JUDGMENT OF THE GENERAL COURT

(Fourth Chamber, Extended Composition)

25 October 2011 *

In Case T-262/10,

Microban International Ltd, established in Huntersville, North Carolina (United States),

Microban (Europe) Ltd, established in Cannock (United Kingdom),

represented by M. Sánchez Rydelski, lawyer,

applicants,

v

European Commission, represented by L. Pignataro and T. Scharf, acting as Agents,

defendant,

* Language of the case: English.

ACTION for annulment of Commission Decision 2010/169/EU of 19 March 2010 concerning the non-inclusion of 2,4,4'-trichloro-2'-hydroxydiphenyl ether in the Union list of additives which may be used in the manufacture of plastic materials and articles intended to come into contact with foodstuffs under Directive 2002/72/EC (OJ 2010 L 75, p. 25),

THE GENERAL COURT (Fourth Chamber, Extended Composition),

composed of I. Pelikánová, President, V. Vadapalas, K. Jürimäe (Rapporteur), K. O'Higgins and M. van der Woude, Judges,

Registrar: N. Rosner, Administrator,

having regard to the written procedure and further to the hearing on 28 September 2011,

gives the following

Judgment

Background to the dispute

1 The applicants, Microban International Ltd and Microban (Europe) Ltd, are engaged in the manufacture and sale of antimicrobial and antibacterial additives designed to

provide antimicrobial and antibacterial protection in a wide range of products. Microban International manufactures the additives and markets them throughout the world. Microban (Europe) is responsible for the marketing, within the European Union, of the additives manufactured by Microban International.

2 On 23 March 1998, RCC Registration and Consulting Company Ltd, acting on behalf of Ciba Inc. ('Ciba'), submitted an application to the European Commission for the inclusion of 2,4,4'-trichloro-2'-hydroxydiphenyl ether ('triclosan') in the list of additives authorised by Commission Directive 90/128/EEC of 23 February 1990 relating to plastic materials and articles intended to come into contact with foodstuffs (OJ 1990 L 75, p. 19).

3 On 22 June 2000, the Scientific Committee on Food, which the Commission was required to consult pursuant to Article 3(3) of Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (OJ 1989 L 40, p. 38), issued an opinion on a number of monomers and additives for food contact materials. In that opinion, the Committee decided, inter alia, that, although triclosan was a substance for which an acceptable or tolerable daily intake could not be established, its use could none the less be accepted.

4 On 15 November 2002, the Scientific Committee on Food having updated its guidelines, Ciba submitted a request for re-evaluation of triclosan.

5 On 15 March 2004, following the re-evaluation of triclosan, the European Food Safety Authority ('EFSA') — which replaced the Scientific Committee on Food by virtue of Article 62 of Regulation (EC) No 178/2002 of the European Parliament and of the

Council of 28 January 2002 laying down the general principles and requirements of food law, establishing EFSA and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1) — adopted an opinion by which it confirmed the view taken by the Scientific Committee on Food in its opinion of 22 June 2000.

6 On 10 April 2008, triclosan was included in the provisional list of additives ('the provisional list') provided for by Article 4a(3) of Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs (OJ 2002 L 220, p. 18). In accordance with Article 4a(4) of that directive, additives not included in the list of additives authorised at European Union level ('the positive list', the term used in the third subparagraph of Article 4(1) of that directive) may continue to be used subject to national law for as long as they are included in the provisional list.

7 On 21 April 2009, Ciba informed the Commission of its decision to withdraw its application for the authorisation of the use of triclosan as an additive for use in the manufacture of plastic materials and articles destined to come into contact with foodstuffs.

8 On 19 March 2010, the Commission adopted Decision 2010/169/EU concerning the non-inclusion of triclosan in the Union list of additives which may be used in the manufacture of plastic materials and articles intended to come into contact with foodstuffs under Directive 2002/72 (OJ 2010 L 75, p. 25; 'the contested decision'). As the legal basis for that decision, the Commission cites Article 11(3) of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October

2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109 (OJ 2004 L 338, p. 4), as amended.

9 In the contested decision, the Commission observed that Ciba had informed it of its decision to withdraw its application for the authorisation of the use of triclosan as an additive in the manufacture of plastic materials and articles intended to come into contact with foodstuffs. As there was no longer a valid application for the use of triclosan as an additive in plastics intended to come into contact with foodstuffs, the Commission concluded that that substance should not be included in Annex III to Directive 2002/72, which contains the positive list. The Commission stated that the substance should therefore be removed from the provisional list of additives. It considered it necessary, however, to provide for a transitional period during which the marketing of plastic materials and articles containing triclosan could continue to be authorised by the Member States.

10 The operative part of the contested decision is worded as follows:

'*Article 1*

[Triclosan] (CAS No 0003380-34-5, ref No 93930) shall not be included in Annex III to Directive 2002/72 …

Article 2

Plastic materials and articles manufactured with [triclosan] and placed on the market before 1 November 2010, may continue to be marketed until 1 November 2011, subject to national law.

Article 3

This Decision is addressed to the Member States.'

Procedure and forms of order sought

11 By application lodged at the General Court Registry on 7 June 2010, the applicants brought the present action.

12 On 31 March 2011, the applicants lodged a request for priority treatment pursuant to Article 55(2) of the Court's Rules of Procedure.

13 Upon hearing the report of the Judge-Rapporteur, the Court decided to open the oral procedure and to give the case priority treatment pursuant to Article 55(2) of the Rules of Procedure.

14 The parties presented oral argument and replied to the questions put by the Court at the hearing on 28 September 2011.

15 The applicants claim that the Court should:

— annul the contested decision;

— order the Commission to pay the costs.

16 The Commission contends that the Court should:

— dismiss the application as inadmissible;

— in the alternative, dismiss the application as unfounded;

— order the applicants to pay the costs.

Admissibility

17 While not formally raising an objection of inadmissibility, the Commission argues that the action is inadmissible in so far as the contested decision is not a regulatory act requiring no implementing measures within the meaning of the fourth paragraph of Article 263 TFEU, and is not of individual concern to the applicants.

18 Under the fourth paragraph of Article 263 TFEU, any natural or legal person may, under the conditions laid down in the first and second paragraphs, institute proceedings against an act addressed to that person or which is of direct and individual concern to them, and against a regulatory act which is of direct concern to them and which does not entail implementing measures.

19 In the present case, it is common ground that the applicants are not addressees of the contested decision. Accordingly, under the fourth paragraph of Article 263 TFEU, the

applicants may bring an action for annulment against that decision only if it is either a regulatory act which is of direct concern to them and does not require implementing measures, or a decision of direct and individual concern to them.

20 It must first be established that the contested decision is a regulatory act within the meaning of the fourth paragraph of Article 263 TFEU.

21 In that regard, it must be recalled that, according to the case-law, the meaning of 'regulatory act' for the purposes of the fourth paragraph of Article 263 TFEU must be understood as covering all acts of general application apart from legislative acts (order of the General Court of 6 September 2011 in Case T-18/10 *Inuit Tapiriit Kanatami and Others* v *Parliament and Council* [2011], not published in the ECR, paragraph 56).

22 In the present case, the legal basis cited by the contested decision is Article 11(3) of Regulation No 1935/2004. That article provides that a measure taken by the Commission on the basis of that article is to be adopted in accordance with the procedure referred to in Article 5a(1) to (4) and (5)(b) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ 1999 L 184, p. 23), as amended. Accordingly, the contested decision was adopted by the Commission in the exercise of implementing powers and not in the exercise of legislative powers.

23 Moreover, the contested decision is of general application in that it applies to objectively determined situations and it produces legal effects with respect to categories of persons envisaged in general and in the abstract.

24 As is apparent from paragraph 9 above, the subject of the contested decision is the non-inclusion of triclosan in the positive list. Pursuant to Article 4a(6)(b) of Directive 2002/72, triclosan has also been removed from the provisional list as a result of that non-inclusion. The direct consequence of the non-inclusion in the positive list and removal from the provisional list is thus that triclosan can no longer be marketed in the Union after 1 November 2011. Thus the contested decision applies to all natural and legal persons who are engaged in the production and/or marketing of triclosan and materials and articles containing that substance.

25 It follows that the contested decision should be considered to be a regulatory act within the meaning of the fourth paragraph of Article 263 TFEU.

26 Second, as regards the concept of direct concern, it must be observed that the expression 'of direct concern to them' appears twice in the fourth paragraph of Article 263 TFEU. Firstly, that provision reiterates the wording of the fourth paragraph of Article 230 EC in referring to 'an act … which is of direct … concern to them'. Secondly, the fourth paragraph of Article 263 TFEU introduces the concept of 'a regulatory act which is of direct concern to them and does not entail implementing measures'.

27 First, as regards the condition of direct concern as laid down in the fourth paragraph of Article 230 EC, it has been held that that condition required that, firstly, the contested Community measure must directly affect the legal situation of the individual and, secondly, it must leave no discretion to its addressees, who are entrusted with the task of implementing it, such implementation being purely automatic and resulting from Community rules without the application of other intermediate rules (see Case C-386/96 P *Dreyfus* v *Commission* [1998] ECR I-2309, paragraph 43, and Joined

Cases C-445/07 P and C-455/07 P *Commission* v *Ente per le Ville vesuviane and Ente per le Ville vesuviane* v *Commission* [2009] ECR I-7993, paragraph 45).

28 In the present case, as mentioned in paragraph 24 above, the consequence of the contested decision is that the marketing of materials and articles containing triclosan intended to come into contact with foodstuffs is prohibited. Given that, as was made clear at the hearing, the applicants buy triclosan and use it to manufacture a product with antimicrobial and antibacterial properties, which is then sold on for use in the manufacture of plastic materials and articles intended to come into contact with foodstuffs, the contested decision directly affects their legal position.

29 Moreover, it must be observed that the contested decision leaves no discretion to the Member States, which are the addressees of the decision and, in that capacity, are responsible for implementing it. According to Article 2 of that decision, materials and articles containing triclosan may continue to be marketed until 1 November 2011, subject to national law, which means that the Member States have the option of prohibiting the marketing of such materials and articles before that date. Although the Member States thus have a measure of discretion as to the date from which they wish to prohibit the marketing of triclosan, the implementation of that ban is none the less automatic and mandatory as of 1 November 2011. Moreover, it must be pointed out that the transitional period laid down by Article 2 of the contested decision is intended to facilitate the implementation of the measure consisting in non-inclusion of triclosan in the positive list, so that it is ancillary to that measure.

30 It follows that the applicants must be considered to be directly concerned by the contested decision within the meaning of the concept of direct concern as laid down in the fourth paragraph of Article 230 EC.

31 Second, as regards the concept of direct concern as recently introduced in the fourth paragraph of Article 263 TFEU, the question fairly arises as to whether that concept must be subject to a different interpretation from that developed in the case-law set out in paragraph 27 above.

32 Nevertheless, it must be observed that, according to case-law, by allowing a natural or legal person to institute proceedings against regulatory acts of direct concern to them which do not entail implementing measures, the fourth paragraph of Article 263 TFEU pursues an objective of opening up the conditions for bringing direct actions (see, to that effect, *Inuit Tapiriit Kanatami and Others* v *Parliament and Council*, paragraph 21 above, paragraph 50). Accordingly, the concept of direct concern, as recently introduced in that provision cannot, in any event, be subject to a more restrictive interpretation than the notion of direct concern as it appeared in the fourth paragraph of Article 230 EC. Since it has been established, at paragraph 30 above, that the applicants were directly concerned by the contested decision, within the meaning of the concept of direct concern as laid down by the fourth paragraph of Article 230 EC, it must be held that they are also directly concerned by the contested decision within the meaning of the concept of direct concern as recently introduced in the fourth paragraph of Article 263 TFEU.

33 Third, as regards the question whether or not the contested decision entails implementing measures within the meaning of the fourth paragraph of Article 263 TFEU, it must be repeated that, as observed at paragraphs 24 and 28 above, the subject of the contested decision is the non-inclusion of triclosan in the positive list. Consequently, pursuant to Article 4a(6)(b) of Directive 2002/72, the contested decision also removed that substance from the provisional list. Moreover, in order to facilitate the implementation of the non-inclusion of the substance on the positive list and its consequent removal from the provisional list, the contested decision introduced, as an ancillary measure, a transitional period, during which the marketing of materials and

articles containing triclosan could be authorised, and which was to expire on 1 November 2011.

34 In that regard, firstly, it must be observed that neither non-inclusion in the positive list nor removal from the provisional list required implementing measures on the part of the Member States. Under Article 4a(4) of Directive 2002/72, only additives appearing in the provisional list can continue to be used after 1 January 2010. Moreover, under Article 4a(6)(b) of Directive 2002/72, an additive is to be removed from the provisional list when a decision is taken by the Commission not to include it in the positive list. Accordingly, the decision not to include it had the immediate consequence of its removal from the provisional list and a prohibition on the marketing of triclosan, without the Member States needing to adopt any implementing measure.

35 In addition, it must be emphasised that, as the applicants observed, Commission Directive 2004/19/EC of 1 March 2004 amending Directive 2002/72 (OJ 2004 L 71, p. 8), and Commission Directive 2008/39/EC of 6 March 2008 amending Directive 2002/72 (OJ 2008 L 63, p. 6), introduced into Directive 2002/72 Article 4a(4) and Article 4a(6)(b) respectively. It follows from the application of Article 2 of Directive 2004/19 and Article 2 of Directive 2008/39 that Article 4a(4) and Article 4a(6)(b) of Directive 2002/72 respectively have been transposed into the law of the Member States. Consequently, it cannot be considered that the prohibition on the marketing of triclosan, following its non-inclusion in the positive list and its removal from the provisional list, required the adoption of implementing measures.

36 Second, the transitional provision, allowing the possibility of marketing triclosan to be extended until 1 November 2011, does not in itself require any implementing measure on the part of the Member States, as any intervention by those States before 1 November 2011 is purely optional.

37 Third, although, in the latter situation, the transitional provision may give rise to implementing measures on the part of the Member States, it must be repeated that it is intended to facilitate the implementation of the contested decision, in that its effect is to prohibit the marketing of triclosan, so that the natural and legal persons affected by that prohibition may make the necessary arrangements. It is thus ancillary to the main purpose of the contested decision which is the prohibition on the marketing of triclosan which, from 1 November 2011, will apply without any implementing measure being necessary.

38 Having regard to the foregoing observations, it cannot be held that the contested decision entails implementing measures.

39 It follows that that decision constitutes a regulatory act of direct concern to the applicants, which does not entail any implementing measures, so that the plea of inadmissibility raised by the Commission must be dismissed without it being necessary to consider whether it was of individual concern to the applicants.

Substance

40 In support of their application, the applicants put forward four pleas in law. The first alleges an error of law in the choice of legal basis for the contested decision. The second alleges a breach of the procedure laid down by Regulation No 1935/2004 and Directive 2002/72. The third alleges a breach of the principle of the protection of

legitimate expectations. The fourth alleges infringement of the principles of sound administration, transparency and legal certainty.

The first plea: error of law in the choice of legal basis

41 In their first plea the applicants submit that the Commission erred in law in basing the contested decision on Article 11(3) of Regulation No 1935/2004. That provision relates to authorisations at European Union level for the marketing of substances incorporated in materials and articles intended to come into contact with foodstuffs, whereas the contested decision does not contain such an authorisation because, on the contrary, it provides that a substance is not to be included in Annex III to Directive 2002/72 and is therefore a measure which bans the use of triclosan as an additive in materials and articles intended to come into contact with foodstuffs.

42 In that regard, it must be borne in mind that, according to the Court's settled case-law, the choice of legal basis for an act of the Union must rest on objective factors which are amenable to judicial review, including in particular the aim and the content of the measure (Case C-440/05 *Commission* v *Council* [2007] ECR I-9097, paragraph 61).

43 Moreover, if an examination of an act of the Union reveals that it pursues a twofold aim, or that it has a twofold component, and if one of those is identifiable as the main one, and the other is merely incidental, the measure must be based on a single legal basis, namely that required by the main aim or component (Case C-91/05 *Commission* v *Council* [2008] ECR I-3651, paragraph 73).

44 In the present case, Article 11(3) of Regulation No 1935/2004 is worded as follows:

'Community authorisation in the form of specific measure, as referred to in paragraph 1, shall be adopted by the Commission. That measure, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(4).'

45 Paragraph 1 of that article provides as follows:

'The Community authorisation of a substance or substances shall take place in the form of the adoption of a specific measure. …'

46 In the light of those provisions, Article 11(3) of Regulation No 1935/2004 concerns only cases in which the Commission intends to authorise the use and marketing, in the Union, of a substance incorporated in materials and articles intended to come into contact with foodstuffs.

47 In the present case, by the contested decision, the Commission prohibited the marketing of triclosan as an additive used for the manufacture of materials and articles intended to come into contact with foodstuffs. In order to do so, in the contested decision, the Commission, firstly, refused to include triclosan on the positive list and, secondly, removed that substance from the provisional list.

48 It follows that, in so far as the purpose of the contested decision is the prohibition of the marketing of triclosan in the Union, it cannot be based on Article 11(3) of Regulation No 1935/2004, which, conversely, concerns marketing authorisations.

49 That conclusion cannot be called into question by the Commission's argument that the contested decision must also be analysed as a decision authorising, until 1 November 2011, the marketing of materials and articles manufactured with triclosan and placed on the market before 1 November 2010.

50 It has already been observed, at paragraph 29 above, that the transitional period established by Article 2 of the contested decision, during which the marketing of triclosan continued to be authorised, subject to national law, was solely intended to facilitate the implementation of the measure prohibiting the marketing of triclosan, given that that prohibition was the direct consequence of the principal objective of the contested decision, that is to say, non-inclusion on the positive list. It follows that the measure intended to establish a transitional period must be considered to be incidental, within the meaning of the case-law cited in paragraph 43 above, to the main objective of the contested decision.

51 Accordingly, the first plea must be upheld and the contested decision set aside as being grounded on the wrong legal basis.

52 Although the Commission's choice of the wrong legal basis justifies in itself the annulment of the contested decision, the Court none the less considers that the second plea should be examined, for the sake of completeness, since that plea, essentially, raises the question whether or not there is any legal basis on which the Commission could have validly based the contested decision.

The second plea: breach of the procedure laid down by Regulation No 1935/2004 and Directive 2002/72

53 In the second plea the applicants submit, essentially, that, in the absence of a risk management decision within the meaning of recital 14 in the preamble to Regulation No 1935/2004, the Commission infringed the procedure laid down by that regulation and by Directive 2002/72, by adopting a decision not to include an additive in the positive list. In particular, invoking the spirit of the procedure laid down by that regulation and that directive, the applicants point out that, in the event of withdrawal of an application for inclusion of an additive in the positive list by the original applicant, the Commission must allow the interested parties the option of maintaining their application in order to be in a position to adopt such a risk management decision.

54 In that regard it is common ground that neither Regulation No 1935/2004 nor Directive 2002/72 lays down any procedure to be followed by the Commission where the original applicant decides to withdraw his application for inclusion of an additive on the positive list. Accordingly, it is necessary to verify whether the procedure to be followed by the Commission in such circumstances can be inferred from the objective and the structure of the two measures, and from the procedure laid down by other acts of the Union which, although concerning other types of substances, pursue a comparable objective which they seek to achieve through comparable procedures.

55 As a preliminary point, it must be observed that Regulation No 1935/2004 is the framework regulation regarding materials and articles intended to come into contact with foodstuffs and that Directive 2002/72 is a specific directive which concerns, in particular, plastic materials and articles intended to come into contact with foodstuffs.

56 First, as to the objective pursued by those two acts, reference should be made to the terms of Article 1 of Regulation No 1935/2004, set out below:

'The purpose of this Regulation is to ensure the effective functioning of the internal market in relation to the placing on the market in the Community of materials and articles intended to come into contact directly or indirectly with food, whilst providing the basis for securing a high level of protection of human health and the interests of consumers.'

57 The procedures put in place by Directive 2002/72 are intended to ensure the primacy of that objective of the protection of human health, with specific regard to the additives used in the manufacture of plastic materials and articles. Under the third paragraph of Article 4(1) of that directive, as from 1 January 2010, only additives included in the positive list may be used in the manufacture of plastic materials and articles. Under Article 4a(1) of that directive, a new additive may only be added to the positive list following an evaluation of its safety by EFSA. Finally, it is clear from Article 4a(3) and (4) of that directive that a substance which is not included in the positive list, but which is under evaluation by EFSA is to be included in a provisional list, which allows it to continue to be used in accordance with the national legislation. In other words, where EFSA has not yet made a decision regarding the safety of a substance, the task of assessing whether the marketing of the substance is compatible with the protection of human health lies with the national authorities.

58 Since the ground for the Commission's decision not to include triclosan in the positive list was that Ciba had withdrawn its application for authorisation, that decision cannot be regarded as seeking to meet the objective of the protection of human health. That conclusion is borne out by the fact that the contested decision was preceded by two scientific opinions, the first adopted on 22 June 2000 by the Scientific Committee

for Food, and the second adopted on 15 March 2004 by EFSA, neither of which raised any objection to the marketing of triclosan.

59 Second, as regards the structure of Regulation No 1935/2004 and Directive 2002/72, it must be observed, firstly, that although, under Article 8 of that regulation, an application for authorisation of a new substance must be made by a person who wishes to obtain such authorisation, the granting of that authorisation, by means of inclusion in the positive list, benefits not only the applicant for authorisation but also all users of the substance for which authorisation has been requested.

60 It is clear from Article 11(4) of Regulation No 1935/2004 that after the authorisation of a substance, any business operator using the authorised substance or materials or articles containing the authorised substance has to comply with any condition or restriction attached to such authorisation. Similarly, under Article 11(5) of that regulation, the applicant or any business operator using the authorised substance or materials or articles containing the authorised substance, must immediately inform the Commission of any new scientific or technical information, which might affect the safety assessment of the authorised substance in relation to human health. Furthermore, Article 12 of Regulation No 1935/2004 provides that the applicant or any business operator using the authorised substance or materials or articles containing the authorised substance may apply for modification of the authorisation. Finally, *a contrario*, Article 5(1)(n) of Regulation No 1935/2004 refers, by way of exception, to a procedure for an individual authorisation of a substance, process, or material or article through a decision addressed to an applicant.

61 Second, as already mentioned in paragraph 57 above, it is clear from Article 4(3) and (4) of Directive 2002/72 that a substance which is not included in the positive list, but which is under evaluation by EFSA, is to be included in a provisional list. Moreover, under Article 4a(6) of that directive, an additive is to be removed from the

provisional list either when it is included in the positive list, or when a decision is taken by the Commission not to include it in the Community list of additives, or where, in the course of evaluation of the substance by EFSA, a request for information by EFSA is not complied with. Finally, according to recital 14 of Regulation No 1935/2004, the safety assessment of substances should be followed by a risk management decision as to whether they should be entered on the positive list.

62 It can be inferred from those provisions that removal from the provisional list should follow either a risk management decision by the Commission that the substance should or should not be included in the positive list, or a refusal by the applicant to cooperate with EFSA in the course of the procedure for the evaluation of the safety of the substance.

63 In the present case, the fact that triclosan was not included in the positive list had the immediate consequence, under Article 4a(6)(b) of that directive, that the substance was removed from the provisional list, although that removal was not the result of a risk management decision or of a refusal by the applicant to cooperate with EFSA, as the latter had already issued a scientific opinion.

64 Third, it must be observed that, although, as the Commission points out, the applicants were in a position to make a fresh application for authorisation pursuant to Article 8 of Regulation No 1935/2004, the wording of Directive 2002/72 does not

make it clear that such an application would entail the inclusion of triclosan on the provisional list again. Article 4a(5)(b) of Directive 2002/72 is worded as follows:

'The inclusion of an additive in the provisional list is subject to the following conditions:

the additive must be permitted in one or more of the Member States no later than 31 December 2006;

the data referred to in paragraph 2 concerning that additive must have been supplied in accordance with [EFSA] requirements no later than 31 December 2006.'

65 According to Article 4a(2) of that directive, any person interested in the inclusion in the positive list of an additive has to submit data for the evaluation of its safety by EFSA by 31 December 2006 at the latest. In the present case, the submission by the applicants of the necessary data for evaluation by EFSA could not take place before 31 December 2006.

66 In addition, while Regulation No 1935/2004 provides, in Article 11(5) and Article 12, for the possibility of re-evaluation of the substance in question by EFSA where new information is submitted to EFSA, it is noteworthy that neither Regulation No 1935/2004 nor Directive 2002/72 provides for the possibility of such re-evaluation if there are no new data liable to affect the initial evaluation and if no authorisation has yet been granted. Similarly, it is clear from the document entitled 'EFSA's note for guidance for petitioners presenting an application for the safety assessment of a substance to be used in food contact materials prior to its authorisation' that, where EFSA has made an initial evaluation of a substance (including in cases where EFSA has concluded, following that evaluation, that the substance should not be authorised), a fresh evaluation may be applied for only if the additional data may lead it to

modify that evaluation. In the present case, given that EFSA has already given a positive opinion on the basis of the information submitted by Ciba, any new application for evaluation from the applicants would not be directed to obtaining a modification of the initial evaluation at all. Moreover, it is probable that the applicants would make their own application for authorisation on the basis of the same information as was submitted initially by Ciba, so that that data would not be new. It follows that, in a case like the present one, the rules do not afford the applicants the possibility of submitting a fresh request for evaluation of the substance at issue, which fact tends to demonstrate that the Commission is required to adopt a risk management decision on the basis of the initial evaluation by EFSA.

67 Given the structure of Regulation No 1935/2004 and Directive 2002/72, the withdrawal by the applicant of its application for authorisation cannot be regarded as a sufficient reason not to pursue the procedure for the adoption of a decision regarding the management of the risks of inclusion or non-inclusion of the substance at issue, because it is not apparent from the wording of those two acts that the applicants would be able to obtain the re-inclusion of triclosan in the provisional list and, also, a new evaluation of that substance by EFSA.

68 Third, as regards other acts of the Union which might be relevant in this case, reference should be made to Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ 2007 L 325, p. 3), cited by the applicants. That regulation provides specifically, in Articles 11 and 12, that in the event of withdrawal of an application for inclusion in the list of authorised biocidal products, a new applicant may take the place of the initial applicant.

69 Having regard to all the foregoing considerations, it must be concluded that the Commission infringed Regulation No 1935/2004 and Directive 2002/72 in adopting a decision not to include an additive solely on the basis of the withdrawal of the initial application for inclusion of triclosan in the positive list, in circumstances where there is no legal basis allowing the adoption of such a decision. Therefore, the second plea in law must also be upheld and, as a result, the contested decision must be annulled, without there being any need to consider the third and fourth pleas.

Costs

70 Under Article 87(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Commission has failed in its submissions and the applicants have applied for costs, the Commission must be ordered to pay the costs.

On those grounds,

THE GENERAL COURT (Fourth Chamber, Extended Composition)

hereby:

1. **Annuls Commission Decision 2010/169/EU of 19 March 2010 concerning the non-inclusion of 2,4,4'-trichloro-2'-hydroxydiphenyl ether in the Union list of additives which may be used in the manufacture of plastic materials and articles intended to come into contact with foodstuffs under Directive 2002/72/EC;**

2. Orders the European Commission to pay its own costs and those incurred by Microban International Ltd and Microban (Europe) Ltd.

Pelikánová Vadapalas Jürimäe

O'Higgins Van der Woude

Delivered in open court in Luxembourg on 25 October 2011.

[Signatures]