OPINION OF ADVOCATE GENERAL TIZZANO

delivered on 30 May 2002 [1]

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1. The present case the Court has to rule for the first time on an application by a Member State against the Commission's refusal to authorise the maintenance of national measures in derogation from a directive adopted under Article 100a of the EC Treaty (now, after amendment, Article 95 EC). Denmark is applying, pursuant to Article 230 EC, for the annulment of Commission Decision 1999/830/EC of 26 October 1999,[2] by which the Commission refuses to approve the maintenance of certain national provisions on the use of sulphites, nitrites and nitrates in foodstuffs, in derogation from Directive 95/2/EC on food additives other than colours and sweeteners (hereinafter 'Directive 95/2').[3] It should be noted, however, that although the Commission's decision was requested under Article 100a of the EC Treaty, it was delivered after the entry into force of the Treaty of Amsterdam and was therefore adopted on the basis of the new Article 95(4) EC.

I — Legal background

A — *Community legislation*

(1) The Treaty

2. The general provision aimed at furthering the harmonisation of legislation for the

2 — OJ 1999 L 329, p. 1.

3 — 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).

realisation of the common market was for a long time only Article 100 of the EC Treaty (marginally amended by the Treaty of Maastricht and now Article 94 EC), which empowered the Council, acting unanimously, to issue directives for the approximation of such laws, regulations or administrative provisions of the Member States as directly affect the establishment or functioning of the common market. However, in order to facilitate the realisation of the internal market, provided for in Article 7a of the EC Treaty (now Article 14 EC), the Single European Act subsequently introduced a new provision, Article 100a, which in turn underwent various amendments as a result of subsequent Treaty revisions.

3. By contrast with Article 100 of the EC Treaty, from which by express definition it constituted a derogation, Article 100a in practice gave the Council the possibility of deciding, in accordance with the cooperation procedure laid down in Article 189b of the EC Treaty (now Article 251 EC), to adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market. Within this framework, paragraph 3 of the article set a high level of protection as the objective for such measures if they concerned health, safety, environmental protection and consumer protection. Indeed, it required the Commission to base its proposals for such matters on a high level of protection. However, as these were measures to be adopted by a qualified majority, and hence entailed the risk of sacrificing national needs worthy of protection, the same article gave Member States the possibility of derogating from the measures in question in order to protect such needs.

4. Paragraph 4 of Article 100a laid down that:

'If, after the adoption of a harmonisation measure by the Council acting by a qualified majority, a Member State deems it necessary to apply national provisions on grounds of major needs referred to in Article 36, or relating to protection of the environment or the working environment, it shall notify the Commission of these provisions.

The Commission shall confirm the provisions involved after having verified that they are not a means of arbitrary discrimination or a disguised restriction on trade between Member States.

By way of derogation from the procedure laid down in Articles 169 and 170, the

Commission or any Member State may bring the matter directly before the Court of Justice if it considers that another Member State is making improper use of the powers provided for in this Article.'

5. The Treaty of Amsterdam made substantive amendments to Article 100a of the EC Treaty, replacing paragraphs 3, 4 and 5 of that article with eight new paragraphs, numbered from 3 to 10. The Article, as amended and renumbered as Article 95 EC, now reads as follows:

'1. By way of derogation from Article 94 and save where otherwise provided in this Treaty, the following provisions shall apply for the achievement of the objectives set out in Article 14. The Council shall, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

2. Paragraph 1 shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons.

3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.

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.

8. When a Member State raises a specific problem on public health in a field which has been the subject of prior harmonisation measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council.

9. By way of derogation from the procedure laid down in Articles 226 and 227, the Commission and any Member State may bring the matter directly before the Court of Justice if it considers that another Member State is making improper use of the powers provided for in this Article.

10. The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 30, provisional measures subject to a Community control procedure.'

(2) The harmonisation directives

6. Directives 89/107/EEC and 95/2/EC are of particular relevance to the question under examination.

(a) Directive 89/107/EEC

7. 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 ('Directive 89/107' or the 'framework directive')[4] is a framework directive adopted on the basis of Article 100a of the EC Treaty.

8. As far as the present case is concerned, I would point out first of all that the framework directive defines the concept of a food additive (Article 1(2)) as 'any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods.' Annex I to the directive lists the various categories of food additives defined in this way.

9. The directive also provides for the adoption of particular provisions 'in a comprehensive directive, including existing specific directives on particular categories of additives' (Article 3(1)). Such specific directives should lay down, in particular, for each category the individual substances authorised for use and the conditions under which they may be used (Article 3(2)).

10. Pursuant to Article 2(3) of the directive, the general criteria for the use of food additives are described in Annex II, the first paragraph of which provides that:

'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

4 — OJ 1989 L 40, p. 27.

judged on the scientific evidence available,

— they do not mislead the consumer.'

11. Furthermore, under paragraph 2 of Annex II, the use of food additives may be considered 'only where there is evidence that the proposed use of the additive would have demonstrable advantages of benefit to the consumer, in other words it is necessary to establish the case for what is commonly referred to as "need"'.

12. To assess the possible harmful effects of a food additive or derivatives thereof, paragraph 3 of Annex II lays down that 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.'

13. Under paragraph 6 of the same Annex, approval for food additives must specify the foodstuffs to which these additives may be added and the conditions under which they may be added; the addition of additives must be limited to the lowest level of use necessary to achieve the desired effect and, as far as possible, must take into account any acceptable daily intake (the 'ADI'). [5]

14. Article 6 of the directive lays down that provisions that may have effect upon public health shall be adopted after consultation with the Scientific Committee for Food (the 'SCF'). [6]

15. Lastly, Article 4 introduces a safeguard clause, worded as follows:

'1. Where a Member State, as a result of new information or of a re-assessment of existing information made since this Directive, or the comprehensive directive referred to in Article 3, was adopted, has detailed grounds for considering that the use of additives in food, although it complies with this Directive or any list drawn up under Article 3, endangers human health, that Member State may

5 — The ADI is the average quantity that a person may ingest each day of their life without risk to health.

6 — See also the sixth recital. The Scientific Committee for Food was set up by Commission Decision 74/234/EEC (OJ 1974 L 136, p. 1).

temporarily suspend or restrict application of the provisions in question in its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

2. The Commission shall examine the grounds given by the Member State referred to in paragraph 1 as soon as possible within the Standing Committee on Foodstuffs, and shall then deliver its opinion forthwith and take the appropriate measures.

3. If the Commission considers that amendments to this Directive or to the comprehensive directive referred to in Article 3 are necessary in order to resolve the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure laid down in Article 11, with a view to adopting those amendments; the Member State which has adopted safeguard measures may in that event retain them until the amendments have been adopted.'

(b) Directive 95/2/EC

16. The lists of permitted food additives were defined in three specific directives implementing the framework directive, one of which is Directive 95/2, which I have already mentioned. [7]

17. As stated in Article 1(1), Directive 95/2 is 'a specific Directive forming a part of the comprehensive Directive, within the meaning of Article 3 of Directive 89/107/EEC, and applies to additives', in particular to food additives acting as a preservative or antioxidant. Preservatives are defined in Article 1(3)(a) as 'substances which prolong the shelf-life of foodstuffs by protecting them against deterioration caused by micro-organisms'; antioxidants are defined in the subsequent subparagraph (b) as 'substances which prolong the shelf-life of foodstuffs by protecting them against deterioration caused by oxidation, such as fat rancidity and colour changes'. The directive authorises the use of various substances in the categories of nitrites, nitrates and sulphites as preservatives and antioxidants.

18. I consider it fitting to point out at the outset that sulphites have a preservative and/or antioxidant effect by inhibiting the formation of bacteria, moulds and yeasts;

7 — The other two are European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs (OJ 1994 L 237, p. 3) and European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs (OJ 1994 L 237, p. 13).

on account of these characteristics they are frequently used in wine,[8] beer, in the preservation of shellfish, in vegetable and fruit-based prepared foods, jams, biscuits, dried fruit and numerous other foods. If ingested in large quantities, sulphites are harmful to health in that they can damage the digestive system; the greatest risk to human health, however, comes from the strong allergic reactions that may be induced in susceptible persons, particular asthmatics, even at low levels of absorption.

19. Nitrates and nitrites are added to food products in order to accentuate, in certain meat products, the preserving effects of smoking, salting or cooking by inhibiting or arresting the development of micro-organisms — which can spoil the product — or pathogenic bacteria, in particular *clostridium botulinum*. A meat product may become contaminated with such bacteria at any point in the production chain or even during consumption. The levels of nitrites and nitrates must therefore be calculated so that they ensure the preservation of the product right up to the time of consumption. When added to meat products, nitrates change into nitrites, which in turn are converted into nitrosamines, with the result that the quantity of the first two classes of substance decreases considerably over time. Nitrosamines — the final product of such degradation — are recognised as carcinogenic and genotoxic substances.

20. Returning to the directive, I would further point out that Article 1(2) echoes the stipulation contained in Article 6 of the framework directive and Annex II thereto by laying down that only additives which satisfy the requirements laid down by the SCF may be used in foodstuffs. Having been asked to assess the safety of additives, the SCF issued a number of opinions which formed the basis of the Commission's draft directives in this regard.

21. With regard to sulphites, the SCF carried out the necessary toxicological assessments in the opinion of 15 January 1981[9] and subsequently in the opinion of 25 February 1994.[10] In the latter it set an acceptable daily intake (ADI) of 0.7 mg of sulphur dioxide per kilogram of body weight, equal to 49 mg/day for an adult and 21 mg/day for a child. In addition, the

8 — For the rules on sulphites in wines, Directive 95/2 refers to Council Regulation (EEC) No 822/87 of 16 March 1987 on the common organisation of the market in wine (OJ 1987 L 84, p. 1), last amended by Council Regulation (EC) No 1627/98 (OJ 1998 L 210, p. 8), Article 65 of which lays down that the total sulphur dioxide content of still wines 'may... not exceed... 160 milligrams per litre for red wines;... 210 milligrams per litre for white and rosé wines'.

9 — SCF reports, 11th series.

10 — SCF reports, 35th series.

Committee indicated that although sulphites are not a danger to the health of the great majority of persons, they may cause serious problems for asthma sufferers. It therefore recommended that their use be limited where possible to those foods where there is sound reason for their inclusion in order that the number of sulphite-containing foods does not increase, but in any case called for their presence to be indicated on the label.

22. The SCF opinions of 19 October 1990 [11] and 22 September 1995 [12] dealt with the technological needs and the health risks associated with the use of nitrites and nitrates in food products. In the first of these the Committee already drew attention to the connection between the addition of nitrites and the production of nitrosamines — carcinogenic and genotoxic substances — and recommended that the amount of nitrites and nitrates added to food products be limited to the minimum needed to obtain the preservative and antioxidant effect and to ensure microbiological safety in order to limit the consumer's exposure to nitrosamines.

23. Article 2(1) of Directive 95/2 provided — on the basis of the SCF's recommendations — that only the substances listed in Annex III to that directive may be used in foodstuffs as preservatives and antioxidants. Article 2(4) then laid down that the additives listed in Annex III may be used only in the foodstuffs referred to in that Annex and under the conditions specified therein.

24. In particular, I would point out that Annex III, Part B, lays down, in the form of a table, the conditions for the use of sulphur dioxide (E 220) and 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). This table [13] lists 61 food products, for each of which it indicates the maximum permitted quantity, in mg/kg or mg/l as appropriate, and expressed in SO_2.

25. Annex III, Part C, then lays down the conditions for the use of potassium nitrite (E 249), sodium nitrite (E 250), sodium nitrate (E 251) and potassium nitrate (E 252). In view of the change that occurs in nitrates and nitrites when added to a meat product, Part C of Annex III deter-

11 — SCF reports, 26th series.

12 — SCF reports, 38th series.

13 — As the table is to be found in paragraph 4 of the contested decision, I do not consider it necessary to reproduce it here.

mines both the indicative amount to be used and the maximum residual quantity.

26. Pursuant to Article 9 of Directive 95/2:

'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.'

B — *The Danish provisions*

27. Before Directive 95/2 came into force, the Danish legislation in this regard, which dated from 1973, laid down the conditions for the use of additives in foodstuffs, including nitrates, nitrites and sulphites, by defining a list of products in which such substances could be used and indicating the permitted quantities; the list was amended subsequently in view of developments in health requirements and technical needs.

28. Directive 95/2 was incorporated into Danish law by means of Order No 1055 issued by the Ministry of Health on 18 December 1995,[14] which was supplemented by Order No 834 of 23 September 1996. The latter decree sets out, in particular, the conditions for the use of sulphites in foodstuffs other than wine. The provisions of the two orders reiterate the substance of the provisions governing sulphites that were in force before the adoption of the directive. They thus authorise the use of such substances in 16 categories of foodstuff, whereas Directive 95/2 extends authorisation to 61 categories, and they also reduce the permitted quantities of additive. The Danish order of

14 — Sundhedsministeriets bekendtgørelse nr. 1055 af 18.12.1995 om tilsætningsstoffrer til levnedsmidler. Sundhedsmin., j.nr. 95-3400-24. Levnedsmiddelstyrelsen, j.nr. 100-0066. Lovtidende A hæfte 198 udgivet den 30.12.1995 s. 5571. GBEK.

1995 also adopts a different approach to that of Directive 95/2 with regard to the use of nitrites and nitrates in meat products. Whereas the directive limits the permitted residue of nitrates and nitrites in foodstuffs and sets indicatively the amount introduced, the Danish legislation sets limits for the amount that may be introduced; moreover, the amounts tend to be lower than those indicated in the directive. For some typical Danish products, however, it permits the use of quantities of nitrites and nitrates that are significantly higher than the general limits.

II — Facts and procedure

A — *The Danish reaction to Directive 95/2*

29. On 15 December 1994, at the time of adoption of Directive 95/2 by the Council, the Danish delegation made the following declaration to accompany its vote against the directive:

'The Danish delegation votes against the adoption of the European Parliament and Council Directive on food additives other than colours and sweeteners. With regard to the use of nitrites/nitrates, sulphites and sodium aluminium phosphates, the Directive does not respond satisfactorily to health requirements, to which the Danish delegation ascribes a crucial importance in provisions regulating food additives.

...

In addition, the Danish Government remains firmly convinced that the Scientific Committee for Food ought, in accordance with the declarations put forward by the Commission, to deliver an opinion on nitrites/nitrates and sulphites as soon as possible. The Government will welcome the conclusions of the Scientific Committee and reserves the right to maintain national provisions needed to safeguard human life and health in accordance with Article 100a(4) of the Treaty.' [15]

30. In accordance with that declaration, Denmark therefore decided to maintain the more restrictive national measures regarding nitrites, nitrates and sulphites that I mentioned above. Consequently, as required by Article 100a(4), it notified them to the Commission over the period from July 1996 to May 1997.

15 — Council Document 11620/94 Add1 of 5 December 1994.

31. By an initial letter dated 15 July 1996, when notifying the measures implementing Directive 95/2, Denmark stated that it had not transposed the provisions of Directive 95/2 concerning nitrates and nitrites in meat products nor those concerning sulphites and referred to the voting declaration. In that context it notified its intention to apply national provisions aimed at protecting public health as provided for in Article 100a(4) of the EC Treaty, appending a scientific report to justify its position.

32. That position was confirmed in a subsequent letter to the Commission, which took note of it but reserved the right to rule once official notification of the Danish request had been received.

33. In the meantime, as a result of a complaint lodged in November 1996 by private commercial operators, on 20 January 1997 the Commission sent the Danish authorities a request for information, to which the latter replied in detail on 20 May 1997.

34. That reply, together with the statement of July 1996, complemented by the exchange of correspondence, was considered by the Commission as official notification of the Danish request.

35. Subsequently, as a result of further complaints from private operators about obstacles to the marketing in Denmark of foodstuffs containing sulphites and meat products containing nitrites and/or nitrates, further informal talks were held between the Commission and the Danish authorities. In particular, officials from the Commission and the Danish Government met on 19 November 1997. Finally, the Danish Government sent the Commission further information on 14 July 1998.

36. It should also be remembered that in the course of the procedure the Commission forwarded the file on the Danish notification to the other Member States for their opinions. Seven Member States responded, of which four expressed reservations about the Danish request. However, their replies were not formally notified to the Danish Government.

B — *The Commission decision*

37. While the procedure was in progress, the Treaty of Amsterdam, which as I have

already mentioned amended *inter alia* Article 100a of the EC Treaty, came into force on 1 May 1999. By letter dated 29 July 1999, the Commission therefore informed the Danish authorities that their notification on the use of sulphites, nitrites and nitrates in foodstuffs would now be considered within the framework of the new provision, now Article 95 EC.

38. It was on this legal authority that on 26 October 1999 the Commission based its refusal to authorise the Danish measures, holding that they did not meet the conditions laid down by that provision. In particular, it denied that the said measures were necessary and proportionate to the objective pursued or that they catered for a situation specific to Denmark; furthermore, it discerned discriminatory aspects in the measures.

C — *The application*

39. Upon receipt of notification of that decision,[16] the Danish Government adopted Order No 822 of 5 November 1999 repealing the national provisions applicable to nitrites, nitrates and sulphites. On the following 6 January, however, it made the present application for annulment of the Commission decision and for the Commission to be ordered to pay the costs.

40. By order of 4 October 2000 the Court granted the Kingdom of Norway and the Republic of Iceland to intervene in support of Denmark. A number of questions were put to the parties before the hearing.

III — Legal assessment

Introduction

41. The Danish Government bases its application for annulment of the Commission decision on a number of arguments, which are amply described in section III of the application and claim formal and substantive defects. As regards the first, it accuses the Commission of having infringed the principle of a fair hearing in the procedure that led to adoption of the contested decision and of having given an inadequate statement of reasons for that decision. The substantive defects alleged in

16 — The contested decision was notified to the Danish Government on 28 October 1999 by letter No SG(99) D/8669.

the application are more numerous, however. I shall begin by examining the first of the formal defects mentioned above, namely that relating to the principle of a fair hearing. By contrast, I shall turn to the second only after having dealt with the substantive defects, as an examination of this claim depends on the prior consideration of such defects.

A — *The alleged infringement of the principle of a fair hearing*

42. The Danish Government, supported on this point by the Icelandic Government, contends that the Commission decision is vitiated by infringement of an essential procedural requirement because it was allegedly adopted without complying with the principle of a fair hearing as defined in the case-law of the Court, primarily because, despite regular contacts between the Danish authorities and the Commission from the outset, the Commission did not give the government concerned the opportunity to express its views on the content or implications of the decision before its adoption nor did it provide it with a precise and complete statement of the reasons on which the decision was based. Moreover, the Danish Government maintains that it was not put in a position to know and comment on the opinions expressed by the other Member States on the national measures it had notified. According to the Danish Government, this is all the more serious in that, as I have said, some of those opinions were expressly taken into consideration by the Commission in the statement of reasons for the decision.

43. In order to adopt a position on this ground of challenge it is necessary first to rule on the nature of the procedure leading to the adoption of a decision within the meaning of Article 95(4) EC. According to the Commission, 'the principle that the procedure must be *inter partes*, which applies in all administrative proceedings initiated against a person which are liable to culminate in a measure adversely affecting that person, is a fundamental principle of Community law, but it does not apply in the context of the legislative process'. [17] In the opinion of the Commission, that is the nature of the procedure provided for by Article 95(4) and (6) EC because it is no more than a stage in the procedure provided for by that article, a procedure that is legislative in character in that it leads to the adoption of an act with general validity. According to the Commission, the procedure for authorising the maintenance of derogating national measures should thus be recognised to be of the same nature, given that it may lead to a partial amendment of the subjective and/or objective field of application of the directive, with effects not only for the Member State to which it is directly addressed but also for the other Member States.

17 — Judgment in Case T-199/96 *Bergaderm and Goupil* v *Commission* [1998] ECR II-2805, paragraph 58; in support of this, see the judgment in Case T-521/93 *Atlanta and Others* v *EC* [1996] ECR II-1707, paragraph 70.

44. I cannot concur with that conclusion, however. It is true, as the Commission maintains, that the derogation from an act with general validity, even if adopted in consideration of individual needs, entails the modification, with effect *erga omnes*, of the field of application of the act from which it derogates because it also indirectly affects the legal situation in the other addressees of the act. That is no reason, however, for considering that the procedure leading to the derogating decision is also part of the legislative procedure leading to the adoption of the general act. This is obviously true when it is a question of directly amending such an act, and indeed Article 95(7) provides that any 'adaptation' of general relevance which the Commission may deem it useful to make to the harmonisation measure, in the light of the needs highlighted by authorised national provisions, shall be the subject of a normal legislative procedure, initiated by a proposal from the Commission to the European Parliament and to the Council. The situation is different, however, in the case of the authorisation procedure under paragraph 4 et seq. of Article 95 EC, which is a formally distinct procedure with characteristics significantly different from those of the procedure leading to the adoption (or amendment) of the harmonisation measure that is the subject of the derogation. One need only consider that the procedure commences when the legislative process has been completed, so that the Commission decision may even be delivered after the legislation has come into force. Furthermore, the adoption of the legislation and of the derogation are the responsibility of different institutions, and the derogation is subject to rules and procedural arrangements typical of an administrative procedure, so that, for example, if the Commission does not issue an opinion within a certain time-limit, the derogating provisions must be deemed to have been authorised [18] in application of the administrative principle of tacit consent.

45. Hence, on the supposition that the procedure in question is an administrative procedure, it is necessary to establish whether compliance with the principle of *audi alteram partem* was ensured in the course of that procedure. I recall in this connection that the Court has had occasion to clarify that, on the basis of that principle, the addressee of a decision liable to seriously affect its interests must be able to express its views during the administrative procedure and hence must also be placed in a position to know the documents used by the Commission. [19] In other words, it must be afforded the opportunity during the

18 — Advocate General Saggio reached the same conclusion in the *Burstein* case, when he observed that 'under Article 100a(4), if, after the adoption of a harmonisation measure, a Member State deems it necessary to apply national provisions justified by the major (non-economic) requirements referred to in Article 36, or relating to protection of the environment or the working environment, it may do so only if it follows a given procedure and subject to a dual system of *supervision, both administrative (entrusted to the Commission)* and, where appropriate, judicial' (Opinion in Case C-127/97 *Burstein* v *Freistaat Bayern* [1998] ECR I-6006, point 19, my italics). In a similar vein, see the Opinion of the same Advocate General in Case C-319/97 *Kortas* [1999] ECR I-3145, point 17).

19 — See in particular the judgments in Case 40/85 *Belgium* v *Commission* [1986] ECR 2321, Joined Cases C-48/90 and C-66/90 *Netherlands and Others* v *Commission* [1992] ECR I-565, paragraph 44, Case C-135/92 *Fiskano* v *Commission* [1994] ECR I-2885, paragraph 39, and Case C-32/95 P *Commission* v *Lisrestal and Others* [1996] ECR I-5373, paragraph 21.

administrative procedure 'to make known its views on the truth and relevance of the facts and circumstances alleged and, if necessary, on the documents used'. [20]

46. For that purpose, however, observance of particular forms is not prescribed, except obviously in cases where they are expressly mentioned in specific provisions. [21] Implementation of the principle must, however, be graduated according to the nature of the procedure in question and the effects that the act adopted is intended to produce. In the case of the procedure of interest here, it seems quite plain to me that the State requesting authorisation has a direct and specific interest in the procedure and must therefore be placed in a position effectively to make known its reasons during the administrative procedure before the Commission. But the other Member States have an equal interest in the outcome of the procedure in question, precisely because to authorise the maintenance of derogating measures limits the scope of application of a general legislative provision. Hence, any decision by which under Article 95(4) EC the Commission authorises the requesting State to maintain derogating national provisions will inevitably also have effects on the other Member States. For this reason, although Article 95 EC does not lay down any obligation in this respect, the Commission follows the practice — correctly, in my opinion — of informing the other Member States that it has received an application within the meaning of the fourth paragraph of the provision and giving each of them the opportunity to express their opinion on the procedure, [22] while specifying that the communication to the other Member States does not formally concern the exercise of rights of defence but is aimed merely at giving those who wish to submit observations on the procedure in progress an opportunity to do so.

47. That having been said, I note that the Commission nevertheless claims to have complied, at least *de facto*, with the principle of *audi alteram partem* in that Denmark had the opportunity to set out its reasons during various meetings and in the exchange of correspondence which I have described in the narration of the facts. [23] In particular, after lodging its request but before the adoption of the contested

20 — Judgment in Case C-69/89 *Nakajima* v *Council* [1991] ECR I-2069, paragraph 108. See also more recently, the judgment in Case C-288/96 *Germany* v *Commission* [2000] ECR I-8237, paragraph 99 et seq., in which the Court confirmed that 'observance of the rights of the defence is, in all procedures initiated against a person which are liable to culminate in a measure adversely affecting that person, a fundamental principle of Community law which must be guaranteed even in the absence of any rules governing the procedure in question'. See also the judgments in Cases 85/76 *Hoffmann-La Roche* v *Commission* [1979] ECR 461 for a procedure involving competition, 264/82 *Timex* v *Council and Commission* [1985] ECR 849 for anti-dumping procedures and 234/84 *Belgium* v *Commission* [1986] ECR 2263 on the procedure regarding State aids.

21 — As, for example, in the case of the procedure governed by Article 88(2) EC regarding State aids.

22 — In its rejoinder the Commission points out that a similar practice was followed for the Decision of 14 September 1994 concerning the prohibition of PCP notified by the Federal Republic of Germany (OJ 1994 L 316, p. 43), for the Decision of 26 February 1996 concerning the prohibition of pentachlorophenol (PCP) notified by Denmark (OJ 1996 L 68, p. 32) and, again, for the Decision of 21 December 1998 on the national provisions notified by the Kingdom of Sweden concerning the use of certain colours and sweeteners in foodstuffs (OJ 1999 L 3, p. 13).

23 — See points 33 to 35 above.

decision, the Danish Government had submitted its observations in the course of a meeting held on 19 November 1997. Moreover, the Commission points out that it responded to Denmark's request by instituting the procedure on the basis of the information provided by the Danish authorities and in the light of the available scientific data (the SCF reports), which in any case were in the public domain.

48. In contrast, the Danish Government disputes that the meeting of 19 November 1997 can be considered a genuine hearing and asserts that it is not sufficient to allow the State in question to set out its reasons in order to ensure compliance with the principle of *audi alteram partem*. According to the applicant, it is necessary to afford the said State the opportunity to make its observations on the Commission's draft decision and on the associated statement of reasons, and in particular to know the opinions expressed by the other Member States.

49. In this regard, however, the Commission replies that it is clear from the exchange of correspondence between Mr Martin Bangemann, Member of the Commission, and Mr Henrik Dam Kristensen, Danish Minister for Food, (letters of 8 February 1999 and 16 March 1999) that the Commission had requested and received such opinions and that the Danish Government had knowledge of them; despite this, the Danish Government had neither requested copies nor asked to comment on them. Furthermore, according to the Commission, the Danish Government was already in possession of the draft decision and had even given its opinion on it in a letter dated 22 October 1999 addressed to Commissioners Byrne and Liikanen.

50. Hence it is apparent from the documents before the Court that although the principle was not scrupulously adhered to, the applicant government was nevertheless involved throughout the entire procedure and was informed of the request for opinions from other Member States (a situation which it should have taken for granted, given the precedents in this regard) and of the receipt of a number of observations. It is also apparent that, despite this, the Danish Government at no time asked to see them; only when bringing proceedings did it decide to complain that it did not have the opportunity to comment on those observations and on the Commission's reaction.

51. I therefore feel able to conclude that in the case in point the principle of *audi alteram partem* was not infringed.

52. I have to add, however, that should the Court take a different view it would remain

to be established, as the Commission has noted, whether infringement of the principle in question had an impact in the case in point. According to settled case-law of the Court, an infringement of the rights of defence does not result in annulment of the decision if it had no influence on the outcome of the procedure. [24]

53. In this regard I must point out that the contested decision is based on scientific data, drawn essentially from the SCF opinions I have mentioned, with which the Danish Government was perfectly acquainted and on which it had ample opportunity to present its own point of view. The decision in question is therefore not based on the opinions expressed by the other Member States in the course of the procedure; although those opinions probably bolstered the Commission's stance, in reality they merely express an assessment on the compatibility of the Danish request with Article 95 EC in the light of the same scientific data as was used by the Commission and Denmark. I recall in this regard that the Court, when replying to a similar objection, stated that 'the contested decision is sufficiently supported by the objective information referred to in the statement of the reasons on which it was based, of which the... government was fully apprised and in respect of which it was afforded every opportunity to make known its views. It follows that, even without the comments which the Commission received from interested third parties in the course of the procedure, the decision could not have been substantively different. In those circumstances the mere fact that the Commission mentioned those comments in its decision without having afforded the Member State concerned an opportunity to comment on them does not justify a declaration that the decision is void.' [25]

54. I would add lastly that, as I have already said, it is clear from the documents before the Court that the Danish Government had knowledge of the draft decision before it was issued and therefore had the opportunity to make known its views on the points of fact and law which the Commission considered relevant for denying the requested authorisation, including the positions expressed by the other Member States as a result of the contested consultation procedure. Now, it may also be maintained that the fact that this was conducted in a way that was, so to speak, indirect and unofficial gives grounds for doubting that the principle of *audi alteram partem* was fully complied with, but this makes it possible to rule out that the alleged infringement of the principle in reality prevented the exercise of the rights of defence and hence, at the end of the day, affected the outcome of the procedure to the extent of justifying the annulment of the act for that reason alone.

55. I therefore consider that the Danish complaint as to the infringement of the principle of *audi alteram partem* must be rejected.

24 — Judgments in Cases 259/85 *France* v *Commission* [1987] ECR 4393, paragraph 13, and C-142/87 *Belgium* v *Commission* [1990] ECR I-959, paragraph 48.

25 — Case 234/84, paragraph 30.

B — *The complaints as to the substance of the decision*

Introduction

56. With regard to the substance, as I have indicated, Denmark raises various claims as to the unlawfulness of the decision, setting them in a highly diverse and complex set of arguments which it is not easy to describe in the order followed in the application without the risk of losing sight of the essence of the dispute, the terms of which became clearer in the course of the case. Hence, in order to highlight above all the substance of the debate, I shall not slavishly follow the order used in the application but will try first and foremost to unravel the logical thread.

57. Underlying the Danish position is the notion that, pursuant to Article 95(4) EC, a Member State may maintain in force national provisions that derogate from Community harmonisation measures if it deems such measures necessary, on the basis of an assessment made unilaterally by that Member State, in order to ensure a higher level of protection of the needs listed in that article. Hence, in order to justify derogating measures the Member State need cite no other justification, and in particular it does not necessarily need to adduce requirements peculiar to itself, but has only to demonstrate that the measures are truly necessary to ensure the higher level of protection it wants and do not exceed that purpose. It goes without saying that this is subject to compliance with the conditions for which Article 95(6) provides for verification by the Commission.

58. Consequently, Denmark rejects the Commission's objections based on the absence of a situation specific to that country that would justify the derogation at issue and goes on to dispute the assessments as to the absence of the requirements of need and proportionality in the national provisions in question and their alleged discriminatory nature. Lastly, Denmark also criticises, together with some minor aspects of the disputed decision, the failure to take Article 95(6) EC into consideration.

59. I shall follow the same chain of logic in my examination of the complaints as to substance.

(a) Erroneous interpretation of the conditions for applying Article 95(4) EC

60. I shall therefore begin with the question which, in my opinion, constitutes the central and most delicate point of the present case from the point of view of principles,

namely whether or not authorisation of the derogation must be subject to the existence of a situation specific to the Member State requesting it. To tell the truth, the procedural debate on this question was rather muted at first, but it became more lively in the course of proceedings as the respective positions became clearer.

Arguments of the parties

61. In order to justify its negative stance on this question, Denmark, partly supported by Iceland and Norway, certainly took account of the fact that the succinct wording of the provision at issue is silent as to the requirement for a specific situation to obtain, but above all it made much of the historical and political context in which Article 100a(4) of the EC Treaty, now Article 95(4) EC, came into being. It recalls in particular that Article 100a was introduced by the Single European Act to offset the change from unanimous voting to qualified majority voting for the adoption of harmonisation measures under the first paragraph of that article and was designed to offer Member States a guarantee against the risk of having to reduce, as a result of harmonisation, the level of protection already achieved in their national legislation. According to the applicant, the provision was therefore the expression of a 'political compromise' intended to preserve Member States' freedom to make a choice different from the Community one in exchange for an amendment to the voting rules.

62. Hence, precisely because from the outset it represented a break with the principle applied until that time with regard to harmonisation, Article 100a of the Treaty could not, according to the Danish Government, be subject to the restrictive criteria usually applicable to derogating provisions. Instead, it has to be interpreted in the light of the political compromise of which it is an expression, and hence in the sense that it leaves the Member State concerned ample freedom to weigh the interests at stake, possibly with a different emphasis from that made by the Community legislature.

63. The Commission, for its part, does not share this view, although in expounding its own position it wavers somewhat between the arguments stated in the contested decision and those set out in the documents of the case, thus confirming, I feel, a lingering underlying uncertainty. However, on the premiss that the assessments of the political setting of the Single European Act and Article 100a do not point unanimously in the direction asserted by Denmark, the Commission recalls that the case-law of the Court has frequently stated that once harmonisation measures in a sector have been introduced a Member State can no longer rely on the needs referred to in Article 30 EC (formerly Article 36) in order to exempt

itself from application of those measures.[26] The same must also apply to harmonisation measures adopted under Article 95(1) EC, and indeed to an even greater extent in the case of such measures, given that, under the third paragraph of the provision, by definition they are aimed at providing a high level of protection for the important needs regarding health, safety, environmental protection and consumer protection. Consequently, according to the Commission, once the Community legislature has examined the relevant information, set the desirable level of protection and issued the measure, a Member State cannot simply substitute its own risk assessment for that made by the Community legislature and on that sole ground presume to derogate from the resulting harmonisation measure. Instead, it must prove, on the basis of new scientific data or facts that should have been taken into consideration by the Community legislature, that the provision is not an adequate means of ensuring a high level of protection for the 'major needs' referred to in the provision in question; but the State concerned can equally claim that in this regard a situation specific to that State obtains which justifies the derogation. Hence, according to the Commission, unlike the fifth paragraph, the fourth paragraph of Article 95 does not necessarily require this latter condition to be fulfilled but allows the State concerned to rely on it as an additional way of justifying the requested derogation.

26 — See, among many others, the judgments in Cases 5/77 *Tedeschi* v *Denkavit* [1977] ECR 1555, paragraph 35, 148/78 *Ratti* [1979] ECR 1629, paragraph 36, 251/78 *Denkavit* [1979] ECR 3369, paragraph 14, 190/87 *Moormann* [1988] ECR 4689, paragraph 10, and C-323/93 *Crespelle* [1994] ECR I-5077, paragraph 31.

Assessment

64. As we have seen, this complaint raises a central aspect of the system outlined by Article 95 EC, and in particular the division of powers between Member States and Community institutions regarding the assessment of the levels of protection of health and the quality of the working and natural environments following the adoption of a Community measure harmonising national measures with an impact on the establishment of the internal market. The disagreement that emerged in this respect between the parties is profound and reflects very different views of the said system. It is therefore necessary to reconsider in global terms the meaning and scope of the provision in question, not least because for my part I feel unable to associate myself with the Danish position, but nor can I fully share that of the Commission.

65. As I have recalled several times, Article 95 EC (and before it Article 100a) creates general powers for the Community to adopt measures harmonising relevant national provisions for the establishment and functioning of the internal market. That power is exercised by the Council deciding jointly with the European Parliament (previously in cooperation with it). When dealing with questions of health, safety, environmental protection and consumer protection, the Commission, in the

exercise of its own powers of proposal, and the other two actors in the legislative process must take as a base a high level of protection; in particular, they must take account of any new development based on scientific facts (paragraph 3). However, once harmonisation has taken place (after the amendments to Article 100a, it no longer matters whether by a qualified majority or in unanimity) a Member State may request a derogation justified on grounds of the protection (of life, of health) of the working environment, of the natural environment (or other major need referred to in Article 30 EC) to maintain national provisions already in force but which conflict with the harmonised rules (paragraph 4) or to introduce new provisions on account of a problem that has arisen (paragraph 5). Finally, paragraph 6 of the provision defines the role of the Commission for the purposes of authorising the derogation in the two cases indicated and reserves it the power to verify compliance with the prohibition on arbitrary discrimination and disguised restrictions on trade between Member States.

66. It is patently obvious, even from this brief description, that the provision in question is aimed at catering for two distinct needs that are not always easy to reconcile: first, to give impetus to the establishment of the common market, and secondly to ensure high standards of protection of health, safety, environmental protection and consumer protection. For the latter, in particular, Article 95 EC openly shows the desire to take account of concerns legitimately expressed by the Member States in a legislative process which, from Article 100a onwards, can now be decided by a qualified majority, although on the premiss that in principle such concerns are presumed to have already been satisfied by the harmonisation measure itself, given that it must by definition be based on a high level of protection. But if that is the case, in other words if that high level of protection is already written, so to speak, into the DNA of the harmonisation measure, two significant indications can already be deduced, on which I shall elaborate later. The first is that there does not appear in principle to be any justification for the claim that the provision in question should be exempted from the application of the settled case-law of the Court, which requires that the conditions for the admissibility of a derogation from the fundamental rules of Community law (in the present case the unity of the market) must be interpreted strictly. [27] The second is that it is not enough to rely generically on the inadequacy of the standard of protection guaranteed by the harmonisation measure to be authorised to maintain or introduce a derogation from that measure.

67. Moving on to examine the question at issue more closely, I must first and fore-

27 — See, among many others, the judgments in Case 222/84 *Johnston* v *Chief Constable of the Royal Ulster Constabulary* [1986] ECR 1651, Joined Cases C-267/95 and C-268/95 *Merck and Beecham* v *Europharm* [1996] ECR I-6285 and Case C-285/98 *Kreil* v *Bundesrepublik Deutschland* [2000] ECR I-69.

most mention that, according to the Danish Government, the fourth paragraph of Article 95 does not state the conditions listed in the fifth paragraph of that provision. It is true that the latter is much more detailed and, at least textually, more restrictive than the paragraph which immediately precedes it, because to allow the introduction of national measures in derogation from the Community harmonisation measure once it has been adopted requires three conditions to be met: the derogating national provisions must be based on new scientific evidence in the sectors indicated, there must be a problem specific to the requesting State and that problem must have arisen after the adoption of the directive.

68. The more general wording of paragraph 4 of Article 95 catering for the possibility of maintaining national measures in derogation from the Community harmonisation measure would thus allow us to conclude that in these cases none of the aforesaid conditions need be met. Indeed, first, in this instance it would not be a question of introducing new national measures and hence it would not be necessary to provide new scientific evidence, and secondly, given the silence of the provision, the Member State concerned would not need to plead the existence of a specific situation. It would only have to prove that the measures in question make it possible effectively to ensure the highest level of protection which, in the judgment of that State, is necessary to meet the 'major needs' referred to in the provision in question, but without exceeding that objective. The Member State would be required to do no more in order legitimately to restrict the field of application of the common legislation, subject of course to verification by the Commission pursuant to Article 95(6) EC.

69. While I recognise that the interpretation of Article 95 is anything but easy, I must say that I find it very difficult to share the view that I have just summarised. In my opinion, that view is not only hard to reconcile with the logic and purpose of the system, as we shall see, but also in all probability springs from a false perspective, that is to say from a hasty comparison between the fourth and fifth paragraphs of the provision and, perhaps, also from an equally hasty reconstruction of the legislative process that effected the transition from Article 100a(4) of the EC Treaty to Article 95(4) and (5) EC. It seems to me, in other words, that the view I have described stems from the notion that Article 100a(4) only provided for the possibility of maintaining national provisions in derogation from a Community harmonisation measure on the basis of an assessment of the need for such measures that was left to the Member State concerned; the subsequent Article 95 EC then reiterated the same hypotheses in paragraph 4 and added another in paragraph 5, governed in a more analytical and restrictive manner, to cater for the possible introduction of new national provisions in derogation from the aforesaid harmonisation measure.

70. I repeat, however, that I consider that reconstruction to be hasty and misleading

for the purposes of a correct interpretation of the provisions in question, for a series of reasons which I shall now attempt to illustrate.

71. First, I would point out that Article 100a(4) was not limited to the hypothesis of 'maintaining' national provisions in derogation from a harmonisation measure; on the contrary, it referred more generally to the situation where a Member State intended to 'apply' such provisions and hence it served to cover both the hypotheses in question, in other words both the maintenance of existing provisions and the introduction of new ones. [28] In the subsequent Article 95 the two hypotheses were explicitly separated and the general term 'apply' became the more specific terms 'maintain' and 'introduce', which in my opinion indirectly confirms that in reality Article 100a previously covered them both.

72. Moreover, it could be objected that only the fourth paragraph of Article 95 repeats the general wording of Article 100a, whereas the fifth explicitly sets the condition that the situation must be specific to the Member State concerned; this would therefore confirm both the continuity between Article 100a(4) and *only* the fourth paragraph of Article 95 and the absence of that condition in the former. I observe, however, that such an objection would in turn rest on a premiss that is not demonstrated and which in my opinion is debatable, namely the premiss that the silence of Article 100a(4) as to the conditions for authorising the derogation implies that the Member State is at complete liberty to assess the need for the derogation. It seems to me, by contrast, for reasons I shall expound shortly, that in fact this illogical conclusion cannot be deduced from the article's silence but that, on the contrary, the preconditions for applying the derogation, although not spelt out in the provision (which is, I repeat, less evolved than the subsequent Article 95), must even then have been capable of being derived from the system and that they undoubtedly included the condition as to the specific nature of the situation relied upon as a basis for the derogating national measures.

73. Moreover, I find it significant that in the very first case involving a Commission decision based on Article 100a(4) (and hence even before it was replaced by Article 95 EC), Advocate General Tesauro acknowledged that the provision represented a 'counterweight' to 'offset' the relinquishment of the principle of unanimity, but emphasised that nevertheless 'clear details should... have been given as to the *specific requirements* justifying the adoption of even more restrictive measures in

28 — Moreover, some of the literature had already taken this view from the very outset (see in particular C. Gulmann, *The Single European Act — Some Remarks from a Danish Perspective*, CMLR 24 (1987), pp. 31 to 40, especially p. 38).

[the Member State concerned]'[29] than those provided for in a harmonisation directive. It is also worth recalling the reference made by Advocate General Saggio, precisely in connection with Article 100a(4), to the established principle that any derogation from the principles of uniform application of Community law and the unity of the market must be interpreted strictly. Hence, as it deals with just such a derogation, this article cannot but be 'narrowly construed, and its operation must be subject to stringent conditions both with respect to the scope of the justifications provided for, and to the procedure for administering this safeguard clause'.[30]

74. The fact remains, however, that whereas Article 95(5) now explicitly lays down the conditions for applying the derogation for the purposes of the situation it envisages, it must be deduced from this that such conditions are not required in the situation provided for by the fourth paragraph of the same provision (as they were not for the corresponding paragraph of Article 100a). There is no doubt that paragraphs 4 and 5 of Article 95 lay down different rules, as they refer to different situations; however, it is necessary to agree where those differences really lie and what consequences they entail. In my opinion, they cannot but relate to the factor which plainly distinguishes the two situations in question from one another, that is to say the fact that the fifth paragraph refers to the introduction of derogating measures *after* the adoption of the Community measure and justified by new scientific evidence. It follows that within the framework of the more precise and developed derogation regime provided for in Article 95 EC the fifth paragraph of the provision is in turn even more 'special', so to speak, than the preceding paragraph (as to some extent is confirmed by the paragraph itself when it gives precedence to that paragraph) and hence makes the hypothesis for which it provides subject to even stricter criteria than those laid down by the fourth paragraph, both as regards the 'major needs' considered — given that in this case it is possible to introduce a safeguard measure only for 'protection of the environment or the working environment' — and above all as regards the conditions for operation of the provision. As I have said, the national measure must be based on 'new scientific evidence' and justified by a problem specific to the Member State concerned arising after the adoption of the directive.

75. But these last two conditions are strictly interdependent, in the sense that the specific nature of the problem is not sufficient to justify the subsequent national measure: new scientific evidence must also

29 — Opinion of Advocate General Tesauro in Case C-41/93 *France* v *Commission* [1994] ECR I-1831, point 14; my italics. The judgment in the case is to be found at ECR I-1829.

30 — Opinion of Advocate General Saggio in the *Kortas* case, point 23.

have emerged. If reference had been made only to the first condition, it would have been possible to find an argument in favour of the position criticised here, but the provision also demands new evidence; it is precisely for this reason that the fifth paragraph, but not the fourth, makes express reference also to the specific nature of the problem. As the evidence in question could be relevant to all or many other Member States, it became necessary here (but not in the fourth paragraph) to set out as clearly as possible a condition specific to the requesting State that is linked to the new evidence and justifies *in a special way* a derogation for that State from the harmonisation measure. If this reconstruction failed to convince, it would have to be explained for what mysterious reason a Member State must rely on a problem specific to itself if it wishes to introduce derogating measures after the adoption of the directive but not if it wants to maintain existing ones, particularly if one considers that it has also had an opportunity to defend its reasons for the latter during the preparation of the directive.

76. The fact that the requirement for a specific problem to exist also applies to the situation referred to in Article 95(4), as it did under Article 100a, appears to me to be confirmed above all by systematic considerations. First and foremost, I must reiterate, in unison with the Commission, that to the extent that it creates 'an exception to the principles of uniform application of Community law and unity of the market', Article 95(4) EC must, like all provisions which allow derogations, 'be strictly interpreted, so as to ensure that it is not extended to cases other than those specifically provided for in it'. [31] By contrast, the Danish proposition, unlike that set out here, effects just such an extension. In any case, to me it seems very difficult to reconcile with that interpretative principle the claim of a Member State to rely on the inadequacy of the standard of protection guaranteed by the Community legislature as grounds for requesting, on the basis of a unilateral assessment of the need for raising that standard, authorisation to maintain or introduce a derogation from the provision and hence from the principle of unity of the market. On the contrary, it seems to me that to allow such a claim would mean transforming Article 95(4) EC into a veritable permanent opt-out clause from any harmonisation directive, in stark contrast with the principles and purposes of the system and with the logic which, in the protection of the general interest, inspires the division of powers between the Community and the Member States.

77. In reality, if that paradoxical consequence is to be avoided, it must be conceded that further justifications and

31 — Opinion of Advocate General Tesauro in Case C-41/93, point 4.

conditions are necessary for the derogation to be legitimately requested, and these cannot but consist in a problem specific to the State concerned for which the general measures contained in the directive are not able to cater. If it were a problem common to all or the majority of Member States, it would presumably already have been resolved by the directive, but if that were not so, it would be necessary to verify whether the conditions for challenging the directive directly were met, given that the directive must already ensure not just general protection but a 'high level' of protection; in any case, the problem would be of a general nature and it is not therefore possible to understand why it should be resolved only for the fortunate citizens of a single more meticulous Member State, to the detriment of the uniform application of the harmonised rules and hence of the functioning of the common market. If, on the other hand, the level of protection were considered adequate, it is still not possible to understand why one Member State should be allowed the liberty to raise it unilaterally, even with the laudable intention of ensuring an even higher level of protection for its own citizens, again to the detriment of the unity of the market, unless this State can demonstrate the existence of a situation specific to itself that justifies such consequences.

78. I would add that the proposition I have outlined here also helps explain why — perhaps already under Article 100a and certainly in the light of Article 95 — the maintenance of higher national measures may also be requested where the directive was adopted unanimously and why it is therefore not confined to States 'placed in a minority' but can even be invoked by a State that has approved the directive. This means that the derogation is not necessarily linked to an adverse assessment of the directive, because a Member State could consider that in general terms the level of protection guaranteed by the Community legislature is adequate and for that reason approves it, while knowing that it has a specific problem in this regard and therefore reserves the right to request a derogation. From the viewpoint of the opposite proposition, however, a request for a derogation from a State that approved the directive would be difficult to explain, given that the point of departure of that proposition should be the State's negative assessment of the level of protection laid down in the directive.

79. It is also significant that the applicant government has not adopted many arguments in support of its claim. It has concerned itself mainly with justifying the systematic incongruities which I have just described, and it has done so, as I have pointed out, by stressing in particular the 'historical and political context in which the provision came into being' and hence the need to interpret it 'in the light of the political compromise of which it is an expression'. I have to say, having in fact been a direct witness to the proceedings,

that I have no difficulty recognising the existence of that 'context' and of the climate of concern that surrounded the negotiations on the Single European Act with regard to Article 100a. I could even cite for that purpose the declaration made by Denmark at the close of the negotiations, which expresses well the intention of some Member States, in particular Denmark, to reserve the possibility of making a choice different from that of the Community. [32] But I do not wish to enter into a detailed discussion of that declaration here, all the more so since it has not even been mentioned by the applicant government. I will merely observe that as far as I can discover it has not been repeated since then, either for the Treaty of Maastricht or for the Treaty of Amsterdam, confirming the fact that it reflected rather the tensions of the negotiations on the changes in voting and that the tensions later gave way to the more considered assessments suggested by the subsequent practice in applying the provision.

80. I feel it is more useful to say a few words about the Danish Government's insistence on the 'context' and the 'political compromise' of which Article 100a(4), and subsequently Article 95(4), are supposedly an expression, and which allegedly justify the applicant's claim. I repeat in this regard that I have no difficulty recognising, together with Advocate General Tesauro, that the possibility afforded to a Member State to maintain national provisions after the adoption of a Community measure harmonising a given matter 'is intended to ensure "reinforced" protection of certain particularly important interests and, above all, to answer the preoccupations expressed by a number of countries during the negotiations leading up to the Single Act to the effect that any harmonisation adopted by a majority vote might result in a diminution of the degree of protection enjoyed by such interests at national level'. [33] That having been said, I must, however, repeat that in my opinion neither the 'political compromise' nor the consequent need for 'reinforced protection' justify overturning the principles of the system, which would be the result of accepting the Danish Government's proposition. All the more so if one considers that the provisions under examination already take ample account of these needs, given that for this very reason they expressly introduce a substantial derogation from the established principle that where Community harmonisation has taken place in a given matter the Member States may no longer adopt unilateral measures justified by the protection of the needs referred to in Article 30 EC (see point 63 above). In the case under examination, provided the conditions are met, such measures can be authorised, and this in my opinion is already in itself a significant reinforcement of the guarantees sought. To go further, and to translate those conditions into a possibility of dero-

32 — I refer to the declaration by the Government of the Kingdom of Denmark (declaration No 18 annexed to the Single European Act) on Article 100a of the Treaty establishing the European Community: 'The Danish Government notes that in cases where a Member State is of the opinion that measures adopted under Article 100a do not safeguard higher requirements concerning the working environment, the protection of the environment or the needs referred to in Article 36, the provisions of Article 100a(4) guarantee that the Member State in question can apply national provisions. Such national provisions are to be taken to fulfil the above-mentioned aim and may not entail hidden protection.'

33 — Opinion in Case C-41/93, point 4.

gations *ad libitum*, would not be a compromise but an abuse.

81. Before concluding on this point, I must also devote a few words to the debatable position adopted by the Commission in the present case. After having given to understand that it too considered that a factor specific to the State requesting the derogation was a necessary condition, raising it in the contested decision and basing one of the main grounds for refusing authorisation on the absence of such a factor, in its submissions the Commission downgraded that condition almost to a subordinate or, at any event, alternative ground by comparison with other conditions. In its opinion, in short, the Member State invoking Article 95(4) can also confine itself to adducing new scientific evidence or factors that should have been taken into consideration in the Community legislation at issue if they were likely to prove that the latter does not ensure adequate protection.

82. It seems to me in reality that whereas the Danish proposition leaves room for arbitrary conduct on the part of the States, in the Commission's proposition the arbitrariness lies in the choice of the conditions indicated above, not only because there is no trace of them in the provision but because they do not even derive from the logic of the system or from criteria of reasonableness. In fact, upon close inspection they do not even serve to resolve the problem at issue but only to transfer it, given that even if it were shown to exist it would still be necessary to demonstrate why, in the absence of a specific need for the Member State requesting the derogation, the new information should work in favour of that State and not in that of all (or most) of the other States. The fifth paragraph of Article 95 gives an unequivocal reply in this regard by demanding that there also be a problem specific to the requesting State; the Commission's proposition, in contrast, does not give such a reply or at least does not give it clearly and unequivocally. I must also add, more specifically, that I find it extremely difficult to imagine that a directive negotiated over a period of years can have overlooked information so crucial as to justify the derogation we are discussing, and above all that this information (or even new scientific evidence) can then emerge in the extremely short period of time between approval of the directive and the request to maintain national provisions, as the case in point demonstrates. What in fact appears normal in the hypothesis for which Article 95(5) caters, and thus justifies its particular wording, frankly appears rather unlikely in the case we are now discussing.

83. I obviously do not contest the soundness of the requirement, underlined by the Commission, that the State concerned prove the inadequacy of the protection

provided by the Community directive, because it is clear that that requirement is closely linked to the condition that there be a specific problem, in the sense that the derogation can be authorised only if it is demonstrated, as stated in Article 95(5), that protection is inadequate in relation to a specific problem encountered by the State concerned. In a certain sense therefore the existence of the problem is the preliminary condition for the State to be entitled to request the derogation; the inadequacy of protection is the substantive condition for granting the derogation.

84. In the light of the foregoing, I therefore consider that the Danish measures regarding sulphites, nitrates and nitrites should be justified by reason of a situation specific to Denmark; since such justification has not been provided, and not even relied upon, this complaint should, in my opinion, be rejected.

(b) The necessity and proportionality of the Danish measures

85. As I indicated above, the applicant government justifies its request to maintain national provisions in derogation from the Community harmonisation measure on the grounds of the inadequacy of the latter and hence the need to maintain higher levels of protection. These arguments are contested by the Commission, which in addition detects discriminatory elements in the derogating national measures. In examining this difference of opinion, I shall seek as far as possible not to allude further to the condition that a specific problem exist, which I have examined at length above, although this issue resurfaces several times and blends with the arguments raised by the parties on the questions now under discussion.

Arguments of the parties

86. The applicant government disputes the conclusions reached by the Commission in the contested decision and defends the necessity and proportionality of its measures, relying in general on the precautionary principle, which according to the applicant permits Member States to raise the level of protection to prevent risks to human health.

87. According to Denmark, this is especially true of sulphites. Denmark does not deny that its legislation is more restrictive than the directive, in that it limits the categories of foodstuffs in which such additives may be used and reduces the

quantity that may be added. However, the applicant contends that such restrictions are necessary because of the dangers to health from the use of such products and from the unjustifiably tolerant approach adopted by the directive, particularly by comparison with the rigidity of other rules of derived Community law relevant to this field.

88. In particular, Denmark first refers to the danger of serious allergic reactions in susceptible persons, which cannot be remedied by the incomplete Community legislation on labelling; secondly, it cites the risk of exceeding the acceptable daily intake (ADI), set in the SCF opinion of 25 February 1994 at 45-50 mg, despite the fact that neither the quantity of additive nor the list of products in which the use of such quantities is permitted under the directive are justified by a sufficient technological need. Furthermore, the decision enunciated in the Danish measures at issue to reduce the population's exposure to sulphites was, according to the Danish Government, necessitated by the impossibility of acting against the use of sulphites in wine, given that the regulation in this regard does not permit the adoption of national safeguard measures; there was therefore no other solution than to limit the use of sulphites in other products.

89. As to nitrites and nitrates, Denmark responds above all to the assertions in the contested decision that the measures in question were neither necessary nor adequate to meet the need to protect health. According to the Commission, first, the quantities of additives authorised by the directive are technologically necessary to ensure the microbiological safety of meat products without any risk of exceeding the ADI of nitrites or nitrates; secondly, the Danish measures nevertheless permit an excessive use of such additives in certain butchery products, giving rise to the formation of high quantities of the very carcinogenic nitrosamines which the Danish Government claims to want to combat.

90. The applicant government objects first that the contested decision commits a manifest error where it maintains that the measures are not necessary in relation to the claimed exceeding of the ADI of nitrites and nitrates, in that Denmark has never claimed that that was the justification for its measures, having linked them instead to the risk arising from the degradation of nitrites and nitrates into nitrosamines.

91. In the view of the applicant government, the directive disregards the clear recommendations of the SCF, permitting an excessive use of nitrites and nitrates and the consequent formation of nitrosamines, substances with well-known carcinogenic

and genotoxic effects. The SCF itself highlighted the correlation between the quantity of added nitrites and nitrates and the formation of volatile nitrosamines. For that reason it found it impossible to set a threshold below which the use of nitrites and nitrates did not entail the risk of tumours and recommended reducing the use of such additives to the minimum needed to obtain the desired preservative effect and to guarantee microbiological safety. According to the Danish Government, such a result can be achieved only by setting maximum input levels.

92. With regard to the reasonableness of its decisions, the applicant government rejects the accusations made in the contested decision that the measures in question are inconsistent because, in the context of a general reduction in the quantity of additives, they permit different and higher amounts for certain products. Denmark points out that technological needs vary from one product to another and thus depend, as the SCF emphasises, on many parameters, such as the temperature of storage and the composition of the product itself. According to the applicant government, the Danish measures simply adapted the dosage of nitrites and nitrates to the needs of the various products, which the applicant government is at pains to describe analytically. The Commission was therefore wrong to take the different levels of nitrates laid down in the Danish list for different products as a basis for accusing it of inconsistency.

93. In the alternative, the Danish Government submits that, whereas in its request it allegedly demonstrated both the inadequacy of the directive and the adequacy of the national measures, the Commission exceeded the limits of its discretion by confining itself to asserting, without any scientific evidence whatsoever, that the limits set in the Danish regulations for the use of nitrites and nitrates in meat products are contrary to the needs based on the principle of proportionality.

94. The Commission, for its part, objects in general terms that the Danish authorities, without having produced any new data, wish to maintain the national provisions at issue on the sole basis of a different interpretation of the very information available to the Council when Directive 95/2 was adopted. As I have stated repeatedly above, the Commission maintains that such a claim is not admissible unless the Member State can prove that the level of protection laid down in the directive is manifestly insufficient or can cite new evidence or demonstrate the existence of factors overlooked by the Community legislature. This did not occur in the case before the Court.

95. As to the substance, the Commission disputes the Danish accusation that it failed to consider that the existence of a technological need is the necessary precondition for authorising an additive. In reality,

according to the defendant, in the present case there is a technological need both for nitrites and nitrates and for sulphites, and due account of this was taken by the Community directive, but not by the Danish provisions.

96. With regard to the substance of the Danish observations, the Commission observes first that the provisions of Directive 95/2 on sulphites are consistent with the relevant opinions of the SCF and are therefore entirely adequate to the protection of public health. More specifically, it objects that the issue of allergic reactions has already been dealt with at Community level by means of rules on the labelling of foodstuffs, so that no national intervention is needed in that regard; if improvements are needed, they should be pursued when the labelling regulations are amended, and certainly not by means of a derogation from Directive 95/2. According to the Commission, the same goes for the problem of sulphites in wines, which also requires, if necessary, a specific measure in a different context. At any event, the Commission continues, by permitting the use of too low quantities of preservative, the Danish measures are not sufficient to meet the technological need addressed by sulphites.

97. With regard to nitrites, the Commission replies that the contested decision made a reasoned response to the concerns of the Danish Government about the correlation between the quantity of additive used and the formation of nitrosamines. In particular, it repeated that the Community legislature was fully apprised of the SCF opinions when it adopted Directive 95/2 and that in reality the level of protection set by that directive accords with the conclusions of the SCF opinion of 19 October 1990 and essentially confirmed by the subsequent opinion of 22 September 1995. The Commission recalls that in its first opinion the SCF had stated that the available data on nitrosamines, which are known to be carcinogenic, indicated that 'aux niveaux auxquels elles ont été détectées dans les aliments, les effets nocifs pour la santé sont probablement faibles'; despite this, the Committee went on to recommend that exposure to preformed nitrosamines in food should be minimised by appropriate technological practices, such as lowering of the levels of nitrate and nitrite added to foods to the minimum required to achieve the necessary preservative effect and to ensure microbiological safety. However, since the SCF did not indicate any particular limit, either for the quantity to be added or for residual quantities, the Commission continues, it is for the Community legislature to define the means of obtaining the recommended results and setting the minimum level required, which must be 'le plus bas que l'on puisse atteindre'. Hence according to the Commission the Danish Government's assertion that Directive 95/2 does not accord with the SCF opinion and is therefore inadequate is manifestly unfounded.

98. By contrast, in the opinion of the Commission, the Danish measures are

inadequate, given that the maximum amounts for which they provide cannot ensure microbiological safety except in particularly safe hygiene conditions. In the absence of the universal and complete adoption of appropriate prevention techniques, such as the 'hazard analysis and critical control points' (HACCP), such conditions are not guaranteed in the Community, at least in the present state of Community law.

Assessment

99. Turning to an assessment of the arguments of the parties, I must first repeat, on a general level, that the judgment of the necessity and proportionality of the derogating national measures must be made, as the Commission notes, in the light of the standard of the harmonised legislation; that is to say, as Advocate General Tesauro observed in his Opinion in Case C-41/93, account must be taken of the fact that 'the control entrusted to the Community institutions by Article 100a(4)... seems necessarily to be inspired by more stringent criteria than those underlying the provisions of Article 36, in that there is no possibility of not taking account of the standards of protection already laid down by the harmonisation rules' (point 6).

100. Continuing from a general point of view, I note that Denmark raised the precautionary principle as a parameter for the Commission's assessment of the necessity and proportionality of the national provisions at issue. Indeed, there can be no doubt but that the possibility of adopting protective measures in consideration of possible dangers to health derives from that principle; it must, however, be stated that as a rule such measures must be taken by the Community institutions, not unilaterally by Member States, and certainly not in sectors in which a Community harmonisation measure has already been introduced. At most, in the name of that principle, the Member States can be authorised to adopt such measures in cases permitted by the Treaty, such as that under examination, but within (and only within) the limits permitted by the Treaty. In the present case this means that, where the safeguard clause provided for by Article 4 of Directive 89/107 does not apply, the maintenance of derogating national measures requires that the conditions described in Article 95(4) be fulfilled. Obviously, if they are not fulfilled, there is no possibility of criticising the Commission decision on the grounds of infringement of the precautionary principle in the context of the said provision, save of course the possibility of bringing separate actions for annulment if the conditions are met.

101. Remaining on the level of principles, I must add one last point: contrary to the surprising claims of the Danish Government, and in contrast to the general prin-

ciples in this matter, it is incumbent not upon the Commission but upon the requesting State, as Advocate General Tesauro stated in the Opinion I have quoted above, 'to prove that [the national derogating] provisions... are necessary and proportionate' (point 7) in relation to the objectives permitted by Article 95(4). Moreover, the very wording of Article 95(4) leaves no room for uncertainty when it refers to 'national provisions justified by major needs', it being clear that it is for the State claiming the need for the derogation to 'justify'.

102. Coming now to the substance of the question, I do not think I need dwell on the debate about sulphites — because I share the pertinent observations made in this regard by the Commission, and therefore merely refer the Court to them — in order to conclude that Denmark has not demonstrated the necessity and proportionality of the national provisions in this matter.

103. I reach a quite different assessment, however, with regard to nitrates and nitrites, in respect of which I feel able to endorse the Danish observations.

104. First, it seems to me that the Commission does not offer convincing arguments for concluding that the harmonised measures are more appropriate than the Danish ones, and even less that the latter are inadequate for their declared objective, that is to say to enhance the protection of consumers' health. Moreover, and it is this that counts the most, I believe that it must be recognised that, while the Danish measures are in line with the recommendations of the SCF, Directive 95/2 appears to be roundly condemned by the opinion issued by the SCF in 1995. Far from reiterating its conclusions of 1990 without further additions, as the Commission incorrectly asserts in the contested decision, the SCF clearly criticised the quantities of additives authorised by the directive as being unnecessary and disproportionate.[34] That criticism is repeated in the notice from the Danish Government and the Commission dismissed it, illegitimately in my opinion, on highly debatable grounds.

105. I therefore feel able to conclude that, as regards the national measures relating to nitrites and nitrates but not those relating to sulphites, Denmark has in fact demonstrated both that they are necessary and that they are proportionate and reasonable. For that reason the Danish criticism must therefore be held to be well founded.

34 — It is true that the SCF recommended, as it did five years previously, 'that exposure to preformed nitrosamines in food should be [reduced]... to the minimum required to achieve the necessary preservative effect and to ensure microbiological safety', but it also noted that 'the residual quantity of nitrites authorised by Directive 95/2/EC (Table 1) is much higher than estimates based on the maximum levels of added nitrites and nitrates which, according to the information obtained by the Committee at the time of the previous report, can be justified on technological grounds' (Opinion of 1995, pp. 3 and 22 et seq.).

(c) The question of the discriminatory nature of the Danish measures

106. Denmark disputes the Commission's remarks about the discriminatory nature of the Danish measures, beginning with those regarding sulphites. In paragraphs 26 and 27 of the contested decision the Commission had objected that the list of products for which the measures authorised the use of additives appeared to be arbitrarily limited, because the list contained only 16 of the 61 categories contemplated by the directive, and all 16 related to products which, although not typically Danish, were already available on the Danish market. In addition, no reason had been given for the exclusion of the other 45 categories.

107. As to the 16 categories included, however, the applicant government denies that the choice is arbitrary and illustrates in each case, partly in response to a specific question from the Court, how the use of sulphites meets a precise technological need.

108. As to the other 45 categories, according to the applicant government their exclusion is a consequence of the limitations imposed by Article 95 EC. The Danish Government observes that legislation would have had to be amended to cover products that it had not previously contemplated, whereas it is well known that the Community measure in question only authorises the maintenance of existing legislation. Believing on the one hand that it was necessary to restrict the exposure of the population to sulphites but on the other not being able to change existing legislation by adding products listed in the directive, the applicant government claims that it had no option but to choose the lesser evil, maintaining the categories already listed in the legislation.

109. As to nitrites and nitrates, Denmark equally rejects the accusation that it made discriminatory choices in that it imposed a substantial reduction in the permitted amounts of preservative for products in general while authorising the use of larger amounts of preservative, comparable to those generally laid down by the directive, solely for certain typical Danish products, such as bacon of the Wiltshire type and rolled meat sausage (*rullepølse*). According to the applicant government, this solution takes account of the particular methods and conditions of manufacture of these typical products, which in fact require a higher quantity of preservative in order to ensure microbiological safety.

110. For my part, I consider that the Commission is right to consider that the

Danish measures are intrinsically discriminatory, both as regards sulphites and as regards nitrites and nitrates.

111. As regards the former, it appears to me that Denmark is relying for its defence on a distorted interpretation of the mechanism created by Article 95(4) EC. The fact that this authorises only the maintenance of existing legislation obviously does not mean that when a Member State transposes the harmonisation directive it cannot, if necessary, partly amend the existing legislation in accordance with the directive but maintain the remainder. On the contrary, by providing for the possibility of authorising the 'maintenance' of (even only) part of the existing legislation, Article 95 presupposes that that legislation must co-exist with the compatible provisions of the directive and with the related implementing laws.

112. Hence, in the case in point Denmark could well have altered the list of products in question, so that it cannot now invoke Article 95 to justify restricting that list to those foods typically or commonly produced or marketed in that country.

113. As regards nitrites and nitrates, I go along with the objections addressed by the Commission to the applicant government that traditional products which by their nature or method of production require higher levels of preservatives are to be found not only in Denmark but also in other Member States. One must therefore ask why such justifications should be valid for some and not for the others. If the method of manufacture and the conditions of production necessitate higher maximum levels of preservative, this should apply not only to Danish products but also to all traditional products of other European regions where similar quantities of preservative are added and for which there is a similar technological need.

114. In the light of the foregoing considerations, I therefore feel able to conclude that both the Danish measures relating to sulphites and those relating to nitrites and nitrates are discriminatory and entail a disguised restriction on trade between Member States.

(d) Erroneous reference to Articles 4 and 7 of Directive 95/2

115. Denmark also takes issue with the Commission — using arguments that, to tell the truth, are not very clear — for

having attributed, in paragraphs 28 and 43 of the decision, a wrong meaning to Article 4 of Directive 89/107 and Article 7 of Directive 95/2, [35] which make it possible to review the Community provisions in this regard and to amend the positive list. According to the Danish Government, the Commission was wrong to base the contested negative decision on the presence of the safeguard clause and a procedure specifically foreseen for amending the harmonised measure, as these elements are not relevant to the assessment that the Commission has to make under Article 95(4). Moreover, the applicant government contends that the provision relating to the safeguard clause is not applicable in any way to the Danish case; whereas the application of that clause presupposes new evidence or scientific data, the Danish request relating to Article 95(4) is based on existing SCF reports.

116. As the Commission notes, however, Denmark's argument appears to be a pretext because the contested passages of the statement of reasons are manifestly irrelevant in the economy of the decision. The Commission did not use the reference to the safeguard clause to reject the Danish request; after having established that the requirements of Article 95(4) EC were not met, in reality it confined itself to pointing out 'that the review of Directive 95/2/EC could be initiated in several ways', including that described in Article 4 of Directive 89/107, which may lead to amendment of the positive list, and that provided for in Article 7 of Directive 95/2, which requires the Member States and the Commission to monitor the consumption of additives so that the Commission may propose amendments where necessary.

117. That complaint should therefore also be rejected.

(e) Erroneous assessment of the facts in the part relating to sulphites

118. Denmark then maintains that the Commission decision rests on a flawed and erroneous assessment of the facts, as it is based on the presumption that the application of Directive 95/2 does not give rise to a health risk. According to the Danish Government, it could be inferred from paragraph 23 of the contested decision that Directive 95/2 is based on the SCF opinion of 25 February 1994, which lays down an ADI for sulphites. In fact, the Council's common position relating to this directive dates back to 16 December 1993, so that the directive would be based on the 1981 opinion on sulphites, which did not state an ADI.

35 — The article provides for the establishment of national systems to monitor the consumption and use of food additives and that the Commission, on the basis of the results of the checks and data on changes in the food additives market, can review the conditions of use of such substances and propose amendments where necessary.

According to the Commission, on the other hand, paragraph 23 of the contested decision does not state that Directive 95/2 is based on the 1994 opinion, but mentions it only indicatively.

119. It seems to me that the literal tenor of the contested paragraph of the decision confirms the Commission's version. Even if that were not the case, however, I do not see how that circumstance could make the decision unlawful, given that any inaccuracy is utterly marginal, particularly as the underlying directive does not necessarily require account to be taken of the ADI [36] and the ADI is merely precautionary, [37] so that exceeding the amount would not entail any actual risk.

(f) Failure to adopt a position under Article 95(6) EC

120. Lastly, in a complaint that is, to say the least, surprising, the Danish Government contends that the position adopted by the Commission under Article 95(6) EC is inadequate. It asserts that by not assessing explicitly whether the Danish provisions are a means of arbitrary discrimination or a disguised restriction on trade between Member States nor whether they constitute an obstacle to the functioning of the internal market, the Commission failed to meet an obligation imposed by the Treaty. Under Article 95(6) EC it should have stated its opinion on these specific aspects and could not base its decision only on the aspect concerning the protection of public health.

121. In reality, from an examination of the decision it is clear that the Commission took the discrimination aspect into account; apart from that, I must none the less observe that the authorisation of national measures in derogation from a harmonisation directive adopted pursuant to Article 95(1) CE presupposes that both the positive conditions described in the fourth paragraph and the negative conditions set out in the sixth paragraph of Article 95 are met. Logic therefore dictates that where it is found that the former are not met, the preconditions for the Commission to reject the request are fulfilled, without it also being necessary to verify the absence of the latter.

122. This is precisely the situation that was ascertained in the present case, so that it seems obvious to me that the complaint is unfounded.

36 — According to paragraph 3 of Annex II to Directive 89/107, the evaluation of the possible harmful effects '*should also* take into account, for example, any cumulative... effect'; this is a guideline, however, not an injunction (the italics are mine).

37 — According to paragraph 24 of the decision, which was not contested as far as this aspect is concerned, the ADI 'comprises a habitual safety factor of 100, which may be as high as 500'.

C — *The complaint as to the statement of reasons for the decision*

123. Lastly, the Danish Government asserts that, for the purpose of assessing its request, the decision should not have confined itself (on the assumption that it did in fact do so) to considering the existence of the conditions set out in the first subparagraph of Article 95(6) CE but should have adopted an explicit position in that regard. Since it was entirely silent on this point, the contested decision is, in the opinion of the applicant government, vitiated by infringement of a substantial procedural requirement on account of the inadequacy of the statement of reasons.

124. The Commission replies that the contested decision fully satisfies the obligation to provide a statement of reasons provided for in Article 235 CE, as interpreted by the Court of Justice, given that in paragraphs 20 to 34 with regard to sulphites and in paragraphs 37 and 38 and 41 to 44 with regard to nitrites and nitrates it contains a reasoned exposition of the elements of fact and law which justify the decision.

125. For my part, and leaving aside any other element, I have to observe that the complaint appears to be unfounded, because the reasons that led the Commission to reject the Danish request emerge clearly from the paragraphs of the decision mentioned by the Commission, as we have seen above. [38]

126. This head of complaint should therefore also be rejected.

Final considerations

127. In summary, I feel able to conclude that the Commission had many reasons for considering that the conditions for authorising the derogation requested by the Danish Government were not met. Although in justifying that conclusion the contested decision does not follow a very rigorous line of argument and in parts it is even open to criticism, I consider that the truly essential passages in the provision are correct and not vulnerable to the complaints made against it by Denmark. For that reason, I am of the opinion that the application must be dismissed in its entirety.

38 — See paragraphs 63, 85, 96, 106 and 109.

Costs

128. Pursuant to Article 69(2) of the Rules of Procedure, the unsuccessful party shall be ordered to pay the costs if they have been applied for in the successful party's pleadings. As the Commission has applied for the costs to be borne by the Kingdom of Denmark, which has failed in its submissions, the latter must be ordered to pay the costs.

129. Article 69(4) of the Rules of Procedure provides that the States which are parties to the EEA Agreement shall bear their own costs if they intervene in the proceedings. The Republic of Iceland and the Kingdom of Norway must therefore bear their own costs.

IV — Conclusion

In the light of the foregoing considerations, I therefore propose that the Court:

(1) dismiss the application;

(2) order the Kingdom of Denmark to pay the costs;

(3) order the Republic of Iceland and the Kingdom of Norway to bear their own costs.