Reports of Cases

JUDGMENT OF THE COURT (Ninth Chamber)

19 December 2019*

(Reference for a preliminary ruling — Regulation (EU) No 528/2012 — Article 3(1)(a) and (c) — Concept of 'biocidal product' — Concept of 'active substance' — Bacterial product containing the bacterial species *Bacillus ferment* — Mode of action other than mere physical or mechanical action — Indirect action — Period within which effect takes place)

In Case C-592/18,

REQUEST for a preliminary ruling under Article 267 TFEU from the College van Beroep voor het bedrijfsleven (Administrative Court of Appeal for Trade and Industry, Netherlands), made by decision of 18 September 2018, received at the Court on 21 September 2018, in the proceedings

**Darie BV**

v

**Staatssecretaris van Infrastructuur en Milieu,**

THE COURT (Ninth Chamber),

composed of S. Rodin (Rapporteur), President of the Chamber, K. Jürimäe and N. Piçarra, Judges,

Advocate General: J. Kokott,

Registrar: Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of

– Darie BV, by H. Lamon and J.A.M. Jonkhout, advocaten,

– the Netherlands Government, by K. Bulterman and C.S. Schillemans, acting as Agents,

– the Austrian Government, initially by G. Hesse and subsequently by J. Schmoll, acting as Agents,

– the Norwegian Government, by J.T. Kaasin and T. Skjeie, acting as Agents,

– the European Commission, by L. Haasbeek and R. Lindenthal, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 17 October 2019,

* Language of the case: Dutch.

gives the following

## Judgment

1 The reference for a preliminary ruling concerns the interpretation of Article 3 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).

2 This request was made in the context of a dispute between Darie BV, a commercial company active on the wholesale market for maintenance, cleaning and washing products, and the Staatssecretaris van Infrastructuur en Milieu (Secretary of State for Infrastructure and the Environment, Netherlands) ('the Secretary of State'), concerning the legality of a decision of the latter ordering it to cease making available on the market a product which the Secretary of State described as a 'biocidal product' and which has not been authorised.

### Legal context

#### *European Union law*

*Regulation No 528/2012*

3 Recital 5 in the preamble to Regulation No 528/2012 is worded as follows:

'Rules concerning the making available on the market of biocidal products within the Community were established 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)]. It is necessary to adapt those rules in the light of experience and in particular the report on the first seven years of the implementation submitted by the Commission to the European Parliament and the Council, which analyses problems with and weaknesses of that Directive.'

4 Article 1 of that Regulation, entitled 'Purpose and subject matter', provides:

'1. The purpose of this 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 human and animal health and the environment. The provisions of this Regulation are underpinned by the precautionary principle, the aim of which is to safeguard the health of humans, the health of animals and the environment. …

2. This Regulation lays down rules for:

(a) the establishment at Union level of a list of active substances which may be used in biocidal products;

(b) the authorisation of biocidal products;

…'

5 Article 2 of that regulation, entitled 'Scope', provides in paragraph 1:

'This Regulation shall apply to biocidal products and treated articles. A list of the types of biocidal products covered by this Regulation and their descriptions is set out in Annex V.'

6 Article 3 of that regulation, entitled ‘Definitions’, provides, in paragraph 1:

‘For the purposes of this Regulation, the following definitions shall apply:

(a) “biocidal product” means

– any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,

– any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

A treated article that has a primary biocidal function shall be considered a biocidal product.

…

(c) “active substance” means a substance or a micro-organism that has an action on or against harmful organisms;

…

(g) “harmful organism” means an organism, including pathogenic agents, which has an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce, on animals or the environment;

…’

7 Article 17(1) of Regulation No 528/2012 provides:

‘Biocidal products shall not be made available on the market or used unless authorised in accordance with this Regulation.’

8 Annex V to that regulation, entitled ‘Biocidal product-types and their descriptions as referred to in Article 2(1)’, classifies those products into four groups, namely disinfectants, preservatives, pest control and other biocidal products. That annex specifies, first, that disinfectants exclude cleaning products that are not intended to have a biocidal effect and, secondly, that preservatives, unless otherwise specified, include only products to prevent microbial and algal development.

*Directive 98/8*

9 Article 2 of Directive 98/8, entitled ‘Definitions’, which was repealed and replaced by Regulation No 528/2012, provided in its paragraph 1:

‘For the purposes of this Directive the following definitions shall apply:

(a) Biocidal products

Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.

…'

*Regulation (EC) No 648/2004*

10 In recital 21 of Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ 2004 L 104, p. 1), it is 'recall[ed] that other horizontal legislation is applicable to detergent surfactants', which includes Directive 98/8.

11 Article 2(1) of that Regulation sets out the definition of 'detergent' for the purposes of that Regulation.

***Netherlands law***

12 Article 1 of the Wet gewasbeschermingsmiddelen en biociden (Law on Plant Protection Products and Biocides, 'the Wgb'), entitled 'Definitions', provides:

'1. In this Law and in the provisions made under it, the following definitions shall apply:

…

Biocidal product: a biocidal product as referred to in Article 3(1)(a) of Regulation (EU) No 528/2012;

…'

13 According to Article 43 of the Wgb, entitled 'Infringements of the Regulation':

'1. It shall be prohibited to act in contravention of Articles 17(1), 17(5) and 17(6) … of Regulation [No 528/2012] or the regulations adopted in implementation thereof.

…'

14 Article 86 of the Wgb, entitled 'Administrative constraint', provides:

'The Minister is authorised to impose an order under administrative constraint to enforce the rules laid down by or pursuant to this Law and Article 5:20 of the Algemene wet bestuursrecht (General Law on Administrative Law), in so far as it concerns the obligation to cooperate with officials appointed under Article 82.'

**The dispute in the main proceedings and the questions referred for a preliminary ruling**

15 By decision of 13 January 2017, the Secretary of State, on the basis of the combined provisions of Articles 43 and 86 of the Wgb and of Article 17(1) of Regulation No 528/2012, ordered Darie, subject to a penalty payment of EUR 1 000 per week, with a ceiling of EUR 25 000, to discontinue the making available on the market of Pure Air, a product which he described as a 'biocidal product' and which has not been authorised by the competent authority, namely the College voor de toelating van gewasbeschermingsmiddelen en biociden (body empowered to authorise plant protection and biocidal products, Netherlands).

16 Darie lodged a complaint against the Secretary of State's decision, claiming that he wrongly classified Pure Air as a 'biocidal product' within the meaning of Article 3(1)(a) of Regulation No 528/2012.

17 By decision of 26 May 2017, the State Secretary rejected that objection.

18 Darie brought an action against that decision before the College van Beroep voor het bedrijfsleven (Court of Appeal for Administrative Disputes in Economic Matters, Netherlands), challenging Pure Air's classification as a 'biocidal product' within the meaning of Article 3(1)(a) of Regulation No 528/2012. According to that company, Pure Air has a probiotic and not a biocidal effect, in that the bacterial species *Bacillus ferment* present in that product generates enzymes that assimilate and consume all the organic waste on which micro-organisms feed, so that, on the surfaces treated with that product, no biotope favourable to the development of micro-organisms such as fungi can form.

19 The referring court states that the label of Pure Air describes that product as a concentrated biodegradable liquid to be sprayed, enriched with probiotics and including the bacterial species *Bacillus ferment*, used 'to ensure the absence of mould' and for the 'elimination and prevention of unpleasant odours', by introducing a healthy and safe microflora to the sprayed surfaces. Pure Air's instructions for use specify, on the one hand, that before spraying that product on the surfaces to be treated, the mould must be removed 'to the point where it is totally eliminated' and, on the other hand, that 'to ensure that the mould does not recur, it is important to continue spraying [Pure Air] once every 3 to 4 weeks, depending on the level of humidity in the home'.

20 That court adds that, on 22 March 2017, the Darie website displayed the information that 'probiotic cleaning products work like traditional techniques. They eliminate visible contamination. There is an important difference, however. Potential pathogens such as mould and harmful bacteria also disappear. By removing their breeding grounds, the number of harmful bacteria and moulds will be greatly reduced. In addition, the product is safe and long-lasting. Its basic components are good bacteria and water, which makes it the most environmentally friendly product available in the professional market'.

21 The referring court questions whether the action of Pure Air, as claimed by Darie, consisting of controlling not harmful organisms but rather the creation or maintenance of the potential habitat of that harmful organism, falls within the concept of a 'biocidal product' referred to in Article 3(1)(a) of Regulation No 528/2012, read in conjunction with Article 3(1)(c) of that regulation.

22 In those circumstances the College van Beroep voor het bedrijfsleven (Administrative Court of Appeal for Trade and Industry) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Should the term "biocidal products" in Article 3 of Regulation 528/2012 be interpreted as also referring to substances which consist of one or more types of bacteria, enzymes or other constituents, given that, due to the specific way in which they act, they have no direct effect on the harmful organism for which they are intended, but on the creation or maintenance of the potential habitat of that harmful organism, and what requirements must then, where appropriate, be imposed on such an effect?

(2) In answering question 1, is it relevant whether the situation in which such a product is used is free of the harmful organism, and, if so, what criterion should be used to assess whether the latter is present?

(3) In answering question 1, does the period within which the effect takes place have any relevance?'

## Consideration of the questions referred

### *Admissibility*

23 Darie argues that the reference for a preliminary ruling must be rejected on the ground that the referring court has all the information it needs to establish, without it being necessary to refer questions to the Court for a preliminary ruling, that the product at issue in the main proceedings is not a biocidal product. In addition, it claims that the Court, in its judgment of 1 March 2012, *Söll* (C-420/10, 'the Söll judgment', EU:C:2012:111), has already answered the first question.

24 In that regard, it must be borne in mind that, in the context of the cooperation between the Court and the national courts established in Article 267 TFEU, it is solely for the national court before which a dispute has been brought, and which must assume responsibility for the subsequent judicial decision, to determine, in the light of the particular circumstances of the case, both the need of a preliminary ruling in order to enable it to deliver judgment and the relevance of the questions which it submits to the Court. Consequently, where the questions submitted concern the interpretation of EU law, the Court is, in principle, bound to give a ruling (judgment of 25 July 2018, *AY (Arrest warrant — witness)*, C-268/17, EU:C:2018:602, paragraph 24 and the case-law cited).

25 It follows that questions on the interpretation of EU law referred by a national court in the factual and legislative context which that court is responsible for defining, the accuracy of which is not a matter for the Court to determine, enjoy a presumption of relevance. The Court may refuse to rule on a request for a preliminary ruling referred by a national court only where it is quite obvious that the interpretation of EU law that is sought is unrelated to the actual facts of the main action or its object, where the problem is hypothetical, or where the Court does not have before it the factual or legal material necessary to give a useful answer to the questions submitted to it (judgment of 25 July 2018, *AY (Arrest warrant — witness)*, C-268/17, EU:C:2018:602, paragraph 25 and the case-law cited).

26 In the present case, a dispute is pending before the referring court concerning, in essence, the classification of the product Pure Air as a 'biocidal product' within the meaning of Article 3(1)(a) of Regulation No 528/2012. Since that court is requesting an interpretation of the concepts of 'biocidal product' and 'active substance' within the meaning of that regulation, and since it has provided the Court with the factual and legal information necessary to provide a useful answer to the questions raised, there can be no doubt that those questions are relevant to the settlement of the dispute and that the conditions for admissibility of the reference for a preliminary ruling, as set out in the previous point, are met.

27 The reference for a preliminary ruling is therefore admissible.

### *Substance*

#### *The first question*

28 By its first question, the referring court asks whether the concept of 'biocidal product' within the meaning of Article 3(1)(a) of Regulation No 528/2012 must be interpreted as comprising substances containing one or more bacterial species, enzymes or other constituents which, due to the specific way in which they act, do not act directly on the target harmful organisms, but on the creation or maintenance of the potential habitat of that harmful organism, and what requirements must then, where appropriate, be imposed on such an effect.

29 In that regard, it should be noted that since Regulation No 528/2012 repealed and replaced Directive 98/8, the Court's interpretation of the provisions of that directive also applies to that regulation whenever the provisions of the two instruments of EU law may be regarded as equivalent (see, to that effect, judgments of 16 November 2016, *Schmidt*, C-417/15, EU:C:2016:881, paragraph 26; of 9 March 2017, *Pula Parking*, C-551/15, EU:C:2017:193, paragraph 31; and of 15 November 2018, *Kuhn*, C-308/17, EU:C:2018:911, paragraph 31).

30 In paragraph 31 of the *Söll* judgment, the Court held that the concept of 'biocidal products' set out in Article 2(1)(a) of Directive 98/8 had to be interpreted as including products which act only by indirect means on the target harmful organisms, so long as they contain one or more active substances provoking a chemical or biological action which forms an integral part of a causal chain, the objective of which is to produce an inhibiting effect in relation to those organisms.

31 In that regard, it should be noted that, in paragraph 24 of the *Söll* judgment, the Court noted that the first subparagraph of Article 2(1)(a) of Directive 98/8 structured the definition of biocidal products around three cumulative elements. Those related to the presence, in the product, of an 'active substance', in the pursuit, by that product, of certain purposes and its chemical or biological mode of action. The Court's conclusion in paragraph 31 of that judgment was based, in particular, on an analysis of the second element of that definition, read in the light of the objectives of that Directive.

32 It is clear from a comparative analysis of the wording of Article 3(1)(a) of Regulation No 528/2012 and Article 2(1)(a) of Directive 98/8 that that element is worded in the same way in those two provisions, in that the classification as 'biocidal product' is, in particular, subject to the fact that the product has the 'intention of destroying, deterring, rendering harmless, preventing the action of or otherwise exerting a controlling effect on, any harmful organism'.

33 In those circumstances, as the Advocate General pointed out in point 29 of her Opinion, the interpretation adopted in the *Söll* judgment, according to which the concept of 'biocidal product' covers not only the direct effects, but also the indirect effects of a product, therefore remains applicable to the concept of 'biocidal product' within the meaning of Article 3(1)(a) of Regulation No 528/2012.

34 Such an interpretation is also consistent with the context of that provision. It should be recalled that Article 3(1)(c) of Regulation No 528/2012 defines the concept of 'active substance', of which a biocidal product may be composed, as 'a substance or micro-organism which has an action on or against harmful organisms'. 'The two alternative strands of that concept, namely action 'on' harmful organisms and action 'against' such organisms, confirm that such a concept includes not only direct actions on harmful organisms, but also indirect actions against such organisms, provided that their effects form an integral part of a causal chain, the objective of which is to produce an inhibiting effect in relation to those organisms.

35 On the other hand, it should be noted that, as regards the mode of action of a biocidal product, Article 3(1)(a) of Regulation No 528/2012, unlike Article 2(1)(a) of Directive 98/8, does not limit it to 'a chemical or biological action' but extends it to any 'action other than simple physical or mechanical action'.

36 As the Advocate General noted in point 27 of her Opinion, that regulation does not adopt the Commission's proposal to expressly limit the concept of 'biocidal product' to biological and chemical effects, as provided for in Article 3(1)(a) of the Commission Proposal of 12 June 2009 for a Regulation concerning the placing on the market and use of biocidal products (COM(2009) 267 final).

37 The extension of the definition of the mode of action of a biocidal product, brought about under Regulation No 528/2012, is consistent with the objective, recalled in recital 5 of that regulation, to adapt the rules of Directive 98/8 'in the light of experience' and to ensure an increased level of protection of human and animal health and of the environment.

38 It follows that the fact that a product has a probiotic effect, and not a chemical effect, does not in itself preclude its classification as a 'biocidal product' within the meaning of Article 3(1)(a) of Regulation No 528/2012. On the contrary, provided that the probiotic effect of a product results from '[an action] other than mere physical or mechanical action', within the meaning of that provision, and that the other conditions thereof are met, that product undoubtedly falls within the scope of that provision.

39 In those circumstances, the answer to the first question must be that the concept of 'biocidal product', within the meaning of Article 3(1)(a) of Regulation No 528/2012, must be interpreted as covering products containing one or more bacterial species, enzymes or other constituents which, due to the specific way in which they act, have no direct effect on the harmful organism for which they are intended, but on the creation or maintenance of a potential habitat of that harmful organism, provided that those products involve an action other than mere physical or mechanical action, which forms an integral part of a causal chain, the objective of which is to produce an inhibiting effect in relation to those organisms.

*The second question*

40 By its second question, the referring court asks whether Article 3(1)(a) of Regulation No 528/2012 must be interpreted as meaning that the fact that a product should only be applied to the surface to be treated after the elimination of target harmful organisms present on that surface, has an impact on the classification of that product as a 'biocidal product' within the meaning of that provision and, if the answer to that question is in the affirmative, what is the criterion against which it is to be assessed whether the surface to be treated is actually free of such organisms following that elimination.

41 In that regard, it is important to note, in the first place, that the gradation of the purposes of biocidal products set out in Article 3(1)(a) of Regulation No 528/2012 lists the purposes of biocidal products. These range from the destruction of the harmful organisms to their prevention (see, to that effect, judgment in *Söll*, paragraph 28). Moreover, Annex V to that regulation, containing the list of biocidal products covered by that regulation, includes in that list products with preventive action which are generally used in contexts free of harmful organisms.

42 It follows that the concept of 'biocidal product', within the meaning of Article 3(1)(a) of Regulation No 528/2012, is broad and extends, inter alia, to preventive products. That broad interpretation is supported by the objective set out in Article 1 of that regulation, based on the precautionary principle, to ensure 'a high level of protection of human and animal health and the environment'.

43 However, that objective cannot be fully achieved if products containing 'active substances', within the meaning of Article 3(1)(c) of Regulation No 528/2012, are not classified as 'biocidal products' because of their merely preventive effect on target harmful organisms and are not subject to the rules concerning the making available on the market and use of such products established by that regulation.

44 Indeed, as the Court held in paragraph 27 of the *Söll* judgment, it is the very presence of the active substance as such which is likely to present a risk to the environment, regardless of whether it acts directly or indirectly on the target organisms.

45 Secondly, the destruction of harmful organisms is not required by the concept of 'active substance' within the meaning of Article 3(1)(c) of Regulation No 528/2012. Indeed, when bacterial species, enzymes or other constituents of a product prevent the creation or maintenance of a potential habitat of those harmful organisms by removing the food environment from them, they act as an active substance against those organisms, by way of a preventive measure.

46 Accordingly, the fact that the target harmful organisms have been previously eliminated by action other than that produced by the substance in question, assuming that to be established, does not call into question the classification of that substance, which acts on the creation of an environment favourable to those harmful organisms, as an 'active substance' within the meaning of Article 3(1)(c) of Regulation No 528/2012.

47 In the third place, the possible cleaning function of a product containing one or more bacterial species, enzymes or other constituents which, because of their specific mode of action, do not act directly on harmful organisms but on the creation or maintenance of the potential habitat of that harmful organism, cannot exclude its classification as a 'biocidal product'.

48 As the Advocate General pointed out in points 32 and 33 of her Opinion, detergent products are not excluded from the scope of Regulation No 528/2012. Moreover, as is apparent from recital 21 of Regulation No 648/2004, a product can be described both as a 'detergent' within the meaning of Article 2(1) of that regulation and as a 'biocidal product' within the meaning of Article 3(1)(a) of Regulation No 528/2012.

49 Therefore, only the characteristics set out in Article 3(1)(a) and (c) of Regulation No 528/2012 are relevant for the purpose of classifying a product as a 'biocidal product'.

50 In view of the above, the answer to the second question must be that Article 3(1)(a) of Regulation No 528/2012 must be interpreted as meaning that the fact that a product must be applied to the surface to be treated only after the removal of target harmful organisms present on that surface does not affect the classification of that first product as a 'biocidal product' within the meaning of that provision.

*The third question*

51 By its third question, the referring court asks whether Article 3(1)(a) of Regulation No 528/2012 must be interpreted as meaning that the period within which a product takes effect affects the classification of that product as a 'biocidal product' within the meaning of that provision.

52 In that regard, it is apparent from the analysis carried out in the context of the second question that only the elements integrating the concepts of 'biocidal product' and 'active substance' within the meaning of Article 3(1)(a) and (c) of Regulation No 528/2012 are relevant to classify a product as a 'biocidal product'. However, the period within which a product takes effect is not one of those elements.

53 The answer to the third question must therefore be that Article 3(1)(a) of Regulation No 528/2012 must be interpreted as meaning that the period within which a product takes effect does not affect the classification of that product as a 'biocidal product' within the meaning of that provision.

## Costs

54 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the referring court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Ninth Chamber) hereby rules:

1. **The concept of 'biocidal product' within the meaning of Article 3(1)(a) of Regulation 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 must be interpreted as covering products containing one or more bacterial species, enzymes or other constituents which, due to the specific way in which they act, have no direct effect on the harmful organism for which they are intended, but on the creation or maintenance of a potential habitat of that harmful organism, provided that those products involve an action other than mere physical or mechanical action, which forms an integral part of a causal chain, the objective of which is to produce an inhibiting effect in relation to those organisms.**

2. **Article 3(1)(a) of Regulation No 528/2012 must be interpreted as meaning that the fact that a product must be applied to the surface to be treated only after the removal of target harmful organisms present on that surface does not affect the classification of that product as a 'biocidal product' within the meaning of that provision.**

3. **The answer to the third question must therefore be that Article 3(1)(a) of Regulation No 528/2012 must be interpreted as meaning that the period within which a product takes effect does not affect the classification of that product as a 'biocidal product' within the meaning of that provision.**

[Signatures]