Reports of Cases

JUDGMENT OF THE GENERAL COURT (Seventh Chamber)

16 November 2022 *

(Biocidal products – Active substances – Silver zeolite and silver copper zeolite – Refusal of approval for product-types 2 and 7 – Article 4 and Article 19(1)(b) of Regulation (EU) No 528/2012 – Efficacy – Active substances for use in treated articles – Assessment of the efficacy of the treated articles themselves – Competence of the Commission – Principle of non-discrimination – Legal certainty – Legitimate expectations)

In Cases T-122/20 and T-123/20,

Sciessent LLC, established in Beverly, Massachusetts (United States), represented by K. Van Maldegem and P. Sellar, lawyers, and V. McElwee, Solicitor,

applicant,

v

European Commission, represented by A. Dawes and R. Lindenthal, acting as Agents,

defendant,

supported by

Kingdom of Sweden, represented by R. Shahsavan Eriksson, C. Meyer-Seitz, A. Runeskjöld, M. Salborn Hodgson, H. Shev, H. Eklinder and O. Simonsson, acting as Agents,

and by

European Chemicals Agency (ECHA), represented by M. Heikkilä, C. Buchanan and T. Zbihlej, acting as Agents,

interveners,

THE GENERAL COURT (Seventh Chamber),

composed, at the time of the deliberations, of R. da Silva Passos, President, I. Reine (Rapporteur) and M. Sampol Pucurull, Judges,

Registrar: P. Cullen, Administrator,

* Language of the case: English.

having regard to the written part of the procedure, particularly the decision of 8 February 2022 joining Cases T-122/20 and T-123/20 for the purposes of the oral part of the procedure,

further to the hearing on 31 March 2022,

gives the following

Judgment [1]

1 By its actions pursuant to Article 263 TFEU, the applicant, Sciessent LLC, seeks the annulment of Commission Implementing Decision (EU) 2019/1960 of 26 November 2019 not approving silver zeolite as an existing active substance for use in biocidal products of product-types 2 and 7 (OJ 2019 L 306, p. 42) and Commission Implementing Decision (EU) 2019/1973 of 27 November 2019 not approving silver copper zeolite as an existing active substance for use in biocidal products of product-types 2 and 7 (OJ 2019 L 307, p. 58) (together, 'the contested decisions').

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IV. Law

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C. Substance

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1. First plea, alleging infringement of Articles 4 and 19 of Regulation No 528/2012

36 The applicant claims that, under Article 19(1)(b) and Article 19(2) of Regulation No 528/2012, the evaluating competent authority, ECHA and the Commission were required to assess the efficacy of the substances concerned, taking into consideration, inter alia, the way in which treated articles treated with the biocidal product could be used. Those provisions do not, however, require that the efficacy of the treated articles themselves be assessed. The note of 14 September 2015 and Delegated Regulation 2021/525, which sets out the requirements for the efficacy assessment in Annexes II and III thereto to that effect, support that claim.

37 According to the applicant, it is apparent from the opinions of the ECHA biocidal products committee, to which the contested decisions refer, that the Commission based its decision incorrectly on an efficacy assessment of the articles to which the substances concerned have been applied, that is, on an assessment of the efficacy of the treated articles themselves, and thus required the applicant to demonstrate that the articles treated with the substances concerned were also effective in reducing or eliminating bacteria or fungi. It submits that that unlawful approach is also apparent from various sections of the June 2017 assessment reports, according to which it should have demonstrated that bacteria were killed on contact and tested the

[1] Only the paragraphs of the present judgment which the Court considers it appropriate to publish are reproduced here.

components of an air conditioning system treated with the substances concerned for product-type 2, and should have shown the growth of trial organisms on non-treated material for product-type 7.

38 The applicant observes that, pursuant to Article 4(1) of Regulation No 528/2012, an active substance must be approved if at least one biocidal product containing that active substance 'may be expected to' meet the criteria laid down in Article 19(1)(b). As a result, there is no obligation to show that an active substance actually meets those criteria. The standard of proof required to demonstrate the efficacy of an active substance is therefore lower. This claim is allegedly confirmed in, inter alia, point 6.6 of Part A of the ECHA guidance on the biocidal products regulation, Volume II Efficacy, of November 2014.

39 Thus, according to the applicant, in order to assess the efficacy of an active substance for use in a treated article, the innate efficacy alone of that substance must be assessed. That innate efficacy must be assessed by way of phase 1 tests, which simulate certain relevant conditions of use and make it possible to provide proof of principle of the efficacy of the active substance. By contrast, a requirement that the efficacy of an active substance be demonstrated by way of phase 2 tests, carried out in realistic conditions, fails to have regard to Regulation No 528/2012, as this is tantamount to requiring that the efficacy of the treated articles themselves be demonstrated.

40 In the present case, the innate efficacy of the substances concerned has, in fact, been established by way of phase 1 tests. The applicant alleges that the data produced clearly show a significant reduction in the number of organisms relevant to the claim made, in conditions that are representative of the use cited, having regard to the untreated control material which was tested in identical conditions. The applicant submits that it has in fact demonstrated sufficient efficacy of the protection imparted on the treated articles by the representative biocidal product containing the substances concerned.

41 The Commission, supported by ECHA and the Kingdom of Sweden, disputes the applicant's arguments.

(a) Preliminary observations on efficacy

42 Article 1(1) of Regulation No 528/2012 provides that its purpose is to ensure a high level of protection of both human and animal health and the environment. That objective cannot be attained if active substances carrying certain risks were approved without the certainty that the organisms targeted by those substances would develop and require human intervention.

43 It is apparent from Article 4(1) of Regulation No 528/2012, read in conjunction with Article 19(1)(b) thereof, that, in order to obtain approval of an active substance, the applicant must, inter alia, demonstrate that at least one biocidal product containing that substance may be expected to meet the efficacy criterion laid down in Article 19(1)(b).

44 In that connection, point 3.1 of Part B+C of the 2017 ECHA efficacy guidance defines efficacy as the ability of a product to fulfil the claims made for it when used according to the directions for use on the product label. It must be ascertained whether the biocidal product is sufficiently effective against target organisms under the conditions specified.

45 It is also apparent from point 4.2.4 of Part B+C of the 2017 ECHA efficacy guidance that, at the active substance approval stage, there is an essential link between the assessment of the efficacy of that active substance and the assessment of its risks to human health and the environment. That risk assessment is carried out while taking into account the concentration at which the efficacy of the active substance has been demonstrated. Moreover, the efficacy must be sufficient for the use assessed in the risk assessment.

46 Moreover, Article 6 of Regulation No 528/2012 provides that, when applying for approval of an active substance, the applicant must provide the evaluating competent authority with a complete dossier for the active substance satisfying the requirements in Annex II to that regulation and a complete dossier satisfying the requirements in Annex III to that regulation for 'at least one' representative biocidal product containing the active substance (see Article 4(1) of the regulation). Thus, each of those dossiers must contain relevant information on efficacy.

47 Annexes II and III to Regulation No 528/2012 detail the data that an applicant is required to produce in order to demonstrate the efficacy of, respectively, an active substance and of the representative biocidal product containing that active substance. Those data must support the applicant's claims, that is, the alleged effects of the active substance and of the product containing that substance. Point 6.6 of Annex II to that regulation and point 6.7 of Annex III to that regulation, in the version applicable to the proceedings, state that an applicant must provide data to support claims on biocidal products and, where label claims are made, on treated articles.

48 It must be added that point 1 of Annex III to Regulation No 528/2012, in the version applicable to the proceedings, sets out the information requirements that must be included in the dossier for the biocidal product accompanying an application for the approval of an active substance in accordance with Article 6(1)(b) of the regulation, and in the dossier accompanying an application for the authorisation of a biocidal product. Those requirements are therefore identical for both types of dossier.

49 Moreover, it is apparent from Article 19(1) of Regulation No 528/2012 that, for the purposes of assessing, inter alia, the efficacy of the biocidal product containing the active substance, it is necessary to take into account the factors listed in Article 19(2) of the regulation. Those factors include the realistic worst case conditions under which the biocidal product may be used, and the way in which articles treated with the biocidal product or containing the biocidal product may be used.

50 In the light of the foregoing, it should be noted, first, that the provisions referred to in paragraphs 42 to 49 above do not require the applicant for approval of an active substance for use in one or more treated articles to demonstrate the efficacy of those treated articles with the representative biocidal product containing the active substance in question.

51 Nevertheless, the applicant must prove that at least one representative biocidal product may be expected to meet the efficacy criterion in the light of the claims which the applicant has him- or herself defined for that product. Where the representative biocidal product chosen by the applicant is intended, according to the applicant, to be incorporated into a treated article in order to impart on that article a certain kind of protection or a certain effect, it is for the applicant to support his or her claims by way of appropriate tests.

52 In that regard, point 1.5.6 of the ECHA transitional guidance on the efficacy of disinfectants states that the efficacy of treated articles that are not biocidal products themselves does not require assessment under Regulation No 528/2012. However, active substances and biocidal products incorporated into treated articles may require an assessment of their efficacy in treated articles as part of the active substance approval procedure (if such uses are applied for).

53 That principle is now set out in recital 7 of Delegated Regulation 2021/525. That recital states that for treated articles, the efficacy of the biocidal properties imparted on the article should be demonstrated.

54 Second, as is apparent from paragraph 49 above, the tests carried out by the applicant for approval of an active substance must make it possible for the efficacy of the representative biocidal product to be assessed, including in the realistic worst case conditions under which the biocidal product may be used. Those tests must also take into account the way in which treated articles treated with the biocidal product or containing the biocidal product may be used. Such tests must be provided for every product-type in respect of which the applicant has submitted an application for approval of the active substance.

55 Thus, where the applicant chooses, as a representative biocidal product, a product intended to be incorporated into a treated article in order to impart on it a certain kind of protection or a certain effect, it cannot merely submit tests carried out under standard conditions, that is, under conditions that do not take account of specific conditions for use of the representative biocidal product, or to provide only proof of principle of the efficacy of the active substance. Phase 1 tests, defined in point 1.4.1 of the ECHA transitional guidance on the efficacy of disinfectants as tests which do not take account of the specific conditions of the intended use of the representative biocidal product, are therefore not sufficient to establish efficacy of the active substance in question for the purposes of its authorisation in accordance with Article 4(1) of Regulation No 528/2012.

56 In the context of the dossier on the representative biocidal product referred to in Article 6(1)(b) of Regulation No 528/2012, it is for the applicant to submit tests which reproduce the realistic worst case conditions under which that product may be used and which take into account the way in which the treated article may be used. It is apparent from point 1.4.1 of the ECHA transitional guidance on the efficacy of disinfectants that such conditions are simulated, in essence, in phase 2 tests, which reproduce, in laboratory conditions, the practical conditions appropriate to the intended use.

57 Admittedly, Annex VI to Regulation No 528/2012 only refers to how the treated articles are used in the context of the assessment of the risks of the active substance. Nevertheless, it is clear from Article 19(2)(b) of the regulation that information on how the treated article may be used is required in order to assess whether the representative biocidal product meets all of the criteria set out in Article 19(1)(b) of the regulation, including the efficacy criterion.

58 Moreover, the fact that, under Article 4(1) of Regulation No 528/2012, an active substance must be approved if at least one biocidal product containing that active substance ‘may be expected to’ meet the criteria laid down in Article 19(1)(b) of the regulation, cannot lead to a finding that phase 1 tests are sufficient to demonstrate the efficacy of that representative biocidal product.

59 Indeed, Article 19(2) of Regulation No 528/2012, to which Article 19(1)(b) of that regulation refers, expressly requires account to be taken – inter alia, in order to demonstrate efficacy of the representative biocidal product – of the realistic worst case conditions under which the biocidal product may be used and the way in which treated articles treated with the biocidal product or containing the biocidal product may be used. It is apparent from paragraph 56 above that those conditions are reflected in phase 2 tests.

60 Similarly, the applicant cannot validly rely on Part A of the ECHA guidance on the biocidal products regulation, Volume II Efficacy, of November 2014, in order to argue that the efficacy assessment of an active substance must be restricted, essentially, to phase 1 tests. That document does not in any way state that only tests carried out in standard conditions are required to demonstrate the efficacy of the representative biocidal product containing the active substance. On the contrary, point 6 of Chapter II of that document, relating to the efficacy data required for the purposes of approval of an active substance, states that the applicant must provide sufficient information on the efficacy of the representative biocidal product and the intended uses of the active substance in order to make it possible to assess that product and define its conditions of use. That requirement flows directly from Article 6 and Article 19(1) and (2) of Regulation No 528/2012.

61 It should be added that it is only 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 and its efficacy on all of the target organisms will be examined in detail and an assessment of the product's efficacy and risks, having regard to each of those uses, will be carried out. Such an in-depth assessment is not required at the approval stage of an active substance, as stated in the ECHA guidance document referred to in paragraph 60 above. The efficacy assessment of an active substance is therefore in actual fact more limited than that of a biocidal product in the context of a marketing authorisation procedure.

62 Third, it should be noted that point 6.4 of Chapter II of the ECHA guidance referred to in paragraph 60 above, read in conjunction with point 6.4 of Chapter III of that document, to which it refers, stresses that it is necessary to justify the selection of the use concentrations for the efficacy tests. The likely use concentration is defined as ideally being the minimum effective concentration under realistic conditions, taking into account all relevant parameters that impact efficacy. From that standpoint, there is therefore also a necessary link between the efficacy assessment of an active substance and of the representative biocidal product, on the one hand, and the real conditions of use of that biocidal product as reflected in phase 2 tests, on the other.

63 It is apparent from the foregoing considerations that, in order to demonstrate the efficacy of an active substance for use in a treated article, the applicant for approval of that substance must prove (i) the innate efficacy of that substance in the dossier referred to in Article 6(1)(a) of Regulation No 528/2012 and (ii) the sufficient efficacy of the protection imparted on the articles treated by the representative biocidal product containing the active substance in the dossier relating to that product referred to in Article 6(1)(b) of the regulation.

64 As for the representative biocidal product, the applicant is required, for each product-type and each claim, to submit tests carried out in realistic worst case conditions and taking into account the way in which the treated articles may be used.

(b) The efficacy assessment in the present situation

65 Here, the representative biocidal products were made up entirely of each of the substances concerned; each of those substances was therefore intended to be incorporated in a treated article.

66 According to point 2.4 of the June 2017 assessment reports, the evaluating competent authority asked the applicant to define at least one example use of the representative biocidal product chosen for each product-type (2 and 7) and for each claim and to demonstrate the efficacy of the product for each of those example uses via, at least, phase 1 and phase 2 tests. It explained in those reports that efficacy was largely dependent on conditions of use, humidity levels in particular, and on the material into which the representative biocidal product was incorporated.

(1) Product-type 2

67 Under Annex V to Regulation No 528/2012, product-type 2 covers disinfectants and algaecides not intended for direct application to humans or animals. This includes, inter alia, products used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.

68 Here, during the assessment procedure of the substances concerned, the applicant proposed two example uses of the representative biocidal products made up entirely of the substances concerned for product-type 2: first, use in wall or floor coverings and, second, use in the components of an air conditioning system. It is apparent from the file, the applicant's replies to the questions put by the Court in the context of measures of organisation of procedure in particular, that the treatment of those materials is intended to reduce the risk of cross-contamination by bacteria. The evaluating competent authority interpreted that objective as intending to have both the effect of 'killing on contact' and the effect of limiting bacterial growth. The second effect was not disputed by the applicant.

(i) The first example use

69 Regarding the first example use, relating to wall or floor coverings, point 7.1 of the June 2017 assessment reports states that the applicant had defined the issue to be resolved as 'a risk for cross contamination of bacteria' on untreated indoor surfaces, in humid areas conducive to bacterial growth. The evaluating competent authority interpreted that claim as that of a fast bactericidal effect (that is, within 5 to 60 minutes) according to the principles applicable to liquid disinfectants.

70 In the light of that claim, the evaluating competent authority considered that the applicant was required to submit tests simulating short contact times in order to demonstrate that bacteria were eliminated rapidly. It also stated that the tests submitted should also simulate splash contamination in dry conditions, given that, in essence, those are less favourable conditions of use. However, such tests were not submitted, which the applicant does not dispute.

71 First of all, it must be stated that the ground on which the evaluating competent authority rejected the tests submitted by the applicant as far as the first example use is concerned is not based on the fact that those tests do not demonstrate the efficacy of the coverings treated with the substances concerned. The June 2017 assessment reports do not contain any reference to the fact that such

efficacy has not been demonstrated or any reference to the working paper presented by the Nordic Council of Ministers, entitled 'Efficacy Assessment of treated articles: a guidance' ('the Nordic Working Paper'), which requires the efficacy of the treated article to be demonstrated.

72 The tests submitted by the applicant were found to be insufficient on the ground that the conditions under which they had been conducted were not relevant in the light of Regulation No 528/2012, given the claimed effects and the example use chosen by the applicant.

73 As is clear from paragraph 56 above, the applicant had to submit tests which reproduced the realistic worst case conditions under which the chosen representative product may be used and which took into account the way in which the treated article may be used.

74 Next, admittedly, for the example uses of product-type 2, the applicant had not claimed expressly that they had a 'killing on contact' effect, only a bacteriostatic effect. The fact remains that the applicant itself had stated, at the request of the evaluating competent authority, that the substances concerned were incorporated into floor and wall coverings in order to 'reduce the risk of cross-contamination'.

75 In that connection, it was for the applicant, as the applicant for approval of active substances, to define carefully, consistently and specifically the claims related to those substances, for each product-type and each example use chosen. Such definition constitutes, in fact, the starting point for the efficacy assessment of those substances.

76 However, as explained by the Commission, and the Kingdom of Sweden in its written replies to the measures of organisation of procedure, the risk of cross-contamination cannot, in practice, be reduced if the representative biocidal products made up entirely of the substances concerned resulted in bacteria remaining on a surface while merely preventing the number of those bacteria from increasing. Such bacteriostatic effect is not sufficient to limit the risk of transmission of an infection from one human to another or one animal to another. Only the net reduction of the number of bacteria within a short period of time would demonstrate efficacy with regard to the effect claimed by the applicant.

77 Moreover, as explained by the Kingdom of Sweden, an inside surface may be contaminated several times over a 24-hour period. Tests which simulate only a single contamination of such a covering during that period do not reflect realistic worst case conditions within the meaning of Article 19(2)(a) of Regulation No 528/2012.

78 It is also clear from point 1.5.6 of the ECHA transitional guidance on the efficacy of disinfectants that it is necessary to demonstrate a very fast effect when a bactericidal claim is made.

79 However, the applicant had only submitted tests relating to a single contamination over a 24-hour period, which does not amount to realistic worst case conditions within the meaning of Article 19(2)(a) of Regulation No 528/2012, in order to demonstrate a fast biocidal effect.

80 It is appropriate to add that, in so far as, during the assessment procedure of the substances concerned, only the ECHA transitional guidance on the efficacy of disinfectants provided specific guidance on the factors to be taken into account in tests to demonstrate the efficacy of such products, the evaluating competent authority was able to base, *mutatis mutandis*, its efficacy assessment of the substances concerned on that guidance.

81 Moreover, it is also true that the applicant had defined the conditions of use of the coverings in question as indoor humid conditions, not dry conditions. However, it is apparent from points 2.3.1 and 2.4 of the June 2017 assessment reports that the antimicrobial effect of substances such as the substances concerned depend to a great extent on several factors, the most significant of which is the complementary presence of a solvent, that is, of a liquid on contact with which the substance will dissolve and produce its effects. Where the surface of the material treated with those substances remains dry, it is therefore unlikely, without a liquid solvent, that such conditions will trigger an antimicrobial effect.

82 Thus, in so far as they had been carried out in humid conditions, not on a dry surface, the tests submitted by the applicant did not reflect the realistic worst case conditions under which the representative biocidal product could be used, in accordance with Article 19(2)(a) of Regulation No 528/2012.

83 Last, it is not in any way apparent from the June 2017 assessment reports or from the opinions of the ECHA biocidal products committee that the applicant should have demonstrated the benefits of the wall and floor coverings treated with the substances concerned. As set out in paragraph 72 above, the tests submitted by the applicant were found to be insufficient because the simulated laboratory conditions under which they had been conducted were not relevant in the light of Regulation No 528/2012, as the applicant had not submitted tests simulating relatively short contact times (that is, between 5 and 60 minutes) or splash contamination, combined with other dry testing conditions.

(ii) The second example use

84 Regarding the second example use, relating to the components of air conditioning systems, it is apparent from point 7.1 of the June 2017 assessment reports that the applicant claimed a bacteriostatic effect and, potentially, a fungistatic effect, and had submitted several tests in that regard. However, the evaluating competent authority found that the tests submitted by the applicant to demonstrate those effects were not appropriate, on various grounds.

85 In particular, as regards the two substances concerned, two tests were rejected on the ground that the untreated sample had not shown any bacterial growth or that no decrease in the growth of the test organisms had been demonstrated.

86 Moreover, regarding the two substances concerned, the evaluating competent authority accepted two tests submitted by the applicant as phase 1 tests, as those tests demonstrated a bacteriostatic effect for various types of materials and various bacteria in humid conditions. It considered, however, that those tests could not be accepted as phase 2 tests.

87 The evaluating competent authority stated that, according to the ECHA transitional guidance on the efficacy of disinfectants, disinfectants for air conditioning systems are applied, in general, by diffusion of an aerosol, a smoke, a vapour or a gas. According to that authority, the applicant was therefore required to demonstrate, through appropriate tests on representative materials, that the disinfecting function of the substances concerned could be fulfilled even by a biocide incorporated into the components of an air conditioning system. However, the applicant did not submit any phase 2 test demonstrating the bacteriostatic efficacy of the substances concerned when they were incorporated directly into the components of that system.

88 Similarly, in its opinions, the ECHA biocidal products committee found that the applicant had not submitted any appropriate test, simulating practical conditions of use, to demonstrate that the required performance standards could be met by a biocidal product containing either of the substances concerned, incorporated into the components of an air conditioning system.

89 The applicant claims, in essence, that, by rejecting certain tests on the grounds set out in paragraphs 85 to 88 above, the evaluating competent authority and the ECHA biocidal products committee required it to demonstrate, in practice, the efficacy of the articles treated with the substances concerned.

90 Here, it must be stated that neither the June 2017 assessment reports nor the opinions of the ECHA biocidal products committee allege that the applicant failed to demonstrate the efficacy of the components of air conditioning systems treated with the substances concerned.

91 In that connection, first of all, contrary to the applicant's claim, the need to demonstrate growth of the test organisms on an untreated polymer cannot be interpreted as an obligation to demonstrate the efficacy of the treated articles themselves.

92 As stated by the applicant itself in its written answers to the measures of organisation of procedure, in order to demonstrate the efficacy of the treatment of an article, it is necessary to show that, on the one hand, the treatment has an effect on the treated sample and, on the other, that those effects are not observed in the untreated sample.

93 In so far as the applicant has claimed a bacteriostatic effect, and, potentially, a fungistatic effect, for the substances concerned – that is, a decrease in the growth of the organisms concerned – it is required to demonstrate, on the one hand, that the representative biocidal products made up entirely of the substances concerned were capable in practice of inhibiting such growth on the treated articles and, on the other, that that effect was not observed in an untreated sample. If the untreated sample does not show any bacterial or fungal growth, there can be no finding that the effect of the active substances is to inhibit the growth of such organisms.

94 Next, as ECHA explained at the hearing, the fact that it is necessary to take into account the realistic worst case conditions under which the representative biocidal product may be used and the way in which the treated articles may be used does not mean that the tests must be carried out on the treated article itself, in the state in which it will be placed on the market. It is for the applicant to conduct its tests on a representative material which can, generally speaking, be used to manufacture the treated article chosen by the applicant as an example use, in relevant conditions in the light of Regulation No 528/2012, having regard to that example use.

95 Regarding the protection imparted on a component of an air conditioning system, the applicant was not, therefore, required to conduct tests on a complete air conditioning system or to provide details as to the position and specific function of the treated parts in that system. As is apparent from ECHA's explanations at the hearing, an appropriate test could have consisted of simply injecting air into a tube made up of a representative material into which the substances concerned had been incorporated, in relevant conditions in the light of Regulation No 528/2012.

96 Last, the evaluating competent authority did not require the applicant to demonstrate the benefits of the treated articles within the meaning of the Nordic Working Paper. Although it is cited in the ECHA transitional guidance on the efficacy of disinfectants, applicable to the assessment of the substances concerned, neither the June 2017 assessment reports nor the opinions of the ECHA

biocidal products committee refer to that document. Similarly, it is not apparent from those reports or opinions that the applicant should have submitted tests on the final article, as set out in the extracts of the Nordic Working Paper cited by the applicant in the reply, in order to demonstrate the efficacy of the substances concerned. It merely follows that the applicant did not submit tests conducted in relevant conditions in the light of Regulation No 528/2012 to prove the efficacy of the protection that the representative biocidal product, made up entirely of the substances concerned, was capable of imparting on representative materials.

97 Admittedly, point 1.5.6 of the ECHA transitional guidance on the efficacy of disinfectants states that, in the case of a polymer coating, treated with a disinfectant product, used for hospital bedside cabinets, the applicant had to demonstrate very fast bactericidal effects in order to show an advantage as compared to an untreated bedside cabinet. Nevertheless, given the express statement in that point that there is no need to prove the efficacy of the treated articles themselves, it is appropriate to interpret that requirement as meaning that the treatment of the representative material had to have an effect which could not be observed on the same material when untreated. The term 'advantage' therefore referred to the efficacy of the protection imparted by the representative biocidal product on the treated article.

98 As a result, for product-type 2, the evaluating competent authority and the ECHA biocidal products committee did not apply Regulation No 528/2012 incorrectly in finding that the applicant had not demonstrated the efficacy of the substances concerned.

(2) Product-type 7

99 Product-type 7 concerns film preservatives. According to Annex V to Regulation No 528/2012, these are products used for the preservation of films or coatings by the control of microbial deterioration or algal growth in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers and art works.

100 In the present situation, during the assessment procedure of the substances concerned, the applicant identified two example uses of the representative biocidal product for which it made a fungistatic claim: a laminated work surface and paint finish. It submitted two tests in that regard.

101 Point 7.1 of the June 2017 assessment reports states that the first test submitted by the applicant for product-type 7 used only filter paper as an untreated sample, not a laminated work surface or paint finish. That filter paper sample was therefore not representative of the example uses chosen by the applicant; the applicant does not dispute this.

102 Contrary to the applicant's claim, the fact that it is necessary to use material that is representative of the example uses does not amount to an obligation to demonstrate the efficacy of the treated articles themselves. As stated in paragraph 94 above, there is no requirement to carry out tests on the treated article itself in the state in which it will be placed on the market. Nevertheless, in order to comply with the criteria in Article 19(2) of Regulation No 528/2012, tests must be carried out on a representative material which is, generally speaking, used to manufacture the treated article chosen by the applicant as an example use, in relevant conditions in the light of that regulation, having regard to that example use.

103 Further, in the June 2017 assessment reports, the evaluating competent authority explained that the material and its conditions of use played an essential role in explaining why deterioration of that material by fungal growth is to be expected. This required a detailed description of the material and its conditions of use.

104 As for the second test submitted by the applicant, the evaluating competent authority found that, although the sample used for that test was indeed a material treated with the representative biocidal product, the untreated sample had not, however, shown any fungal growth. The applicant has not called that finding into question.

105 On the grounds set out in paragraphs 91 to 93 above, given that the applicant had chosen to claim a fungistatic effect, it was required to demonstrate fungal growth on an untreated sample.

106 Admittedly, in order to demonstrate the efficacy of silver zeolite, the applicant had also referred to other tests involving silver copper zeolite and silver zinc zeolite. Nevertheless, the evaluating competent authority explained that a cross-reference in that regard was not possible, which the applicant has not disputed. What is more, neither had the first of those two tests shown fungal growth on an untreated sample relating to silver zinc zeolite. As for the second test, the applicant had not submitted the test protocols, despite the fact that they are necessary, merely submitting summaries of results, which it has similarly not disputed.

107 Further, on the same grounds as those set out in paragraphs 96 and 97 above, the applicant cannot, again, claim that it was subject to an unlawful obligation to prove the benefit of the treated articles.

108 Moreover, the obligation to prove that there is a risk that the target organisms may develop and that the representative biocidal product used in a treated article can be used to control those organisms was reproduced in point 4.1 and in the conclusion of Chapter 5 of the ECHA transitional guidance on the biocidal products regulation, relating to efficacy assessments for preservatives of May 2014.

109 Having regard to the foregoing considerations, for product-type 7, the evaluating competent authority and the ECHA biocidal products committee did not apply the principles in Regulation No 528/2012 incorrectly in finding that the applicant had not sufficiently demonstrated the efficacy of the substances concerned, having regard to the example uses chosen and the claims that it had made.

110 Consequently, the first plea must be rejected.

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On those grounds,

THE GENERAL COURT (Seventh Chamber)

hereby:

1. Joins Cases T-122/20 and T-123/20 for the purposes of the present judgment;

2. Dismisses the actions;

3. Orders Sciessent LLC to bear its own costs and to pay those incurred by the European Commission;

4. Orders the Kingdom of Sweden and the European Chemicals Agency (ECHA) to each bear their own costs.

da Silva Passos Reine Sampol Pucurull

Delivered in open court in Luxembourg on 16 November 2022.

[Signatures]