JUDGMENT OF THE COURT
14 October 1987

In Case 278/85

Commission of the European [Union], represented by Johannes Føns Buhl, a member of its Legal Department, acting as Agent, with an address for service in Luxembourg .at the office of G. Kremlis, Jean Monnet Building, Kirchberg,

applicant,

v

Kingdom of Denmark, represented by Laurids Mikaelsen, Legal Adviser m the Ministry of Foreign Affairs, with .an address for service in Luxembourg at the Royal Danish Embassy, c/o .the Danish charge d'affaires *ad interim,*

defendant,

APPLICATION for a declaration that Denmark has failed to fulfil its obligations under the Treaty [on the Functioning of the European Union] by not adopting within the prescribed period the measures necessary to comply with Council 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 (Official Journal 1979, L 259, p. 10),

THE COURT,

composed of: Lord Mackenzie Stuart, President, G. Bosco, O. Due and G. C. Rodriguez Iglesias, Presidents .of Chambers, T. Koopmans, K. Bahlmann, C. Kakouris, .R. Joliet and F. Schockweiler, Judges,

Advocate General: J. L. da Cruz Vilaça
Registrar: D. Louterman, Administrator

having regard to the Report for the Hearing and further to the hearing on 11 February 1987,

after hearing the Opinion of the Advocate General delivered at the sitting on 7 April 1987,

gives the following

Judgment

1 By an application lodged at the Court Registry on 11 September 1985, the Commission of the European [Union] brought an action under [Article 258 TFEU] for a declaration that by not adopting alt the Jaws, regulations and administrative provisions necessary to comply with Council 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 (Official Journal 1979, L 259, p. 10), the Kingdom of Denmark had failed to fulfil its obligations under the Treaty [on the Functioning of the European Union].

2 The Commission considers that certain provisions of the Danish legislation adopted to implement Directive 79/831/EEC, in particular provisions of Law No 212 of 23 May 1979 on chemical substances and products (hereinafter referred to as 'the Law') and of Decree No 409 of the Ministry of the Environment of 17 September 1980 on the notification of chemical substances (hereinafter referred to as 'the Decree'), do not adequately transpose the directive into national law.

3 Reference is made to the Report for the Hearing for a fuller account of the facts of the case, the course of the procedure and the submissions and arguments of the parties, which are mentioned or discussed hereinafter only in so far as is, necessary for the reasoning of the Court.

4 Before the individual complaints made by the Commission with· regard to the Danish legislation are examined, it is appropriate to describe the scheme of Directive 67/548/EEC, as amended by Directive 79/831/EEC (hereinafter referred to as 'the Directive').

The scheme of the Directive

5 Directive 79/831/EEC amends for the sixth time Directive 67/548/EEC, which laid down the basic rules on the classification, packaging and labelling 'of dangerous substances and preparations.

6 Directive 79/831/EEC introduced certain amendments to that scheme in the form, in particular, of reinforced controls in order - as is stated in the first recital of the preamble to the Directive - to protect man and the environment against potential risks which could arise from the placing on the market of new substances.

7 The Directive contains, first of all, rules governing the placing on the [Union] market of new substances and, secondly, rules governing old dangerous substances, that is to say substances which were placed on the market prior to 18 September 1981, the date on which the amendments introduced by Directive 79/836/EEC entered into force, and which were previously governed by the preceding provisions.

8 As regards new substances, Article 6 of the Directive requires any manufacturer or importer into the [Union], at the latest 45 days before a substance is placed on the market, to submit to the competent national authority appointed by the Member State in accordance with Article 7 of the Directive a notification including a technical dossier supplying the information necessary for evaluating the foreseeable risks and the information and results of scientific studies and the methods used, a declaration concerning the unfavourable effects of the substance in terms of the various uses envisaged, the proposed classification and labelling of the substance and proposals for any recommended precautions relating to the safe use of the substance. Under Article 13 (2) of the Directive, all substances so notified are to be included on a list kept by the Commission. In addition, all notification dossiers and information received by the Member States are to be forwarded by the Commission to the other Member States. Provision is also made for direct consultation between the competent authorities of the Member States and the Commission. Paragraphs (2) and (3) of Article 6 provide for simplified procedures for the notification of substances which have already been notified. Lastly, Article 6 (4) lays down an obligation to provide information about substances already notified in the event of changes in the quantities

placed on the market, new knowledge of the effects of the substance, new uses or any change in the properties of the substance.

9 As regards old substances, that is to say those already placed on the market before 18 September 1981, the Directive lays down different rules. Article 13 (1) requires the Commission to draw up an inventory of such substances, on the basis in particular of information provided by the Member States. Article 1 (4) provides that the obligation to notify does not apply to old substances until six months after the publication of the inventory and, six months after publication of the inventory, to substances which appear in that inventory. Furthermore, the second subparagraph of Article 5 (2) provides that substances included in the list or already on the market before 18 September 1981 must be packaged and labelled in accordance with the rules of the Directive.

10 In addition, there are provisions in the Directive which apply to both old and new substances. In particular, Article 22 provides that the Member States may not prohibit, restrict or impede the placing on the market of any substances which comply with the Directive, whether old or new, on grounds relating to notification, classification, packaging or labelling.

11 Article 23 also applies to all substances covered by the Directive. It provides that where a substance, although satisfying the requirements of the Directive, constitutes a hazard for man or the environment, a Member State may provisionally prohibit the sale of that substance or subject it to special conditions in its territory; however, the Member State concerned must immediately inform the Commission and the other Member States of such action and, after consulting the Member States within six weeks, the Commission must give its view without delay and take the appropriate measures.

12 It is clear from that description of the scheme of the Directive that the [Union] legislature has laid down an exhaustive set of rules governing the notification, classification, packaging and labelling of substances, both old and new, and that it has not left the Member States any scope to introduce other measures in their national legislation.

The individual complaints

Article 11 (2) of the national law

13 Article 11 (2) of the law provides as follows:

'A chemical substance. shall be regarded as new if it has not been placed on the market or imported into Denmark as a chemical substance or constituent of a chemical product before 1 October 1980.'

14 The Commission complains that, in adopting that provision, the Danish Government departed from the Directive by fixing a date prior to 18 September 1981 and by thus imposing an obligation to notify even substances placed on the market before 18 September 1981 and exempting only substances placed on the market before 1 October 1980.

15 The Danish Government acknowledges that the obligation to notify imposed by the national provision is wider than that provided for in the Directive, but denies that the provision is contrary to the Directive. It maintains that the Directive is not meant to regulate 'old substances', that is to say substances which were placed on the market before 18 September 1981; such substances therefore continue to be subject to national rules.

16 It should be noted in the first place, that Directive 79/831/EEC is designed to attain two objectives: the protection of the population and the environment and the elimination of obstacles to trade in dangerous substances in the [Union]. Although it is true that in its preamble Directive 79/831/EEC refers only to the first objective, it should not be overlooked that the second objective is mentioned in the preamble to Directive 67/548/EEC, to which Directive 79/831/EEC merely introduced amendments, intended in particular to reinforce the controls provided for; the second objective is also referred to in Article 22 of the Directive.

17 Secondly, it must be pointed out that the date provided for in the Directive, 18 September 1981, was meant to be the date from which both objectives, in particular the measures concerning the obligation to notify new substances, were to take effect. It follows that in the Directive the [Union] legislature has laid down exhaustive rules on this point and that it has not left the Member States any scope to introduce earlier or later dates in their rules adopted to implement the Directive.

18 It follows from the foregoing that the Danish Government's argument cannot be upheld and that the Commission's complaint is well founded.

Article 11 (3) of the national law

19 Article 11 (3) of the national law provides as follows:

'The provisions applicable to new chemical substances also apply to any chemical substance sold or imported into Denmark before 1 October 1980, where it is marketed or imported after that date for an essentially different use or in substantially larger quantities.'

20 The Commission complains that in that provision the Danish Government requires fresh notification for substances already on the market, even though the Directive does not provide for such a possibility, and therefore the Member States cannot require notification of such substances.

21 The Danish Government does not deny that the national legislation is drafted differently but maintains that the provision at issue is consistent with the general objective of the Directive, which is to protect man and the environment. The national provision has the same preventive purpose as the Directive. The protection of workers and of the population referred to in the sixth amendment to the original directive would be illusory if there was no fresh notification of substances sold in substantially larger quantities or used for essentially different purposes.

22 As was stated when the first complaint was examined, the protection of man and the environment is only one of the objectives of the Directive; the other objective is to eliminate obstacles to trade in the substances in question within the [Union]. Consequently, the rules of the Directive relating to notification are not meant to be rules providing a minimum degree of protection which leave the Member States free to widen the obligations provided for therein, but are intended to be exhaustive.

23 It follows that old substances may not be treated like new substances for the purposes of notification and that this complaint of the Commission is also well founded.

Article 17 of the Law and Article 9 (3) of the Decree

24 Article 17 of the Danish Law provides as follows:

'The Minister may adopt provisions under which notification in another Member State of the European [Union] may, on certain conditions, be regarded as notification in Denmark.'

25 Pursuant to that enabling provision, the Minister of the Environment provided in Article 9 (1) and (2) of the Decree that new substances imported into Denmark which have already been notified in another Member State are exempt from the obligation to notify. Article 9 (3), however, provides as follows:

'As regards the chemical substances referred to in paragraphs (1) and (2) of this article, any importer into Denmark shall, however, be required to inform the National Agency for the Protection of the Environment prior to importation into Denmark of the substance concerned and to declare that that substance has been notified in another Member State of the [Union] in accordance with the provisions of paragraphs (1) and (2) of this article.'

26 It appears from the explanations . contained in the reply that the

Commission complains that, in Article 9 (3) adopted pursuant to Article 17 of the Law, the Danish Government requires importers to inform the competent Danish authority before they import into Denmark a substance already notified in another Member State. According to the Commission, that requirement is contrary to the Directive.

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27 The Danish Government contends that paragraphs (1) and (2) of Article 9 of the Decree exempt from fresh 'notification' in Denmark substances already notified in another Member State. Although Article 9 (3) imposes an obligation to 'inform' the authorities, that obligation is compatible with the Directive and is intended to enable the competent authority to fulfil its obligation, laid down in Article 5 of the Directive, to check whether the pre-conditions for placing substances on the market have been satisfied.

28 It must be stated that the mere requirement to 'inform' the authorities about imported substances is not in itself contrary to the Directive in view, in particular, of Article 5, which requires the Member States to take all the measures necessary to ensure that when substances are placed on the market the requirements regarding notification, packaging and labelling are observed.

29 However, the obligation to inform the authorities laid down in Article 9 (3) of the Decree is a pre-condition for importation and non-compliance results in the imposition of a penalty, provided for in Article 22 (1) of the Decree. Furthermore, the required notice must be given to the same national authority, namely the National Agency for the Protection of the Environment, that is authorized to receive notification of substances placed on the market. Under those circumstances, such a requirement is liable to cause uncertainty among traders and to create obstacles to intra-[Union] trade in the substances concerned, contrary to the provisions of the Directive.

30 In that regard, reference should be made to Article 22 of the Directive, cited above, and to Article 10, whose purpose is precisely to establish a system for forwarding to the other Member States information received by the Commission following notifications communicated to it by the national authorities. Elsewhere in the Directive, provision is also made for the exchange of information between the Member States and the Commission in

order to avoid the risks presented by dangerous substances without, however, creating unjustified obstacles to intra- [Union] trade.

31 Consequently, the Commission's complaint is well founded.

Article 18 of the Decree

32 Article 18 of the Decree provides as follows:

'Derogation

(1) In individual cases, the National Agency for the Protection of the Environment may grant a derogation from the provisions of Chapter II and of Article 12 (1) of this Decree.

(2) The National Agency for the Protection of the Environment may also, in individual cases, grant a derogation from the provisions of Chapter III of this Decree.'

33 In the reply, the Commission indicated that its action was directed against this provision, whereas in its original application it simply referred, in the section concerned with the Law, to 'Article 18'. Article 18 of the Law provides as follows:

'The Minister may adopt provisions relating to the analysis and notification of certain categories of chemical substances which do not need to be notified under Article 12 (1), including provisions indicating the information which must be supplied at the time of such notification.'

34 The Danish Government objects to such a change in the subject-matter of the action and also points out that, even in the reasoned opinion, the Commission did not state precisely the provision to which it objected but

merely referred to 'Article 18' of the Danish legislation.

35 It must be observed that both in the arguments and in the relevant conclusions of its application the Commission referred only to Article 18 of the Danish Law as a provision granting the Minister a discretionary power to grant exemptions not provided for by the Directive.

36 However, in its reply, the Commission stated, in the light of explanations contained in the defence of the Danish Government, that it was 'changing' its complaint *so* as to direct it against Article 18 of the Decree.

37 It is established case-law of the Court that a party may not change the subject- matter of the dispute in the course of the proceedings. It follows that the substance of the application must be examined only with regard to the conclusions contained in the application originating the proceedings.

38 It follows that the 'changed' complaint is not admissible and, consequently, that the complaint must be rejected.

Article 6 of the Decree

39 Article 6 of Decree No 409/80 provides that:

> 'The new chemical substances listed below shall not be subject to the notification required in Article 5 of this Decree:
>
> (1) Substances marketed or imported in quantities of less than one tonne per annum per manufacturer or importer ... '.

40 The Commission claims that because this provision grants exemption from notification both to the manufacturer and to the importer, it is contrary to the fourth indent of Article 8 (1) of the Directive, which grants such

exemption to the manufacturer alone. The widening of the exemption to include importers could give rise to abuse and undermine the possibilities of control afforded by the normal notification procedure.

41 The Danish Government argues that the widening of the exemption to include importers is in line with the Council's wish to see importers and manufacturers treated in the same way in law, as is clear from a declaration made by the Council when the Directive was adopted. Furthermore, it does not consider that Article 6 of the Decree may give rise to any abuse.

42 It should be borne in mind that one of the fundamental elements of the Directive is the obligation to notify, imposed on any manufacturer or importer in the [Union] of the substances in question, in order to control the effects on man and the environment, as is stated in the third recital of the preamble to the Directive. For that purpose, Articles 6 and 7 of the Directive lay down detailed rules regarding the notification procedure. According to those provisions, any new substance covered by the Directive must, as a general rule, be notified to the competent authorities before it is placed on the market by the manufacturer or importer.

43 Exceptions to that rule are provided for in Article 8 (1) of the Directive and are justified by the fact that, because the substances concerned are placed on the market in limited quantities or for scientific or research purposes, they may be controlled and the risks are limited. For that reason, the fourth indent of Article 8 (1) exempts from the obligation to notify 'substances placed on the market in quantities of less than one tonne per year per manufacturer ...'. According to Article 2 (1) (e) of the Directive, importation is deemed to be placing on the market for the purposes of the Directive.

44 Considered in the light of the abovementioned provisions of the Directive, Article 6 of the Decree constitutes a widening of the exception provided for by the Directive which was not intended by the [Union] legislature. Article 6 may be interpreted as meaning that the same manufacturer may place on the market, through different importers, quantities of substances of less than one tonne several times a year. This does not accord with the aim of the Directive of ensuring that the placing of new substances on the market without notification is restricted to small quantities and occurs only for precisely defined purposes, whilst · it also renders the control of such substances ineffective.

45 Consequently, the Commission's complaint is well founded.

46 It follows from all the foregoing considerations that by not adopting all the laws, regulations and administrative provisions necessary to comply with Council 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 Kingdom of Denmark has failed to fulfil its obligations under the Treaty.

Costs

47 Under Article 69 (2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs. Since the Danish Government has essentially failed in its submissions, it must be ordered to bear the costs.

On those grounds

THE COURT

hereby:

(1) Declares that by not adopting all the laws, regulations and administrative provisions necessary to comply with Council 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 Kingdom of Denmark has failed to fulfil its obligations under the Treaty;

(2) Orders the Kingdom of Denmark to bear the costs.

Mackenzie Stuart Bosco Due Rodriguez
Iglesias Koopmans Bahlmann Kakouris Joliet Schockweiler

Delivered in open court in Luxembourg on 14 October 1987.

P. Heim
Registrar

G. Bosco
President of Chamber,
acting as President