JUDGMENT OF THE COURT (Grand Chamber)

7 July 2009 *

In Case C-558/07,

REFERENCE for a preliminary ruling under Article 234 EC from the High Court of Justice (England & Wales), Queen's Bench Division (Administrative Court) (United Kingdom), made by decision of 11 October 2007, received at the Court on 17 December 2007, in the proceedings

**The Queen,** on the application of:

**S.P.C.M. SA,**

**C.H. Erbslöh KG,**

**Lake Chemicals and Minerals Ltd,**

**Hercules Inc.**

* Language of the case: English.

v

**Secretary of State for the Environment, Food and Rural Affairs,**

THE COURT (Grand Chamber),

composed of V. Skouris, President, C.W.A. Timmermans, A. Rosas, K. Lenaerts, M. Ilešič, Presidents of Chambers, A. Tizzano, J. N. Cunha Rodrigues, R. Silva de Lapuerta, P. Kūris (Rapporteur), J. Malenovský, J. Klučka, U. Lõhmus and J.-J. Kasel, Judges,

Advocate General: J. Kokott,
Registrar: C. Strömholm, Administrator,

having regard to the written procedure and further to the hearing on 27 January 2009,

after considering the observations submitted on behalf of:

— S.P.C.M. SA and Hercules Inc., by D. Vaughan, QC, D. Scannell, Barrister, M. Lohn, K. Van Maldegem and R. Cana, Solicitors,

— C.H. Erbslöh KG and Lake Chemicals and Minerals Ltd, by H. Scheidmann, U. Karpenstein and F. Bredt, Rechtsanwälte,

— the Polish Government, by M. Dowgielewicz, acting as Agent,

— the European Parliament, by I. Anagnostopoulou and A. Neergaard, acting as Agents,

— the Council of the European Union, by F. Florindo Gijón and G. Kimberley, acting as Agents,

— the Commission of the European Communities, by P. Oliver, acting as Agent,

after hearing the Opinion of the Advocate General at the sitting on 10 March 2009,

gives the following

## Judgment

1 This reference for a preliminary ruling concerns the interpretation and validity of Article 6(3) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006 L 396, p. 1, and corrigendum OJ 2007 L 136, p. 3) ('the REACH Regulation').

2 The reference has been made in the course of proceedings between, on the one hand, S. P.C.M. SA., an undertaking established in France which manufactures water-soluble polymers used in the wastewater treatment industries, C.H. Erbslöh KG, an undertaking established in Germany which is a distributor and wholesaler of specialty and industrial chemicals, including preparations and polymers, Lake Chemicals and Minerals Ltd, a company incorporated under English law which imports chemicals, including polymers and preparations, and Hercules Inc., a holding corporation established in the United States which supplies water- and organo-soluble polymer-based products, and, on the other hand, the Secretary of State for the Environment, Food and Rural Affairs, concerning the registration requirements applicable to monomer substances.

## Legal background

3 Recital 1 in the preamble to the REACH Regulation provides:

'This Regulation should ensure a high level of protection of human health and the environment as well as the free movement of substances, on their own, in preparations and in articles, while enhancing competitiveness and innovation. …'

4 Recital 16 in the preamble to that regulation states:

'This Regulation lays down specific duties and obligations on manufacturers, importers and downstream users of substances on their own, in preparations and in articles. This Regulation is based on the principle that industry should manufacture, import or use substances or place them on the market with such responsibility and care as may be required to ensure that, under reasonably foreseeable conditions, human health and the environment are not adversely affected.'

5 Under Recital 19 in the preamble to the REACH Regulation:

'… the registration provisions should require manufacturers and importers to generate data on the substances they manufacture or import, to use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures. …'

6 Recital 41 in the preamble to the REACH Regulation is worded as follows:

'For reasons of workability and because of their special nature, specific registration requirements should be laid down for intermediates. Polymers should be exempted from registration and evaluation until those that need to be registered due to the risks posed to human health or the environment can be selected in a practicable and cost-efficient way on the basis of sound technical and valid scientific criteria.'

7 Article 1 of the REACH Regulation provides:

'1. The purpose of this 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.

…

3. This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.'

8 The scope of the REACH Regulation is defined in Article 2 thereof. Article 2(9) provides that '[t]he provisions of Titles II and VI shall not apply to polymers'.

9 Article 3 of the REACH Regulation states:

'For the purposes of this Regulation:

(1) Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

(2) Preparation: means a mixture or solution composed of two or more substances;

…

(5) Polymer: means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:

(a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;

(b) less than a simple weight majority of molecules of the same molecular weight.

In the context of this definition a "monomer unit" means the reacted form of a monomer substance in a polymer;

(6) Monomer: means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process;

…

(9) Manufacturer: means any natural or legal person established within the Community who manufactures a substance within the Community;

…

(11) Importer: means any natural or legal person established within the Community who is responsible for import;

…'

10 Article 5 of the REACH Regulation, entitled 'No data, no market', provides:

'Subject to Articles 6, 7, 21 and 23, substances on their own, in preparations or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.'

11 Article 6 of that regulation, entitled 'General obligation to register substances on their own or in preparations', provides as follows:

'1. Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more preparation(s), in quantities of 1 tonne or more per year shall submit a registration to the [European Chemicals] Agency.

…

3. Any manufacturer or importer of a polymer shall submit a registration to the [European Chemicals] Agency for the monomer substance(s) or any other substance(s) that have not already been registered by an actor up the supply chain, if both the following conditions are met:

(a) the polymer consists of 2% weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);

(b) the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year.

…'

12 Article 8 of the REACH Regulation states:

'1. A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under this Title.

2. The representative shall also comply with all other obligations of importers under this Regulation. …

3. If a representative is appointed in accordance with paragraphs 1 and 2, the non-Community manufacturer shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation.'

13 Article 27 of the REACH Regulation provides:

'1. Where a substance has previously been registered less than 12 years earlier …, the potential registrant:

(a) shall, in the case of information involving tests on vertebrate animals; and

(b) may, in the case of information not involving tests on vertebrate animals,

request from the previous registrant(s) the information he requires … in order to register.

2. When a request for information has been made according to paragraph 1, the potential and the previous registrant(s) as referred to in paragraph 1 shall make every effort to reach an agreement on the sharing of the information requested by the potential registrant(s) … Such an agreement may be replaced by submission of the matter to an arbitration board and acceptance of the arbitration order.

3. The previous registrant and potential registrant(s) shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way. This may be facilitated by following cost-sharing guidance based on those principles which is adopted by the [European Chemicals] Agency … Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.

…'

14 Article 138(2) of the REACH Regulation provides:

'The Commission may present legislative proposals as soon as a practicable and cost-efficient way of selecting polymers for registration on the basis of sound technical

and valid scientific criteria can be established, and after publishing a report on the following:

(a) the risks posed by polymers in comparison with other substances;

(b) the need, if any, to register certain types of polymer, taking account of competitiveness and innovation, on the one hand, and the protection of human health and the environment, on the other.'

**The dispute in the main proceedings and the questions referred for a preliminary ruling**

15 According to the referring court, the applicant companies in the main proceedings are challenging the interpretation and also the validity of Article 6(3) of the REACH Regulation.

16 Relying on two expert opinions compiled by the Netherlands Organisation for Applied Scientific Research (TNO), the applicants in the main proceedings submit that reacted monomers cease to exhibit their own individual chemical characteristics and that polymers are generally stable and safe. In their view, it follows that, if the words 'monomer substances' in Article 6(3) of the REACH Regulation were to mean or include reacted monomers, it would make no sense to exempt polymers from registration while requiring the registration of monomer substances. Moreover, such an interpretation would, they argue, be inconsistent with the objectives of that regulation and would be discriminatory and disproportionate.

17 The High Court of Justice (England & Wales), Queen's Bench Division (Administrative Court) granted leave to the applicants in the main proceedings to apply for judicial review and decided to stay proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'1. In light of the fact that the registration requirements in Title II of the [REACH] regulation do not apply to polymers by virtue of Article 2(9) of the regulation, does the reference to "monomer substances" in Article 6(3) mean:

(a) reacted monomers, that is, monomers which have reacted together such that they are indissociable from the polymer of which they form part;

(b) unreacted monomers, that is, monomers that are residual to the polymerisation process and which retain their own chemical identities and properties separate from the polymer after that process is complete; or

(c) both reacted and unreacted monomers?

2. If the answer to Question 1 is either (a) or (c), is the application of Article 6(3) of the [REACH] regulation to manufacturers or importers of polymers unlawful by reason that the requirements are irrational, discriminatory or disproportionate?'

## The questions referred for a preliminary ruling

*The first question*

18 By its first question, the referring court seeks clarification of the concept of 'monomer substance' as used in Article 6(3) of the REACH Regulation.

19 As a preliminary point, it must first be observed that, under that provision, the manufacturer or importer of a polymer must submit a registration for the monomer substance(s) or any other substance(s) that have not already been registered by an actor up the supply chain, if the polymer consists of 2% w/w or more of such monomer substance(s) or other substance(s) in the form of monomeric units and the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year.

20 Second, unreacted monomers must, according to Article 6(1) and (2) of the REACH Regulation, be registered inasmuch as they constitute substances on their own. By contrast, polymers are, in accordance with Article 2(9) of that regulation, excluded from the registration obligation.

21 Next, it must be observed, first, that it is clear from the wording of Article 3(5) of the REACH Regulation that polymers are composed of monomer units, which are defined as monomer substances in a reacted form.

22 Second, under Article 3(6) of the regulation, a monomer, by contrast, is a 'substance' within the meaning of Article 3(1) when it is in an unreacted form.

23 Third, it follows from Article 6(3) of the REACH Regulation that registration concerns monomer substances or any other substances which are constituents of polymers.

24 Consequently, account being taken of the definition of polymer given in Article 3(5) of the REACH Regulation set out in paragraph 21 of the present judgment, registration concerns reacted monomer substances.

25 The fact that the words 'monomeric units' are used in Article 6(3) of the REACH Regulation rather than the words 'monomer units', which appear in Article 3(5) of the English and French versions of the REACH Regulation, cannot affect that finding.

26 It is clear from the document of the Council of the European Union of 5 November 2004 (No 13788/04, p. 5) that those words were added at the request of the Kingdom of Sweden. The Swedish-language version of the REACH Regulation uses the same words 'monomer units' in Articles 3(5) and 6(3) of the regulation.

27 It follows that the concept of 'monomer substances' in Article 6(3) of the REACH Regulation relates only to reacted monomers which are incorporated in polymers.

28 That finding cannot be called into question by the examination of the general scheme of the regulation.

29 Contrary to the submissions of the applicants in the main proceedings, the obligation to register monomer substances is not an exception to the exemption from registration which applies to polymers.

30 First, a reading of Recital 19 in the preamble to the REACH Regulation confirms the obligation to register substances, irrespective of whether they are manufactured or imported.

31 Second, Article 6 of the REACH Regulation, entitled 'General obligation to register substances on their own or in preparations', sets out a general principle of registration, and not of exemption.

32 Furthermore, it is also necessary to reject the argument put forward by the applicants in the main proceedings that an interpretation such as that adopted in paragraph 27 of the present judgment would render meaningless the exemption for polymers from the obligation to register laid down in Article 2(9) of the REACH Regulation.

33 In that connection, it must be observed that Article 6(3) of that regulation refers to monomer substances which have not yet been registered up the supply chain.

34 It follows that it is not polymers which are affected by the registration obligation but only monomer substances with their own characteristics as they existed before polymerisation.

35 Finally, the conclusion set out in paragraph 27 of this judgment is confirmed by the objectives of the REACH Regulation, as defined by Recital 1 in the preamble and Article 1(1) of the regulation, which consist in ensuring a high level of protection of human health and the environment and the free movement of substances while enhancing competitiveness and innovation.

36 The obligation to register monomer substances is designed to protect human health and the environment since those substances have inherent characteristics liable to have an adverse effect on them.

37 The objective of free movement of substances in the internal market while enhancing competitiveness and innovation is liable, not to call into question the definition of 'monomer substances', but to affect the validity of Article 6(3) of the REACH Regulation, which is the subject of the second question.

38 It follows from all of the foregoing that the answer to the first question is that the concept of 'monomer substances' in Article 6(3) of the REACH Regulation relates only to reacted monomers which are integrated in polymers.

*The second question*

39 By its second question, the referring court asks essentially whether Article 6(3) of the REACH Regulation is invalid in so far as it requires manufacturers and importers of polymers to submit an application for registration of monomer substances, as defined in paragraph 38 of the present judgment.

The irrationality of Article 6(3) of the REACH Regulation

40 This complaint must be regarded as coming under the complaint relating to the infringement of the principle of proportionality.

Infringement of the principle of proportionality

41 According to settled case-law, the principle of proportionality, which is one of the general principles of Community law, requires that measures implemented through Community provisions should be appropriate for attaining the objective pursued and must not go beyond what is necessary to achieve it (Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco* [2002] ECR I-11453, paragraph 122 and the case-law cited).

42 With regard to judicial review of the conditions referred to in the previous paragraph, the Community legislature must be allowed a broad discretion in an area such as that

involved in the present case, 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 competent institution is seeking to pursue (*British American Tobacco (Investments) and Imperial Tobacco*, paragraph 123 and the case-law cited).

43 In the present case, it is necessary to examine whether the obligation to register monomer substances, as defined in paragraph 38 of this judgment and satisfying the cumulative conditions laid down in Article 6(3) of the REACH Regulation, constitutes a proportionate means to achieve the objectives of that regulation.

44 As has been stated in paragraph 35 of the present judgment, the objectives of the REACH Regulation, set out in Article 1 thereof, are to 'ensure a high level of protection of human health and the environment … as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation'.

45 However, regard being had to Recital 16 in the preamble to the REACH Regulation, it must be stated that the Community legislature established, as the main purpose of the obligation to register laid down in Article 6(3) thereof, the first of those three objectives, namely to ensure a high level of protection of human health and the environment.

46 The means by which to achieve that objective is, as Recital 19 in the preamble to the REACH Regulation states, the registration obligation imposed on manufacturers and importers, which includes the obligation to generate data on the substances which they

manufacture or import, to use those data to assess the risks related to those substances and to develop and recommend appropriate risk management measures.

47 Under the terms of Article 6(1) of the REACH Regulation, that registration obligation concerns all types of substances manufactured or imported into the Community in quantities of one tonne or more per year. It also applies to substances whether or not they are classified as dangerous, except where there is an express exemption.

48 Account being taken of the finding set out in paragraph 38 of the present judgment, reacted monomers which are constituents of polymers are subject to that obligation, whereas polymers are exempted.

49 With regard to the objective of protecting human health and the environment, it must be stated from the outset that the registration of substances serves to improve information for the public and professionals down the supply chain as to the risks and that, consequently, such registration must be regarded as a means of enhancing that protection.

50 In that connection, it must be observed that, although polymers are exempted from registration for practical reasons related to their large number, that situation is liable to be reviewed in accordance with Article 138(2) of the REACH Regulation as soon as it is possible to establish a practicable and cost-efficient way of selecting polymers.

51 Thus, the obligation to register monomer substances, which are less numerous than polymers, makes information available not only on the risks specific to those substances

but also on those of monomers found as residues after polymerisation or in monomer form after the possible degradation of the polymer.

52 As the Advocate General observed in point 94 of her Opinion, where polymers are manufactured in the Community the advantages of registration of monomers is obvious, since monomer substances are used as unreacted monomers within the Community, with the result that it is necessary that the registration information be known there in order to address potential risks.

53 Furthermore, where polymers are imported into the Community, the obligation to register reacted monomers contributes, under the same conditions, to the protection of human health and the environment, since that obligation also enables better knowledge to be obtained of polymers.

54 In addition, such an obligation to register monomers satisfies the precautionary principle as referred to in Article 1(3) of the REACH Regulation.

55 The registration obligation imposed on importers leads to a more equitable attribution of the costs of registration between Community manufacturers and importers.

56 Such equality of treatment prevents distortions of competition and thereby guarantees fair competition within the Community.

57 As the Advocate General observed in point 105 of her Opinion, protecting Community producers against competitive disadvantages which might result from a different situation for importers is a permissible objective of the Community legislature.

58 It follows that the obligation to register reacted monomers in polymers is an appropriate means by which to realise the objectives of the REACH Regulation.

59 However, whether that obligation goes beyond what is necessary in order to realise those objectives remains to be determined.

60 In order to ensure genuine competition within the Community, importers of monomer substances must be subject to the same obligations as those to which manufacturers are subject or to similar obligations which lead to an adjustment of costs.

61 Any other arrangement designed to offset the absence of registration costs for importers would not necessarily be less restrictive for those importers.

62 Likewise, any limitation on the registration obligation solely to monomers produced in the Community would be contrary to the objective of competitiveness and innovation, since the importation of monomers at a lower price, without account being taken of registration costs, would discourage any Community manufacturer from starting or pursuing research on those monomers.

63 It follows that the obligation to register reacted monomer substances which are components of polymers does not go beyond that which is necessary to meet the objectives of the REACH Regulation.

64 However, the applicants in the main proceedings dispute the proportionality of that registration obligation, taking the view, first, that importers are faced with serious practical difficulties arising, in particular, from the fact that they are unaware of the composition of the imported polymer and, second, that the costs of the registration procedure are grossly disproportionate in relation to the turnover achieved and the quantities of substances concerned.

65 In that connection, it must be observed, first of all, that Article 8(1) of the REACH Regulation provides for the possibility of designating a sole representative for the manufacturer of substances on their own or contained in preparations or which produces an article imported into the Community.

66 That representative ensures compliance with all of the obligations applicable to importers, which are informed of this and are thus regarded as downstream users. The registration obligations are consequently the responsibility of the representative, who is designated by a manufacturer not established in the Community and whose trust he enjoys.

67 Second, as regards the costs generated by the registration procedure, the procedure is identical whether the products are manufactured in the Community or outside it and, consequently, the burden is not heavier for manufacturers not established in the Community or importers than it is for Community manufacturers.

68 Furthermore, as the Advocate General noted in point 130 of her Opinion, the REACH Regulation provides for a sharing of information in order to reduce the costs relating to substances between the various registrants with respect to the same substance.

69 Thus, Recital 33 in the preamble to the REACH Regulation states that '[j]oint submission and the sharing of information on substances should be provided for in order to increase the efficiency of the registration system, to reduce costs and to reduce testing on vertebrate animals'.

70 The implementation of those objectives is guaranteed by Article 27(3) of the REACH Regulation, which provides for the sharing of information in order to reduce the costs between the registrants.

71 Consequently, taking account of the limited number of potential monomer substances, the 12-year period of validity for a previous registration of substances, as provided for in Article 27 of the REACH Regulation, and the possibility of sharing information in order to reduce costs, the burden deriving from the obligation to register reacted monomer substances in polymers does not appear to be manifestly disproportionate in the light of the free movement of goods on the internal market open to fair competition.

72 It follows that Article 6(3) of the REACH Regulation is not invalid on the ground that it infringes the principle of proportionality.

Infringement of the principle of equal treatment

73 The applicants in the main proceedings claim that, although the obligation to register monomer substances is identical, Community manufacturers of polymers are in a position to register those substances more easily than are importers inasmuch as they know the composition of their products, whereas importers are, for their part, subject to the good will of their suppliers outside Community territory.

74 According to settled case-law, the principle of equal treatment or non-discrimination requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified (Case C-344/04 *IATA and ELFAA* [2006] ECR I-403, paragraph 95 and the case-law cited).

75 In that connection, it must be observed, first, that the obligation to register is identical for Community manufacturers and for importers.

76 Second, reacted monomer substances in polymers manufactured or imported into the Community are in a comparable situation since they are interchangeable or identical.

77 Third, Community manufacturers and importers are in a different situation as the former have knowledge of their products, whereas the latter are dependent on the provision of information by suppliers outside Community territory.

78 Nevertheless, the identical treatment required in those different situations is objectively justified by compliance with the competition rules applicable in the internal market.

79 If importers of reacted monomer substances were to be treated differently to manufacturers of those same substances within the Community, the former would be treated more favourably than the latter.

80 It follows that no infringement of the principle of equal treatment can be found and, therefore, that Article 6(3) of the REACH Regulation is not invalid on the ground that that principle has been infringed.

81 It follows from all of the foregoing that examination of the second question has revealed no factor of such a kind as to affect the validity of Article 6(3) of the REACH Regulation.

## Costs

82 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Grand Chamber) hereby rules:

1. **The concept of 'monomer substances' in Article 6(3) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC relates only to reacted monomers which are integrated in polymers.**

2. **Examination of the second question has revealed no factor of such a kind as to affect the validity of Article 6(3) of Regulation No 1907/2006.**

[Signatures]