Case C-809/23

Summary of the request for a preliminary ruling pursuant to Article 98(1) of the Rules of Procedure of the Court of Justice

Date lodged:

22 December 2023

Referring court:

Conseil d'État (France)

Date of the decision to refer:

20 December 2023

Applicant:

Sumitomo Chemical Agro Europe SAS

Defendants:

Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)

Compagnie européenne de réalisations antiparasitaires SAS France (CERA)

1. Subject matter of the dispute

1 Sumitomo Chemical Agro Europe markets a biocidal product for mosquito control known as 'Vectobac', the active substance of which is Bacillus Thuringiensis israelensis, serotype H14, strain AM65-52 (Bti-AM65-52).

2 This substance is on the list of active substances agreed at Community level for inclusion in biocidal products set out in Annex I to Directive 98/8/EC.

3 On 30 August 2013, the Compagnie européenne de réalisations antiparasitaires (CERA) applied to the Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (French Agency for Food, Environmental and Occupational Health and Safety; ANSES) for national marketing authorisation for three biocidal products with the same purpose, known as 'Aquabac XT', 'Aquabac DF3000' and 'Aquabac 200G'. The active substance in each product is

the same bacillus of the same serotype, but the strain is BMP 144 (Bti-BMP 144), which is not on the list of EU-approved substances.

4 CERA requested the confidential treatment of data relating to trade secrets which it has disclosed to ANSES.

5 The requested authorisation was granted by three ANSES decisions of 19 August 2019, based on an assessment report which concluded that the active substances Bti-BMP 144 and Bti-AM65-52 were technically equivalent.

6 Sumitomo, which disputes this technical equivalence, asked ANSES to send it the assessment report. ANSES only forwarded part of the report (cover page, summary and a conclusion in the form of a table), on the ground that some parts contained technical information constituting trade secrets.

7 The undisclosed extracts from the assessment report concern Part I, on the methodology used by ANSES to determine whether the active substance contained in Aquabac products, namely Bacillus Thuringiensis israelensis, serotype H14, strain BMP 144, is technically equivalent to the active substance Bacillus Thuringiensis israelensis, serotype H14, strain AM65-52 (BtiAM65-52), an active substance which has been approved at EU level, and the first subsection of Part II, which implements that methodology for the active substances at issue. That subsection contains information on the identity and contact details of the applicant and the manufacturer of the active substance BMP 144, the location of the plant in which it is manufactured, the name of the active micro-organism, the classification of the active substance, its manufacturing process, the active substance content in the biocidal products at issue, details of the relevant toxins and metabolites, fermentation residues and contaminants, the ‘analysis profile’ consisting of comparing the composition of five batches of the biocidal products at issue, the analytical methods for identifying the pure active micro-organism in the active micro-organism as manufactured and the analytical methods for determining impurities and toxins, fermentation residues and contaminants in that micro-organism.

8 Sumitomo appealed against that decision before the tribunal administratif de Melun (Administrative Court, Melun, France), which upheld its application in part, although it did not order the disclosure of the full report.

9 Sumitomo then appealed to the Conseil d’État (Council of State, France).

2. Provisions of European Union law relied on

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

10 Article 19 provides:

'1. Without prejudice to Council Directive 90/313/EEC of 7 June 1990 on the freedom of access to information on the environment, an applicant may indicate to the competent authority the information which he considers to be commercially sensitive and disclosure of which might harm him industrially or commercially and which he therefore wishes to be kept confidential from all persons other than the competent authorities and the Commission. …

3. After the authorisation has been granted, confidentiality shall not in any case apply to:

…

(f) physical and chemical data concerning the active substance and biocidal product;

…

(k) methods of analysis referred to in Article 5(1)(c); [1]

(l) methods of disposal of the product and of its packaging;'

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

11 Article 66 provides:

'…

2. The Agency and the competent authorities shall refuse access to information where disclosure would undermine the protection of the commercial interests or the privacy or safety of the persons concerned. …

3. Notwithstanding paragraph 2, after the authorisation has been granted, access to the following information shall not in any case be refused:

…

(d) the content of the active substance or substances in the biocidal product and the name of the biocidal product;

[1] Article 5, entitled 'Conditions for issue of an authorisation', provides:

'1. Member States shall authorise a biocidal product only if … (c) the nature and quantity of its active substances and, where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants, and its residues of toxicological or environmental significance, which result from authorised uses, can be determined according to the relevant requirements in Annex IIA, IIB, IIIA, IIIB, IVA or IVB; …'.

(e) physical and chemical data concerning the biocidal product;

…

(j) methods of analysis referred to in Article 19(1)(c);' [2]

12 Article 67 provides:

'1. From the date on which the Commission adopts an implementing Regulation providing that an active substance is approved, as referred to in point (a) of Article 9(1), the following up-to-date information held by the Agency or the Commission on that active substance shall be made publicly and easily available free of charge:

(h) analytical methods referred to under Sections 5.2 and 5.3 of Title 1, and Section 4.2 of Title 2 of Annex II.

…

3. From the date on which the Commission adopts an implementing Regulation providing that an active substance is approved …, the Agency shall, except where the data supplier submits a justification in accordance with Article 66(4) accepted as valid by the competent authority or the Agency as to why such publication is potentially harmful for its commercial interests or any other party concerned, make publicly available, free of charge, the following up-to-date information on that active substance:

… (e) the assessment report. …

4. From the date on which a biocidal product is authorised, the Agency shall, except where the data supplier submits a justification in accordance with Article 66(4) accepted as valid by the competent authority or the Agency as to why such publication is potentially harmful for its commercial interests or any other party concerned, make publicly available, free of charge, the following up-to date information:

…

[2] Article 19 reads as follows:

1. 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:

…

(c) the chemical identity, quantity and technical equivalence of active substances in the biocidal product and, where appropriate, any toxicologically or ecotoxicologically significant and relevant impurities and non-active substances, and its residues of toxicological or environmental significance, which result from uses to be authorised, can be determined according to the relevant requirements in Annexes II and III;

(b) the assessment report.'

13 Article 96 provides:

'… Directive 98/8/EC is repealed with effect from 1 September 2013.'

14 Annex II, as amended by Commission Delegated Regulation (EU) 2021/525 of 19 October 2020 amending Annexes II and III to Regulation (EU) No 528/2012, lists in a table under Title 2 on micro-organisms the information required to support the approval of a substance.

Section 4.2 concerns 'Analytical methods for the analysis of the micro-organism as manufactured'.

Section 4.3 concerns 'Methods used for monitoring purposes to determine and quantify residues (viable or non-viable)'.

15 Annex III lists in a table under Title 2 on micro-organisms the information required to support the authorisation of a biocidal product.

Section 2.5 specifies with regard to the identity of biocidal products:

'Where the biocidal product contains an active substance that has been manufactured in locations or according to processes or from starting materials other than those of the active substance evaluated for the purpose of approval pursuant to Article 9 of this Regulation, evidence has to be provided that technical equivalence has been established in accordance with Article 54 of this Regulation or has been established, following an evaluation having started before 1 September 2013, by a competent authority designated in accordance with Article 26 of Directive 98/8/EC.'

Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC

16 Article 4, entitled 'Exceptions', provides:

'…

2. …

Member States may not, by virtue of paragraph 2(a), (d), (f), (g) and (h), provide for a request to be refused where the request relates to information on emissions into the environment.'

17 Article 11 provides:

'Repeal

Directive 90/313/EEC is hereby repealed with effect from 14 February 2005.

References to the repealed Directive shall be construed as referring to this Directive and shall be read in accordance with the correlation table in the Annex.'

3. Succinct presentation of the reasoning in the request for a preliminary ruling

Determination of the applicable text

18 The marketing authorisations for biocidal products in the 'Aquabac' range, applied for before the repeal of Directive 98/8 and its replacement by Regulation No 528/2012, on 1 September 2013, were granted on the basis of the national provisions transposing Directive 98/8, in accordance with Article 91(1) of Regulation No 528/2012.

19 After those authorisations had been issued, the national authority was contacted by a third party requesting access to information on the biocidal products it had authorised and the active substance they contain, in particular its technical equivalence with an authorised active substance.

20 It must be determined whether the national authority should examine that request for access in the light of the rules on confidentiality provided for by the national provisions transposing Article 19 of Directive 98/8 or those provided for by Articles 66 and 67 of Regulation No 528/2012. This forms the subject of the first question referred.

The interpretation of Directive 98/8

21 Article 19 of Directive 98/8 applies without prejudice to Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ 2003 L 41, p. 26), as found by the Court of Justice of the European Union in paragraph 44 of its judgment of 23 November 2016, *Bayer CropScience and Stichting De Bijenstichting* (C-442/14, EU:C:2016:890).

22 The question arises whether Article 19(3)(f) and (k) of Directive 98/8 makes it possible to obtain any detailed information on the methods and composition of the active substance or biocidal product or only general information. That is the subject matter of the second question referred.

The interpretation of Regulation No 528/2012

Whether or not Directive 2003/4 applies

23 Unlike Article 19 of Directive 98/8, Articles 66 and 67 of Regulation No 528/2012 do not expressly stipulate that Directive 2003/4 applies.

24 The question arises whether the EU legislature intended to define a specific and comprehensive regime for the communication to the public of information on biocidal products and their active substances, and thus disapply the provisions of Directive 2003/4 in so far as they provide, on the one hand, that a trade secret may not prevent the communication of information on emissions into the environment and, on the other hand, that if the disclosure of other environmental information could harm the commercial interests of an undertaking, the competent administrative authority must, prior to any refusal of communication, weigh the interest of that undertaking against the public interest.

Rules applicable to the publication of the 'assessment report'

25 Unless the applicant has requested confidential treatment, Article 67 of Regulation No 528/2012 provides for the publication of the assessment report on approved active substances (Article 67(3)(e)) and the assessment report on an authorised biocidal product (Article 67(4)(b)).

26 Regulation No 528/2012 does not lay down, particularly in Article 54 which governs the procedure for assessing the technical equivalence between active substances of biocidal products, the rules for accessing a report assessing the technical equivalence between an approved active substance and the active substance contained in a biocidal product which is not itself approved, carried out when examining the application for a marketing authorisation for that product.

27 The question arises whether the publication of the assessment report is governed by Article 67(3)(e) or Article 67(4)(b), or whether the report drawn up in the present case is a separate document from the 'assessment report' referred to in Article 67 of the Regulation, subject to its own rules on communication.

Access to methods of analysis

28 Article 66(3)(j) of Regulation No 528/2012 provides that after the authorisation has been granted, and notwithstanding paragraph 2 which lists information where disclosure would undermine the protection of the commercial interests or the privacy or safety of the persons concerned, access to the 'methods of analysis referred to in Article 19(1)(c)' shall not 'in any case be refused'.

29 According to the latter provision, those methods of analysis concern, inter alia, 'the technical equivalence of active substances in the biocidal product'.

30 The question arises whether the purpose of the 'methods of analysis' normally disclosed allows the applicant to obtain any relative detailed information on those methods, even if its disclosure could endanger trade secrets, or only general information on the nature of those methods and any conclusions that may be drawn from them.

Article 67(1)(h)

31 This provision states that from the date on which an active substance is approved, the 'analytical methods referred to under … Section 4.2 of Title 2 of Annex II' are to be made publicly available free of charge, with regard to active substances composed of micro-organisms.

32 Section 4.2, in the original version of the regulation, concerned 'methods used for monitoring purposes to determine and quantify residues (viable or non-viable)'. Since the adoption of Commission Delegated Regulation (EU) 2021/525 of 19 October 2020 amending Annexes II and III to Regulation (EU) No 528/2012, those provisions have become Section 4.3, with Section 4.2 of Title 2 of Annex II now referring to 'analytical methods for the analysis of the micro-organism as manufactured'.

33 The question arises whether that provision should be interpreted as actually referring to the provisions of Section 4.3 of Title 2 of Annex II.

34 If not – in other words, if that provision does refer to the provisions of Section 4.2 of Title 2 of Annex II in their current wording – the question arises whether, assuming those provisions apply to an active substance which has not been approved but is recognised as technically equivalent to an approved active substance, the communicability in principle of the 'analytical methods for the analysis of the micro-organism as manufactured' mentioned in Section 4.2 allows the applicant to obtain any detailed information on those methods, even if its disclosure could endanger trade secrets, or only general information on the nature of those methods and any conclusions that may be drawn from them.

35 This forms the subject of the first, second, third and fourth indents of the third question referred.

The interpretation of Directive 2003/4

36 In the event that Directive 2003/4 does apply in the present case, the question whether the description 'information on emissions into the environment' within the meaning of Article 4(2) of that directive, which includes information on the nature, composition, quantity, date and place of those emissions, and data concerning the medium- to long-term consequences of those emissions on the environment, could apply to information produced or received by the competent authority when examining the technical equivalence of an active substance with an approved active substance, or whether it can only apply to information on the

biocidal product containing that substance, since it is that product, with all its components, which is emitted into the environment, and not the active substance alone.

37 This forms the subject of the fourth question referred.

4. Questions referred:

38 The Conseil d'État (Council of State, France) refers the following questions for a preliminary ruling:

1. Where the competent national authority, having received an application for marketing authorisation for a biocidal product before 1 September 2013 and, pursuant to Article 91 of Regulation No 528/2012, having examined that application on the basis of the national provisions transposing Directive 98/8/EC, receives, after granting that authorisation, a request from a third party for access to information on the biocidal product it has authorised and the active substance it contains, including its technical equivalence with an authorised active substance, must that authority examine that request for access in the light of the rules on confidentiality provided for by the national provisions transposing Article 19 of Directive 98/8/EC, or those provided for by Articles 66 and 67 of Regulation No 528/2012?

2. If such a request for access is governed by Directive 98/8/EC, Article 19 of which applies without prejudice to Directive 2003/4 of the European Parliament and of the Council of 28 January 2003:

– Does paragraph 3(k) of that article, which provides that after the marketing authorisation for the biocidal product has been granted, confidentiality does not in any case apply to the 'methods of analysis referred to in Article 5(1)(c)', allow the applicant to obtain any detailed information on those methods, even if its disclosure could endanger trade secrets, or only general information on the nature of those methods and any conclusions that may be drawn from them?

– Do the 'physical and chemical data concerning the active substance and biocidal product', which cannot be kept confidential after the authorisation has been granted under Article 19(3)(f), allow the applicant to request the disclosure of detailed data on the composition of the active substance or biocidal product, even if they may directly or indirectly reveal the manufacturing processes?

3. If, on the other hand, such a request for access is governed by Regulation No 528/2012:

– Did the EU legislature, by Articles 66 and 67 of that regulation, which do not refer to Directive 2003/4, intend to define a specific and comprehensive regime for the communication to the public of information on biocidal products and their active substances, and thus disapply the provisions of Directive 2003/4

in so far as they provide, on the one hand, that a trade secret may not prevent the communication of information on emissions into the environment and, on the other hand, that if the disclosure of other environmental information could harm the commercial interests of an undertaking, the competent administrative authority must, prior to any refusal of communication, weigh the interest of that undertaking against the public interest?

– Is the communication of an assessment report on the technical equivalence between an approved active substance and the active substance contained in a biocidal product, prepared in the context of an application for marketing authorisation for that product, governed by Article 67(3)(e) of Regulation No 528/2012, which provides for the publication of the assessment report on approved active substances unless confidential treatment is requested by the applicant, by Article 67(4)(b), which provides for the publication of the assessment report on an authorised biocidal product unless confidential treatment is requested by the applicant, or by other rules?

– Does Article 66(3)(j) of Regulation No 528/2012, which provides that after the authorisation to place a biocidal product on the market has been granted, access to the 'methods of analysis referred to in Article 19(1)(c)' shall not 'in any case be refused', allow any detailed information on those methods to be obtained, even if its disclosure could endanger trade secrets, or only general information on the nature of those methods and any conclusions that may be drawn from them?

– Is Article 67(1)(h) of the same regulation, which provides that from the date of approval of an active substance, the 'analytical methods referred to under … Section 4.2 of Title 2 of Annex II' are to be made publicly available free of charge, to be interpreted as actually referring to the provisions of Section 4.3 of Title 2 of Annex II, to which it referred before the intervention of Commission Delegated Regulation of 19 October 2020 amending Annexes II and III to Regulation No 528/2012? If those provisions are to be interpreted as referring to the provisions currently in force of Section 4.2 of Title 2 of Annex II, and assuming those provisions apply to an active substance which has not been approved but is recognised as technically equivalent to an approved active substance, does the communicability in principle of the 'analytical methods for the analysis of the micro-organism as manufactured' mentioned in Section 4.2 allow the applicant to obtain any detailed information on those methods, even if its disclosure could endanger trade secrets, or only general information on the nature of those methods and any conclusions that may be drawn from them?

4. Lastly, if the provisions of Directive 2003/4 do apply to the present dispute, could the description 'information on emissions into the environment' within the meaning of Article 4(2) of that directive, which includes information on the nature, composition, quantity, date and place of those emissions, and data concerning the medium- to long-term consequences of those emissions on the environment, apply to information produced or received by the competent authority when examining the technical equivalence of an active substance with

an approved active substance, or can it only apply to information on the biocidal product containing that substance, since it is that product, with all its components, which is emitted into the environment, and not the active substance alone?