JUDGMENT OF THE GENERAL COURT (Fifth Chamber, Extended Composition)

25 September 2015 (*)

(REACH — Identification of acrylamide as a substance of very high concern — Intermediates — Action for annulment — Whether directly concerned — Admissibility — Proportionality — Equal treatment)

In Case T-268/10 RENV,

Polyelectrolyte Producers Group GEIE (PPG), established in Brussels (Belgium),

SNF SAS, established in Andrézieux-Bouthéon (France),

represented by R. Cana, D. Abrahams and E. Mullier, lawyers,

applicants,

v

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

defendant,

supported by

Kingdom of the Netherlands, represented by B. Koopman, acting as Agent,

and by

European Commission, represented by D. Kukovec, E. Manhaeve and K. Talabér-Ritz, acting as Agents,

interveners,

APPLICATION for annulment of the decision of ECHA (EC No 201-173-7) identifying acrylamide as a substance fulfilling 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), in accordance with Article 59 thereof,

THE GENERAL COURT (Fifth Chamber, Extended Composition),

composed of A. Dittrich (Rapporteur), President, F. Dehousse, J. Schwarcz, V. Tomljenović and A.M. Collins, Judges,

Registrar: L. Grzegorczyk, Administrator,

having regard to the written procedure and further to the hearing on 15 April 2015,

gives the following

Judgment

Background to the dispute

1 The first applicant, Polyelectrolyte Producers Group GEIE (PPG), is a European economic interest grouping established in Belgium. It represents the interests of companies that are producers or importers of polyelectrolytes, polyacrylamide or other polymers containing acrylamide. The member companies of the first applicant are also users of acrylamide and manufacturers or importers of acrylamide or polyacrylamide. All European Union producers of acrylamide are members of the first applicant.

2 The second applicant, SNF SAS, is a member company of the first applicant. It is principally active in the manufacture of acrylamide and polyacrylamide which it sells directly to its customers. It has production plants in France, the United States, China and South Korea.

3 Polyelectrolytes are water-soluble, synthetic and organic polymers that are produced from different monomers; one of these monomers is acrylamide. They are used, for example, to purify drinking water, treat waste water, produce paper and extract precious minerals.

4 Polyacrylamide is a polymer formed by polymerisation of the monomer acrylamide that is most commonly used in water treatment, the paper industry, the mining industry, the oil industry, in agriculture, as a textile additive and in the cosmetics and personal-care fields.

5 On 25 August 2009, the Kingdom of the Netherlands submitted to the European Chemicals Agency (ECHA) a dossier that it had drawn up concerning the identification of acrylamide as a substance fulfilling the criteria set out in Article 57(a) and (b) 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), subsequently amended, inter alia, by 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 (OJ 2008 L 353, p. 1), making reference to the classification of acrylamide as a category 2 carcinogen and a category 2 mutagen in Annex VI, Part 3, to Regulation No 1272/2008. On 31 August 2009, ECHA published a notice on its website inviting interested parties to submit comments on the acrylamide dossier. On the same day, ECHA also invited competent authorities from other Member States to submit comments on this

subject.

6 After receiving comments on the dossier in question, in particular from the first applicant, and the responses to those comments from the Kingdom of the Netherlands, ECHA referred the dossier to its Member State Committee, which, on 27 November 2009, unanimously agreed on the identification of acrylamide as a substance of very high concern, because acrylamide fulfilled the criteria set out in Article 57(a) and (b) of Regulation No 1907/2006.

7 On 22 December 2009 the Executive Director of ECHA adopted Decision ED/68/2009 to include acrylamide, on 13 January 2010, in the list of substances identified with a view to their eventual inclusion in Annex XIV to Regulation No 1907/2006 ('the candidate list of substances').

8 Following an application for interim relief brought by the second applicant in Case T-1/10 R, by order of the President of the Court of 11 January 2010, operation of the decision of ECHA identifying acrylamide as a substance fulfilling the criteria set out in Article 57 of Regulation No 1907/2006, pursuant to Article 59 of that regulation, was suspended until the order terminating those proceedings for interim relief had been made. Following that order, ECHA suspended the inclusion of acrylamide in the candidate list of substances.

9 By order of 26 March 2010 in PPG and SNF v ECHA (T-1/10 R, EU:T:2010:128), the second applicant's application for interim relief was dismissed.

10 On 30 March 2010, ECHA published the candidate list of substances including acrylamide.

Procedure before the General Court and the Court of Justice and forms of order sought

11 By application lodged at the Registry of the General Court on 10 June 2010, the applicants brought an action for annulment of the decision of ECHA identifying acrylamide as a substance fulfilling the criteria set out in Article 57 of Regulation No 1907/2006 and including acrylamide in the candidate list of substances, in accordance with Article 59 of that Regulation ('the contested decision').

12 By letters registered at the Registry of the General Court on 19 and 25 November 2010 respectively, the Kingdom of the Netherlands and the European Commission sought leave to intervene in support of the form of order sought by ECHA. After hearing the principal parties, that leave was granted by order of 10 January 2011.

13 By order of 21 September 2011 in PPG and SNF v ECHA (T-268/10, ECR, EU:T:2011:508), the General Court (Seventh Chamber, Extended Composition) dismissed the action as being inadmissible.

14 By application lodged at the Registry of the Court of Justice on 30 November 2011, the applicants brought an appeal against the order in PPG and SNF v ECHA, cited in paragraph 13 above (EU:T:2011:508).

15 By judgment of 26 September 2013 in PPG and SNF v ECHA (C-625/11 P, ECR, EU:C:2013:594; ‘the appeal judgment’), the Court of Justice set aside the order in PPG and SNF v ECHA, cited in paragraph 13 above (EU:T:2011:508). The Court of Justice held that the General Court had erred in law in so far as it held that the action had been brought out of time due to the fact that the rule, according to which the time period for bringing proceedings starts to run from the end of the 14th day following the date of publication of the contested decision, provided for in Article 102(1) of the Rules of Procedure of the General Court of 2 May 1991, applied only to measures published in the Official Journal of the European Union and not to measures published on the Internet (appeal judgment, paragraph 37).

16 Since the state of the proceedings did not permit final judgment to be given in the matter, the Court of Justice referred the case back to the General Court and reserved the costs.

17 The case was allocated to the Fifth Chamber (Extended Composition) of the General Court in accordance with Article 118(1) of the Rules of Procedure of 2 May 1991.

18 Since the written procedure had not been completed when the appeal judgment was delivered, ECHA was invited, by decision of the General Court (Fifth Chamber, Extended Composition) of 24 October 2013, to lodge a defence in accordance with Article 119(2) of the Rules of Procedure of 2 May 1991.

19 By document lodged at the Registry of the General Court on 5 December 2013, ECHA raised an objection of inadmissibility pursuant to Article 114(1) of the Rules of Procedure of 2 May 1991.

20 By order of the General Court (Fifth Chamber, Extended Composition) of 17 June 2014, consideration of the objection of inadmissibility was reserved for the final judgment and the costs were reserved.

21 The Kingdom of the Netherlands lodged its statement in intervention on 16 September 2014. By documents lodged at the Court Registry on 10 November 2014, ECHA and the applicants submitted their observations on that document.

22 The Commission lodged its statement in intervention on 17 September 2014. By document lodged at the Court Registry on 10 November 2014, ECHA submitted its observations on that statement in intervention. The applicants have submitted no observations on that statement in intervention.

23 Upon hearing the report of the Judge-Rapporteur, the General Court (Fifth Chamber, Extended Composition) decided to open the oral procedure.

24 In the context of measures of organisation of procedure provided for in Article 64 of the Rules of Procedure of 2 May 1991, the Court requested, first, ECHA to provide documents and, secondly, all parties to respond to certain questions. The parties complied with those requests within the time allowed.

25 The parties presented oral argument and answered the questions put by the Court at the hearing on 15 April 2015.

26 The applicants claim that the Court should:

- declare the action to be admissible and well founded;

- annul the contested decision;

- order ECHA to pay the costs.

27 ECHA, the Kingdom of the Netherlands and the Commission contend that the Court should:

- dismiss the action as being inadmissible or, in the alternative, as being unfounded;

- order the applicants to pay the costs.

Law

28 Before examining the parties' substantive pleas and arguments, it is appropriate to examine the objection of inadmissibility raised by ECHA.

Admissibility

29 In support of its objection of inadmissibility, ECHA, supported by the Kingdom of the Netherlands and the Commission, raises a plea of inadmissibility on the ground that the applicants are not directly concerned.

30 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 of that article, 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.

31 In the present case, it is common ground that since the contested decision was not sent to the applicants, they are not addressees of that act. 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.

32 As regards the admissibility of the first applicant's action, it must be observed that it has already been held that an association responsible for defending the collective interests of its members, was, as a rule, entitled to bring an action for annulment only if the undertakings that it represented or some of these undertakings themselves had locus standi or if it could prove an interest of its own (see, to that effect, judgment of 22 June 2006 in Belgium and Forum 187 v Commission, C-182/03 and C-217/03, ECR, EU:C:2006:416, paragraph 56 and the case-law cited). That rule also applies to a European economic interest grouping which, like the first applicant, was created in order to defend the interests of a category of undertakings (see order of 24 June 2014 in PPG and SNF v ECHA, T-1/10 RENV, EU:T:2014:616, paragraph 30 and the case-law cited).

33 In the present case, the first applicant did not produce any evidence to show that its own interests were directly affected. Even on the assumption that it is under a duty to organise and coordinate a harmonised approach to the obligations under Regulation No 1907/2006 for the entire sector in

question, it did not assert its own interests, but those of its members. Consequently, the first applicant is entitled to bring an action for annulment only if its members or some of them, such as the second applicant, are directly concerned by the contested decision.

34 As regards direct concern, it has consistently been held that that condition requires (i) that the impugned measure directly affect the individual's legal situation and (ii) 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 the EU rules alone, without the application of other intermediate rules (judgments of 5 May 1998 in Dreyfus v Commission, C-386/96 P, ECR, EU:C:1998:193, paragraph 43; 29 June 2004 Front national v Parliament, C-486/01 P, ECR, EU:C:2004:394, paragraph 34; and 10 September 2009 Commission v Ente per le Ville vesuviane and Ente per le Ville vesuviane v Commission, C-445/07 P and C-455/07 P, ECR, EU:C:2009:529, paragraph 45).

35 The applicants claim that the contested decision is of direct concern to them in that the legal situation of the first applicant's members and that of the second applicant are affected because of the obligations provided for in Article 31(9)(a) of Regulation No 1907/2006. As a result of the identification of acrylamide as a substance of very high concern, the first applicant's members and the second applicant are required to update the safety data sheet for acrylamide in accordance with that provision.

36 It must be pointed out that, in accordance with Article 31(1)(a) of Regulation No 1907/2006, suppliers of a substance or a mixture must provide the recipient of that substance or mixture with a safety data sheet where the substance meets the criteria for classification as hazardous in accordance with Regulation No 1272/2008. 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.

37 In the present case, it is not disputed that the first applicant's members and the second applicant had to provide the recipients of acrylamide with a safety data sheet since that substance met the criteria for classification as hazardous in accordance with Regulation No 1272/2008. Acrylamide has inter alia been classified among category 2 carcinogens and category 2 mutagens (see paragraph 5 above).

38 However, it is disputed that the identification of acrylamide as a substance of very high concern, resulting from the procedure provided for by Article 59 of Regulation No 1907/2006, pursuant to Article 57(a) and (b) of that regulation, constitutes, as the applicants argue, new information within the meaning of Article 31(9)(a) of that regulation, 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 first applicant's members and that of the second applicant.

39 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. That annex sets out the requirements that the supplier must fulfil for the compilation of a safety data sheet that is provided for a

substance in accordance with Article 31 of Regulation No 1907/2006. The safety data sheet must enable users to take the necessary measures relating to protection of human health and safety at the workplace, and protection of the environment.

40 According to the applicants, the identification of acrylamide as a substance of very high concern as a result of the procedure laid down in Article 59 of Regulation No 1907/2006, on the ground that that substance meets the criteria referred to in Article 57(a) and (b) of that regulation, constitutes new information relating, in particular, to Article 31(6)(15) of that regulation, as amended by Commission Regulation (EU) No 453/2010 of 20 May 2010, amending Regulation No 1907/2006 (OJ 2010 L 133, p. 1), which refers to regulatory information.

41 As regards Article 31(6)(15) of Regulation No 1907/2006, Section 15 of Part A of Annex II to that regulation, as amended by Regulation No 453/2010, states that that section of the safety data sheet is to describe the other regulatory information on the substance that has not already been provided in the safety data sheet. The information to be provided under Section 15.1 of Part A of Annex II to Regulation No 1907/2006 is, first, information regarding relevant European Union safety, health and environmental provisions, for example, Seveso category and named substances in Annex I to Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances (OJ 1997 L 10, p. 13), or national information on the regulatory status of the substance or mixture, including the substances contained in the mixture, including advice regarding action that should be taken by the recipient as a result of these provisions. Secondly, if the substance or mixture covered by the safety data sheet is the subject of specific provisions in relation to protection of human health or the environment at EU level, such as authorisations granted under Title VII of Regulation No 1907/2006 or restrictions applied under Title VIII of that regulation, those provisions are to be mentioned.

42 The ECHA decision resulting from the procedure laid down in Article 59 of Regulation No 1907/2006 constitutes a European Union safety, health and environmental measure concerning the regulatory status of a substance. By that decision, a substance is identified as of very high concern which may be included in Annex XIV to that regulation, which annex contains the list of substances subject to authorisation. Consequently, the suppliers of such a substance or of mixtures containing that substance must mention that identification on the safety data sheet and provide advice as to the obligations on recipients as a consequence of that identification and, inter alia, as to the information obligations under Articles 7 and 33 of Regulation No 1907/2006. Therefore, the identification of a substance as being of very high concern as a result of the procedure laid down in Article 59 of Regulation No 1907/2006, on the ground that that substance meets the criteria referred to in Article 57(a) and (b) of that regulation, constitutes new information that may require the suppliers of that substance to update the safety data sheet concerned.

43 It follows that the ECHA decision identifying a substance as being of very high concern as a result of the procedure laid down in Article 59 of Regulation No 1907/2006 may directly affect the legal situation of the suppliers of that substance as a result of the obligation which it sets out.

44 In the present case, that conclusion is not called into question either by the fact that, at the time of lodging the application on 10 June 2010, when the conditions of admissibility of the action must be determined (see order of 7 September 2010 in Etimine and Etiproducts v Commission, T-539/08, ECR, EU:T:2010:354, paragraph 76 and the case-law cited), Regulation No 453/2010 had not yet entered into force, nor by the fact that, according to the applicants, acrylamide was a substance registered and used exclusively as an intermediate.

45 In the first place, as regards the fact that, at the time of lodging the application on 10 June 2010, Regulation No 453/2010 had not yet entered into force, it is true that, according to Article 3, that regulation entered into force on the 20th day following its publication in the Official Journal. The regulation having been published in the Official Journal on 31 May 2010, it therefore entered into force on 20 June 2010. However, the possibility that Regulation No 453/2010 would not enter into force following its adoption on 20 May 2010 and its publication in the Official Journal was, at the time of lodging the application, purely theoretical (see, to that effect, judgment of 17 January 1985 in Piraiki-Patraiki and Others v Commission, 11/82, ECR, EU:C:1985:18, paragraph 9).

46 In that regard, the Court rejects ECHA's argument, which refers to paragraph 76 of the order in Etimine and Etiproducts v Commission, cited in paragraph 44 above (EU:T:2010:354), according to which the question of the admissibility of an action must be resolved on the basis of the rules in force at the date on which it was brought. The present case does not concern the question of the temporal application of the rules determining the conditions of admissibility of an action for annulment brought by an individual before the European Union judicature. Regulation No 435/2010 is a substantive rule.

47 With regard to the fact that Annex II to Regulation No 1907/2006 was amended, in accordance with Article 1 of Regulation No 453/10, only with effect from 1 December 2010, it suffices to note here that the fact that the effects of an act do not materialise until a subsequent date determined in the same act does not preclude an individual from being directly affected by it as a result of an obligation entailed by that act (see, to that effect, order of 11 July 2005 in Bonino and Others v Parliament and Council, T-40/04, ECR, EU:T:2005:279, paragraphs 46 and 47).

48 In the second place, with regard to the fact that, according to the applicants, acrylamide was a substance registered and used exclusively as an intermediate, it should be noted that, under Article 2(1)(c) of Regulation No 1907/2006, that regulation is not applicable to non-isolated intermediates and that, under Article 2(8)(b) of that regulation, isolated intermediates are exempt from Title VII of that regulation relating to the authorisation procedure, which includes the procedure for identifying a substance as of very high concern.

49 In the present case, it is unnecessary to rule on the question whether, under those provisions, the applicants are exempt from the information requirements set out in Article 31(9)(a) of Regulation No 1907/2006 since, in any event, at the time of lodging the application, the acrylamide supplied by the first applicant's members and by the second applicant was not used exclusively as an intermediate.

50 According to the definition set out in Article 3(15) of Regulation No 1907/2006, an intermediate is a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (‘synthesis’). In accordance with Article 3(15)(a) of that regulation, a non-isolated intermediate is an intermediate that, during synthesis, is not intentionally removed, except for sampling, from the equipment in which the synthesis takes place. Article 3(15)(b) and (c) of that regulation contains the definition of an on-site isolated intermediate and a transported isolated intermediate. The former is an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities. The latter is an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites.

51 It is true that it is apparent from Section 1.1 of the dossier drawn up by the Kingdom of the Netherlands on acrylamide, which concerns ‘information on exposure’, that 99.9% of acrylamide was used as an intermediate. However, in that regard, it is correctly pointed out that there were other uses as an agent in grouting products and for on-site preparation of polyacrylamide electrophoresis gels.

52 First, with regard to the use of acrylamide for grouting products, that consists, inter alia, in its use for water shut-off, concrete repair and salt damp remediation (judgment of 1 February 2013 in Polyelectrolyte Producers Group and Others v Commission, T-368/11, EU:T:2013:53, paragraph 2). It is apparent from the description of that use, set out in paragraph 1.1 of the file drawn up by the Kingdom of the Netherlands on acrylamide and which, according to the applicants, is correct, that when the acrylamide grout polymerises or gels, it solidifies into a stiff gel that is impervious to water.

53 The applicants argue that that process demonstrates that acrylamide is used as an intermediate in accordance with the definition set out in Article 3(15) of Regulation No 1907/2006. Acrylamide is manufactured or imported in order to be consumed or used in the synthesis of another substance, namely a water-impervious polymer. A polymer is defined as being a substance in Article 3(5) of that regulation.

54 That argument cannot be accepted. According to the definition set out in Article 3(15) of Regulation No 1907/2006, an intermediate is a substance that is manufactured for chemical processing and consumed in or used in that processing in order to be synthesised. In the present case, it is true that the acrylamide-based grouting agent is used in the manufacture of another substance during which it is itself transformed into that other substance, namely a polymer. However, as ECHA states, the acrylamide is not used for the purposes of undergoing synthesis, as defined in Article 3(15) of Regulation No 1907/2006. It is not used with the aim of manufacturing that other substance, the main purpose of the chemical process being to obtain a sealing function that occurs when the acrylamide grouting agent polymerises. Upon polymerisation, it solidifies into a rigid gel that is waterproof when used in grouting applications. The use of acrylamide as a grouting agent is not an intermediate use, but rather an end use of the substance.

55 That conclusion is supported, moreover, by the ‘Definition of intermediates as agreed by Commission, Member States and ECHA on 4 May 2010’. According to Section 4 of that definition, which concerns industrial end use other than in manufacturing of another substance, where a substance A is used by the manufacturer himself or by a downstream user and chemically reacts in a process other than the manufacturing of another substance, the substance A cannot be an intermediate. Further, it provides where the main aim of the chemical process is not to manufacture another substance, but rather to achieve another function, specific property, or a chemical reaction as an integrated part of producing articles, the substances used for this activity should not be regarded as intermediates under Regulation No 1907/2006. Those considerations are also reflected in Section 2 of that definition, which contains an analysis of the definition of an intermediate within the meaning of Article 3(15) of Regulation No 1907/2006.

56 Secondly, as regards the use of acrylamide for the preparation of polyacrylamide electrophoresis gels, it is apparent from Section 1.1 of the file drawn up by the Kingdom of the Netherlands on acrylamide, which concerns ‘information on exposure’, that the gels were used as research tools for separating nucleic acids in research establishments, universities and hospitals.

57 The applicants argue that the use of acrylamide in the manufacture of polyacrylamide electrophoresis gels is an intermediate use since the acrylamide is transformed into another substance, namely the gel which is a polymer.

58 As ECHA states, unless the context under which the chemical reaction leading to polyacrylamide gels takes place is specified, such an argument is not sufficient to establish that the acrylamide used in the manufacture of electrophoresis gels was used exclusively as an intermediate. It has already been noted (see paragraphs 54 and 55 above) that acrylamide constituted an intermediate where that substance was used for the purpose of undergoing synthesis. As ECHA states, this is not the case, in particular, as regards the use of acrylamide in the preparation of polyacrylamide gel handcasts. The intention behind the handcast preparation, which is one of the steps in the electrophoresis protocol, is not the manufacturing of polyacrylamide but the analytical separation of molecules by electrophoresis.

59 Thirdly, as regards the applicants’ argument that the three registration dossiers for acrylamide listed on the ECHA database of registered substances all identified that substance as an intermediate, it should be noted that, in accordance with the first paragraph of Article 20(2) of Regulation No 1907/2006, ECHA undertakes a completeness check of the registration dossier, which does not include, however, an assessment of the quality or adequacy of the data or justifications submitted. Furthermore, it is apparent from Article 6(1) of that Regulation that, save where that regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more mixture(s), in quantities of one tonne or more per year, is to submit a registration to ECHA. It cannot therefore be excluded that certain manufacturers or importers do not register acrylamide because they use lower quantities of it. The fact that there were only registration dossiers for acrylamide as an intermediate does not mean, therefore, that that substance was used exclusively as an intermediate.

60 In the light of the above, the applicants are directly concerned by the contested decision as a result of the information requirements set out in Article 31(9)(a) of Regulation No 1907/2006. The objection of inadmissibility must therefore be rejected.

61 Consequently, as the other conditions of admissibility have been fulfilled, which, moreover, is not contested by the parties, the action is admissible.

Substance

62 In support of the action, the applicants put forward four pleas in law which allege (i) infringement of Article 2(8)(b) and Article 59 of Regulation No 1907/2006, (ii) manifest error of appraisal, (iii) breach of the principle of proportionality and, (iv) breach of the principle of equal treatment.

The first plea in law, alleging infringement of Article 2(8)(b) and Article 59 of Regulation No 1907/2006

63 The applicants claim that, by identifying acrylamide as a substance of very high concern, ECHA infringes Article 2(8)(b) and Article 59 of Regulation No 1907/2006 because acrylamide is a substance registered and used exclusively as an intermediate and is therefore exempt from Title VII of that regulation. According to the applicants, during the procedure provided for in Article 59 of Regulation No 1907/2006, only evidence to the effect that acrylamide is an intermediate substance was advanced. That is the case, in particular, where that substance is used in grouting products and for the manufacture of electrophoresis gels, which are the only uses referred to by the Kingdom of the Netherlands in its dossier on acrylamide as examples of the use of that substance as such and not as an intermediate.

64 It should be noted that, by the contested decision, acrylamide was identified as a substance of very high concern in accordance with the procedure referred to in Article 59 of Regulation No 1907/2006. That procedure is included in the authorisation procedure set out in Title VII of that regulation. Under Article 2(8)(b) of that regulation, on-site isolated intermediates and transported isolated intermediates are exempted from that title. It is therefore appropriate to examine whether, as a result of that exemption, the contested decision is unlawful in so far as it identified acrylamide as a substance of very high concern.

65 In the first place, it should be noted that the procedure provided for by Article 59 of Regulation No 1907/2006 concerns the identification of substances. It should also be noted that, in accordance with Article 1(2) of Regulation No 1907/2006, the latter lays down provisions on substances and mixtures, within the meaning of Article 3 thereof, that apply to the manufacture, placing on the market or use of such substances on their own, in mixtures or in articles, and to the placing on the market of mixtures. According to the definition set out in Article 3(1) of that regulation, a substance is a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. A substance is therefore defined by its intrinsic properties. In the light of those provisions and

since it is established that acrylamide constitutes a substance within the meaning of that definition, it could properly be subject to the identification procedure provided for by Article 59 of Regulation No 1907/2006.

66 In the second place, it must be noted that the fact that a substance may have intermediate status does not mean that it is exempt from identification as being of very high concern in accordance with the procedure referred to in Article 59 of Regulation No 1907/2006. It is true that, under Article 2(8)(b) of that regulation, on-site isolated intermediates and transported isolated intermediates are exempted from Title VII of that regulation with regard to the authorisation procedure that includes the identification procedure. However, it is apparent from the definition of an intermediate, laid down in Article 3(15) of Regulation No 1907/2006, that the classification of a substance as an intermediate depends on the intended purpose of its manufacture and use. As has already been pointed out (see paragraph 50 above), according to that definition, an intermediate is a substance that is manufactured for chemical processing and consumed in or used in that processing in order to be synthesised. In so far as any substance may, in principle, be manufactured for chemical processing and consumed in or used in that processing in order to be synthesised and, therefore, have the status of an intermediate, the fact that a substance has, in a specific case, the status of an intermediate cannot exempt it from the identification procedure provided for by Article 59 of Regulation No 1907/2006.

67 Those considerations are confirmed by the fact that the criteria laid down in Article 57 of Regulation No 1907/2006, in order to identify a substance as being of very high concern in accordance with the procedure referred to in Article 59 of that regulation, relate to the instrinsic properties of that substance. Under Article 57(a) to (e) of that regulation, a substance may be identified if it meets the criteria for classification as carcinogenic, germ cell mutagenic or toxic for reproduction or if it is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative. Article 57(f) of Regulation No 1907/2006 allows identification of a substance that has serious effects on human health or the environment which give rise to a level of concern equivalent to that resulting from the use of other substances listed in Article 57(a) to (e). Whereas a substance within the meaning of Regulation No 1907/2006 is defined by its intrinsic properties (see paragraph 65 above), the concept of an intermediate laid down in that regulation does not relate to the properties of a substance and does not change those properties in any way, but defines an intermediate according to the intended purpose of the manufacture and use of a substance.

68 In that regard, in relation to the applicants' claim that the exemption for intermediates provided for in Article 2(8)(b) of Regulation No 1907/2006 is not expressly based on the uses of a substance, it must be noted that, according to the definition of intermediate laid down in Article 3(15) of that regulation, it is necessary to take into account the intended objective of the manufacture and use of that substance in order to determine whether it has the status of an intermediate.

69 In so far as the applicants claim that, under Article 59 of Regulation No 1907/2006, the identification of acrylamide should have been based on all

the information contained in the dossier drawn up by the Kingdom of the Netherlands pursuant to Annex XV to that regulation, according to which that substance is used as an intermediate only, that argument must also be rejected. Even if that dossier refers only to examples of the use of that substance as an intermediate, that is not relevant for the purposes of identifying acrylamide as a substance of very high concern meeting the criteria referred to in Article 57 of Regulation No 1907/2006, given that that information does not concern the intrinsic properties of acrylamide. As ECHA states, that information could become relevant in the later stages of the authorisation procedure provided for under Title VII of Regulation No 1907/2006, namely during the procedure for submitting a substance for authorisation and during the procedure for granting authorisations for specific uses. In any event, it has already been established that it cannot be concluded that all the uses of acrylamide referred to by the Kingdom of the Netherlands in its dossier were intermediate in nature (see paragraphs 49 to 59 above).

70 Furthermore, as regards the applicants' claim that ECHA infringed the principle of good administration in that it did not justify the identification of acrylamide as a substance of very high concern, having regard to its alleged exclusive use as an intermediate, it should be noted, first, that use of that substance as an intermediate did not preclude its identification as a substance of very high concern and, secondly, that the dossier drawn up by the Kingdom of the Netherlands, which constituted the basis of the identification procedure, indicated two uses of acrylamide which were, according to that dossier, other than intermediate. That argument must therefore be rejected.

71 Consequently, the first plea in law must be rejected.

The second plea in law, alleging a manifest error of appraisal

72 The applicants claim that ECHA committed a manifest error of assessment in so far as it relied, for the purposes of identifying acrylamide as a substance of very high concern, on the proposal of the Kingdom of the Netherlands which contained no information proving that 0.1% of acrylamide is not used as an intermediate. According to the applicants, the use of that substance in grouting products and for the manufacture of electrophoresis gels, which are the only uses referred to by the Kingdom of the Netherlands in its dossier on acrylamide as examples of the use of that substance as such and not as an intermediate, are not conclusive. Those are uses of acrylamide as an intermediate. In the absence of information on a use of acrylamide other than as an intermediate, the contested decision is arbitrary.

73 First of all, it should be pointed out that, in accordance with settled case-law, where the authorities of the European Union have a broad discretion, in particular as to the assessment of highly complex scientific and technical facts in order to determine the nature and scope of the measures which they adopt, review by the European Union judicature is limited to verifying whether there has been a manifest error of assessment or a misuse of powers, or whether those authorities have manifestly exceeded the limits of their discretion. In such a context, the European Union judicature cannot substitute its assessment of scientific and technical facts for that of the authorities of the European Union on which alone the TFEU has placed that task (judgments of 21 July 2011 in Etimine, C-15/10, ECR, EU:C:2011:504,

paragraph 60, and 7 March 2013 Bilbaína de Alquitranes and Others v ECHA, T-93/10, ECR, EU:T:2013:106, paragraph 76).

74 Nevertheless, the broad discretion of the authorities of the European Union, which implies limited judicial review of its exercise, applies not only to the nature and scope of the measures to be taken but also, to some extent, to the finding of the basic facts. However, even though such judicial review is of limited scope, it requires that the European Union authorities which have adopted the act in question must be able to show before the European Union judicature that in adopting the act they actually exercised their discretion, which presupposes that they took into consideration all the relevant factors and circumstances of the situation the act was intended to regulate (judgments of 8 July 2010 in Afton Chemical, C-343/09, ECR, EU:C:2010:419, paragraphs 33 and 34, and Bilbaína de Alquitranes and Others v ECHA, cited in paragraph 73 above, EU:T:2013:106, paragraph 77).

75 In the light of that case-law, the applicants' argument must be rejected.

76 It must be noted that the dossier drawn up by the Kingdom of the Netherlands in accordance with Annex XV to Regulation No 1907/2006 indicates that 99% of acrylamide in the European Union was used as an intermediate in the production of polyacrylamides for a number of applications and that there were other uses as an agent in grouting products and for on-site preparation of polyacrylamide gels. Furthermore, it should be noted that the Member State Committee support document, on which the identification of acrylamide as a substance of very high concern was based, does not any contain information on the use of that substance.

77 However, as is clear from the examination of the first plea in the present action, in order to identify a substance as being of very high concern in accordance with the procedure referred to in Article 59 of Regulation No 1907/2006, the intrinsic properties of that substance must be taken into account. Moreover, it should be pointed out that, under Article 59(2) and (3) of that regulation, a dossier prepared for the purpose of identifying a substance of very high concern may be limited, if appropriate, to a reference to an entry in Part 3 of Annex VI to Regulation No 1272/2008 containing the list of harmonised classification and labelling of hazardous substances and may, therefore, contain no information relating to the use of the substance concerned.

78 In any event, it has already been established that it cannot be concluded that all the uses of acrylamide referred to by the Kingdom of the Netherlands in its dossier were intermediate in nature (see paragraphs 49 to 59 above).

79 The second plea must therefore be rejected.

The third plea in law, alleging breach of the principle of proportionality

80 The applicants claim that the treatment of acrylamide is disproportionate because ECHA had a choice of measures and the choice of identifying the substance at issue as being of very high concern causes disadvantages which are excessive in relation to the aims pursued. According to the applicants, the identification procedure is designed to ensure that careful attention is paid to the most dangerous substances. Certain types of substances such as

intermediates are exempted from Title VII of Regulation No 1907/2006 because they do not pose the same level of risk as other substances. Notwithstanding that legislative intent, it is claimed, ECHA used that procedure to identify a substance that would be used only as an intermediate, which is disproportionate. Furthermore, the risk to workers from exposure to acrylamide is, eliminated or reduced as a result of specific EU legislation on the protection of workers. The authorities had the opportunity to choose a different measure, namely not to act, which would have been more appropriate and more proportionate. In any event, ECHA could have provided that acrylamide is identified as a substance of very high concern only in so far as it is not used as an intermediate or could have decided that the use of acrylamide would be subject to the restrictions provided for in Title VIII of Regulation No 1907/2006.

81 According to settled case-law, the principle of proportionality, which is part of the general principles of EU law, requires that EU measures do not exceed the limits of what is appropriate and necessary in order to achieve the objectives legitimately pursued by the legislation in question; when there is a choice between several appropriate measures recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (see judgment in Etimine, cited in paragraph 73 above, EU:C:2011:504, paragraph 124 and the case-law cited).

82 As regards judicial review of the conditions referred to in the previous paragraph, ECHA must be allowed a broad discretion in a field which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments. The legality of a measure adopted in that field can be affected only if the measure is manifestly inappropriate having regard to the objective which the legislature is seeking to pursue (see, to that effect, judgment in Etimine, cited in paragraph 73 above, EU:C:2011:504, paragraph 125 and the case-law cited).

83 In the present case, it is apparent from Article 1(1) of Regulation No 1907/2006 that the objective of that regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. Having regard to recital 16 in the preamble to that regulation, the legislature established the first of those three objectives as the main objective, namely to ensure a high level of protection of human health and the environment. As regards, more specifically, the aim of the authorisation procedure, which includes the identification procedure set out in Article 59 of that regulation, Article 55 of Regulation No 1907/2006 states that its aim is essentially to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that those substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable (judgment in Bilbaína de Alquitranes and Others v ECHA, cited in paragraph 73 above, EU:T:2013:106, paragraph 116).

84 In the first place, as regards the applicants' argument that the contested decision is not appropriate for achieving the objectives pursued by Regulation No 1907/2006, it should be recalled that the contested decision

identified acrylamide as a substance of very high concern as a result of the procedure set out in Article 59 of that regulation. Where a substance is identified as being of very high concern, the economic operators concerned are subject to information obligations (judgment in Bilbaína de Alquitranes and Others v ECHA, cited in paragraph 73 above, EU:T:2013:106, paragraph 117).

85 As regards the objective of protecting human health and the environment, it must be stated from the outset that the identification of a substance as being of very high concern serves to improve information for the public and professionals as to the risks and hazards incurred and that, consequently, such identification must be regarded as a means of enhancing that protection (see judgment in Bilbaína de Alquitranes and Others v ECHA, cited in paragraph 73 above, EU:T:2013:106, paragraph 118 and the case-law cited).

86 As regards, more specifically, the applicants' argument that the contested decision is inappropriate in that regard since acrylamide is used as an intermediate only and is therefore exempted from Title VII of Regulation No 1907/2006 pursuant to Article 2(8)(b) thereof, it should be noted that it has already been established that it cannot be concluded that acrylamide was used as an intermediate only (see paragraphs 49 to 59 above). In any event, there is no reason to conclude that uses of acrylamide other than as intermediates are precluded. The identification of that substance does not seem, therefore, to be manifestly inappropriate in relation to the aims pursued.

87 Consequently, the applicants' argument concerning the allegedly inappropriate nature of the contested decision must be rejected.

88 In the second place, the applicants argue that the contested decision exceeds the limits of what is necessary to achieve the objectives pursued, since the option of not acting, the adoption of restrictions provided for in Title VIII of Regulation No 1907/2006 or the identification of acrylamide as a substance of very high concern only in so far as it is not used as an intermediate, would constitute less onerous measures. Moreover, according to the applicants, the risk to workers is eliminated or reduced as a result of legislation on the protection of workers.

89 First, with regard to the option of not acting, the applicants claim that that would be more proportionate and less onerous since the identification of acrylamide as a substance of very high concern is not designed for intermediates, but for other types of substances which raise greater concerns. That argument must be rejected. Given that it cannot be concluded that acrylamide was used solely as an intermediate and that, in any event, there is no reason to conclude that uses of acrylamide other than as intermediates are precluded (see paragraph 86 above), omission to act does not constitute a measure that is as appropriate as identification of that substance as being of very high concern.

90 Secondly, with regard to restriction measures concerning the use of acrylamide, on the one hand, it must be observed that the mere fact that a substance appears in the candidate list of substances does not prevent that substance from being subject to restrictions rather than to an authorisation. As is apparent from Article 58(5) and Article 69 of Regulation No 1907/2006, the Commission or a Member State may always propose that the manufacture, the

placing on the market or the use of a substance be managed by restrictions rather than by an authorisation (judgment in Bilbaína de Alquitranes and Others v ECHA, cited in paragraph 73 above, EU:T:2013:106, paragraph 128). In the present case, it is apparent, in particular, from the judgment in Polyelectrolyte Producers Group and Others v Commission, cited in paragraph 52 above (EU:T:2013:53), that acrylamide was subject to restrictions for grouting applications as from 5 November 2012.

91 On the other hand, as is apparent from Annex XVII to Regulation No 1907/2006, restrictions applicable to the manufacture, the placing on the market and the use of certain dangerous substances, mixtures and articles, adopted in accordance with the procedure set out in Title VIII of that regulation, may range from specific conditions imposed on the manufacture or the placing on the market of a substance to a total ban on the use of a substance. Even if restriction measures are also appropriate for the achievement of the objectives pursued by that regulation, they thus do not constitute, as such, less onerous measures compared with the identification of a substance which solely entails information obligations (judgment in Bilbaína de Alquitranes and Others v ECHA, cited in paragraph 73 above, EU:T:2013:106, paragraph 129).

92 Thirdly, in so far as the applicants take the view that the existing legislation concerning the protection of workers allows the risk to those workers to be eliminated or reduced, suffice it to point out that that legislation, which provides for risk management measures for workers, cannot constitute an appropriate and less onerous measure for the achievement of the objectives pursued by Regulation No 1907/2006 as regards the treatment of substances of very high concern and, in particular, of the objective of progressively replacing substances of very high concern by suitable alternative substances or technologies where these are economically and technically viable (see paragraph 83 above).

93 Fourthly, the applicants claim that ECHA could have provided that acrylamide is identified as a substance of very high concern only in so far as it is not used as an intermediate. In that regard, it suffices to note that the legislature introduced specific rules relating to intermediates in Article 2(1)(c) and Article 2(8)(b) of Regulation No 1907/2006 (see paragraph 48 above).

94 In the light of the foregoing considerations, it cannot be concluded that the contested decision breached the principle of proportionality.

95 The third plea in law must therefore be rejected.

The fourth plea in law, alleging breach of the principle of equal treatment

96 The applicants claim that the identification of acrylamide as a substance of very high concern breaches the principle of equal treatment because other substances in an identical situation are not subject to such identification. According to the applicants, acrylamide was classified among carcinogenic and mutagenic category 2 substances and toxic for reproduction category 3 substances along with a considerable number of other substances which have the same or higher properties. No reasoning was given as to why acrylamide had been chosen and not other substances having identical properties, even though it is established that at least 99% of its use is exempt from the

identification procedure.

97 It must be observed that, by Regulation No 1907/2006, the legislature set up a system for the registration, assessment and authorisation of chemical substances and the restrictions applicable to those substances, in order to ensure, inter alia, according to recital 1 in the preamble to that regulation, a high level of protection of human health and the environment as well as the free movement of substances in the internal market, while enhancing competitiveness and innovation. In particular, Regulation No 1907/2006 provides, in Title VII, for an authorisation procedure. The objective of that procedure, according to Article 55 of the regulation, is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable (judgment in Bilbaína de Alquitranes and Others v ECHA, cited in paragraph 73 above, EU:T:2013:106, paragraph 69).

98 The authorisation procedure applies to all substances meeting the criteria set out in Article 57 of Regulation No 1907/2006. The first phase of the authorisation procedure is the identification of the substances referred to in that article, for which a procedure in several stages is set out in Article 59 of Regulation No 1907/2006. According to recital 77 in the preamble to the regulation, in view of workability and practicality considerations, both as regards natural or legal persons, who have to prepare application files and take appropriate risk management measures, and as regards the authorities, who have to process authorisation applications, only a limited number of substances should be subjected to the authorisation procedure at the same time. As regards the choice of substances, Article 59(2) and (3) of Regulation No 1907/2006 provides that it is for the Commission or the Member State concerned to decide whether substances meet the criteria set out in Article 57 of the regulation. The legislature thus gave the Commission and the Member States a wide discretion, allowing a progressive implementation of the rules on the substances of very high concern set out in Title VII of Regulation No 1907/2006 (judgment in Bilbaína de Alquitranes and Others v ECHA, cited in paragraph 73 above, EU:T:2013:106, paragraph 70).

99 In the light of the foregoing observations, the identification procedure does not confer on ECHA any power as regards the choice of the substance to be identified; that prerogative belongs exclusively to the Commission and the Member States pursuant to Article 59 of Regulation No 1907/2006 (order of 22 May 2014 in Bilbaína de Alquitranes and Others v ECHA, C-287/13 P, EU:C:2014:599, paragraph 51, and judgment in Bilbaína de Alquitranes and Others v ECHA, cited in paragraph 73 above, EU:T:2013:106, paragraph 71).

100 In the present case, the identification procedure laid down by Article 59 of Regulation No 1907/2006 was observed as regards the choice of the substance to be identified. It appears from the dossier that acrylamide was chosen by the Kingdom of the Netherlands because it considered that that substance met the criteria listed in Article 57 of that regulation. Moreover, in the absence of the production of a dossier prepared by a Member State relating to a substance that also has carcinogenic, mutagenic or toxic properties, or a request from the Commission for the preparation of such a

dossier by ECHA, ECHA cannot proceed to identify that substance, pursuant to the procedure set out in Article 59 of Regulation No 1907/2006, without exceeding its powers. It follows that, by identifying acrylamide, and not the allegedly comparable substances, as a substance of very high concern, ECHA did not breach the principle of equal treatment (see, to that effect, judgment in Bilbaína de Alquitranes and Others v ECHA, cited in paragraph 73 above, EU:T:2013:106, paragraph 72).

101 Finally, as regards the argument that no reasoning was given as to why acrylamide had been chosen and not other substances having identical properties, even though it is established that at least 99% of its use is exempt from the identification procedure, it should be noted that it is apparent from the contested decision that the Kingdom of the Netherlands presented its proposal to identify acrylamide as a substance of very high concern due to its carcinogenic and mutagenic properties. Given that, under Article 59(3) of Regulation No 1907/2006, any Member State may prepare a dossier in accordance with Annex XV to that regulation for substances which in its opinion meet the criteria set out in Article 57 of that regulation, no other reasoning was necessary.

102 In the light of the foregoing considerations, given that the legality of the procedure set out in Article 59 of Regulation No 1907/2006 was not disputed by the applicants and ECHA observed that procedure, the fourth plea in law must be rejected.

103 Consequently, the action must be dismissed as unfounded.

Costs

104 In the judgment on appeal, the Court of Justice reserved the costs. It is therefore for the General Court to decide, in the present judgment, on all the costs relating to the various proceedings, in accordance with Article 219 of the Rules of Procedure of the General Court.

105 Under Article 134(1) 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. Under Article 138(1) of those rules, Member States and institutions which intervene in the proceedings are to bear their own costs.

106 As the applicants have been unsuccessful, they must be ordered to pay their own costs and those incurred by ECHA, in accordance with the form of order sought by ECHA. The Kingdom of the Netherlands and the Commission must bear their own costs.

On those grounds,

THE GENERAL COURT (Fifth Chamber, Extended Composition)

hereby:

1. Dismisses the action;

2. Orders Polyelectrolyte Producers Group GEIE (PPG) and SNF

SAS to pay their own costs and those incurred by the European Chemicals Agency (ECHA);

3. Orders the Kingdom of the Netherlands and the European Commission to bear their own costs.

Dittrich Dehousse Schwarcz

Tomljenović Collins

Delivered in open court in Luxembourg on 25 September 2015.

[Signatures]

---

* Language of the case: English.