Reports of Cases

Case T-667/22

SBM Développement SAS
v
European Commission

Judgment of the General Court (Fourth Chamber) of 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)

1. *Action for annulment – Natural or legal persons – Measures of direct and individual concern to them –Cancellation or amendment of national marketing authorisations issued in the context of mutual recognition procedures – Commission decision, addressed to the Member States, relating to unresolved objections concerning the authorisation conditions of a biocidal product – Decision changing the system of mutual recognition of that product and obliging those States to review the authorisations issued – Action by an undertaking which holds a marketing authorisation for that product in several Member States – Admissibility*
(Art. 263, 4th para., TFEU; European Parliament and Council Regulation No 528/2012, Art. 36 (3))

(see paragraphs 29-31, 33-44, 46-50)

2. *Approximation of laws – Biocidal products – Regulation No 528/2012 – Cancellation, review and amendment of marketing authorisations – Mutual recognition procedures – Cancellation or amendment of national marketing authorisations issued in the context of that procedure – Competent authority of a Member State – Concept – Competent authority of each Member State that issued a national authorisation – Included – Restriction solely to the reference Member State that issued the initial national authorisation – Absence*
(European Parliament and Council Regulation No 528/2012, Arts 36 and 48)

(see paragraphs 54-58, 68-81, 84, 85)

3. *Approximation of laws – Biocidal products – Regulation No 528/2012 – Cancellation, review and amendment of marketing authorisations – Mutual recognition procedures –*

Cancellation or amendment of national marketing authorisations issued in the context of that procedure – Unresolved objections of Member States concerning the authorisation conditions of a biocidal product – Referral of those objections to the Commission – Member State responsible for that referral – Member State that adopted the decision to cancel or amend the issued authorisation – Commission's power to adopt a decision on those objections, obliging the Member States to review the authorisations issued
(European Parliament and Council Regulation No 528/2012, Arts 35, 36(1) and 48(3))

(see paragraphs 94-102, 104, 105)

4. *Approximation of laws – Biocidal products – Regulation No 528/2012 – Cancellation, review and amendment of authorisations – Mutual recognition procedures – Cancellation or amendment of authorisations issued in the context of that procedure – Commission decision, addressed to the Member States, relating to unresolved objections concerning the authorisation conditions of a biocidal product –No obligation for that institution to carry out a new, exhaustive examination of compliance with those conditions – Discretion of that institution – Scope – Judicial review – Limits – Breach of principle of proportionality – None*
(European Parliament and Council Regulation No 528/2012, Arts 19(5), 36(1) and (2), and 48(3))

(see paragraphs 125, 126, 140-142, 144, 149-151)

Résumé

The General Court dismisses the action for annulment brought by the owner of a marketing authorisation of a biocidal product against a decision of the European Commission on unresolved objections concerning the conditions of authorisation of that product.[1] In doing so, it rules for the first time on the interpretation and application of Articles 35, 36 and 48 of Regulation No 528/2012,[2] concerning the possibility for a Member State to cancel or amend the authorisation of a biocidal product previously granted in accordance with the principle of mutual recognition.

SBM Développement SAS is the holder, in several Member States, of a marketing authorisation for a biocidal product containing the active substance alphachloralose, which is marketed under various names in the European Union and is intended for use indoors and against mice ('the biocidal product at issue'). On 17 June 2013, the biocidal product at issue was approved by the competent authority of the United Kingdom.[3] Between 2014 and 2019 that authorisation was the subject of a mutual recognition in sequence in several Member States,[4] including the French Republic and the Kingdom of Sweden. In December 2019, those two countries amended the national authorisation for the biocidal product at issue,[5] in response to the communication of several cases of primary poisoning incidents involving dogs and secondary poisoning incidents

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

[2] 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).

[3] In accordance with the national authorisation procedure laid down by 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). That authorisation was maintained following the entry into force of Regulation No 528/2012.

[4] Pursuant to Article 33 of Regulation No 528/2012.

[5] Under Article 48 of Regulation No 528/2012.

involving cats linked to alphachloralose. In April 2020, the Kingdom of Denmark and the Federal Republic of Germany referred, to the coordination group,[6] objections to those amendments. As no agreement was reached in the coordination group, the Kingdom of Sweden in August 2020 and the French Republic in October 2020, referred the unresolved objections[7] to the Commission 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.

On 23 June 2022, the Commission adopted an implementing decision concerning the biocidal product at issue,[8] in which it considered that that product did not fully meet the conditions for granting an authorisation laid down in Article 19 of Regulation No 528/2012.[9] In this case, the Commission considered, first, that the biocidal product at issue could be authorised only in the Member States which considered 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.[10] Second, 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.

Findings of the Court

In the first place, the Court rules on the admissibility of the action.[11] In that context, it examines, first, the question whether the applicant is directly concerned by the contested decision, and more specifically whether that decision directly affected the applicant's situation. In that regard, it points out that the contested measure changes the system of mutual recognition applicable until then to the biocidal product at issue,[12] in that it requires each Member State to review the authorisation granted[13] 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. The Court concludes that, by calling into question the authorisations issued by the Member States for the biocidal product at issue, the contested decision changes the criteria to which those authorisations are subject and the legal rules applicable to the mutual recognition of that product. Therefore, it directly affects the applicant's legal situation.

As to whether the contested decision leaves discretion to the addressees responsible for implementing it, the Court notes that that decision has the effect of automatically subjecting the biocidal product at issue to the comparative assessment procedure[14] which must be carried out by the Member States for all existing or future authorisations for that product. Furthermore, it automatically amends the legal rules applicable to mutual recognition of authorisations for the biocidal product at issue. For those reasons, the contested decision directly affects the applicant's legal situation, as holder of the national authorisations for the biocidal product at issue, and leaves

6 Set up under Article 35 of Regulation No 528/2012.

7 Pursuant to Article 36(1) of Regulation No 528/2012.

8 That decision was adopted on the basis of Article 36(3) of Regulation No 528/2012.

9 More specifically, Article 19(1)(b)(iii) of Regulation No 528/2012. Pursuant to that provision, a biocidal product is authorised where it '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'.

10 Under Article 19(5) of Regulation No 528/2012.

11 In accordance with the fourth paragraph of Article 263 TFEU.

12 As established by Article 32 of Regulation No 528/2012.

13 Pursuant to Article 36(4) of Regulation No 528/2012.

14 Laid down in Article 19(5) of Regulation No 528/2012.

no discretion to the Member States responsible for its implementation, since they are required to review existing authorisations. Consequently, the applicant is directly concerned by the contested decision.

Concerning, second, the question as to whether the applicant is individually concerned by the contested decision, the Court emphasises that the applicant is cited in that decision as the current holder of the authorisation of the biocidal product at issue and that it participated in the conciliation procedure within the coordination group.[15] It follows 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. Accordingly, the Court concludes that the applicant has standing to bring an action for annulment of the contested decision, since it is directly and individually concerned by it.

In the second place, the Court notes, as a preliminary point, that the rules on mutual recognition[16] are one of the cornerstones of Regulation No 528/2012. However, under that regulation, the improvement of the free movement of biocidal products within the European Union, which the mechanism of mutual recognition provided for by 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. In that respect, only products which comply, in particular, with Article 19 of Regulation No 528/2012 may be made available on the market. For those reasons, the rule of mutual recognition[17] is not an absolute principle. That regulation contains exceptions to that rule, provided in the interest of protecting human and animal health and the environment, which are in the general interest.[18]

In the light of the foregoing, the Court rejects, first, the argument that, in accordance with the principle of mutual recognition, only the reference Member State[19] that issued the initial national authorisation in the European Union is entitled to cancel or amend the authorisation which it granted.[20] On the contrary, it is apparent from the use of the expression 'national authorisation' in Regulation No 528/2012 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 Regulation No 528/2012.

Second, the Court finds that, by adopting the contested decision even though the unresolved objections were referred to it by a State other than the reference Member State within the meaning of Article 33 of Regulation No 528/2012, the Commission did not exceed the powers conferred on it by Articles 35 and 36 of Regulation No 528/2012. In the case of disagreement between 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,[21] the procedures laid down in Articles 35 and 36 of that regulation are to apply '*mutatis mutandis*'.[22] Article 36(1) of that regulation must thus be applied in the specific context

15 Provided for in Article 35 of Regulation No 528/2012.

16 As provided for in Articles 32 to 40 of Regulation No 528/2012.

17 As set out in Article 32(2) of Regulation No 528/2012.

18 Article 37 of Regulation No 528/2012 provides for derogations from the rule of mutual recognition of authorisations to place biocidal products on the market on grounds that are exhaustively listed and relate to the general interest.

19 Within the meaning of Article 33(1) of Regulation No 528/2012.

20 On the basis of Article 48(1) of Regulation No 528/2012.

21 Under Article 48(1) of Regulation No 528/2012.

22 Article 48(3) of Regulation No 528/2012.

of the cancellation or amendment of a national authorisation which had already been granted, which differs from that of the grant of a first authorisation by way of mutual recognition. [23] In that context, the referral to the reference Member State in Article 36(1) of Regulation No 528/2012 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. In addition, the Court states that 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 Regulation No 528/2012, which provide for the Commission to intervene where no agreement could be reached within the coordination group on expiry of the period laid down by that regulation. [24]

Third, the Court considers that the contested decision is not vitiated by a manifest error of assessment and rejects, inter alia, the argument that the Commission did not carry out a detailed examination of whether the biocidal product at issue complied with the conditions laid down in Article 19(1) of Regulation No 528/2012. In that respect, it points out that, although the Commission may request the Chemicals Agency (ECHA) to give an opinion on scientific or technical issues raised by the Member States, [25] that consultation is an option for that institution and not an obligation. In addition, the Court points out 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. In the context of mutual recognition procedures, 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 public interest, exhaustively listed in Regulation No 528/2012, justifying the refusal to grant an application for such recognition. In that regard, the role conferred on the Commission by Article 36 of that regulation 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. Therefore, in view of the unacceptable effects on animal health of the biocidal product at issue, reported by several Member States, the Commission has indeed resolved the disagreement between the EU Member States which authorised that product.

[23] Governed by Articles 32 to 40 of Regulation No 528/2012.

[24] In particular, by means of Article 35(3) of Regulation No 528/2012.

[25] Under Article 36(2) of Regulation No 528/2012.