

OPINION OF ADVOCATE GENERAL
KOKOTT

delivered on 10 March 2009¹

I — Introduction

1. The High Court of Justice of England and Wales asks the Court what is to be understood by the term ‘monomer substance’.

2. At first sight the reference for a preliminary ruling appears peculiar. One might have expected the question to be addressed to a chemist. However, a closer examination shows that the question can and must be answered with the tools of Community law.

3. The Court must therefore, for the first time, interpret 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 (‘the REACH Regulation’).²

II — Legal context

4. The fundamental provision for the present case is Article 5 of the REACH Regulation,

¹ — Original language: German.

² — Full title: 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; corrected version OJ 2007 L 136, p. 3). The amendments so far made to the regulation are not relevant to the present case.

which lays down the obligation to register substances:

6. Article 3(5) of the REACH Regulation defines the term polymer:

‘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.’

‘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:

5. Article 3(1) of the REACH Regulation defines the fundamental concept of a substance:

(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.

‘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’.

In the context of this definition a “monomer unit” means the reacted form of a monomer substance in a polymer’.

7. The term monomer is defined in Article 3(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’.

8. Under Article 2(9) of the REACH Regulation, Titles II and VI of the regulation — hence in particular the registration obligation in Article 5 — are not to apply to polymers.

9. That provision is explained in recital 41 in the preamble to the regulation:

‘... 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.’

10. Accordingly, Article 138(2) provides with respect to the conditions for a possible future obligation of registration for certain polymers:

‘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.’

11. Article 6(3) of the REACH Regulation, on the other hand, governs the conditions under

which monomer substances which are contained in polymers must be registered:

Affairs, the government department responsible for applying the REACH Regulation in the United Kingdom.

‘Any manufacturer or importer of a polymer shall submit a registration to the 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:

13. The proceedings are aimed at removing doubts as to the interpretation of Article 6(3) of the REACH Regulation or clarifying whether that provision should be declared invalid.

~~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);

14. The High Court therefore refers the following questions to the Court for a preliminary ruling:

~~the~~ total quantity of such monomer substance(s) or other substance(s) makes up one tonne or more per year.’

‘(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:

III — Main proceedings and questions referred

12. The proceedings in the national court were brought by undertakings which inter alia manufacture polymers or import them into the European market. The defendant is the Department for Environment, Food and Rural

(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

IV — Legal assessment

A — The reference for a preliminary ruling in the overall context of the REACH Regulation

- (c) both reacted and unreacted monomers?

16. The REACH Regulation governs the registration, evaluation, authorisation and restriction of chemicals. The first stage is registration.

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

17. In principle, all importers and manufacturers must register all the chemicals they import or manufacture and provide certain information in so doing. The extent of the information needed depends on the quantities of the substance they import or manufacture. If they do not yet have that information available, they must obtain it before registration, if necessary by having studies carried out.

15. C.H. Erbslöh KG and Lake Chemicals and Minerals Ltd (referred to together as ‘Erbslöh’ below) and S.P.C.M. SA and Hercules Incorporated (referred to together as ‘S.P.C.M.’ below), as applicants in the main proceedings, took part in the written procedure, as did the Republic of Poland, the Parliament, the Council and the Commission. All, with the exception of Poland, took part in the oral hearing on 27 January 2009.

18. That information makes it possible, first, for manufacturers, importers and downstream users to ensure, in accordance with Article 1(3) of the REACH Regulation, that they do not adversely affect human health or the environment when they manufacture substances, place them on the market and use them.

19. In addition, chemicals can be evaluated on the basis of registration and other information. The evaluation may lead to the conclusion that the Commission should restrict the substances, that is, prohibit certain uses. In certain circumstances the Commission can even prohibit any use of a substance. Use then requires authorisation.

20. The present case concerns the registration of monomers. Monomers are in a manner of speaking the building blocks of which more complex molecules known as polymers are made up. Thus polyethylene, which is what many plastic foils are made of, is a polymer. As the name itself suggests, the original substance is the usually gaseous monomer ethylene or ethene (C_2H_4). The relatively small ethene molecules are joined by polymerisation into polyethylene molecules in the form of long sequences.

21. According to the Commission, there are a few hundred monomers which can be combined into some 70 000 to 400 000 different polymers.

22. Unreacted monomers must be registered under Article 6(1) and (2) of the REACH

Regulation, as they are independent substances. Polymers, on the other hand, are excluded from the registration obligation, under Article 2(9).

23. The point at issue is whether reacted monomers in polymers have to be registered on the basis of a specific provision, Article 6(3) of the REACH Regulation, even though they are not independent substances. This primarily affects the import of polymers, since the monomers used for the manufacture of polymers outside the Community have not yet been registered.

B — The first question — interpretation of Article 6(3) of the REACH Regulation

24. Under Article 6(3) of the REACH Regulation, the manufacturer or importer of a polymer must, for monomer substances that have not already been registered by an actor up the supply chain, submit a registration dossier if the polymer consists of 2% weight by weight or more of the monomer substance in the form of monomeric units and the total quantity of the monomer substance amounts to one tonne or more a year.

25. The first question referred to the Court is intended to clarify how the term monomer substance should be understood in this connection. The answer can be deduced essentially from the wording of the relevant provisions. Additionally, however, I will also address some arguments which S.P.C.M. and Erbslöh derive from the system and objectives of the REACH Regulation.

1. The wording of the relevant provisions

26. The wording of Article 6(3)(a) of the REACH Regulation suggests that what is meant is reacted monomers in polymers, since the monomers are in principle subject to the obligation of registration if a polymer *consists* of them.

27. A polymer consists, under Article 3(5) of the REACH Regulation, essentially of a sequence of monomers bound together, the monomer units. The last sentence of Article 3(5) accordingly defines a monomer unit as the reacted form of a monomer substance in a polymer.

28. That definition is taken up by the additional phrase in Article 6(3)(a) of the REACH Regulation, ‘in the form of monomeric units and chemically bound substance (s)’. That makes clear that in that provision the

Community legislature was concerned with the reacted form of the monomer.

29. The express mention of monomeric units in Article 6(3)(a) of the REACH Regulation, on the other hand, rules out the possibility of including unreacted monomers as in variant (b) of the first question. Where they are present in the polymer as residues of the polymerisation process, they are indeed a component of the polymer under the general definition of substances in Article 3(1), but Article 6(3) relates only to reacted monomers in the form of monomeric units.

30. Erbslöh and S.P.C.M., however, regard it as contradictory to relate Article 6(3) of the REACH Regulation to reacted monomers. According to the definition in Article 3(6), monomers have not yet combined to form polymers but are merely capable of forming such compounds.

31. It is correct that, if one looks exclusively at the general definition of substances in Article 3(1) of the REACH Regulation, only unreacted monomers can be substances.

32. Article 3(1) of the REACH Regulation defines a substance as a chemical element and its compounds. Chemical substances are characterised inter alia by specific properties, such as their melting point. Monomers and polymers are therefore substances, since they are compounds of their constituent chemical elements.

33. Component groups of polymers, that is, reacted monomers, are not independent compounds, on the other hand. As Erbslöh and S.P.C.M. emphasise, they have no independent chemical properties, but the properties of the polymers of which they are components. Those component groups are thus in principle not substances within the meaning of Article 3(1) of the REACH Regulation.

34. Erbslöh and S.P.C.M. ignore the fact, however, that the REACH Regulation lays down a special rule with regard to monomer substances which diverges from the general definition of substances. The concept of a monomer unit is defined in Article 3(5) as the reacted form of a monomer substance in a polymer. From that it may be deduced that the REACH Regulation contemplates two forms of monomer substances, namely a reacted form — the monomer unit as a component of polymers — and an unreacted form — the monomer defined in Article 3(6).

35. S.P.C.M. objects that Article 6(3) of the REACH Regulation speaks of monomer substances, not monomer units. Indent (a) of that provision makes it clear, however, that monomer substances in the form of monomeric units are meant. Moreover, that provision also encompasses other substances which are to be registered as components of polymers, not in their form in accordance with the definition, i.e. unreacted, but expressly in their bound form.

36. Nor may any other conclusion be derived from the fact that some language versions, in particular the English and French versions, do not use precisely the same term in Article 6(3) (a) of the REACH Regulation as in Article 3(5). In English the terms used are '*monomer* unit' on the one hand and '*monomeric* units' on the other, and in French '*unité monomère*' and '*unités monomériques*'.

37. Those minor differences probably derive from imprecise translation during the discussions in the Council, however. The definition of polymers in Article 3(5), which also determines the concept of a monomer unit, was taken unchanged from the Commission's proposal. It was the Council, by contrast, following a suggestion by the Swedish delegation, which added the phrase 'in the form of

monomeric units and chemically bound substance(s)' in Article 6(3)(a).³ In Swedish and also in German (*Monomereinheit*), the two provisions use the same term for a monomer unit.⁴ The Swedish original version in particular is evidence that the differences in English and French do not aim at any other meaning.

38. It therefore follows from the wording of the relevant provisions in the light of their legislative history that the term 'monomer substances' in Article 6(3) of the REACH Regulation refers only to reacted monomers, that is, monomers which have reacted together in such a way that they are bound in the polymer of which they are components.

40. Erbslöh relies here on the general principle of interpretation of Community law that exceptions to general rules are to be interpreted strictly. It says that the obligation of registration for monomer substances is an exception to the exemption for polymers, and must therefore be interpreted strictly.

41. But Erbslöh overlooks the fact that the principle of the REACH Regulation is registration. The exemption for polymers is therefore itself an exception which must be interpreted strictly. If the obligation of registration for the monomers contained in polymers were an exception to the exemption, it would then have to be interpreted broadly, as a reversion to the rule.⁵

2. The system of the REACH Regulation

39. This interim conclusion, however, encounters various objections based on the system of the REACH Regulation. They focus in particular on the exception to the obligation of registration for polymers laid down in Article 2(9).

42. In fact, the obligation of registration for monomer substances in the form of monomeric units is not an exception to the exemption for polymers, but an independent component of the obligation system in the REACH Regulation. It cannot therefore be regarded as an exception to be interpreted strictly.

3 — See Council document No 13788/04 of 5 November 2004, p. 5, footnote 25.

4 — *Monomerenhet* in Swedish.

5 — See Case C-346/95 *Blasi* [1998] ECR I-481, paragraph 19, and my Opinion in Case C-428/02 *Fonden Mærzelsborg Lystbådehavn* [2005] ECR I-1527, point 16; contra, the Opinion of Advocate General Alber in Case C-446/98 *Fazenda Pública* [2000] ECR I-11435, point 71.

43. Erbslöh and S.P.C.M. further submit that an obligation of registration for reacted monomers in polymers would make the exception from the obligation of registration for polymers meaningless.

According to that provision, it suffices that an actor up the supply chain registers the monomer. But that actor may not necessarily know what polymers are being produced from his monomers. Perhaps the monomer is even used in the manufacture of a great many different polymers.

44. It might indeed be supposed that, when registering monomer substances in the form of monomeric units, that is, reacted components of polymers, information on the polymer would have to be submitted. Monomer substances in the form of monomeric units, it should be remembered, possess only the properties of the polymer in which they are bound.

47. However, the Commission's submissions give rise to at least some beginnings of the registration of the properties of polymers. If monomer substances are manufactured or imported in quantities of 10 tonnes or more a year, a chemical safety report must be submitted on registration, under Article 14(1) of and Annex I to the REACH Regulation. That report must, according to the Commission, include the life cycle of the polymer produced.

45. Understood in that way, Article 6(3) of the REACH Regulation would indeed — as argued by Erbslöh and S.P.C.M. — be in conflict with Article 2(9). Practically every polymer marketed in Europe would have to be registered indirectly via its monomer substances.

46. Article 6(3) of the REACH Regulation makes it clear, however, that it is not the properties of the polymers which are to be registered but — as the Commission considers — the properties of the monomers.

48. That position leads in the direction of depriving the exemption of polymers of its meaning. It is not convincing, however, because the life cycle of the monomer ends at the moment when it reacts into a polymer. Under point 0.3. of Annex I to the REACH Regulation, the life cycle of a substance covers its manufacture and identified uses. A polymer is not a use but a separate substance within the meaning of the definition of a substance in Article 3(1) of the REACH Regulation. It therefore has a life cycle of its own.

49. The information on the use of the monomer therefore extends to the circumstance that it is used for the manufacture of certain polymers, but not to the properties of those polymers. Where the monomer has already been registered by an actor up the supply chain who is not aware of its use for the manufacture of that polymer, that use must be notified by the downstream manufacturer in accordance with Articles 37 and 38 of the REACH Regulation.

50. The obligation to register reacted monomers in polymers does not therefore render the exemption of polymers meaningless. The obligation to register monomer substances does not correspond to an indirect obligation to register polymers.

51. For that reason alone, the argument of Erbslöh and S.P.C.M. that small risks proceed from polymers does not contradict the above interpretation of Article 6(3) of the REACH Regulation. The risks of polymers are of no direct importance for the registration of monomer substances. Moreover, the Commission rightly emphasises that the obligation of registration does not presuppose a particular risk but is intended to identify risks.

52. The obligation of registration for monomer substances contained in polymers does not therefore conflict with other provisions of the REACH Regulation.

3. The objectives of the REACH Regulation

53. Finally, the objectives of the REACH Regulation are put forward as an argument against the obligation of registration for monomers contained in polymers.

54. There are two strands of argument. On the one hand, stress is laid on the exemption of polymers, which is said to be undermined by an obligation to register monomers. However, it has already been shown that this is not the case.

55. On the other hand, it is questioned whether the obligation to register monomers serves the general objectives of the REACH Regulation. In accordance with Article 1(1) of the REACH Regulation, its purpose is to ensure a high level of protection of human health and the environment, including the

promotion of alternative methods for the assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

56. No conflict with those objectives can be seen. Nor are there any indications that those objectives could require a different interpretation of Article 6(3) of the REACH Regulation.

57. Whether the obligation to register monomers may be allocated to those aims is of interest, on the other hand, especially for the second question referred, in particular in so far as that question concerns the compatibility of Article 6(3) of the REACH Regulation with the principle of proportionality. This should therefore be examined in connection with the second question.

4. Interim conclusion

58. The answer to the first question is therefore that the term ‘monomer substances’ in Article 6(3) of the REACH Regulation refers only to reacted monomers, that is, monomers which have reacted together in such a way that they are bound in the polymers of which they are components.

C — The second question — validity of Article 6(3) of the REACH Regulation

59. By its second question the referring court seeks to know whether the application of Article 6(3) of the REACH Regulation to manufacturers or importers of polymers is unlawful because the provision is irrational, discriminatory or disproportionate. It must therefore be considered whether that provision is valid.

1. Preliminary observation on the duty to state reasons

60. Erbslöh and S.P.C.M. complain of the inadequate reasons stated for Article 6(3) of the REACH Regulation.

61. The order for reference does not raise the question of the statement of reasons, but the Court has repeatedly held in connection with direct actions against individual decisions that an inadequate statement of reasons, in breach of Article 253 EC, constitutes an infringement of an essential formal requirement within the meaning of Article 230 EC⁶ and is moreover a

⁶ — See, for instance, Case 158/80 *Rewe-Handelsgesellschaft Nord and Rewe-Markt Steffen* [1981] ECR 1805, paragraphs 25 to 27; Case 45/86 *Commission v Council* [1987] ECR I 493, paragraph 9; and Case C-390/06 *Nuova Agricast* [2008] ECR I-0000, paragraphs 79 to 86.

matter which the Community judicature can and must examine of its own motion.⁷ The lack of a statement of reasons, or a manifestly inadequate statement of reasons, cannot (in principle) be cured by the fact that the person concerned learns of the reasons for the measure during the procedure before the Community judicature.⁸ That is because the statement of reasons for an adverse decision must enable the court to exercise its power of review and must provide the person concerned with the information necessary to ascertain whether the decision is well founded and whether it is worth bringing legal proceedings.⁹ It is therefore an indispensable condition of the judicial review of a measure.

review. According to the case-law, however, it is not necessary for all relevant factual and legal aspects to be mentioned in the reasons given for the measure. The question whether the statement of the reasons for a measure meets the requirements of Article 253 EC must be assessed with regard not only to its wording but also to its context and to all the legal rules governing the matter in question. In particular, if the contested measure clearly discloses the essential objective pursued by the Community institution, it would be excessive to require a specific statement of reasons for the various technical choices made.¹⁰

62. The statement of reasons required by Article 253 EC must, according to settled case-law, be appropriate to the nature of the measure concerned. It must disclose in a clear and unequivocal fashion the reasoning followed by the Community institution which adopted the measure in such a way as to make the persons concerned aware of the reasons for the measure. That is a precondition for them to be able to assert their rights and for the Court to exercise its power of

63. It is true that no specific reasons are stated for the obligation of registration for monomers contained in polymers, but that provision is a technical choice which does not require a specific statement of reasons. As will be shown below, in particular with reference to the principle of proportionality, that provision can be attributed to the general reasons for the REACH Regulation. The attribution of a specific technical provision to the general reasons does not necessarily have to be spelt out expressly in the statement of reasons for a general measure. It can in appropriate cases be established by subsequent explanations.

64. Consequently, no infringement of the obligation to state reasons can be found.

7 — Case C-166/95 P *Commission v Daffix* [1997] ECR I-983, paragraph 24, and Case C-413/06 P *Bertelsmann and Sony Corporation of America v Impala* [2008] ECR I-0000, paragraph 174.

8 — Case 195/80 *Michel v Parliament* [1981] ECR 2861, paragraph 22; Case C-351/98 *Spain v Commission* [2002] ECR I-8031, paragraph 84; Case C-353/01 P *Mattila v Council and Commission* [2004] ECR I-1073, paragraph 32; Joined Cases C-199/01 P and C-200/01 P *IPK-München v Commission* [2004] ECR I-4627, paragraph 66; Joined Cases C-189/02 P, C-202/02 P, C-205/02 P to C-208/02 P and C-213/02 P *Dansk Rørindustri and Others v Commission* [2005] ECR I-5425, paragraph 463; Case T-228/02 *Organisation des Modjahedines du peuple d'Iran v Council* [2006] ECR II-4665, paragraph 139; and Case T-256/07 *People's Mojahedin Organization of Iran v Council* [2008] ECR II-0000, paragraph 182.

9 — *Daffix*, cited in footnote 7, paragraph 23.

10 — Joined Cases C-27/00 and C-122/00 *Omega Air and Others* [2002] ECR I-2569, paragraphs 46 and 47.

2. The complaint of irrationality

65. The national court asks whether Article 6(3) of the REACH Regulation is invalid because it is irrational. It is not usual to examine Community law as to whether or not it is logical, but the submissions of the parties show that what is primarily concerned is the principle of legal certainty, in the form of the requirement that the law is clearly defined.

66. Erbslöh and S.P.C.M. submit that the lack of logic results from the contradiction with the exemption for polymers. A genuine contradiction between two provisions of equal rank could indeed cast doubt on their validity, if it could not be resolved by interpretation or by principles of the conflict of rules (e.g. *lex posterior* or *lex specialis*). In such a case it could not be ascertained which rule had to be applied. Such a contradiction would infringe the principle of legal certainty. That fundamental principle of Community law requires rules to be clear and precise, so that the persons concerned are able to ascertain unequivocally what their rights and obligations are and take steps accordingly.¹¹ However, it has already been shown that the obligation of registration for monomers

reacted in polymers and the exemption of polymers do not contradict each other.¹²

67. Article 6(3) of the REACH Regulation is not therefore irrational in the sense of being a contradictory provision.

3. The principle of proportionality

68. The principle of proportionality is one of the general principles of Community law which the Community legislature must observe.¹³ The acts of the Community institutions may not therefore exceed the bounds of what is appropriate and necessary to attain the objectives legitimately pursued by the legislation in question. When there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued.¹⁴

11 — Case 169/80 *Gondrand and Garancini* [1981] ECR 1931, paragraph 17; Case C-143/93 *Van Es Douane Agenten* [1996] ECR I-431, paragraph 27; Case C-110/03 *Belgium v Commission* [2005] ECR I-2801, paragraph 30; and Case C-344/04 *IATA and ELFAA* [2006] ECR I-403, paragraph 68. See also my Opinion in Case C-299/05 *Commission v Parliament and Council* [2007] ECR I-8695, point 55.

12 — See above, point 43 et seq.

13 — Case 25/70 *Köster, Berodt & Co.* [1970] ECR 1161, paragraphs 21 and 22; Case 137/85 *Maizena and Others* [1987] ECR 4587, paragraph 15; Case C-331/88 *Fedesa and Others* [1990] ECR I-4023, paragraph 13; *IATA and ELFAA*, cited in footnote 11, paragraph 79; Case C-310/04 *Spain v Council* [2006] ECR I-7285, paragraph 97; and Joined Cases C-37/06 and C-58/06 *Viamex Agrar Handel* [2008] ECR I-69, paragraph 33.

14 — See, to that effect, *Koster, Berodt & Co.*, paragraphs 28 and 32, *Fedesa and Others*, paragraph 13, and *Viamex Agrar Handel*, paragraph 35, all cited in footnote 13; Case 265/87 *Schröder HS Kraftfutter* [1989] ECR 2237, paragraph 21; and Case C-189/01 *Jippes and Others* [2001] ECR I-5689, paragraph 81.

a) Burden of proof and criterion of assessment

69. According to Erbslöh, the Community legislature must prove that measures of health and environment protection which restrict competition are proportionate. That view is based on the case-law on Articles 28 EC and 30 EC, which, however, is not transferable — as far as the burden of proof is concerned — to the principle of proportionality.

70. If a Member State makes use of an exception to the general rule in Article 28 EC — the free movement of goods — it must indeed prove that the conditions of that exception are met.¹⁵ On the other hand, there is in principle a presumption of the lawfulness of Community law.¹⁶ That presumption implies that the burden of proving unlawfulness rests on the person casting doubt on the validity of a Community measure.¹⁷

71. As in many other areas of legislation, so also in the case of the REACH Regulation, observance of the principle of proportionality

is not subject to any further strict judicial review. Rather, the Community legislature enjoys a wide margin of assessment and action ('discretion') when it makes complex technical and/or political choices.¹⁸ In the case of the REACH Regulation, a difficult compromise had to be reached between environment and health policy objectives on the one hand and economic interests on the other.

72. When reviewing the exercise of such a power, the court may not substitute its own assessment for that of the Community legislature, and must confine itself to examining whether the legislature's assessment contains a manifest error or constitutes a misuse of powers or whether the legislature clearly exceeded the bounds of its discretion.¹⁹

73. What this means in terms of the examination of proportionality is not always clear in the case-law. Some judgments state that the lawfulness of a measure adopted by the legislature can be affected only if it is manifestly inappropriate in relation to the objective which the competent institution

15 — Case 251/78 *Denkavit* [1979] ECR 3369, paragraph 24, and Case C-128/89 *Commission v Italy* [1990] ECR I-3239, paragraph 23.

16 — Case 101/78 *Granaria* [1979] ECR 623, paragraph 4; Case C-137/92 P *Commission v BASF and Others* [1994] ECR I-2555, paragraph 48; Case C-475/01 *Commission v Greece* [2004] ECR I-8923, paragraph 18; and Case C-199/06 *Centre d'exportation du livre français* [2008] ECR I-469, paragraph 59.

17 — Joined Cases T-110/03, T-150/03 and T-405/03 *Sison v Council* [2005] ECR II-1429, paragraph 98; see also Kokott, J., 'Die Durchsetzung der Normenhierarchie im Gemeinschaftsrecht', in Müller, G. and others, *Festschrift für Günter Hirsch zum 65. Geburtstag*, C.H. Beck, 2008, p. 122 et seq.

18 — Case C-380/03 *Germany v Parliament and Council* [2006] ECR I-11573, paragraph 145. On environment policy, see in this respect Case C-284/95 *Safety Hi-Tech* [1998] ECR I-4301, paragraph 37, and Case C-86/03 *Greece v Commission* [2005] ECR I-10979, paragraph 88. See also Kokott, cited in footnote 17, p. 124 et seq.

19 — Joined Cases C-248/95 and C-249/95 *SAM Schiffahrt and Stapf* [1997] ECR I-4475, paragraph 24, and *Omega Air and Others*, cited in footnote 10, paragraph 64.

seeks to pursue.²⁰ In some cases it is even expressly stated that what matters is not whether the measure adopted by the legislature was the only one or the best one possible but whether it was manifestly inappropriate.²¹

74. Those statements are liable to be misunderstood, however. If there are clearly less oppressive measures available which are equally effective, or if the measures adopted are obviously out of proportion to the aims pursued, the persons affected must be given judicial protection. Otherwise the principle of proportionality, which is part of primary law, would be deprived of its practical effect.

75. Accordingly, in many judgments the Court also examines in particular whether there are obviously less intrusive measures²²

or even whether the burdens are proportionate to the aims pursued.²³

76. Under what conditions a measure is clearly incompatible with the principle of proportionality has not yet been explicitly defined by the Court. The decisive criterion must ultimately be the consideration that the Community judicature must in principle not substitute its own assessment of difficult questions for the legislature's assessment.

77. Such an assessment by the Community legislature can as a rule be called in question only if no reasonable basis can be discerned.²⁴ In this connection review by the Community judicature extends also to verifying whether all the relevant facts which should have been considered in assessing a complex situation were considered when the decision was taken, and whether they are capable of supporting the conclusions drawn from them.²⁵

20 — See, on agricultural policy, *Schröder HS Kraftfutter*, cited in footnote 14, paragraph 22; *Fedesa and Others*, cited in footnote 13, paragraph 14; *Jippes and Others*, cited in footnote 14, paragraph 82; and *Viamex Agrar Handel*, cited in footnote 13, paragraph 36; and, on harmonisation in the internal market, Case C-434/02 *Arnold André* [2004] ECR I-11825, paragraph 46; Case C-210/03 *Swedish Match* [2004] ECR I-11893, paragraph 48; and Joined Cases C-154/04 and C-155/04 *Alliance for Natural Health and Others* [2005] ECR I-6451, paragraph 52.

21 — *Jippes and Others*, cited in footnote 14, paragraph 83, and *Viamex Agrar Handel*, cited in footnote 13, paragraph 36.

22 — Case C-280/93 *Germany v Council* [1994] ECR I-4973, paragraph 94 et seq.; Case C-84/94 *United Kingdom v Council* [1996] ECR I-5755, paragraph 58 et seq.; Case C-233/94 *Germany v Parliament and Council* [1997] ECR I-2405, paragraph 54 et seq.; Case C-17/98 *Emesa Sugar* [2000] ECR I-675, paragraph 53 et seq.; Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco* [2002] ECR I-11453, paragraphs 123, 126, 128 et seq., 132, 139 and 140; Joined Cases C-453/03, C-11/04, C-12/04 and C-194/04 *ABNA and Others* [2005] ECR I-10423, paragraphs 69 and 83; and *IATA and ELFAA*, cited in footnote 11, paragraph 87. See also Case C-127/07 *Arcelor Atlantique et Lorraine and Others* [2008] ECR I-0000, paragraph 59, on the examination of the principle of proportionality in connection with the justification of different treatment.

23 — *IATA and ELFAA*, cited in footnote 11, paragraphs 88 and 89.

24 — Compare *Omega Air and Others*, cited in footnote 10, paragraph 72, and my Opinion in Case C-525/04 P *Spain v Lenzing* [2007] ECR I-9947, paragraph 71.

25 — See, on decisions of the Commission relating to competition and the environment, Case C-12/03 P *Commission v Tetra Laval* [2005] ECR I-987, paragraph 39; Case C-326/05 P *Industrias Químicas del Vallés v Commission* [2007] ECR I-6557, paragraph 77; *Spain v Lenzing*, cited in footnote 24, paragraph 57; *Bertelsmann*, cited in footnote 7, paragraph 145; and Case C-405/07 P *Netherlands v Commission* [2008] ECR I-0000, paragraph 55.

78. In this light it must be examined whether the obligation of registration for monomers is a proportionate means for achieving a legitimate aim.

inter alia to ensure a high level of protection of human health and the environment. That corresponds to the requirements of Articles 95(3) EC, 152(1) EC and 174(1) and (2) EC.

b) Objectives of the measure and its appropriateness

79. The institutions submit that the measure pursues two objectives. First, the environment and health are to be protected, since the registration of monomers makes it possible to counter certain risks associated with polymers. Second, the obligation of registration for monomers is intended to create equality of competition on the European market for polymers.

81. In accordance with the first indent of Article 174(3) EC, the Community, in preparing its policy on the environment, is to take account inter alia of the available scientific and technical data. Where the existence or the extent of risks to human health is uncertain despite that information, the institutions, applying the precautionary principle laid down in Article 174(2) EC, may take protective measures without having to wait until the reality and seriousness of those risks become clear.²⁶

Environmental and health risks

82. As the Parliament and the Council in particular stress, the registration of substances serves precisely to improve knowledge of the risks associated with them. It is thus by its very nature an instrument for putting into practice an effective policy for the protection of the environment and health.

80. The REACH Regulation, according to Article 1 and recital 1 in the preamble, aims

²⁶ — Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, paragraph 63; Case C-504/04 *Agrarproduktion Staebelow* [2006] ECR I-679, paragraph 39; and Case C-219/07 *Nationale Raad van Dierenkwekers en Liefhebbers and Andibel* [2008] ECR I-0000, paragraph 38.

83. The parties are at odds over the question whether and to what extent risks to health and the environment are associated with polymers.²⁷ Since, however, not polymers but only the monomers used to produce them have to be registered, the only risks that can be relevant are those which can be assessed better as a result of that registration.

recital 41 in its preamble. These state that 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. The Commission and the Council submit that the registration of monomers is necessary to perform that task.

84. In this respect, it follows from the scientific studies submitted by S.P.C.M. and Erbslöh, which are not in principle doubted by the institutions, that information about the monomers used does not necessarily enable conclusions to be drawn as to the properties and risks of the polymers produced. It is acknowledged that monomer substances are usually stable in polymers and basically do not contain their own separate risks.

86. The Commission in particular develops that submission to the effect that, in connection with registration, a safety report must cover also the life cycle of the polymer manufactured from the monomer. However, this argument is not convincing.

85. The institutions' core argument for a connection between the registration of monomers and the risks of polymers are Article 138(2) of the REACH Regulation and

27 — That certain polymers can be hazardous is not in dispute. The Commission refers to Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products (OJ 2007 L 325, p. 3), in which various polymers are recognised as effective biocides. Article 12 of Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ, English Special Edition 1967, p. 234), introduced by Council Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC (OJ 1992 L 154, p. 1), and Commission Directive 93/105/EC of 25 November 1993 laying down Annex VII D, containing information required for the technical dossier referred to in Article 12 of the seventh amendment of Council Directive 67/548/EEC (OJ 1993 L 294, p. 21) also show that the legislature has in the past regarded polymers as sufficiently hazardous to require notification.

87. It has already been shown that the safety report for a monomer substance does not deal with the risks emanating from a polymer manufactured from the monomer.²⁸ That would indeed devalue the exemption for polymers and exaggerate the concept of the life cycle of a chemical substance. The safety report therefore includes only the identification of the polymer which is manufactured from the monomer.

28 — See above, point 47 et seq.

88. The Commission, however, referring to expert evidence put before the High Court,²⁹ mentions two specific risks of polymers that are linked to the monomers used for their manufacture.

89. First, not all properties of a monomer are necessarily lost on polymerisation. The loss of properties depends rather on which functional groups of the monomer molecule have taken part in the chemical reaction. Functional groups which continue to exist could give the polymer properties of the monomer.

90. Whether monomer properties continue obviously depends on the chemical reaction involved, that is, on the polymer produced. In so far as the registration of monomers includes an identification of the polymer produced³⁰ and the chemical nomenclature indicates the structure of the polymer molecule in question,³¹ it allows conclusions to be drawn as to continuing properties of the monomer. To that extent the registration of monomers used is appropriate for countering that risk of a polymer.

91. The obligation to register reacted monomer substances which the importer imports in quantities from 1 to 10 tonnes is of no use for that purpose, however. A clear identification of the polymer produced is — so far as I can see — necessary only if a safety report has to be produced under Article 14 of the REACH Regulation. But that presupposes that more than 10 tonnes a year of the substance in question are imported, whereas the registration obligation for reacted monomers already applies from a quantity of over one tonne. Without a definite chemical identification of the polymer, reliable statements on continuing monomer properties are not possible.

92. Second, under certain conditions polymers may degrade. The Commission explicitly acknowledges, however, that polymers very rarely release the monomers they contain when they degrade. Whether and under what conditions a polymer degrades clearly depends above all on the polymer in question. To what extent the monomers contained in a polymer are relevant to degradation of this kind is not apparent. No sufficient connection has therefore been demonstrated between registration of monomers and the risk of degradation of the polymer into the monomers used.

93. In addition, the obligation to register monomers reacted in polymers could serve to counter the risks which proceed from

29 — Statement of Gary Dougherty, Annex 4 to the order for reference.

30 — See above, point 47 et seq.

31 — See Leigh, G.J. and others, *Principles of Chemical Nomenclature, A Guide to IUPAC Recommendations*, Blackwell Science, 1998, p. 104 et seq. (http://old.iupac.org/publications/books/principles/principles_of_nomenclature.pdf). Precisely in the case of polymers, however, a definite nomenclature appears to create considerable difficulties.

unreacted monomers. It is not disputed that risks to the environment and health are associated with unreacted monomers. Monomers are relatively small, highly reactive molecules, which can thus have harmful effects.

94. In the case of the manufacture of polymers in the Community, the advantages of registration of the monomers contained are self-evident. The monomer substances are used as unreacted monomers within the Community and the registration information must therefore be known there, so that any risks can be controlled. However, Article 6(3) of the REACH Regulation is probably only of subordinate importance for those monomers, since they must also be registered under Article 6(1) and (2) when manufactured or imported, regardless of their use for the manufacture of polymers. Erbslöh and S.P.C.M. therefore raise no specific objections in this respect.

95. Those two parties stress, however, that the situation is quite different in the case of the import of polymers. In that case monomers are used only outside the Community. The Community in principle comes into contact with monomer substances only in the form of reacted monomer units of polymers.

96. The registration of monomer substances which are reacted in imported polymers contributes to the protection of the environment and health in the Community only to the extent described above.

97. There are also, however, risks which proceed from unreacted monomer residues. It is not disputed that impurities in polymers can derive from such residues and that those monomers can come into contact with the environment when the polymer is used.

98. The Commission emphasises this risk in its observations, and put it forward before the Committee on Technical Barriers to Trade of the WTO as a reason for registration of reacted monomers.³²

99. Registration of monomers reacted in polymers can indeed provide indications of the risk of monomer residues. The types of

32 — See the minutes G/TBT/M/41 of 12 June 2008 of the meeting of the WTO Committee on Technical Barriers to Trade of 21 March 2007, point 40.

monomers used for the manufacture of the polymer are presumably the ones which also occur as residues. The types of monomers used possibly also allow conclusions as to the likeliness of residues.

the Community market in polymers if at least the importers have to register the starting substances.

100. The obligation of registration would therefore be appropriate for controlling the risk caused by monomer impurities.

103. The obligation of registration for importers also leads to a fairer distribution of registration costs among the various undertakings which manufacture the polymer in question in the Community or import it into the Community. The REACH Regulation contains provisions intended to divide up among applicants the costs of the studies needed for a registration. Such a division of the costs corresponds to the responsibility and the benefits associated with the marketing of a polymer. It is therefore a realisation of the polluter-pays principle, which in turn is an aspect of the principle of proportionality.³³

Equality of competition

101. The Council emphasises, as Poland also does, that the registration of reacted monomer substances promotes fair competition between Community manufacturers and importers of polymers.

102. The prices of Community polymers as a rule include a proportion of the costs of registration of the monomers used. That is to say, it may be presumed that those monomers have already been registered as independent substances on their manufacture or import. Outside the Community, on the other hand, polymers can be produced without the starting substances having to be registered. This distortion of competition is prevented on

104. Creation of fair competition may be attributed to the objective of enhancing competitiveness mentioned in Article 1(1) of the REACH Regulation.³⁴ Furthermore, equal

³³ — See on this point my Opinion in Case C-188/07 *Commune de Mesquer* [2008] ECR I-0000, point 120.

³⁴ — Aligning the obligation of registration with equality of competition is also not unknown to the REACH Regulation. Although a single registration per substance would be enough to protect the environment and health, *every* manufacturer and *every* importer must register the substance.

treatment of importers and manufacturers is an express aim of the REACH Regulation, as stated in recital 3:

106. Article 6(3) of the REACH Regulation is thus not manifestly inappropriate for attaining the legitimate aim of equality of competition.

‘That legislation should be applied in a non-discriminatory manner whether substances are traded on the internal market or internationally in accordance with the Community’s international commitments.’

Interim conclusion

105. Protection of Community producers against competitive disadvantages is in principle a permissible objective of the Community legislature.³⁵ It may be left open whether that objective leads to problems in the context of the World Trade Organisation. The provision under examination has indeed been discussed repeatedly in the Committee on Technical Barriers to Trade.³⁶ Compatibility with rules of the World Trade Organisation is not the subject of the present proceedings, however. Moreover, the Court does not measure Community law by that criterion.³⁷

107. The obligation of registration for monomers reacted in polymers is appropriate for three legitimate aims. It is appropriate for countering environmental and health risks that result from impurities in polymers caused by monomer residues. It can also be of use, in some cases, for evaluating risks caused by the continued existence of monomer properties in polymers. Registration further contributes to fair competition between Community manufacturers and importers of polymers.

c) Necessity of the obligation of registration

35 — See, for example, Case 232/86 *Nicolet Instrument* [1987] ECR 5025; Case C-353/92 *Greece v Council* [1994] ECR I-3411, paragraph 50; *Germany v Council*, cited in footnote 22, paragraph 92; and Case C-342/03 *Spain v Council* [2005] ECR I-1975, paragraph 18.

36 — See in particular the minutes G/TBT/M/44 of 10 June 2008 of the meeting of 20 March 2008, points 119 and 120 (USA) and point 140 (Japan), and G/TBT/M/45 of 9 September 2008 on the meeting of 1 and 2 July 2008, point 36 (Brazil).

37 — Case C-149/96 *Portugal v Council* [1999] ECR I-8395, paragraph 47; Case C-377/02 *Van Parrys* [2005] ECR I-1465, paragraph 39; and Joined Cases C-120/06 P and C-121/06 P *FIAMM and FIAMM Technologies v Council and Commission* [2008] ECR I-0000, paragraph 111.

108. It must be examined whether the obligation of registration for reacted monomers in polymers is necessary in order to attain the objectives that I have just mentioned.

109. As regards the objectives of protection of the environment and health, there are indeed doubts as to the necessity of the obligation of registration.

110. The utility of comprehensive information on monomers for the evaluation of risks arising from the continued existence of monomer properties in polymers appears very limited. There is much to suggest that a duty to provide information about the polymer, restricted in extent but targeted, would be less burdensome and at least as effective.

111. For evaluating the risks of monomer residues, on the other hand, information on the monomer is undoubtedly relevant. It cannot be ruled out, however, that with reference to this risk an obligation of registration that focused on monomer impurities as such would be enough.

112. Erbslöh and S.P.C.M. propose, on those lines, that Article 6(3) of the REACH Regulation should be interpreted in such a way that only the unreacted monomer residues are to be registered. However, a restriction to unreacted monomers or monomer residues would in all probability largely deprive Article 6(3) of the REACH Regulation of its practical effect. It seems improbable that many polymers contain 2% or more by

weight of monomer residues. A product that was so impure would scarcely meet the requirements of the user of the polymer.

113. A corresponding registration obligation would instead have to be linked to actually occurring impurities. Erbslöh submitted at the hearing, without being contradicted, that such impurities could be identified without great difficulty by means of vacuum distillation and gas chromatography.

114. In the end, however, it may be left open whether those doubts are effective or could perhaps be laid to rest by further submissions from the institutions, taking account of the legislature's margin of discretion, pursuant to the precautionary principle.

115. That is because the obligation of registration is undoubtedly necessary in order to achieve the objective of equality of competition.

116. It is admittedly conceivable that measures to protect the competitive position of Community manufacturers could be

limited to the markets in which they actually operate. The registration obligation for the monomers used would then take effect only in the case of polymers that were also produced in the Community.³⁸ Potential competition would not, however, be protected as effectively. New Community production of polymers can only be taken up once the monomers used have been registered. A new Community producer, with no income as yet from his own production, would have to invest resources in the registration of monomers, while external competitors could still (at first) supply polymers to the Community without such costs.

117. Nor does a levy on imported polymers, in order to compensate on a flat-rate basis for the costs saved by not registering the monomers used, appear to be an equally effective, less burdensome means.

118. The provision is thus necessary, at least in relation to the objective of equality of competition between manufacturers in the Community and in non-member countries.

38 — See *Nicolet Instrument*, cited in footnote 35, on a customs exemption which takes effect only if no Community production is affected.

d) Proportionality of the obligation of registration

119. Finally, the question arises whether the disadvantages for the import of polymers caused by the obligation of registration are proportionate to the objectives pursued.

120. According to Erbslöh and S.P.C.M., importers are faced with great difficulties in practice. It is unlikely that the monomers will already have been registered by undertakings further up the supply chain, the manufacturers of the monomers or polymers. Those manufacturers are not as a rule subject to registration as Community manufacturers, and might perhaps also have no interest in registering the monomer substances through an only representative.

121. They submit that importers, on the other hand, often do not know which monomer substances are bound in the polymers they import. Their suppliers regularly treat that information as a business secret. Effective methods of analysis for identifying the reacted monomer substances do not exist.

122. The Commission does not contradict those submissions. It argues correctly, however, that that problem is solved by the market. If suppliers of polymers wish to sell them on the European market, they will make it possible to register the monomer substances or — preserving their business secrets — register them themselves with the assistance of an only representative. Otherwise they will have to do without that market. Importers and any users of the polymers can influence that decision by the prices they are prepared to pay.

123. Erbslöh fears an additional complication on the basis of doubts as to whether the registration of monomers by external producers in fact releases the importer from the obligation of registration, but these doubts are not convincing.

124. The institutions state that suppliers of polymers outside the Community can, under Article 8 of the REACH Regulation, appoint an only representative who registers monomers instead of the importer. Erbslöh doubts that such registration would be done by an actor up the supply chain within the meaning of Article 6(3), as the only representative is not a previous actor and the actor outside the Community is not obliged to register.

125. The appointment of an only representative presupposes, however, that a registration by him frees the downstream members of the supply chain from registration obligations.

Otherwise it would make no sense. Accordingly, Article 8 of the REACH Regulation expressly lays down that the only representative fulfils the importer's obligations. A registration by him must consequently also have the effect of releasing the importer from his obligations under Article 6(3) of the REACH Regulation.

126. Moreover, calling on other members of the supply chain is a basic feature of the REACH Regulation. For other chemicals as well, registration requires information to be obtained from other undertakings. Registration must deal with the risks that are linked to identified uses of the substance. Information on those uses and risks can often be provided only by the purchasers of the substances. If they do not take part in the registration, they may sometimes themselves have to procure information on the risks of their use of the substance (see Article 37 et seq. of the REACH Regulation).

127. Even if the registration of monomers were impossible in practice in certain cases,

the *Guidance for monomers and polymers* of the European Chemicals Agency³⁹ indicates a way of nevertheless marketing the polymer: treating it as a substance of unknown or variable composition, a complex reaction product or biological material. In that case the polymer could exceptionally be registered itself as an expedient.⁴⁰

least partly, be divided up between the various applicants for registration of the same substance. Since a limited number of monomer substances can be combined to make a very great number of polymers,⁴¹ it is to be expected that registration of the same monomer substances will be applied for by various manufacturers and importers. By using the coordination procedures of the REACH Regulation, they can divide the costs among themselves.

128. A further objection is based on the costs of registration. According to Erbslöh and S.P. C.M., the costs are clearly disproportionate to turnover, especially of the undertaking Lake, and to the quantities of substances concerned.

129. In principle, however, these costs affect all users of chemicals. It is a fundamental structural element of the REACH Regulation that such a burden is to be accepted. If a substance is no longer in demand on the market as a result of the costs of registration, that must in principle be accepted.

131. The burden caused by the obligation to register monomer substances reacted in polymers thus largely corresponds to the general burdens associated with REACH. It is counterbalanced in particular by the aim of ensuring fair competition between Community manufacturers of polymers and manufacturers in non-member countries. That relationship is not obviously unbalanced.

130. Moreover, under the REACH Regulation the costs of the necessary studies can, at

132. There is therefore no breach of the principle of proportionality.

39 — As at May 2008, http://guidance.echa.europa.eu/docs/guidance_document/polymers_en.pdf.

40 — *Guidance*, p. 9.

41 — See above, point 21.

4. The principle of equal treatment or non-discrimination

133. It must be examined, in conclusion, whether Article 6(3) of the REACH Regulation leads to unlawful discrimination. This part of the second question referred is aimed at compatibility with the principle of equal treatment or non-discrimination. That principle requires that similar situations are not treated differently and different situations not treated in the same way, unless such treatment is objectively justified.⁴²

134. A difference in treatment is justified if it is based on an objective and reasonable criterion, that is, if the difference relates to a legally permitted aim pursued by the legislation in question, and it is proportionate to the aim pursued by the treatment.⁴³ The provision concerned must therefore be proportionate to the differences and similarities of the particular situation.⁴⁴

135. As with the principle of proportionality, however, so also when considering the prohibition of discrimination, it must be noted that the Community legislature enjoys a margin of discretion.⁴⁵ It is obliged, however, to base its decision on objective criteria that are appropriate to the aim pursued by the legislation in question, and to take into account all the facts and the technical and scientific data available at the time of adoption of the act in question.⁴⁶ In addition to the principal objective of the legislation, it must also take account of all the interests involved.⁴⁷

136. Erbslöh and S.P.C.M. object that importers and Community manufacturers of polymers are indeed subject to the same obligation, but this places a much heavier burden on importers.

137. Community manufacturers of polymers can apply to register the monomer substances used much more easily than importers of polymers. Manufacturers know which monomers are used and can thus register them.

42 — *IATA and ELFAA*, cited in footnote 11, paragraph 95; Case C-300/04 *Eman and Sevinger* [2006] ECR I-8055, paragraph 57; and Case C-227/04 P *Lindorfer v Council* [2007] ECR I-6767, paragraph 63.

43 — *Arcelor Atlantique et Lorraine and Others*, cited in footnote 22, paragraph 47.

44 — See the Opinion of Advocate General Poiras Maduro in Case C-524/06 *Huber* [2008] ECR I-0000, point 7, and my Opinion in Case C-540/03 *Parliament v Council* [2006] ECR I-5769, point 107 with further references.

45 — See above, point 69. On the taking into account of discretion in relation to the prohibition of discrimination, see Case C-292/97 *Karlsson and Others* [2000] ECR I-2737, paragraphs 35 and 49; *Lindorfer*, cited in footnote 42, paragraph 78; and *Arcelor Atlantique et Lorraine*, cited in footnote 22, paragraph 57.

46 — *Arcelor Atlantique et Lorraine*, cited in footnote 22, paragraph 58.

47 — *Arcelor Atlantique et Lorraine*, cited in footnote 22, paragraph 59.

138. Importers, on the other hand, need the support of the external suppliers before they can take steps to register. Erbslöh and S.P.C. M. are afraid that the suppliers will neither provide the importers with the necessary information on the monomer substances used, nor themselves register those monomer substances via an only representative.

139. However, that dependency of the importers is a necessary consequence of the lack of Community competence to impose binding obligations on undertakings in non-member countries.

140. The obligation of registration crystallises in the person of the importer. It is, however, directed at his suppliers. They are comparable in principle with Community manufacturers. Moreover, imported polymers are not in principle different from polymers manufactured in the Community. Similar situations are thus treated in the same way.

141. In view of the objective stated above of the obligation of registration, namely to create equality of competition, there is justification for imposing similar requirements on those similar situations. Producers in non-member countries are free to accept those burdens or to do without the Community market.

142. A comparison between importers and Community producers admittedly leads to the conclusion that they are not affected equally, but they are not in a similar situation either. Importers are covered solely as the only available representatives of the external producers — at least as long as those producers do not appoint an only representative within the meaning of Article 8 of the REACH Regulation. That they are affected differently by the obligation of registration corresponds to that difference from the position of a producer.

143. There is therefore no infringement of the principle of equal treatment.

V — Conclusion

144. I therefore propose that the Court give the following answer to the reference for a preliminary ruling:

- (1) The term ‘monomer substances’ in Article 6(3) of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals refers only to reacted monomers, that is, monomers which have reacted together in such a way that they are bound in the polymer of which they are components.
- (2) Consideration of Question 2 has not disclosed anything capable of affecting the validity of Article 6(3) of Regulation No 1907/2006 having regard to the principles of legal certainty, proportionality and non-discrimination.