



Reports of Cases

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

7 March 2013 *

(REACH — Identification of anthracene oil as a substance of very high concern — Actions for annulment — Actionable measure — Regulatory act not entailing implementing measures — Direct concern — Admissibility — Equal treatment — Proportionality)

In Case T-94/10,

Rütgers Germany GmbH, established in Castrop-Rauxel (Germany),

Rütgers Belgium NV, established in Zelzate (Belgium),

Deza, a.s., established in Valašské Meziříčí (Czech Republic),

Industrial Química del Nalón, SA, established in Oviedo (Spain),

Bilbaína de Alquitranes, SA, established in Luchana-Baracaldo (Spain),

represented initially by K. Van Maldegem, R. Cana, lawyers, and P. Sellar, Solicitor, and subsequently by K. Van Maldegem and R. Cana,

applicants,

v

European Chemicals Agency (ECHA), represented by M. Heikkilä and W. Broere, acting as Agents, assisted by J. Stuyck, lawyer,

defendant,

ACTION for the partial annulment of the decision of the ECHA, published on 13 January 2010, to identify anthracene oil (EC No 292-602-7) as a substance meeting the criteria set out 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, in accordance with Article 59 of REACH,

THE GENERAL COURT (Seventh Chamber, Extended Composition),

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

* Language of the case: English.

Registrar: N. Rosner, Administrator,

having regard to the written procedure and further to the hearing on 13 September 2012,

gives the following

Judgment

Background to the disputes

- 1 The applicants, Rütgers Germany GmbH, Rütgers Belgium NV, Deza, a.s., Industrial Química del Nalón, SA, and Bilbaína de Alquitranes, SA, are producers and suppliers of anthracene oil (EC No 292-602-7) in the European Union.
- 2 According to the description in tables 3.1 and 3.2 in 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), the substance at issue in the present case, namely anthracene oil, is a complex combination of polycyclic aromatic hydrocarbons ('PAHs') obtained from coal tar having an approximate distillation range of 300° C to 400° C and composed primarily of phenanthrene, anthracene and carbazole. This substance is among the substances of unknown or variable composition, complex reaction products or biological materials ('UVCB substances'), because it cannot be fully identified by its chemical composition. Anthracene oil is used mainly as an intermediate for the production of carbon black, a pigment and a reinforcing filler in rubber products, especially tyres. It is also used as an intermediate for the production of pure anthracene.
- 3 Anthracene oil was included in Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ, English Special Edition 1967, p. 234) by Commission Directive 94/69/EC of 19 December 1994 adapting to technical progress for the 21st time Council Directive 67/548 (OJ 1994 L 381, p. 1). As a result of that inclusion, anthracene oil was classified as a carcinogenic substance in category 2. That classification has been taken over by Regulation No 1272/2008.
- 4 On 28 August 2009, the Federal Republic of Germany submitted to the European Chemicals Agency ('ECHA') a dossier which it had prepared on the identification of anthracene oil, because of its persistent, bioaccumulative and toxic properties ('PBT properties') and its very persistent and very bioaccumulative properties ('vPvB properties'), as a substance meeting the criteria set out in Article 57(d) and (e) 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, subsequently amended, inter alia, by Regulation No 1272/2008.
- 5 On 31 August 2009, the ECHA published a notice on its website inviting interested parties to submit their observations on the dossier drawn up on anthracene oil and also called on the competent authorities of the Member States to submit their observations in that regard.

- 6 In the course of that procedure, the Coal Chemicals Sector Group, of which the applicants are members, and the ECHA, inter alia, submitted comments. The ECHA stated, in that regard, that anthracene oil was classified as a carcinogenic substance and therefore met the criteria set out in Article 57(a) of Regulation No 1907/2006.
- 7 Having received the reply of the Federal Republic of Germany the ECHA sent the dossier to the Member State Committee referred to in Article 76(1)(e) of Regulation No 1907/2006 on 16 November 2009. On 2 December 2009, that committee reached unanimous agreement on the identification of anthracene oil as a substance of very high concern meeting the criteria set out in Article 57(a), (d) and (e) of Regulation (EC) No 1907/2006.
- 8 On 7 December 2009, the ECHA published a press release announcing, first, that the Member State Committee had unanimously agreed on the identification of 15 substances, including anthracene oil, as substances of very high concern in so far as those substances met the criteria set out in Article 57 of Regulation No 1907/2006 and, second, that 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') would be formally updated in January 2010. On 22 December 2009, the Executive Director of the ECHA took Decision ED/68/2009 to proceed, on 13 January 2010, to publish and update the candidate list as regards those 15 substances.
- 9 On 13 January 2010 the candidate list of substances including anthracene oil was published on the website of the ECHA.

Procedure and forms of order sought

- 10 By application lodged at the Registry of the General Court on 17 February 2010, the applicants brought the present action for partial annulment of the decision of the ECHA, published on 13 January 2010, identifying anthracene oil as a substance meeting the criteria set out in Article 57 of Regulation No 1907/2006, in accordance with Article 59 of that Regulation ('the contested decision').
- 11 By letter lodged at the Registry of the General Court on 8 April 2010, the ECHA sought the joinder of the present case with Cases T-93/10 *Bilbaina de Alquitranes and Others v ECHA*, T-95/10 *Cindu Chemicals and Others v ECHA* and T-96/10 *Rütgers Germany and Others v ECHA*, pursuant to Article 50(1) of the Rules of Procedure of the General Court. The President of the Eighth Chamber of the Court decided, after hearing the parties, not to join those cases for the purposes of the written procedure and to reserve the Court's decision on the application for joinder for the purposes of the oral procedure and the decision closing the proceedings.
- 12 By separate document lodged at the Registry of the Court on 23 June 2010, the ECHA raised an objection of inadmissibility under Article 114(1) of the Rules of Procedure.
- 13 By letter registered at the Registry of the Court on 3 June 2010, the Kingdom of Denmark applied for leave to intervene in support of the form of order sought by the ECHA. After hearing the main parties, the President of the Eighth Chamber of the General Court granted leave to intervene, by order of 6 July 2010. By a document lodged at the Registry of the Court on 23 August 2010, the Kingdom of Denmark withdrew its intervention in the present proceedings.
- 14 The applicants submitted their observations on the objection of inadmissibility on 23 August 2010.
- 15 Following a change in the composition of the Chambers of the Court, the Judge-Rapporteur was assigned to the Seventh Chamber, to which the present case was accordingly allocated.

- 16 By decision of 30 March 2011, the Court referred the present case to the Seventh Chamber, Extended Composition, under Article 51(1) of its Rules of Procedure.
- 17 By order of the General Court (Seventh Chamber, Extended Composition) of 3 May 2011, consideration of the objection of inadmissibility was reserved for the final judgment and the costs were reserved.
- 18 Upon hearing the report of the Judge-Rapporteur, the General Court (Seventh Chamber, Extended Composition) decided to open the oral procedure.
- 19 By order of the President of the Seventh Chamber, Extended Composition, of the General Court of 20 June 2012, the present case and Cases T-93/10 *Bilbaina de Alquitranes and Others v ECHA*, T-95/10 *Cindu Chemicals and Others v ECHA* and T-96/10 *Rütters Germany and Others v ECHA* were joined for the purposes of the oral procedure, pursuant to Article 50 of the Rules of Procedure.
- 20 By letter of 30 August 2012, the applicants lodged their observations on the report for the hearing.
- 21 The parties presented oral argument and their answers to the questions put by the Court at the hearing on 13 September 2012. In particular, the parties were heard concerning the admissibility of the second plea in law, alleging a breach of Article 59(5) and (7) of Regulation No 1907/2006.
- 22 The applicants claim that the Court should:
- declare the action admissible and well-founded;
 - annul the contested decision in so far as it concerns anthracene oil;
 - order the ECHA to pay the costs.
- 23 The ECHA contends that the Court should:
- declare the action inadmissible or, at least, unfounded;
 - order the applicants to pay the costs.

Law

- 24 Before the merits of the case are examined, the questions raised by the ECHA in its objection of inadmissibility should be answered.

The objection of the inadmissibility of the action

- 25 The pleas of inadmissibility raised by the ECHA relate to the nature of the contested decision, the fact that it is not of direct concern to the applicants and the fact that the contested decision, which is not a regulatory act within the meaning of the fourth paragraph of Article 263 TFEU, is not of individual concern to the applicants.

The nature of the contested decision

- 26 The ECHA argues, in essence, that the applicants, by referring to the unanimous agreement of the ECHA Member State Committee of 2 December 2009, contested a preparatory act that was not intended to produce legal effects vis-à-vis third parties within the meaning of the second sentence of

the first paragraph of Article 263 TFEU. According to the ECHA, the act that produces a potential legal effect is the publication of the updated candidate list of substances on the ECHA website in accordance with Article 59(10) of Regulation No 1907/2006.

- 27 Under the second sentence of the first paragraph of Article 263 TFEU, acts of bodies, offices or agencies of the Union intended to produce legal effects vis-à-vis third parties are subject to review.
- 28 According to settled case-law, an action for annulment is available in the case of all measures adopted by the institutions, whatever their nature or form, which are intended to have legal effects (Case 22/70 *Commission v Council* [1971] ECR 263, paragraph 42; see also Joined Cases C-138/03, C-324/03 and C-431/03 *Italy v Commission* [2005] ECR I-10043, paragraph 32, and order of 14 July 2008 in Case T-322/06 *Espinosa Labella and Others v Commission*, not published in the ECR, paragraph 25 and the case-law cited).
- 29 In the case of acts or decisions worked out in stages, in particular at the end of an internal procedure, only measures definitively laying down the position of the institution, body, office or agency of the Union concerned at the end of that procedure, are, in principle, acts against which an action for annulment will lie. Consequently, measures of a preliminary or purely preparatory nature cannot be the subject of an action for annulment (Case 60/81 *IBM v Commission* [1981] ECR 2639, paragraph 10; see also Joined Cases T-355/04 and T-446/04 *Co-Frutta v Commission* [2010] ECR II-1, paragraph 33 and the case-law cited).
- 30 It must be observed that the procedure laid down in Article 59 of Regulation No 1907/2006, consisting of the identification of the substances referred to in Article 57 of that regulation, takes place in several stages.
- 31 Thus, after the identification procedure has been initiated and after the ECHA has made the dossier relating to a substance available to the Member States and published on its website a notice inviting all interested parties to submit comments (Article 59(2) to (4) of Regulation No 1907/2006), the Member States, the ECHA and all interested parties may comment on the identification proposed in the dossier (Article 59(4) and (5) of that regulation). If, as in the present case, such comments are submitted, the ECHA is to refer the dossier to the Member State Committee and, if that Committee reaches a unanimous agreement on the identification, the ECHA is to include the substance in the candidate list of substances (Article 59(7) and (8) of that regulation). Finally, without delay after a decision on inclusion of the substance has been taken, the ECHA is to publish and update the candidate list of substances on its website (Article 59(10) of that regulation).
- 32 In the present case, it must be observed that the applicants referred not only to the agreement of the Member State Committee of the ECHA of 2 December 2009 identifying anthracene oil as a substance meeting the criteria set out in Article 57 of Regulation No 1907/2006, but also to the publication on the website of the ECHA on 13 January 2010 and to code ED/68/2009, which was the code of the decision of the Executive Director of the ECHA to include that substance on the candidate list of substances published on the website on 13 January 2010, although the applicants had no knowledge of that last fact. Therefore, without any doubt, the applicants were challenging the decision of the ECHA identifying anthracene oil as a substance meeting the criteria set out in Article 57 of Regulation No 1907/2006, the content of which had been determined by unanimous agreement of the Member State Committee of the ECHA reached on 2 December 2009 and implemented by its Executive Director, who ordered the inclusion of that substance in the candidate list of substances published in its entirety on the website on 13 January 2010, in accordance with Article 59 of that regulation. In referring to the version of the list published on the website of the ECHA on 13 January 2010, to the unanimous agreement of its Member State Committee in 2009 and to code ED/68/2009, the applicants unequivocally identified the subject-matter of the dispute. The objection based on the allegedly preparatory nature of the agreement of the Member State Committee of the ECHA alone is therefore ineffective.

- 33 The act of identifying a substance resulting from the procedure referred to in Article 59 of Regulation No 1907/2006 is intended to produce binding legal effects vis-à-vis third parties within the meaning of the second sentence of the first paragraph of Article 263 TFEU. That act can indeed give rise, inter alia, to the information obligations set out in Article 7(2), Article 31(1)(c), Article 31(3)(b) and Article 33(1) and (2) of that regulation. Those provisions make reference to the substances identified under Article 59(1) of that regulation or to the substances included in, or appearing in, the list drawn up under Article 59(1) of that regulation. They refer, therefore, to legal obligations arising from the act that results from the procedure referred to in Article 59 of Regulation No 1907/2006.
- 34 In the light of the foregoing, the plea of inadmissibility based on the nature of the contested decision must be rejected.

Direct concern to the applicants

- 35 The ECHA argues that the action is inadmissible because the contested decision is not of direct concern to the applicants.
- 36 Under the fourth paragraph of Article 263 TFEU, any natural or legal person may, under the conditions laid down in the first and second paragraphs, institute proceedings against an act addressed to that person or which is of direct and individual concern to them, and against a regulatory act which is of direct concern to them and does not entail implementing measures.
- 37 In the present case, it is common ground that the contested decision was not addressed to the applicants; it is not, therefore, an act addressed to them. That being the case, in accordance with the fourth paragraph of Article 263 TFEU, the applicants may institute proceedings for annulment of that act only if it is of direct concern to them.
- 38 With regard to direct concern, it has consistently been held that that condition requires, first, that the measure complained of directly affect the legal situation of the individual and, second, that it leave no discretion to the addressees of that measure, who are entrusted with the task of implementing it, such implementation being purely automatic and resulting from European Union rules without the application of other intermediate rules (Case C-386/96 P *Dreyfus v Commission* [1998] ECR I-2309, paragraph 43; Case C-486/01 P *Front national v Parliament* [2004] ECR I-6289, paragraph 34; and Joined Cases C-445/07 P and C-455/07 P *Commission v Ente per le Ville vesuviane and Ente per le Ville vesuviane v Commission* [2009] ECR I-7993, paragraph 45).
- 39 In the first place, as regards the applicants' argument that the contested decision is of direct concern to them in that their legal situation is affected by Article 31(9)(a) of Regulation No 1907/2006, it must be observed that that provision concerns the updating of a safety data sheet which is to be compiled under Article 31(1). Under Article 31(1)(a) to (c) of Regulation No 1907/2006, the suppliers of a substance must provide the recipient with a safety data sheet where the substance meets the criteria for classification as dangerous in accordance with Directive 67/548, where the substance has PBT or vPvB properties in accordance with the criteria set out in Annex XIII to that regulation, or where the substance is included in the list established in accordance with Article 59(1) of Regulation No 1907/2006 for reasons other than those previously referred to. 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.

- 40 In the present case, it is not disputed that the applicants, who are the suppliers of a substance as defined in Article 3(32) of Regulation No 1907/2006, should, under Article 31(1)(a) of that regulation, provide the recipient of the substance in question with a safety data sheet where that substance meets the criteria for classification as dangerous in accordance with Directive 67/548. Anthracene oil has been classified as a carcinogenic substance in category 2 by Directive 94/69 (see paragraph 3 above).
- 41 However, it is disputed that, as the applicants argue, the identification of anthracene oil as a substance of very high concern as a result of the procedure provided for by Article 59 of Regulation No 1907/2006, on the ground that that substance has PBT or vPvB properties, constitutes new information within the meaning of Article 31(9)(a) of Regulation No 1907/2006 capable of triggering the obligation referred to in that provision, namely the updating of the safety data sheet, with the result that the contested decision directly affects the legal situation of the applicant.
- 42 As regards the safety data sheet, Article 31(1) of Regulation No 1907/2006 provides that it must be compiled in accordance with Annex II to that regulation. According to that annex, which contains a guide to the compilation of safety data sheets, those sheets must provide a mechanism for transmitting appropriate safety information on classified substances, down the supply chain to the immediate downstream users. The purpose of that Annex is to ensure consistency and accuracy in the content of each of the mandatory headings listed in Article 31(6) of Regulation No 1907/2006, so that the resulting safety data sheets will enable users to take the necessary measures relating to protection of human health and safety at the workplace, and protection of the environment.
- 43 According to the applicants, the identification of anthracene oil as a substance of very high concern as a result of the procedure provided for by Article 59 of Regulation No 1907/2006, on the ground that that substance has PBT or vPvB properties, constitutes new information with regard to Article 31(6)(2) (hazards identification), (3) (composition/information on ingredients) and (15) (regulatory information) of Regulation No 1907/2006.
- 44 With regard to Article 31(6)(2) of Regulation No 1907/2006 (hazards identification), according to point 2 of Annex II to Regulation No 1907/2006, the classification of a substance which arises from application of the classification rules in Directive 67/548 must be given under that heading. The main hazards a substance presents to man and the environment must be indicated clearly and briefly.
- 45 It is common ground that a substance which has PBT or vPvB properties presents a risk to the environment. However, according to the ECHA, that risk is not created by the contested decision but is due to the inherent properties of the substance itself, which the applicants should have assessed and been aware of before the adoption of the contested decision.
- 46 In that regard, it must be observed that point 2 of Annex II to Regulation No 1907/2006 makes reference, as regards the identification of the hazards corresponding to the classification of a substance under Directive 67/548, to the application of the classification rules set out in that directive, that is to say, to the application of the rules of European Union law. Therefore, the carcinogenic properties of a substance, as mentioned in Article 57(a) of Regulation No 1907/2006, must be indicated, together with the main hazards caused by those properties, on the safety data sheet, in cases where a substance has been classified as a carcinogenic substance in accordance with the classification rules set out in Directive 67/548. In the present case, the applicants do not dispute the fact that the carcinogenic properties of anthracene oil and the main hazards caused by those properties must be indicated on the safety data sheet and constitute the reason why the applicants must provide such a sheet.
- 47 The criteria for the identification of the PBT and vPvB properties of a substance, as mentioned in Article 57(e) and (d) of Regulation No 1907/2006, were defined in Annex XIII to Regulation No 1907/2006. In order to identify a substance as a substance of very high concern because of its PBT and vPvB properties, in accordance with Article 59 of that regulation, the criteria set out in Annex XIII

of that regulation must therefore be applied. It follows that the PBT and vPvB properties of a substance are determined in the course of the identification procedure, which was also explained in the minutes of the ECHA workshop held on 21 and 22 January 2009 concerning the candidate list of substances and authorisation as instruments of risk management, according to which inclusion in the candidate list is the main official identification mechanism for PBT and vPvB substances. The identification of the PBT and vPvB properties of a substance is therefore based on the application of the rules of European Union law, that is to say, in the present case, on the application of the criteria set out in Annex XIII to Regulation No 1907/2006. Consequently, given that, by the contested decision, the PBT and vPvB properties of anthracene oil were determined in accordance with those criteria, it is because of that decision that those properties and the main hazards caused by them must be indicated on the safety data sheet. This is a case equivalent to the classification of a substance in accordance with the rules set out in Directive 67/548, for which the obligation to include that classification and the main hazards caused by the properties classified in the safety data sheet is clear from point 2 of Annex II to Regulation No 1907/2006.

- 48 As regards the ECHA's argument that the dangerous nature of the substance at issue is caused by its inherent properties, which the applicants should have assessed and should have been aware of before the adoption of the contested decision, first, it must be observed, that the ECHA refers to the discussions held in a subgroup of the European Chemicals Bureau (ECB) on the question whether the substance at issue met the PBT and vPvB criteria. While it is true that the hazards caused by a substance are the result of its inherent properties, those dangers must be assessed and determined in accordance with defined rules of law. In its argument concerning the discussions held in that subgroup, the ECHA does not indicate the rules of law which allowed that subgroup to determine the PBT and vPvB properties. Moreover, the ECHA does not state that the conclusions of that subgroup were binding on the applicants. On the other hand, the applicants pointed out that no exchange of views was held on the PBT and vPvB properties of anthracene oil. Second, the ECHA states that the applicants should have assessed the inherent properties of anthracene oil and should, as a result, be aware of the PBT and vPvB properties of that substance. As is apparent from the case-file and as the applicants confirmed at the hearing, it is precisely the PBT and vPvB properties of anthracene oil which they dispute. Thus they did not conclude, in the context of their assessment concerning anthracene oil, that that substance had PBT and vPvB properties.
- 49 Therefore, in the light of heading 2 (hazard identification) of the safety data sheet, the identification of anthracene oil as a substance of very high concern as a result of the procedure referred to in Article 59 of Regulation No 1907/2006, on the ground that that substance had PBT or vPvB properties, amounted to new information which could allow users to take measures for the protection of human health and safety at work and for the protection of the environment. That identification thus amounted to new information capable of affecting the risk management measures, or new information on hazards within the meaning of Article 31(9)(a) of Regulation No 1907/2006, and therefore the applicants were obliged to update the safety data sheets concerned. Consequently, the contested decision directly affects the legal situation of the applicants as a result of the obligation it provides for without it being necessary to examine headings 3 (composition/information on ingredients) and 15 (regulatory information) of the safety data sheet (see, as regards heading 15, Case T-343/10 *Etimine and Etiproduits v ECHA* [2011] ECR II-6611, paragraphs 33 to 36, and Case T-346/10 *Borax Europe v ECHA* [2011] ECR II-6629, paragraphs 34 to 37).
- 50 In the second place, as regards the applicants' argument that the contested decision is of direct concern to them in that their legal situation is affected by Article 34(a) of Regulation No 1907/2006, it must be noted that, according to that provision, any actor in the supply chain of a substance must communicate new information on hazardous properties, regardless of the uses concerned, to the next actor or distributor up the supply chain.

51 Since the identification of anthracene oil as a substance of very high concern by the contested decision on the ground that that substance had PBT or vPvB properties contained new information as regards the hazardous properties of anthracene oil (see paragraphs 47 to 49 above), it triggers the obligation to communicate information under Article 34(a) of Regulation No 1907/2006. It follows that the contested decision also produces direct effects on the legal situation of the applicants because of the obligation provided for by that provision.

52 Consequently the contested decision is of direct concern to the applicants. This plea of inadmissibility must therefore be rejected.

The concept of regulatory act not entailing implementing measures and whether the applicants are individually concerned

53 The ECHA argues that the action is inadmissible because the contested decision is not a regulatory act within the meaning of the fourth paragraph of Article 263 TFEU and that, therefore, the applicants should be individually concerned but do not fulfil that condition.

54 Under the fourth paragraph of Article 263 TFEU, the present action for annulment is admissible only if the contested decision constitutes a regulatory act which does not entail implementing measures or if it is of individual concern to them.

55 As regards the question whether the contested decision constitutes a regulatory act within the meaning of the fourth paragraph of Article 263 TFEU, the ECHA states, essentially, that the acts adopted by it are not regulatory acts. The exercise of the regulatory power under Regulation No 1907/2006 is reserved to the Commission. Moreover, the identification of a substance is merely a preparatory act for a potential future decision by the Commission to include that substance in Annex XIV to that Regulation.

56 In the first place, as regards the question whether the contested decision constitutes a regulatory act for the purposes of the fourth paragraph of Article 263 TFEU, it must be recalled that the meaning of 'regulatory act' for the purposes of that provision must be understood as covering all acts of general application apart from legislative acts (Case T-262/10 *Microban International and Microban (Europe) v Commission* [2011] ECR II-7697, paragraph 21).

57 In the present case, it must be observed that the contested decision is of general application inasmuch as it applies to situations which have been determined objectively and have legal effects as regards a category of persons viewed in a general and abstract manner, that is to say with regard to every natural or legal person falling within the scope of Article 31(9)(a) and Article 34(a) of Regulation No 1907/2006.

58 Moreover, the contested decision does not constitute a legislative act since it was not adopted in accordance with either the ordinary legislative procedure or the special legislative procedure within the meaning of paragraphs 1 to 3 of Article 289 TFEU. The contested decision is an act of the ECHA adopted on the basis of Article 59 of Regulation No 1907/2006 (see, to that effect, order of 4 June 2012 in Case T-381/11 *Eurofer v Commission* [2012] ECR, paragraph 44).

59 The contested decision therefore constitutes a regulatory act within the meaning of the fourth paragraph of Article 263 TFEU.

60 Contrary to the ECHA's contention, the fourth paragraph of Article 263 TFEU does not indicate that only the Commission has the regulatory power to adopt such an act. There is no support for the ECHA's argument in that regard in the FEU Treaty. The first paragraph of Article 263 TFEU

expressly mentions the review of the legality of acts of bodies, offices or agencies of the Union intended to produce legal effects vis-à-vis third parties. The authors of the FEU Treaty thus intended, generally, to make the acts of the ECHA, too, subject to review by the Courts of the European Union.

- 61 What is more, contrary to what the ECHA alleges, its task under Article 75(1) of Regulation No 1907/2006, which is to manage and in some cases to implement the technical, scientific and administrative aspects of Regulation No 1907/2006 and to ensure consistency in the European Union, does not preclude the power to adopt a regulatory act. In that regard, it must be observed that the ECHA accepts that the acts it has adopted may trigger legal obligations vis-à-vis third parties, albeit to a limited extent.
- 62 Moreover, under the identification procedure referred to in Article 59 of Regulation No 1907/2006, two procedures are laid down for the case where comments are made on the proposed identification of a substance as a substance of very high concern. Under the first procedure, the ECHA refers the dossier to the Member State Committee, which reaches a unanimous agreement on the identification (Article 59(7) and (8) of the regulation). Under the second, if the Member State Committee fails to reach a unanimous agreement, the decision on the identification of the substance is taken by the Commission in accordance with the procedure referred to in Article 133(3) of Regulation No 1907/2006, which makes reference to the regulatory procedure laid down by Article 5 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ 1999 L 184, p. 23) (Article 59(9) of the regulation). It follows from a comparison of those two procedures that, under the first, the agreement of the Member State Committee corresponds to the Commission decision taken under the second procedure on the identification of a substance. It cannot be argued that, while the decision involving the participation of the Commission constitutes a regulatory act, the decision which does not involve its participation, but has the same content and the same effect, does not constitute such an act.
- 63 It is true that a Commission decision under Article 58 of Regulation No 1907/2006 to include a substance in Annex XIV to the regulation entails more serious legal consequences for the users of a substance, that is to say, a ban on marketing without authorisation, than those following from the contested decision, that is to say, information obligations inter alia. However, that finding cannot mean that the contested decision has no consequences. Rather, the information obligations to which the contested decision gives rise are one of the consequences of the responsibility for the management of the risks of the substances which should apply throughout the supply chain, as recital 56 of the preamble to Regulation No 1907/2006 indicates. It follows that the argument of the ECHA in that regard should be rejected.
- 64 In the second place, as regards the question whether the contested decision entails implementing measures, it must be observed that the identification of the substance at issue as a substance of very high concern as a result of the procedure referred to in Article 59 of Regulation No 1907/2006 gives rise to information obligations for the applicants without any other measures being necessary (see paragraph 33 above). The contested decision does not therefore entail any implementing measures.
- 65 In particular, the next stage of the authorisation procedure, which consists of the inclusion in order of priority of the candidate substances in Annex XIV to Regulation No 1907/2006, that is to say, in the list of substances subject to authorisation, is not a measure implementing the contested decision. The conclusion of the identification procedure triggers its own information obligations which do not depend on the subsequent stages of the authorisation procedure.
- 66 It follows that the contested decision constitutes a regulatory act which does not entail implementing measures, so that the present plea of inadmissibility must be rejected without it being necessary to examine whether it is of individual concern to the applicants.

- 67 In the light of all the foregoing considerations, the objection of inadmissibility is unfounded. The present action is therefore admissible.

Substance

- 68 Five pleas in law are raised in support of the present action. The first two pleas concern alleged breaches of procedural requirements relating to Article 59(3), (5) and (7) of and Annex XV to Regulation No 1907/2006. The other three pleas allege breach of the principle of equal treatment, an error of assessment or an error of law regarding the identification of a substance as having PBT or vPvB properties on the basis of its constituent ingredients and breach of the principle of proportionality.

The first plea, alleging breach of Article 59(3) of and Annex XV to Regulation No 1907/2006

- 69 The applicants argue that, contrary to what is provided in Article 59(3) of and point II 2 of Annex XV to Regulation No 1907/2006, in its dossier on anthracene oil the Federal Republic of Germany did not give information on alternative substances even though it had been informed by the applicants of the existence of such substances, namely petroleum-based preparations. The ECHA accepted that dossier without alternative substances having been identified. According to the applicants, it cannot be ruled out that, without that irregularity and if the fact that the alternative substances also contained PBT constituents had been known, the contested decision might not have been adopted and a different procedure might have been triggered.
- 70 In that regard it must be observed that, under Article 59(3) of Regulation No 1907/2006, the identification procedure may be initiated by a Member State which may prepare a dossier in accordance with Annex XV to the regulation for substances which in its opinion meet the criteria set out in Article 57 and forward it to the ECHA. Where the dossier concerns the identification of a substance with PBT or vPvB properties, point II 2 of Annex XV to the regulation provides, under the heading ‘Information on exposures, alternative substances and risks’, that ‘[t]he available use and exposure information and information on alternative substances and techniques shall be provided’.
- 71 As regards the dossier on anthracene oil, it is common ground that the Federal Republic of Germany entered the words ‘[n]o information available’ in the section of the dossier on alternative substances.
- 72 It is true that the wording of point II 2 of Annex XV to Regulation No 1907/2006 distinguishes between the obligation to produce ‘the available use and exposure information’, on the one hand and ‘information on alternative substances and techniques’, on the other. None the less, a Member State may only give the information which is available to it. The statement by the Federal Republic of Germany that no information is available relates to the existence of alternative substances which would allow that Member State to fulfil its formal obligation to state its view on alternative substances.
- 73 In any event, the letter to the competent German authorities of 17 July 2009 from the Coal Chemicals Sector Group, of which the applicants are members, did not refer to any alternative substances. Asking the German authorities to adopt ‘a more balanced approach not penalizing a single industry sector’, the group pointed out that ‘it is well known that many streams of petroleum conversion contain anthracene as well’. That letter thus makes reference to substances which, according to the group, present a comparable level of danger to that of anthracene oil and not to substances which can be used as alternatives because they are capable of being used instead of anthracene oil to perform the same function. Finally, it must be observed that, in the light of Article 60(5) of Regulation No 1907/2006, point II 2 of Annex XV to the regulation must be interpreted as referring to appropriate alternative substances, which, because of their anthracene content, petroleum-based preparations are not.

- 74 It follows that the procedural requirements set out in Article 59(3) of the regulation were respected.
- 75 Even if, in the present case, there were an irregularity owing to the failure to respect Article 59(3) of Regulation No 1907/2006, that irregularity would entail the annulment of that decision only if it were established that, were it not for that irregularity, that decision would have had a different content (Case C-86/03 *Greece v Commission* [2005] ECR I-10979, paragraph 42).
- 76 The applicants state, in that regard, that it cannot be ruled out that, in the absence of that irregularity and given that the alternatives also have PBT constituents, the contested decision might not have been adopted and a different procedure might have been triggered.
- 77 However, that is not what happened in the present case. The content of the contested decision is the identification of anthracene oil as a substance meeting the criteria set out in Article 57(a), (d) and (e) of Regulation No 1907/2006. It is not apparent from the identification procedure set out in Article 59 of that regulation that the information on alternative substances is relevant as regards the outcome of that procedure. The criteria set out in Article 57(a), (d) and (e) of the regulation make no reference to the existence or otherwise of alternative substances. Rather, for a substance to be identified as meeting the criteria set out in Article 57(d) and (e) of that regulation, it is sufficient that it meet the relevant criteria for the identification of substances with PBT and vPvB properties set out in Annex XIII to Regulation No 1907/2006. However, although that annex contains a substantial number of criteria which must be fulfilled, none of those criteria concerns alternative substances. It is, therefore, not established that the existence of information on alternative substances would have been capable of altering the content of the contested decision as regards the identification of anthracene oil as fulfilling the criteria set out in Article 57(d) and (e) of that regulation. That is also the case as regards the identification of that substance as fulfilling the criteria set out in Article 57(a) of that regulation. The criteria for classification as a carcinogenic substance are set out in Directive 67/548. The classification of anthracene oil as a carcinogenic substance was already undertaken by Directive 94/69 (see paragraph 3 above).
- 78 For the rest, it must be observed that information on alternative substances is relevant inter alia for the subsequent authorisation procedure, in which the identification of a substance pursuant to Article 59 of Regulation No 1907/2006 constitutes only the first stage. Under Article 60(4)(c) and (5)(b) of that regulation, such information is relevant for the purposes of taking a decision on a request for authorisation concerning a substance included in the list of substances subject to authorisation.
- 79 Consequently, the first plea in the appeal must be rejected.

The second plea, alleging breach of Article 59(5) and (7) of Regulation No 1907/2006

- 80 The applicants observe that the ECHA had no authority to amend the proposal made by the Federal Republic of Germany concerning the inclusion of anthracene oil in the candidate list of substances, which was based solely on the fact that that substance had PBT and vPvB properties. Following that amendment, anthracene oil was identified as a substance of very high concern on the basis not only of its PBT and vPvB properties as alleged, but also of its carcinogenic properties. Since that substance could not have been identified as being of very high concern on the basis of its PBT and vPvB properties, the reference to its carcinogenic properties remains the only reason for its inclusion in the candidate list of substances.
- 81 In the present case, the dossier prepared by the Federal Republic of Germany pursuant to Annex XV to Regulation No 1907/2006 in fact contained only the proposal to identify anthracene oil as a substance fulfilling the criteria set out in Article 57(d) and (e) of that regulation, that is to say, as a

substance with PBT and vPvB properties and not as fulfilling the criteria set out in Article 57(a) of that regulation, that is to say, as being carcinogenic, even if that dossier indicated that that substance was classified as a carcinogenic substance.

- 82 It appears from the dossier that, in the course of the procedure set out in Article 59(5) of Regulation No 1907/2006, the ECHA submitted comments stating that anthracene oil was classified under carcinogenic substances and therefore fulfilled the criteria set out in Article 57(a) of that regulation. Anthracene oil was therefore identified as a substance of very high concern fulfilling the identification criteria set out in Article 57(a), (d) and (e) of that regulation.
- 83 It follows that, in arguing that the ECHA had no authority to amend the proposal of the Federal Republic of Germany concerning the inclusion of anthracene oil in the candidate list of substances, the applicants are essentially contesting the identification of that substance as being of very high concern on the basis of its carcinogenic properties.
- 84 It cannot be argued that, in identifying a substance on the basis not only of the grounds proposed in the dossier originally prepared for that substance, but also on the basis of a ground not mentioned in that file, the ECHA exceeded its powers, as provided for by Article 59 of Regulation No 1907/2006.
- 85 First, it must be pointed out that, under Article 59(1) of Regulation No 1907/2006, the procedure set out in paragraphs 2 to 10 of that article is to apply for the purpose of identifying substances meeting the criteria referred to in Article 57 of Regulation No 1907/2006. The contested decision identifying anthracene oil on the ground that it meets the criteria set out in Article 57 of that regulation is consistent with that objective. The applicants' argument concerning the identification of a substance on the basis of a ground not mentioned in the dossier originally prepared for that substance does not, therefore, concern the authority of the ECHA.
- 86 Second, the wording of Article 59 of Regulation No 1907/2006 does not provide that the grounds set out in Article 57 of that regulation, on the basis of which a substance is identified, must correspond to those indicated in the dossier originally prepared. Moreover, as is apparent from Article 59(2) and (3) of Regulation No 1907/2006, the Member States do not have an exclusive right to initiate the identification procedure. The Commission may also ask the ECHA to prepare a dossier pursuant to Annex XV to that regulation.
- 87 Third, it is implicit in the objective of the authorisation procedure set out in Article 55 of Regulation No 1907/2006, which 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, that the identification of a substance, which constitutes the first stage in the authorisation procedure, is based on grounds which are as full as possible.
- 88 Fourthly, it should be borne in mind that, under Article 59(5) of Regulation No 1907/2006, the ECHA may comment on the identification of the substance in relation to the criteria in Article 57 in the dossier sent to it. That provision is intended to ensure that the ECHA is in a position to put forward its point of view effectively. It follows that it must be possible to incorporate the comments made by the ECHA in the contested decision.
- 89 The second plea in law must therefore be rejected.

The third plea, alleging breach of the principle of equal treatment

- 90 The applicants submit that the identification of anthracene oil as a substance of very high concern breaches the principle of equal treatment. That substance is comparable, from the point of view of its content in chemical substances and of market competition to other UVCB substances containing anthracene. However, the ECHA, without any objective justification, identified only anthracene oil, and not those other substances, as a substance of very high concern.
- 91 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, intended, *inter alia*, according to recital 1 of the preamble to the regulation, to ensure a high level of protection of human health and the environment as well as the free movement of substances, while enhancing competitiveness and innovation. In particular, Regulation No 1907/2006 provides, under 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.
- 92 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 of 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.
- 93 In the light of the foregoing observations, the identification procedure set out in Article 59 of Regulation No 1907/2006 thus does not confer on the ECHA any power as regards the choice of the substance to be identified. However, 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 proceed to identify that substance in accordance with the conditions set out in that article.
- 94 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 anthracene oil was chosen by the Federal Republic of Germany because it considered that the substance met the criteria listed in Article 57 of that regulation. Moreover, in the absence of the production of any dossiers prepared by a Member State relating to other substances containing anthracene, or a request from the Commission for the preparation of such a dossier by the ECHA, the ECHA could not proceed to identify those other substances, pursuant to the procedure set out in Article 59 of Regulation No 1907/2006, without exceeding its powers. It follows that, in identifying anthracene oil and not the allegedly comparable substances as a substance of very high concern, the ECHA did not breach the principle of equal treatment.
- 95 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 the ECHA observed that procedure, the third plea must be rejected.

The fourth plea, alleging an error of assessment or an error of law in the identification of a substance as PBT or vPvB on the basis of its constituents

- 96 This plea in law comprises three submissions. First, the applicants point out that the dossier prepared by the Federal Republic of Germany for the substance at issue did not observe the requirements set out in Article 59(2) and (3) and Annexes XIII and XV to Regulation No 1907/2006 because it was based, not on an assessment of the substance itself, but on an assessment of the properties of its constituents. Second, the rule that a substance can be identified as having PBT or vPvB properties provided that the substance has a constituent which has PBT or vPvB properties and is present in a concentration of 0.1% or more, is not laid down in Annex XIII to Regulation No 1907/2006. Third, the assessment of the constituents of the substance at issue did not furnish a sufficient basis to identify it as having PBT or vPvB properties since those constituents were not individually identified as having PBT or vPvB properties.
- 97 Since the first and second submissions concern the identification of anthracene oil as having PBT and vPvB properties on the basis of its constituents present in a concentration of at least 0.1%, it seems appropriate to examine them together.
- 98 As a preliminary point, it should be pointed out that, in accordance with settled case-law, where the European Union authorities 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 institutions on which alone the FEU Treaty has placed that task (Case C-15/10 *Etimine* [2011] ECR I-6681, paragraph 60).
- 99 Nevertheless, it must be stated that 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 institutions which have adopted the act in question must be able to show before the Union judicature that in adopting the act they actually exercised their discretion, which presupposes the taking into consideration of all the relevant factors and circumstances of the situation the act was intended to regulate (Case C-343/09 *Afton Chemical* [2010] ECR I-7023, paragraphs 33 and 34).
- The first and second submissions, concerning the identification of anthracene oil as having PBT and vPvB properties on the basis of its constituents present in a concentration of at least 0.1%
- 100 The applicants stress that the dossier prepared by the Federal Republic of Germany for anthracene oil did not observe the requirements set out in Article 59(2) and (3) and in Annexes XIII and XV to Regulation No 1907/2006 because it was not based on an assessment of the substance itself but on an assessment of the properties of its constituents. Moreover, the rule that a substance may be identified as having PBT or vPvB properties provided that it contains a constituent which has PBT or vPvB properties and is present in a concentration of 0.1% or more is not provided for in Annex XIII to Regulation No 1907/2006 and therefore has no legal basis. The lack of any concentration threshold was intended by the legislature because concentration thresholds were laid down elsewhere in Regulation No 1907/2006, inter alia for the chemical safety assessment under Article 14 of that regulation. In so far as the contested decision is based on the assessment of the properties of the constituents of anthracene oil present in a concentration of at least 0.1%, it is vitiated by a manifest error of assessment.

- 101 It appears from the dossier on the identification of anthracene oil as a substance of very high concern, on which the Member State Committee reached a unanimous agreement on 2 December 2009, that this substance was identified as being of very high concern, meeting the criteria necessary to be regarded as having PBT and vPvB properties under Article 57(d) and (e) of Regulation No 1907/2006, because of the PBT and vPvB properties of the constituents present in that substance in a concentration of at least 0.1%.
- 102 Indeed, it is apparent from section 6 of the dossier on the identification of anthracene oil that the committee concluded that the substance should be considered to have PBT and vPvB properties since, on the one hand, it contained three PAH constituents present in a concentration of at least 0.1%, two of which should be considered to have PBT and vPvB properties, namely fluoranthene and pyrene, and one of which met the necessary criteria to be considered to have vPvB properties, namely phenanthrene, and, on the other hand, it contained anthracene in a concentration of between 3% and 25% which met the necessary criteria to be considered to have PBT properties. Thus it concluded that anthracene oil was a substance which contained at least 16% of PAH constituents with PBT or vPvB properties.
- 103 As regards, first of all, the alleged infringement of the procedure laid down by Article 59(2) and (3) of Regulation No 1907/2006 read in conjunction with Annex XV to that regulation, it is sufficient to note that those provisions require the preparation of a dossier on a substance which is considered to meet the criteria set out in Article 57 of that regulation. The dossier prepared by the Federal Republic of Germany and the contested decision did concern a substance within the meaning of Article 3(1) of that regulation which was considered to meet the criteria set out in Article 57 of Regulation No 1907/2006. The ECHA did not therefore infringe those provisions.
- 104 In order to examine, next, whether the approach followed by the ECHA in identifying anthracene oil as having PBT and vPvB properties is vitiated by a manifest error, it must be observed that the criteria for identifying a substance as having PBT and vPvB properties are defined in Annex XIII to Regulation No 1907/2006. Consequently, as the applicants point out, according to the applicable version of that annex, in the identification of a substance as having PBT and vPvB properties it is that substance which must meet the necessary criteria to be considered to have PBT and vPvB properties as set out in sections 1 and 2 of that annex.
- 105 However, as the constituents of a substance are an integral part of it, it cannot simply be held that the ECHA made a manifest error of assessment in taking the view that the substance at issue had PBT and vPvB properties on the ground that its constituents had such properties. Such a conclusion does not take sufficient account of the objective pursued by Regulation No 1907/2006, set out in Article 1(1) thereof, which 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. Although the wording of Annex XIII to Regulation No 1907/2006, in the version applicable to this case, does not expressly indicate that the identification of substances with PBT and vPvB properties must also take account of the PBT and vPvB properties of the relevant constituents of a substance, it does not preclude such an approach. However, it cannot be held that, merely because a constituent of a substance has a certain number of properties, the substance itself also has them, but, rather, the proportion in which that constituent is present and the chemical effects of such presence must be considered (see, to that effect, Case 187/84 *Caldana* [1985] ECR 3013, paragraph 17).
- 106 Contrary to the applicants' allegation, Article 14(2)(f) of Regulation No 1907/2006 does not demonstrate the legislature's intention to minimise the risks associated with PBT or vPvB constituents of a substance only through the chemical safety assessment provided for by that article. First, no such intention is apparent either from the wording of that provision or from the recitals of the preamble to Regulation No 1907/2006 relating to that provision. Second, Article 14(2)(f) of that regulation forms part of the registration procedure for the substances referred to in Title II of the regulation and

applies, in principle, to all substances as such or contained in preparations or articles referred to in Articles 6 and 7 of the regulation. As is apparent from recital 69 of the preamble to Regulation No 1907/2006, the legislature wanted careful attention to be paid to the substances of very high concern which are subject to the identification procedure provided for by Article 59 of the regulation.

- 107 In the present case, it must be borne in mind that anthracene oil is one of the UVCB substances whose composition is unknown or variable. UVCB substances are multiple constituent substances, that is to say substances which contain several different constituents. Annex XIII to Regulation No 1907/2006 does not lay down specific rules for the identification of UVCB substances as having PBT or vPvB properties.
- 108 According to the ECHA, the approach according to which a UVCB substance can be identified as having PBT or vPvB properties on the ground that its constituents are identified as having PBT or vPvB properties is based, first, on a well-established practice rooted in a principle recognised in European Union legislation and, second, on scientific reasons. The application of the 0.1% threshold as a factor entailing the identification of the substance in question on the basis of its constituents is founded in European Union legislation.
- 109 In the first place, as regards the argument concerning a well-established practice rooted in a principle recognised in European Union legislation, it must be observed that, while it is true that it appears from recital 75 of the preamble to and Article 53(2) of Regulation No 1272/2008 that that regulation does not apply to the classification and labelling of substances with PBT and vPvB properties but does apply, *inter alia*, to the classification and labelling of carcinogenic, mutagenic and toxic substances, the fact remains that it is apparent from Article 10(1) of that regulation that the legislature recognised the principle that a substance with certain properties and present in another substance may lead to the classification of that substance as having those properties. The first subparagraph of Article 10(1) of Regulation No 1272/2008 provides that specific concentration limits and generic concentration limits are limits assigned to a substance indicating a threshold at or above which the presence of that substance in another substance or in a mixture as an identified impurity, additive or individual constituent leads to the classification of the substance or mixture as hazardous.
- 110 Several factors confirm that that principle is applicable to the procedure for the identification of a substance as a substance of very high concern. First, Article 57 of Regulation No 1907/2006, in the context of the examination of substances to be included in the candidate list, places substances with PBT and vPvB properties at the same level as carcinogenic, mutagenic and toxic substances. Second, the applicability of the principle is confirmed by Article 56(6)(a) of Regulation No 1907/2006. According to that article, essentially, the prohibition on the placing on the market of a substance subject to authorisation does not apply for the use of substances referred to in Article 57(d) to (f) of that regulation, below a concentration limit of 0.1% weight by weight, where they are present in preparations. It is true that that provision applies to preparations and not to a substance such as that at issue. However, the classification of a substance on the basis of the properties of its constituents appears comparable to the classification of a preparation on the basis of the properties of its substances. In that regard, it must be observed that the applicants also refer, in support of their assertion that the legislature intended to minimise the risks associated with PBT and vPvB constituents of a substance only through the chemical safety assessment, to a provision which applies, not to the constituents of a substance, but to the substances contained in a preparation, namely Article 14(2)(f) of Regulation No 1907/2006 (see paragraph 106 above).
- 111 In the second place, the ECHA bases its approach on scientific reasons.
- 112 First, it is important to assess a UVCB substance on the basis of its constituents because, once in the environment the individual constituents of such a substance will behave as independent substances. The substances in question will release several PAHs with PBT or vPvB properties during use, for example by heating during processing or by leaching upon contact with water.

- 113 Second, although the study of a UVCB substance as a whole is possible in certain specific cases, such an approach does not lead to significant results for the great majority of substances, including anthracene oil. In that majority of cases, an understanding of the properties of a substance is only possible on the basis of an assessment of the properties of its relevant constituents. Most of the testing methods available for determining the inherent properties of those substances are only suitable for the study of substances made up of a single main constituent. For example, persistence of UVCB substances can normally not be assessed by using biodegradation testing methods that measure summary parameters, as these tests measure the properties of the whole substance but do not provide information on its constituents. Accordingly, even if in such a test the whole substance might appear to be readily biodegradable, the presence of non-biodegradable constituents cannot be ruled out. According to the ECHA, similar difficulties are encountered in bioaccumulation and toxicity testing for certain UVCB substances. The physical form of such a substance may impede the release of its individual constituents to any significant extent if the substance is tested as such. Consequently, as regards bioaccumulation and toxicity testing, accumulation and toxicity might not be detected in testing but, in reality, after a certain time PAH constituents will be released into the environment.
- 114 The criticisms voiced by the applicants of those scientific considerations are not such as to demonstrate that the scientific reasons put forward by the ECHA are vitiated by a manifest error.
- 115 First, the applicants' argument that the fact that a substance may break down into its constituents is addressed in the chemical safety assessment which must be carried out as part of the registration of the substance under Article 14 of Regulation No 1907/2006 does not contradict the assessment of the ECHA but merely indicates that decomposition must also, where appropriate, be taken into account in the course of another procedure under Regulation No 1907/2006 (in that regard, see also paragraph 106 above).
- 116 Second, the applicants' argument that, contrary to what the ECHA alleges, most test methods can be performed with UVCBs, or where existing methods are not appropriate, the 'weight of evidence' approach can be used, is not substantiated by the scientific data at all and is thus not sufficient for the rejection of the approach followed by the ECHA as vitiated by a manifest error.
- 117 In the third place, as regards the application of the 0.1% threshold as a factor entailing the identification of the substance in question on the basis of its constituents, the applicants argue that, although they do not dispute the application of such a threshold in general, the criterion of a 0.1% threshold is not found in Annex XIII to Regulation No 1907/2006. Furthermore, they state that, while it is true that there are instruments which contain references to 0.1% as being in some instances a threshold over which a hazard classification will apply, that threshold may vary from 0.1% to 1%, depending on the hazard.
- 118 While it is true that no concentration threshold is provided for in Annex XIII to Regulation No 1907/2006, it must be observed that the application of such a threshold as a factor entailing identification of the substance in question on the basis of its constituents does not require that threshold to be specified in that annex.
- 119 Moreover, it appears from Regulation No 1907/2006 that the threshold of 0.1% has been applied by European Union legislation several times for the classification of a preparation on the basis of the substances contained in it. Article 31(3)(b) of Regulation No 1907/2006 imposes an information obligation on suppliers of a preparation if it contains a substance with PBT or vPvB properties in accordance with the criteria set out in Annex XIII in a concentration of 0.1% or more. Moreover, Article 14(2)(f) of that regulation requires an undertaking to make a chemical safety assessment of a preparation if the concentration of the substance in the preparation which meets the criteria in Annex XIII of the regulation is 0.1% or more. What is more, Article 56(6) of Regulation

No 1907/2006 provides that the authorisation obligation is not applicable *inter alia* to the use of substances meeting the criteria set out in Article 57(d) and (e) of that regulation, where they are contained in preparations below a concentration limit of 0.1%.

120 Since the classification of a substance on the basis of the properties of its constituents appears comparable to the classification of a preparation on the basis of the properties of its substances (see paragraph 110 above) and the applicants do not dispute the application of the 0.1% threshold in general, it cannot be concluded that the contested decision is vitiated by a manifest error in that the 0.1% threshold was applied as a factor entailing the identification of the substance at issue on the basis of its constituents.

121 In the light of all the foregoing considerations, it must be concluded that anthracene oil was not identified as having PBT and vPvB properties solely because a constituent of that substance has a certain number of PBT and vPvB properties, but that the proportion in which such a constituent is present and the chemical effects of the presence of such a constituent were also taken into account (see paragraph 105 above). The applicants' argument concerning the identification of anthracene oil as having PBT and vPvB properties on the basis of its constituents present in a concentration of at least 0.1% does not demonstrate that the contested decision is vitiated by a manifest error.

122 The first and second submissions must therefore be dismissed.

– The third submission concerning the identification of the constituents of the substance at issue as having PBT or vPvB properties

123 The applicants observe, essentially, that the assessment of the constituents of the substance at issue is not a sufficient basis for its identification as having PBT or vPvB properties since those constituents have not been individually identified as having PBT or vPvB properties in a separate ECHA decision based on a thorough assessment for that purpose.

124 To recapitulate, anthracene oil was identified as having PBT and vPvB properties because it had two constituents which had to be considered to have PBT and vPvB properties, namely phenanthrene, which met the criteria to be considered to have vPvB properties and anthracene, which met the criteria to be considered to have PBT properties (see paragraph 102 above).

125 In the first place, the question arises whether the identification of the substance at issue as a substance of very high concern because of its PBT and vPvB properties, on the basis of the PBT and vPvB properties of its constituents, requires that those constituents must themselves have first been identified as having PBT and vPvB properties by a separate decision of the ECHA. In that regard, it must be observed that Article 57(d) and (e) and Article 59 of Regulation No 1907/2006 provide only that the criteria set out in Annex XIII to the regulation must be met. Moreover, the implementation of the procedure set out in Article 59 of Regulation No 1907/2006 for the independent identification of the relevant constituents of anthracene oil as having PBT and vPvB properties, does not bring any added value to the identification of the substance at issue as a substance of very high concern because of its PBT and vPvB properties on the basis of the PBT and vPvB properties of its constituents. In the context of the dossier prepared in accordance with Annex XV to that regulation concerning the substance at issue, a comparison should also have been made of the information available and the criteria under Annex XIII to the regulation. The applicants' argument on that point must therefore be rejected.

126 Second, the applicants dispute the contention that the identification of the constituents at issue, other than anthracene, as constituents with PBT or vPvB properties is based on a thorough assessment. As regards anthracene, it is common ground that it was identified as a substance of very high concern on

the basis of its PBT properties. According to the case-law cited in paragraphs 98 and 99 above, it is therefore appropriate to examine whether the contested decision is vitiated by a manifest error in that respect.

127 The applicants refer, in support of their argument, to the comments made by the group of leading oil companies carrying out research on environmental issues relevant to the oil industry during the consultation period on the dossier prepared pursuant to Annex XV to Regulation No 1907/2006 for the substance at issue. A report analysing the bioaccumulation properties of 15 PAHs is attached to those comments. According to those comments, since the working group of the ECB responsible had not agreed on the PBT or vPvB properties of those constituents, it is premature and inappropriate to draw definitive conclusions for them in the dossier prepared in accordance with Annex XV to the regulation. According to that report, the available evidence does not support the broad, tentative conclusions included in that dossier that those constituents meet bioaccumulative or very bioaccumulative criteria, since reliable laboratory data demonstrate only a low bioaccumulation potential of those constituents.

128 In that regard, it must be observed that the applicants' argument is essentially confined to a reference to the submission of comments and a report drawn up in the course of the procedure provided for by Article 59(4) of Regulation No 1907/2006. Anthracene oil was identified as a substance of very high concern on the basis of the analysis in the dossier prepared by the Federal Republic of Germany and approved by the Member State Committee on 2 December 2009, pursuant to Article 59(8) of that regulation, in the light of those comments and that report. Section 6 of that dossier assesses in detail the PBT and vPvB properties respectively of the relevant constituents of the substance at issue. In the light of the foregoing observations, the general reference to the fact that the working group of the ECB responsible, which, in any case, no longer exists under the regime of Regulation No 1907/2006, did not agree on the PBT and vPvB properties of the constituents at issue, on the one hand, and to the allegedly insufficient evidence, without disclosing which aspect of the analysis in that dossier is incorrect, on the other, is not sufficient to support a conclusion that the contested decision is vitiated by a manifest error.

129 It follows that the third submission must be rejected.

130 Consequently, the fourth plea must be rejected in its entirety.

The fifth plea in law, alleging a breach of the principle of proportionality

131 The applicants submit that the contested decision does not respect the principle of proportionality. That decision is not suitable for the attainment of the objective of Regulation No 1907/2006, which is to ensure a high level of protection of human health and the environment. The applicants observe in that regard that the substances which can be used to replace anthracene oil also have PBT or vPvB properties. According to the applicants, the ECHA could have taken other appropriate and less onerous measures, namely the application of risk management measures on the basis of the chemical safety assessment in the registration dossier prepared by the applicants under Article 14 of Regulation No 1907/2006 or the presentation of a dossier concerning the substance at issue under Title VIII of that regulation.

132 According to settled case-law, the principle of proportionality, which is one of the general principles of European Union law, requires that measures adopted by European Union institutions do not exceed the limits of what is appropriate and necessary in order to attain 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 *Etimine*, paragraph 98 above, paragraph 124 and the case-law cited).

- 133 With regard to judicial review of the conditions referred to in the previous paragraph, it must be acknowledged that the ECHA has a broad discretion in a sphere 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 sphere 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, *Etimine*, paragraph 98 above, paragraph 125 and the case-law cited).
- 134 In the present case, it is apparent from Article 1(1) of Regulation No 1907/2006 that the regulation seeks 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. Regard being had to recital 16 of the preamble to the regulation, it must be stated that the legislature established, as the main objective, the first of those three objectives, namely to ensure a high level of protection of human health and the environment (see, to that effect, Case C-558/07 *S.P.C.M. and Others* [2009] ECR I-5783, paragraph 45). As regards, more specifically, the aim of the authorisation procedure, Article 55 of the regulation provides that it seeks 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.
- 135 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 must be recalled that the contested decision identified anthracene oil as a substance of very high concern as a result of the procedure referred to in Article 59 of the regulation. Where a substance is identified as being of very high concern economic operators are subject to information obligations (see paragraph 33 above).
- 136 With regard to 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 dangers incurred and that, consequently, such identification must be regarded as a means of enhancing that protection (see, to that effect, *S.P.C.M. and Others*, paragraph 134 above, paragraph 49).
- 137 As regards, more specifically, the applicants' argument that the contested decision is inappropriate in that regard since the substances capable of being used to replace the substance at issue also have PBT or vPvB properties, it must be observed that the contested decision does not entail a prohibition on placing anthracene oil on the market thereby obliging the operators concerned to use alternative substances. Such a consequence only follows, under Article 56 of Regulation No 1907/2006, for substances included in Annex XIV to that regulation, that is to say, the list of substances subject to authorisation. Moreover, although Article 59(1) of that regulation provides that the identification procedure applies for the purpose of eventual inclusion in Annex XIV to that regulation, it is apparent from the procedure set out in Article 58 of Regulation No 1907/2006 in that regard that the inclusion of a substance in the candidate list of substances does not automatically entail its inclusion in Annex XIV to that regulation. Under Article 58(1) and (3) of that regulation, the ECHA is to recommend priority substances to be included in that annex taking into account the opinion of the Member State Committee and specifying for each substance inter alia the uses or categories of uses exempted from the authorisation requirement. A substance may be subject to authorisation only as a result of a decision by the Commission to include that substance in Annex XIV.
- 138 Moreover, Regulation No 1907/2006 lays down, for the purpose of the identification of substances of very high concern, a procedure designed to subject those substances progressively to the authorisation procedure. In that regard, recital 77 of the preamble to the regulation states that, 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. Accordingly, it is possible that, in the course of that progressive approach, the alternative substances referred to by the applicants might also be subject to the identification procedure set out in Article 59 of Regulation No 1907/2006.

139 The applicants' argument that the identification of anthracene oil as a substance of very high concern is not appropriate for the achievement of the objectives pursued by Regulation No 1907/2006 since the risks of exposure to that substance are low because anthracene oil is principally used as an intermediate in the production of carbon black. Since anthracene oil constitutes an intermediate, the substance is exempted from Title VII of Regulation No 1907/2006, pursuant to Article 2(8) of that regulation and is thus not concerned by the information obligations entailed by the identification of a substance as being of very high concern under Article 59 of that regulation. Moreover, it must be held that the applicants' argument is ineffective since it follows from it that the substance at issue is not used exclusively as an intermediate.

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

141 In the second place, the applicants argue that the contested decision exceeds the limits of what is necessary to achieve the objectives pursued, given that the application of risk management measures or the presentation of a dossier pursuant to Annex XV to Regulation No 1907/2006 for restrictions concerning the substance at issue would also serve to provide a high level of protection of human health and of the environment, but would be less onerous.

142 First, as regards risk management measures, the applicants refer to the obligations set out in Article 14 of Regulation No 1907/2006. Under Article 14(1), they must carry out a chemical safety assessment and complete a chemical safety report for the substance at issue. According to Article 14(3)(d), the chemical safety assessment of a substance has to include a PBT and vPvB assessment. If that assessment leads to the conclusion that a substance has PBT or vPvB properties, the applicants have to carry out an exposure assessment and risk characterisation concerning the uses identified, pursuant to Article 14(4). Moreover, under Article 14(6) of Regulation No 1907/2006, the applicants must identify and apply the appropriate measures to adequately control the risks. As that assessment was not yet available at the time of the identification of the substance at issue as being of very high concern by the contested decision, the ECHA could have decided to wait for the presentation of the assessment in order to examine the chemical safety report and the proposed risk management measures, rather than identifying the substance at issue as being of very high concern.

143 There is no evidence in Regulation No 1907/2006 that the legislature intended to make the identification procedure carried out pursuant to Article 59 of that regulation, which is part of the authorisation procedure for a substance set out in Title VII of that regulation, subject to the registration procedure provided for in Title II of that regulation, which covers the obligations set out in Article 14 of that regulation. It is true that those obligations also serve to improve information for the public and professionals on the dangers and risks of a substance. However, since the substances registered should be allowed to circulate on the internal market, as is apparent from recital 19 of 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 is part, is, inter alia, progressively to replace substances of very high concern with other appropriate substances or technologies, where they are economically or technically viable (see paragraph 134 above). Moreover, as is apparent from recital 69 of the preamble to Regulation No 1907/2006, the legislature wished to pay careful attention to substances of very high concern.

144 Consequently, contrary to what the applicants allege, the risk management measures proposed under Article 14(6) of Regulation No 1907/2006 do not constitute appropriate measures for the achievement of the objectives pursued by that regulation as regards the treatment of substances of very high concern and are thus not less onerous measures in the present case.

- 145 Finally, as regards the applicants' argument that the ECHA could have waited, before identifying anthracene oil as a substance of very high concern, for the presentation of the registration dossier on the substance at issue containing the chemical safety assessment, because such a dossier allegedly constitutes the best source of information, it is sufficient to note that the identification was made on the basis of information contained in the dossier concerning the substance at issue unanimously approved by the Member State Committee (see paragraph 101 above). That committee did not find that there was no information concerning the validity and relevance of the data. Furthermore, as registration of the substance at issue was required, under Article 23(1) of Regulation No 1907/2006, to take place only by 1 December 2010, thus two and a half years from the date from which the authorisation procedure was applicable pursuant to Article 141(2) of that regulation, that is to say, 1 June 2008, an alleged duty to wait for the presentation of the registration dossier at issue would damage the effectiveness of Regulation No 1907/2006.
- 146 Second, as regards the restriction measures, the applicants argue that a dossier concerning the proposal of such measures pursuant to Annex XV to Regulation No 1907/2006 must include available information about the existence of suitable alternatives, including information on the risks to human health and the environment related to the manufacture and use of these alternatives, availability and the technical and economical availability. Such a proposal, which would therefore have been based on similar parameters to 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.
- 147 In that regard, 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 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.
- 148 Furthermore, as is apparent from Annex XVII to Regulation No 1907/2006, restrictions, adopted in accordance with the procedure set out in Title VIII of that regulation, applicable to the manufacture, the placing on the market and the use of certain dangerous substances and certain preparations and dangerous articles, 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 does not entail information obligations.
- 149 Moreover, in so far as the applicants argue that the information contained in the dossier concerning a proposal for a restriction measure pursuant to Annex XV to Regulation No 1907/2006 demonstrates that the identification of the substance at issue was not necessary, it is sufficient to point out that such identification was carried out in accordance with the procedure set out in Article 59 of Regulation No 1907/2006, which constitutes a different procedure from that set out in Title VIII of the same regulation (see paragraph 147 above).
- 150 In the light of the foregoing considerations, it cannot be concluded that the contested decision breached the principle of proportionality.
- 151 Consequently, the fifth plea in law and, therefore, the action in its entirety must be dismissed.

Costs

- 152 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.

¹⁵³ As the applicants have been unsuccessful, they must be ordered to pay the costs in accordance with the form of order sought by the ECHA.

On those grounds,

THE GENERAL COURT (Seventh Chamber, Extended Composition)

hereby:

- 1. Dismisses the action;**
- 2. Orders Rütgers Germany GmbH, Rütgers Belgium NV, Deza, a.s., Industrial Química del Nalón, SA and Bilbaína de Alquitranes, SA to pay the costs.**

Dittrich

Dehousse

Wiszniewska-Białecka

Prek

Szwarcz

Delivered in open court in Luxembourg on 7 March 2013.

[Signatures]