Reports of Cases

JUDGMENT OF THE GENERAL COURT (Fifth Chamber)

30 April 2015 *

(REACH — Identification of certain respiratory sensitisers as substances of very high concern — Equivalent level of concern — Action for annulment — Whether directly concerned — Admissibility — Rights of the defence — Proportionality)

In Case T-135/13,

**Hitachi Chemical Europe GmbH**, established in Düsseldorf (Germany),

**Polynt SpA**, established in Scanzorosciate (Italy),

**Sitre Srl**, established in Milan (Italy),

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

applicants,

supported by

**REACh ChemAdvice GmbH**, established in Kelkheim (Germany), represented by C. Mereu and K. Van Maldegem,

and by

**New Japan Chemical**, established in Osaka (Japan), represented by C. Mereu and K. Van Maldegem,

interveners,

v

**European Chemicals Agency (ECHA)**, represented by M. Heikkilä, W. Broere and T. Zbihlej, acting as Agents,

defendant,

supported by

**Kingdom of the Netherlands**, represented by B. Koopman, M. Bulterman and C. Schillemans, acting as Agents,

and by

* Language of the case: English.

**European Commission**, represented by K. Mifsud-Bonnici and K. Talabér-Ritz, acting as Agents,

interveners,

APPLICATION for annulment in part of Decision ED/169/2012 of the ECHA of 18 December 2012 concerning the inclusion of substances of very high concern in the list of candidate substances, in accordance with Article 59 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 so far as it concerns hexahydromethylphthalic anhydride (EC No 247-094-1), hexahydro-4-methylphthalic anhydride (EC No 243-072-0), hexahydro-1-methylphthalic anhydride (EC No 256-356-4) and hexahydro-3-methylphthalic anhydride (EC No 260-566-1),

THE GENERAL COURT (Fifth Chamber),

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

Registrar: L. Grzegorczyk, Administrator,

having regard to the written procedure and further to the hearing on 20 November 2014,

gives the following

## Judgment

### Background to the dispute

1 The first applicant, Hitachi Chemical Europe GmbH, and the second applicant, Polynt SpA, manufacture and import hexahydromethylphthalic anhydride (EC No 247-094-1), hexahydro-4-methylphthalic anhydride (EC No 243-072-0), hexahydro-1-methylphthalic anhydride (EC No 256-356-4) and hexahydro-3-methylphthalic anhydride (EC No 260-566-1) (together, 'MHHPA') for industrial use as intermediates or monomers in the chemical synthesis of chemicals and polymers, as well as for the manufacture of articles, as co-monomers or intermediates, in the manufacture of polymer resins.

2 The third applicant, Sitre Srl, uses MHHPA as a hardener for epoxy resins as intermediate or co-monomer in the manufacturing of epoxy-based electrical insulators for transformers for medium-voltage power distribution.

3 MHHPA is a cyclic acid anhydride. It has been listed in Table 3.1 of Part 3 of Annex VI to 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). By that listing, MHHPA has inter alia been classified among the category 1 respiratory sensitisers, which may cause allergy or asthma symptoms or breathing difficulties if inhaled.

4 On 6 August 2012, the Kingdom of the Netherlands sent to the European Chemicals Agency (ECHA) a dossier that it had prepared concerning the identification of MHHPA as a substance of very high concern in accordance with the procedure laid down in Article 59 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 No 1272/2008. In that dossier, the Kingdom of the Netherlands proposed that MHHPA be identified as a substance for which there was scientific evidence of probable serious effects on human health or the environment which gave rise to a level of concern equivalent to those of other substances listed in Article 57(a) to (e) of Regulation No 1907/2006, in accordance with Article 57(f) of that regulation.

5 On 3 September 2012, the ECHA requested interested parties to submit their comments on the dossier prepared concerning MHHPA. Within the framework of that consultation procedure, the first and second applicants submitted comments through a trade association of which they were members.

6 Subsequently, the ECHA referred the dossier to its Member State Committee, as referred to in Article 76(1)(e) of Regulation No 1907/2006, which, on 13 December 2012, reached a unanimous agreement on the identification of MHHPA as a substance of very high concern meeting the criteria set out in Article 57(f) of Regulation No 1907/2006.

7 By its Decision ED/169/2012 of 18 December 2012 on the inclusion of substances of very high concern in the candidate list ('the contested decision'), the ECHA identified MHHPA as a substance meeting the criteria referred to in Article 57(f) of Regulation No 1907/2006, in accordance with Article 59 of that regulation.

## Procedure and forms of order sought

8 By application lodged at the Court Registry on 28 February 2013, the applicants brought the present action for partial annulment of the contested decision, in so far as it concerned MHHPA.

9 By letter registered at the Court Registry on 14 June 2013, the European Commission applied for leave to intervene in support of the form of order sought by the ECHA. After hearing the main parties, that application was granted by order of 9 September 2013.

10 By document lodged at the Court Registry on 27 June 2013, the Kingdom of the Netherlands applied for leave to intervene in support of the form of order sought by the ECHA. After hearing the main parties, that application was granted by order of 9 September 2013. Since the application by the Kingdom of the Netherlands for leave to intervene was made after the expiry of the period prescribed in Article 115(1) of the Rules of Procedure of the General Court, it was decided that the Kingdom of the Netherlands could submit its observations only during the oral procedure, in accordance with Article 116(6) of those Rules of Procedure.

11 By documents lodged at the Court Registry on 21 and 24 June 2013, respectively, REACh ChemAdvice GmbH and New Japan Chemical applied for leave to intervene in support of the form of order sought by the applicants. After hearing the main parties, those applications were granted by orders of 10 December 2013 in *Hitachi Chemical Europe and Others* v *ECHA* (T-135/13, EU:T:2013:716 and EU:T:2013:734).

12 The Commission lodged its statement in intervention on 28 October 2013. By documents lodged at the Court Registry on 10 December 2013 and 6 January 2014, respectively, the ECHA and the applicants submitted their observations on that statement.

13 REACh ChemAdvice and New Japan Chemical lodged their statements in intervention on 30 January 2014. By documents lodged at the Court Registry on 17 and 18 March 2014, respectively, the ECHA and the applicants submitted their observations on those statements.

14 On hearing the report of the Judge-Rapporteur, the Court (Fifth Chamber) decided to open the oral procedure.

15 By order of 15 October 2014, after hearing the parties, the present case and the case *Polynt and Sitre* v *ECHA*, with the reference T-134/13, were joined for the purposes of the oral procedure, in accordance with Article 50 of the Rules of Procedure.

16 In the context of measures of organisation of procedure provided for in Article 64 of the Rules of Procedure, the Court requested the ECHA to provide a document. The ECHA did so within period prescribed. In addition, in the context of those measures, the Court requested that the parties deal with certain questions in particular, in their oral arguments.

17 By letter of 31 October 2014, the applicants lodged their observations on the report for the hearing.

18 The parties presented oral argument and answered the questions put to them by the Court at the hearing on 20 November 2014.

19 The applicants claim that the Court should:

— declare the action admissible and well founded;

— annul the contested decision in part in so far as it concerns MHHPA and its monomers;

— order the ECHA to pay the costs.

20 The ECHA contends that the Court should:

— declare the action inadmissible or, at least, unfounded;

— order the applicants to pay the costs.

21 REACh ChemAdvice and New Japan Chemical claim that the Court should:

— declare the action admissible and well founded;

— annul the contested decision in part in so far as it concerns MHHPA and its monomers.

22 The Kingdom of the Netherlands and the Commission contend that the Court should declare the action inadmissible or, at least, unfounded, and order the applicants to pay the costs.

**Law**

23 Without formally raising a plea of inadmissibility, the ECHA, supported by the Kingdom of the Netherlands and the Commission, disputes the admissibility of the action. Therefore, before the substance of the case is examined, the questions raised by the ECHA concerning the admissibility of the action must be answered.

1. *Admissibility*

24 The ECHA, supported by the Kingdom of the Netherlands and the Commission, contends that the applicants lack *locus standi* since the contested decision is not of direct concern to them.

25 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.

26 In the present case, it is common ground that the contested decision was not addressed to the applicants; they are not, therefore, the 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.

27 As regards 'direct concern', it is settled case-law that that condition requires, first, that the measure in question directly affect the legal situation of the individual and, secondly, 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 only from EU rules, 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 in *Front national* v *Parliament*, C-486/01 P, ECR, EU:C:2004:394, paragraph 34; and 10 September 2009 in *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).

28 The applicants argue that the contested decision is of direct concern to them in that the legal situation of the first and second applicants is affected by Article 31(9) of Regulation No 1907/2006 and that of the third applicant is affected by Article 7(2) and Article 33 of that regulation.

29 As regards whether the first and second applicants are directly concerned, the applicants, supported by REACh ChemAdvice and New Japan Chemical, argue that as a result of the identification of MHHPA as a substance of very high concern, those applicants were required to update the safety data sheet for MHHPA, pursuant to Article 31(9) of Regulation No 1907/2006.

30 The Court notes that, under Article 31(1)(a) of Regulation No 1907/2006, the suppliers of a substance must provide the recipient of that substance 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) of Regulation No 1907/2006 states 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.

31 In the present case, it is not disputed that the first and second applicants had to provide the recipients of MHHPA with a safety data sheet since MHHPA met the criteria for classification as hazardous in accordance with Regulation No 1272/2008. MHHPA has inter alia been classified among the category 1 respiratory sensitisers, which may cause allergy or asthma symptoms or breathing difficulties if inhaled (see paragraph 3 above).

32 However, what is disputed is whether, as the applicants argue, the identification of MHHPA as a substance of very high concern, as a result of the procedure laid down in Article 59 of Regulation No 1907/2006 pursuant to Article 57(f) of that regulation, constitutes new information for the purposes of Article 31(9)(a) of Regulation No 1907/2006, which triggers 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 and second applicants. The substances which meet the criteria referred to in Article 57(f) of Regulation No 1907/2006 are those for which there is

scientific evidence of probable serious effects on human health or the environment which give rise to an equivalent level of concern to those of substances listed in Article 57(a) to (e) of that regulation, namely hazard class carcinogenicity category 1 substances; hazard class germ cell mutagenicity category 1 substances; hazard class reproductive toxicity category 1 substances; persistent, bioaccumulative and toxic ('PBT') substances; or very persistent and very bioaccumulative ('vPvB') substances.

33 As regards the safety data sheet, Article 31(1) of Regulation No 1907/2006 states that it must be compiled in accordance with Annex II to that regulation. That annex sets out the requirements that the supplier must comply with 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.

34 According to the applicants, the identification of MHHPA 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 MHHPA meets the criteria referred to in Article 57(f) of that regulation, constitutes new information relating, in particular, to Article 31(6)(15) of that regulation, which refers to regulatory information.

35 As regards Article 31(6)(15) of Regulation No 1907/2006, section 15 of Part A of Annex II to that regulation 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 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.

36 The contested decision constitutes a European Union safety, health and environmental measure concerning the regulatory status of MHHPA. By the contested decision, MHHPA has been identified as a substance of very high concern as a result of the procedure laid down in Article 59 of Regulation No 1907/2006, which may be included in Annex XIV to that regulation, which annex contains the list of substances subject to authorisation. Consequently, the first and second applicants, which are suppliers of MHHPA, 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 MHHPA 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 MHHPA meets the criteria referred to in Article 57(f) of that regulation, constituted new information requiring the first and second applicants to update the safety data sheet concerned.

37 It follows that the contested decision directly affects the legal situation of the first and second applicants as a result of the obligation which it entailed.

38 Consequently the contested decision is of direct concern to the first and second applicants.

39 As regards whether the third applicant is directly concerned, it should be recalled that, according to the case-law, which is based on reasons of procedural economy, if the same decision is challenged by several applicants and it is established that one of them has *locus standi*, there is no need to examine

the other applicants' standing to bring proceedings (see, to that effect, judgments of 24 March 1993 in *CIRFS and Others* v *Commission*, C-313/90, ECR, EU:C:1993:111, paragraph 31, and 9 June 2011 in *Comitato 'Venezia vuole vivere' and Others* v *Commission*, C-71/09 P, C-73/09 P and C-76/09 P, ECR, EU:C:2011:368, paragraphs 36 and 37).

40 Consequently, since the contested decision constitutes a regulatory act which does not entail implementing measures (see, to that effect, judgment of 7 March 2013 in *Bilbaína de Alquitranes and Others* v *ECHA*, T-93/10, ECR, EU:T:2013:106, paragraphs 52 to 65), the action is admissible.

2. *Substance*

41 In support of the present action, the applicants raise four pleas in law alleging, first, errors of law and of assessment; secondly, infringement of the rights of the defence; thirdly, breach of the principle of proportionality; and, fourthly, infringement of essential procedural requirements.

*The first plea in law, alleging errors of law and of assessment*

42 This plea in law is divided into two parts. The first part alleges that Article 57(f) of Regulation No 1907/2006 does not apply to respiratory sensitisers, while the second alleges that the ECHA took the view, incorrectly, that MHHPA gives rise to a level of concern equivalent to those of category 1 carcinogenic substances, mutagenic substances and substances toxic to reproduction.

First part of the first plea in law, alleging that Article 57(f) of Regulation No 1907/2006 does not apply to respiratory sensitisers

43 The applicants, supported by REACh ChemAdvice and New Japan Chemical, argue that Article 57(f) of Regulation No 1907/2006 does not apply to respiratory sensitisers such as MHHPA, since there is no reference to that category of substances in that provision. They state that the legislature envisaged that provision including only the substances that are expressly mentioned therein and those whose types of effects were not yet known at the time Regulation No 1907/2006 was drafted.

44 The Court notes that Article 57(f) of Regulation No 1907/2006 concerns substances — such as those having endocrine disrupting properties or those having PBT properties or vPvB properties, which do not fulfil the criteria of Article 57(d) or (e) — for which there is scientific evidence of probable serious effects on human health or the environment which give rise to an equivalent level of concern to those of other substances listed in Article 57(a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59 of Regulation No 1907/2006.

45 First, it must be stated that the wording of Article 57(f) of Regulation No 1907/2006 does not rule out the inclusion of respiratory sensitisers such as MHHPA within scope of that provision. Although it is true, as the applicants state, that Article 57(f) does not make any reference to that category of substances, the fact remains that the substances expressly mentioned in that provision are mentioned solely by way of example, as is apparent from the legislature's use of the words 'such as those'.

46 Secondly, it is apparent from Article 1(1) of Regulation No 1907/2006 that the purpose 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, it must be held that 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 (see, to that effect, judgments of 7 July 2009 in *S.P.C.M. and Others*, C-558/07, ECR, EU:C:2009:430, paragraph 45, and *Bilbaína de Alquitranes and*

*Others* v *ECHA*, cited in paragraph 40 above, EU:T:2013:106, paragraph 116). As the ECHA states, the applicants' restrictive interpretation of Article 57(f) of Regulation No 1907/2006 goes against that objective in that a large number of dangerous substances having serious effects on human health and the environment would be removed from the ambit of the authorisation procedure laid down in Title VII of that regulation.

47 It should also be stated that, in indicating in recital 115 in the preamble to Regulation No 1907/2006 that resources should be focused on substances of the highest concern, the legislature expressly refers to respiratory sensitisers.

48 Thirdly, it should be observed that there is no support in the *travaux préparatoires* of Regulation No 1907/2006 for the applicants' claim that the legislature envisaged including only the substances whose types of effects were not yet known at the time that regulation was drafted. By contrast, it is apparent from the initial proposal for a regulation presented by the Commission on 29 October 2003 concerning Regulation No 1907/2006 (COM(2003) 644 final), that the provision set out in Article 57(f) of that regulation was aimed at substances giving rise to an equivalent level of concern to those of the substances referred to in Article 57(a) to (e) of that regulation for which there were clear and objective criteria for identification. According to that proposal, those substances were to be identified through other scientific or technical evidence on a case-by-case basis.

49 Moreover, as regards the applicants' argument that their interpretation of Article 57(f) of Regulation No 1907/2006 is borne out by the document drawn up by the ECHA entitled 'Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern' ('guidance for the identification of substances of very high concern'), suffice it to point out that that document constitutes a working tool produced by the ECHA in order to facilitate the implementation of Regulation No 1907/2006. As the guidance correctly states, the text of Regulation No 1907/2006 is the only authentic legal reference and the information contained in that guidance does not constitute legal advice.

50 The first part of the first plea in law must therefore be rejected.

Second part of the first plea in law, alleging that the level of concern is not equivalent to those of category 1 carcinogenic substances, mutagenic substances and substances toxic for reproduction

51 The applicants argue that the ECHA took the view, incorrectly, that MHHPA gave rise to a level of concern equivalent to those of category 1 carcinogenic substances, mutagenic substances and substances toxic to reproduction. In the context of this part of the plea, the applicants state, first, that the effects of respiratory sensitisation are not irreversible; secondly, that no consumers or workers are exposed to MHHPA; thirdly, that the ECHA's assessment is based on old and outdated data; fourthly, that the ECHA did not take into account all the relevant data; and fifthly, that the ECHA based its assessment, incorrectly, on a read-across from cyclohexane-1,2-dicarboxylic anhydride (EC No 201-604-9), cis-cyclohexane-1,2-dicarboxylic anhydride (EC No 236-086-3) and trans-cyclohexane-1,2-dicarboxylic anhydride (EC No 238-009-9) (together, 'HHPA') on the one hand, to MHHPA on the other.

52 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 FEU Treaty has placed that task (judgments of 21 July 2011 in *Etimine*, C-15/10, ECR, EU:C:2011:504, paragraph 60, and *Bilbaína de Alquitranes and Others* v *ECHA*, cited in paragraph 40 above, EU:T:2013:106, paragraph 76).

53 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 40 above, EU:T:2013:106, paragraph 77).

– The first complaint, regarding the absence of irreversible effects

54 The applicants state that the effects of respiratory sensitisation are not irreversible. They state that the sensitisation process is a two-phase process, with a symptom-free first phase of induction and, after a subsequent exposure, a second elicitation phase that may lead to symptoms. They state that biomarkers such as immunoglobulins of types E and G (IgE and IgG) enable rapid detection of exposure as from the first sensitisation phase. In such a case, further exposure and the potentially severe clinical symptoms that may result can be efficiently avoided by removing the worker concerned from the exposed working environment. In accordance with applicable legislation on the protection of workers, they carry out regular health checks. Furthermore, they state that recent studies have shown that the levels of biomarkers decrease once the exposure of the worker has ceased. Even induction may therefore be reversible.

55 It should be pointed out that, as is apparent from section 6.3 of the support document for the identification, on the basis of Article 57(f) of Regulation No 1907/2006, of MHHPA as a substance of very high concern because of its respiratory sensitising properties, adopted by the Member State Committee of the ECHA on 13 December 2012 ('the support document'), the ECHA examined whether MHHPA gave rise to a level of concern equivalent to those of category 1 carcinogenic substances, mutagenic substances and substances toxic for reproduction, taking into account, inter alia, the seriousness of the effects, the irreversibility of health effects, the consequences for society and the difficulties in carrying out a risk assessment based on MHHPA concentration. As indicated in the considerations in question, those criteria are set out in the guidance drawn up by the ECHA for the identification of substances of very high concern.

56 As regards the criterion relating to the irreversibility of health effects, section 6.3.1.2 of the support document states that exposure to MHHPA has the potential to induce irreversible sensitisation to that substance. Such sensitisation is irreversible but does not have an adverse effect per se, except if the person sensitised is exposed to MHHPA again. The sensitised subject may also respond to other acid anhydrides when cross reactivity has occurred. According to those documents, in most cases, a subject is sensitised for the rest of his life. Furthermore, prolonged exposure can lead to permanent lung damage.

57 The arguments put forward by the applicants do not show that the ECHA's assessment as to the irreversible nature of the effects on health is vitiated by a manifest error.

58 It is common ground that the sensitisation process is characterised by two phases, namely the induction phase and the elicitation phase of sensitisation. During the induction phase of sensitisation, the immune system develops a heightened susceptibility to react to MHHPA. During the elicitation phase of sensitisation, exposure to MHHPA evokes a classical hypersensitivity inflammatory reaction, resulting for example in chronic inflammation of the lungs.

59 As regards the first phase, the applicants dispute the irreversible nature of induction by referring to two scientific studies according to which the levels of biomarkers decrease once the exposure of the worker has ceased. It should be pointed out that the applicants did not produce either of those studies to support their arguments. For its part, the ECHA did submit one of those studies. That study mentions only the fact that, when an individual who has been through the induction phase is no longer exposed, his levels of biomarkers gradually decrease, which is a sign that the symptoms linked to elicitation gradually disappear. However, that does not mean that those markers have disappeared nor, after subsequent exposure, including also to other cyclic anhydrides due to the cross reactivity of this category of substances, that those levels will not increase, as the ECHA states. The applicants' arguments therefore do not show that the induction phase is reversible.

60 As regards the second phase, it is common ground that the effects on health are, in principle, reversible. However, nothing put forward by the applicants permits the inference that the statement, in section 6.3.1.2 of the support document, that prolonged exposure to MHHPA can lead to irreversible effects, namely permanent lung damage, is incorrect. Even if biomarkers enable early detection of exposure during the first phase and the applicants carry out regular health checks, as they claim, the observations of the Member State Committee of the ECHA in sections 6.3.1.1 and 6.3.1.2 of the support document, according to which irreversible effects may occur before a health problem is identified, in particular because the effects on health may be mild at first, are not manifestly incorrect.

61 The applicants argue that the fact that the second phase is reversible precludes there being a level of concern equivalent to those of category 1 carcinogenic substances, mutagenic substances and substances toxic for reproduction, because, for those latter substances, there are no early markers and it is impossible to reverse the effects by removing the person from exposure once the symptoms appear. That argument must be rejected. It is apparent from Article 60(2) of Regulation No 1907/2006 that the fact that the negative effects associated with the use of a substance can be controlled adequately does not preclude its identification as a substance of very high concern. If this were not so, the possibility, pursuant to the provision in question, of authorising a substance the risks of which can be adequately controlled, would be rendered meaningless, as the ECHA states. Furthermore, it should be recalled that the occurrence of irreversible effects is not excluded (see paragraph 60 above). Moreover, it must be stated that the existence of irreversible effects was only one of the reasons why the ECHA concluded that there was such a level of concern. As is apparent from section 6.3 of the support document, the Member State Committee of the ECHA also took into account, inter alia, the seriousness of the effects, the consequences for society and the difficulties in carrying out a risk assessment based on the concentration of the substances in question (see paragraph 55 above).

62 In addition, an effects-threshold below which sensitisation is excluded does not exist for MHHPA, as is apparent from sections 6.3.1.4 and 6.3.2 of the support document. Also, as the ECHA states and as is apparent from section 6.3.3 of the support document, exposure to MHHPA already causes respiratory health problems for workers at relatively low exposure levels.

63 Lastly, in so far as REACh ChemAdvice and New Japan Chemical argue that the ECHA's decisions are not consistent, referring to a substance evaluation report on m-tolylidene diisocyanate dated November 2013, their argument must be rejected. First, the substance evaluation procedure laid down in Articles 44 to 48 of Regulation No 1907/2006 constitutes a procedure different from that for the identification of a substance of very high concern. Secondly, the author of that report is the Republic of Poland and not the ECHA.

64 The first complaint must therefore be rejected.

– The second complaint, regarding the absence of consumer or worker exposure

65 The applicants argue that no consumers or workers are exposed to MHHPA. They state that that substance is used only in industrial processes and the finished products do not contain any free MHHPA. Even if small quantities of unreacted MHHPA might be present in the final article, these cannot be quantified. In accordance with the programmes for the monitoring of products and the applicable legal requirements, MHHPA is used in closed systems which prevent exposure and ensure a very limited to near zero risk of exposure. Furthermore, in the case of potential exposure whilst the substances are mixed in batch processes or transferred, exhaust ventilation is used and workers are required to wear individual protective equipment, which ensures the safe handling of the substance and prevents exposure. The applicants refer to a report of the second applicant's company doctor, according to which there have been no cases of disease of the respiratory tract caused by sensitisation since 1992. In addition, the applicants argue that the ECHA has recognised that in assessing whether a substance gives rise to an equivalent level of concern, it is necessary to examine whether it is possible adequately to address the risks of the serious effects observed by means of a normal risk assessment.

66 That line of argument does not permit the inference that the ECHA's assessment that MHHPA gives rise to a level of concern equivalent to those of the substances listed in Article 57(a) to (e) of Regulation No 1907/2006 is vitiated by a manifest error.

67 First, it should be observed that, even according to the applicants' arguments, it is not possible completely to exclude consumers' and workers' exposure to MHHPA. The applicants accept that small quantities of unreacted MHHPA may still be present in the final article, even if they cannot be quantified. In this connection, it must be recalled that it is apparent from sections 6.3.1.4, 6.3.2 and 6.3.3 of the support document that an effects-threshold below which sensitisation is excluded does not exist for MHHPA and that exposure to MHHPA already causes respiratory health problems for workers at relatively low exposure levels (see paragraph 62 above).

68 Secondly, even if all users of MHHPA do implement effective risk management measures, a situation which the applicants however have not established, it must be stated that that fact does not permit the inference that the ECHA's assessment is vitiated by a manifest error. As already stated (see paragraph 61 above), it is apparent from Article 60(2) of Regulation No 1907/2006 that the fact that the negative effects associated with the use of a substance can be controlled adequately does not preclude its identification as a substance of very high concern. If this were not so, the possibility, pursuant to the provision in question, of authorising a substance the risks of which can be adequately controlled, would be rendered meaningless. This is confirmed by Article 58(2) of Regulation No 1907/2006, under which uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific EU legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled.

69 It should also be pointed out that the Court of Justice has held that a distinction must be made between hazards and risks. Hazard assessment constitutes the first stage of the process of risk assessment, which is a more specific concept. Thus, an assessment of the hazards linked to the intrinsic properties of a substance must not be limited in light of specific circumstances of use, as in the case of a risk assessment, and may be properly carried out regardless of the place where the substance is used, the route by which contact with the substance might arise and the possible levels of exposure to the substance (judgment in *Etimine*, cited in paragraph 52 above, EU:C:2011:504, paragraphs 74 and 75).

70 The classification and labelling of substances established by 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) are based on the transmission of information on the hazards linked to the substances' intrinsic properties (judgment in *Etimine*, cited in paragraph 52 above, EU:C:2011:504, paragraph 74). That classification has been taken over by Regulation No 1272/2008.

71 Since classification among category 1 carcinogenic substances, mutagenic substances and substances toxic for reproduction is sufficient for a substance to be identified as being of very high concern pursuant to Article 57(a) to (c) of Regulation No 1907/2006, it cannot be concluded that, in order for a substance to be identified in accordance with Article 57(f) of Regulation No 1907/2006, the ECHA must take a risk assessment into consideration.

72 Moreover, pursuant to Article 57(d) and (e) of Regulation No 1907/2006, PBT substances and vPvB substances can be identified as being of very high concern if the criteria set out in Annex XIII to that regulation are satisfied. That annex does not provide for the taking into account of a risk assessment, but contains the criteria for determining the PBT and vPvB properties of a substance (see, to that effect, judgment in *Bilbaína de Alquitranes and Others* v *ECHA*, cited in paragraph 40 above, EU:T:2013:106, paragraph 46).

73 Furthermore, as regards the fact that section 6.3 of the support document, which refers to the guidance for the identification of substances of very high concern in this connection, mentions a normal risk assessment, it should be pointed out that, according to that section, whether it is possible to prevent the effects of a substance within the framework of a normal risk assessment is but one of the considerations that ought to be taken into account by the ECHA in the context of the procedure for the identification of a substance as being of very high concern under Article 57(f) of Regulation No 1907/2006 ('the identification procedure'). According to section 6.3 of the support document, if a normal risk assessment is deemed inadequate and if there is sufficient scientific evidence to conclude that serious effects are probable and that exposure of human beings to the substance in question is likely to occur under normal conditions of use, then the substance in question should be considered to be of an equivalent level of concern. In the present case, it is apparent from section 6.3 of the support document that the identification was the consequence of the assessment of several criteria, which included, inter alia, the assessment of the seriousness of the effects, the irreversibility of health effects, the consequences for society and the difficulties in carrying out a risk assessment based on MHHPA concentration (see paragraph 55 above). As regards the last criterion, it has been stated that for most substances, a risk assessment can be performed. In the context of those assessments, a 'derived no-effect level' can be established. However, section 6.3.1.4 of the support document states that sensitisation to MHHPA must be regarded as an effect for which no exposure threshold can be determined and, consequently, it is not possible to determine a derived no-effect level. It is apparent from those considerations that it was not sufficient to carry out a normal risk assessment because no derived no-effect level could be established.

74 Thirdly, in so far as the applicants state that, according to a report of the second applicant's company doctor, no cases of disease of the respiratory tract have been caused by sensitisation since 1992, suffice it to state, first, that that report serves only to inform about the specific situation of that applicant's installations and does not contain any information as to other installations in the European Union. Secondly, even as regards that applicant's installations, the report is of only limited evidential value since respiratory function was examined by the doctor in question only every two years, no details being provided as to the measures for monitoring the persons concerned during that period, nor any indications being given as to how the persons who left those installations were monitored.

75 Fourthly, the applicants refer to other studies in order to show that there is no exposure to MHHPA through consumer products.

76 They refer to a survey of downstream users, representing a variety of approximately 20 downstream users in Europe and outside Europe, according to which no clinical symptoms of respiratory sensitisation have been observed during the 10 years preceding 2012. In this connection, it should be stated that since that survey, which — according to the ECHA — has methodological problems, was not produced before the Court, that line of argument does not show that there is no exposure to MHHPA.

77 The applicants also refer to a survey carried out by the Danish Ministry of the Environment, dated 2007, according to which no emission of phthalic anhydride derivatives, including MHHPA, has been observed in products potentially containing MHHPA. In this connection, it must be pointed out that, even if — according to that survey — there is no risk of sensitisation for consumers from products potentially containing MHHPA, this would not permit the inference that there is likewise no risk for workers. Furthermore, such a statement would contradict the applicants' line of argument that small quantities of unreacted MHHPA may still be present in the final article, even if they cannot be quantified (see paragraph 67 above).

78 Consequently, the second complaint must be rejected.

– The third complaint, that the ECHA took into account old and outdated data

79 The applicants argue that the ECHA's assessment was based on old and outdated data. They state that the ECHA did not take into account current working conditions, the health checks required by the legislation on the protection of workers, the risk management measures or the monitoring programmes implemented. The ECHA referred to cases dating back more than 10 years, whereas working conditions have changed significantly during the last 10 years. According to a recent survey of downstream users, no clinical symptoms of respiratory sensitisation have been observed during the last 10 years. Furthermore, even though the Kingdom of the Netherlands applied, in its assessment of MHHPA, a reference value related to a no-exposure level, it did not report any cases of serious effects on health in the last 10 years.

80 That line of argument does not show that the ECHA made a manifest error of assessment in identifying MHHPA as a substance of very high concern on the basis of Article 57(f) of Regulation No 1907/2006.

81 First, as regards the applicants' argument that working conditions, the health checks required by the legislation on the protection of workers, the risk management measures and the monitoring programmes implemented have changed during the last 10 years, suffice it to point out that the hazards arising from the intrinsic properties of MHHPA have not changed, and the fact that the negative effects associated with the use of a substance can be controlled adequately does not preclude its identification as a substance of very high concern (see paragraph 68 above).

82 Secondly, in so far as the applicants state that no cases of serious effects on health have been reported in the last 10 years, it must be pointed out that that reasoning does not show that the statement, in section 6.3.1.1 of the support document relating to the seriousness of the effects, that most of the cases taken into account by the Member State Committee of the ECHA date back to the period 1990 to 2006 and that more recent cases have not been found in the literature, is manifestly incorrect. Moreover, in so far as the applicants refer, in this connection, to a survey of downstream users representing a variety of approximately 20 downstream users in Europe and outside Europe, their arguments have already been rejected (see paragraph 76 above). In so far as the applicants also rely on a database in the United Kingdom concerning illnesses at the workplace, it should be stated, first, that that database was not produced, and secondly, that it is based — according to the ECHA — on a sample of voluntary declarations by physicians and it therefore does not attest to the absence of cases in the United Kingdom or in the European Union.

83 The third complaint must therefore be rejected.

– The fourth complaint, that not all of the relevant data was taken into account

84 The applicants argue that the ECHA based its decision on an assessment that did not take all the relevant data into account. The applicants and other interested parties provided new data that were not taken into account by the ECHA. They state that on many occasions during the consultation procedure provided for in Article 59(4) of Regulation No 1907/2006, the response had been that all available literature had been taken into account or that the information would be taken into consideration in the process of priority setting for Annex XIV to Regulation No 1907/2006. According to the applicants, in order to establish whether a substance gives rise to a level of concern equivalent to those of the substances listed in Article 57(a) to (e) of Regulation No 1907/2006, the ECHA ought to have taken that information into account.

85 That line of argument must be rejected.

86 First, it is apparent from the responses to the comments submitted by the first and second applicants and other interested parties that all the comments in question were taken into consideration during the identification procedure. Moreover, the applicants do not put forward any specific comment to which no response was given and which was not taken into account.

87 Secondly, in so far as the applicants take the view that the response merely stating that all available literature had been taken into account was insufficient, it should be observed that the comments to which that response was given concern the alleged absence of recent cases of serious effects on health in the last 10 years. As is apparent from the considerations set out in paragraphs 76 and 82 above, it does not follow from that response that the ECHA made a manifest error of assessment because of a failure to take all the relevant data into account.

88 Thirdly, in so far as the applicants state that the ECHA, by merely referring to the process of priority setting for Annex XIV to Regulation No 1907/2006, did not take sufficient account of the comments made during the identification procedure, it should be stated that that response was given several times in the context of comments made in relation to the use, exposure, alternatives and risks of MHHPA. In this connection, suffice it to recall that the fact that the negative effects associated with the use of a substance can be controlled adequately does not preclude its identification as a substance of very high concern (see paragraphs 68 and 81 above). Furthermore, the applicants do not cite any specific piece of data submitted in the context of those comments which, wrongly, was not taken into consideration by the ECHA in the procedure for the identification of MHHPA as a substance of very high concern. Moreover, it has already been held that it is not apparent from the identification procedure set out in Article 59 of Regulation No 1907/2006 that information on alternative substances is relevant as regards the outcome of that procedure (judgment of 7 March 2013 in *Rütgers Germany and Others* v *ECHA*, T-94/10, ECR, EU:T:2013:107, paragraph 77).

89 Fourthly, in so far as the applicants argue that comments concerning the existence of risk management measures were not taken into consideration by the ECHA since the latter did not assess whether a normal risk assessment was adequate, that line of argument has already been rejected in the context of the examination of the second complaint (see paragraph 73 above).

90 Lastly, in so far as REACh ChemAdvice and New Japan Chemical refer to the need for a risk management option analysis according to the document entitled 'Roadmap on Substances of Very High Concern' drawn up by the Commission in 2013, suffice it to state that such an analysis is not part of the identification procedure set out in Regulation No 1907/2006.

91 The fourth complaint must therefore be rejected.

– The fifth complaint, that the read-across to MHHPA of data relating to HHPA was incorrect

92 The applicants argue that the assessment of MHHPA is based mainly on the assessment of HHPA because only very limited data were available in respect of MHHPA. Referring to a scientific study, they state that the read-across from HHPA to MHHPA as regards sensitisation potential is scientifically questionable, in particular because of different biomarker induction patterns and different exposure-response relationships between those substances based on the total plasma protein adducts formed.

93 That line of argument does not show that the identification of MHHPA as a substance of very high concern on the basis of Article 57(f) of Regulation No 1907/2006 is vitiated by a manifest error.

94 First, as is apparent from the support document, MHHPA was not identified as a substance of very high concern because of a read-across to it of data relating to HHPA. As the ECHA confirmed at the hearing, MHHPA was inter alia classified among the category 1 respiratory sensitisers, which may cause allergy or asthma symptoms or breathing difficulties if inhaled (see paragraph 3 above), on the basis of its intrinsic properties and not on the basis of a read-across from data relating to HHPA.

95 Furthermore, it is true, as is apparent from section 6.3.3 of the support document, that most of the studies taken into account by the ECHA concerned exposure to HHPA and MHHPA, since MHHPA was commonly used in a specific mixture with HPPA. However, as is apparent from the proposal to classify MHHPA under Directive 67/548, it was already established that there was cross-reactivity between HHPA and MHHPA and that, on the basis of the data available, HHPA and MHHPA are inter alia expected to behave the same way in the body, both having the potential to act as haptens and react with body proteins. The cross-reactivity between HHPA and MHHPA is confirmed by the dossier prepared by the Kingdom of the Netherlands for the identification of MHHPA as a substance of very high concern, which refers to scientific studies in this regard, and the support document, which contains the same references. According to section 4 of the dossier and section 4 of the support document, the structures of HHPA and MHHPA are closely related and the observed effects on health are the same, inasmuch as the two substances have similar characteristics.

96 Secondly, as regards the scientific study mentioned by the applicants, it should be observed that in that study, the author uses the total plasma proteins adducts of HHPA and MHHPA as indices of the exposure. It is true that in that study, the levels of protein adducts were actually higher for MHHPA than for HHPA, even though the air exposure levels to those substances were almost identical. However, the conclusion as to the reasons for and implications of possible different patterns is left open, and, according to that study, there were several potential scenarios for explaining the findings observed concerning the difference of the biomarker induction pattern for HHPA and MHHPA. Those scenarios ranged from the observation that HHPA is more sensitising than MHHPA to the statement that MHHPA is so potent that even the lowest exposure levels studied have caused sensitisation. Accordingly, that study cannot support the conclusion that the ECHA's assessment is vitiated by a manifest error arising from the fact that the ECHA relied on studies concerning exposure to HHPA and MHHPA.

97 The fifth complaint must therefore be rejected.

98 In the light of the foregoing, the second part of the first plea in law and, consequently, that plea in law in its entirety must be rejected.

*The second plea in law, alleging infringement of the rights of the defence*

99 The applicants submit that the ECHA infringed their rights of defence. First, they state that, because of the lack of objective criteria applied in order to determine whether a substance gives rise to a level of concern equivalent to those of other substances listed in Article 57(a) to (e) of Regulation No 1907/2006 for the purposes of Article 57(f) of Regulation No 1907/2006, in particular in the case of a respiratory sensitiser, they did not have the opportunity to fully defend their case. The criteria developed by the Kingdom of the Netherlands do not make it possible to determine, on a case-by-case basis, whether a substance meets the criteria laid down in that provision because they are general in nature, could be applied to an indefinite category of respiratory sensitisers and are arbitrary given that they have not been approved by the authorities nor been the subject of public debate. Secondly, their rights of defence have been infringed because the ECHA did not take into account all the data provided. Thirdly, the applicants argue that their rights of defence have been infringed because the ECHA did not assess MHHPA under the scheme set out in Title VI of Regulation No 1907/2006, which constituted the most appropriate process. The application of that scheme would have allowed them to discuss that assessment and to provide relevant scientific data.

100 That line of argument must be rejected.

101 First, as regards the argument that the applicants' rights of defence were infringed because of the lack of objective criteria for determining whether a substance gives rise to a level of concern equivalent to those of other substances listed in Article 57(a) to (e) of Regulation No 1907/2006 for the purposes of Article 57(f) of Regulation No 1907/2006, it should be pointed out that the objective of the latter provision is precisely to make it possible to identify a substance as being of very high concern, on a case-by-case basis, where the objective criteria laid down in Article 57(a) to (e) of Regulation No 1907/2006 are absent. In that context, there must be scientific evidence of a substance's probable serious effects on human health or the environment which give rise to a level of concern equivalent to those of other substances listed in Article 57(a) to (e) of Regulation No 1907/2006. Since the applicants have not raised a plea of illegality against Article 57(f) of that regulation, it is not apparent from their arguments how the ECHA may have infringed their rights of defence in applying that provision.

102 Furthermore, it must be observed that, in order to show that MHHPA can have serious effects on human health or the environment which give rise to a level of concern equivalent to those of other substances listed in Article 57(a) to (e) of Regulation No 1907/2006, the Kingdom of the Netherlands and the ECHA applied the criteria laid down in section 3.3.3.2 of the guidance for the identification of substances of very high concern, as is clear from section 6.3 of the dossier prepared by that Member State concerning the identification of MHHPA and section 6.3 of the support document. Those criteria include, inter alia, the seriousness of the effects, the irreversibility of health effects, the consequences for society and the difficulties in carrying out a risk assessment based on the concentration of the substance in question. They do not preclude other factors being taken into account.

103 Although it is true that those criteria are general in nature and are applicable not only to respiratory sensitisers, the fact remains that they are sufficiently precise to enable interested parties, properly and effectively, to make known their views as to the assessment of whether a substance gives rise to a level of concern equivalent to those of other substances listed in Article 57(a) to (e) of Regulation No 1907/2006.

104 In so far as the applicants state, in support of an alleged infringement of their rights of defence, that those criteria were neither approved by the competent authorities nor debated with the interested parties and are therefore arbitrary, it must be pointed out that, even if that were established, it cannot give rise to an infringement of the applicants' rights of defence, since the applicants had full knowledge of the criteria and their application in this case from the dossiers prepared by the Kingdom of the Netherlands concerning the identification of MHHPA. Indeed, the applicants have not argued that

their rights of defence were infringed when the criteria applied in order to determine whether MHHPA gave rise to a level of concern equivalent to those of other substances listed in Article 57(a) to (e) of Regulation No 1907/2006 were established.

105 Moreover, it is apparent from the comments submitted by the first and second applicants through a trade association of which they are members, within the framework of the consultation procedure provided for in Article 59(4) of Regulation No 1907/2006, that the assessment carried out by the Kingdom of the Netherlands, according to which MHHPA gave rise to a level of concern equivalent to those of other substances listed in Article 57(a) to (e) of Regulation No 1907/2006, was sufficiently clear to enable those applicants, properly and effectively, to make known their views.

106 Secondly, as regards the applicants' argument that the ECHA did not take into account all the data provided, that argument has already been rejected in the Court's examination of the fourth complaint in the second part of the first plea in law (see paragraphs 84 to 91 above). In the context of the present plea in law, the applicants do not put forward additional arguments.

107 Thirdly, in so far as the applicants also maintain, in support of their arguments concerning infringement of their rights of defence, that the ECHA was required to assess MHHPA under the evaluation procedure laid down in Title VI of Regulation No 1907/2006, since that procedure would have allowed them to discuss the assessment in question and to provide relevant scientific data, suffice it to point out that the identification procedure carried out pursuant to Article 59 of that regulation, which forms part of the authorisation procedure for a substance set out in Title VII of that regulation, constitutes a different procedure from that set out in Title VI of that regulation. It is not apparent from Regulation No 1907/2006 that the legislature intended to make the identification procedure subject to the evaluation procedure that is carried out on the basis of the dossier submitted by a registrant in the context of the registration of a substance (see, to that effect, judgment in *Bilbaína de Alquitranes and Others* v *ECHA*, cited in paragraph 40 above, EU:T:2013:106, paragraph 124). By identifying MHHPA on the basis of Article 57(f) of Regulation No 1907/2006, without first assessing it in the context of an evaluation procedure, the ECHA accordingly did not infringe the applicants' rights of defence. Furthermore, it has already been held that if a dossier on a substance is prepared by a Member State or, at the request of the Commission, by the ECHA, the latter must, subject to compliance with the conditions set out in Article 59 of Regulation No 1907/2006, proceed to identify that substance (see, to that effect, judgment in *Bilbaína de Alquitranes and Others* v *ECHA*, cited in paragraph 40 above, EU:T:2013:106, paragraph 71).

108 The second plea in law must therefore be rejected.

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

109 The applicants argue that the ECHA infringed the principle of proportionality by identifying MHHPA as a substance of very high concern. They state that instead of such identification, the ECHA could have decided to examine the chemical safety reports for MHHPA and adopted the risk management measures proposed. Furthermore, the applicants state that, as a result of the application of the provisions on the protection of workers and health and safety systems at work, the risk of exposure to MHHPA is reduced to near zero. They state that since MHHPA is mainly used as an intermediate or as a monomer, which are exempt from the application of Title VII of Regulation No 1907/2006 in accordance with Article 2(8) of that regulation, MHHPA is used by professionals and the articles produced do not contain MHHPA, the objective of consumer protection will not be achieved through the contested decision. It would have been more appropriate for the ECHA to assess MHHPA under the evaluation procedure laid down in Title VI of Regulation No 1907/2006. Lastly, the applicants state that the presentation of a dossier on restrictions for consumer products, such as cosmetics, would have been a less onerous measure than identifying MHHPA as a substance of very high concern.

110 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 52 above, EU:C:2011:504, paragraph 124 and the case-law cited).

111 As regards judicial review of the conditions referred to in the previous paragraph, the 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 52 above, EU:C:2011:504, paragraph 125 and the case-law cited).

112 In the present case, it has already been held (see paragraph 46 above), that 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, of which the identification procedure set out in Article 59 of Regulation No 1907/2006 forms part, Article 55 of that regulation 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 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 40 above, EU:T:2013:106, paragraph 116).

113 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 MHHPA as a substance of very high concern as a result of the procedure set out in Article 59 of the regulation. Where a substance is identified as being of very high concern, the economic operators concerned are subject to information obligations (see, to that effect, judgment in *Bilbaína de Alquitranes and Others* v *ECHA*, cited in paragraph 40 above, EU:T:2013:106, paragraph 117).

114 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 40 above, EU:T:2013:106, paragraph 118 and the case-law cited).

115 As regards, more specifically, the applicants' argument that the contested decision is inappropriate in that regard since MHHPA is used mainly as an intermediate or as a monomer, which are exempt from the application of Title VII of Regulation No 1907/2006 in accordance with Article 2(8) of the regulation, it is apparent — from a response given to the comments submitted by the first and second applicants within the framework of the consultation provided for in Article 59(4) of Regulation No 1907/2006 — that MHHPA is not used exclusively as intermediate or monomer, a point which indeed the applicants have not specifically disputed.

116 As regards the argument that MHHPA is used by professionals and the articles produced do not contain MHHPA, it must be stated, first, that the applicants have not excluded all exposure to MHHPA for workers and, secondly, that they also state that the third applicant would not be able to prove that there was no unreacted MHHPA in its articles.

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

118 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 evaluation of MHHPA and the application of risk management measures or the presentation of a dossier, in accordance with Annex XV to Regulation No 1907/2006, on restrictions concerning consumer products, such as cosmetics, would constitute less onerous measures.

119 First, as regards the evaluation of MHHPA and the application of risk management measures, the applicants refer, on the one hand, to Articles 44 to 48 of Regulation No 1907/2006 and, on the other, to the obligations set out in Article 14 of that regulation. Under Article 14(1), they would have to perform a chemical safety assessment and complete a report concerning MHHPA in that regard. Under Article 14(3)(a), the chemical safety assessment would also have to include an assessment of the human health hazard properties of MHHPA. That assessment might require the applicants to carry out an exposure assessment and estimation, and to characterise the risks of identified uses in accordance with Article 14(4). Furthermore, under Article 14(6) of Regulation No 1907/2006, the applicants would be required to identify and apply the appropriate measures to adequately control the risks.

120 However, it is not apparent from Regulation No 1907/2006 that the legislature intended to make the identification procedure carried out pursuant to Article 59 of that regulation, which forms part of the authorisation procedure for a substance set out in Title VII of that regulation, subject to the registration procedure laid down in Title II of the regulation and of which the obligations set out in Article 14 of that regulation form part, or to the evaluation procedure set out in Articles 44 to 48 of the regulation. It is true that the registration procedure and the evaluation procedure, which is intended as a follow-up to registration according to recital 20 in the preamble to Regulation No 1907/2006, also serve to improve information for the public and professionals as to the hazards and risks of a substance, as is apparent from recitals 19 and 21 of that regulation. However, whereas the substances registered should be allowed to circulate on the internal market, as is apparent from recital 19 in the preamble to Regulation No 1907/2006, the objective of the authorisation procedure, of which the identification procedure set out in Article 59 of that regulation forms part, is, inter alia, progressively to replace substances of very high concern by suitable alternative substances or technologies, where these are economically and technically viable (see paragraph 112 above). Furthermore, as is apparent from recital 69 in the preamble to Regulation No 1907/2006, the legislature wanted particular attention to be paid to substances of very high concern.

121 In so far as the applicants argue that the presentation of a substance's registration dossier, containing its chemical safety assessment, constitutes the best source of information, suffice it to state that the legislature did not intend to make the identification procedure subject to the registration procedure (see paragraph 120 above). Furthermore, the applicants' line of argument that the ECHA based its assessment on old and outdated data and did not take into account all the relevant data has already been rejected (see paragraphs 79 to 91 above).

122 Consequently, contrary to what the applicants claim, neither the evaluation of a substance provided for in Articles 44 to 48 of Regulation No 1907/2006, nor the risk management measures proposed under Article 14(6) of that regulation, constitute appropriate measures for the achievement of the objectives pursued by that regulation as regards the treatment of substances of very high concern and they are

thus not less onerous measures in the circumstances of present case (see, to that effect, judgment in *Bilbaína de Alquitranes and Others* v *ECHA*, cited in paragraph 40 above, EU:T:2013:106, paragraphs 123 to 126).

123 Secondly, as regards restriction measures concerning consumer products, such as cosmetics, the applicants argue that a dossier concerning the proposal of such a measure pursuant to Annex XV to Regulation No 1907/2006 must include available information about the existence of alternatives, including information on the risks to human health and the environment related to the manufacture and use of those alternatives, their availability and their technical and economic viability. Such a proposal, which would therefore have been based on parameters similar to those used for a dossier for the purpose of identifying a substance as being of very high concern, would have avoided the negative consequences of such identification and led to the same result as regards the objectives of Regulation No 1907/2006.

124 It should be observed that the mere fact that a substance appears in the list referred to in Article 59(1) of Regulation No 1907/2006 does not prevent that substance from being subject to restrictions rather than to an authorisation where it is contained in an article. As is apparent from Article 58(5) and Article 69 of Regulation No 1907/2006, the Commission or a Member State may still propose that the manufacture, the placing on the market or the use of a substance on its own, in a mixture or in an article be managed by restrictions rather than by an authorisation (see, to that effect, judgment in *Bilbaína de Alquitranes and Others* v *ECHA*, cited in paragraph 40 above, EU:T:2013:106, paragraph 128).

125 Furthermore, 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 and certain preparations and dangerous 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 (see, to that effect, judgment in *Bilbaína de Alquitranes and Others* v *ECHA*, cited in paragraph 40 above, EU:T:2013:106, paragraph 129).

126 Moreover, in so far as the applicants take the view that the existing legislation concerning the protection of workers already applies, 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 112 above).

127 As regards the argument of REACh ChemAdvice and New Japan Chemical that, in another case involving a respiratory sensitiser, the use of risk management measures was considered appropriate to control occupational exposure and possible risks for workers, that argument must be rejected. The fact that a Member State has prepared an evaluation report on a substance and subsequently has decided not to initiate the identification procedure for that substance does not prevent another Member State or the ECHA, at the request of the Commission, from presenting a dossier proposing that another substance be identified as a substance of very high concern.

128 Lastly, in so far as REACh ChemAdvice and New Japan Chemical state, referring to the situation in Sweden, that the reduction of exposure levels of MHHPA has been considered to be an adequate means of controlling risks, it must be stated that the Member State Committee of the ECHA, including the Kingdom of Sweden, reached a unanimous agreement on the identification of MHHPA as a substance of very high concern.

129 In the light of the foregoing, it cannot be concluded that the contested decision infringed the principle of proportionality.

130 The third plea in law must therefore be rejected.

*The fourth plea in law, alleging infringement of essential procedural requirements*

131 In their reply, the applicants submit that the contested decision is vitiated by an infringement of essential procedural requirements. They state that the Member State Committee of the ECHA did not reach a unanimous agreement on the identification of MHHPA since one Member State did not take part in the vote.

132 That line of argument must be rejected as unfounded. Admittedly, under Article 59(8) of Regulation No 1907/2006, the Member State Committee of the ECHA must reach a unanimous agreement on the identification of a substance in order for the ECHA to be able to include it on the list referred to in Article 59(1). Furthermore, the minutes of the 27th meeting of the Member State Committee of the ECHA of 10 to 13 December 2012 state that one Member State was deliberately absent for the vote on the identification of MHHPA as a substance of very high concern. However, that absence does not preclude, in the circumstances of the present case, the Member State Committee of the ECHA reaching a unanimous agreement. Under Article 238(4) TFEU, on which that Committee's procedural practice was based on the day of the vote on the identification of MHHPA as a substance of very high concern, abstentions by members present in person or represented do not prevent the adoption of acts which require unanimity. Furthermore, under Article 19(1) of the Rules of Procedure for the Member State Committee of the ECHA, in the version applicable on the day of the vote in question, any member neither present nor represented by a proxy at the meeting was considered to have given his tacit agreement to the consensus or majority view of the Committee when an issue was under voting.

133 Consequently, the fourth plea in law and, therefore, the action in its entirety must be dismissed.

**Costs**

134 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. Under the first subparagraph of Article 87(4) of those Rules, the Member States and institutions which have intervened in the proceedings are to bear their own costs. The Court may, moreover, pursuant to the third subparagraph of Article 87(4) of those Rules, order an intervener — other than non-Member-State States which are parties to the EEA Agreement and the EFTA Surveillance Authority — to bear its own costs.

135 Since the applicants have been unsuccessful, they must be ordered to bear their own costs and to pay those incurred by the ECHA, in accordance with the form of order sought by the ECHA. The interveners must bear their own costs.

On those grounds,

THE GENERAL COURT (Fifth Chamber)

hereby:

**1. Dismisses the action;**

**2. Orders Hitachi Chemical Europe GmbH, Polynt SpA and Sitre Srl to bear their own costs and to pay those incurred by the European Chemicals Agency (ECHA);**

**3. Orders the Kingdom of the Netherlands, the European Commission, REACh ChemAdvice GmbH and New Japan Chemical to bear their own costs.**

Dittrich Schwarcz Tomljenović

Delivered in open court in Luxembourg on 30 April 2015.

[Signatures]