Reports of Cases

JUDGMENT OF THE GENERAL COURT (Seventh Chamber)

14 November 2013*

(REACH — Transitional measures concerning the restrictions on the manufacture, marketing and use of cadmium and its compounds — Annex XVII to Regulation (EC) No 1907/2006 — Restrictions on the use of cadmium pigments in plastic materials — Manifest error of assessment — Risk analysis)

In Case T-456/11,

International Cadmium Association (ICdA), established in Brussels (Belgium),

Rockwood Pigments (UK) Ltd, established in Stoke-on-Trent (United Kingdom),

James M Brown Ltd, established in Stoke-on-Trent,

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

applicants,

v

European Commission, represented initially by P. Oliver and E. Manhaeve, acting as Agents, assisted by K. Sawyer, barrister, and subsequently by P. Oliver and E. Manhaeve,

defendant,

APPLICATION for partial annulment of Commission Regulation (EU) No 494/2011 of 20 May 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Cadmium) (OJ 2011 L 134, p. 2) in so far as it restricts the use of cadmium pigments in plastic materials other than plastic materials in which that use was restricted before the adoption of Regulation No 494/2011,

THE GENERAL COURT (Seventh Chamber),

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

Registrar: S. Spyropoulos, Administrator,

having regard to the written procedure and further to the hearing on 27 June 2013,

gives the following

* Language of the case: English.

Judgment

Background to the dispute

1 The first applicant, International Cadmium Association (ICdA), is an international non-profit association established in Belgium. Its members are producers, consumers, processors and recyclers of cadmium and its compounds. Pursuant to its statutes, its purpose is to promote the interests of the cadmium industry, including the representation of its members before any private or public organisation or before any national or international authority. The second and third applicants, Rockwood Pigments (UK) Ltd and James M Brown Ltd, are companies which are members of the ICdA. Their main activity is the manufacture within the European Union and the sale throughout the European Union and worldwide of cadmium pigments, namely cadmium sulpho-selenide orange (No CAS 1256-57-4), cadmium sulpho-selenide red (No CAS 58339-34-7) and cadmium zinc sulphide (No CAS 8048-07-5).

2 Cadmium (No CAS 7440-43-9) is a minor metallic element found throughout the environment from natural sources and processes such as the erosion and abrasion of rocks and soils, and from specific events such as forest fires and volcanic eruptions. Cadmium is produced for commercial purposes mainly as a by-product of zinc, and, to a lesser degree, copper and lead, production. For some of its intentional uses, cadmium metal is processed or converted into cadmium compounds. Cadmium pigments are stable inorganic colouring agents which can be produced in a range of brilliant shades of orange, red, yellow and maroon. Those pigments are used in plastic products.

3 Cadmium was classified as carcinogenic and mutagenic and as toxic to reproduction under Commission Directive 2004/73/EC of 29 April 2004 adapting to technical progress for the twenty-ninth time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 2004 L 152, p. 1). That classification was repeated by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ 2008 L 353, p. 1).

4 On 27 July 1976 the Council of the European Communities adopted Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (OJ 1976 L 262, p. 201). By Directive 91/338/EEC of 18 June 1991 amending for the 10th time Directive 76/769 (OJ 1991 L 186, p. 59), the Council restricted the marketing and the use of cadmium and its compounds, so that they could not be used to give colour to finished products manufactured from the substances and preparations listed in Directive 91/338 and could not be used to stabilise the finished products exhaustively listed, manufactured from polymers or copolymers of vinyl chloride (PVC).

5 On 23 March 1993, the Council adopted Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances (OJ 1993 L 84, p. 1). In accordance with Article 8 of that regulation, the Commission of the European Communities, in consultation with Member States, had to regularly draw up lists of priority substances or groups of substances requiring immediate attention because of their potential effects on man or the environment. Pursuant to Article 10 of that regulation, for each substance on the priority lists, a Member State was to be given responsibility for the evaluation of the risks that substance posed for man or the environment and, where appropriate, to suggest a strategy for limiting these risks, including control measures and/or surveillance programmes.

6 By Commission Regulation (EC) No 143/97 of 27 January 1997 concerning the third list of priority substances as foreseen under Regulation No 793/93 (OJ 1997 L 25, p. 13), cadmium and cadmium oxide (No CAS 1306-19-0) were included on that list and the Kingdom of Belgium was designated as responsible for the evaluation of those substances.

7 In September 1998, the report entitled 'Assessment of the Risks to Health and to the Environment of Cadmium Contained in Certain Products and of the Effects of Further Restrictions on their Marketing and Use', prepared for the Commission by a consultancy established in the United Kingdom ('the 1998 report') was completed.

8 In an opinion of 1999, the Scientific Committee on Toxicity, Ecotoxicity and the Environment, established in accordance with Commission Decision 97/579/EC of 23 July 1997 setting up Scientific Committees in the field of consumer health and food safety (OJ 1997 L 237, p. 18) criticised the 1998 report. To respond to that criticism, the Commission ordered the report entitled 'The Risks to Health and Environment by Cadmium used as a Colouring Agent or a Stabiliser in Polymers and for Metal Plating', prepared by another consultancy established in the United Kingdom on 19 December 2000 ('the 2000 report'). The 2000 report was the subject of an opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment delivered on 30 October 2001.

9 The European Union risk assessment report relating to cadmium and to cadmium oxide, drawn up by the Kingdom of Belgium and part I of which, relating to the environment, had been the subject of an opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment of 28 March 2004, was published in 2007. That report contained findings relating to the need to limit the risks concerning the exposure of the environment and human health to cadmium and cadmium oxide.

10 Following the publication of the European Union risk assessment report, the Commission adopted, in accordance with Article 11(2) of Regulation No 793/93, the Recommendation of 29 May 2008 on risk reduction measures for the substances: cadmium, cadmium oxide (OJ 2008 L 156, p. 22) and the Communication on the results of the risk evaluation and the risk reduction strategies for the substances: cadmium and cadmium oxide (OJ 2008 C 149, p. 6). So far as concerns the risks for workers linked to cadmium and cadmium oxide, the Commission recommended, in that communication, setting, inter alia, occupational exposure limit values. So far as concerns the risks posed by cadmium for consumers, the Commission recommended considering marketing and use restrictions in Directive 76/769 for brazing sticks and jewellery containing cadmium. So far as concerns the risks for humans exposed via the environment, linked to cadmium and cadmium oxide, the Commission recommended considering a revision of the limits for concentrations of cadmium and cadmium oxide in foodstuffs, setting a limit for cadmium in tobacco blends and tobacco leaves and setting maximum concentrations for cadmium and cadmium oxide in fertilisers.

11 With effect from 1 June 2008 and 1 June 2009 respectively, Regulation No 793/93 and Directive 76/769 were repealed, under Article 139 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 and repealing Regulation No 793/93 and Commission Regulation (EC) No 1488/94 as well as Directive 76/769 and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006 L 396, p. 1).

12 Under Commission Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation No 1907/2006 as regards Annex XVII (OJ 2009 L 164, p. 7), the restrictions on the marketing and use of cadmium and its compounds, established initially by Directive 91/338, were transferred to Annex XVII to Regulation No 1907/2006 which contains restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles.

13 Article 137(1)(a) of Regulation No 1907/2006 contains transitional measures. It provides that, by 1 June 2010, the Commission is, if necessary, to prepare a draft amendment to Annex XVII to that regulation in accordance with any risk evaluation and recommended strategy for limiting risks that has been adopted at Community level in accordance with Article 11 of Regulation No 793/93 as far as it includes proposals for restrictions in accordance with Title VIII of Regulation No 1907/2006 but for which a decision under Directive 76/769 has not yet been taken.

14 In May 2010, the Commission drew up a draft amendment of Annex XVII to Regulation No 1907/2006 so far as concerns cadmium, which was submitted to the competent authorities for Regulations Nos 1907/2006 and 1272/2008 in June 2010 and notified to the World Trade Organisation (WTO) in accordance with the WTO Technical Barriers to Trade Agreement, which is set out in Annex 1A to the Agreement establishing the WTO, approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) (OJ 1994 L 336, p. 1). That draft amendment contained an exhaustive list of plastic materials in which the use of cadmium and its compounds was restricted.

15 On 21 October 2010, that draft amendment was the subject of an opinion of the Forum for Exchange of Information on Enforcement of Regulation No 1907/2006, referred to in Article 76(1)(f) of that regulation, which coordinates a network of Member State authorities responsible for enforcement of that regulation.

16 On 5 November 2010, the Commission submitted to the committee established under Article 133(1) of Regulation No 1907/2006 an amended version of the draft amendment of Annex XVII to that regulation so far as concerns cadmium. According to that version, which was discussed by that committee at its meeting on 25 November 2010, the proposed restrictions were no longer limited to the use of cadmium and its compounds in certain plastic materials but were applicable to all plastic materials.

17 On 20 May 2011, the Commission adopted Regulation (EU) No 494/2011 amending Regulation No 1907/2006 as regards Annex XVII (cadmium) (OJ 2011 L 134, p. 2; 'the contested regulation') which was accompanied by an impact analysis of the same date. The contested regulation was applicable, according to the second paragraph of Article 2 thereof, from 10 December 2011. By Article 1 of the contested regulation, entry No 23 of Annex XVII to Regulation No 1907/2006 was amended. As a result of that amendment, cadmium and its compounds could no longer be used in mixtures and articles produced from any synthetic organic polymers ('plastic materials'), apart from articles coloured with mixtures containing cadmium for safety reasons.

Procedure and forms of order sought

18 By application lodged at the General Court Registry on 12 August 2011, the applicants brought the present action.

19 By letter lodged at the Court Registry on 16 May 2012, the Commission forwarded a draft regulation which it had adopted amending entry No 23 of Annex XVII to Regulation No 1907/2006 and stated that, from the date of the entry into force of that draft, the applicants would no longer have any legal interest in bringing proceedings. By letter lodged at the Court Registry on 4 July 2012, the applicants submitted their observations on that letter.

20 On 18 September 2012, on the basis of that draft regulation, the Commission adopted Regulation (EU) No 835/2012 amending Regulation No 1907/2006 as regards Annex XVII (Cadmium) (OJ 2012 L 252, p. 1).

21 By document lodged at the Court Registry on 12 October 2012, the applicants confirmed that they still had a legal interest in bringing proceedings after the adoption of Regulation No 835/2012.

22 By letter lodged at the Court Registry on 11 February 2013, the applicants requested that two new offers of evidence concerning their legal interest in bringing proceedings after the adoption of Regulation No 835/2012 be added to the file, namely two documents of the European Chemicals Agency (ECHA), relating to the launching of a restriction procedure under Article 69 of Regulation No 1907/2006, relating to cadmium and its compounds in plastic materials. By decision of the President of the Seventh Chamber of the Court of 18 February 2013, that request was granted. By letter lodged at the Court Registry on 6 March 2013, the Commission submitted its observations on the letter of 11 February 2013.

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

24 By way of measures of organisation of procedure as provided for in Article 64 of the Rules of Procedure, the Court requested the Commission to produce documents and put a written question to it. The Commission complied with that request within the prescribed time-limit.

25 The oral arguments of the parties were heard, and their replies to the questions asked by the Court were given, at the hearing of 27 June 2013.

26 The applicants claim that the Court should:

— declare the action admissible and well-founded;

— annul the contested regulation in so far as it restricts the use of cadmium pigments in plastic materials other than those in respect of which that use was restricted before the adoption of that regulation;

— order the Commission to pay the costs.

27 The Commission contends that the Court should:

— declare the action unfounded;

— order the applicants to pay the costs.

Law

The applicants' legal interest in bringing proceedings

28 The Commission disputes that the applicants have a legal interest in bringing proceedings. It submits that the applicants lost all legal interest in bringing proceedings on account of the entry into force of Regulation No 835/2012. That regulation reintroduces the restrictions on cadmium compounds used as pigments as they stood before the adoption of the contested regulation with retroactive effect from the date of application of the contested regulation. At the hearing, the Commission also submitted that the applicants do not have any legal interest in bringing proceedings in so far as their application for annulment concerns cadmium pigments other than cadmium sulpho-selenide orange, cadmium sulpho-selenide red and cadmium zinc sulphide. Those cadmium pigments are the only ones manufactured by the second and third applicants.

29 Since the conditions of admissibility of an action, in particular whether there is a legal interest in bringing proceedings, concern an absolute bar to proceedings, it is for the Court to consider of its own motion whether an applicant has an interest in obtaining annulment of the act it contests (see Case T-299/05 *Shanghai Excell M&E Enterprise and Shanghai Adeptech Precision* v *Council* [2009] ECR II-565, paragraph 42 and the case-law cited).

30 According to established case-law, an applicant's interest in bringing proceedings must, in the light of the purpose of the action, exist at the time at which the action is brought, failing which it will be inadmissible. That purpose must continue until the final decision, failing which there will be no need to adjudicate, which presupposes that the action must be liable, if successful, to procure an advantage to the party bringing it (see Joined Cases C-373/06 P, C-379/06 P and C-382/06 P *Flaherty and Others* [2008] ECR I-2649, paragraph 25 and the case-law cited) and that that party has a vested and present interest in the annulment of the contested act (see judgment of 19 June 2009 in Case T-269/03 *Socratec* v *Commission*, not published in the ECR, paragraph 36 and the case-law cited).

31 It is also apparent from the case-law that it is the applicant itself which must prove that it has an interest in making its application, which is an essential and fundamental prerequisite for any legal proceedings (order of the President of the Second Chamber of the Court of 31 July 1989 in Case C-206/89 R *S.* v *Commission* [1989] ECR 2841, paragraph 8, and Case T-141/03 *Sniace* v *Commission* [2005] ECR II-1197, paragraph 31).

32 In the first place, as regard the applicants' legal interest, at the time the present action was brought, in obtaining annulment of the contested regulation so far as it concerns cadmium pigments other than the three manufactured by the second and third applicants, the applicants have not provided any evidence which suggests that such an annulment would procure an advantage for them. Concerning those other pigments, the applicants claimed a legal interest in bringing proceedings, essentially, because it was possible that the second and third applicants would in the future also manufacture other cadmium pigments than cadmium sulpho-selenide orange, cadmium sulpho-selenide red and cadmium zinc sulphide. Since the manufacture by those applicants of cadmium pigments other than the three mentioned above is purely hypothetical and the applicants have not substantiated their claim by any evidence, they do not have any vested and present interest in the annulment of the contested regulation in so far as it concerns cadmium pigments other than the three manufactured by the second and third applicants. The present action may therefore, at this stage, be regarded as admissible only in so far as it concerns cadmium sulpho-selenide orange, cadmium sulpho-selenide red and cadmium zinc sulphide ('the cadmium pigments at issue').

33 In the second place, as regards the alleged loss of a legal interest in bringing proceedings on account of the entry into force of Regulation No 835/2012, the applicants submit that that regulation does not provide for the repeal of the contested regulation. The applicants submit that they still have a legal interest in bringing proceedings because, firstly, the annulment of the contested regulation would have an impact on any future restriction on the use of cadmium adopted by the Commission and, secondly, a finding that the contested regulation was unlawful would serve as a basis for an action for damages.

34 It follows from the case-law that an applicant may retain an interest in seeking the annulment of an act of an institution, first, in order to prevent its alleged unlawfulness recurring in the future (see judgment of 7 June 2007 in Case C-362/05 P *Wunenburger* v *Commission*, not published in the ECR, paragraph 50 and the case-law cited) and, secondly, in order to obtain a finding, by the European Union judicature, that an unlawful act has been committed against him, so that such a finding can then be the basis for any action for damages aimed at properly restoring the damage caused by the contested act (see, to that effect, Case 76/79 *Könecke Fleischwarenfabrik* v *Commission* [1980] ECR 665, paragraphs 8 and 9; Joined Cases C-68/94 and C-30/95 *France and Others* v *Commission* [1998] ECR I-1375, paragraph 74, and *Shanghai Excell M&E Enterprise and Shanghai Adeptech Precision* v *Council*, paragraph 29 above, paragraph 53).

35 Without it being necessary to rule on the issue of a legal interest in bringing proceedings being maintained in order to avoid an alleged unlawfulness recurring in the future, it must be stated that the applicants retain an interest at least as a basis for a possible action for damages.

36 First, the subject-matter of the proceedings has been retained, since the contested regulation was not formally repealed by the Commission (see, to that effect, *Wunenburger* v *Commission*, paragraph 34 above, paragraph 48, and *Shanghai Excell M&E Enterprise and Shanghai Adeptech Precision* v *Council*, paragraph 29 above, paragraph 47).

37 Secondly, it must be stated that the withdrawal by Regulation No 835/2012, with retroactive effect from the date of application of the contested regulation, of the restrictions relating to the cadmium pigments at issue which were introduced by that latter regulation, does not in itself oblige the European Union judicature to declare that there is no need to adjudicate for lack of purpose or for lack of interest in bringing proceedings at the date of the delivery of the judgment (see, to that effect, *Wunenburger* v *Commission*, paragraph 34 above, paragraph 47). The annulment of the contested regulation which has already been carried out is still capable of procuring an advantage for the applicants, even if the restrictions at issue, introduced by that regulation, were withdrawn in the meantime with retroactive effect from the date of application of that regulation. The contested regulation could have produced legal effects during the period when it governed the restrictions applicable to the cadmium pigments at issue, namely from the time of its application on 10 December 2011 to the time of the entry into force of Regulation No 835/2012, on 19 September 2012 (see, to that effect, judgment of 6 June 2013 in Case C-183/12 P *Ayadi* v *Commission*, not published in the ECR, paragraph 79, and Case T-102/96 *Gencor* v *Commission* [1999] ECR II-753, paragraph 41).

38 Thirdly, it must be noted that, during that period, the contested regulation prohibited the use of the cadmium pigments at issue in mixtures and articles from all plastic materials, apart from articles which are coloured with mixtures containing cadmium for safety reasons. In that context, the applicants still have an interest in having the contested regulation declared to be partly unlawful because that finding will bind the European Union judicature in any action for damages and could constitute the basis for any extrajudicial negotiations between the Commission and the applicants aimed at reparation of the damage allegedly suffered by them (see, to that effect, *Shanghai Excell M&E Enterprise and Shanghai Adeptech Precision* v *Council*, paragraph 29 above, paragraphs 54 and 55).

39 Having regard to the foregoing considerations, it must be concluded that the applicants, following the adoption of Regulation No 835/2012, still have a legal interest in seeking the annulment of the contested regulation in so far as it restricts the use of the cadmium pigments at issue in plastic materials other than those in respect of which that use was restricted before the adoption of the contested regulation.

Substance

40 In support of their action, the applicants raise eight pleas in law, alleging (i) an infringement of Articles 137(1)(a) and 68 to 73 of Regulation No 1907/2006, (ii) a manifest error of assessment, (iii) infringement of the principles of legal certainty and legitimate expectations, (iv) infringement of Regulation No 1907/2006 in so far as the contested regulation imposes restrictions on a group of substances, namely cadmium compounds, not evaluated individually, (v) infringement of the WTO Technical Barriers to Trade Agreement, (vi) infringement of the applicants' procedural rights, (vii) infringement of the obligation to state reasons and, (viii) infringement of the principle of proportionality.

41 It seems appropriate to examine the second plea, relating to a manifest error of assessment, first of all.

42 This plea consists of two parts. While the first part alleges a failure to carry out a risk analysis, the second part concerns the failure to carry out an impact analysis relating to the restrictions on the use of cadmium pigments imposed by the contested regulation.

43 In respect of the first part, alleging a failure to carry out a risk analysis, the applicants submit that the Commission committed a manifest error of assessment by failing to analyse the risks posed by the use of the cadmium pigments at issue, which are different substances from cadmium, in plastic materials other than those in respect of which that use was restricted before the adoption of the contested regulation. Those cadmium pigments are expressly exempt from the harmonised hazard classification of cadmium compounds, under Annex VI to Regulation No 1272/2008.

44 The contested regulation was adopted on the basis of Article 131 of Regulation No 1907/2006. As is apparent from Article 1(1) of Regulation No 1907/2006, the purpose of that regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. Having regard to recitals 87, 89 and 91 in the preamble to Regulation No 1907/2006, it must be stated that the legislature set, as the main purpose of the establishment of new restrictions and the amendment of the existing restrictions provided for in Title VIII of that regulation, 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).

45 In order to be able to pursue those objectives efficiently, the point must be made that, in an area of evolving and complex technology such as that in the present case, 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, whereas review by the European Union judicature has to be limited to verifying whether the exercise of such powers has been vitiated by a manifest error of appraisal 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, the only bodies to which the TFEU has entrusted that task (see, to that effect, Case C-343/09 *Afton Chemical* [2010] ECR I-7027, paragraph 28, and Case C-15/10 *Etimine* [2011] ECR I-6681, paragraphs 59 and 60).

46 Nevertheless, it must be stated that the EU authorities' broad discretion, which implies limited judicial review of their exercise of that discretion, applies not only to the nature and scope of the measures to be taken but also applies, to some extent, to the finding of the basic facts. However, even though such judicial review is of limited scope, it requires that those authorities which have adopted the act in question must be able to show before the European Union judicature that in adopting the act they actually exercised their discretion, which presupposes the taking into consideration of all the relevant factors and circumstances of the situation the act was intended to regulate (see, to that effect, *Afton Chemical*, paragraph 45 above, paragraphs 33 and 34).

47 In the present case, it must be observed that, although the contested regulation was adopted by recourse to the transitional measures referred to in Article 137(1)(a) of Regulation No 1907/2006, the fact remains that, in order to amend Annex XVII to that regulation, the conditions set out in Article 68 of that regulation must be satisfied. The transitional measures referred to in Article 137(1)(a) of that regulation constitute procedural provisions and can, as such, only replace the procedural rules provided for in Articles 69 to 73 of that regulation and not the substantive conditions for establishing new restrictions or amending existing restrictions, referred to in Article 68 of Regulation No 1907/2006. In addition, it is apparent from Article 137(1)(a) of that regulation that the proposals for restrictions must be in accordance with Title VIII of that regulation, namely Articles 68 to 73 thereof.

48 The establishment by the contested regulation of new restrictions on the cadmium pigments at issue therefore presupposed that the conditions set out in Article 68(1) of Regulation No 1907/2006 were satisfied. That provision states that, when there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a European Union-wide basis, Annex XVII to that regulation is to be amended by adopting new restrictions for the manufacture, use or placing on the market of substances on their own, in mixtures or in articles. Any such decision has to take into account the socio-economic impact of the restriction, including the availability of alternatives.

49 Consequently, the adoption of the contested regulation required that the Commission had to be entitled to take the view that the use of the cadmium pigments at issue in plastic materials other than those in respect of which that use was restricted before the adoption of the contested regulation involved an unacceptable risk to human health or the environment which needed to be addressed on a European Union-wide basis.

50 Even if, as the Commission contended at the hearing, the measures adopted under Article 137(1)(a) of Regulation No 1907/2006 are required to satisfy, not the substantive conditions set out in Article 68 of that regulation, but the rules in force before that regulation, namely Article 11 of Regulation No 793/93, it must be noted that that latter provision also provided that restrictions could only be adopted on the basis of an evaluation of the risks.

51 In the light of the arguments put forward by the applicants, it is thus necessary to examine whether the contested regulation is based on a manifest error of assessment on the part of the Commission on account of a failure to evaluate the risks posed by the cadmium pigments at issue in plastic materials other than those in respect of which the use of those pigments was restricted before the adoption of the contested regulation.

52 In this connection, where experts carry out a scientific evaluation of the risks, the Commission must be given sufficiently reliable and cogent information to allow it to understand the ramifications of the scientific question raised and decide upon a policy in full knowledge of the facts. Consequently, if it is not to adopt arbitrary measures, which cannot in any circumstances be rendered legitimate by the precautionary principle, the Commission must ensure that any measures that it takes, even preventive measures, are based on as thorough a scientific evaluation of the risks as possible, account being taken of the particular circumstances of the case at issue (see, to that effect, Case T-13/99 *Pfizer Animal Health* v *Council* [2002] ECR II-3305, paragraph 162).

53 It must be noted that the Commission concedes that the European Union risk assessment report deals with the cadmium pigments only indirectly, that is to say, in so far as the sites where those pigments are produced are concerned. That is confirmed by recitals 1 and 2 in the preamble to Regulation No 835/2012, from which it is apparent that the extension of the restriction as regards the use of cadmium and its compounds to all plastic materials was not based upon that report. However, the Commission submits that its decision to extend the restriction on the use of all cadmium compounds as colouring agents for plastic materials other than those in respect of which that use was restricted before the adoption of the contested regulation was based on other information it had taken into account.

54 In that regard, first, the Commission refers to the Council Resolution of 25 January 1988 on a Community action programme to combat environmental pollution by cadmium (OJ 1988 C 30, p. 1). In that resolution, the Council conceded that the exposure of humans and the environment to cadmium came from multiple sources and in particular from emissions from the disposal of waste. Admittedly, the applicants' argument that the Commission could not rely on that resolution because it had been adopted before the introduction of restrictions under Directive 91/338 must be rejected.

That resolution recommends an approach in stages and nothing indicates that that approach has been fully implemented by Directive 91/338. However, that resolution does not contain, as such, an evaluation of the risks posed by cadmium pigments in plastic materials.

55 Secondly, the Commission refers to the 2000 report, which relied on the 1998 report and estimated the percentage of cadmium released from coloured plastics during the life of the product at 0.005%. The 2000 report, which was the subject of an opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment dating from 30 October 2001, identified the incineration of plastics containing cadmium pigments and the landfill and corresponding leaching of plastic waste and ash from incinerators as a source of cadmium in the environment. However, no conclusion could be reached on the precise sources of cadmium detected in landfill leachate.

56 In this connection, the applicants submit that the Commission could not rely on the 2000 report, given that it had been finalised before the European Union risk assessment report. Having regard to its wide discretion, which also applies to the finding of the basic facts (see paragraph 46 above), nothing prevented the Commission, admittedly, from taking into consideration scientific data from resources other than the European Union risk assessment report, such as the 2000 report. In addition, the European Union risk assessment report indicates, in part I thereof, at point 0.1.1, that it does not cover all the fields concerned by cadmium and cadmium oxide or all the compounds of those substances. Furthermore, it refers to several other studies without referring to them exhaustively. However, it must be observed that the fact that the European Union risk assessment report, which dates from 2007, does not include the results of the 2000 report shows that the latter is of limited relevance. That is confirmed by the opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment on that report, according to which its results could not be used in isolation and the importance of the possible risks linked to the uses of cadmium referred to in that report should be evaluated in a wider context.

57 Thirdly, the Commission refers to the study entitled ‘The Behaviour of PVC in Landfill’, prepared by a German company for the Commission in 2000, which states that the acidogenic stage of early landfill development shows the highest leaching efficiency. According to that study, due to the acidity of fermentation products occurring in the water phase, the pH of the leachate will be low and heavy metals may be dissolved during this phase. According to the Commission, this is important in terms of release of cadmium ions, even from compounds defined as insoluble such as the cadmium pigments.

58 In this connection, it is necessary to reject the applicants’ arguments that the fact that the Commission did not forward that study to the third applicant following its request for access of 24 May 2011 to all the documents relating to the draft amendment of Annex XVII to Regulation No 1907/2006, under Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ 2001 L 145, p. 43), shows that the Commission did not base its evaluation of the risks on that document.

59 The Commission states that it did not forward that document because, in its view, that document did not relate to the compiling of that draft, in so far as it was not a document required by the applicable legislative provisions or by the relevant administrative procedure for the purposes of the compilation of that draft. As is apparent from the file, the Commission forwarded 47 documents to the third applicant following its request. Even if the Commission failed to meet its obligations under Regulation No 1049/2001 in so far as it did not forward all the relevant documents, that fact is not such as to demonstrate that the Commission did not take account of those documents in its evaluation of the risks. The procedure culminating in the amendment of Annex XVII to Regulation No 1907/2006 and that relating to the request for access to the Commission’s documents under Regulation No 1049/2001 are separate procedures which are not mutually interdependent.

60 However, it must be observed that, as the applicants claim, the study entitled 'The Behaviour of PVC in Landfill' relates only to PVC. While, admittedly, that study contains data on the evaluation of the risks from cadmium pigments, its value is nevertheless limited so far as concerns plastic materials other than PVC.

61 In that context, it must be recalled that the recitals in the preamble to the contested regulation concern only the prohibition on the use of cadmium in all articles made of PVC (recitals 9 to 12 of the contested regulation), without referring to other plastic materials, and that, under paragraph 4 of entry No 23 in Annex XVII to Regulation No 1907/2006, as amended by the contested regulation, PVC is the only plastic material in respect of which a specific derogation from the restrictions at issue was provided for, namely that for mixtures produced from PVC waste, referred to as 'recovered PVC'. In addition, it must be pointed out that the draft amendment to Annex XVII to Regulation No 1907/2006, submitted by the Commission to the competent authorities for Regulations Nos 1907/2006 and 1272/2008 in time for their meeting of 15 to 17 June 2010 during the preparation stages for the contested regulation, contained a proposal for '[p]rohibition of use of Cadmium in all plastics including PVC' and that it is possible to construe that proposal as not applying to 'all plastics, including PVC'. Having regard to the foregoing, the Court considers that it is not apparent from the study entitled 'The Behaviour of PVC in Landfill' either that the Commission also examined the issue of whether the behaviour of plastic materials other than PVC could be distinguished from that of PVC so far as concerned cadmium pigments or, if so, to what extent all the other plastic materials concerned by the restrictions at issue were comparable to PVC in that regard.

62 Fourthly, the Commission refers to the Communication on the results of the risk evaluation and the risk reduction strategies for the substances: cadmium and cadmium oxide, according to which the environmental exposure to cadmium is calculated based on all known current anthropogenic emissions of cadmium, namely cadmium that is emitted by the cadmium/cadmium oxide producers and processors and cadmium in diffuse sources such as fertilisers, steel production, oil and coal combustion, traffic, waste incineration and landfills. In respect of the evaluation of the risks to human health, that communication refers, in order to justify the finding that there is a need for specific measures to limit the risks, to the risks of genotoxicity and carcinogenicity as a consequence of environmental exposure arising from all exposure scenarios, since that substance is considered to be a non-threshold carcinogen. So far as concerns the evaluation of the risks to the environment, that communication refers, inter alia, to the risk of a landfill site leaching directly to surface water, to risks as regards waters in the UK and the Walloon region of Belgium where there is a high concentration of cadmium and to risks as regards soils in the United Kingdom at regional level.

63 In this connection, it must be stated that that communication presents the results of the evaluation of the risks contained in the European Union risk assessment report and the recommended strategies to limit the risks posed by cadmium and cadmium oxide. As it has already been noted (see paragraph 53 above), the European Union risk assessment report only deals with cadmium pigments indirectly, that is to say in so far as the sites of the production of those pigments are concerned.

64 Furthermore, the use of cadmium pigments was, admittedly, restricted in a large number of plastic materials before the entry into force of the contested regulation, under Directive 91/338 (see paragraph 4 above) and, pursuant to Regulation No 552/2009, those restrictions were transferred to Annex XVII to Regulation No 1907/2006 (see paragraph 12 above). However, it must also be stated that, as the applicants claim, the cadmium pigments at issue were expressly exempted from the harmonised hazard classification of cadmium compounds, in accordance with Annex VI to Regulation No 1272/2008.

65 Fifthly, the Commission refers to the study entitled 'Study to Analyse the Derogation Request on the use of Heavy Metals in Plastic Crates and Plastic Pallets', dated 29 September 2008, which concerns the behaviour of cadmium and heavy metal pigments in landfills. That study contains an extract of a report of the Nordic Council of Ministers of 2003, according to which the mobility of cadmium inside

landfills is low and according to which a complete wash-out of cadmium by rain may require hundreds to thousands of years and in some cases even more, but which states that no evidence exists that landfills can be regarded as permanent containment of cadmium. Next, the study indicates that the stability of heavy metals seems to depend on the integrity of the crate/pallet. That study refers to a documented case in which the storage of high-density polyethylene (HDPE) granulates coloured with cadmium pigments outside in the open air for 5-6 years gave rise to elevated cadmium concentrations in the soil and surrounding water courses. Furthermore, that study refers to two other studies. According to the first, cadmium sulphide yellow pigments have excellent resistance – except in the presence of moisture – and are thus not very sensitive to external changes. According to the second, cadmium pigments are lightfast, but can slowly be oxidised to soluble sulphates by light (UV rays), air and water. That photo-oxidation is more pronounced in cadmium yellow than cadmium red. However, according to that second study, the capacity of the substance's resistance to light and the weather depends on the pigment and also on the medium in which the pigment is used, namely whether the crates and pallets are whole or granulated.

66 In this connection, for the same reasons as those set out in paragraphs 58 and 59 above, the applicants' line of argument that the fact that the Commission did not send that study and the report of the Council of Nordic Ministers to the third applicant, following his request for access of 24 May 2011, shows that the Commission did not base its evaluation of the risks on those documents, must be rejected.

67 However, as the applicants claim, that study and the report of the Council of Nordic Ministers mentioned therein are of limited relevance for the purposes of determining the risks posed by the cadmium pigments at issue in plastic materials other than those in respect of which the use of those pigments was restricted before the adoption of the contested regulation.

68 First, the report of the Council of Nordic Ministers does not deal with the use of cadmium pigments, but with the behaviour of cadmium in landfills in general. Moreover, whereas it indicates that the mobility of cadmium inside landfills is slow and that a complete wash-out of cadmium by rain may require hundreds to thousands of years and in some cases even more, even though no evidence exists that landfills can be regarded as a permanent containment of cadmium, that report clearly does not constitute a sufficient basis for the evaluation of risks posed by the use of the cadmium pigments at issue in plastic materials.

69 Secondly, the content of that study, admittedly, concerns also the behaviour of cadmium pigments in landfill sites. In that regard, the applicants' arguments that the Commission has not shown there to be a link between the use of cadmium pigments and leaching in landfill sites and according to which the main source of cadmium in landfill sites, noted in the European Union risk assessment report, is cadmium oxide, must be rejected. That study expressly referred to a case in which the storage of HDPE granulates coloured with cadmium pigment led to pollution of the soil and water caused by cadmium following prolonged exposure to bad weather. Furthermore, even if cadmium oxide constitutes the main source of cadmium in landfill sites, it must be observed that, as the Commission contends, the global impact on the environment depends on the absolute quantities found in the environment and changes in solubility stemming from environmental conditions and the deterioration of the cadmium pigments.

70 However, although that study indicates that the capacity to resist light and bad weather is dependent inter alia on the medium in which the cadmium pigment is used, namely on whether the crates or pallets are whole or granulated, it does not contain any new information as regards the presence or behaviour of cadmium pigments in the various plastic materials. However, the present case specifically concerns the evaluation of the risks posed by the cadmium pigments at issue in plastic materials other than those in respect of which the use of those pigments was restricted before the adoption of the contested regulation. In addition, it must be stated that that study concerned only those plastic materials used for the purposes of the manufacture of the crates or pallets.

71 Having regard to the foregoing, the file does not show that the Commission evaluated all the relevant factors and circumstances of the situation which the contested regulation was intended to govern. By concluding, on the basis of the scientific evidence mentioned in paragraphs 54 to 70 above, that there was a risk to human health or the environment which needed to be addressed on a European Union-wide basis, the Commission therefore committed a manifest error of assessment.

72 Consequently, the first part of this plea in law must be upheld.

73 In the light of the foregoing considerations, and without there being any need to rule either on the second part of this plea in law or on the other pleas in law raised by the applicants, the action must be upheld and the contested regulation must be partly annulled in so far as it restricts the use of the cadmium pigments at issue in mixtures and articles made from plastic materials other than those in respect of which that use was restricted before the adoption of that regulation. On the other hand, the action must be rejected as inadmissible as to the remainder.

Costs

74 Article 87(3) of the Rules of Procedure provides that the Court may order that costs be shared or that the parties bear their own costs if each party succeeds on some and fails on other heads. In the present case, since the Commission has substantially failed, the Court considers it fair, having regard to the circumstances of the case, to order the Commission to bear 90% of its own costs and pay 90% of the costs incurred by the applicants, those latter bearing 10% of their own costs and paying 10% of the costs incurred by the Commission.

On those grounds,

THE GENERAL COURT (Seventh Chamber)

hereby:

1. **Annuls Commission Regulation (EU) No 494/2011 of 20 May 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Cadmium) in so far as it restricts the use of cadmium sulpho-selenide orange (No CAS 1256-57-4), cadmium sulpho-selenide red (No CAS 58339-34-7) and cadmium zinc sulphide (No CAS 8048-07-5) in mixtures and articles produced from synthetic organic polymers other than those in respect of which that use was restricted before the adoption of Regulation No 494/2011;**

2. **Dismisses the action as to the remainder;**

3. **Orders the European Commission to bear 90% of its own costs and to pay 90% of the costs incurred by International Cadmium Association (ICdA), Rockwood Pigments (UK) Ltd and James M Brown Ltd;**

4. **Orders ICdA, Rockwood Pigments (UK) and James M Brown to bear 10% of their own costs and to pay 10% of the costs incurred by the Commission.**

Dittrich Wiszniewska-Białecka Prek

Delivered in open court in Luxembourg on 14 November 2013.

[Signatures]