and the objective of that regulation.

89 As regards the principle of the protection of legitimate expectations, it should be recalled that, according to settled case-law, the right to rely on that principle presupposes that precise, unconditional and consistent assurances originating from authorised, reliable sources have been given to the person concerned by the competent authorities of the European Union (see judgment of 14 June 2016, *Marchiani* v *Parliament*, C-566/14 P, EU:C:2016:437, paragraph 77 and the case-law cited). In the present case, the applicant has failed to show that precise assurances had been given to it by the Commission regarding the restriction of the concept of 'competent authority', provided for in Article 48(1) of Regulation No 528/2012, solely to the authorities of the originating reference Member State.

90 The first plea must therefore be dismissed.

The second plea, alleging infringement of Article 48(3) of Regulation No 528/2012, substantial procedural defects resulting from the failure to take full account of Articles 35 and 36 of that regulation and excess of powers of the Commission

91 The applicant submits that, in the event of disagreements between Member States, Article 48(3) of Regulation No 528/2012 provides for the application '*mutatis mutandis*' of the procedures laid down in Articles 35 and 36 of that regulation. Such an application '*mutatis mutandis*' allows only the necessary changes, without, however, it being possible to depart from the basic legal principle. In the present case, in the interpretation of Article 48(3) of Regulation No 528/2012, the Commission changed the definitions of the terms 'the reference Member State' and that of 'the Member State[s] concerned', used in Article 33(1) of that regulation, and thus infringed the principle of legal certainty.

92 According to the applicant, Article 36(1) of Regulation No 528/2012 clearly indicates that, if the Member States fail to reach an agreement, 'the reference Member State' is immediately to inform the Commission thereof. That is the State which granted the initial national authorisation of the biocidal product in accordance with Article 17 of that regulation. The French Republic and the Kingdom of Sweden, which referred the unresolved objections to the Commission in the present case, do not satisfy, concerning the biocidal product at issue, that definition. The Commission's decision not to dismiss their referral within the meaning of Article 36 of Regulation No 528/2012 constitutes a 'substantial procedural error'. By accepting those objections, the Commission made errors in law and 'procedures' and exceeded its powers.

93 The Commission, supported by the Republic of Finland, disputes the applicant's arguments.

94 In the present case, it is apparent from Article 48(3) of Regulation No 528/2012 that, in the case of disagreement between the competent authorities of certain Member States concerning national authorisations subject to mutual recognition, following the cancellation or amendment of an authorisation by a Member State in accordance with Article 48(1) of that regulation, the procedures laid down in Articles 35 and 36 of that regulation are to apply '*mutatis mutandis*'.

95 In that regard, it is true that Article 36(1) of Regulation No 528/2012 requires the 'reference Member State' to inform the Commission of the disagreement which persists between the Member States following discussions within the coordination group.

96 However, as is apparent from the use of the expression '*mutatis mutandis*' in Article 48(3) of Regulation No 528/2012, Article 36(1) of that regulation must be applied in a specific context, namely the cancellation or amendment of a national authorisation which had already been granted. Such a context differs from that of the grant of a first authorisation by way of mutual recognition, governed by Articles 32 to 40 of that regulation.

97 In the context of the grant of a national authorisation by a competent authority, Articles 33 and 34 of Regulation No 528/2012 relating, respectively, to the procedure for mutual recognition in sequence and the procedure for mutual recognition in parallel, give the reference Member State a predominant role. That Member State is responsible for assessing the first application for authorisation of the biocidal product. It is on the basis of that assessment and the subsequent national authorisation that the applicant will be able to obtain mutual recognition, in one or more Member States concerned, of that national authorisation. Any objections by one of the

Member States concerned therefore relate to the results of the assessment carried out by the reference Member State and the question whether the biocidal product meets the conditions for granting an authorisation in Article 19 of Regulation No 528/2012, as is apparent from the first subparagraph of Article 35(1) of that regulation.

98 It is in that context that, in the absence of agreement between the Member States within the period of 60 days laid down in Article 35(3) of Regulation No 528/2012, the reference Member State must immediately inform the Commission and provide it with a detailed statement of the matters on which the Member States have been unable to reach agreement, as well as the reasons for their disagreement, in accordance with Article 36(1) of that regulation. The designation of the reference Member State in such a context is thus explained by the central position it occupies in the context of the mutual recognition procedure.

99 However, where national authorisations have already been granted in the context of a mutual recognition procedure but, by reason, in particular, of developments in scientific or technical knowledge or the emergence of particular effects, the competent authority of a Member State finds that that authorisation should be cancelled or amended on the grounds laid down in Article 48(1) of Regulation No 528/2012, it is no longer the authorisation decision of the reference Member State which must be recognised, but the cancellation or amendment decision of the Member State which adopted that decision. It is also that cancellation or amendment decision that should, in principle, be applied in other Member States.

100 Since the application of Articles 35 and 36 of Regulation No 528/2012 must be carried out '*mutatis mutandis*', in accordance with the very terms of the third subparagraph of Article 48(3) of that regulation, the referral to the reference Member State in Article 36(1) of that regulation cannot be interpreted as meaning that only that Member State can inform the Commission of the disagreement which exists as regards the annulment or amendment decision at issue.

101 Furthermore, as the Republic of Finland rightly points out, such an interpretation makes it possible to ensure the effectiveness of the mechanism provided for in Article 48(3) of Regulation No 528/2012, since the Member State which adopted the decision to cancel or amend has the best knowledge of the factors on which its decision is based and which may lead to a cancellation or an amendment of the national authorisation in the other Member States. That Member State is thus best placed to inform the Commission and provide it with the description required by Article 36(1) of that regulation, applicable *mutatis mutandis*.

102 In any event, even if Article 36(1) of Regulation No 528/2012 had been infringed on the ground that that communication had been made by another Member State, it cannot be held that such an irregularity must, in the present case, lead to the annulment of the contested decision. The designation of the competent authority of the 'reference' Member State as the authority responsible for informing the Commission pursues above all a practical objective, without, however, conferring rights on individuals the infringement of which would affect the substance of the Commission's decision.

103 Since the alleged infringement of Article 36(1) of Regulation No 528/2012 is based at most on a procedural irregularity, that irregularity could entail the annulment of the contested decision in whole or in part only if it is shown that, in the absence of such irregularity, the decision being challenged might have been substantively different (see, to that effect, judgment of 11 March 2020, *Commission* v *Gmina Miasto Gdynia and Port Lotniczy Gdynia Kosakowo*, C-56/18 P, EU:C:2020:192, paragraph 80 and the case-law cited). The applicant has not put

forward any arguments capable of demonstrating that, if the Italian Republic had informed the Commission of the disagreement between the Member States, instead of the French Republic and the Kingdom of Sweden, the contested decision might have been substantively different.

104 Lastly, under recital 42 of Regulation No 528/2012, relating to the dispute resolution mechanism provided for in Articles 35 and 36 of that regulation, the Commission should be empowered to take a decision in the event that the coordination group fails to reach an agreement within a specified period of time. The Commission's power to take such a decision thus stems not from the referral by the 'reference Member State' but from Articles 35 and 36 of the regulation themselves, which provide for the Commission to intervene as soon as the 60-day period laid down in Article 35(3) of that regulation has expired without any agreement having been reached. It is common ground between the parties that, on the expiry of the aforementioned period, the Member States, meeting within the coordination group, had not reached an agreement on the decisions of the French Republic and the Kingdom of Sweden to amend the authorisation of the biocidal product at issue.

105 It follows that, in adopting the contested decision, the Commission did not exceed the powers conferred on it by Articles 35 and 36 of Regulation No 528/2012.

106 Consequently, the second plea must be rejected.

The third plea, alleging infringement of Article 51 of Regulation No 528/2012 and infringement of the principles of legal certainty and the protection of legitimate expectations, and excess of powers of the Commission

107 The applicant claims that the Commission infringed Article 51 of Regulation No 528/2012, since it did not define, by means of implementing acts, the detailed rules for the application of Article 48 of that regulation. That was, however, necessary in view of the doubts which the application of that provision raised with the Member States and authorisation holders for biocidal products. The Commission merely adopted administrative guidelines, as is apparent from Annexes A14, A15 and A29 of the application, and sent ad hoc interpretative opinions to the competent authorities of the Member States, infringing the principles of legal certainty and the protection of legitimate expectations. By adopting interpretative statements before and after the contested decision, it also exceeded its powers, since the interpretation of EU law is reserved for the Court of Justice of the European Union.

108 The Commission, supported by the Republic of Finland, disputes the applicant's arguments.

109 It is apparent from Article 51 of Regulation No 528/2012 that, in order to ensure a harmonised approach to the cancellation and amendment of authorisations, the Commission is to lay down detailed rules for the application of Articles 47 to 50 of that regulation by means of implementing acts.

110 Admittedly, the Commission acknowledges that it has not yet adopted such implementing acts. However, in the present case, the legality of the contested decision must be assessed, above all, in the light of Article 48 of Regulation No 528/2012, read in conjunction with Articles 35 and 36 of that regulation, as adopted by the EU legislature. In accordance with the second paragraph of Article 288 TFEU, that regulation is binding in its entirety and directly applicable in all Member

States. The Commission's failure to adopt implementing acts does not therefore in any way preclude the application of Article 48 of Regulation No 528/2012 and does not render that application unlawful.

111 It should be added that, in the present case, the applicant has not brought an action for failure to act against the Commission on the basis of Article 265 TFEU, but rather an action for annulment of the contested decision, on the basis of Article 263 TFEU.

112 Thus, even assuming that the Commission had infringed Article 51 of Regulation No 528/2012, or the principles of legal certainty and the protection of legitimate expectations, by failing to adopt the necessary implementing acts, in the present case, such an infringement would not permit a finding that the contested decision is unlawful and, therefore, lead to the annulment of that decision. That argument is therefore ineffective.

113 Moreover, the applicant does not in any way explain how the Commission's failure to adopt implementing measures led to an infringement of the principles of legal certainty and the protection of legitimate expectations. Since it is not substantiated, that argument must therefore be rejected.

114 Furthermore, as regards the Commission's 'administrative guidance', to which the applicant refers, it should be noted that the documents in Annexes A14 and A29 of the application are, in the first place, a note to the Coordination Group for Biocidal Products and, in the second place, a note inviting the competent authorities of the Member States to find an agreement on the harmonisation of authorisations for biocidal products containing alphachloralose. Those two notes state at the outset that they do not represent the official position of the Commission and that the Member States are not legally bound to follow them, since only the Court of Justice of the European Union can give authoritative interpretations of EU law.

115 As regards the exchange of emails in Annex A15 of the application, it does not contain any indication of an allegedly binding interpretation of Article 48 of Regulation No 528/2012 by the Commission.

116 Consequently, and in any event, the applicant is not justified in claiming that the Commission exceeded its powers by adopting the 'administrative guidance' concerned.

117 Accordingly, the third plea must be rejected.

The fourth plea, alleging a manifest error of assessment, infringement of the principles of legal certainty, protection of legitimate expectations and proportionality and infringement of the right to freedom to conduct a business

118 The applicant claims that the information in recital 16 of the contested decision, on which the Commission relied in adopting that decision, concerns only the active substance alphachloralose. The scientific data examined by the Commission do not contain any information on the use of biocidal products or the insufficiency of the risk mitigation measures put in place to reduce the risk of secondary poisoning involving dogs and cats. That information constitutes, at most, 'indication[s]' of a causal link with the use of the biocidal product at issue.

119 According to the applicant, the Commission failed to take account of the fact that the existence of a risk of secondary poisoning had already been examined and found acceptable at EU level in the context of the approval procedure for the active substance alphachloralose, provided that certain risk mitigation measures were put in place. The applicant complied with those requirements, and even went beyond them, by offering the biocidal product at issue in pre-filled bait boxes. In addition, the United Kingdom of Great Britain and Northern Ireland concluded that the risk of poisoning of cats was negligible, given the characteristics of the active substance and the form in which the biocidal products at issue were made available on the market.

120 In the applicant's view, the scientific information submitted by the Republic of Finland and the Kingdom of Sweden relates to general information on the toxic properties of the active substance alphachloralose and the clinical symptoms of poisoning by that substance. The data from the Swedish competent authority, set out in Annex B9 to the defence, do not in any way substantiate the Commission's position, which adopted a purely hypothetical approach to risk. Furthermore, the French Republic has not submitted any scientific data justifying the alleged cases of poisoning on its territory.

121 In that regard, according to the applicant, the Commission and the Member States concerned did not carry out any detailed examination of the scientific evidence presented in order to verify that the conditions of Article 19(1) of Regulation No 528/2012 were in fact no longer met. Moreover, the applicant requested the Commission, pursuant to Article 36(2) of Regulation No 528/2012, to call upon the Chemicals Agency (ECHA) to provide an opinion on whether the biocidal product at issue met the conditions of Article 19(1)(b)(iii) of Regulation No 528/2012. The Commission rejected that application in view of the ongoing procedure for the renewal of the approval of the active substance alphachloralose, which should not result in a decision until 2026 at the earliest.

122 In the reply, the applicant adds that the Commission has not communicated the scientific data and analyses supporting its conclusions, or the assessment method used to establish a link between the biocidal product at issue and the reported cases in Finland and Sweden.

123 The contested decision thus constitutes an arbitrary decision infringing the principle of proportionality, in particular in view of the applicant's major investments for the purposes of authorising its biocidal product and renewing the approval procedure for the active substance alphachloralose. In addition, the manifest error of assessment led to an infringement of the principles of legal certainty, protection of legitimate expectations and proportionality, as well as an infringement of the applicant's fundamental right to freedom to conduct a business protected by Article 16 of the Charter of Fundamental Rights of the European Union.

124 The Commission disputes the applicant's arguments.

125 As a preliminary point, it should be noted that the present action, which concerns the mutual recognition of biocidal products, falls within a highly complex scientific and technical context that is evolving. As such, the EU authorities have a broad discretion, in particular as to the assessment of highly complex scientific and technical facts in order to determine the nature and scope of the measures which they adopt. Review by the European Union judicature is limited to verifying whether the exercise of such powers has been vitiated by a manifest error of assessment or a misuse of powers, or whether those authorities have manifestly exceeded the limits of their discretion. In such a context, the European Union judicature cannot substitute its assessment of

scientific and technical facts for that of the institutions on which alone the FEU Treaty has placed that task (see, to that effect, judgment of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 60 and the case-law cited).

126 In addition, in order to establish that an institution committed a manifest error in assessing complex facts such as to justify the annulment of an act, the evidence adduced by the applicant must be sufficient to make the factual assessments used in the act implausible (judgment of 13 October 2021, *European Union Copper Task Force* v *Commission*, T-153/19, not published, EU:T:2021:688, paragraph 65).

127 In the present case, in recital 16 of the contested decision, it is stated that the Commission relied, first, on the information submitted by the Member States and by the applicant and, second, on the opinion of the Finnish Food Authority and the Finnish Veterinary Association, as well as on the reports of the University Animal Hospital in Uppsala (Sweden) and of the Sveriges Veterinärförbund (Veterinary Association, Sweden) according to which the biocidal product at issue has unacceptable effects on animal health and in which it was confirmed, by analytical tests conducted on the poisoned animals, that a significant number of poisoning incidents with alphachloralose involving cats had occurred.

128 It is apparent from a report by the veterinary clinic of the Swedish University of Agricultural Sciences of 19 November 2019 on suspected cases of alphachloralose poisoning between 2014 and 2019, that alleged cases of secondary intoxication by alphachloralose were recorded by that veterinary clinic since 2014, with a dramatic increase in those cases in 2019. In particular, that clinic states that it dealt with almost one case of intoxication per day in November and December of that year. In several of those cases, the owners of the animals concerned saw their cat developing symptoms of intoxication within 30 to 60 minutes after eating a rodent, while rodent carcasses were found in the stomach of other intoxicated animals.

129 In addition, the cases of secondary poisoning of cats due to alphachloralose were confirmed following a study carried out by researchers at the Statens veterinärmedicinska anstalt (Swedish National Veterinary Institute), the veterinary clinic of the Swedish University of Agricultural Sciences and the Department of Medical Chemistry of the University of Uppsala, the results of which were published on 27 July 2021 in the *Journal of Analytical Toxicology*. That study is itself based on various scientific articles. The notification which the Swedish competent authority sent on 18 December 2019 to the competent authorities of the other Member States pursuant to Article 48 of Regulation No 528/2012 also contained supporting documents annexed thereto.

130 It is moreover apparent from the opinion of the Finnish Food Authority of 8 June 2021 on the effects of alphachloralose preparations on pets and wildlife that a first confirmed case of poisoning of a cat was reported in 2018. Subsequently, that authority received several alerts from veterinarians and animal owners concerning suspected alphachloralose poisoning cases. A survey of veterinarians was carried out in 2019, and a joint Nordic research project in 2020-2021 on those suspected cases of poisoning. Although the report of that research project had not yet been finalised and no laboratory in Finland carried out detection tests for alphachloralose at that time, the Finnish Food Authority concluded that the preparations based on that substance caused significant suffering to pets and wildlife, and that the number of poisoning cases reported was considerable. In an opinion of 4 June 2021, the Finnish Veterinary Association also concluded that alphachloralose was a particularly dangerous poison for cats.

131 The applicant has not put forward any evidence capable of demonstrating that the assertions set out in paragraphs 128 and 129 above were incorrect, with the result that the Commission could not rely on them or that the Commission interpreted that information in a manifestly incorrect way. Furthermore, the fact that, in the contested decision, the Commission referred to the documents submitted by the Member States without responding specifically to each argument raised by the applicant in the context of its comments on the draft decision in accordance with Article 36(2) of Regulation No 528/2012 does not mean that it wrongly ignored those arguments.

132 In that regard, first, it is true that the documents mentioned in paragraph 131 above do not expressly concern the biocidal product at issue, and do not establish any express causal link between the cases of poisoning identified and that product in particular. However, the biocidal product at issue, like other biocidal products containing alphachloralose, could be authorised by the Member States only in accordance with the conditions laid down in the Annex to Directive 2009/93 (see paragraph 11 above). In particular, those products could not be authorised for outdoor use and only products intended for use in tamper-resistant and securely closed bait boxes were authorised.

133 The applicant does not state how its biocidal product is different from other biocidal products containing alphachloralose placed on the Swedish or Finnish markets, such that the risk of secondary poisoning which it poses for cats is lower than that of those other products. It is true that the applicant claimed that it marketed its biocidal product in pre-filled bait boxes. However, all alphachloralose products had necessarily to be used in tamper-resistant and securely sealed bait boxes. In addition, as early as 2019, the Republic of Finland had restricted the marketing of biocidal products containing alphachloralose to pre-filled boxes such as those of the applicant. However, that additional requirement had not sufficiently reduced the number of cases of poisoning involving cats (recital 12 of the contested decision).

134 Second, it is true that the risk of secondary poisoning was considered acceptable at EU level in the context of the procedure for the approval of the active substance alphachloralose. However, the inclusion of that substance in Annex I to Directive 98/8 on 31 July 2009 was based on the data submitted by the applicant for approval at the time in accordance with Article 11 of that same directive. The available data on an active substance may evolve as a result of scientific and technical progress, as is apparent from recital 13 of Regulation No 528/2012. For that reason, active substances approved at EU level must regularly be examined, as part of the renewal or review of approval of those substances, in accordance with Articles 12 to 16 of that regulation.

135 As regards the first authorisation of the biocidal product at issue, in the United Kingdom, it is apparent from the assessment report of that State's competent authority, drawn up in June 2013, that, taking into account, first, the similarities between the applicant's biocidal product and the representative biocidal product examined in the context of the approval procedure for the active substance and, second, the fact that the intended uses were the same, the environmental exposure assessment would be taken from the assessment report for the active substance alphachloralose, dated 30 May 2008. In that regard, in order to conclude that there was a negligible risk of secondary poisoning, the evaluation report relied on studies from the years 2000, 2001 and 2003 on the behaviour of rodents having ingested alphachloralose and on the small quantity of the substance necessary to produce effects. In addition, it should be noted that, in that assessment report, the assessment of the risk of secondary poisoning was based on the rapid effect of the biocidal product on mice and on the small quantities ingested, without referring to the method of packaging the paste containing the active substance.

136 That assessment of the risk of secondary poisoning was nevertheless called into question by subsequent data, mostly dating from 2019, which showed that, despite the conditions of use and labelling imposed, an increasing number of secondary poisonings had taken place, at least in some Member States, as is apparent from paragraphs 128 to 130 above.

137 Third, it is true that the information from the French Republic and the Republic of Finland in the file is of a general nature and does not provide scientific numerical data. However, the reports mentioned in paragraphs 128 and 129 above, concerning the situation in Sweden, contain precise indications as to the cases of poisoning identified. In addition, the article mentioned in paragraph 129 above provides detailed explanations relating to the in-depth study carried out on cases of secondary alphachloralose poisoning of cats. For the reasons set out in paragraphs 132 and 133 above, that information cannot be regarded as irrelevant on the sole ground that it relates to the active substance, and not to the biocidal product itself.

138 In addition, as is apparent from Article 1(1) of Regulation No 528/2012, read in the light of recital 3 of the same regulation, the purpose of that regulation is to improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products, whilst ensuring a high level of protection of both human and animal health, and the environment, its provisions being based on the precautionary principle, the aim of which is to protect human health, animal health and the environment. In that respect, as the Court has already ruled, it is the very presence of an active substance as such in a product that is likely to present a risk to the environment or animal health (see, to that effect, judgment of 14 October 2021, *Biofa*, C-29/20, EU:C:2021:843, paragraph 35).

139 Fourth, as regards the Commission's alleged failure to carry out a thorough examination of the scientific evidence submitted in order to verify that the conditions of Article 19(1) of Regulation No 528/2012 were in fact no longer met, the applicant does not indicate what data the Commission ignored or misinterpreted.

140 In addition, it is apparent from Article 36(2) of Regulation No 528/2012 that the Commission may request the ECHA to give an opinion on scientific or technical issues raised by Member States. Thus, consultation with the ECHA is merely an option for the Commission and not an obligation.

141 It should also be recalled that it is at the authorisation stage of a biocidal product, with a view to placing it on the market, that all the intended uses of that product are examined in detail and that an assessment of the product's risks having regard to each of those uses is carried out (see, to that effect, judgment of 16 November 2022, *Sciessent* v *Commission* T-122/20 and T-123/20, EU:T:2022:712, paragraph 61). In the context of the mutual recognition procedures provided for in Chapter VII of Regulation No 528/2012, it is for the reference Member State to carry out such an examination, since the authorisation of biocidal products is then a matter for the Member States concerned, and not for the Commission. It is therefore for each Member State concerned to verify whether a biocidal product may be mutually recognised or whether there are grounds in the general interest, exhaustively listed in Regulation No 528/2012, justifying the refusal to grant an application for such recognition.

142 In that regard, the role conferred on the Commission by Article 36 of Regulation No 528/2012 is not to be confused with that of the Member States in the context of their national authorisation procedure. It is solely for the Commission to adopt a decision on the questions referred to it, in order to find a solution to disputes between those States. In that context, although the Commission is required to act in accordance with the principle of sound administration and to

examine, carefully and impartially, all the information submitted to it in order to resolve that dispute, it is not for it to carry out a new, exhaustive examination of compliance with all the conditions of Article 19 of Regulation No 528/2012.

143 In the present case, the question submitted to the Commission concerned the existence of unacceptable effects on animal health caused by the biocidal product at issue, in so far as it contains alphachloralose. In that regard, the applicant does not state in what respect consultation with the ECHA was necessary in order to enable the Commission to take a decision, or on which scientific or technical questions an opinion should have been delivered, even though the documents in the file show that there were cases of alphachloralose poisoning of cats in Sweden, or in other Member States, despite the strict conditions for the placing on the market of products containing that substance.

144 In view of those unacceptable effects on animal health, reported by several Member States, the Commission has indeed resolved the disagreement between the EU Member States which authorised the biocidal product, and applied Article 19(5) of Regulation No 528/2012. Such a solution is in no way precluded by Article 48(3), read in conjunction with Article 36, of the same regulation.

145 As regards the argument that the Commission did not communicate the scientific data and analyses supporting its conclusions, or the assessment method used to establish a link between the biocidal product at issue and the cases reported in Finland and Sweden, it should be noted that that argument, which is based, in essence, on an infringement of the applicant's right of access to the information in the dossier, was raised for the first time at the stage of the reply.

146 It is clear from Article 84(1) of the Rules of Procedure that no new plea in law may be introduced in the course of proceedings unless it is based on matters of law or of fact which come to light in the course of the procedure. In that regard, a plea which may be regarded as amplifying a plea put forward previously, whether directly or by implication, in the originating application, and which is closely connected therewith, must be held admissible. By contrast, a plea which cannot be regarded as being based on matters of law or of fact which came to light in the course of the proceedings has to be held inadmissible. In the circumstances of the present case, there was nothing to prevent the applicants from raising that plea at the stage of the application (see, to that effect, judgment of 9 September 2008, *Bayer CropScience and Others* v *Commission*, T-75/06, EU:T:2008:317, paragraph 134 and the case-law cited).

147 Since it was only at the stage of the reply that the applicant raised the argument relating to the failure to communicate certain scientific data and information, and since that argument is not based on factors which came to light after the action was brought, it must be held to be out of time and, therefore, inadmissible.

148 As regards the alleged infringement of the principle of proportionality, it should be recalled that that principle, which is one of the general principles of EU law, requires that measures adopted by EU institutions do not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by the legislation in question; where there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (see, to that effect, judgment of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 124 and the case-law cited).

149 With regard to judicial review of the conditions referred to in paragraph 148 above, in so far as the adoption by the Commission of a decision entails political, economic and social choices on its part, in the context of which it is called upon to undertake complex assessments, it has a broad discretion in that respect, with the result that judicial review of the legality of those acts is necessarily limited. The legality of a measure adopted in that sphere can be affected only if the measure is manifestly inappropriate having regard to the objective which the Commission is seeking to pursue (see, to that effect, judgment of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 125 and the case-law cited).

150 In the present case, although the contested decision finds that the biocidal product at issue does not fully meet the conditions laid down in Article 19(1)(b)(iii) of Regulation No 528/2012, it nevertheless leaves it to each Member State to verify whether that product may nevertheless be authorised by means of appropriate risk mitigation measures, in accordance with Article 19(5) of that regulation. Thus, the Member States which, like the Republic of Finland and the Kingdom of Sweden, have expressed concerns as to the numerous cases of poisoning of cats on their territory may, where appropriate, decide to amend, or even withdraw, the authorisation of the biocidal product, in the interest of protecting animal health and of the precautionary principle, as has been pointed out in paragraphs 55 to 57 above. Such a decision is, however, without prejudice to the possibility for other Member States to consider that the conditions laid down in the first subparagraph of Article 19(5) of Regulation No 528/2012 have been met and to authorise the product without imposing new risk mitigation measures. In view of that broad discretion left to the Member States, it cannot be concluded that the contested decision is manifestly inappropriate having regard to the objective pursued, namely to put an end to the dispute between Member States concerning the biocidal product at issue pursuant to Article 36 of Regulation No 528/2012.

151 Consequently, the applicant has not shown that the contested decision was vitiated by a manifest error of assessment or an infringement of the principle of proportionality.

152 Lastly, since the applicant's arguments alleging a manifest error of assessment have been rejected, the applicant cannot claim that that error led to an infringement of the principles of legal certainty and the protection of legitimate expectations and an infringement of the fundamental right to freedom to conduct a business in accordance with Article 16 of the Charter of Fundamental Rights.

153 The fourth plea must therefore be rejected as being in part inadmissible and in part unfounded.

154 Since all the applicant's pleas in law have been rejected, the action must therefore be dismissed.

Costs

155 Under Article 134(1) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the applicant has been unsuccessful, it must be ordered to pay the costs.

156 Under Article 138(1) of the Rules of Procedure, the Member States which have intervened in the proceedings are to bear their own costs. Consequently, the Republic of Finland must bear its own costs.

On those grounds,

THE GENERAL COURT (Fourth Chamber)

hereby:

1. **Dismisses the action.**

2. **Orders SBM Développement SAS to bear its own costs and those of the European Commission.**

3. **Orders the Republic of Finland to bear its own costs.**

da Silva Passos Gervasoni Reine

Delivered in open court in Luxembourg on 3 July 2024.

V. Di Bucci M. van der Woude
Registrar President