OPINION OF ADVOCATE GENERAL TIZZANO
delivered on 7 April 2005 [1]

1. By separate orders, [2] courts of three Member States (the High Court of Justice, Queen's Bench Division (United Kingdom), the Consiglio di Stato (Council of State) (Italy) and the Rechtbank te 's-Gravenhage (District Court, The Hague) (Netherlands)) have requested the Court of Justice to give a ruling under Article 234 EC on the validity of Directive 2002/2/EC of the European Parliament and of the Council of 28 January 2002 amending Council Directive 79/373/EEC on the circulation of compound feedingstuffs and repealing Commission Directive 91/357/EEC (hereinafter 'Directive 2002/2' or simply 'the Directive'). [3]

2. In particular, all of those courts are seeking to ascertain whether, in imposing an obligation on manufacturers of feedingstuffs to indicate — on the labelling and at the request of customers — the quantities of feed materials used in their products, Directive 2002/2 is invalid as having been adopted on an incorrect legal basis or because it is contrary to the principle of proportionality and to the fundamental right to property. The Consiglio di Stato has also questioned the Court as to the validity of the Directive in the light of the precautionary principle and the principle of non-discrimination, while the Rechtbank te 's-Gravenhage has referred in this regard also to the principle of the freedom to pursue a trade or profession.

3. Finally, the Consiglio di Stato and the Rechtbank te 's-Gravenhage have also raised a number of issues of interpretation. The former has asked, with specific reference to the Directive, whether it is applicable in the absence of an appropriate list setting out the feed materials which may be used in compound feedingstuffs; the Rechtbank asks, more generally, whether national administrative authorities may, in the same way as judicial bodies, temporarily suspend the implementation of internal rules giving effect to Community provisions of questionable validity.

1 — Original language: Italian.

2 — Orders of 6 October 2003 of the High Court of Justice, Queen's Bench Division (United Kingdom), of 11 December 2003 of the Consiglio di Stato (Italy), and of 22 April 2004 of the Rechtbank te 's-Gravenhage (Netherlands).

3 — OJ 2002 L 63, p. 23.

I — Community law

Article 152 EC

4. Prior to the Treaty of Amsterdam, measures relating to the common agricultural policy which also pursued the objective of protecting public health had to be adopted, in accordance with the consultation procedure, on the basis of Article 37 EC.

5. Since the Treaty of Amsterdam entered into force, some of those measures may be based on Article 152 EC, which, following the amendments made to it, now provides as follows:

'1. A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.

Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education.

...

4. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting:

...

(b) by way of derogation from Article 37, measures in the veterinary and phytosanitary fields which have as their direct objective [4] the protection of public health;

...'.

4 — This footnote is relevant only to the Italian version of the Opinion.

Community legislation on the labelling of compound animal feedingstuffs and Directive 2002/2/EC

6. The manufacture and marketing of compound animal feedingstuffs are governed by Council Directive 79/373/EEC of 2 April 1979 ('Directive 79/373'). [5]

7. That directive has been amended on numerous occasions by a variety of directives, particularly in the area of most interest here relating to the labelling of compound feedingstuffs for production animals.

8. A first amendment in this regard was made by Directive 90/44/EC ('Directive 90/44'). [6] That directive harmonised the labelling requirements in accordance with the 'flexible declaration' system (eighth recital in the preamble), under which the person responsible for labelling had to list the feed materials used in descending order by weight, but without, however, being required to indicate the quantity thereof. That person could also choose whether to designate those materials by their specific names or by the generic designation of the category to which they belonged (Article 1 (5)).

9. The crises precipitated by bovine spongiform encephalopathy ('BSE') and by dioxin forced the legislature to abandon the foregoing system and to introduce, in Directive 2002/2, which was adopted on the basis of Article 152(4)(b) EC, the more stringent formula of the 'open declaration'.

10. According to the legislature, those crises had demonstrated the inadequacy of the existing provisions and 'the need for more detailed qualitative and quantitative information on the composition of compound feedingstuffs' (fourth recital in the preamble). Such indications, in particular those relating to quantity, in addition to constituting 'an important item of information for stock farmers' (eighth recital in the preamble), are — also according to the legislature — 'beneficial to public health' inasmuch as they 'may help to ensure that potentially contaminated feed materials can be traced to specific batches'. This information also makes it possible to 'avoid the destruction of products which do not present a significant risk to public health' (fifth recital in the preamble).

11. Thus, Article 1(1)(a) of Directive 2002/2, which amends Article 5(1)(j) of Directive 79/373, provides that the labelling must now also include:

'the batch reference number'.

5 — Directive on the marketing of compound feedingstuffs (OJ 1979 L 86, p. 30).

6 — Council Directive of 22 January 1990 amending Directive 79/373/EEC on the marketing of compound feedingstuffs (OJ 1990 L 27, p. 35).

12. In addition, Article 1(1)(b), which amends Article 5(1) of Directive 79/373, provides that the labelling must also feature:

'in the case of compound feedingstuffs other than those intended for pets, the indication "the exact percentages by weight of feed materials used in this feedingstuff may be obtained from: ..." (name or trade name, address or registered office, telephone number and e-mail address of the person responsible for the particulars referred to in this paragraph). This information shall be provided at the customer's request'.

13. Article 1(4), which amends Article 5c of Directive 79/373, provides that:

'1. All feed materials used in the compound feedingstuff shall be listed by their specific names.

2. The listing of feed materials for feedingstuffs shall be subject to the following rules:

(a) compound feedingstuffs intended for animals other than pets:

(i) listing of feed materials for feedingstuffs with an indication, in descending order, of the percentages by weight present in the compound feedingstuff;

(ii) as regards the above percentages, a tolerance of ± 15% of the declared value shall be permitted;

...'.

14. Finally, Article 1(5), which adds a second paragraph to Article 12 of Directive 79/373, provides as follows:

'[The Member States] shall stipulate that the manufacturers of compound feedingstuffs are obliged to make available to the authorities responsible for carrying out official inspections, on request, any document concerning the composition of feedingstuffs intended to be put into circulation which enables the accuracy of the information given by the labelling to be verified'.

15. In conclusion, in so far as may be of interest in the present context, it should be pointed out that, in addition to the provisions cited, Directive 2002/2 called, in the 10th recital in its preamble, on the Commission to submit to the European Parliament and the Council, 'on the basis of a feasibility study, ... a report ... by 31 December 2002, accompanied by an appropriate proposal for the establishment of a positive list, taking account of the conclusions of the report.'

16. In compliance with that request, the Commission, on 24 April 2003, submitted a report (COM(2003) 178), in which it declared, however, that the drafting of a 'positive list', that is to say, 'an exclusive list of materials that upon assessment are considered safe for human and animal health and can therefore be used in animal feed', did not 'contribute to feed safety'. As a result of that finding, the Commission decided not to submit any proposal in that regard. [7]

Regulation (EC) No 178/2002

17. Although it is not directly relevant to the outcome of the present cases, reference should also be made here to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. [8]

18. Article 3.15 of that regulation defines 'traceability' as meaning:

'the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be, incorporated into a food or feed, through all stages of production, processing and distribution'.

19. Article 7(1), furthermore, which deals with the precautionary principle, provides as follows:

'In specific circumstances where, following an assessment of available information, the

7 — Report of 24 April 2003 from the Commission on the feasibility of a positive list of feed materials.

8 — OJ 2002 L 31, p. 1

possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment'.

II — National legislation

20. Directive 2002/2 was transposed:

— in the United Kingdom, by the Feeding Stuffs (Sampling and Analysis) and the Feeding Stuffs (Enforcement) (Amendment) (England) Regulations 2003 ('the English Regulations'), [9] which amend the Feeding Stuffs Regulations 2000; [10]

— in Italy, by the Decree of the Ministro delle Politiche agricole e forestali (Minister for Agricultural and Forestry Policies) of 25 June 2003 concerning additions and amendments to the annexes to Law No 281 of 15 February 1963 on the rules governing the preparation and marketing of feedingstuffs, adopted in implementation of Directive 2002/2/EC of 28 January 2002 ('the Italian Decree'); [11]

— in the Netherlands, by Verordening (Regulation) No PDV-25 of 11 April 2003 ('the Netherlands Regulation'), [12] which amends Verordening PDV Diervoeders 2003 (2003 Regulation of the Produktschap Diervoeder on animal feedingstuffs).

III — Facts and procedure

In Case C-453/03

21. By a claim form dated 8 September 2003, ABNA Ltd, Denis Brinicombe (a partnership), BOCM Pauls Ltd, Devenish Nutrition Ltd, Nutrition Services (International) Ltd and Primary Diets Ltd (hereinafter referred to collectively as 'ABNA'), all of which are companies engaged in the manufacture of

9 — SI 2003/1503.
10 — SI 2000/2481.
11 — GURI of 6 August 2003, No 181.
12 — PDO-Blad No 42 of 27 June 2003.

compound feedingstuffs for animals, challenged the English Regulations implementing Directive 2002/2 before the High Court of Justice.

22. As it entertained serious doubts as to the validity of Article 1(1)(b) and 1(4) of Directive 2002/2 and took the view that application of the corresponding provisions of national law which gave effect to that directive could result in serious and irreparable damage to ABNA, the High Court of Justice decided to suspend those provisions and to request a ruling by the Court on the following question:

'Are Article 1(1)(b) of Directive 2002/02 and/or Article 1(4) of Directive 2002/02, to the extent that it amends Article 5c(2)(a) of Directive 79/373 by requiring percentages to be listed, invalid by reason of:

a. the absence of a legal basis in Article 152(4)(b) EC;

b. infringement of the fundamental right to property;

c. infringement of the principle of proportionality?'

23. Written observations have been submitted in the proceedings thus instituted by ABNA, by the United Kingdom, French, Greek, Spanish and Netherlands Governments, and by the European Parliament, the Council and the Commission.

In Joined Cases C-11/04 and C-12/04

Case C-11/04

24. By application notified on 17 September 2003, Fratelli Martini & C. spa and Cargill srl (hereinafter collectively referred to as 'Fratelli Martini'), which are also companies operating in the feedingstuff manufacturing sector, challenged before the Tribunale Amministrativo del Lazio (Lazio Administrative Court) ('the Tribunale') the Italian decree which transposed Directive 2002/2, seeking the annulment of that decree, subject to suspension of provisional enforcement, on the ground that it was at variance with both Community and national law.

25. The Tribunale dismissed the application for interlocutory relief. An appeal against

the order dismissing the application was thereupon lodged with the Consiglio di Stato.

26. As the Consiglio di Stato — in like manner to the High Court in England — entertained serious doubts as to the validity of Directive 2002/2, in particular on the ground that it imposes a requirement of detailed quantitative information also in respect of vegetable-based feedingstuffs, which the Consiglio di Stato regarded as posing no threat to public health, it suspended the national provisions under challenge by way of an order of 11 November 2003. By a separate measure, it then referred the following questions to the Court for a preliminary ruling:

'1. Must Article 152(4)(b) EC be interpreted as being the correct legal basis for the adoption of measures on labelling, contained in Directive 2002/2/EC, where they refer to the labelling of vegetable feedingstuffs?

2. In so far as it imposes an obligation to indicate the precise feed materials contained in compound feedingstuffs, which applies even to vegetable-based feedingstuffs, is Directive 2002/2/EC justified on the basis of the precautionary principle in the absence of a risk assessment, based on scientific studies, which requires that precautionary measure on the basis of a possible correlation between the quantity of feed materials used and the risk of the diseases to be prevented? And is that directive nevertheless justified in the light of the principle of proportionality, in so far as the obligations on the part of the feedingstuffs industry to disclose information to the public authorities, which are required to maintain business secrecy, and are competent to monitor health protection, are not sufficiently directed to the attainment of the public health objectives supposed to be the purpose of the measure, instead imposing general rules requiring the indication of the percentage quantities of feed materials used on the labels of vegetable-based feedingstuffs?

3. In so far as it fails to respect the principle of proportionality, does Directive 2002/2/EC conflict with the fundamental right of property of the citizens of the Member States?'

Case C-12/04

27. By separate applications, Ferrari Mangimi srl and the Associazione nazionale

produttori alimenti zootecnici — ASSALZOO (hereinafter referred to collectively as 'Ferrari Mangimi') challenged the Italian decree before the Tribunale Amministrativo del Lazio, also seeking its annulment, subject to suspension of its provisional enforcement.

28. As in the case of the first claimants, the Tribunale Amministravo del Lazio dismissed the application for interlocutory relief. In this case also, the claimants appealed against the order dismissing their application to the Consiglio di Stato, which, after suspending the contested decree, referred to the Court under Article 234 EC similar questions on the validity of Directive 2002/2, in addition to a question of interpretation, all of which are worded as follows:

'1. Must Article 152(4)(b) EC be interpreted as being the correct legal basis for the adoption of measures on labelling, contained in Directive 2002/2/EC, where they refer to the labelling of vegetable feedingstuffs?

2. In so far as it imposes an obligation to indicate the precise feed materials contained in compound feedingstuffs, which applies even to vegetable-based feedingstuffs, is Directive 2002/2/EC justified on the basis of the precautionary principle in the absence of a risk assessment, based on scientific studies, which requires that precautionary measure on the basis of a possible correlation between the quantity of feed materials used and the risk of the diseases to be prevented? And is that directive nevertheless justified in the light of the principle of proportionality, in so far as the obligations on the part of the feedingstuffs industry to disclose information to the public authorities, which are required to maintain business secrecy, and are competent to monitor health protection, are not sufficiently directed to the attainment of the public health objectives supposed to be the purpose of the measure, instead imposing general rules requiring the indication of the percentage quantities of feed materials used on the labels of vegetable-based feedingstuffs?

3. Must Directive 2002/2/EC be interpreted as meaning that its application, and therefore its effectiveness, is subject to the adoption of a positive list of feed materials containing their specific names, as set out in the tenth recital to the preamble and the Commission Report (COM 2003 178) dated 24 April 2003 or must the implementation of the directive in the Member States take place before the adoption of the positive

list of feed materials laid down by the directive, with reference to a list of the feed materials contained in the compound feedingstuffs by the names and generic definitions of their commodity classes?

4. Is Directive 2002/2/EC to be regarded as unlawful on the grounds of infringement of the principle of equal treatment and non-discrimination to the detriment of feedingstuff producers when compared with the producers of foodstuffs for human consumption in so far as the former are subject to rules requiring indications of the quantities of feed materials in compound feedingstuffs?'

Procedure before the Court

29. By order of the President of the Court of 25 March 2004, Cases C-11/04 and C-12/04 were joined for the purposes of the written and oral procedure and the judgment.

30. Written observations were submitted by Fratelli Martini, Ferrari Mangimi, the Greek and Spanish Governments, and by the European Parliament, the Council and the Commission.

In Case C-194/04

31. The opposing parties in the proceedings in the Netherlands are the Productschap Diervoeder (Commodity Board for Animal Feedingstuffs) ('the Productschap') and the Nederlandse Vereniging Diervoederindustrie (Netherlands Association for the Animal Feedingstuff Industry) Nevedi ('Nevedi').

32. The Productschap is the public body in the Netherlands empowered to adopt regulations concerning animal feedingstuffs; in order to be effective, however, such regulations must be approved by the Netherlands Minister for Agriculture, Nature and Fisheries ('the Minister').

33. After having transposed Directive 2002/2 within the prescribed period by way of its own regulation duly approved by the Minister, the Productschap reached the conclusion that that directive was invalid. For that reason it drafted a new regulation designed to abrogate the regulation which was already in force.

34. That new regulation did not, however, obtain the requisite approval of the Minister, who stated that a purely administrative suspension of the rules implementing the Directive would be contrary to Community law, which reserves such a power exclusively to the national judicial authorities.

35. As the government authorities had not directly provided for any such power, Nevedi applied to the Rechtbank te 's-Gravenhage for suspension of the regulation of the Productschap.

36. The Rechtbank found that the obligation laid down in the Directive to indicate the percentages by weight of the feed materials used in the feedingstuffs did not — as required by Article 152 EC — have any direct connection with the protection of public health and forced manufacturers to reveal to their competitors confidential information that was essential for their business.

37. On that ground, and having regard also to the question of validity already referred by the English High Court, the Rechtbank upheld the request for suspension and referred the following questions to the Court for a preliminary ruling under Article 234 EC:

'1. Are Article 1(1)(b) of Directive 2002/2 and/or Article 1(4) of Directive 2002/2, to the extent to which it amends Article 5c(2)(a) of Directive 79/373 by requiring percentages to be listed, invalid by reason of:

(a) the absence of a legal basis in Article 152(4)(b) EC;

(b) infringement of fundamental rights, such as the right to property and the right freely to exercise a trade or profession;

(c) infringement of the principle of proportionality?

2. If the conditions are satisfied under which a national court of a Member State is entitled to suspend implementation of a contested measure of the Community institutions, in particular also the condition that the question concerning the validity of the contested measure has already been referred by a national court of that Member State to the Court of Justice, are the competent public authorities of the other Member States themselves also entitled, without judicial intervention, to suspend the contested measure until such time as the Court of Justice has given a ruling on the validity of that measure?'

38. In the proceedings thus instituted, written observations were submitted by Nevedi, by the Netherlands, Greek and Italian Governments, and by the European Parliament, the Council and Commission.

39. For the present case and for Cases C-453/03, C-11/04 and C-12/04, a joint hearing was held on 30 November 2004 and was attended by ABNA, Fratelli Martini, Ferrari Mangimi, Nevedi (hereinafter also referred to collectively as the 'claimants in the main proceedings'), the Italian, Danish, French, Greek, Spanish and Netherlands Governments, and the European Parliament, the Council and the Commission.

IV — Legal analysis

40. As will already have been seen, the cases described above raise in essence three questions.

41. The central question concerns the validity of Article 1(1)(b) and 1(4) of Directive 2002/2, under which manufacturers of compound feedingstuffs for production animals are required to:

— list on the labelling the feed materials used, specifying, with a tolerance of ± 15%, the percentage of each in relation to the total weight of the feedingstuff (Article 1(4));

— notify to customers, at their request, the exact percentage by weight of each feed material used in the feedingstuff (Article 1(1)(b)).

42. According to the national courts, those provisions may have been adopted on an incorrect legal basis (Article 152(4)(b) EC, rather than Article 37 EC) and may infringe the fundamental rights of property and freedom to carry on a trade or profession, in addition to the principle of proportionality, the precautionary principle and the principle of non-discrimination.

43. As I have already indicated, the Consiglio di Stato in Case C-12/04 also submitted, alongside that main question, a question of interpretation as to the possibility of applying Directive 2002/2 in the absence of an appropriate positive list of feed materials which may be used in compound animal feedingstuffs.

44. The third question is also in the nature of a question of interpretation. By that question the Netherlands Rechtbank asks in general whether the administrative authorities of a Member State may suspend the application of rules giving effect to a Community measure of questionable validity in a case where a court of another Member State has already referred a question of validity in that regard for a preliminary ruling.

45. As the main question is in large measure a common one, I shall examine it jointly for all three sets of proceedings and shall then examine the other problems raised in those cases in the order outlined above.

46. First of all, however, I shall consider the admissibility of the questions referred to the Court in Case C-194/04, which has been the subject of challenge by the Parliament, the Council and the Commission in their written observations.

A — *The admissibility of the questions submitted in Case C-194/04*

47. The institutions which have submitted observations argue as a preliminary point that the questions referred by the Rechtbank are inadmissible inasmuch as, in their view, that court has failed adequately to set out the factual and legal context of the main proceedings and has failed adequately to indicate why it has doubts as to the validity of the Directive.

48. In my view, however, that criticism smacks of excessive formalism.

49. I would point out in this regard that, in order to establish whether an order for reference 'define[s]' sufficiently 'the factual and legal context of the questions it is asking',[13] and is consequently admissible, a purely functional evaluation should be made, and thus an evaluation which, rather than stressing quantitative or formal considerations, emphasises the purpose and the structure of the preliminary reference procedure.

50. In other words, what is more important is not so much to evaluate the quantity of information contained in the order or the manner in which that information is presented by the referring court, but rather to determine whether that information makes it

13 — Joined Cases C-320/90, C-321/90 and C-322/90 *Telemarsicabruzzo and Others* [1993] ECR I-393, paragraph 6, Case C-284/95 *Safety Hi-Tech* [1998] ECR I-4301, paragraph 69, Case C-341/95 *Bettati* [1998] ECR I-4355, paragraph 67, and Joined Cases C-115/97, C-116/97 and C-117/97 *Brentjens'* [1999] ECR I-6025, paragraph 38.

possible, on the one hand, for the Court 'to reply usefully' to the national court and, on the other, for 'the governments of the Member States and other interested parties to submit observations pursuant to Article 23 of the Statute of the Court of Justice'. [14]

51. After setting out the relevant legal context, the Rechtbank stated in its order that Nevedi had contested the regulation of the Productschap transposing Directive 2002/2 and that the Rechtbank itself had serious doubts as to the validity of certain provisions of that directive.

52. The Rechtbank also set out the reasons for those doubts. It does so in part directly, by explaining that — in its view — the contested provisions do not have, as required by Article 152 EC, a direct connection with public health, and that, contrary to the right to property and the freedom to carry on a trade or profession, they require manufacturers of feedingstuffs to reveal to their competitors essential confidential information. In part, the Rechtbank also sets out those doubts indirectly by referring, in particular with regard to the issue of proportionality, to the more detailed grounds contained in the order referred by the English High Court.

14 — Judgment in Case C-207/01 *Altair Chimica* [2003] ECR I-8875, paragraph 25. See also the orders in Joined Cases C-128/97 and C-137/97 *Testa and Modesti* [1998] ECR I-2181, paragraph 6, in Case C-325/98 *Anssens* [1999] ECR I-2969, paragraph 8, and in Case C-116/00 *Laguillaumie* [2000] ECR I-4979, paragraph 15.

53. It seems to me that the Rechtbank has in this way adequately set out the legal and factual context of the issues raised and has explained to the requisite degree the reasons for its reference to the Court. That information enabled the interested parties, including the institutions which have submitted observations in this case, as in the other related cases, to submit their own observations on the questions posed, which may in my view be purposefully resolved by the Court.

54. For those reasons I hold that the order of the Rechtbank te 's-Gravenhage is admissible and merits, in like manner to the orders from the High Court and the Consiglio di Stato, a reply by the Court.

B — *The validity of the Directive*

55. As already stated, the cases in issue request in particular an examination as to the validity of Article 1(1)(b) and 1(4) of Directive 2002/2 which the European Parliament and the Council adopted on the basis of Article 152(4)(b) EC as a result of the BSE and dioxin crises.

Introduction

56. Before embarking on such an examination, it seems to me necessary at the outset to indicate certain fixed points from which it is, in my view, necessary to depart when, as in the present context, the Court is requested to appraise the legality of measures relating to the common agricultural policy which, as intended by the institutions, seek to safeguard public health.

57. The first point consists in the finding that in an area such as the common agricultural policy, which requires appraisals of complex political, economic and social factors, the Community legislature enjoys a 'broad discretion'. [15] Consequently, within such an area, the judicial review of the Court must be directed at ascertaining whether the contested measure is free from *manifest* defects; more precisely, the Court must confine itself to examining whether the competent institution 'has *manifestly* exceeded the limits of its discretion' or whether the measure which it has adopted 'has been vitiated by *manifest* error or misuse of powers'. [16]

58. The second point is represented by the cardinal importance attributed to public health within the Community order. The provision of 'a contribution to the attainment of a high level of health protection' represents one of the objectives of the Community (Article 3(p) EC) to be ensured 'in the definition and implementation of all Community policies and activities' (Article 152(1) EC). This is therefore a requirement which is 'imperative' and '[relates] to the public interest', and which the institutions must always 'take into account in exercising their powers'. [17] In the balancing of those interests, which such an exercise involves, the institutions must recognise that requirement as taking 'precedence over economic considerations', [18] and as being such 'as to justify even substantial negative financial consequences for certain traders'. [19]

59. Viewed in this light, the Court has in the past treated as valid, or rather as not manifestly invalid, agricultural policy measures which have been extremely onerous for traders and have legitimised an 'even substantial' adverse effect on their interests.

15 — See Case C-280/93 *Germany* v *Council* [1994] ECR I-4973, paragraph 47. See also Case 179/84 *Bozzetti* [1985] ECR 2301, paragraph 30, Case 265/87 *Schrader* [1989] ECR 2237, paragraph 22, Joined Cases C-267/88 to C-285/88 *Wuidart and Others* [1990] ECR I-435, paragraph 14, and Case C-311/90 *Hierl* [1992] ECR I-2061, paragraph 13.

16 — Case C-331/88 *Fedesa and Others* [1990] ECR I-4023, paragraphs 8 and 14; Case C-84/94 *United Kingdom* v *Council* [1996] ECR I-5755, paragraph 58. Emphasis added.

17 — Judgment in Case 68/86 *United Kingdom* v *Council* [1988] ECR 855, paragraph 12; order in Case C-180/96 R *United Kingdom* v *Commission* [1996] ECR I-3903, paragraph 63.

18 — Case C-183/95 *Affish* [1997] ECR I-4315, paragraphs 43 and 57.

19 — *Fedesa and Others*, cited above, paragraph 17, and *Affish*, cited above, paragraph 42.

60. Thus, in *Affish* — which is indubitably a representative case — the Court regarded as valid, precisely because it was designed to pursue the 'imperative' requirement of public health protection, a decision by which, after having visited *seven* Japanese undertakings specialising in the processing of certain species of fish and seafood and having established that *some* of those undertakings presented serious health risks, the Commission decided to suspend imports of *all* fish products from Japan. [20]

61. It is thus from this perspective of, so to speak, *self-restraint* that I shall embark on the analysis of the individual grounds of criticism of Directive 2002/2, which I shall now examine.

(1) Legal basis

62. The first ground on which the national courts entertain doubts as to the validity of Directive 2002/2, in particular Article 1(1)(b) and 1(4) thereof, relates to the propriety of the legal basis chosen for that directive. In particular, the national courts are unsure whether those provisions could lawfully be based on Article 152(4)(b) EC, which authorises the European Parliament and the Council to adopt, 'by way of derogation from Article 37, measures in the veterinary and phytosanitary fields which have as their direct objective [21] the protection of public health'.

63. I would note at the outset that, according to well-established case-law, 'in the context of the organisation of the powers of the Community the choice of the legal basis for a measure must rest on objective factors which are amenable to judicial review'. Those factors include, in particular, 'the aim and the content of the measure'. [22]

64. With regard to the scope, as the institutions which have submitted observations have correctly pointed out, with support on this point from the French, Greek, Italian and Netherlands Governments, it is clear from the recitals in the preamble to the Directive that, after the serious health crises caused by BSE and dioxin, the Community legislature regarded as inadequate the provisions of Directive 79/373 which limited the obligations of feedingstuff manufacturers solely to listing on the labelling the feed materials used (fourth recital in the preamble).

20 — Judgment in *Affish*, cited above.

21 — This footnote is relevant only to the Italian version of the Opinion.

22 — Case C-269/97 *Commission* v *Council* [2000] ECR I-2257, paragraph 43; Case C-36/98 *Spain* v *Council* [2001] ECR I-779, paragraph 58; Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco* [2002] ECR I-11453, paragraph 93.

65. The Community legislature for that reason decided to extend those obligations by making it compulsory to provide detailed 'qualitative' and 'quantitative' information. The intention is that such information 'will be beneficial to public health' in so far as it 'may help to ensure that potentially contaminated feed materials can be traced to specific batches'. That information should also make it possible to 'avoid the destruction of products which do not present a significant risk to public health' (fifth recital in the preamble).

66. The objectives outlined by the legislature in the recitals are subsequently confirmed in the content of the Directive.

67. In addition to imposing a requirement that 'the batch reference number' of feed materials be indicated (Article 1(1)(a)), the Directive specifically requires feedingstuff manufacturers to list the percentages by weight of such feed materials with a tolerance of ± 15% (Article 1(4)) and to provide the exact percentages by weight of such feed materials to customers who so request (Article 1(1)(b)). In addition, manufacturers are obliged to make available to the inspecting authorities 'any document concerning the composition of feedingstuffs intended to be put into circulation which enables the accuracy of the information given by the labelling to be verified' (Article 1(5)).

68. It follows, in my view, from this analysis of the scope and content of the Directive that the disputed provisions, in conjunction with the other provisions cited above, had as their direct objective to increase the level of protection of public health by imposing more stringent requirements as to the information on the composition of feedingstuffs to be provided to stock farmers and the public authorities.

69. I am, however, in agreement with the claimants in the main proceedings and with the Netherlands Government in their contention that that is not sufficient for a finding that the legal basis chosen was the correct one.

70. As the Court declared in the well-known judgment in *Germany* v *Parliament and Council*, if it is desired to prevent 'judicial review of compliance with the proper legal basis [from being] rendered nugatory', it will also be necessary to establish whether, beyond the abstract declarations and forecasts of the legislature, 'the measure whose validity is at issue *in fact* pursues the objectives stated by the Community legislature'. [23]

71. In other words, if I have correctly understood the Court's reasoning in that

23 — Case C-376/98 [2000] ECR I-8419, paragraphs 84 and 85. Emphasis added.

judgment, it is necessary, when determining whether a legal basis is correct, to establish not only whether the contested measure sets itself an objective which the Treaty recognises as falling within the legislative competence of the institutions but also whether that measure is 'in fact' intended for that objective and, above all, whether it is capable of attaining it.

72. If my interpretation is correct, then, as the Danish Government also emphasised at the hearing, it will be necessary in our examination of the legal basis to conduct an examination of the appropriateness of the measure to achieve the objective pursued which is very similar to that involving the principle of proportionality, which, as will be known, requires that measures implemented through Community provisions be 'appropriate for attaining the objective pursued' and 'must not go beyond what is necessary to achieve it'. [24]

73. As, moreover, the allegedly disproportionate nature of Article 1(1)(b) and 1(4) of Directive 2002/2 has also been specifically challenged in the cases under examination, I shall now embark on a contextual examination of that issue.

(ii) Proportionality and the fundamental rights of property and freedom to carry on a business or profession

74. The central ground alleging invalidity in the present cases is unquestionably that relating to proportionality. This is all the more true in view of the fact that the relevant case-law does not only, as has been seen, cover in part the ground relating to the legal basis but also, as can be clearly seen in the present context, is superimposed on the review of the compliance with the fundamental rights of property and freedom to carry on a trade or profession, thereby rendering a specific analysis of that review unnecessary.

75. According to the Court's case-law, 'in the light of the social function of the activities protected thereunder', those two fundamental rights may be 'restricted', although such restrictions may not constitute 'a disproportionate ... interference' in relation to the objectives of general interest which they pursue. [25] In other words, measures which may be restrictive must themselves comply with the principle of proportionality.

24 — *British American Tobacco*, cited above, paragraph 122. See also Case 137/85 *Maizena* [1987] ECR 4587, paragraph 15; Case C-339/92 *ADM Ölmühlen* [1993] ECR I-6473, paragraph 15; Case C-426/93 *Germany* v *Council* [1995] ECR I-3723, paragraph 42; Case C-84/94 *United Kingdom* v *Council*, cited above, paragraph 57; and Case C-210/00 *Käserei Champignon Hofmeister* [2002] ECR I-6453, paragraph 59.

25 — *Schräder*, cited above, paragraph 15; Case 5/88 *Wachauf* [1989] ECR 2609, paragraph 18; Case C-177/90 *Kühn* [1992] ECR I-35, paragraph 16; and Case C-426/93 *Germany* v *Council*, cited above, paragraph 78. With specific reference to the right to property, see also Case 44/79 *Hauer* [1979] ECR 3727, paragraph 23, and Case C-293/97 *Standley and Others* [1999] ECR I-2603, paragraph 54. With specific reference to the freedom to carry on a trade or profession, see *Affish*, cited above, paragraph 42.

76. Consequently, as the Commission has correctly observed, in order to reply to the questions posed by the national courts, it is not necessary in the cases under consideration to resolve the problem — which was discussed at length by the parties but is ultimately immaterial in the present context — of the patentability of the formulas for feedingstuffs and the possibility that commercial secrets might feature among the intellectual property rights protected by Community law.

77. Rather, it is sufficient, as even ABNA in large measure acknowledges, to ascertain whether the provisions of Directive 2002/2 which require feedingstuff manufacturers to disclose those formulas are appropriate and necessary to attain the objective of protecting public health which they seek to pursue. If they are, then those provisions will comply with the principle of proportionality, whether considered independently or as a limit on potential restrictions on the aforementioned fundamental rights. If they are not, that will be sufficient to render them unlawful, and thus without any further appraisals being necessary.

78. That said, I shall finally pass on to an examination of whether the obligations set out in Article 1(1)(b) and 1(4) of Directive 2002/2 are (a) appropriate for pursuing the objective of protecting public health, and (b) do not go beyond what is necessary to attain that objective.

(a) The appropriateness of the quantitative information for pursuing the objective of protecting public health

79. The claimants in the main proceedings, supported on this point by the Governments of Spain and the United Kingdom, submit that the detailed quantitative information required by the Directive is not appropriate for safeguarding public health.

80. The claimants submit that, contrary to what the fifth recital in the preamble to the Directive declares, that information does not make any effective contribution to the traceability of contaminated feed materials. In their view, reference to the quantities of materials used, without any reference to the supplier or to the batch to which they belong, does not provide stock farmers with any information as to the origin of those materials and for that reason does not enable them to identify the presence of such materials in the feedingstuffs which they purchase.

81. Even if such information were to contribute to traceability, the provisions under challenge would still, the claimants argue, be inappropriate for safeguarding public health inasmuch as they apply only to manufacturers of compound feedingstuffs intended for sale and do not also apply to manufacturers of feedingstuffs intended for own use, that is to say, those undertakings which

manufacture compound feedingstuffs on their own premises for feeding to their own animals. In the opinion of the claimants, as much as 65% of the total volume of such products in this way circumvents the labelling requirements laid down in the Directive.

82. Let me say right away that, in my view, this last ground of complaint must be rejected.

83. Notification of quantitative information — to customers or on labelling — makes sense only if the manufacturer and the user are different individuals. If the person who administers the feedingstuff is also the person who manufactured it, he will obviously be well aware of what he has used and in what quantity he has used it, and he will therefore know how to act in the event of contamination. The extension to manufacturers for own use of the labelling requirements in issue would therefore be totally pointless and, as such, disproportionate (as being entirely unnecessary) in relation to the objective of safeguarding health pursued by the Directive.

84. With regard to traceability, I would first of all point out that, according to the definition set out in Regulation No 178/2002, which lays down the general principles of Community legislation relating to food and animal feed (Article 1(2)), that term is to be understood as meaning 'the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution' (Article 3.15).

85. According to Regulation No 178/2002, the traceability of products is intended to provide 'information ... to consumers or control officials' and to allow 'targeted and accurate withdrawals' in such a way as to avoid, when the actual safety of the foodstuffs is not in jeopardy, 'unnecessary wider disruption' (28th recital).

86. That said, I would point out — as does the Commission — that the traceability of the feed materials used in animal feedingstuffs is primarily guaranteed by the indication of the batch number of those materials, which, under Article 1(1)(a) of Directive 2002/2, must now feature on the labelling alongside the disputed quantitative information. In the event of contamination, it is precisely by virtue of that number that it will be possible to identify the individual feedingstuff batch containing the dangerous substance and thus trace it back to its manufacturer.

87. However, as has been pointed out by the Commission and by the Netherlands and Danish Governments, the quantitative information can also *'help to ensure* that [potentially contaminated materials] can be traced' (fifth recital),[26] thereby in fact making identification of the contaminated ingredients more *rapid* and making possible the *targeted* destruction of the feedingstuffs which contain those ingredients.

88. Indeed, as the Netherlands Government has correctly pointed out, when a dangerous substance is identified in an animal or in a foodstuff derived from that animal, the quantitative information allows the stock farmer and the authorities to identify quickly, and with a reasonable degree of accuracy, the ingredient in the feedingstuff which contains that substance and thus speed up the reconstruction of the course taken by that ingredient at the production, processing and distribution stages.

89. If the level of the substance found in the animal is high, a reasonable assumption may be made that that substance is contained in the ingredient or in one of the ingredients present in the feedingstuff in greater quantity. If, on the other hand, the level is very low, it may reasonably be inferred that the substance is present in an ingredient of smaller quantity. That much can be derived without having to await the results of laboratory analyses but by simply basing oneself on the information contained on the labelling or requested from the manufacturer.

90. At the hearing the Danish Government provided a concrete example which clarifies very well this type of contribution.

91. In August 2004, the Danish Government stated, routine checks indicated that the milk produced by a Danish farmer contained an excessively high level of aflatoxin, a carcinogen produced by certain types of fungus which develop in particular on cereals. The labelling of the feedingstuffs administered to the livestock of that farmer pointed to the presence of a high percentage of Italian biological maize from the 2003 marketing year. From simply reading the labelling the Danish authorities were able to establish that, in all probability, the contaminated material was the Italian maize itself. On the basis of this initial simple quantitative information, the Danish authorities were thus able to set in place sufficient control measures for all consignments of feedingstuffs from the same manufacturer which had an equally high content of that cereal. By contrast, if those authorities had not had available to them that quantitative informa-

26 — Emphasis added.

tion, they would have been obliged to await the results of laboratory analyses and thus constrained to delay the requisite health measures or, more likely, to adopt generalised precautionary measures.

92. As has been noted by a number of the parties which submitted observations, quantitative information also *contributes* to the attainment of another typical objective of traceability, that is to say, the objective of avoiding, in the event of contamination, unjustified disruptions which go further than is necessary for the protection of public health.

93. Where a manufacturer discovers that a feed material which he has used has been contaminated by a dangerous substance, that manufacturer can, by indicating the batch number, alert stock farmers who have purchased feedingstuffs containing that substance. At that point, however, the stock farmers themselves and the authorities are, by virtue of the quantitative information, in a position to establish how much of that substance has been consumed by the animals and consequently to increase gradually the requisite measures while excluding, wherever possible, the slaughter of livestock and unjustified withdrawals of feedingstuffs.

94. As matters now stand, it appears possible to conclude that a *contribution* to traceability, albeit limited, does exist and is effective.

95. I accordingly find that, in taking the view that detailed quantitative information is appropriate for safeguarding public health and in basing Directive 2002/2, in particular Article 1(1)(b) and 1(4) thereof, on Article 152(4)(b) EC, the Community legislature did not exercise in a manifestly incorrect manner its own discretion in regard to agricultural and health policy.

96. The claimants in the main proceedings, however, still object that, unlike the exact information which must be provided to customers under Article 1(1)(b), the quantitative information which must be provided on the labelling pursuant to Article 1(4) is not in any wise detailed, inasmuch as it permits a tolerance margin of 15%. That information at least — so the claimants continue — is therefore not appropriate for the purpose of attaining the objective pursued.

97. The Danish Government submitted in this regard during the course of the hearing that, on the basis of its own experience, the information to be provided on the labelling, although it provides for a tolerance margin, is appropriate for identifying the contaminated ingredients in a feedingstuff rapidly and in accordance with the procedures outlined above.

98. That position strikes me as one which I can share; particularly when one bears in mind the fact that the appraisal which stock farmers and the authorities are required to carry out is approximate and does not require a precise indication to the very last gram. Indeed, according to what was stated in the course of the hearing, it is sufficient, within the scope of such an appraisal, to ascertain whether a high or low percentage of the ingredient is present in the feedingstuff so as to be able to establish rapidly whether it is to that ingredient that the high or low level of contamination found to exist can be attributed.

99. If, however, matters stand thus, in other words — as I have stated — the flexible quantitative information is in itself sufficient to achieve that limited contribution to traceability intended by the Directive, it will then be necessary to determine whether the further precise information which must be provided to customers is truly indispensable for that purpose or whether, on the contrary, this goes beyond what is actually necessary.

100. Such an appraisal, however, comes under the heading of the need for the contested provisions and it is therefore in relation to that heading that I now pass on to an examination thereof.

(b) The need for quantitative information

101. The claimants in the main proceedings, supported on this point by the Spanish and United Kingdom Governments, point out in particular that the obligation to provide stock farmers with detailed quantitative information on the composition of feedingstuffs is for them a source of serious damage. Such an obligation, they contend, forces them to disclose to their own customers the feedingstuff formulas which they themselves have developed through the investment of huge resources in scientific research and which they have, for that reason, hitherto kept strictly confidential. It is, they argue, thanks solely to that research, which they claim is rendered pointless by the provisions here in issue, that they are able to supply ever more efficient feedingstuffs and to adjust the composition of those feedingstuffs periodically in accordance with the feed materials available on the market and the individual requirements of stock farmers.

102. That said, the claimants aver, using arguments that are also outlined by the national courts, that the measures in question go beyond what is necessary to safeguard public health inasmuch as:

(i) they also apply to vegetable-based compound feedingstuffs, which, as stressed in

particular by the Consiglio di Stato, it is widely known pose no danger to human health;

(ii) the objective pursued by those measures, namely that of averting a repetition of food crises such as those of BSE and dioxin, is already ensured by the provisions which prohibit the introduction into feedingstuffs of contaminated materials or materials that are in any event regarded as unsuitable for animal feed, such as animal meal (potential vectors for BSE) or products containing high levels of dioxin; [27]

(iii) more generally, the objective of public health protection could be attained through the use of less restrictive measures, such as the simple listing of the feed materials in descending order of weight, confidential notification of quantitative data to the supervisory authorities alone, or communication of those data also to stock farmers, but in the form of 'brackets', that is to say, within minimum and maximum ranges. [28]

103. In the appraisal of those arguments, I would make the following comments.

104. (i) Concerning the allegedly harmless nature of vegetable-based feedingstuffs, I agree with the Council in its submission that that assertion is factually incorrect. Many of the deleterious substances in animal feedingstuffs [29] are in fact of vegetable origin and are found or develop specifically in foodstuffs of vegetable origin.

105. The Council has pointed out in this regard, without being contradicted by the parties to the main proceedings or the other parties which have submitted observations, that one of the most widely known danger factors in animal feed is constituted by aflatoxins, which are highly carcinogenous toxins produced by certain species of fungus which develop precisely on vegetables and

27 — Nevedi cites in this regard: Council Decision 2000/766/EC of 4 December 2000 concerning certain protection measures with regard to transmissible spongiform encephalopathies and the feeding of animal protein (OJ 2000 L 306, p. 32); Commission Regulation (EC) No 1234/2003 of 10 July 2003 amending Annexes I, IV and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Regulation (EC) No 1326/2001 as regards transmissible spongiform encephalopathies and animal feeding (OJ 2003 L 173, p. 6); Council Directive 2001/102/EC of 27 November 2001 amending Council Directive 1999/29/EC on the undesirable substances and products in animal nutrition (OJ 2002 L 6, p. 45); Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed — Council statement (OJ 2002 L 140, p. 10); and Commission Directive 2003/57/EC of 17 June 2003 amending Directive 2002/32/EC of the European Parliament and of the Council on undesirable substances in animal feed (OJ 2003 L 151, p. 38).

28 — During the legislative passage, the Council had proposed a system of this type which imposed an obligation on the person responsible for labelling to declare the feed materials contained in compound feedingstuffs on the basis of their percentage by weight, in descending order, within five 'ranges' or 'brackets' (first bracket: > 30%; second bracket: > 15%-30%; third bracket: > 5%-15%; fourth bracket: 2%-5%; fifth bracket: < 2%). See the common position adopted by the Council on 19 December 2000 (OJ 2001 C 36, p. 35).

29 — See in this regard Commission Directive 2003/100/EC of 31 October 2003 amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council on undesirable substances in animal feed (OJ 2003 L 285, p. 33).

plants, in particular cereals and nuts. Among other things, it was specifically those toxins which gave rise to the contamination of biological maize which occurred in the summer of 2004 in Denmark (see point 91 above).

106. In the light of those factors, it cannot be stated with certainty that vegetable-based feedingstuffs are necessarily safe and that an extension to such feedingstuffs of the labelling requirements laid down by Directive 2002/2 would for that reason be disproportionate.

107. (ii) With regard to the provisions which interdict the use of potentially dangerous substances in compound feedingstuffs, I would point out that these cannot specifically prevent deleterious substances from ending up, even if only accidentally, in animal feed. Should that happen, those provisions, in contrast to the rules on labelling, say nothing as to how a food-related crisis should be dealt with. In particular, they do not in any way contribute to traceability of the contaminated material, as does, by contrast, Article 1(1)(b) and 1(4) of the Directive. Even where there are limitations on the use of specified substances in feedingstuffs, the provisions just cited do not therefore become redundant, but on the contrary retain their specific usefulness.

108. (iii) With regard, finally, to the possible less restrictive measures to which I have alluded above (see point 102), I would point out first of all that the legislature is obligated to have recourse to such measures only if there is a choice from among 'several ... measures' which are equally 'appropriate'. [30]

109. That is, first of all, not the case with regard to the simple listing of ingredients in descending order by weight. Such listing, which was already provided for by Directive 90/44 and was considered by the legislature itself to be inadequate (see the fourth recital in the preamble to Directive 2002/2; points 8 to 10 above) in so far as it excludes any quantitative information, cannot contribute in any way to traceability, which is, by contrast, made possible by the contested provisions, and is therefore not appropriate for safeguarding public health to the same degree as are those provisions.

110. Not even the confidential provision of quantitative data to the public supervisory authorities alone allows, in my opinion, a level of health protection equivalent to that provided by information which is also addressed to stock farmers. In the event of contamination, it is precisely those farmers who will be in a position to check and to withdraw the contaminated products in the shortest possible time as they have direct

30 — *Schräder*, cited above, paragraph 21. See also Joined Cases C-254/94, C-255/94 and C-269/94 *Fattoria autonoma tabacchi and Others* [1996] ECR I-4235, paragraph 55.

control over the livestock; it is also they who will be able immediately to alert the supervisory authorities.

111. It would therefore, in my view, be illogical and at variance with the objective of ensuring a high level of health protection to exclude from information on animal feed those who breed the animals and market them and are therefore the individuals most interested and responsible for the safety of their livestock and of the end consumers.

112. Finally, with regard to the possibility of having recourse to a declaration by way of 'brackets', that is to say, a declaration of the percentages of ingredients within minimum and maximum ranges, I concur with the Council in its observation that the system adopted by the Directive in Article 1(4) is precisely a system of that kind and therefore cannot be described as disproportionate.

113. Under Article 1(4), manufacturers of feedingstuffs are required to indicate on the labelling the percentages by weight of the feed materials used with a margin of tolerance of ± 15%. Specifically, this means that if a compound feedingstuff contains 80% grain, the relevant information must come within a bracket of 68% to 92%.

114. In my view, this, in conjunction with the abovementioned practice whereby manufacturers alter slightly but continually the composition of feedingstuffs, rules out the possibility of serious harm ensuing which those manufacturers argue would follow from the obligation on them to disclose the exact formulas of their products.

115. The same does not, however, hold true of the further obligation imposed by Article 1 (1)(b), which obliges manufacturers to inform customers, on request, of the *exact* quantitative composition of their feedingstuffs, thus precisely the formula which the national courts have defined as being 'essential' for the very existence of the undertakings in question.

116. In my view, this second obligation clearly goes beyond what is necessary for safeguarding public health.

117. First of all, it is provided for in a general manner. On the basis of a simple customer request, and thus also in cases in which there is no danger of contamination, feedingstuff manufacturers are obliged to disclose their secret recipes. Furthermore, they are required to do so to their own customers,

who, as they frequently have advanced agricultural structures, may, by exploiting the information received, also become potential competitors by producing for their own use or even for external marketing.

118. That is not all. As I have emphasised above (see points 97 to 99), this obligation is, to no purpose, tantamount to the more flexible obligation laid down in Article 1(4), which is in itself capable of guaranteeing that limited contribution to traceability sought by the legislature. As we have seen, although it provides for a 15% margin of tolerance, Article 1(4) per se allows a rapid and approximate identification of the contaminated ingredients and makes possible a more targeted removal of the feedingstuffs which contain them.

119. It is thus not clear, in the light of that objective, what is intended to be, and what can be, added by the more stringent provision in Article 1(1)(b). On the contrary, the additional disadvantages which this provision is likely to visit on feedingstuff manufacturers can be set in contrast against the modest novel or useful effect which it adds to the protection of public health.

120. I accordingly take the view that that provision must be regarded as being manifestly disproportionate.

121. If we thus draw together the reasoning developed in the foregoing examination relating to the legal basis and proportionality, we can, I believe, arrive for now at the following conclusion.

122. In forming the view that detailed quantitative information was appropriate for safeguarding public health and for that reason basing Directive 2002/2, in particular Article 1(1)(b) and 1(4) thereof, on Article 152(4)(b) EC, the Community legislature did not exercise in a manifestly erroneous way its discretion in regard to agricultural and health policy. However, as the objective of safeguarding public health can be pursued by simply laying down an obligation that the feed materials used must be listed on the labelling, by specifying, with a margin of tolerance of ± 15%, their percentage in relation to the overall weight (Article 1(4)), the further requirement of an obligation also to inform customers, on request, of the exact percentages by weight of those feed materials (Article 1(1)(b)) is manifestly disproportionate and, for that reason, invalid.

(3) The precautionary principle

123. By the first part of its second question in Cases C-11/04 and C-12/04, the Consiglio

di Stato is essentially asking whether, in so far as it imposes an obligation to indicate *exactly* the feed materials used in compound feedingstuffs, Directive 2002/2 is at variance with the precautionary principle.

124. I have, however, only just concluded that, in so far as it imposes a requirement of *exact* quantitative information, Directive 2002/2 should be declared invalid on the ground that it infringes the principle of proportionality. It therefore strikes me as redundant, in principle, to determine whether the Directive also infringes the precautionary principle in that regard. That said, for requirements of completeness, I shall also examine this ground of invalidity.

125. According to the Consiglio di Stato, that principle has been infringed inasmuch as the Community legislature did not, prior to adopting the Directive, conduct a study to establish scientifically that exact quantitative information would be useful in averting food-related crises.

126. I should first of all point out in this regard that, according to the Court's case-law, 'where there is uncertainty as to the existence or extent of risks to human health', the precautionary principle allows the institutions to 'take protective measures without having to wait until the reality and seriousness of those risks become fully apparent'. [31]

127. I should also point out that this principle has now been codified and set out in clearer terms in Article 7(1) of Regulation No 178/2002, which provides that *'[i]n specific circumstances* where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, *provisional risk management measures* necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment'. [32]

128. As the Council has correctly pointed out, and as Fratelli Martini have also ultimately recognised, the precautionary principle is not applicable in the present context.

129. Directive 2002/2 is not a specific provisional risk management measure which prohibits specific products or practices the harmful nature of which is the subject of scientific uncertainty. Rather, Directive 2002/2 is a legislative measure which is general in its scope and, with a view to

31 — Judgment in Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, paragraph 63.

32 — Emphasis added.

improving the level of public health protection (see the fourth and fifth recitals in the preamble), harmonises the requirements relating to the labelling of feedingstuffs in a manner more restrictive than that obtaining hitherto.

130. Directive 2002/2 is, however, covered by application of the more general principle, already confirmed by the Court, under which '[l]egislative action by the Community ... cannot be limited exclusively to circumstances where the justification for such action is scientifically demonstrated'. [33] Progress in 'scientific knowledge' is not 'the only ground on which the Community legislature can decide to adapt Community legislation'. In exercising the discretionary power available to it, particularly in matters relating to agricultural and health policies, the Community legislature can thus 'also take into account other considerations', [34] such as, for example, the increased importance of food safety at the political and social levels, the social unease generated by food-related crises and the resulting mistrust of consumers towards certain commercial operators and the authorities which are supposed to monitor them.

131. In the light of the foregoing, I accordingly hold that the precautionary principle is not applicable in the context of the present cases.

33 — Case C-84/94 *United Kingdom* v *Council*, cited above, paragraph 39.

34 — Judgment in *British American Tobacco*, cited above, paragraph 80.

(4) The principle of equality

132. By its fourth question in Case C-12/04, the Consiglio di Stato asks whether, by imposing on feedingstuff manufacturers labelling obligations that are more stringent than those imposed on manufacturers of foodstuffs for human consumption, Article 1 (1)(b) and 1(4) of the Directive infringes the principle of equality.

133. Ferrari Mangimi, supported by the Spanish Government, submits that the Directive introduces unjustified discrimination between such traders inasmuch as it requires undertakings which manufacture feedingstuffs to provide quantitative information on the feed materials used, whereas no similar obligation is imposed on manufacturers of foodstuffs intended for human consumption, which are required only to list on the labelling the ingredients used, in descending order of weight, identifying them by name or, in some cases, by category, but without any information as to quantity (Article 6(5) and (6) of Directive 2000/13 [35]).

35 — Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ 2000 L 109, p. 29).

134. According to well-established case-law of the Court, the general principle of equality requires that 'comparable situations must not be treated differently and different situations must not be treated in the same way unless such treatment is objectively justified'. [36] Therefore, in order to determine whether a potential difference in treatment may give rise to prohibited discrimination, it is necessary to ascertain whether the two situations under comparison are analogous and, if they are, whether the difference in treatment between them is based on objective justification.

135. With regard to the first point, it seems that I can share the view taken by Ferrari Mangimi when it argues that the situation of feedingstuffs for livestock and that of foodstuffs for human consumption are comparable in that each of those situations involves products intended directly or indirectly for human consumption and thus constituting a potential risk to human health.

136. That position also seems to me to be consistent with Regulation No 178/2002, already cited several times, which, in view of the fact that livestock given feedingstuffs are 'intended [to be] food-producing animals' (seventh recital in the preamble), establishes the general principles and requirements in foodstuff legislation which apply specifically to both animal feed and foodstuffs for human consumption.

137. I am, however, unable to follow Ferrari Mangimi in its argument that the difference in treatment in question is unjustified.

138. As the European Parliament and the Commission, supported on this point by the Greek Government, have correctly pointed out, it is precisely the animal feedingstuff sector that was at the origin of the most recent BSE and dioxin health crises and consequently requires more stringent restrictions and safeguards.

139. Furthermore, unlike foodstuffs for human consumption, animal feedingstuffs are at the start of the food chain. Consequently, while contamination of foodstuffs for human consumption that are manufactured or marketed by an undertaking may endanger the health of the limited circle of that undertaking's customers, a crisis within the animal feedingstuff sector may spread exponentially to all animals consuming the

36 — See, inter alia, Case C-56/94 *SCAC* [1995] ECR I-1769, paragraph 27; Case C-15/95 *EARL de Kerlast* [1997] ECR I-1961, paragraph 35; Case C-354/95 *National Farmers' Union and Others* [1997] ECR I-4559, paragraph 61; and Case C-292/97 *Karlsson and Others* [2000] ECR I-2737, paragraph 39.

feedingstuff in question and subsequently to all products derived from those animals, with potentially adverse effects for a very large number of end consumers.

140. It is specifically this consideration which induces me to take the view that more stringent rules for animal feedingstuffs are objectively justified and that therefore there cannot in such a case be any question of discrimination.

141. For those reasons I find that Article 1 (1)(b) and 1(4) of the Directive does not infringe the principle of equality.

142. Concluding the analysis of the validity of the Directive, I accordingly propose that the Court rule as follows:

— Article 1(1)(b) of Directive 2002/2 is invalid;

— Examination of the question under consideration has not otherwise indicated any factors of such a kind as to invalidate Directive 2002/2.

C — The applicability of the Directive in the absence of a positive list of feed materials which may be used in compound feedingstuffs

143. By its third question in Case C-12/04, the Consiglio di Stato is essentially asking whether the application of Directive 2002/2 is conditional on the adoption of a positive list which sets out, with their specific names, the feed materials which may be used in animal feedstuffs and whether, in the absence of such a list, Member States may transpose the Directive by referring to a list of the feed materials with the generic definitions of their commodity classes.

144. In raising that question, the Consiglio di Stato appears to be taking the view that the 10th recital in the preamble to Directive 2002/2 does in fact make the application of the Directive conditional on the adoption of that positive list, the absence of which would render the new rules objectively inapplicable. Ferrari Mangimi and the Spanish Government share that view.

145. The Consiglio di Stato also points out that, in transposing the obligation under the Directive to list by their specific names the feed materials indicated on the labelling, the Italian authorities had allowed manufacturers to have recourse to the designations contained in Annex VII, Part A, to Law No 281/63 and, for those not included therein, to the designations contained in Part B of

that annex, which correspond to the generic categories of feed materials established by Directive 91/357, which has now been repealed by Directive 2002/2. Ferrari Mangimi also demonstrated this method for transposing the Directive in the Italian legal system and considers it to be incorrect.

146. It is in this regard first of all necessary to recapitulate some of the matters which I have already touched on when setting out the legislative framework in the present Opinion (see points 8 to 16 above).

147. In this context, we have seen that the labelling requirements for compound feedingstuffs intended for production animals were initially harmonised by Directive 90/44 pursuant to the system of 'flexible declaration' under which the person responsible for labelling could, inter alia, decide whether to designate the feed materials used by their specific name or by the generic designation of the commodity classes to which they belong (Article 1(5)).

148. As a result of the BSE and dioxin crises, the legislature introduced, by way of Directive 2002/2, a more stringent system which, in addition to the quantitative information examined above, imposed a mandatory obligation to list feed materials by their *specific names* (Article 1(4), amending Article 5c of Directive 79/373).

149. Following the logic of that provision, Directive 2002/2 repealed Commission Directive 91/357, which established the *categories* of feed materials which could be used to indicate the composition of compound feedingstuffs (see the 12th recital and Article 2). [37]

150. It should also be recalled that, in the 10th recital in its preamble, Directive 2002/2 called on the Commission to submit to the European Parliament and the Council, '[o]n the basis of a feasibility study, ... a report ... by 31 December 2002, accompanied by an appropriate proposal for the establishment of a positive list, taking account of the conclusions of the report'.

151. Complying with that instruction, the Commission submitted a report on 24 April 2003, in which, however, it declared that the drafting of a 'positive list' or a 'positive list of feed materials [which] is an exclusive list of materials that upon assessment are considered safe for human and animal health and can therefore be used in animal feed' is not 'decisive in ensuring feed safety'. In the light of that view, the Commission decided not to submit any proposal in the matter.

37 — Commission Directive 91/357/EEC of 13 June 1991 laying down the categories of ingredients which may be used for the purposes of labelling compound feedingstuffs for animals other than pet animals (OJ 1991 L 193, p. 34).

152. That said, I will state forthwith that, in my view, the transposition and application of the obligation under the Directive to mention the feed materials used by their specific names are not conditional on the compilation of the abovementioned 'positive list', and the Member States cannot meet that obligation by allowing the information in question to be provided by way of generic category designations.

153. In particular, contrary to the view apparently taken by the Consiglio di Stato, and as the Commission has correctly pointed out, it does not follow from the provisions of Directive 2002/2, the recitals in its preamble or the Commission report that the transposition or application of Directive 2002/2 is conditional on the adoption of that list.

154. As the European Parliament has also pointed out, that literal fact is subsequently confirmed by a chronological examination of the obligations to be met under the Directive.

155. As has been seen, the 10th recital in the preamble, which does not as such have any prescriptive value, called on the Commission to submit by *31 December 2002*, on the basis of a feasibility study, a report accompanied by an appropriate proposal in regard to the problem of the 'list'. Article 3(1) went on to set *6 March 2003* as the date by which the Directive had to be transposed. Finally, the national implementing rules had to be applied with effect from 6 November 2003.

156. It strikes me as illogical to suggest that the legislature imposed an obligation to implement the Directive by 6 March 2003 while at the same time making its application subject to the adoption of a further measure which, *even if it were feasible*, would have begun its legislative course scarcely two months previously and would therefore in all probability have been protracted well beyond that date. In other words, it would be illogical to argue that the legislature itself intended to impose on its own measure a condition which would in practice have rendered its transposition nugatory and resulted in its being almost automatically inapplicable.

157. In fact, we must not forget that, although it is detailed, Directive 2002/2 is, as such, limited to imposing an obligation as to results which it is up to the Member States to achieve by employing whatever means and forms may be appropriate.

158. In that regard, the Directive laid down the obligation to list the feed materials used in feedingstuffs by their specific names. It was thereafter up to the Member States as to how that was to be achieved within their respective legal systems.

159. That task would certainly have been more straightforward had there been some degree of Community standardisation of specific names to which Member States could have referred. In addition, as the Commission itself acknowledged, such standardisation, while not having to amount to an exhaustive list of materials which may be used, is none the less desirable in order to guarantee more extensive protection for customers. The Commission might therefore reconsider its utility within the context of the new report on implementation of the Directive to be submitted by 6 November 2006 (see Article 1(6)).

160. In the absence of such standardisation, however, it is the Member States themselves which must identify the most appropriate means of transposition, having recourse, should the need arise, to those suggested by the Commission in its written observations and at the hearing (drafting of non-exhaustive national lists or use of the current specific designations of feed materials).

161. In any event, it is not for the Court to indicate which of those means is better or more easily achievable. However, what the Court can immediately rule out is that transposition of the obligation of specific designation may take place through recourse (as the Italian legislature appears to have done) to a list of those materials containing the generic designations of their commercial categories, that is to say, by way of a system which, through the repeal of Directive 91/357, the Community legislature has expressly excluded.

162. In the light of the foregoing considerations, I hold that the transposition and application of Directive 2002/2, in particular of the obligation to list the feed materials used in compound feedingstuffs by their specific names, as laid down in Article 1(4) thereof, are not conditional on the compilation of a list of feed materials which may be used in animal feedingstuffs.

163. Member States cannot transpose that obligation by using a list of those materials containing the generic designations of their commercial categories.

D — *The extension to national administrative authorities of the power to suspend national provisions which implement Community measures of questionable validity*

164. By its second question, finally, the Netherlands Rechtbank asks whether the administrative authorities of a Member State,

which without any doubt cannot therefore be regarded as being courts or tribunals within the terms of Article 234 EC, have the power to suspend the implementation of national measures which give effect to Community provisions of contested validity, in the case where a court of another Member State has already requested the Court of Justice to rule on the validity of those provisions.

165. According to Nevedi, that question should be answered in the affirmative. It points out that, in the judgment in *Fratelli Costanzo*, [38] the Court has already recognised that national administrative authorities are, in the same way as judicial authorities, under an obligation to refrain from applying provisions of national law which are at variance with directives having direct effect, and thus without obliging individuals to bring pointless judicial proceedings. That solution, Nevedi continues, could also be transposed to the present proceedings: if the relevant conditions are satisfied, national administrative authorities also should be able to suspend the provisions giving effect to rules of Community law of questionable validity in order to dispense individuals from having to bring pointless judicial proceedings and incurring all the resultant heavy costs.

166. In my view, however, such a solution cannot be upheld.

167. I would first point out that the *ratio* for an obligation devolving on national authorities to refrain from applying such rules does not lie in requirements of procedural economy, but rather in the fact that 'the obligations arising under [directly effective Community] provisions are binding upon all the authorities of the Member States', [39] whether those authorities are judicial or administrative.

168. Apart from that, however, the judgment in *Fratelli Costanzo* has, in my view, no relevance whatever for the resolution of the issue here under consideration. The matter for examination in that case was whether the national administrative authorities could refrain from applying national provisions at variance with *Community rules* which were unquestionably *valid*. Here, by contrast, the question is whether national administrative authorities can suspend national provisions implementing Community rules *which it is thought may be invalid*.

169. It will thus be evident that the cases here under consideration do not feature the requirements of the protection of the full and uniform application of Community law which were present in *Fratelli Costanzo*.

38 — Judgment in Case 103 88 *Fratelli Costanzo* [1989] ECR 1839.

39 — *Fratelli Costanzo*, cited above, paragraph 30.

170. That judgment cannot therefore serve as a basis for any reply to the Netherlands Rechtbank; rather, that basis is to be found in those rulings — which I shall now examine — in which the Court recognised national *judicial authorities* as having the suspensory power which it is now sought to extend also to administrative authorities. [40]

171. As has been rightly observed by the Netherlands Government and the Commission, it emerges in particular from those judgments that the recognition that national courts have that power amounts to a 'tempering' of the monopoly which the Court of Justice enjoys over the review of the legality of acts adopted by the Community institutions and of the principle of the uniform application of Community law. [41] That power implies the possibility for courts of a Member State to gainsay provisionally the validity of the Community measure which, in the event of suspension, should not be applied in that State, even on a provisional basis.

172. Such 'tempering', as the Greek Government and the Commission have stressed, is, however, justified by two requirements, each of which is fundamental.

173. The first is full 'judicial protection' for individuals, which requires that 'individuals [be placed] in a position, where certain conditions are satisfied, to obtain a decision granting suspension of enforcement which would make it possible for the effects of the [Community measure the validity of which they are challenging] to be rendered for the time being inoperative as regards them'. [42]

174. The second is the 'coherence' of the Community judicial system, in particular the 'system of interim legal protection', which requires that 'the interim legal protection which Community law ensures for individuals' must not vary according to whether such individuals directly challenge a Community measure before the Court (in which case that protection is expressly provided for by Article 242 EC) or arraign its validity before national courts, in the latter case irrespective of whether 'they contest the compatibility of national legal provisions with Community law or the validity of secondary Community law'. [43]

175. Although justified by such requirements, suspension of the implementation of a national measure adopted pursuant to a Community measure may, precisely because it affects the fundamental principles outlined

40 — See in particular the judgments in Joined Cases C-143/88 and C-92/89 *Zuckerfabrik Süderdithmarschen and Zuckerfabrik Soest* [1991] ECR I-415 and in Case C-465/93 *Atlanta and Others* [1995] ECR I-3761.

41 — *Zuckerfabrik Süderdithmarschen and Zuckerfabrik Soest*, cited above, paragraph 17; Case 314/85 *Foto-Frost* [1987] ECR 4199, paragraph 19.

42 — *Zuckerfabrik Süderdithmarschen and Zuckerfabrik Soest*, cited above, paragraphs 16 and 17.

43 — *Zuckerfabrik Süderdithmarschen and Zuckerfabrik Soest*, cited above, paragraphs 18 to 20.

above, be granted by a national court only subject to specific conditions. The following requirements apply in particular:

— that court must have grave reservations as to the validity of the Community measure and must take steps directly to make a preliminary reference, it being assumed that the question of validity of the contested measure has not already been referred to the Court;

— grounds of extreme urgency must obtain and the applicant must be facing the risk of incurring serious and irreparable damage;

— finally, the national court must take full cognisance of the Community's interests by requiring, where necessary, that the person seeking the interim relief provide adequate guarantees, such as the lodging of a deposit or other security.[44]

176. It seems to me that neither the requirements nor the conditions laid down in the case-law cited above apply in the case where the authority in question is an administrative authority.

177. In particular, there is not the need to safeguard the coherence of the Community judicial system such as justifies national courts also being recognised as having powers to suspend measures. Unlike national courts, national administrative authorities do not deliver, under conditions of full impartiality and independence, rulings which are designed to ensure respect for rights deriving from Community law and in the course of which a question may be referred to the Court. National administrative authorities do not therefore form part of the system centred by the Treaty on the parallel existence of direct legal remedies and of the preliminary reference procedure, and the coherence of which the Court has sought to preserve by extending to the second the power to adopt measures which the Treaty provisions envisage only for the first.

178. In addition, as has been quite correctly pointed out by the Netherlands and Italian Governments and by the Commission, the conditions outlined for the suspension of national rules implementing a Community measure are difficult to reconcile with the position and powers of the aforementioned authorities.

179. In particular, it seems to me that the condition relating to the existence of serious and irreparable damage for an individual calls for an evaluation by a third party which is independent and impartial, and cannot be carried out by the same authority as that which, as in the present instance, adopted the measure to be suspended and which might therefore have an interest in rendering its application permanent.

44 — *Zuckerfabrik Süderdithmarschen and Zuckerfabrik Soest*, cited above, paragraphs 22 to 33.

180. Equally, the measures to be adopted for the purpose of safeguarding the Community's interests, in particular freezing the disposal of goods, are typically judicial measures which, as they impinge on the subjective rights of individuals, are normally reserved for the jurisdiction of courts. In the absence of measures of this kind, those interests cannot be properly safeguarded and the Community would be exposed to unacceptable risks, including risks that are financial in nature.

181. For the foregoing reasons, I therefore take the view that the administrative authorities of a Member State do not have the power to suspend the implementation of national measures which give effect to Community provisions of disputed validity, even when a court of another Member State has already requested the Court of Justice to give a ruling on the validity of those provisions.

V — Conclusion

182. In the light of the foregoing considerations, I propose that the Court rule as follows:

— in Cases C-453/03, C-11/04 (first, second and third questions), C-12/04 (first, second and fourth questions) and C-194/04 (first question):

'(1) Article 1(1)(b) of Directive 2002/2/EC of the European Parliament and of the Council of 28 January 2002 amending Council Directive 79/373/EEC on the circulation of compound feedingstuffs and repealing Commission Directive 91/357/EEC is invalid;

(2) Examination of the question has not otherwise indicated any factors of such a kind as to affect the validity of Directive 2002/2/EC of the European Parliament and of the Council of 28 January 2002 amending Council Directive 79/373/EEC on the circulation of compound feedingstuffs and repealing Commission Directive 91/357/EEC.'

— in Case C-12/04 (third question):

'Transposition and application of Directive 2002/2, in particular of the obligation to list the feed materials used in compound feedingstuffs by their specific names, provided for by Article 1(4) thereof, are not conditional on the establishment of a list of feed materials which may be used in animal feedingstuffs.

Member States cannot meet that obligation by having recourse to a list of those materials containing the generic designations of their commodity codes.'

— in Case C-194/04 (second question):

'The administrative authorities of a Member State do not have the power to suspend the implementation of internal measures giving effect to Community provisions of disputed validity, even in the case where a court of another Member State has already requested the Court to deliver a ruling on the validity of those provisions.'