or to subject to special conditions the sale of dangerous substances liable to constitute a hazard for man or the environment by reason of their classification, packaging or labelling, does not require that notification to the Commission and the other Member States of the measures adopted be in any particular form or that the Member State using the clause expressly mention in the measures adopted their provisional nature.

REPORT FOR THE HEARING
in Case C-43/90 *

I — Community legislation

1. 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 (Official Journal, English Special Edition 1967, p. 234), the legal basis of which is Article 100 of the EEC Treaty, lays down the basic rules on the classification, packaging and labelling of dangerous substances and preparations. Its aim is to protect the public and to prevent differences between national provisions from hindering trade in the substances and preparations in question within the Community.

2. Council Directive 79/831/EEC (Official Journal L 259, p. 10), which also has Article 100 of the EEC Treaty as its legal basis, introduced amendments to the system established by Directive 67/548/EEC. The amendments are intended, in particular, to reinforce controls in order 'to protect man and the environment against potential risks which could arise from the placing on the market of new substances' (first recital in the preamble).

3. The directive in question contains rules governing the placing on the Community market of new dangerous substances and rules governing old dangerous substances, namely those which were placed on the market before 18 September 1981, the date on which the amendments introduced by the directive in question entered into force. The remaining rules laid down by the directive apply both to old and to new substances.

4. With regard to *new* substances, the directive requires any manufacture or importer into the Community to submit to the national authorities appointed by the Member States a *notification* including a technical dossier, a declaration concerning the unfavourable effects of the substance in

* Language of the case: German.

question, a proposed classification and labelling and proposals for any recommended precautions relating to their safe use (Articles 6 and 7). Article 13(2) provides that all the substances so notified are to be entered on a *list* to be kept by the Commission.

5. With regard to *old* substances, Article 13(1) provides that 'the Commission shall, on the basis in particular of information provided by the Member State, draw up an inventory of substances on the Community market by 18 September 1981'. The second subparagraph of Article 5(2) is worded as follows:

'Dangerous substances not yet appearing in Annex I but included in the list referred to in Article 13(1) or already on the market before 18 September 1981 must, in so far as the manufacturer whether or not established in the Community may reasonably be expected to be aware of their dangerous properties, be packaged and provisionally labelled by the manufacturer or his representative in accordance with the rules laid down in Articles 15 to 18 and with the criteria in Annex VI.'

6. Article 22 is worded as follows:

'The Member States may not, on grounds relating to notification, classification, packaging or labelling within the meaning of this directive, prohibit, restrict or impede the placing on the market of substances which comply with the requirements of this directive and the annexes thereto.'

7. Finally, Article 23(1) contains the following safeguard clause:

'Where a Member State has detailed evidence that a substance, although satisfying the requirements of this directive, constitutes a hazard for man or the environment by reason of its classification packaging or labelling, it may provisionally prohibit the sale of that substance or subject it to special conditions in its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.'

8. The directive in question provides that the Member States are to implement the measures necessary to comply with Article 5(2) no later than 18 September 1983 and are to inform the Commission thereof, whereas the other provisions of the directive are to be implemented by 18 September 1981.

II — Facts and procedure

9. On 1 October 1986 the Federal Republic of Germany sent to the Commission the text of the German regulation on dangerous substances (Gefahrstoffverordnung of 26 August 1986, BGBl I, p. 1470), which was intended to transpose Directive 79/831 into national law.

10. By letter of 23 July 1987 (formal notice), the Commission gave its views on the German regulation. It pointed out to the German Government that the regulation in question did not comply with Directive 79/831 in certain respects and gave the

Federal Republic the opportunity to submit its observations within a period of two months, pursuant to Article 169 of the EEC Treaty. The Commission's objections concerned, first, differences between the requirements of the German regulation and those of the directive with regard to the labelling of certain dangerous substances and, secondly, the incompatibility of the requirements of the German regulation as regards certain substances with the provisions of Article 5(2) of the directive.

11. On 2 February 1988 the German Government replied to the Commission in substance that it did not agree with its interpretation of Article 5(2) of the directive.

12. By letter of 5 February 1988 the Federal Republic of Germany notified to the Commission the text of the regulation of 16 December 1987 amending the original regulation on dangerous substances.

13. By letter of 1 March 1988, the Commission requested the German Government to inform it whether certain provisions of the German regulation were to be amended in such a way that in future only the provisional labelling of the substances covered by those provisions would be authorized.

14. On 11 July 1988 the German Government replied in substance that the labelling of the substances covered by the German regulation was provisional and that no amendments to that regulation were planned.

15. Following that reply the Commission sent to the German Government, on 17 October 1988, a reasoned opinion listing the substances for which, according to the Commission, the German regulation laid down unlawful labelling requirements. The German Government was given two months within which to comply with the opinion.

16. On 17 March 1989 the German Government replied in substance that several substances on whose labelling there were differences would soon be given a new Community classification and that the German regulation contained only provisional measures for substances whose classification departed from the current Community classification. The German Government consequently requested the Commission to suspend the procedure.

17. On 14 July 1989 the German Government informed the Commission that it had initiated the procedure under Article 23 of the directive for 21 substances in respect of which an urgent request had been made in November 1987 to the Commission for Community classification.

18. On 29 August 1989 the German Government informed the Commission that it had also initiated the procedure under Article 23 in respect of 42 other substances on the labelling of which there was a considerable delay within the Commission.

19. On 15 February 1990 the Commission brought the present action, claiming that the Court should:

— declare that, by not duly implementing and correctly applying the provisions of Article 5(2) in conjunction with Article 23(1) of Directive 79/831/EEC of 18 September 1979 amending for the sixth time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, the Federal Republic of Germany has failed to fulfil its obligations under the EEC Treaty;

— order the defendant to pay the costs.

20. The Federal Republic of Germany contended that the Court should:

— dismiss the application as unfounded;

— order the Commission to pay the costs.

21. Upon hearing the Report of the Judge-Rapporteur and the views of the Advocate General, the Court decided to open the oral procedure without any preparatory inquiry. However, it requested the parties to reply in writing to certain questions.

III — Pleas in law and arguments of the parties

22. The complaints in the Commission's application concern certain provisions of the German regulation relating to the labelling of *old* substances.

23. According to the Commission, the defendant maintained in the 1986 regulation, amended in 1987, contrary to the second subparagraph of Article 5(2) of Directive 67/548, as amended by Directive 79/831, provisions on labelling for a whole series of old substances which, under the directive, are to be packaged and labelled by the manufacturer on his own responsibility, according to his awareness of the dangers of the substance in question and in compliance with the provisions of the directive.

24. National provisions imposing special conditions on the marketing, and in particular on the importation of substances which meet the conditions laid down in the second subparagraph of Article 5(2) of Directive 67/548, constitute impediments to trade which are incompatible with the objective of the directive and with Article 22 thereof.

25. The substances in question may therefore, under the directive, circulate freely within the common market provided that the procedure laid down in Article 23 of that directive has not been initiated. That procedure permits imports into a Member State to be restricted provisionally if the Member State in question has detailed evidence that a particular substance constitutes a hazard for man or the environment.

26. The Commission claims that, under Article 5 of the German regulation, old substances are subject to a labelling requirement once the German authorities have detailed evidence of their carcinogenic effects. The system so established constantly gives rise to new impediments to the free movement of goods without, however, fulfilling the conditions essential for the maintenance of the single market, imposed by the directive for national measures that may be justified by reasons relating to the protection of health, namely immediate communication to the Commission and the introduction of provisional measures pending the adoption of a decision pursuant to Article 23 of the directive.

27. According to the Commission, the provisional nature of the measures cannot in any event be justified by the fact that the competent authorities' finding that a substance constitutes a hazard is, according to the defendant, capable of being refuted. Article 5(2) of the German regulation is therefore incompatible with Directive 67/548, in particular with the second subparagraph of Article 5(2) and Articles 22 and 23, in so far as the system does not provide that communication is to be made to the Commission or that the labelling requirements are provisional.

28. Next, the Commission claims that although the substances referred to in the letter of 14 July 1989 of the German Government were communicated in accordance with Article 23 of the directive, the defendant did not make it clear that the provisions — as yet unchanged — of the regulation on dangerous substances and the consequent impediments to marketing were provisional. The conditions for justification laid down in the safeguard clause have therefore not been fulfilled and the regulation on dangerous substances is consequently incompatible with the directive as regards those substances.

29. The Commission concludes that it is inappropriate for the regulation on dangerous substances to require special labelling for all the substances referred to at points 3 to 5 of the letter of formal notice and at points 5 to 8 and 11 of Part II of the reasoned opinion, thereby subjecting trade in those products to conditions which are not laid down by the directive.

30. The *Federal Republic of Germany* makes the preliminary observation that the preparation of its defence was hindered by the fact that the Commission's application mentions the majority of the substances only indirectly, by reference to the previous correspondence between the parties.

31. The Federal Republic maintains that the Commission has misconstrued the second subparagraph of Article 5(2), inserted in Directive 67/548 by Directive 79/831, in claiming that the Member States are required to abolish their national classifications with regard to old substances not yet included in Annex I to the directive, and to entrust the labelling of those products to manufacturers in accordance with their awareness of the dangerous nature of the substances in question.

32. In the opinion of the Federal Republic, that was not the aim of the authors of Directive 79/831, which would have

resulted in a reduction in the degree of health protection achieved at national level.

33. The requirement to abolish existing national classifications is also inconsistent with the practice adopted by the Community for the approximation of national laws on dangerous substances, as introduced by Directive 67/548, which provides for the progressive replacement of national rules by Community rules.

34. Thus in so far as there are no Community rules, the Member States can decide for themselves the level of health protection to be accorded to their nationals under Article 36 of the Treaty. The Federal Republic has already made use of that possibility by adopting the regulation of 29 July 1980 on dangerous substances in the workplace.

35. The Federal Republic considers that the Commission has acted inconsistently: it did not criticize the draft regulation on dangerous substances sent to it on 2 December 1983, which maintained the national classification, and took action only when the draft was at a more advanced stage of preparation. That shows that it was only later that the Commission formed a view of the content of the second subparagraph of Article 5(2), which was different from that of all those involved when the directive was adopted.

36. Nevertheless, in a spirit of cooperation, the German Government undertook, by way of a concession to the Commission, that it would not make any further additions to the national list of dangerous substances. In doing so, it merely accepted that the provision at issue should relate to all the old substances not included in Annex I to Directive 67/548, which, on the entry into force of Directive 79/831, had not yet been classified at national level either. It also expressed its readiness to facilitate, by means of active cooperation, a rapid decision concerning the inclusion in Annex I to Directive 67/548 of substances classified as carcinogenic at national level but for which the aforementioned directive did not yet lay down a special labelling requirement.

37. With regard, in particular, to carcinogenic substances, the Federal Republic maintains that the substances referred to in the regulation under Nos 127, 336, 575, 591, 690, 850, 1130, 1241, 1247 and 1260 have in the meantime been classified at Community level as carcinogenic by Directives 86/431 and 87/432, cited above, and by Commission Directive 88/490 of 22 July 1988 on the tenth adaptation to technical progress of Council Directive 67/548. Thus, with regard to those substances, the German provisions and the Community rules are in agreement.

38. As regards the carcinogenic substance referred to under No 1119, the procedure laid down in Article 23 was implemented by the abovementioned communication of 14 July 1989 and its inclusion in the Community list of carcinogenic substances is imminent.

39. In relation to the 78 toxic substances not classified at Community level, the Federal Republic refers first of all to its

communication of 29 August 1989 concerning the implementation of the procedure under Article 23. Moreover, by the second regulation amending the original regulation, it removed from the latter the substances classified under Nos 76, 94, 119, 160, 173, 205, 206, 330, 345, 350, 355, 360, 387, 398, 405, 676, 705, 795, 812, 818, 856, 865, 866, 880, 915, 917, 933, 965, 1078, 1186, 1194, 1267, 1274, 1293 and 1309 (35 substances), and by a further amending regulation now in preparation it proposes to remove the substances classified under Nos 21, 96, 186, 193, 393, 799, 879, 1067 and 1234. The substance classified under No 361 is already classified at Community level.

40. For the remainder of the substances covered by the German regulation, the Federal Republic initiated the procedure under Article 23 by its communication of 29 August 1988, cited above. Those substances have been classified as dangerous for a very long time by the *Länder*. The German provisions are naturally valid pending the adoption of a definitive decision at Community level.

41. Next, the Federal Republic refers to Article 5 of the German regulation, to which the Commission has raised objections. It appears that those objections, which are not clearly formulated in the application, are based on the fact that, under the provision in question, it is not exclusively the manufacturer's *awareness* that the substances in question are dangerous that makes him subject to the labelling requirement.

42. In that regard, the Federal Republic claims that the directive does not say how the Member States are to establish that the manufacturer is aware that a substance is dangerous if he does not disclose it himself. The Member States may, therefore, themselves lay down the conditions under which *the manufacturer may be presumed to be aware* that a substance is dangerous.

43. The German law raises a presumption that, in principle, the manufacturer is aware that a substance is dangerous *when the danger has been scientifically established beyond doubt.* The provision at issue of the German regulation assumes such awareness, in the case of carcinogenic substances, when definite scientific findings have been made by the 'Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe der Deutschen Forschungsgemeinschaft' (Senate Committee on the testing of dangerous substances used in the workplace of the German research association — hereinafter referred to as the 'Senatskommission'). The findings of the Senatskommission raise no more than a rebuttable presumption.

44. The Federal Republic contends, finally, that, as shown by the proposal for a Council directive submitted by the Commission on 26 January, amending for the seventh time Directive 67/548 (Official Journal C 33, p. 3), the Member States should have some scope for interpretation in determining awareness on the part of the manufacturer and, to that extent, there is a need for harmonization. Its proposal for the acceptance of a form of wording whereby the manufacturer must use provisional labelling *when he can be expected to be aware of the dangerous properties of a substance* is to be welcomed.

45. In response, the *Commission* states that, as the Court acknowledged in its judgment in Case 278/85 (*Commission* v *Denmark* [1987] ECR 4069, at paragraph 12), 'the Community legislature has laid down an exhaustive set of rules governing the ... labelling of substances, both old and new, and ... it has not left the member States any scope to introduce other measures in their national legislation'. Consequently, it is not possible to interpret the second subparagraph of Article 5(2) of the directive as meaning that the area in question may still be regulated at national level, or to rely on Article 36 of the Treaty in order to do so. Moreover, it is clearly stipulated in the sixth recital in the preamble to Directive 79/831 that the amendments made by that directive also cover the provisional labelling of dangerous substances not appearing in Annex I.

46. According to the Commission, therefore, the directive also covers old substances with regard to which it provides not for the maintenance of national legislation, but for their labelling to be the responsibility of the manufacturer pending the inclusion of the substances in question in Annex I. National legislation may be maintained or introduced only by means of the procedure laid down in Article 23.

47. That interpretation of the safeguard clause contained in Article 23 provides every guarantee that the level of health protection achieved at national level will not be reduced. Moreover, it also authorizes Community review of national measures and, where necessary, their withdrawal when they do not appear justified. That balance was decided on by the Council with the agreement of the Federal Republic.

48. With regard to the allegations made by the Federal Republic concerning inconsistent conduct on the part of the Commission, the applicant points out that it has never interpreted the directive differently. The German draft regulations were considered in the light of Article 30 of the EEC Treaty, but not from the point of view of compliance with the directive. The fact that it did not make any observations in that regard does not mean that it relied at the time on an interpretation of the second subparagraph of Article 5(2) that was different from the one that it is defending now. The mere absence of observations can in no way be treated as justification for an objectively existing infringement of the provision in question.

49. With regard to awareness of the dangerous properties of substances on the part of the manufacturer, the Commission accepts that the way in which that awareness is to be established is not laid down in the directive. It follows that where there is doubt, awareness must be established on a case-by-case basis, but not that the Member States are at liberty to adopt provisions under which the awareness of the manufacturer is, in a general way, assumed, otherwise the meaning of the provision would be stood on its head. Moreover, the findings of the German Senatskommission may be of interest to a German manufacturer but not to manufacturers in other Member States.

50. As regards the aforesaid proposal for a directive amending Directive 67/548, the Commission claims that it reinforces the responsibility of the manufacturer and makes it more objective by adopting as a criterion, not his actual awareness, but his *duty to be aware* that a substance is

dangerous, a criterion for which the findings of expert committees may provide important evidence. However, that amendment also adheres to the principle that the manufacturer is personally responsible, which was adopted in the provision at present in force.

51. In relation to the different categories of substances, the Commission observes, first of all, that while it is true that substance *No 690* (1, 2 — *Epoxypropane*) appears in Annex I to the directive, its classification as a carcinogenic substance at Community level takes effect with the Directive of 1 July 1990 on the tenth adaptation (Official Journal 1988, L 259, p. 1). Before that date, national provisions generally requiring labelling which refers to the carcinogenic nature of a substance are incompatible with the directive.

52. With regard to the 78 toxic substances, the Commission points out that since neither of the two German amending regulations relied on by the Federal Republic has yet entered into force, a statement such as that made in the defence can only be interpreted as an admission.

53. The Commission again refers to the procedure laid down in Article 23 of the directive, introduced for certain substances by the Federal Republic, in maintaining that that procedure does not affect the unlawful nature of the German provisions at issue. Those provisions cannot be regarded as provisional, according to their letter and spirit, since they make no mention either of their provisional nature or of the procedure initiated pursuant to Article 23 of the directive. Moreover, substance No 143 is not covered by the Article 23 procedure.

54. In conclusion, the Commission withdraws its complaint with regard to substances *Nos 127, 336, 575, 591, 850, 1130, 1241, 1247 and 1260* and, for the remainder, maintains in full the claims in the application.

55. The *German Government* contends in its rejoinder, with regard to the Commission's claim that Directive 67/548 is an exhaustive set of rules governing the labelling of dangerous substances, that that claim must be moderated. The wording of the sixth recital in the preamble to Directive 79/831, which provides that 'it is necessary to introduce measures for the packaging and provisional labelling of dangerous substances not yet appearing in Annex I to Directive 67/548/EEC', also admits of the interpretation that the directive merely lays down minimum requirements for provisional labelling.

56. Furthermore, the Commission does not take sufficient account of the fact that the objective of Directive 79/831 is to reinforce the control of dangerous substances in order to protect man and the environment (first recital in the preamble to the directive), an objective that was confirmed by the judgment of the Court in Case 278/85, cited above. Consequently, any interpretation of the directive in question must not focus on impediments to trade alone.

57. The passage in the abovementioned judgment of the Court to which the Commission refers must be considered in the context of that case, which concerned the fact that the Member State in question had laid down a requirement to notify substances which were not subject to such a

requirement under the directive. In the present case, however, what is at issue is a labelling requirement imposed, under the directive, on all substances. The contested German provisions do not extend the range of substances for which the directive has laid down labelling requirements.

58. With regard to the wording of the second subparagraph of Article 5(2) of Directive 79/831, under which the manufacturer may '*reasonably be expected to be aware*' of the dangerous properties of a given substance, the Federal Republic contends that, for reasons of legal certainty, that criterion should be made more specific since the administration must be in a position to determine whether the manufacturer has failed to fulfil his obligations.

59. The Commission has itself acknowledged the need for legislation in that regard when it stated in its reply that the proposal for a directive amending Directive 67/548 envisages as a criterion the *duty* of the manufacturer *to be aware* of the dangerous properties of a substance. The Federal Republic contends that until that criterion is made more specific at Community level, it is entitled to determine itself, when implementing Directive 79/831, what criteria lead to the conclusion that the manufacturer is aware of the dangerous properties of a substance.

60. One of the obligations of a manufacturer is to keep abreast of the results of scientific studies carried out in other Member States on the dangerous properties of the substances that he manufactures, such as those carried out by the German Senatskommission which is internationally recognized for its scientific competence.

61. As regards substance *No 690*, to which the Commission refers in its reply, the German Government contends that it is classified as a carcinogenic substance both by the German regulation (second amending measure of 23 April 1990) and by Directive 88/490, cited above. Article 2 of the that directive provides that the Member States are to implement its provisions *no later than* 1 July 1990. However, the substance in question is classified as carcinogenic at Community level *with effect from 22 July 1988*, the date on which the directive was adopted. Thus the directive in question had already been implemented in Germany before 1 July 1990.

62. With regard to the 78 toxic substances, the Federal Republic denies that the arguments it puts forward in its defence amount to an admission. A first group of the substances in question was removed from the German regulation by the second amending regulation, and the remainder should be removed by the third amending regulation in the course of 1990.

63. The German Government emphasizes that Article 23 of the directive in no way required it expressly to describe the national legislation at issue as 'provisional'. Such legislation may, moreover, acquire the status of rules of indeterminate duration when a subsequent decision adopted at Community level recognizes that it complies with Community law. To describe the national legislation at issue as 'provisional' would therefore be pointless and would be likely to increase confusion from a legal point of view.

64. The Commission was requested by the Court to reply in writing to the following questions:

'Leaving aside the question whether, in the light of Article 19 of the Protocol on the Statute of the Court of Justice and of Article 38 of the Rules of Procedure of the Court, pleas in law and arguments or information not contained in the text of an application but indicated by reference to other documents, even annexed to the application, are admissible, the Commission is requested to specify clearly, by means of a list, the dangerous substances in respect of which it maintains its complaint concerning the labelling requirements imposed by the German regulation at issue.

The Commission is also requested to state for which of those substances and on which dates the Federal Republic implemented the procedure under Article 23 of Directive 67/548, and the stage reached by the procedure initiated by the Commission in that regard.

In addition, the Commission is requested to explain the extent to which it took account, in its action against the Federal Republic of Germany, of the procedure initiated by that Member State on 29 August 1989 under Article 23 of Directive 67/548 in relation to 42 dangerous substances.'

65. The Commission replied to those questions as follows:

1. *Substances for which the complaint is maintained with regard to the labelling requirement under the German regulation*

(a) In its reply of 20 May 1990, the Commission acknowledged that the substances referred to at Section II.1. a of the application had been mentioned inadvertently, and it withdrew its complaint on that point.

(b) The Commission cannot accept the submissions relied upon by the defendant with regard to the substances referred to at Section II.1. b of the application (cf. reply, Section II.3). To the extent that, as the defendant states (rejoinder, p. 5), those substances have since been removed from the regulation on dangerous substances, the complaint may be regarded as devoid of purpose; since, however, the relevant regulations (annexed to the rejoinder) did not come into force until 28 April 1990 and 15 June 1991 respectively, the Commission's complaint was in any event well founded at the outset.

With regard to 42 other substances, the defendant contended that it had sent to the Commission, on 29 August 1989, the information referred to in Article 23 of the directive (cf. the communication — not dated — and the list of substances annexed to the defence); six of those substances (Nos 183, 351, 678, 721, 782 and 833) are now covered by Community rules following the adoption of Directive 91/325/EEC adapting Directive 67/548 for the twelfth time to technical progress (Official Journal L 180, p. 1), with the result that, in relation to those substances as well, the Commission's complaint has become devoid of purpose. Thirty-one substances (Nos 114, 294, 532, 534, 667, 718, 784, 786, 832, 887, 964, 984, 1064, 1067, 1151, 1163, 1202, 1227, 1231, 1233, 1264, 1268, 1284, 1328, 1329, 1331, 1334, 1366, 1370 and 1431) are covered by the proposal for a directive adapting

Directive 67/548 for the fifteenth time to technical progress which, according to the competent committee, is due to be submitted for adoption in September 1991. In regard to those substances too, the Commission's complaint could become devoid of purpose before the end of the present proceedings. With regard to only five substances can it be assumed that rules will not now be adopted in good time or that the decision adopted was unfavourable:

No 102 Azocyclotine: no information sheet has yet been submitted;

No 376 Cycloheximide: negotiations in progress;

No 878 Ioxynil octanoate: negotiations in progress;

No 1332 Temephos: labelling not necessary;

No 1344 Tetrachlorovinphos: labelling not necessary.

In respect of those substances, the Commission maintains its specific complaint with regard to the German rules on labelling.

(c) With regard to the group of substances referred to at Section II.1. c of the application, they are not specific products, but substances abstractly defined in Article 5(2) of the regulation on dangerous substances to which that regulation (obligation to label as carcinogenic in so far as that property has been established by the Senatskommission) applies in a general manner. All old substances not covered by rules, in other words those placed on the market before 18 September 1981 and not subject to the Community labelling requirement, potentially belong in that category. It is not possible to list all those substances, but nor does it appear necessary to do so since what is at issue is the incompatibility of Article 5(2) of the regulation on dangerous substances itself.

(d) Substance No 1119, Tetracarbonylnickel (which the defendant's communication of 14 July 1989 mentions under No 19, "Carbonylnickel") will be made subject to Community rules on labelling in the autumn of 1991 by the directive adapting Directive 67/548 for the fifteenth time to technical progress. With regard to that substance, the Commission's complaint will become devoid of purpose. As regards substance No 690, 1, 2-Epoxypropane, Community rules on labelling have in fact been in existence since 1988 so that the Commission also withdraws its complaint on that point.

In reply to Question 1, it may be *concluded* that the complaint concerning the labelling requirement imposed by the German regulation on dangerous substances in breach of the relevant Community directives:

— has been withdrawn in respect of certain substances (cf. under (a) and (d) above);

— has become or will become devoid of purpose for a large number of substances (cf. under (b) and (d) above) on the entry into force of the directive adapting Directive 67/548 for the fifteenth time to technical progress;

— is maintained in respect of five substances (cf. under (b) above).

However, in the Commission's opinion, what is of decisive importance is not which particular substances may be subject to a labelling requirement in breach of the relevant Community rules, but the very principle of the compatibility of Article 5 of the regulation on dangerous substances with the second subparagraph of Article 5(2), Article 22 and Article 23 of Directive 67/548 since Article 5 of the German regulation allows a large number of old substances to be subjected to a labelling requirement that is not provided for in Community law (cf. under (c) above).

2. *Initiation of the procedure under Article 23 by the defendant*

On the basis of the documents sent to the Commission, the procedure under Article 23 of the directive was formally initiated by the defendant only on 14 July 1989 (cf. Annex 6 to the application). The files relating to the 21 substances in question were sent to the competent Working Party on the Classification and Labelling of Dangerous Substances on 8 August 1989 and were examined by the latter for the first time at its meeting of 14 and 15 September 1989. All the substances on the list, with the exception of two, were classified as subject to a labelling requirement. They are the subject of the Directive of 1 March 1991 adapting Directive 67/548 for the twelfth time to technical progress, or of the proposal for a directive adapting that directive for the fifteenth time to technical progress which is due to be adopted in the autumn of 1991 (cf. Annex 1). As is clear from a recent review of the documents, 42 other substances have not in fact been the subject of a formal communication to the Commission. However, most of those substances, which are listed in the communication of 29 August 1991 annexed to the defence, have in the meantime been made subject to Community rules or will be subjected to an appropriate labelling requirement by the directive adapting Directive 67/548 for the fifteenth time to technical progress (cf. under (b) above and Annex 2).

3. *Consideration of the communication of 29 August 1991*

In the letter of formal notice which it sent to the Federal Republic of Germany on 23 July 1987, the Commission called into question the labelling requirement imposed by the regulation on dangerous substances with regard to the 42 substances at issue (and 36 additional substances which have since been removed from the scope of that regulation) (cf. point 5 of Annex 1 to the application). The defendant contended in that regard that it was entitled to lay down a provisional labelling requirement nationally for old dangerous substances not covered by any rules (point 5 of Annex 2 to the application). In its reasoned opinion the Commission replied that such action could be taken only under the conditions laid down in Article 23 of the directive and that

those conditions had not been met in the present case (point II.7 of Annex 4 to the application). Since the communication of 29 August 1989 is not one of the documents submitted pursuant to Article 23 of the directive, was not sent to the Commission in the context of the procedure for failure by the State to fulfil its obligations, and was not drawn to its attention in any other way, that communication was not taken into account in the present proceedings until the reply stage. At that stage, the Commission drew attention to the fact that, in any event, there was no indication that the national labelling requirement was only *provisional* (reply, p. 6), assuming, in the absence of further verification, that the communication had in fact been made. When the conditions laid down in Article 23 (provisional nature, communication) have not been fulfilled, the number and the nature of the substances subject to the rules laying down a labelling requirement for old substances have no bearing on the essential element of the procedure, namely the incompatibility of such rules with Community law. In that regard, the Commission reiterates that for the vast majority of the substances originally listed, the complaint became devoid of purpose (as a result of Community legislation or the removal of the substances in question from the German regulation) only during the procedure under Article 169 of the EEC Treaty and that, for some substances, the complaint still stands.

66. The German Government was also requested by the Court to reply in writing to the following question:

'In its rejoinder the German Government contends, with regard to certain substances, that those that were not removed from the original German regulation by the second amending regulation are due to be removed by a third amending regulation in the course of 1990. The German Government is requested to inform the Court in writing if that has happened and to specify the substances which have not yet been removed.'

The German Government gave the following reply:

'At point 4 of its rejoinder of 27 July 1990, the German Government announced a third regulation amending the regulation on dangerous substance, which has since been adopted. Article 1(12)(a) of the third regulation amending the German regulation on dangerous substances — an amending regulation of 5 June 1991 (Bundesgesetzblatt I, p. 1218; annexed hereto) — removed substances Nos 21, 96, 143, 186, 193, 393, 799, 879, 1067 and 1234, all of which the second amending regulation had inadvertently omitted to remove.

The substances for which the Federal Republic of Germany initiated, by letter of 29 August 1989, the procedure under Article 23 of Directive 79/831/EEC, have not been removed.'

C. N. Kakouris
Judge-Rapporteur