



Reports of Cases

Case T-94/10

Rütgers Germany GmbH and Others
v
European Chemicals Agency (ECHA)

(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)

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 anthracene oil as a substance of very high concern — Act intended to produce legal effects — Included*

(Art. 263, first para., TFEU; European Parliament and Council Regulation No 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 anthracene oil 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 1907/2006, Arts 31(1)(a) to (c), and (9)(a), 34(a), 57(a), (d) and (e), and 59; 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 to 59 and 75(1))

4. *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 — Procedure started on the initiative of a Member State —*

Obligations concerning information to be provided as regards replacement substances — Scope — Possible relevance of such information to a decision identifying a substance as being of very high concern — Limits

(European Parliament and Council Regulation No 1907/2006, Arts 57(a), (b), (d) and (e), 59(3), and 60(5), and Annexes XIII and XV, point II 2; Council Directive 67/548)

5. *Approximation of laws — Registration, evaluation, authorisation and restriction of chemicals — REACH regulation — Substances of very high concern — Identification procedure — Identification on the basis of a ground not mentioned in the dossier originally prepared for the substance — European Chemicals Agency (ECHA) not thereby exceeding its powers*

(European Parliament and Council Regulation No 1907/2006, Arts 55, 57 and 59 and Annex XV)

6. *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)

7. *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)

8. *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)

9. *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 anthracene oil 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 anthracene oil 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 28, 29, 33)

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 anthracene oil 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 38, 39, 49, 51, 52)

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 a substance as being 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 56-61, 64, 66)

4. 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 persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties (PBT or vPvB properties), whilst point II 2 of Annex XV to the regulation 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, a Member State may nevertheless give only the information which is available to it. In that regard, a statement by a Member State that no information is available as to the existence of replacement substances allows that Member State to fulfil its formal obligation to state its view on alternative substances. Moreover, in the light of Article 60(5) of Regulation No 1907/2006, point II 2 of Annex XV to the said regulation must be interpreted as referring to appropriate replacement substances.

In any event, it is not apparent from the identification procedure set out in Article 59 of Regulation No 1907/2006 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 a substance 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 or mutagenic substance are set out in Directive 67/548 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

(see paras 70, 72, 73, 77)

5. It cannot be argued that, in identifying a substance as being of very high concern under Article 57 of Regulation No 1907/2006 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.

First, 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. A decision identifying a substance as being of very high concern on the ground that it meets the criteria set out in Article 57 of that regulation is consistent with that objective. An 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.

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.

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.

Fourth, 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 a decision identifying a substance as being of very high concern.

(see paras 84-88)

6. 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 92-94, 98, 99)

7. 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. Thus it is with 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 104, 105, 118-120)

8. 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. 125)

9. 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 anthracene oil 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 said decision does not involve prohibiting marketing the substance, requiring the operators concerned to use replacement 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 133-137, 144, 148)