



## Reports of Cases

### Case T-93/10

#### **Bilbaína de Alquitranes, SA and Others v European Chemicals Agency (ECHA)**

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

Summary — Judgment of the General Court (Seventh Chamber Extended Composition), 7 March 2013

1. *Actions for annulment — Actionable measures — Concept — Measures producing binding legal effects — Preparatory measures — Not included — Decision of the European Chemicals Agency (ECHA) identifying pitch, coal tar, high temperature as a substance of very high concern — Act intended to produce legal effects — Included*

(Art. 263, first para., TFEU; European Parliament and Council Directive 1907/2006, Arts 7(2), 31(1)(c), and (3)(b), 33(1) and (2), 57 and 59)

2. *Actions for annulment — Natural or legal persons — Measures of direct and individual concern to them — Whether directly concerned — Criteria — Decision of the European Chemicals Agency (ECHA) identifying pitch, coal tar, high temperature as a substance of very high concern — Action by companies producing that substance — Identification triggering the obligation to communicate to users of the substance and updated safety data sheet — Admissibility*

(Art. 263, fourth para., TFEU; European Parliament and Council Regulation No 1907/2006, Arts 31(1)(a) to (c), and 9(a), 34(a), 57(a),(d) and (e), and 59; Council Directive 67/548) Council Directive 67/548)

3. *Actions for annulment — Natural or legal persons — Meaning of ‘regulatory act’ in Article 263, fourth paragraph, TFEU — Any act of general scope for legislative measures — Decision of the European Chemicals Agency (ECHA) identifying a substance as being of very high concern — Included — Act not containing implementing measures within the meaning of that provision of the Treaty*

(Arts 263, fourth para., TFEU and 289(1) to (3) TFEU; European Parliament and Council Regulation No 1907/2006, Arts 31(9)(a), 34(a), 57, 59 and 75(1))

4. *Approximation of laws — Registration, evaluation, authorisation and restriction of chemicals — REACH regulation — Substances of very high concern — Identification procedure — Discretion of the EU authorities — Scope — Judicial review — Limits — No breach of the principle of equal treatment by the European Chemical Agency (ECHA)*

(European Parliament and Council Regulation No 1907/2006, Arts 57 and 59)

5. *Approximation of laws — Registration, evaluation, authorisation and restriction of chemicals — REACH regulation — Substances of very high concern — Identification procedure — Substances with persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties — Classification on the basis of the properties of the constituents — Lawfulness — Application of a concentration threshold for the purposes of classification — Lawfulness*

*(European Parliament and Council Regulation No 1907/2006, Arts 14(2)(f), 31(3)(b), 56(6), and 57(d) and (e), and Annex XIII)*

6. *Approximation of laws — Registration, evaluation, authorisation and restriction of chemicals — REACH regulation — Substances of very high concern — Identification procedure — Substances with persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties — Classification on the basis of the properties of the constituents — No obligation to carry out a separate procedure with regard to the constituents*

*(European Parliament and Council Regulation No 1907/2006, Arts 57(d) and (e), and 59 and Annex XIII)*

7. *Approximation of laws — Registration, evaluation, authorisation and restriction of chemicals — REACH regulation — Substances of very high concern — Identification procedure — Decision of the European Chemicals Agency (ECHA) identifying pitch, coal tar, high temperature as a substance of very high concern — No breach of the principle of proportionality*

*(European Parliament and Council Regulation No 1907/2006, Recital 16 and Arts 1(1), 14(6), and 59 and Annex XV)*

1. 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. 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.

A decision of the European Chemicals Agency (ECHA) identifying pitch, coal tar, high temperature as a substance meeting the criteria set out in Article 57 of Regulation No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) in accordance with Article 59 of that regulation thus constitutes an act against which an action will lie, since such a decision is designed to produce binding legal effects vis-à-vis third parties.

In that regard, 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 Regulation No 1907/2006. 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.

(see paras 27, 28, 32)

2. The condition for admissibility of an annulment action that the natural or legal person concerned be directly affected 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 EU rules without the application of other intermediate rules.

In that regard, a decision of the European Chemicals Agency (ECHA) identifying pitch, coal tar, high temperature as a substance of very high concern meeting the criteria set out in Article 57(a), (d) and (e) of Regulation No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) must be regarded as directly affecting the producers of that substance, in so far as, since identification of the latter amounts to new information capable of affecting risk management measures, or new information on hazards within the meaning of Article 31(9)(a) of Regulation No 1907/2006, the producers are obliged to update the safety data sheets concerned. Under Article 31(1)(a) to (c) of the said regulation, those safety data sheets must be provided by the suppliers of a substance to its downstream users where it meets the criteria for classification as a dangerous substance in accordance with Directive 67/548 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Identification also triggers the obligation to communicate information under Article 34(a) of Regulation No 1907/2006. It thus produces direct effects on the legal situation of producers because of the obligations laid down by the above provisions.

(see paras 37, 38, 48, 50, 51)

3. The meaning of ‘regulatory act’ for the purposes of the fourth paragraph of Article 263 TFEU must be understood as covering all acts of general application apart from legislative acts.

A decision of the European Chemicals Agency (ECHA) identifying pitch, coal tar, high temperature as a substance of very high concern meeting the criteria set out in Article 57 of Regulation No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) constitutes a regulatory act. That 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. Moreover, that 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. Such a decision is an act of the ECHA adopted on the basis of Article 59 of Regulation No 1907/2006. It does not entail any implementing measures, since identification of a substance as being of very high concern triggers obligations to provide information without any other measures being necessary.

Moreover, since 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. In that regard, the task of the ECHA 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.

(see paras 55-60, 63, 65)

4. Where the European Union authorities have a broad discretion, as is the case where the Commission proceeds to a progressive implementation of the rules on the substances of very high concern set out in Title VII of Regulation No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), 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.

Nevertheless, 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 the Community institutions which have adopted the act in question must be able to show before the Court 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.

Since the procedure under Article 59 of Regulation No 1907/2006 for identifying a substance as being of very high concern does not confer on the ECHA any power as regards the choice of the substance to be identified, inasmuch as Article 59(2) and (3) of Regulation No 1907/2006 provide 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 ECHA cannot be accused of breaching the principle of equal treatment by identifying a substance as being of very high concern without having proceeded to the identification of other, allegedly comparable substances.

(see paras 70-72, 76, 77)

5. With regard to a decision identifying a substance as being of very high concern on account of its persistent, bioaccumulative and toxic properties ('PBT properties') and its very persistent and very bioaccumulative properties ('vPvB properties'), meeting the criteria set out in Annex XIII to Regulation No 1907/2006, it cannot simply be held that the ECHA has 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, since the constituents of a substance are an integral part of it. Although the wording of Annex XIII to Regulation No 1907/2006 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.

Moreover, whilst it is true that no concentration threshold is laid down in Annex XIII to Regulation No 1907/2006, 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. In that regard, the threshold of 0.1% has been applied by EU legislation several times for the classification of a preparation on the basis of the substances contained in it. The same is true of Articles 14(2)(f), 31(3)(b), 56(6) and 57(d) and (e) of Regulation No 1907/2006. Where 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, it cannot be concluded that the ECHA 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.

(see paras 82, 83, 97-99)

6. In the procedure for identifying a substance referred to in Article 59 of Regulation No 1907/2006, where the ECHA identifies a substance as being of very high concern by reason of its PBT and vPvB properties, on the basis of the PBT and vPvB properties of its constituents, it is not a requirement



that those constituents must themselves have first been identified as having PBT and vPvB properties by a separate decision of the ECHA. 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.

(see para. 104)

7. With regard to judicial review of the conditions for implementing the principle of proportionality, 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. Regard being had to recital 16 of Regulation No 1907/2006, the legislature established, as the main objective, the first of the three objectives set out in Article 1(1), namely to ensure a high level of protection of human health and the environment.

A decision of the ECHA identifying pitch, coal tar, high temperature as a substance of very high concern resulting from the procedure under Article 59 of Regulation No 1907/2006 does not infringe the principle of proportionality.

First, the decision is appropriate for achieving the objectives pursued by Regulation No 1907/2006, since 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, consequently, such identification must be regarded as a means of enhancing that protection. Moreover, the decision does not entail a prohibition on placing the substance on the market thereby obliging the operators concerned to use alternative substances.

Second, the decision does not exceed the limits of what is necessary to achieve the objectives pursued by Regulation No 1907/2006, given that 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. The same applies to the presentation of a dossier pursuant to Annex XV to Regulation No 1907/2006 for restrictions, since restrictions, adopted in accordance with the procedure referred to in Title VIII of that regulation, may range from specific conditions imposed on the manufacture or the placing on the market of a substance to a total ban on the use of a substance. Even if restriction measures are also appropriate for the achievement of the objectives pursued by that regulation, they thus do not constitute, as such, less onerous measures compared with the identification of a substance which does not entail information obligations.

(see paras 115-119, 125, 129)