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Provisional text

JUDGMENT OF THE COURT (First Chamber)

20 June 2024 (*)

(Reference for a preliminary ruling – Approximation of laws – Biocidal products – Regulation (EU) No 528/2012 – Article 72 – Disinfectant containing biocidal products – Advertising restrictions – Concept of ‘any similar indication’ – Purpose of ensuring a high level of protection of both human and animal health and the environment’

In Case C-296/23,

REQUEST for a preliminary ruling under Article 267 TFEU from the Bundesgerichtshof (Federal Court of Justice, Germany), made by decision of 20 April 2023, received at the Court on 10 May 2023, in the proceedings

Zentrale zur Bekämpfung unlauteren Wettbewerbs eV

v

dm-drogerie markt GmbH & Co. KG,

THE COURT (First Chamber),

composed of A. Arabadjiev, President of the Chamber, T. von Danwitz, P.G. Xuereb (Rapporteur), A. Kumin and I. Ziemele, Judges,

Advocate General: N. Emiliou,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

– the Zentrale zur Bekämpfung unlauteren Wettbewerbs eV, by C. Rohnke, Rechtsanwalt,

– dm-drogerie markt GmbH & Co. KG, by O. Bludovsky and D. Braunwarth, Rechtsanwälte,

– the Estonian Government, by M. Kriisa, acting as Agent,

– the Greek Government, by E. Leftheriotou and A.-E. Vasilopoulou, acting as Agents,

– the Lithuanian Government, by V. Kazlauskaitė-Švenčionienė, acting as Agent,

– the European Commission, by R. Lindenthal and M. Noll-Ehlers, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of the second sentence of Article 72(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 The request has been made in proceedings between the Zentrale zur Bekämpfung unlauteren Wettbewerbs eV (Association for Protection against Unfair Competition, Germany; 'the ZBUW') and dm-drogerie markt GmbH & Co. KG ('dm') a drugstore chain operating throughout Germany, concerning the description of a biocidal product in the advertising of that product.

Legal context

European Union law

3 According to recitals 1, 3, 53 and 61 of Regulation No 528/2012:

'(1) Biocidal products are necessary for the control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured materials. However, biocidal products can pose risks to humans, animals and the environment due to their intrinsic properties and associated use patterns.

…

(3) The purpose of this Regulation 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. Particular attention should be paid to the protection of vulnerable groups, such as pregnant women and children. This Regulation should be underpinned by the precautionary principle to ensure that the manufacturing and making available on the market of active substances and biocidal products do not result in harmful effects on human or animal health or unacceptable effects on the environment. With a view to removing, as far as possible, obstacles to trade in biocidal products, rules should be laid down for the approval of active substances and the making available on the market and use of biocidal products, including rules on the mutual recognition of authorisations and on parallel trade.

…

(53) To enable consumers to make informed choices, to facilitate enforcement and to provide an overview of their use, treated articles should be appropriately labelled.

…

(61) Effective communication of information on risks resulting from biocidal products and risk management measures is an essential part of the system established by this Regulation. …'

4 Article 1 of that regulation, entitled 'Purpose and subject matter', provides, in paragraph 1 thereof:

‘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 both 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. Particular attention shall be paid to the protection of vulnerable groups.’

5 Article 3 of that regulation, entitled ‘Definitions’, is worded as follows:

‘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.

…

(y) “advertisement” means a means of promoting the sale or use of biocidal products by printed, electronic or other media;

…’

6 Article 17 of that regulation, entitled ‘Making available on the market and use of biocidal products’, states:

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

…

5. Biocidal products shall be used in compliance with the terms and conditions of the authorisation stipulated in accordance with Article 22(1) and the labelling and packaging requirements laid down in Article 69.

Proper use shall involve the rational application of a combination of physical, biological, chemical or other measures as appropriate, whereby the use of biocidal products is limited to the minimum necessary and appropriate precautionary steps are taken.

Member States shall take necessary measures to provide the public with appropriate information about the benefits and risks associated with biocidal products and ways of minimising their use.

…’

7 Chapter XV of Regulation No 528/2012, entitled ‘Information and communication’, includes, in Section 2 thereof, entitled ‘Information about biocidal products’, Articles 69 to 73.

8 Article 69 of that regulation, entitled ‘Classification, packaging and labelling of biocidal products’, provides:

‘1. Authorisation holders shall ensure that biocidal products are classified, packaged and labelled in accordance with the approved summary of biocidal product characteristics, in particular the hazard statements and the precautionary statements, as referred to in point (i) of Article 22(2), and with Directive 1999/45/EC [of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ 1999 L 200, p. 1),] and, where applicable, Regulation (EC) No 1272/2008 [of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ 2008 L 353, p. 1)].

In addition, products which may be mistaken for food, including drink, or feed shall be packaged to minimise the likelihood of such a mistake being made. If they are available to the general public, they shall contain components to discourage their consumption and, in particular, shall not be attractive to children.

2. In addition to compliance with paragraph 1, authorisation holders shall ensure that labels are not misleading in respect of the risks from the product to human health, animal health or the environment or its efficacy and, in any case, do not mention the indications “low-risk biocidal product”, “non-toxic”, “harmless”, “natural”, “environmentally friendly”, “animal friendly” or similar indications. …

…’

9 Under Article 72 of Regulation No 528/2012, entitled ‘Advertising’:

‘1. Any advertisement for biocidal products shall, in addition to complying with Regulation [No 1272/2008], include the sentences “Use biocides safely. Always read the label and product information before use.”. The sentences shall be clearly distinguishable and legible in relation to the whole advertisement.

2. Advertisers may replace the word “biocides” in the prescribed sentences with a clear reference to the product-type being advertised.

3. Advertisements for biocidal products shall not refer to the product in a manner which is misleading in respect of the risks from the product to human health, animal health or the environment or its efficacy. In any case, the advertising of a biocidal product shall not mention “low-risk biocidal product”, “non-toxic”, “harmless”, “natural”, “environmentally friendly”, “animal friendly” or any similar indication.’

German law

10 Paragraph 3 of the Gesetz gegen den unlauteren Wettbewerb (Law against unfair competition) of 3 July 2004 (BGB1. 2004 I, p. 1414), in the version applicable to the main proceedings, prohibits unfair commercial practices.

11 Under Paragraph 3a of that law, entitled ‘Infringement of the law’:

‘Anyone who infringes a statutory provision intended, inter alia, to regulate market conduct in the interest of market players commits an unfair act where that infringement is capable of having an appreciable effect on consumers, other market players or competitors.’

12 Paragraph 8 of that law, entitled ‘Elimination and omission’, provides, in paragraph 1 thereof:

‘Any commercial practice which is unlawful under Paragraph 3 or Paragraph 7 may give rise to an order to cease and desist and, in the event of recurrence, an order to refrain or a prohibition order. …’

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

13 It is apparent from the request for a preliminary ruling that dm offered for sale, including via the internet, a disinfectant with the name 'BioLYTHE' ('the product at issue'). The label affixed to that product contains, under its name, the statements 'Ecological Universal Broad-Spectrum Disinfectant', 'Skin, hand and surface disinfection', 'Effective against SARS-Corona' and 'Skin friendly • Organic • Alcohol-free'.

14 Considering that the advertising was unfair because of an alleged infringement by dm of the rules of behaviour on the market concerned provided for by Regulation No 528/2012, and following an unsuccessful formal warning letter, the ZBUW brought an action before the Landgericht Karlsruhe (Regional Court, Karlsruhe, Germany) seeking, in essence, that dm be ordered, on pain of punitive administrative measures to compel specific conduct, to refrain from designating or marketing the product at issue as an 'ecological universal broad-spectrum disinfectant' and/or 'skin friendly' and/or 'organic' in advertisements or on the product label.

15 By judgment of 25 March 2021, that court upheld that action.

16 Dm brought an appeal against that decision before the Oberlandesgericht Karlsruhe (Higher Regional Court, Karlsruhe, Germany), which partially reversed that decision. That court found at the outset that the product at issue was a biocidal product within the meaning of Article 3(1)(a) of Regulation No 528/2012, and that the contested statements featured on that product's label, in particular the indication 'skin friendly', were covered by the concept of 'advertisement' as defined in Article 3(1)(y) of that regulation and governed by Article 72 thereof.

17 That court considered that the indications listed in the second sentence of Article 72(3) of Regulation No 528/2012 share the common feature of downplaying, by means of a blanket statement, the risks from the biocidal product to human health, animal health or the environment or its efficacy. Accordingly, statements relating to the risks from the biocidal product, which, in so far as they downplay those risks in a general manner, are comparable to the indications listed as examples in that provision, are covered by the concept of 'similar indication', within the meaning of that provision.

18 In that context, that court concluded that the indication 'skin friendly', used by dm for the product concerned, was not a 'similar indication' within the meaning of the second sentence of Article 72(3) of Regulation No 528/2012. That indication 'skin friendly' did not qualify the level of risk from the product at issue, its effects or their potential to cause harm (as the indications 'low-risk biocidal product', 'non-toxic', 'harmless' do) either in a general manner or, at least, specifically with regard to human health, animal health or the environment as global criteria. According to the Oberlandesgericht Karlsruhe (Higher Regional Court, Karlsruhe), the indication 'skin friendly' describes, albeit in very general terms, the effect of the product on a specific organ, namely human skin.

19 The ZBUW brought an appeal on a point of law (*Revision*) against that judgment of the Oberlandesgericht Karlsruhe (Higher Regional Court, Karlsruhe) before the Bundesgerichtshof (Federal Court of Justice, Germany), which is the referring court.

20 That court considers, first of all, that the question of what is to be understood by 'similar indication' within the meaning of the second sentence of Article 72(3) of Regulation No 528/2012 cannot be answered solely on the basis of the wording of that provision. It takes the view, however, that the purpose of that provision and its interaction with the first sentence of Article 72(3) of that regulation support the position taken by the Oberlandesgericht Karlsruhe (Higher Regional Court, Karlsruhe).

21 The referring court is of the opinion that the indications referred to in the second sentence of Article 72(3) of Regulation No 528/2012 are prohibited in the advertising of biocidal products, irrespective of whether they may mislead the user in respect of the risks from those products to human health, animal

health or the environment or their efficacy. In that regard, that court considers, like the Oberlandesgericht Karlsruhe (Higher Regional Court, Karlsruhe), that that regulation is not intended to prohibit indications per se, in the advertising of biocidal products, which concern the presence and, as the case may be, the extent or absence of any of those risks, irrespective of the veracity of those indications, which must be assessed in the light of the prohibition on misleading the user, within the meaning of the first sentence of Article 72(3) of that regulation.

22 Consequently, according to the referring court, the second sentence of Article 72(3) of Regulation No 528/2012 does not exclude from those indications – which are, in particular, not misleading – that are permitted in the advertising of biocidal products, substantiated specific statements relating to the absence of risk or to the low risk from such products, or even to their beneficial effects in certain respects. That court states in that regard that blanket statements have, at best, little or no informative value for consumers. On the other hand, those substantiated specific statements may provide consumers with valuable and useful information. Such an interest in informing consumers must be included in the specific balance which that regulation seeks to strike between the free movement of biocidal products and the pursuit of a high level of protection of human and animal health and of the environment.

23 The referring court is therefore of the opinion that the concept of 'similar indication', within the meaning of the second sentence of Article 72(3) of Regulation No 528/2012, must be interpreted as meaning that all of the properties common to the indications given as examples in that provision are relevant, that is to say not only their content which downplays the risks, but also their general nature. Accordingly, a statement which relates only to specific aspects of the biocidal product, without denying the existence of potential harmful side effects, is not a 'similar indication' within the meaning of that provision.

24 As regards a disinfectant like the product at issue, that court notes that the average consumer, who is reasonably well informed and circumspect, interprets the indication 'skin friendly' only as a qualification of the harmful side effects thereof. Therefore, that indication does not make consumers less discerning regarding the use of the product at issue. That understanding of the public is supported by the labelling requirement laid down in the first sentence of Article 72(1) of Regulation No 528/2012.

25 Lastly, the referring court considers that, since the ZBUW cannot apply for a cease and desist order in respect of the advertising, which designates the product at issue as 'skin friendly', on the basis that it infringes the prohibition on misleading the user referred to in the first sentence of Article 72(3) of Regulation No 528/2012, the interpretation of the second sentence of Article 72(3) of that Regulation is relevant in the present case.

26 In those circumstances, the Bundesgerichtshof (Federal Court of Justice) decided to stay the proceedings and to refer the following question to the Court of Justice for a preliminary ruling:

'Is a "similar indication" within the meaning of the second sentence of Article 72(3) of [Regulation No 528/2012] only such an indication contained in an advertisement which, in the same manner as the terms expressly listed in that provision, downplays properties of the biocide as regards the risks from the product to human health, animal health or the environment or its efficacy by means of a blanket statement, or does a "similar indication" include all terms which, in respect of the risks from the product to human health, animal health or the environment or its efficacy, downplay the risks in a manner comparable to the terms expressly listed but are not necessarily also general in nature like those terms?'

Consideration of the question referred

27 By its question, the referring court asks, in essence, whether the second sentence of Article 72(3) of Regulation No 528/2012 must be interpreted as meaning that the concept of 'any similar indication', within the meaning of that provision, includes any indication in the advertising for biocidal products which, like the

indications referred to in that provision, downplay the risks from a biocidal product to human health, animal health or the environment or its efficacy, without being general in nature.

28 In that regard, it must be recalled that, in accordance with the Court's settled case-law, in order to interpret a provision of EU law, it is necessary to consider its wording, the context in which it occurs and the objectives pursued by the rules of which it is part (judgment of 5 March 2024, *Défense Active des Amateurs d'Armes and Others*, C-234/21, EU:C:2024:200, paragraph 34 and the case-law cited).

29 As regards the wording of Article 72(3) of Regulation No 528/2012, that paragraph provides, in the first sentence thereof, that advertisements for biocidal products must not refer to the product in a manner which is misleading in respect of the risks from the product to human health, animal health or the environment or its efficacy. The second sentence of that paragraph states that in any case, the advertising of a biocidal product must not mention 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' or any similar indication.

30 In respect of the concept of 'any similar indication' in particular, within the meaning of the second sentence of Article 72(3) of that regulation, it should be observed that the terms 'any … indication' and 'similar' are used in reference to the indications listed in that sentence, that is to say 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly' and 'animal friendly'.

31 First, it follows from the text of those indications that they are inconsistent, in their very wording, with the existence of the risks which biocidal products pose to humans, animals and the environment, as is apparent from Article 3(1)(a) of that regulation, read in conjunction with recital 1 thereof, due to their intrinsic properties and associated use patterns.

32 Secondly, it should be noted that the wording of the second sentence of Article 72(3) of Regulation No 528/2012 contains no indication that the prohibition is limited only to the use of blanket statements in the advertising of biocidal products.

33 It is therefore apparent from the wording of the second sentence of Article 72(3) of Regulation No 528/2012 that the commonality of the indications listed in that provision lies in the fact that they downplay the risks from biocidal products to human health, animal health or the environment or their efficacy, or even deny the existence of those risks, without necessarily being general in nature.

34 As regards the context in which the second sentence of Article 72(3) of Regulation No 528/2012 occurs, it should be observed, first of all, that, as is apparent from recital 61 of that regulation, the effective communication of information on risks resulting from biocidal products is, in particular, an essential part of the system established by that regulation. Accordingly, the advertising of biocidal products must allow consumers to obtain a sufficient level of information on the risks of using those products so as not to underestimate those risks and to make an informed decision when buying such products.

35 Next, it should be noted that Article 72(3) of Regulation No 528/2012 must be read in conjunction with the rules on labelling biocidal products provided for in Article 69 thereof. It is apparent from paragraph 1 of that article, read in the light of recital 53 of that regulation, that the labelling of such products provides consumers with information about those products which enables them to make informed choices and contains, in particular, the hazard statements and the precautionary statements as referred to in Directive 1999/45 and Regulation No 1272/2008.

36 Lastly, Article 69(2) of Regulation No 528/2012 lays down, in a single sentence, the prohibition on labels of biocidal products being misleading in respect of the risks from those products to human health, animal health or the environment or their efficacy, and provides that, in any case, those labels must not mention the indications that it lists, which are identical to those provided for in Article 72(3) of that regulation, which are manifestly misleading.

37 In that context, it must be found that Article 72(3) of Regulation No 528/2012 establishes general rules on the advertising of biocidal products which are based on consumers' reactions so far as concerns the perception of the risks from those products to human health, animal health or the environment and which apply irrespective of the risks and the actual properties of those products.

38 The indications referred to in the second sentence of Article 72(3) of Regulation No 528/2012, and the statement 'any similar indication', amount to examples of indications that are manifestly misleading in respect of those risks and the use of which in advertising for biocidal products is prohibited under Article 72(3) of that regulation.

39 It follows that, as regards the relevance of the supposed general nature of the indications referred to in the second sentence of Article 72(3) of that regulation, both general and specific indications may manifestly mislead the user in respect of the risks of using biocidal products by downplaying the risks from those products to human health, animal health or the environment or their efficacy, or even by denying the existence of those risks, with the result that such a general nature cannot be relevant for the purposes of ascertaining whether an indication concerning a biocidal product is covered by the concept of 'any similar indication', within the meaning of the second sentence of Article 72(3) of that regulation.

40 As regards the objective pursued by Regulation No 528/2012, as is apparent from Article 1(1) of that regulation, read in the light of recital 3 thereof, 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 (judgment of 14 October 2021, *Biofa*, C-29/20, EU:C:2021:843, paragraph 35 and the case-law cited).

41 In that regard, it should be noted that it is apparent from the third subparagraph of Article 17(5) of that regulation that Member States must take necessary measures to provide the public with appropriate information about the benefits and risks associated with biocidal products and ways of minimising their use.

42 Accordingly, the EU legislature sought to strike a specific balance between the free movement of biocidal products and a high level of protection of human and animal health and the environment (judgment of 19 January 2023, *CIHEF and Others*, C-147/21, EU:C:2023:31, paragraph 64).

43 To that end, by the second sentence of Article 72(3) of Regulation No 528/2012, the EU legislature intended to regulate, in a detailed and comprehensive manner, the wording of statements on the risks of using of biocidal products which may appear in advertisements for those products, in that that article provides for the existence of a mandatory statement, that it expressly prohibits certain statements and that it seeks, more generally, to prohibit any advertising statement which is liable to mislead the user as to the risks that such products may present (judgment of 19 January 2023, *CIHEF and Others*, C-147/21, EU:C:2023:31, paragraph 63).

44 In those circumstances, it must be held that, as follows from paragraph 33 above, the use in the advertising of biocidal products of indications that do not downplay or deny the risks from those biocidal products to human health, animal health or the environment or their efficacy is not, in principle, prohibited under Article 72(3) of that Regulation.

45 By contrast, the use of advertising statements for biocidal products which refer to the absence of risk, to a low risk or to certain beneficial effects of those products with a view to downplaying or even denying those risks, are not permitted. As the European Commission has, in essence, noted in its written observations, such statements may encourage excessive, negligent or incorrect use of those products, contrary to the objective of minimising their use.

46 In the present case, with respect to the indication ‘skin friendly’ used in the advertising of the biocidal product concerned, it need only be observed that such an indication which has, prima facie, a positive connotation that avoids suggesting any risk, may qualify the harmful side effects of that product or even, as the Greek Government and the Commission submit, in essence, in their written observations, imply that that product could be beneficial for skin. Such an indication is misleading within the meaning of Article 72(3) of Regulation No 528/2012, which justifies the prohibition of its use in the advertising of that product.

47 That interpretation is not called into question by the fact that, by reason of the mandatory statement provided for in the first sentence of Article 72(1) of Regulation No 528/2012, the advertisement must indicate, in a clear and legible manner, that biocidal products must be used safely and that the label and product information must always be read before use. As the Commission noted in its written observations, reading the label may even divert consumers’ attention from other information featured on that label.

48 In light of all the foregoing considerations, the answer to the question raised is that the second sentence of Article 72(3) of Regulation No 528/2012, must be interpreted as meaning that the concept of ‘any similar indication’, within the meaning of that provision, includes any indication in the advertising for biocidal products which, like the indications referred to in that provision, refers to those products in a manner which is misleading in respect of the risks from the product to human health, animal health or the environment or their efficacy, by downplaying those risks or even denying their existence, without necessarily being general in nature.

Costs

49 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 (First Chamber) hereby rules:

The second sentence of Article 72(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

must be interpreted as meaning that the concept of ‘any similar indication’, within the meaning of that provision, includes any indication in the advertising for biocidal products which, like the indications referred to in that provision, refers to those products in a manner which is misleading in respect of the risks from the product to human health, animal health or the environment or their efficacy, by downplaying those risks or even denying their existence, without necessarily being general in nature.

[Signatures]

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* Language of the case: German.