ORDER OF THE GENERAL COURT (Seventh Chamber)

21 September 2011 *

In Case T-343/10,

Etimine SA, established in Bettembourg (Luxembourg),

AB Etiproducts Oy, established in Espoo (Finland),

represented by C. Mereu and K. Van Maldegem, lawyers,

applicants,

v

European Chemicals Agency (ECHA), represented by M. Heikkilä and W. Broere, acting as Agents, and by J. Stuyck and A.-M. Vandromme, lawyers,

defendant,

* Language of the case: English.

supported by

European Commission, represented by P. Oliver and E. Manhaeve, acting as Agents, and by K. Sawyer, Barrister,

intervener,

APPLICATION for annulment of the decision of the ECHA, published on 18 June 2010, identifying boric acid (EC No 233-139-2) and disodium tetraborate, anhydrous (EC No 215-540-4) as substances meeting the criteria referred to in Article 57 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006 L 396, p. 1), and including those substances in the candidate list for eventual inclusion in Annex XIV to Regulation No 1907/2006, in accordance with Article 59 of that regulation,

THE GENERAL COURT (Seventh Chamber),

composed of A. Dittrich (Rapporteur), President, I. Wiszniewska-Białecka and M. Prek, Judges,

Registrar: E. Coulon,

makes the following

Order

Background to the dispute

1 The first applicant, Etimine SA, is a company governed by Luxembourg law. The second applicant, AB Etiproducts Oy, is a company governed by Finnish law. The applicants are engaged in the importation and sale in the European Union of boric acid (EC No 233-139-2) and disodium tetraborate, anhydrous (EC No 215-540-4) (collectively, 'the borates'), which are supplied to them by their parent company, a company governed by Turkish law.

2 Uses of the borates include, in particular, glass and insulation fibre glass. The borates are also used in detergents and cleaning products as well as in wood preservatives.

3 The borates were included in Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ, English Special Edition 1967, p. 234) by Commission Directive 2008/58/EC of 21 August 2008 amending, for the purpose of its adaptation to technical progress, for the 30th time, Directive 67/548 (OJ 2008 L 246, p. 1), which entered into force on 5 October 2008. As a result of that inclusion, the borates were classified as toxic for reproduction category 2.

4 With the entry into force on 20 January 2009 of 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), Annex I to Directive 67/548 was repealed and its content, as applicable prior to amendment by Directive 2008/58, was transferred to Part 3 of Annex VI to Regulation No 1272/2008. There was, therefore, no reference to the borates in Annex VI to Regulation No 1272/2008 at the time when that regulation entered into force.

5 With the entry into force on 25 September 2009 of Commission Regulation (EC) No 790/2009 of 10 August 2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation No 1272/2008 (OJ 2009 L 235, p. 1), the classification of the borates as toxic for reproduction category 2 was referred to in Part 3 of Annex VI to Regulation No 1272/2008. According to Article 2(2) and (3) of Regulation No 790/2009, that classification applied from 1 December 2010, but could be applied before that date.

6 On 8 March 2010, the Federal Republic of Germany and the Republic of Slovenia submitted to the European Chemicals Agency (ECHA) a dossier which they had prepared concerning the identification of boric acid as a substance meeting the criteria referred to in Article 57(c) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006 L 396, p. 1), amended subsequently by, inter alia, Regulation No 1272/2008, in which they referred to the classification of boric acid as toxic for reproduction category 2 in Part 3 of Annex VI to Regulation No 1272/2008.

7 On the same day, the Kingdom of Denmark submitted to the ECHA a dossier which it had prepared concerning the identification of disodium tetraborate, anhydrous as a substance meeting the criteria referred to in Article 57(c) of Regulation No 1907/2006, and referring to the classification of disodium tetraborate, anhydrous as toxic for reproduction category 2 in Part 3 of Annex VI to Regulation No 1272/2008.

8 Subsequently, the ECHA published notices on its website inviting interested parties to submit comments on the dossiers prepared in relation to the borates. After receiving comments on the dossiers concerned, including from the European Borates Association, of which the applicants are members, and also from the first applicant, the ECHA referred those dossiers to its Member State Committee. On 9 June 2010 that committee reached unanimous agreement on the identification of the borates as substances of very high concern meeting the criteria set out in Article 57(c) of Regulation No 1907/2006.

9 On 18 June 2010, the list of substances in the candidate list for eventual inclusion in Annex XIV to Regulation No 1907/2006 ('the candidate list') including the borates was published on the ECHA's website.

Procedure and forms of order sought by the parties

10 By application lodged at the Registry of the Court on 18 August 2010, the applicants brought an action for annulment of the decision of the ECHA, published on 18 June 2010, identifying the borates as substances meeting the criteria referred to in Article 57 of Regulation No 1907/2006 and including those substances in the candidate list in accordance with Article 59 of that regulation ('the contested decision').

11 By letter registered at the Registry of the Court on 10 December 2010, the European Commission applied for leave to intervene in the present proceedings in support of the form of order sought by the ECHA. After hearing the main parties, the President of the Seventh Chamber of the General Court granted leave to intervene, by order of 12 January 2011.

12 By separate document lodged at the Registry of the Court on 14 December 2010, the ECHA raised an objection of inadmissibility under Article 114(1) of the Rules of Procedure of the General Court. The applicants lodged their observations concerning the plea of inadmissibility on 31 January 2011.

13 By document lodged at the Registry of the Court on 18 February 2011, the Commission waived its right to lodge a statement in intervention just on the question of admissibility.

14 In their application the applicants claim that the Court should:

— declare the action admissible and well founded;

— annul the contested decision;

— declare Regulation No 790/2009 unlawful in so far as it relates to the borates;

— order the ECHA to pay the costs.

15 In its objection of inadmissibility the ECHA contends that the Court should:

— declare the action inadmissible;

— order the applicants to pay the costs.

16 In their observations on the plea of inadmissibility, the applicants claim that the Court should reject the plea of inadmissibility or reserve its decision until final judgment on the substance of the case.

Law

17 Under Article 114(1) and (4) of the Rules of Procedure, if a party so requests, the Court may make a decision on a plea of admissibility without ruling on the substance of the case. In accordance with Article 114(3), unless the Court otherwise decides, the remainder of the proceedings is to be oral. The Court finds that, in the present case, it has sufficient information from the case-file not to open the oral procedure.

18 In support of the form of order sought, the ECHA raises two pleas of inadmissibility, alleging that there is a lack of direct concern to the applicants and that the contested decision, which is not a regulatory act within the meaning of the fourth paragraph of Article 263 TFEU, is not of individual concern to them.

19 It is appropriate to consider, first of all, the plea of inadmissibility alleging a lack of direct concern to the applicants.

20 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 does not entail implementing measures.

21 In the present case, it is common ground that the contested decision was not addressed to the applicants; it is not, therefore, an act addressed to them. That being the case, in accordance with the fourth paragraph of Article 263 TFEU, the applicants may institute proceedings for annulment of that act only if it is of direct concern to them.

22 With regard to direct concern, it has consistently been held that that condition requires, first, that the measure complained of directly affect the legal situation of the individual and, second, that it leave no discretion to the addressees of that measure, who are entrusted with the task of implementing it, such implementation being purely automatic and resulting from European Union rules without the application of other intermediate rules (Case C-386/96 P *Dreyfus* v *Commission* [1998] ECR I-2309, paragraph 43; Case C-486/01 P *Front national* v *Parliament* [2004] ECR I-6289, paragraph 34; 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).

23 In the first place, with regard to the applicants' argument that the contested decision is of direct concern to them in that their legal situation is affected by Article 31(9)(a) of Regulation No 1907/2006, it must be noted that that provision refers to the updating of a safety data sheet the compiling of which is provided for under Article 31(1). In accordance with Article 31(1)(a) of Regulation No 1907/2006, the supplier of a substance must provide the recipient of that substance with a safety data sheet where the substance meets the criteria for classification as dangerous in accordance with

Directive 67/548. Article 31(9)(a) of Regulation No 1907/2006 provides in that regard that suppliers must update that safety data sheet without delay as soon as new information which may affect the risk management measures or new information on hazards becomes available.

24 The Court must therefore consider whether the identification in the contested decision of the borates as substances of very high concern as a result of the procedure referred to in Article 59 of Regulation No 1907/2006 constitutes new information within the meaning of Article 31(9)(a) of Regulation No 1907/2006 capable of triggering the obligation referred to in that provision, namely the updating of the safety data sheet, with the result that the contested decision directly affects the legal situation of the applicants.

25 As regards the safety data sheet, Article 31(1) of Regulation No 1907/2006 provides that it must be compiled in accordance with Annex II to that regulation. According to that annex, which contains a guide to the compilation of safety data sheets, the sheets must provide a mechanism for transmitting appropriate safety information on classified substances down the supply chain to the immediate downstream user(s). The purpose of Annex II is to ensure consistency and accuracy in the content of each of the mandatory headings listed in Article 31(6) of Regulation No 1907/2006, so that the resulting safety data sheets will enable users to take the necessary measures relating to protection of human health and safety at the workplace, and protection of the environment.

26 According to the applicants, the identification of the borates as substances of very high concern as a result of the procedure referred to in Article 59 of Regulation No 1907/2006 constitutes new information in relation to headings 2 (hazards identification) and 15 (regulatory information) of Article 31(6) of that regulation.

27 With regard to heading 2 (hazards identification), according to section 2 of Annex II to Regulation No 1907/2006, the classification of a substance which arises from application of the classification rules in Directive 67/548 must be given under that heading. The hazards a substance presents to man and the environment must be indicated clearly and briefly.

28 In the present case, the identification of the borates as substances of very high concern as a result of the procedure referred to in Article 59 of Regulation No 1907/2006 does not concern the classification of those substances in accordance with Directive 67/548. The identification was made on the basis that, under Article 57(c) of Regulation No 1907/2006, the borates met the criteria for classification as toxic for reproduction category 2 in accordance with Directive 67/548. However, the fact that the borates meet those criteria was already established in Annex I to Directive 67/548, as amended by Directive 2008/58, and subsequently in Part 3 of Annex VI to Regulation No 1272/2008, as amended by Regulation No 790/2009 (see paragraphs 3 to 5 above). In accordance with Article 59(3) of Regulation No 1907/2006, the Member States concerned referred in the dossiers they submitted to the ECHA on 8 March 2010 to the inclusion of the borates in Part 3 of Annex VI to Regulation No 1272/2008 (see paragraphs 6 and 7 above).

29 It is true that when the contested decision was published on 18 June 2010, the applicants were not bound by a mandatory classification of the borates. With the entry into force on 20 January 2009 of Regulation No 1272/2008, Annex I to Directive 67/548 which included the borates was repealed, and the obligation to classify the borates in accordance with the harmonised classification defined in Part 3 of Annex VI to Regulation No 1272/2008, as amended by Regulation No 790/2009, did not apply since Article 2(2) of Regulation No 790/2009 specified 1 December 2010 as the starting date in that regard.

30 However, the hazards which had resulted in the classification of the borates had been legally defined to the requisite legal standard at the time of publication of the contested decision. It was clear to all interested parties that those hazards had not disappeared

merely because Annex I to Directive 67/548 had been deleted and its content had to be transferred to Part 3 of Annex VI to Regulation No 1272/2008. Moreover, with the entry into force of Regulation No 790/2009 on 25 September 2009, the classification of the borates as toxic for reproduction category 2 was referred to in Part 3 of Annex VI to Regulation No 1272/2008. The fact that that classification was not mandatory before 1 December 2010 does not affect the validity of the finding that the classification criteria were met as soon as Regulation No 790/2009 entered into force. Article 2(2) of Regulation No 790/2009 merely defers until 1 December 2010 the legal obligations arising from that classification under Regulation No 1272/2008, as amended by Regulation No 790/2009. That conclusion is supported by the fact that it is clear from Article 2(3) of Regulation No 790/2009 that the harmonised classification in Part 3 of Annex VI to Regulation No 1272/2008, as amended by Regulation No 790/2009, could be applied before 1 December 2010.

31 It follows that the identification of the borates as substances of very high concern did not contain new information on the hazardous properties of those substances but represented the outcome of the identification procedure referred to in Article 59 of Regulation No 1907/2006. The contested decision did not therefore produce any new information on hazards identification within the meaning of heading 2 of Article 31(6) of Regulation No 1907/2006.

32 With regard to heading 15 (regulatory information) of Article 31(6) of Regulation No 1907/2006, it must be noted that, according to section 15 of Annex II to that regulation, if the substance covered by the safety data sheet is the subject of specific provisions in relation to protection of man or the environment at European Union level, such as authorisations given under Title VII of the regulation or restrictions imposed under Title VIII, those provisions must, as far as is possible, be stated.

33 In that regard, first, it must be observed that, although the identification of a substance as a substance of very high concern as a result of the procedure referred to in Article 59 of Regulation No 1907/2006 can trigger information obligations on the part of economic operators, that does not have the effect of making the substance in question fall within a particular regime and thus of making it the subject of specific provisions. On the contrary, such identification has no impact on the placing on the market and use of the substance.

34 Second, as regards the authorisation procedure provided for in Title VII of Regulation No 1907/2006 and the restrictions imposed under Title VIII, the only examples listed in section 15 of Annex II to that regulation as being caught by that provision are the authorisations given and the restrictions. Since the identification of a substance as a substance of very high concern as a result of the procedure referred to in Article 59 of Regulation No 1907/2006 does not relate to the restrictions imposed under Title VIII of that regulation but is part of the authorisation procedure provided for under Title VII, the reference to the restrictions in section 15 of Annex II to Regulation No 1907/2006 does not support the proposition that such identification falls under heading 15 of Article 31(6) of that regulation.

35 As regards the authorisations given, it is apparent from Title VII of Regulation No 1907/2006 that these are the authorisations granted in accordance with Article 60 of that regulation, which are part of a subsequent stage of the authorisation procedure (Articles 60 to 64 of Regulation No 1907/2006). They may be requested from the ECHA pursuant to Article 62(1) of that regulation for one or several uses of a substance which it is prohibited to place on the market because of its inclusion in Annex XIV to that regulation. However, it must be noted that, with regard to the authorisation procedure provided for in Title VII of Regulation No 1907/2006, identification of a substance as a substance of very high concern as a result of the procedure referred to in Article 59 of that regulation was not expressly mentioned by the legislature in section 15 of Annex II to that regulation. It is true that the reference to authorisations given under Title VII of that regulation is provided by way of example only, but the fact remains that that is the only reference relating to the authorisation procedure under Title VII of Regulation No 1907/2006. While it cannot be ruled out

that heading 15 of the safety data sheet is affected by other specific provisions in relation to protection of man or the environment at European Union level, so far as the authorisation procedure provided for under Title VII of Regulation No 1907/2006 is concerned, that consideration would also indicate that authorisations alone fall under that heading. That conclusion is supported by the fact that Article 31(9)(b) of that regulation provides that the safety data sheet must be updated once an authorisation has been granted or refused.

36 It follows that the identification of a substance as a substance of very high concern as a result of the procedure referred to in Article 59 of Regulation No 1907/2006 does not have the effect of making a substance the subject of specific provisions in relation to protection of man or the environment at European Union level within the meaning of section 15 of Annex II to that regulation.

37 In light of the foregoing, the identification of the borates as substances of very high concern as a result of the procedure referred to in Article 59 of Regulation No 1907/2006 did not amount to new information capable of affecting the risk management measures, or new information on hazards within the meaning of Article 31(9)(a) of Regulation No 1907/2006, and therefore the applicants were not obliged to update the safety data sheet. Consequently, the contested decision does not directly affect the legal situation of the applicants on the basis of the obligation provided for by that provision.

38 In the second place, as regards the applicants' argument that the contested decision is of direct concern to them in that their legal situation is affected by Article 34(a) of Regulation No 1907/2006, it must be noted that, according to that provision, any actor in the supply chain of a substance must communicate new information on hazardous properties, regardless of the uses concerned, to the next actor or distributor up the supply chain.

39 In that regard, first, it must be observed that, contrary to the applicants' assertion, that provision does not impose information requirements on the applicants vis-à-vis their customers. Article 34(a) of Regulation No 1907/2006 covers the obligation to provide information to the next actors or distributors up, not down, the supply chain. Second, since the identification in the contested decision of the borates as substances of very high concern did not include new information on the hazardous properties of those substances (see paragraphs 27 to 31 above), the applicants were not subject to the information requirements referred to in Article 34(a) of Regulation No 1907/2006. It follows that, again, the contested decision does not directly affect the legal situation of the applicants on the basis of the duty provided for by that provision.

40 In the third place, as regards the applicants' argument that, in view of the criminal penalties imposed by the Member States for infringement of the obligations imposed by Regulation No 1907/2006, downstream consumers must be informed of the identification, which will help them to become aware of their obligations under Article 7(2) and Article 33 of that regulation, it is common ground that those provisions are not of concern to the applicants since their status is not that of a producer or importer of articles, nor are they a supplier of an article, as defined in Article 3(4), (11) and (33) of the regulation. The obligations laid down under Article 7(2) and Article 33 of that regulation clearly cover directly therefore only the applicants' customers in so far as those customers are producers or importers of articles or suppliers of an article. Admittedly, recital 18 in the preamble to Regulation No 1907/2006 and Article 1 of that regulation emphasise the responsibility for management of the risks of substances that lies with the manufacturers, importers and downstream users of those substances. However, Regulation No 1907/2006 establishes a detailed system of obligations which cannot be extended on the basis of the general considerations contained in those provisions.

41 In the fourth place, as regards the applicants' argument that the contested decision is of direct concern to them in that it affects their material situation, it must be noted that the mere fact that a measure may exercise an influence on an applicant's material

situation cannot suffice to allow him to be regarded as directly concerned. Only the existence of specific circumstances may enable a person subject to European Union law and claiming that the measure affects his position on the market to bring proceedings under the fourth paragraph of Article 263 TFEU (Joined Cases 10/68 and 18/68 *Eridania and Others* v *Commission* [1969] ECR 459, paragraph 7, and order in Case T-189/97 *Comité d'entreprise de la Société française de production and Others* v *Commission* [1998] ECR II-335, paragraph 48). In the present case, the applicants have merely claimed that their customers will be reluctant to continue to buy products which are on the candidate list; they have thus failed to prove the existence of those specific circumstances.

42 In light of the foregoing, it must be held that the contested decision does not directly affect the legal situation of the applicants. Since the first criterion of direct effect has not been met, the contested decision is not of direct concern to the applicants.

43 Therefore, the present plea of inadmissibility must be upheld and the action dismissed as inadmissible, and there is no need to consider the other plea of inadmissibility raised by the ECHA.

Costs

44 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. Furthermore, under Article 87(4), the institutions which have intervened in the proceedings are to bear their own costs.

45 Since the applicants have been unsuccessful, they must be ordered to bear their own costs and to pay those of the ECHA, as applied for by the ECHA. The Commission shall bear its own costs.

On those grounds,

THE GENERAL COURT (Seventh Chamber)

hereby orders:

1. The action is dismissed as inadmissible.

2. Etimine SA and AB Etiproducts Oy shall bear their own costs and pay those incurred by the European Chemicals Agency (ECHA).

3. The European Commission shall bear its own costs.

Luxembourg, 21 September 2011.

E. Coulon
Registrar

A. Dittrich
President