JUDGMENT OF THE COURT
20 March 2003 *

In Case C-3/00,

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

applicant,

supported by

Republic of Iceland, represented by H.S. Kristjánsson, acting as Agent,

and by

Kingdom of Norway, represented by B.B. Ekeberg, acting as Agent,

interveners,

* Language of the case: Danish.

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

defendant,

APPLICATION for the annulment of Commission Decision 1999/830/EC of 26 October 1999 on the national provisions notified by the Kingdom of Denmark concerning the use of sulphites, nitrites and nitrates in foodstuffs (OJ 1999 L 329, p. 1),

THE COURT,

composed of: G.C. Rodríguez Iglesias, President, J.-P. Puissochet, M. Wathelet and R. Schintgen (Presidents of Chambers), C. Gulmann, D.A.O. Edward, A. La Pergola, P. Jann, V. Skouris, F. Macken, N. Colneric, S. von Bahr and J.N. Cunha Rodrigues (Rapporteur), Judges,

Advocate General: A. Tizzano,
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 25 September 2001,

after hearing the Opinion of the Advocate General at the sitting on 30 May 2002,

gives the following

Judgment

1 By application lodged at the Court Registry on 6 January 2000, the Kingdom of Denmark brought an action under the first paragraph of Article 230 EC for the annulment of Commission Decision 1999/830/EC of 26 October 1999 on the national provisions notified by the Kingdom of Denmark concerning the use of sulphites, nitrites and nitrates in foodstuffs (OJ 1999 L 329, p. 1, hereinafter 'the contested decision').

2 By order of the President of the Court of 4 October 2000, the Republic of Iceland and the Kingdom of Norway were granted leave to intervene in support of the form of order sought by the Kingdom of Denmark.

Legal framework

Article 95 EC

3 The Treaty of Amsterdam, which entered into force on 1 May 1999, substantially amended Article 100a of the EC Treaty and renumbered it as Article 95 EC. Article 95(4) to (7) EC provides:

'4. If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 30, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.

5. Moreover, without prejudice to paragraph 4, if, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.

6. The Commission shall, within six months of the notifications as referred to in paragraphs 4 and 5, approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs 4 and 5 shall be deemed to have been approved.

When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.

7. When, pursuant to paragraph 6, a Member State is authorised to maintain or introduce national provisions derogating from a harmonisation measure, the Commission shall immediately examine whether to propose an adaptation to that measure.'

Directive 89/107/EEC

4 Adopted on the legal basis of Article 100a of the Treaty, Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption (OJ 1989 L 40, p. 27, hereinafter 'the

framework directive') defines food additives, sets the basic conditions for their use in foodstuffs and lays down the framework for the subsequent development of a positive list of additives. In accordance with Article 3(2) of that directive, that positive list establishes the additives whose use is authorised, to the exclusion of all others, the foodstuffs to which those additives may be added and the conditions of that use.

5 Pursuant to Article 2(3) of the framework directive, food additives are to be included in the list on the basis of the general criteria described in Annex II to the directive.

6 Annex II to the framework directive, entitled 'General criteria for the use of food additives', provides, in paragraphs 1, 3 and 6:

'1. Food additives can be approved only provided that:

— there can be demonstrated a reasonable technological need and the purpose cannot be achieved by other means which are economically and technologically practicable,

— they present no hazard to the health of the consumer at the level of use proposed, so far as can be judged on the scientific evidence available,

— they do not mislead the consumer.

...

3. To assess the possible harmful effects of a food additive or derivatives thereof, it must be subjected to appropriate toxicological testing and evaluation. The evaluation should also take into account, for example, any cumulative, synergistic or potentiating effect of its use and the phenomenon of human intolerance to substances foreign to the body.

...

6. Approval for food additives must:

...

(b) be limited to the lowest level of use necessary to achieve the desired effect;

(c) take into account any acceptable daily intake, or equivalent assessment, established for the food additive and the probable daily intake of it from all sources....'

7 Article 6 of the framework directive states that provisions that may have an effect upon public health are to be adopted after consultation with the Scientific Committee for Food (hereinafter 'the SCF').

Directive 95/2/EC

8 Pursuant to the framework directive, the content of the positive list was set out in three specific directives: European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs (OJ 1994 L 237, p. 3), European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs (OJ 1994 L 237, p. 13) and European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners (OJ 1995 L 61, p. 1).

9 Adopted on the legal basis of Article 100a of the Treaty, Directive 95/2 applies to the conditions of use of food additives other than colours and sweeteners. At the time of its adoption, the Danish delegation voted against that directive, stating, in a voting declaration made on 15 December 1994, that the directive did not respond satisfactorily to health requirements to which the delegation ascribed crucial importance as regards, *inter alia*, the use of nitrites, nitrates and sulphites as food additives.

10 Under Article 1(2) of Directive 95/2:

'Only additives which satisfy the requirements laid down by the Scientific Committee for Food may be used in foodstuffs.'

11 In accordance with Article 2 of Directive 95/2, the food additives permitted in foodstuffs are listed in Annexes I, III, IV and V thereto. Specifically, it follows from Article 2(4) that the additives listed in Annex III may only be used in the foodstuffs referred to in that annex and under the conditions specified therein.

12 Part B of Annex III to Directive 95/2 lists, in the following table, the conditions of use for sulphur dioxide (E 220) and for sulphites — sodium sulphite (E 221), sodium hydrogen sulphite (E 222), sodium metabisulphite (E 223), potassium metabisulphite (E 224), calcium sulphite (E 226), calcium hydrogen sulphite (E 227) and potassium hydrogen sulphite (E 228). Maximum levels are expressed in mg/kg or in mg/l of SO_2, as appropriate, and concern the total amount available, taking all sources into account.

Foodstuff	Maximum level (mg/kg or mg/l as appropriate), expressed as SO_2
Burger meat with a minimum vegetable and/or cereal content of 4%	450
Breakfast sausages	450
Longaniza fresca and *butifarra fresca*	450
Dried salted fish of the Gadidae species	200
Crustaceans and cephalopods:	
— fresh, frozen and deep-frozen	150(1)
Crustaceans, *penaeidae solencerides, aristeidae* family:	
— up to 80 units	150(1)
— between 80 and 120 units	200(1)
— over 120 units	300(1)
— cooked	50(1)

Foodstuff	Maximum level (mg/kg or mg/l as appropriate), expressed as SO_2
Dry biscuit	50
Starches (excluding starches for weaning foods, follow-on formulae and infant formulae)	50
Sago	30
Pearl barley	30
Dehydrated granulated potatoes	400
Cereal- and potato-based snacks	50
Peeled potatoes	50
Processed potates (including frozen and deep-frozen potatoes)	100
Potato dough	100
White vegetables, dried	400
White vegetables, processed (including frozen and deep-frozen white vegetables)	50
Dried ginger	150
Dried tomatoes	200
Horseradish pulp	800
Onion, garlic and shallot pulp	300
Vegetables and fruits in vinegar, oil or brine (except olives and golden peppers in brine)	100
Golden peppers in brine	500
Processed mushrooms (including frozen mushrooms)	50
Dried mushrooms	100

Foodstuff	Maximum level (mg/kg or mg/l as appropriate), expressed as SO_2
Dried fruits:	
— apricots, peaches, grapes, prunes and figs	2000
— bananas	1000
— apples and pears	600
— other (including nuts in shell)	500
Dried coconut	50
Candied, crystallized or glacé fruit, vegetables, angelica and citrus peel	100
Jam, jelly and marmalade as defined in Directive 79/693/EEC (except extra jam and extra jelly) and other similar fruit spreads, including low-calorie products	50
Jams, *jellies* and *marmalades* made with sulphited fruit	100
Fruit-based pie fillings	100
Citrus-juice-based seasonings	200
Concentrated grape juice for home wine-making	2 000
Mostarda di frutta	100
Jellying fruit extract, liquid pectin for sale to the final consumer	800
Bottled whiteheart cherries, rehydrated dried fruit and lychees	100
Bottled, sliced lemon	250
Sugars as defined in Directive 73/437/EEC, except glucose syrup, whether or not dehydrated	15
Glucose syrup, whether or not dehydrated	20
Treacle and molasses	70
Other sugars	40
Toppings (syrup for pancakes, flavoured syrups for milkshakes and ice cream; similar products)	40

Foodstuff	Maximum level (mg/kg or mg/l as appropriate), expressed as SO_2
Orange, grapefruit, apple and pineapple juice for bulk dispensing in catering establishments	50
Lime and lemon juice	350
Concentrates based on fruit juice and containing not less than 2.5% barley (*barley water*)	350
Other concentrates based on fruit juice or comminuted fruit; *capilé groselha*	250
Non-alcoholic flavoured drinks containing fruit juice	20 (carry-over from concentrates only)
Non-alcoholic flavoured drinks containing at least 235 g/l glucose syrup	50
Grape juice, unfermented, for sacramental use	70
Glucose-syrup-based confectionary	50 (carry-over from the glucose syrup only)
Beer including low-alcohol and alcohol-free beer	20
Beer with a second fermentation in the cask	50
Wines	In accordance with Council Regulations (EEC) No 822/87, (EEC) No 4252/88, (EEC) No 2332/92 and (EEC) No 1873/84 and their implementing regulations ...
Alcohol-free wine	200
Made wine	260
Cider, perry, fruit wine, sparkling fruit wine (including alcohol-free products)	200
Mead	200
Fermentation vinegar	170
Mustard, excluding Dijon mustard	250
Dijon mustard	500
Gelatin	50
Vegetable- and cereal-protein-based meat, fish and crustacean analogues	200

(1) In edible parts.

13 Part C of Annex III to Directive 95/2 lists in a table the conditions of use for nitrites and nitrates in foodstuffs. The contents of that table may be shown as follows:

Potassium nitrite (E 249) and sodium nitrite (E 250):

Foodstuff	Indicative ingoing amount (mg/kg)	Residual amount (mg/kg)
Non-heat-treated, cured, dried meat products	150(2)	50(3)
Other cured meat products Canned meat products Foie gras, foie gras entier, blocs de foie gras	150(2)	100(3)
Cured bacon		175(3)

(2) Expressed as $NaNO_2$.
(3) Residual amount at point of sale to the final consumer, expressed as $NaNO_2$.

Sodium nitrate (E 251) and potassium nitrate (E 252):

Foodstuff	Indicative ingoing amount (mg/kg)	Residual amount (mg/kg)
Cured meat products Canned meat products	300	250(4)
Hard, semi-hard and semi-soft cheese Dairy-based cheese analogue		50(4)
Pickled herring and sprat		200(5)

(4) Expressed as $NaNO_3$.
(5) Residual amount, nitrite formed from nitrate included, expressed as $NaNO_2$.

14 The first paragraph of Article 9 of Directive 95/2 provides:

'Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this directive not later than 25 September 1996 in order to:

— allow, by 25 September 1996 at the latest, trade in and use of products conforming to this directive,

— prohibit by 25 March 1997 at the latest, trade in and use of products not conforming to this directive; products put on the market or labelled before that date which do not comply with this directive may, however, be marketed until stocks are exhausted.'

Danish legislation

15 The first general legislation on food additives was adopted by the Kingdom of Denmark in 1973. That legislation included, *inter alia*, a positive list of authorised additives. Only the additives mentioned in that list could be used, and their use was authorised only under the conditions laid down in that list.

16 The Danish list progressively evolved in response to health assessments and technological needs, in parallel with the adoption of Community rules on additives.

17 With the exception of the provisions on sulphites, nitrites and nitrates, Directive 95/2 was implemented in Danish law by Order No 1055 of the Ministry of Health of 18 December 1995 on food additives (Lovtidende A 1995 hæfte 198 udgivet den 30.12.1995, s. 5571), subsequently amended by Order No 834 of the Ministry of Health of 23 September 1996 (Lovtidende A 1996 hæfte 145 udgivet den 24.9.1996, s. 5089) and by Order No 942 of the Ministry of Food of 11 December 1997 (Lovtidende A 1997 hæfte 183 udgivet den 11.12.1997, s. 5614) (hereinafter 'Order No 1055/95').

18 The annexes to Order No 1055/95 set out, in the form of tables, the conditions of use of sulphites in foodstuffs other than wine (Community rules concerning wine

apply to Denmark). Their contents may be shown as follows:

Foodstuff	Maximum amount added ;(mg/kg or mg/l, as appropriate), expressed as SO_2
Garlic pulp	300
Horseradish pulp	600
Apricots	1 000(6)
Granulated potatoes	100
Jams, jellies, marmalades and chestnut purée (covered by Directive 79/693/EEC)	50(6)
Other jams	50(6)
Glucose-syrup-based confectionary	50(6)
Dry biscuits	150
Deep-water fresh lobster	30
Frozen crustaceans	30
Cooked crustaceans	30
Sugar products (covered by Directive 73/437/EEC)	15(6)
Glucose syrup	20(6)
Vinegar with an acid content of 8%	100
Lime juice	100
Lemon juice	350
Flavoured drinks based on concentrated fruit juice	20(6)
Beer	20
Cider and perry	50
Fruit wine	300

(6) Residual amount.

19 The annexes to Order No 1055/95 also state the conditions of use for nitrites and nitrates in foodstuffs. Their contents may be shown as follows:

Potassium nitrite (E 249) and sodium nitrite (E 250):

Foodstuff	Amount added [7] (mg/kg)
Non-heat-treated meat-based products derived from whole pieces of meat, including slices of products	60
Bacon of the Wiltshire type and related cuts, including saltcured ham	150
Heat-treated meat-based products derived from whole pieces of meat, including slices of products	60
Rullepølse (rolled meat sausage)	100
Entirely preserved or semi-preserved heat-treated meat-based products derived from whole pieces of meat, including slices of products	150
Non-heat-treated meat-based products derived from minced meat	60
Fermented Danish salami	100
Entirely preserved or semi-preserved non-heat-treated meat-based products derived from minced meat	150
Heat-treated meat-based products derived from minced meat	60
Meatballs or liver paté	0
Entirely preserved or semi-preserved heat-treated meat-based products derived from minced meat	150

(7) Calculated as $NaNO_2$.

Sodium nitrate (E 251) and potassium nitrate (E 252):

Foodstuff	Quantity added [8] (mg/kg)
Bacon of the Wiltshire type and related cuts, including saltcured ham	300

(8) Calculated as $NaNO_3$.

The contested decision

20 By letter of 15 July 1996, confirmed by letter of 20 May 1997, the Danish Government, pursuant to Article 100a(4) of the Treaty, notified to the Commission its national provisions on the use of sulphites, nitrites and nitrates (hereinafter 'the contested provisions') with a view to maintaining them, by way of derogation from the provisions of Directive 95/2.

21 Following informal contacts with the Commission services, the Danish Government sent the Commission additional information on 14 July 1998. The Commission then sent the notification file to the other Member States for an opinion. Seven of them issued opinions, several of which expressed reservations concerning that government's request.

22 The Commission, on 26 October 1999, adopted the contested decision on the legal basis of Article 95(6) EC. In that decision the Commission found that the contested provisions 'are aimed at protecting public health, [but] they are excessive in relation to this aim' (paragraph 44 of the grounds of the contested decision) and therefore decided not to approve them.

23 The contested decision was notified to the Danish Government on 28 October 1999.

24 In response to that notification, the Danish Government repealed the contested provisions by adopting Order No 822 of 5 November 1999 (Lovtidende A 1999, hæfte 160 udgivet den 9.11.1999, s. 5713).

Scientific facts

Sulphites

25 It is clear from the case-file that the addition of sulphites to foodstuffs produces a preservative effect. They are used in, *inter alia*, wine, jam, biscuits and dried fruit, where they inhibit the development of micro-organisms which cause the deterioration of foodstuffs, and the development of mould and of yeasts.

26 Ingested in large amounts, however, sulphites can be harmful to health, in particular by causing lesions in the digestive tract. They can also provoke serious allergic reactions in asthmatics and even lead to death in the most serious cases. Such reactions may occur even where the sufferer ingests only very small amounts of sulphites.

27 The SCF carried out a toxicological assessment of sulphites in 1981 (SCF reports, 11th series, p. 47, hereinafter 'the 1981 opinion'). Subsequently, on 25 February 1994, the SCF gave an opinion on sulphites used as food additives (SCF reports, 35th series, p. 23, hereinafter 'the 1994 opinion'). In that opinion, the SCF established an acceptable daily intake (ADI) for sulphur dioxide at 0-0.7 mg/kg of body weight. In addition, the SCF recommended, in the light of the incidence of severe allergic reactions, that the use of sulphites should be limited as much as possible and that their presence in foodstuffs should be indicated on labels.

Nitrites and nitrates

28 According to the information available to the Court in the present case, nitrites and nitrates are food additives which have a preserving effect in foodstuffs and can be dangerous for humans in a variety of ways.

29 The addition of nitrites and nitrates to foodstuffs reinforces the preserving effect of smoking, salting or cooking, for example in meat products. Those substances inhibit the growth of bacteria which can cause the deterioration of those foodstuffs, as well as that of bacterial pathogens such as *Clostridium botulinum*, which causes botulism. However, in meat products, nitrites are transformed into nitrosamines, *inter alia* by means of a reaction between the nitrites and certain substances which are naturally present in meat. Nitrosamines are recognised carcinogens.

30 The SCF examined the technological needs and health risks attached to the addition of nitrites and nitrates in its opinions of 19 October 1990 (SCF reports, 26th series, p. 21, hereinafter 'the 1990 opinion') and 22 September 1995 (SCF reports, 38th series, p. 1, hereinafter 'the 1995 opinion'). In the first of those opinions, it stated, *inter alia:*

'It would be prudent to reduce the levels of pre-formed nitroso compounds in the diet as far as possible. The Committee therefore recommends that exposure to preformed nitrosamines in food should be minimised by appropriate technological practices such as lowering the levels of nitrites and nitrates added to foods to the minimum required to achieve the necessary preservative effect and to ensure microbiological safety. These levels should be the lowest achievable in accordance with the information provided to the Committee during the course of the present review.' (SCF reports, 26th series, pp. 27 and 28).

31 In its 1995 opinion, the SCF pointed out that nitrosamines are carcinogens and stated that it is impossible to determine a level below which they pose no carcinogenic risk. The SCF reiterated the conclusion contained in its 1990 opinion, that exposure to nitrosamines in food should be minimised (SCF reports, 38th series, pp. 22 and 23, paragraphs 3.3.2.2 and 3.3.2.3).

Application

32 In support of its application for annulment of the contested decision, the Kingdom of Denmark relies on five series of pleas in law, alleging, first, infringement of essential procedural requirements; secondly, failure to observe the conditions of application of Article 95(4) EC; thirdly, errors in law and as to the facts, specifically vitiating the rejection of the contested provisions concerning the use of sulphites; fourthly, errors in law and as to the facts specifically vitiating the rejection of the contested provisions concerning the use of nitrites and nitrates; and fifthly, failure to adopt a position and failure to state reasons.

Infringement of essential procedural requirements

Arguments of the parties

33 By its first plea, the Kingdom of Denmark, supported by the Republic of Iceland, claims that the contested decision is vitiated by infringement of essential procedural requirements in that the Commission failed to observe the principle of Denmark's right to be heard before it adopted that decision. The decision is based on incorrect findings — *inter alia*, that the provisions of Directive 95/2 comply with the updated opinions of the SCF — which could have been corrected if the Commission had given the Danish Government the opportunity to do so.

34 By its second plea, the Kingdom of Denmark, supported by the Republic of Iceland, states that the contested decision is vitiated by the infringement of essential procedural requirements in that the Commission did not give the Danish Government the opportunity to hear the opinions expressed by the other Member States or to comment on them. The Commission on its own initiative sent the notification file to the Member States for an opinion, although no provision of the EC Treaty provides that it must request their opinion before adopting a decision pursuant to Article 95(6) EC. Yet several of the complaints made in the contested decision against the contested provisions coincide with those opinions, which can thus be assumed to have influenced that decision. Those opinions contain incorrect views which are repeated in that decision and which the Danish Government could have corrected had it been consulted.

35 In reply to the first and second pleas the Commission contends, as its principal argument, that the principle of the right to be heard is not applicable in the case of a notification pursuant to Article 95(4) EC. The procedure established by that provision in fact constitutes one stage of a legislative procedure, that is to say, it results in the adoption of measures of general application. To authorise the maintenance of derogating national measures under Article 95(4) EC would be

tantamount to amending a directive or adopting a transitional regime in the framework of a directive.

36 The Commission contends, in the alternative, that in the present case it observed the principle of the right to be heard. The Danish Government was genuinely given the opportunity to make its views known. First, under the legislative procedure which preceded the adoption of Directive 95/2, that government had the opportunity to make known its view on the level of protection provided by that directive. Secondly, in its notification pursuant to Article 95(4) EC, it set out the elements which it considered to justify the use of that provision. Had the Danish Government been heard before the Commission adopted the contested decision, it would thus have had a third opportunity to make its views known. The Commission adds that, after notification of the contested provisions pursuant to Article 95(4) EC but prior to the Commission's adoption of the contested decision, a meeting took place on 19 November 1997 between the Commission and the Danish authorities in order to discuss the case. The Danish Government had ample opportunity to raise other questions regarding its notification at that meeting.

37 In the further alternative, even if the Court should hold that there was a failure to observe the principle of the right to be heard, the Commission contends that that infringement had no effect on the outcome of the procedure in the present case. It maintains that, according to the Court's case-law, infringement of the right to a fair hearing can result in annulment only when there is reason to consider that, had it not been for that irregularity, the outcome of the procedure might have been different. However, the Commission informed the Danish Government, *inter alia* by letter of 16 March 1999 from Mr Bangemann, Member of the Commission, that it had requested and received observations from the other Member States, but the Danish Government never asked to be allowed to comment on the information obtained from the other Member States. It expressed that wish for the first time in its application for annulment. Moreover,

on 22 October 1999, the Danish Government sent letters to two Members of the Commission, in which it commented on a number of the technical elements in the draft decision. It follows from this that that government had knowledge of that draft prior to its adoption and that it made its observations on the subject known before the contested decision was adopted.

Findings of the Court

38 First of all, the nature of the procedure provided in Article 95(4) and (6) EC must be considered.

39 It is of course true, as the Commission contends, that a Commission decision adopted under that procedure, approving the maintenance of a national provision which derogates from a Community measure of general application, results in the modification *erga omnes* of the scope of that measure. None the less, the procedure which leads to such a decision cannot be considered as part of the legislative process resulting in the adoption of a measure of general application.

40 The procedure for approval of derogating national provisions referred to in Article 95(4) and (6) EC is different from that which results in the adoption of the harmonisation measure derogated from. Under Article 95(1) EC, such a measure is adopted, under the co-decision procedure referred to in Article 251 EC, by the Council and the European Parliament acting on a Commission proposal after consulting the Economic and Social Committee. By contrast, the approval procedure is initiated, under Article 95(4) EC, after the legislature adopts the

harmonisation measure. Its purpose is to assess the specific needs of a Member State, since the Commission is required, under Article 95(7) EC, to examine whether to propose to the Community legislature an adaptation of the harmonisation measure, immediately after approving national provisions which derogate from it.

41 The Commission's argument based on the legislative nature of the procedure therefore cannot be upheld.

42 None the less, it should be pointed out that no provision provides for the application of the principle of the right to be heard to the decision procedure laid down in Article 95(4) and (6) EC relating to the approval of national provisions derogating from a harmonisation measure adopted at Community level.

43 Similarly, no provision requires the Commission, under that procedure, to gather opinions from the other Member States, as it has done in the present case.

44 It is therefore important to establish whether the principle of the right to be heard is applicable even in the absence of specific legislation, in particular in the situation where such opinions have been requested.

45 The principle of the right to be heard, whose observance is ensured by the Court of Justice, requires the public authority to hear interested parties before adopting a decision which concerns them (Case C-315/99 P *Ismeri Europea* v *Court of Auditors* [2001] ECR I-5281, paragraph 28).

46 The Court has consistently held that the principle of the right to a fair hearing, to which the principle of the right to be heard is closely linked, applies not only to citizens but also to the Member States. As regards the latter, that principle has been recognised in the context of proceedings brought by a Community institution against Member States, such as those concerning the review of State aid or the monitoring of Member State conduct as regards public enterprises (see, for example, Joined Cases C-48/90 and C-66/90 *Netherlands and PTT Nederland* v *Commission* [1992] ECR I-565, paragraph 44, and Case C-288/96 *Germany* v *Commission* [2000] ECR I-8237, paragraph 99).

47 However, the procedure provided for under Article 95(4) and (6) EC is initiated not by a Community institution but by a Member State, with the decision of the Community institution being adopted merely in response to that initiative.

48 That procedure is initiated at the request of a Member State seeking the approval of national provisions derogating from a harmonisation measure adopted at Community level. In its request, that Member State is at liberty to comment on the decision it asks to have adopted, as is quite clear from Article 95(4) EC, which requires that Member State to state the grounds for maintaining the national provisions in question. The Commission in turn must be able, within the prescribed period, to obtain the information which proves to be necessary without being required once more to hear the applicant Member State.

49 That conclusion is confirmed by the second subparagraph of Article 95(6) EC, according to which the derogating national provisions are deemed to have been approved if the Commission does not take a decision within a certain period. In addition, under the third subparagraph of Article 95(6) EC, no extension of that period is allowed where there is a danger for human health. It is therefore clear that the authors of the Treaty intended, in the interest of both the applicant

Member State and the proper functioning of the internal market, that the procedure laid down in that article should be speedily concluded. That objective would be difficult to reconcile with a requirement for prolonged exchanges of information and observations.

50 It follows that the principle of the right to be heard does not apply to the procedure provided under Article 95(4) and (6) EC. Consequently, the first two pleas put forward by the Kingdom of Denmark must be rejected as unfounded.

Misinterpretation of the conditions of application in Article 95(4) EC

Arguments of the parties

51 By the second part of its third plea in law, the Kingdom of Denmark, supported by the Republic of Iceland, claims, as regards both sulphites and nitrites and nitrates, that the contested decision does not fully recognise that Article 95(4) EC offers Member States the opportunity to maintain national provisions derogating from harmonisation measures adopted by the Community legislature. Article 95(4) and (6) EC seeks to make it possible for Member States which consider it necessary to maintain national derogating provisions on the basis of an assessment other than that carried out by the Community legislature. However, the contested decision, and in particular paragraph 42 of its grounds, is based on the idea that, once the Community legislature has examined the relevant information and has enacted a legal measure, the Member States may no longer question that assessment. In that regard, the contested decision is based on an error in law.

52 Moreover, paragraphs 28 and 43 of the grounds for the contested decision point out that the harmonisation measures relating to sulphites and to nitrites and nitrates are still likely to be the subject of review under Articles 4 of the framework directive and 7 of Directive 95/2. However, the presence of a safeguard clause is not relevant for the purpose of the assessment which the Commission must carry out under Article 95(4) and (6) EC. It was wrong to include a safeguard clause in the grounds for its refusal to approve the contested provisions. In that regard as well, the contested decision is vitiated by an error in law.

53 By its sixth plea in law, the Kingdom of Denmark, supported by the Republic of Iceland and the Kingdom of Norway, recalls that the contested decision refused approval to the contested provisions on the ground, *inter alia*, that the Danish Government had demonstrated neither the existence of a particular health problem for the Danish population in relation to the use of sulphites (paragraph 32 of the grounds for the decision) nor the existence of a specific situation for that population with regard to the danger which the use of nitrites and nitrates could represent (paragraph 43 of the grounds for the decision). Yet the existence in the Member State concerned of a specific situation which is deemed to justify the use of Article 95(4) EC is not one of the requirements laid down in that provision. It mentions 'major needs referred to in Article 30, or relating to the protection of the environment or the working environment', but not to a specific situation in the applicant State. That latter criterion is relevant in the case where a decision is adopted pursuant to Article 95(5) EC, concerning the introduction of new national provisions based on new scientific evidence. The contested decision therefore infringes Article 95(4) EC.

54 The Commission maintains that the interpretation of Article 95 EC must be based above all on the fact that paragraph 1 of that provision allows for the adoption of measures for the approximation of Member State provisions which have as their object the internal market. Community measures based on Article 95(1) EC can effect full harmonisation of the area they cover. In such a case, Article 95(4) EC allows a Member State to maintain derogating national provisions in certain

circumstances. That provision introduces an exception to the principle of the uniform application of Community law and of the unity of the internal market and must therefore be strictly interpreted. Moreover, it falls to the Member State concerned to prove that the national provisions which it intends to apply provide a higher level of protection than the Community harmonisation measures from which they derogate.

55 A Member State may maintain derogating national provisions under Article 95(4) EC where a situation specific to that Member State justifies maintaining such provisions or where there is a gap in Community legislation, in that it does not ensure a 'high level of protection' within the meaning of Article 95(3) EC. A Member State cannot, however, substitute its own risk assessment for that carried out by the Community legislature. The fact that a Member State assesses a risk differently from the Community legislature does not constitute a 'justification' for maintaining derogating national provisions under Article 95(4) EC. Member States which invoke that provision must establish the existence of new scientific evidence or of facts which should have been taken into account and which show that the Community legislation does not ensure sufficient protection. That interpretation is supported by Article 95(7) EC, which makes clear that when a Member State is authorised to maintain national provisions derogating from a harmonisation measure, the Commission must immediately examine whether to propose an adaptation to that measure.

Findings of the Court

56 It should be recalled that the EC Treaty seeks progressively to establish the internal market, which comprises an area without internal borders, within which the free movement of goods, persons, services and capital is assured. To that end, the EC Treaty provides for the adoption of measures for the approximation of the legislation of the Member States. In the course of the evolution of primary law, the Single European Act introduced a new provision, Article 100a, into that Treaty.

57 Article 95 EC, which under the Treaty of Amsterdam replaces and amends Article 100a of the Treaty, distinguishes between notified provisions according to whether they are national provisions which existed prior to harmonisation or national provisions which the Member State concerned wishes to introduce. In the first case, provided for in Article 95(4) EC, the maintenance of existing national provisions must be justified on grounds of the major needs referred to in Article 30 EC or relating to the protection of the environment or the working environment. In the second case, provided for in Article 95(5) EC, the introduction of new national provisions must be based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure.

58 The difference between the two situations envisaged in Article 95 is that, in the first, the national provisions predate the harmonisation measure. They are thus known to the Community legislature, but the legislature cannot or does not seek to be guided by them for the purpose of harmonisation. It is therefore considered acceptable for the Member State to request that its own rules remain in force. To that end, the EC Treaty requires that such national provisions must be justified on grounds of the major needs referred to in Article 30 EC or relating to the protection of the environment or the working environment. By contrast, in the second situation, the adoption of new national legislation is more likely to jeopardise harmonisation. The Community institutions could not, by definition, have taken account of the national text when drawing up the harmonisation measure. In that case, the requirements referred to in Article 30 EC are not taken into account, and only grounds relating to protection of the environment or the working environment are accepted, on condition that the Member State provides new scientific evidence and that the need to introduce new national provisions results from a problem specific to the Member State concerned arising after the adoption of the harmonisation measure.

59 It follows that neither the wording of Article 95(4) EC nor the broad logic of that article as a whole entails a requirement that the applicant Member State prove that maintaining the national provisions which it notifies to the Commission is justified by a problem specific to that Member State.

60 However, when a problem specific to the applicant Member State in fact exists, that circumstance can be highly relevant in guiding the Commission as to whether to approve or reject the notified national provisions. It is a factor which, in the present case, the Commission should have taken into account when it adopted its decision.

61 It is apparent from the broad general logic of the contested decision that the Commission considered the possible existence of a situation specific to the Kingdom of Denmark merely as a useful element in assessing what decision to adopt. The contested decision does not deal with such a situation as a condition of approval for already existing derogating national provisions. It follows that the plea by the Kingdom of Denmark alleging a misinterpretation by the Commission of Article 95(4) EC, as requiring that a specific situation exist, is not founded.

62 Analogous considerations apply to the requirement for new scientific evidence. That condition is imposed under Article 95(5) EC for the introduction of new derogating national provisions, but it is not laid down in Article 95(4) EC for the maintenance of existing derogating national provisions. It is not one of the conditions imposed for maintaining such provisions.

63 In addition, the applicant Member State may, in order to justify maintaining such derogating national provisions, put forward the fact that its assessment of the risk to public health is different from that made by the Community legislature in the harmonisation measure. In the light of the uncertainty inherent in assessing the public health risks posed by, *inter alia*, the use of food additives, divergent assessments of those risks can legitimately be made, without necessarily being based on new or different scientific evidence.

64 A Member State may base an application to maintain its already existing national provisions on an assessment of the risk to public health different from that accepted by the Community legislature when it adopted the harmonisation measure from which the national provisions derogate. To that end, it falls to the applicant Member State to prove that those national provisions ensure a level of health protection which is higher than the Community harmonisation measure and that they do not go beyond what is necessary to attain that objective.

65 That interpretation of Article 95(4) EC is confirmed by Article 95(7) EC, under which, when a Member State is authorised to maintain derogating national provisions, the Commission is immediately to examine whether to propose an adaptation of the harmonisation measure. Such an adaptation could be appropriate when the national provisions approved by the Commission offer a level of protection which is higher than the harmonisation measure as a result of a divergent assessment of the risk to public health.

66 The specific provisions of the contested decision as they relate to the use of the additives at issue, that is, sulphites on the one hand and nitrites and nitrates on the other, should be considered in the light of the interpretation of Article 95(4) EC set out in paragraphs 62 to 64 above.

67 Before carrying out that examination, and to conclude consideration of the pleas based on the misinterpretation of the conditions of application of Article 95(4) EC, it is necessary to assess the argument by the Kingdom of Denmark that the contested decision is vitiated by an error in law because of the statement, in paragraphs 28 and 43 of the grounds for that decision, that the harmonisation measures relating to sulphites, nitrites and nitrates could in future be amended pursuant to Articles 4 of the framework directive and 7 of Directive 95/2.

68 The decision whether or not to approve the maintenance of the national provisions notified must be taken in the light of the circumstances at the time that decision is taken. Consequently, the possibility of amending the harmonisation measure cannot serve as the basis for that decision.

69 It is apparent from the broad logic of the contested decision as a whole that the point made in paragraphs 28 and 43 of its grounds did not affect the position adopted by the Commission. That reference must be considered superfluous. Therefore, its lack of relevance does not in itself constitute a ground for annulment of the contested decision. The argument put forward on that point by the Kingdom of Denmark must therefore be rejected.

Errors in law and as to facts vitiating the rejection of the contested provisions concerning the use of sulphites

Arguments of the parties

70 The pleas put forward by the Kingdom of Denmark which relate to the use of sulphites must be considered. Those include the first part of the third plea, the fifth plea and the first part of the seventh plea.

71 In the first part of the third plea, the Kingdom of Denmark, supported by the Republic of Iceland, points out that, according to paragraph 20 of the grounds for the contested decision, the elements presented by the Danish Government as regards the technological need to use sulphites have nothing to do with the

objective of public health protection mentioned in Article 30 EC or the other objectives listed in Article 95(4) EC and are therefore not relevant. According to the Kingdom of Denmark, it is, however, not possible to separate the assessment of the health effects of a given substance from the assessment of technological need which justifies its use. Technological need therefore constitutes a relevant criterion in assessing issues relating to the health of persons referred to in Article 30 EC and, accordingly, Article 95(4) EC. To that extent, the contested decision is based on an error in law. Thus, the Commission did not address the arguments put forward by the Danish Government as regards technological need. That is clear from paragraph 21 of the grounds for the contested decision, the end of which states that the argument concerning technological need 'cannot be invoked for the purposes of public health protection, since it is up to the Danish authorities to establish that the presence of sulphites constitutes a risk to public health'.

72 The Commission accepts that, where there is no technological need which justifies the use of an additive, there is no reason to run the possible health risk resulting from authorisation of the use of that additive. It nevertheless maintains that, in the present case, it carefully studied all the arguments put forward by the Danish Government concerning the technological need for the use of sulphites. Therefore the contested decision is not based on an error in law, even if the wording of paragraph 20 of its grounds may lead to misunderstandings.

73 By its fifth plea in law, the Kingdom of Denmark, supported by the Republic of Iceland, claims that the contested decision, in rejecting the contested provisions concerning the use of sulphites, is based on an error in law, and, in particular, an incorrect application of the principle of proportionality.

74 First, the Commission is wrong to claim, in paragraph 27 of the grounds for the contested decision, that the Danish Government has not justified its selection of

only 16 categories of foodstuffs in which sulphites may be used out of the 61 included in Part B of Annex III to Directive 95/2. In fact Article 95(4) EC allows only national provisions which are in force to be maintained, so that the Danish Government confined itself to reproducing the Danish positive list which was in force when Directive 95/2 was adopted, without making a further selection.

75 Next, the Commission wrongly maintains, in paragraph 26 of the grounds for the contested decision, that the Danish Government, rather than derogating from the provisions of Directive 95/2, should have sought to tighten up the conditions of the use of sulphites in wine. The Kingdom of Denmark accepts that two glasses of wine contain some 40 mg of sulphites although, according to the ADI established by the SCF, an adult can ingest 45 to 50 mg of sulphites a day. However, the Community's legislation on wine is based on Article 37 EC which, unlike Article 95 EC, does not authorise the maintenance of derogating national provisions. The fact that the ADI for sulphites may be exceeded by the ingestion of a small quantity of wine should in no way prevent the Member States from limiting the addition of sulphites to other products for the purpose of generally reducing the risk of exceeding the ADI.

76 Finally, the contested decision is based on an incorrect application of the principle of proportionality, since the Danish contested provisions concerning the use of sulphites are not, contrary to the Commission's claims, disproportionate. Those provisions merely follow the recommendations of the SCF, in particular its 1994 opinion, which states, *inter alia*, that serious asthmatic reactions may occur even at relatively low levels of exposure to sulphites.

77 In reply, the Commission points out that the provisions of Directive 95/2 apply in particular to the use of sulphites as additives in foodstuffs. That use is justified by a technological need. A general reduction in the amount of sulphites which can be used in foodstuffs is not justifiable in the light of the technological function of

those additives. However, the problems raised by the Danish Government regarding the ADI being exceeded as the result of the addition of sulphites to wine should essentially be resolved in the framework of the legislation on wine.

78 On the question of the risk of allergic reactions to sulphites, the Commission states that allergies provoked by the use of additives concern individuals. The Community legislature, aware of that risk, chose to resolve the problem of allergies by providing information for consumers. Moreover, the 1981 opinion, on the basis of which Directive 95/2 was adopted, and the 1994 opinion, do not contain anything which calls into question the maximum amounts set by that directive. Furthermore, the SCF did not state that labelling constitutes an inadequate measure.

79 By the first part of its seventh plea in law, the Kingdom of Denmark claims that it is apparent from paragraph 23 of the grounds for the contested decision that Directive 95/2 is based on the 1994 opinion, which established an ADI for sulphites. In fact, the Council's common position on the draft directive was determined in 1993, before the notification of the 1994 opinion. Directive 95/2 was adopted on 20 February 1995 without any modification of its original text. It is therefore based on the SCF's earlier evaluation of sulphites, published in 1981, which does not include the establishment of any ADI.

80 Moreover, the considerations set out in paragraphs 30 and 31 of the grounds of the contested decision concerning labelling do not take account of the 1994 opinion, which states that the use of sulphites should be limited as far as possible in order to take account of the risk of serious allergic reactions. According to that opinion, labelling is not sufficient in the case of sulphites.

81 The Commission replies that paragraph 23 of the grounds for the contested decision do not state that Directive 95/2 is based on the 1994 opinion, but refers to that opinion merely by way of guidance. For the rest, it refers to the arguments which it put forward under the third, fourth and fifth pleas.

Findings of the Court

82 As regards the first part of the third plea, concerning the technological need to use sulphites, it must be accepted that technological need is closely related to the assessment of what is necessary in order to protect public health. In the absence of a technological need justifying the use of an additive, there is no reason to incur the potential health risk resulting from authorisation of the use of that additive. The statement contained in paragraph 20 of the grounds for the contested decision, that the elements put forward by the Danish Government with regard to the technological need for the use of sulphites have nothing to do with the objective of public health protection, is clearly incorrect.

83 Despite that incorrect statement, it is apparent from paragraphs 21, 24 and 27 and from footnote 20 of the grounds for the contested decision that the Commission in fact thoroughly assessed the arguments put forward by the Danish Government relating to the technological need for the use of sulphites in foodstuffs. The contested decision is therefore not based on an error in law in that regard.

84 That conclusion is not invalidated by the statement in paragraph 21 of the grounds for the contested decision that it is up to the national authorities to establish that the presence of sulphites constitutes a risk to public health. It is precisely the Member State which invokes Article 95(4) EC which must prove that the conditions for application of that provision have been met. The statement in paragraph 21 does not contain any error in law.

85 It follows from the preceding considerations that the first part of the third plea, relating to technological need, is not founded.

86 As regards the first argument put forward under the fifth plea, concerning the reasons stated for the Danish Government's choice, the essential difference between the contested provisions and Directive 95/2 is the number of categories of food products in which the use of sulphites is authorised. The contested provisions authorise the use of sulphites in only 16 categories of the 61 allowed under that directive. In the light of the information presented to the Court, it must be held that the Danish Government has not justified its decision to prohibit the use of sulphites in the other 45 categories of foodstuffs.

87 The Danish Government's argument in that connection that it follows from Article 95(4) EC that a Member State can exclusively request to maintain in force the national positive list which was in place when Directive 95/2 was adopted, without being able to select further foodstuffs, cannot be upheld. The fact that that provision only allows the maintenance of existing national provisions does not mean that a Member State may not amend those provisions in part when transposing the harmonisation directive, while maintaining the rest. By providing for the possibility of authorising the maintenance of certain existing national provisions, Article 95 EC necessarily presupposes that those provisions can coexist with other national provisions which implement the harmonisation directive.

88 As regards the second argument raised under the fifth plea, concerning the use of sulphites in wine, it must be pointed out that the present case relates to the use of additives in foodstuffs, not in wine, and on that basis falls within the scope of Directive 95/2 and not the legislation on wine. If wine contains significant

amounts of sulphites which are likely to pose a risk to human health, it is important for the Community legislature to take the measures necessary to deal with that risk in good time.

89 On the other hand, the presence of large amounts of sulphites in wine cannot justify, under the procedure laid down in Article 95(4) EC, a general prohibition on the use of sulphites as additives in foodstuffs. To the extent that an applicant Member State requests authorisation to maintain national provisions derogating from Directive 95/2 in respect of certain foodstuffs, it has the task of justifying those national provisions in relation to those foodstuffs, and not in relation to other products.

90 In those circumstances, the argument relating to the sulphite content of wine cannot constitute a ground for the annulment of the contested decision and must be rejected.

91 As regards the third argument raised under the fifth plea, relating to the application of the principle of proportionality, it is incorrect to interpret the 1994 opinion as critical of labelling in the case of sulphites. On the contrary, although recommending that this use be limited, that opinion concludes that they do not constitute a danger to the health of the great majority of people and recommends labelling for the benefit of persons likely to be allergic to them. Recommendation (iii) of that opinion states, 'people at risk should be able to identify the presence of sulphites added to foodstuffs and to non-alcoholic drinks as a result of the list of ingredients on the label'.

92 Directive 95/2 sets maximum amounts for the use of sulphites as additives, while Council Directive 79/112/EEC of 18 December 1978 on the approximation of the

laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (OJ 1979 L 33, p.1) requires that information be provided to persons who are allergic to certain ingredients in foodstuffs, thereby addressing the twofold concern expressed in the 1994 opinion, that the use of sulphites should be limited and the public alerted to their presence through labelling.

93 It follows that, as regards sulphites, the Community's harmonisation measures appear to be sufficient in the light of the 1994 opinion, and that the contested decision does not contain any error of fact or of assessment in that regard. Consequently, the argument that the Commission has incorrectly applied the principle of proportionality is not founded.

94 As regards the first part of the seventh plea, concerning an error as to the facts, it must be held that, in contrast to the claim by the Kingdom of Denmark, paragraph 23 of the grounds for the contested decision in no way states that Directive 95/2 is based on the 1994 opinion. On the contrary, it is clear that that decision mentions the 1994 opinion because the Danish Government relied on that opinion in support of its application. In the paragraphs following paragraph 23 of the grounds of the contested decision, the Commission carries out a detailed examination of certain arguments put forward by that government on the basis of the 1994 opinion.

95 In that context, the first part of the seventh plea, alleging an error as to the facts, must be rejected as not founded.

96 For the rest, that part of the plea concerning the risk of allergic reactions to sulphites essentially reiterates the third argument raised under the fifth plea. Like that argument, this part of the seventh plea must therefore be rejected for the reasons set out in paragraphs 91 to 93 of the present judgment.

97 It follows from the preceding considerations that the entirety of the pleas which specifically concern the rejection of the contested provisions relating to the use of sulphites must be rejected as unfounded.

Errors in law and as to the facts vitiating the rejection of the contested provisions concerning the use of nitrites and nitrates

Arguments of the parties

98 The pleas in law put forward by the Kingdom of Denmark relating to the use of nitrites and nitrates must be considered. They include principally the first part of the fourth plea and, alternatively, the second part of that plea, and the second part of the seventh plea.

99 By the first part of the fourth plea, as its principal argument, the Kingdom of Denmark claims that the contested decision, in rejecting the contested provisions concerning the use of nitrites and nitrates, is based on an incorrect application of the principle of proportionality.

100 The Kingdom of Denmark, supported by the Republic of Iceland and the Kingdom of Norway, points out that, according to paragraph 44 of the grounds for the contested decision, the contested provisions 'are aimed at protecting public health, [but] are excessive in relation to this aim'. As regards nitrites and nitrates, that conclusion is based *inter alia* on paragraphs 35, 37 and 38 of the grounds for the contested decision, which state, without proof, that the levels of

nitrites and nitrates set by Order No 834 of the Danish Ministry of Health, of 23 September 1996, do not guarantee that the presence of additives in products at the end of the food production process is sufficient to perform their technological function, which is to guarantee the microbiological safety of products.

101 The Danish Government claims that, under Article 95(6) EC, the Commission must approve national provisions which are notified to it if they are proportionate to the objective sought, that is, the protection of human health. That conclusion also follows from points 1 to 3 and 6 of Annex II to the framework directive, which sets the general criteria for the use of food additives. However, the 1990 and 1995 opinions, which record a correlation between the level of nitrites added to foodstuffs and the formation of carcinogenic nitrosamines, establish that it is impossible to set a level of added nitrites and nitrates below which the formation of tumours can be excluded. Those opinions therefore conclude that the level of nitrites added to foodstuffs should be brought to the minimum needed to obtain the required preservative effect. Given the scientifically established link between the addition of nitrites and nitrates and the formation of nitrosamines, the contested provisions on the use of nitrites and nitrates, which set maximum amounts corresponding to the technological needs which are strictly necessary for the purpose of obtaining the required preservative effect in the meat products at issue and guaranteeing microbiological safety, are proportionate to their objective of protecting human health. Those provisions also comply with the precautionary principle, which is recognised in the case-law of the Court of Justice.

102 Therefore, in considering, in the contested decision, that the contested provisions constitute superfluous overprotection of public health, the Commission misinterpreted the requirements following from the principle of proportionality. The error in law thereby committed should entail annulment of that decision.

103 The Commission contends that the level of protection set by Directive 95/2 is in line with the SCF's 1990 opinion. The SCF's 1995 opinion essentially upheld the

conclusions of the 1990 opinion. Where, as in the present case, harmonisation measures are in place, the proportionality of the national provisions which a Member State seeks to maintain must be assessed in relation to the level of protection set by the Community legislature. An assessment of the level of protection based on the same elements as were available to the Council when Directive 95/2 was adopted should not in principle lead to a result different from that reached by the Community legislature, unless it can be established that the protection guaranteed under that directive is clearly inadequate. No such proof was put forward by the Danish Government in its request under Article 95(4) EC. Moreover, a Member State cannot unilaterally invoke the precautionary principle in order to maintain derogating national provisions. In an area where Member State legislation has been harmonised, it is for the Community legislature to apply the precautionary principle.

104 By the second part of the fourth plea, the Kingdom of Denmark claims in the alternative that the contested decision, in so far as it rejects the contested provisions concerning the use of nitrites and nitrates, is based on a clear abuse of the Commission's discretion in applying the principle of proportionality.

105 The Kingdom of Denmark, supported by the Republic of Iceland and the Kingdom of Norway, states that the Commission in any case exceeded its discretion by merely finding, without any scientific proof, that the maximum amounts set by the contested provisions for the use of nitrites and nitrates in foodstuffs are contrary to the requirements of the principle of proportionality. The contested provisions concerning the use of nitrites and nitrates are consistent with the recommendations of the SCF set out in its 1990 and 1995 opinions.

106 The Commission replies that Directive 95/2 is consistent with the SCF's recommendations. In the conclusions to its 1990 opinion, the SCF does not

recommend any maximum amount for nitrites and nitrates in foodstuffs. It simply recommends that 'exposure to preformed nitrosamines in foodstuffs should be minimised by appropriate technological practices such as lowering levels of nitrites and nitrates added to foods to the minimum required to achieve the necessary preservative effect and to guarantee microbiological safety'. However, the contested provisions do not guarantee that the presence of additives at the end of the food production process is sufficient to perform their technological function, which is to guarantee the microbiological safety of products.

107 By the second part of the seventh plea, the Kingdom of Denmark claims that the Commission's assessment, in so far as it covers the contested provisions on the use of nitrites and nitrates, is vitiated by factual errors. It maintains that, in contrast to what is stated in paragraphs 37 and 38 of the grounds for the contested decision, those provisions adequately guarantee microbiological safety and are fully consistent with the SCF's 1990 opinion. In contrast to the statements in paragraphs 35, 37, 41 and 42 of the grounds for the contested decision, they are not inconsistent with the stated objective of protecting public health since, for all the meat products concerned, they set authorised levels for nitrites and nitrates which are considerably lower than those laid down in Directive 95/2. The contested provisions set a maximum ingoing amount for nitrates, while Directive 95/2 sets a maximum residual amount.

108 In reply, the Commission refers to the arguments which it developed under the third, fourth and fifth pleas.

Findings of the Court

109 As regards the second part of the seventh plea, alleging factual errors, it should be pointed out that the 1995 opinion on nitrites and nitrates expressly considered

the provisions of Directive 95/2 relating to those additives. In that opinion, the SCF notes that the residual amounts of nitrites permitted by that directive 'are much higher than those to be expected from the maximum levels of added nitrites and nitrates which the [SCF] was informed in its previous review are justifiable on technological grounds'.

110 That highly critical evaluation of the maximum amounts set by Directive 95/2 is not contradicted by the fact that, in the same opinion, the SCF reiterated the recommendations expressed in its 1990 opinion. On the contrary, those recommendations confirm the need to reduce to a minimum the levels of nitrites and nitrates added to foodstuffs. According to point 3.3.2.3 of the 1995 opinion:

'Therefore, the [SCF] repeats its previous opinion that exposure to preformed nitrosamines in food should be minimised by appropriate technological practices such as the lowering of levels of nitrates and nitrites added to foods to the minimum required to achieve the necessary preservative effects to ensure microbiological safety.'

111 The contested decision did not take sufficient account of the 1995 opinion. It failed to mention in that connection that the maximum amounts of nitrites set in Directive 95/2 are called into question by the 1995 opinion.

112 It must be borne in mind that the SCF's 1990 opinion, given its date, could not comment on Directive 95/2, which was first proposed in 1992 and adopted in 1995. However, in drafting its 1995 opinion, the SCF was specifically instructed to, among other things, study the safety of the use of nitrites and nitrates used as

food additives under the conditions set by Directive 95/2. In carrying out that task, it criticised the conditions of use for nitrites under that directive. The fact that the 1995 opinion confirmed the 1990 opinion in that regard suggests that the amounts of nitrites authorised by Directive 95/2 are also open to criticism in the light of the 1990 opinion.

113 The observations by the SCF in that regard are relevant in assessing whether the contested provisions are justified.

114 It follows that, to the extent that the Commission failed duly to take into account the 1995 opinion in assessing the justification for the contested provisions concerning the use of nitrites and nitrates, its decision is vitiated by a defect which renders it unlawful.

115 It follows that the contested decision must be annulled in so far as it rejects those provisions.

116 In those circumstances, there is no need to consider the fourth plea.

Failure to adopt a position and failure to state reasons

117 Finally, by its eighth plea in law, the Kingdom of Denmark claims that the Commission failed to take a view on the question of whether the contested

provisions are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether they constitute an obstacle to the functioning of the internal market. Nevertheless, under Article 95(6) EC, the Commission should have ruled on those points and should not have based its position solely on the fact that the contested provisions were not justified by the protection of public health. The Kingdom of Denmark is of the opinion that inadequate comment constitutes an infringement of Article 95(6) EC and, accordingly, a ground for annulment under Article 230 EC.

118 However, an application under Article 95(4) EC must be assessed in the light of the conditions laid down in both that paragraph and paragraph 6 of that article. If any one of those conditions is not met, the application must be rejected without there being a need to examine the others. Since the Commission rejected the application in the present case on the basis of the major need to protect public health, a condition referred to in Article 95(4) EC, it was not required to consider its compliance with the three other conditions set out in paragraph 6 of that article.

119 It follows that the present plea is not founded and must be rejected.

120 By its ninth plea in law, which is presented in the alternative to the preceding plea, the Kingdom of Denmark claimed that the contested decision should be annulled for failure to state adequate reasons.

121 The Kingdom of Denmark states that, even if the elements referred to in Article 95(6) EC had effectively been taken into account by the Commission in adopting the contested decision, that would have to have been specifically stated in the decision. In those circumstances, the decision is vitiated by an inadequate statement of reasons.

122 The Commission replies that the contested decision fully complies with the obligation to state reasons laid down in Article 235 EC, as interpreted in the case-law of the Court. The decision sets out, in paragraph 20 to 34 of its grounds as regards sulphites, and in paragraphs 37 and 38 and 41 to 43 of its grounds as regards nitrites and nitrates, a detailed account of the elements of fact and of law which justify the position taken by the Commission.

123 In order to assess the present plea, it is first necessary to investigate the assumption on which it is based, that is, that the contested decision was in fact based on one or more of the three elements referred to in Article 95(6) EC.

124 In assessing the justification for the contested provisions with regard to the major need to protect public health, the contested decision makes certain references, *inter alia* in paragraphs 37, 41 and 42 of its grounds, to the contested provisions authorising the use of nitrites and nitrates in conditions comparable to those laid down by Directive 95/2 in traditional Danish products such as bacon of the Wiltshire type, rolled meat sausage (rullepølse) and fermented Danish salami, and in that regard it expressly mentions discriminatory treatment in paragraph 37 of those grounds.

125 However, the Commission does not assess whether or not the contested provisions are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they constitute an obstacle to the functioning of the internal market within the meaning of Article 95(6) EC. It is important to make clear in that regard that the assessment of that question is a matter for the Commission, and that the Court cannot, in an application for annulment such as the present case, substitute its assessment for that of the Commission.

126 Paragraphs 45, 46 and 47 of the grounds for the contested decision state that the Commission did not, in the present case, verify the conditions relating to the absence of arbitrary discrimination, the absence of a disguised restriction on trade between Member States and the absence of an obstacle to the functioning of the internal market. In its defence, the Commission maintains that, by the contested decision, it rejected the Danish Government's application on the sole ground that it was not sufficiently justified by major needs within the meaning of Article 95(4) EC. In addition, it must be held that the statement of reasons for that rejection, which is found in paragraphs 19 to 44 of the grounds for the contested decision, is set out in terms of the major need of public health protection.

127 In the light of those considerations, it appears that the contested decision is not based on one or more of the elements referred to in Article 95(6) EC. It follows that the assumption underlying the present plea is not established. Accordingly, that plea must be rejected.

Costs

128 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. However, under Article 69(3) of those Rules, the Court may order that the costs be shared or that the parties bear their own costs where each party succeeds on some and fails on other heads. In this case, since the parties have each been partially unsuccessful, each must be ordered to bear its own costs.

129 Under the second subparagraph of Article 69(4) of the Rules of Procedure, the Republic of Iceland and the Kingdom of Norway, which intervened in these proceedings, are to bear their own costs.

On those grounds,

THE COURT

hereby:

1. **Annuls Commission Decision 1999/830/EC of 26 October 1999 on the national provisions notified by the Kingdom of Denmark concerning the use of sulphites, nitrites and nitrates in foodstuffs in so far as it rejects those national provisions relating to the use of nitrites and nitrates in foodstuffs;**

2. **Dismisses the remainder of the application;**

3. **Orders the parties to pay their own costs;**

4. **Orders the Republic of Iceland and the Kingdom of Norway to pay their own costs.**

Rodríguez Iglesias Puissochet Wathelet

Schintgen Gulmann Edward La Pergola

Jann Skouris Macken

Colneric von Bahr Cunha Rodrigues

Delivered in open court in Luxembourg on 20 March 2003.

R. Grass

Registrar

G.C. Rodríguez Iglesias

President