JUDGMENT OF THE COURT

23 September 2003 *

In Case C-192/01,

Commission of the European Communities, represented by H. C. Støvlbæk, acting as Agent, with an address for service in Luxembourg,

applicant,

v

Kingdom of Denmark, represented by J. Molde, acting as Agent, with an address for service in Luxembourg,

defendant,

* Language of the case: Danish.

APPLICATION for a declaration that, by applying an administrative practice which entails that enriched foodstuffs lawfully produced or marketed in other Member States may be marketed in Denmark only if it is shown that such enrichment with nutrients meets a need in the Danish population, the Kingdom of Denmark has failed to fulfil its obligations under Article 28 EC,

THE COURT,

composed of: J.-P. Puissochet, President of the Sixth Chamber, acting for the President, M. Wathelet, R. Schintgen and C.W.A. Timmermans (Presidents of Chambers), C. Gulmann, A. La Pergola, F. Macken (Rapporteur), N. Colneric, S. von Bahr, J.N. Cunha Rodrigues and A. Rosas, Judges,

Advocate General: J. Mischo,
Registrar: H. von Holstein, Deputy Registrar,

having regard to the Report for the Hearing,

after hearing oral argument from the parties at the hearing on 1 October 2002,

after hearing the Opinion of the Advocate General at the sitting on 12 December 2002,

gives the following

Judgment

1 By an application lodged at the Court Registry on 4 May 2001, the Commission of the European Communities brought an action under Article 226 EC for a declaration that, by applying an administrative practice which entails that enriched foodstuffs lawfully produced or marketed in other Member States may be marketed in Denmark only if it is shown that such enrichment with nutrients meets a need in the Danish population, the Kingdom of Denmark has failed to fulfil its obligations under Article 28 EC.

2 It is common ground that, at the date relevant to this action, there were no provisions of Community legislation laying down the conditions under which nutrients, such as vitamins and minerals, could be added to foodstuffs for daily consumption.

3 As regards foodstuffs intended for particular nutritional uses, certain of them have been the subject of directives adopted by the Commission under Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (OJ 1989 L 186, p. 27).

National legislation

4 Article 14 of lov n° 471 om fødevarer m.m. (Law No 471 on Foodstuffs) of 1 July 1998 (Lovtidende A 1998, p. 2826), which replaced Law No 310 of 6 June 1973, leaving the law on additives unchanged, provides that:

'For the purposes of this law, a food additive is any substance which, without itself being a food or a usual ingredient of compound foods, is intended to be added to foods in order to modify their nutritional value, their shelf-life, colour, flavour, taste or for technical or other purposes.'

5 Under Article 15(1) of Law No 471, only substances authorised by the Minister for Food (hereinafter 'the Minister') may be used or sold as additives.

6 According to Article 15(2) of that law, the Minister may draw up rules relating to the conditions of use of additives, *inter alia* the aim, the quantities and the products with which they are associated, as well as rules relating to the identity and purity of additives.

7 Bekendtgørelse n° 282 om tilsætningsstoffer til fødevarer (Decree No 282 on Food Additives) of 19 April 2000 (Lovtidende A 2000, p. 1861), imposes the obligation to declare additives to the Food and Veterinary Office (hereinafter 'the Office') six months before their use.

8 Under Article 20 of Decree No 282:

'1. The following additives may be used six months after their declaration to the Food and Veterinary Office:

bacterial cultures,

moulds and yeasts,

enzymes, and

nutrients.

2. The use of an additive under paragraph 1 is always subject to the condition that the Office has not previously prohibited the declared additive.

3. The Office may authorise the use of the additive prior to the expiry of the time-limit of six months from the date of the declaration.'

9 Before the entry into force of Decree No 282, such declaration was made to the Minister in accordance with the provisions of Article 16(2) of Law No 471.

10 As regards the addition of vitamins and minerals to foodstuffs, the functioning of the Danish system of prior authorisation is characterised by the existence of an administrative practice, based on the provisions of Law No 471 and of Decree No 282 mentioned in paragraphs 4 to 9 of this judgment, which makes authorisation of the addition of such ingredients subject to one or more of the criteria laid down in accordance with the general principles for the addition of essential nutrients to foods, taken from the Codex Alimentarius, established in 1963 by the FAO (United Nations Food and Agriculture Organisation) and the WHO (World Health Organisation) (hereinafter 'the Danish administrative practice').

11 By virtue of the Danish administrative practice additives such as vitamins and minerals may be lawfully added only in the following cases:

— the addition of the additive is required to correct (or prevent) a situation where a large part of the population has an insufficient intake of the nutrient in question (for example, the addition of iodine to salt);

— the addition of the additive must have the purpose of restoring any loss of a product's nutritional value during industrial processing (for example, the addition of vitamin C to fruit juices);

— the addition relates to new foodstuffs, or similar products, which may be used in place of and in the same way as a traditional product (for example, the addition of vitamin A to margarine, which is a butter substitute);

— the addition relates to foodstuffs that constitute a meal in themselves or are intended as special-purpose foods (for example, breast milk substitutes, baby foods or slimming products).

Pre-litigation procedure

12 In 1998, a complaint casting doubt on the compliance of the Danish administrative practice with the provisions of Articles 28 EC and 30 EC was made to the Commission by an economic operator because of obstacles to the marketing of a foodstuff lawfully marketed in other Member States.

13 On 4 November 1999, the Commission sent a letter of formal notice to the Kingdom of Denmark, in which it drew the attention of that Member State to the fact that the Danish administrative practice constitutes an unjustified obstacle to trade for the purposes of Articles 28 EC to 30 EC, since the Office applies the said practice in such a way as to prohibit the marketing in Denmark of foodstuffs to which nutrients, in particular vitamins and minerals, have been added, unless there is a nutritional need for those elements in the Danish population.

14 In their answer of 22 December 1999, the Danish authorities maintained that, in light of the fact that the degree of harmfulness of vitamins and of minerals cannot be determined with sufficient certainty and in accordance with the judgment in Case 174/82 *Sandoz* [1983] ECR 2445, Member States have only to show that

the enrichment of the foodstuffs with vitamins and minerals does not meet a real need, in order to found their reliance on Article 30 EC.

15 Since it was not satisfied by that reply, the Commission, on 12 September 2000, issued a reasoned opinion requesting the Kingdom of Denmark to comply with its obligations under Articles 28 EC and 30 EC within two months of the date of notification of that opinion. The Commission claimed, in particular, that a prohibition on marketing by virtue of the Danish administrative practice on the ground that the addition of vitamins and minerals does not meet any nutritional need constitutes an unjustified interference with trade for the purposes of those provisions. For such interference to be justified under Article 30 EC, the Danish authorities would have to show that the product to which the nutrients were added constitutes a real threat to public health if it was marketed and consumed on the Danish market. According to the Commission, that means that those authorities would have to outline the scientific data upon which they based their refusal of authorisation, as well as the reasons why the vitamin and mineral content of the relevant products represents a threat to public health.

16 By letter of 6 November 2000, the Danish authorities replied to the reasoned opinion. They claimed that the Court had clearly indicated in its judgment in *Sandoz*, cited above, that Member States, when they apply a prohibition on addition of vitamins, are not required to establish a real risk associated with the relevant product, a task which is impossible under existing circumstances. According to those authorities, in order to ensure observance of the principle of proportionality, Member States have only to establish that the addition of the nutrient in question does not meet a real need.

17 Since it was not convinced by the Danish authorities' reply to the reasoned opinion, the Commission brought this action.

The action

Arguments of the parties

18 The Commission submits that the Danish administrative practice constitutes an obstacle to the free movement of goods.

19 The Danish Government does not dispute the fact that its practice constitutes an obstacle to the free movement of goods, but it contends that it is justified under Article 30 EC.

20 The Commission submits that the general prohibition, in the absence of a nutritional need in the Danish population, of the marketing of food products to which vitamins or minerals have been added is not justified by any of the grounds set out in Article 30 EC and, in particular, the protection of human life and health. The absence of nutritional need is not, according to the Commission, a justification under Article 30 EC.

21 Whilst fully recognising the necessity for the Member States to establish a food policy intended to improve the state of the population's general health, the Commission maintains, none the less, that general preoccupations relating to the desired composition of the nutritional regime of the population of those States cannot constitute a lawful justification for obstacles to trade between them.

22 As regards the judgment in *Sandoz*, cited above, the Commission maintains that the prohibition on marketing at issue in the proceedings which gave rise to that judgment was justified not by the absence of a nutritional need, but by the fact that the presence of two particular vitamins in the products in question in those proceedings posed a risk to public health.

23 The Commission submits that the interpretation by the Danish authorities of the judgment in *Sandoz* is based on an erroneous *a contrario* deduction from paragraph 20 thereof. It maintains that that paragraph establishes only that a prohibition on marketing of foodstuffs to which vitamins have been added is contrary to the principle of proportionality when the addition meets a nutritional need. Conversely, that judgment cannot be validly relied upon to support the argument that, in all cases where there is no nutritional need in the relevant population, the addition of vitamins to foodstuffs poses a risk to public health.

24 The Commission points out that a Member State which seeks to justify, by relying on Article 30 EC, a prohibition on marketing a product lawfully manufactured and/or marketed in other Member States, such as that in issue in this case, must, in accordance with that provision, show that such prohibition is necessary for the protection of public health.

25 Referring to paragraph 28 of the judgment of the EFTA Court of 5 April 2001 in Case E-3/00 *EFTA Surveillance Authority* v *Norway* (EFTA Court Report 2000/01, p. 73), the Commission submits that the mere finding of the absence of a nutritional need is not enough to justify a general prohibition on foodstuffs enriched with vitamins or minerals. Such a prohibition should at the very least be made subject to the condition that the risks to public health posed by the addition of such vitamins be proved by a detailed analysis of those risks.

26 According to the Commission, the Member State must show, in each case, by referring to the scientific data justifying the refusal of authorisation, the reasons why the vitamin and mineral content of the foodstuffs in question is a threat to public health.

27 As regards this case, the Commission claims, first, that general considerations such as those invoked by the Danish authorities with regard to the potential risk from excessive consumption of vitamins do not constitute sufficient proof of the existence of a risk to public health in relation to the addition of vitamins to foodstuffs. Secondly, it argues that the fact that there is a specific risk associated with the ingestion of certain vitamins, such as vitamins A or D, does not justify a general or systematic prohibition on the enrichment of foodstuffs in all cases other than those covered by the Codex Alimentarius.

28 For its part, the Danish Government maintains that the Court has already observed in the judgment in *Sandoz* that, where Member States apply a prohibition on addition of vitamins, they do not have to show an actual risk associated with each foodstuff, such a task being impossible in the current state of scientific knowledge. According to that government, in order to comply with the principle of proportionality, it is sufficient to establish that the enrichment of foodstuffs does not meet a nutritional need in the population concerned.

29 As regards the establishment of a risk to public health, the Danish Government submits that it is also clear from the judgment in *Sandoz* that it is sufficient to determine that the ingestion of high doses of vitamins and minerals can have harmful effects, that scientific research is not yet in a position to lay down with certainty the critical limits or to determine the precise effects of such ingestion and that, therefore, the existence of a danger to human health cannot be excluded, since the consumer ingests additional quantities which it is not possible to foresee or monitor.

30 According to it, a specific evaluation of the danger on a case-by-case basis finds no support in the Court's case-law and would not be possible in practice. The Danish Government claims that, in order to maintain a genuine view of the overall quantities of vitamins and minerals absorbed by the population through the consumption of foodstuffs, it is necessary to implement an overall policy of prevention, which takes into consideration the fact that the sources of absorption of such nutrients are many and which takes account of the complex interaction occurring in the course of the ingestion thereof and in the course of absorption of other substances important for the organism.

31 In that regard, the Danish Government refers to various scientific studies on vitamins and minerals which, according to it, show the harmful effect of the ingestion of those nutrients not only in large doses, but also in relatively low doses because of the way in which those nutrients combine.

32 Thus, with regard to vitamins A, D and B 6, the Danish Government claims that, even in relatively low doses, it can be established that they have a toxic effect.

33 As regards the judgment in *EFTA Surveillance Authority* v *Norway*, cited above, to which the Commission refers, the Danish Government submits that it can be explained by the specific circumstances surrounding the treatment of the originating application submitted by the Kellogg's company in that case.

34 According to the Danish Government, for a prohibition on marketing to be justified on the basis of Article 30 EC, it is not necessary to prove that the quantities of nutrients added to a given product are so large as to constitute a risk to public health.

35 It maintains, in addition, that the Court has already accepted, in particular in *Sandoz* and in Case C-473/98 *Toolex* [2000] ECR I-5681, that the scientific uncertainty, which underlies the precautionary principle, can justify a prudent approach of Member States in relation to the existence of potential dangers.

36 The Danish Government adds that its administrative practice is directly inspired by the Codex Alimentarius to which the Court's case-law frequently refers.

37 In short, that government claims that its administrative practice is justified by the fact that there is a potential risk to public health inasmuch as vitamins and minerals are added to foodstuffs although, in Denmark, there is no nutritional need.

Findings of the Court

38 The free movement of goods between Member States is a fundamental principle of the EC Treaty which finds its expression in the prohibition, set out in Article 28 EC, of quantitative restrictions on imports between Member States and all measures having equivalent effect.

39 The prohibition on measures having an effect equivalent to restrictions set out in Article 28 EC covers all commercial rules enacted by the Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade (see, in particular, Case 8/74 *Dassonville* [1974] ECR 837,

paragraph 5; Case 178/84 *Commission* v *Germany* [1987] ECR 1227 ('*Beer purity law*'), paragraph 27; and Case C-12/00 *Commission* v *Spain* [2003] ECR I-459, paragraph 71).

40 It is not disputed that the Danish administrative practice is a measure having equivalent effect to quantitative restrictions within the meaning of Article 28 EC.

41 Indeed, that practice, which requires that the marketing of foodstuffs enriched with vitamins and minerals coming from other Member States where they are lawfully manufactured or marketed be made subject to proof of a nutritional need in the Danish population, makes the marketing of such foodstuffs more difficult, if not impossible, and, consequently, hinders trade between the Member States.

42 As regards the question whether that administrative practice may none the less be justified on the basis of Article 30 EC, it is for the Member States, in default of harmonisation and to the extent that uncertainties continue to exist in the current state of scientific research, to decide on their intended level of protection of human health and life and on whether to require prior authorisation for the marketing of foodstuffs, always taking into account the requirements of the free movement of goods within the Community (see *Sandoz*, paragraph 16; Case C-42/90 *Bellon* [1990] ECR I-4863, paragraph 11; and Case C-400/96 *Harpegnies* [1998] ECR I-5121, paragraph 33).

43 That discretion relating to the protection of public health is particularly wide where it is shown that uncertainties continue to exist in the current state of scientific research as to certain substances, such as vitamins, which are not as a

general rule harmful in themselves but may have special harmful effects solely if taken to excess as part of the general nutrition, the composition of which cannot be foreseen or monitored (see *Sandoz*, paragraph 17).

44 Community law does not therefore, in principle, preclude a Member State from prohibiting, save for prior authorisation, the marketing of foodstuffs incorporating nutrients, such as vitamins or minerals other than those whose use is lawful under Community legislation.

45 However, in exercising their discretion relating to the protection of public health, the Member States must comply with the principle of proportionality. The means which they choose must therefore be confined to what is actually necessary to ensure the safeguarding of public health; they must be proportional to the objective thus pursued, which could not have been attained by measures which are less restrictive of intra-Community trade (see *Sandoz*, paragraph 18; *Bellon*, paragraph 14; and *Harpegnies*, paragraph 34).

46 Furthermore, since Article 30 EC provides for an exception, to be interpreted strictly, to the rule of free movement of goods within the Community, it is for the national authorities which invoke it to show in each case, in the light of national nutritional habits and in the light of the results of international scientific research, that their rules are necessary to give effective protection to the interests referred to in that provision and, in particular, that the marketing of the products in question poses a real risk to public health (see, to that effect, *Sandoz*, paragraph 22; Case 227/82 *Van Bennekom* [1983] ECR 3883, paragraph 40; *Beer purity law*, cited above, paragraph 46; and Case C-228/91 *Commission* v *Italy* [1993] ECR I-2701, paragraph 27).

47 A prohibition on the marketing of foodstuffs to which nutrients have been added must therefore be based on a detailed assessment of the risk alleged by the Member State invoking Article 30 EC (see, to that effect, *EFTA Surveillance Authority* v *Norway*, cited above, paragraph 30).

48 A decision to prohibit marketing, which indeed constitutes the most restrictive obstacle to trade in products lawfully manufactured and marketed in other Member States, can only be adopted if the real risk alleged for public health appears sufficiently established on the basis of the latest scientific data available at the date of the adoption of such decision. In such a context, the object of the risk assessment to be carried out by the Member State is to appraise the degree of probability of harmful effects on human health from the addition of certain nutrients to foodstuffs and the seriousness of those potential effects.

49 It is clear that such an assessment of the risk could reveal that scientific uncertainty persists as regards the existence or extent of real risks to human health. In such circumstances, it must be accepted that a Member State may, in accordance with the precautionary principle, take protective measures without having to wait until the reality and seriousness of those risks are fully demonstrated (see, to that effect, Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, paragraph 63). However, the risk assessment cannot be based on purely hypothetical considerations (see, to that effect, *EFTA Surveillance Authority* v *Norway*, paragraph 29, and Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105, paragraph 106).

50 In assessing the risk in question, it is not only the particular effects of the marketing of an individual product containing a definite quantity of nutrients which are relevant. It could be appropriate to take into consideration the cumulative effect of the presence on the market of several sources, natural or artificial, of a particular nutrient and of the possible existence in the future of additional sources which can reasonably be foreseen (see *EFTA Surveillance Authority* v *Norway*, paragraph 29).

51 In many cases, the assessment of those factors will demonstrate that there is a high degree of scientific and practical uncertainty in that regard. A proper application of the precautionary principle presupposes, in the first place, the identification of the potentially negative consequences for health of the proposed addition of nutrients, and, secondly, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research (see, to that effect, *EFTA Surveillance Authority* v *Norway*, paragraph 30, and *Monsanto Agricoltura Italia and Others*, paragraph 113).

52 Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures (see, to that effect, *EFTA Surveillance Authority* v *Norway*, paragraph 31).

53 Such measures must not be allowed unless they are non-discriminatory and objective (see, to that effect, *EFTA Surveillance Authority* v *Norway*, paragraph 32).

54 It must be added that, in such a context, the criterion of the nutritional need of the population of a Member State can play a role in its detailed assessment of the risk which the addition of nutrients to foodstuffs may pose for public health. However, contrary to the interpretation of the *Sandoz* judgment suggested by the Danish Government, the absence of such a need cannot, by itself, justify a total prohibition, on the basis of Article 30 EC, of the marketing of foodstuffs lawfully manufactured and/or marketed in other Member States.

55 In the present case, the Danish administrative practice is disproportionate since, apart from the four restrictively defined cases of what is considered to constitute a nutritional need and which are mentioned in paragraph 11 of this judgment, it systematically prohibits the marketing of all foodstuffs to which vitamins and minerals have been added, without distinguishing according to the different vitamins and minerals added or according to the level of risk which their addition may possibly pose to public health.

56 Indeed, the systematic prohibition under the Danish administrative practice on the marketing of enriched products which do not meet a nutritional need of the population does not enable Community law to be observed in regard to the identification and assessment of a real risk to public health, which requires a detailed assessment, case-by-case, of the effects which the addition of the minerals and vitamins in question could entail.

57 In light of the foregoing, it must be declared that, by applying an administrative practice which entails that enriched foodstuffs lawfully produced or marketed in other Member States can be marketed in Denmark only if it is shown that such enrichment with nutrients meets a need in the Danish population, the Kingdom of Denmark has failed to fulfil its obligations under Article 28 EC.

Costs

58 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Commission has applied for costs and the Kingdom of Denmark has been unsuccessful, the latter must be ordered to pay the costs.

On those grounds,

THE COURT

hereby:

1. **Declares that by applying an administrative practice which entails that enriched foodstuffs lawfully produced or marketed in other Member States can be marketed in Denmark only if it is shown that such enrichment with nutrients meets a need in the Danish population, the Kingdom of Denmark has failed to fulfil its obligations under Article 28 EC;**

2. **Orders the Kingdom of Denmark to pay the costs.**

Puissochet	Wathelet	Schintgen
Timmermans	Gulmann	La Pergola
Macken	Colneric	von Bahr
Cunha Rodrigues		Rosas

Delivered in open court in Luxembourg on 23 September 2003.

R. Grass

Registrar

J.-P. Puissochet

For the President