ORDER OF THE PRESIDENT OF THE COURT OF FIRST INSTANCE
11 April 2003 *

In Case T-392/02 R,

Solvay Pharmaceuticals BV, established in Weesp (Netherlands), represented by C. Meijer, F. Herbert and M.L. Struys, lawyers, with an address for service in Luxembourg,

applicant,

v

Council of the European Union, represented by M. Balta and Ruggeri Laderchi, acting as Agents,

defendant,

supported by

Commission of the European Communities, represented by A. Bordes, acting as Agent, with an address for service in Luxembourg,

intervener,

* Language of the case: French.

APPLICATION for suspension of operation of Council Regulation (EC) No 1756/2002 of 23 September 2002 amending Council Directive 70/524/EEC concerning additives in feedingstuffs as regards withdrawal of the authorisation of an additive and amending Commission Regulation (EC) No 2430/1999 (OJ 2002 L 265, p. 1),

THE PRESIDENT OF THE COURT OF FIRST INSTANCE OF THE EUROPEAN COMMUNITIES

makes the following

Order

1 Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ 1970 L 270, p. 1) laid down the Community rules applying to the authorisation, and withdrawal of authorisation, of additives for incorporation in feedingstuffs.

2 Directive 70/524 has been amended and supplemented on several occasions. In particular, it was heavily amended by Council Directive 84/587/EEC of 29 November 1984 (OJ 1984 L 319, p. 13) and by Council Directive 96/51/EC of 23 July 1996 (OJ 1996 L 235, p. 39). It was supplemented by the decisions cited in paragraphs 14 and 15 below.

3 Directive 96/51 established new rules for authorisation, and withdrawal of authorisation, of additives in feedingstuffs ('the new rules') in place of the rules which had applied until then ('the original rules'). The new rules entered into force on 1 October 1999.

4 Under the original rules, additives were defined in Article 2 of Directive 70/524, as amended by Directive 84/587, as 'substances... which, when incorporated in feedingstuffs, are likely to affect their characteristics or livestock production'.

5 Under the original rules, the substance Nifursol, a coccidiostat of the nitrofuran group, was provisionally authorised as an additive in feedingstuffs by Commission Directive 82/822/EEC of 19 November 1982 amending the Annexes to Directive 70/524 (OJ 1982 L 347, p. 16). Commission Directive 89/23/EEC of 21 December 1988 amending the Annexes to Directive 70/524 (OJ 1989 L 11, p. 34), included Nifursol definitively in the former Annex 1 of Directive 70/524, as amended.

6 According to the third recital in the preamble to Directive 96/51, it was considered necessary, under the new rules, to draw a distinction between 'additives which are widely used and present no particular dangers for the manufacture of feedingstuffs' and 'high technology additives with a very specific composition for which the person responsible for putting them into circulation must receive authorisation, in order to avoid copies which might not be in conformity and might therefore be unsafe'. Effect is given to that distinction by Article 2 of Directive 70/524, as amended by Article 1(3)(i) of Directive 96/51. The new Article 2 contains the following definitions:

'(a) "additives": substances or preparations used in animal nutrition in order to:

— ...

— prevent or reduce the harmful effects caused by animal excretions or improve the animal environment;

(aa) "micro-organisms": micro-organisms forming colonies;

(aaa) "additives subject to authorisation linked to the person responsible for putting them into circulation": the additives listed in Part I of Annex C;

(aaaa) "other additives": additives not subject to authorisation linked to the person responsible for putting them into circulation and referred to in Part II of Annex C'.

7 It is apparent from Annex C to Directive 70/524, as inserted by Article 1(20) of Directive 96/51, that all additives belonging to the group of antibiotics or the group of growth promoters fall within the class of additives covered by Article 2(aaa) and are therefore subject to authorisation linked to the person responsible for putting them into circulation. Under Article 2(1) of Directive 70/524, as amended by Directive 96/51, 'person responsible for putting into circulation' is defined as: 'the natural or legal person who has responsibility for the conformity of the additive which has been granted Community authorisation and for putting it into circulation'.

8 Under the new rules (more specifically, under Article 3 of Directive 70/524 as amended by Directive 96/51), only additives which have a Community authorisation granted under a Commission regulation may be put into circulation. Under Article 3a of Directive 70/524, as amended, authorisation of an additive is given inter alia if:

'...

(b) taking account of the conditions of use, it does not adversely affect human or animal health or the environment, nor harm the consumer by impairing the characteristics of animal products;

...'

9 For additives which were authorised under the original rules and whose authorisation Directive 96/51 thereafter linked to the person responsible for putting them into circulation, Articles 9g, 9h and 9i of Directive 70/524, introduced by Directive 96/51, provide for a transitional period during which those additives remain provisionally authorised but must be the subject of a new authorisation under the new rules.

10 Article 9h(1) of Directive 70/524, as amended, provides for the provisional authorisation, from 1 April 1998, and the transfer to Chapter II of Annex B, as amended by Directive 96/51, of additives such as Nifursol, which, under the original rules, were included in Annex I after 31 December 1987. Those additives

must be authorised — or, where appropriate, prohibited — no later than 1 October 1998, without prior re-evaluation. Under Article 9h(2), and 'with a view to their re-evaluation', such applications for authorisation must be accompanied by the monographs and the identification notes from the dossier on the basis of which the authorisation was granted under the original rules. Article 9h(3)(a) provides for the withdrawal of the provisional authorisation through the adoption of a regulation in accordance with the procedure laid down in Article 23 (see paragraph 13 below), 'if the documents prescribed in paragraph 2 are not submitted within the time allowed or if, after scrutiny of the documents, it is established that the monographs and identification notes are not in accordance with the data in the dossier on the basis of which the original authorisation was given'. If they are not withdrawn, Article 9h(3)(b) provides that the provisional authorisations referred to in Article 1 are to be replaced 'by authorisations linked to the person responsible for putting them into circulation granted for a period of 10 years' and that the additives concerned are accordingly to be included in Chapter I of the list referred to in Article 9t(b).

11 In accordance with Article 9h of Directive 70/524, as amended, Article 1 of Commission Regulation (EC) 2430/1999 of 16 November 1999 linking the authorisation of certain additives belonging to the group of coccidiostats and other medicinal substances in feedingstuffs to persons responsible for putting them into circulation (OJ 1999 L 296, p. 3) provides for the provisional authorisation of certain additives, among them additive E 769 Nifursol, to be replaced by authorisations granted to the person responsible for putting them into circulation until 30 September 2009.

12 Under the new rules, Article 9m of Directive 70/524 provides that the authorisation of an additive is to be withdrawn by means of a regulation, *inter alia*, 'if any one of the conditions for the authorisation... referred to in Article 3a are no longer met' (second indent) and 'if the person responsible for putting the additive into circulation does not provide, within a given period of time, the information requested by a person responsible at the Commission' (fifth indent). Under the new Article 9r, '[a]mendments to be made to the Annexes shall be adopted in accordance with the procedure laid down in Article 23'.

13 Article 23 of Directive 70/524, as amended by Directive 84/587 and most recently by Annex I of the Act concerning the Conditions of Accession of the Kingdom of Norway, the Republic of Austria, the Republic of Finland and the Kingdom of Sweden and the adjustments to the Treaties on which the European Union is founded (OJ 1994 C 241, p. 21 provides:

'1. Where the procedure laid down in this Article is to be followed, matters shall be referred without delay by the chairman, either on his own initiative or at the request of a Member State, to the Standing Committee for Feedingstuffs.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time-limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the [EC] Treaty [(now Article 205(2) EC)] in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that article. The Chairman shall not vote.

3. The Commission shall adopt the measures and implement them forthwith where they are in accordance with the opinion of the Committee. Where they are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall adopt the measures by a qualified majority.

...'

14 The Standing Committee for Feedingstuffs ('the Standing Committee'), which is referred to in Article 23 of Directive 70/524, was established by Council Decision 70/372/EEC of 20 July 1970 setting up a Standing Committee for Feedingstuffs (OJ, English Special Edition 1970 (II), p. 534). It consists of representatives of the Member States with a representative of the Commission as chairman.

15 By Decision 76/791/EEC of 24 September 1976 establishing a Scientific Committee for Animal Nutrition (OJ 1976 L 279, p. 35), replaced by Commission Decision 97/579/EC of 23 July 1997 setting up Scientific Committees in the field of consumer health and food safety (OJ 1997 L 237, p. 18), the Commission appointed a Scientific Committee for Animal Nutrition ('SCAN'). Article 2(1) of Decision 97/579 provides *inter alia* that the Commission may decide to consult SCAN on questions 'of particular relevance to consumer health and food safety', while, according to Article 2(3), '[a]t the Commission's request, [SCAN] shall provide scientific advice on matters relating to consumer health and food safety'.

16 Under Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ 1990 L 224, p. 1), as amended by Council Regulation (EEC) No 2901/93 of 18 October 1993 amending Annexes I, II, III and IV of Regulation No 2377/90 (OJ 1993 L 264, p. 1), almost all the nitrofurans were included in Annex IV of Regulation No 2377/90. The result of that inclusion is that it is prohibited to administer those nitrofurans to food-producing animals as veterinary medicinal products. The prohibition was extended to the final nitrofuran not subject to the original prohibition (namely, furazolidone) by Commission Regulation (EC) No 1442/95 of 26 June 1995 amending Annexes I, II, III and IV of Regulation No 2377/90 (OJ 1995 L 143, p. 26).

Facts and proceedings

Background to the dispute

17 It is not disputed in these proceedings that Nifursol is an additive in feedingstuffs which provides an effective preventive treatment against histomoniasis (black-head) in turkeys. Histomoniasis is a parasitic disease to which turkeys are particularly susceptible and the occurrence of which may lead to mortality rates of between 50% and 90% of a farm's population.

18 The Commission decided, by letter sent to the applicant on 20 July 1998 through the United Kingdom Veterinary Medicines Directorate ('the VMD', rapporteur in this matter), to reassess the section in the Nifursol file relating to 'safety', without requesting additional studies.

19 Acting on an initial response from the applicant on 10 September 1998, in which, referring to various reports and data already available, it had asked for details of the additional reports or data which might be needed to enable the Commission to determine that Nifursol was harmless, the VMD replied, by letter of 23 September 1998, informing the applicant that 'the aspects relating to genotoxicity and mutagenicity had been adequately dealt with', but that it was necessary to 're-examine the safety of Nifursol, concentrating on the aspects concerning carcinogenicity and on the differences in toxicity between Nifursol and the other nitrofurans, particularly Furazolidone'.

20 On 28 December 1998 the applicant sent the VMD an additional file containing *inter alia* a report re-examining the question of carcinogenicity.

21 The authorisation of Nifursol was extended until 30 September 2009 by Regulation No 2430/1999 (see paragraph 11 above).

22 By letter of 28 January 1999, the VMD informed the applicant that the Commission was satisfied with the additional file concerning the harmlessness of Nifursol and asked the applicant to send copies of it to the members of SCAN and the Standing Committee.

23 The VMD informed the applicant, by letter of 3 August 1999, that a SCAN working group had just been set up to examine the file.

24 In response to questions raised by certain Member States, in particular those from the Kingdom of Sweden, which were communicated to the applicant by the VMD on 9 February 2000, the applicant suggested a programme of additional tests on the harmlessness of Nifursol.

25 On 22 May 2000 the VMD informed the applicant that the Commission had just asked it to prepare an evaluation report on the basis of the data provided by the applicant.

26 In response to that report, which identified a certain number of points on which additional data were necessary, on 27 June 2000 the applicant sent the VMD several studies, of which copies were subsequently sent to SCAN on 28 September 2000.

27 On 11 October 2001, SCAN adopted an opinion on Nifursol, in which it concluded that, on the basis of the mutagenicity, genotoxity and carcinogenicity studies provided by the applicant, and owing to the lack of available data on toxicity, it was not possible to determine an acceptable daily intake for consumers (i.e. a level of intake by humans of residues of the substances which could be regarded as safe, hereinafter 'the ADI'). Therefore, SCAN concluded that it was impossible to guarantee that Nifursol was harmless.

28 On 22 November 2001, the Commission, at a meeting with the applicant's representatives, informed the applicant that it intended, in the light of the SCAN opinion, to withdraw the authorisation to place Nifursol on the market.

29 On 8 January 2002, the applicant was informed by the Commission that, in order to obtain an amendment of that opinion, it would need to produce additional scientific data in respect of all the gaps identified by SCAN.

30 At the meetings of 17 and 18 April 2002 SCAN approved the minutes of its meetings of 5 and 6 February 2002, at which it had concluded, on the basis of the additional data provided by the applicant, that the risk of carcinogenicity presented by Nifursol was no longer a problem. However, according to that committee, since doubts persisted as to the potential genotoxicity of Nifursol, and as there were no kinetic studies on the residues of that substance in turkey-meat, it had to adhere to the conclusion of its opinion of 11 October 2001.

31 During the meetings of 17 and 18 April, as emerges from the minutes approved at the meetings of 18 and 19 June 2002, SCAN examined a kinetic study submitted by the applicant and found it only partly satisfactory. With regard to evidence of the absence of genotoxicity, it asked the applicant to carry out a further *in vivo* test on tissues other than the marrow.

32 In accordance with the procedure laid down in Article 23 of Directive 70/524, as amended, the Commission submitted to the Standing Committee, for its opinion, a proposal for a regulation concerning the withdrawal of the authorisation of the additive Nifursol.

33 Since the Standing Committee was unable to issue an opinion on that proposal at its meeting of 23 May 2002, on 8 July 2002 the Commission submitted to the Council a proposal for a regulation withdrawing the authorisation of Nifursol (COM (2002) 367 final).

34 On 23 September 2002, Council Regulation (EC) No 1756/2002 of 23 September 2002 amending Directive 70/524 concerning additives in feedingstuffs as regards withdrawal of the authorisation of an additive and amending Commission Regulation (EC) No 2430/1999 (OJ 2002 L 265, p. 1, 'the contested regulation') was adopted.

The contested regulation

35 The contested regulation is based on Directive 70/524, as amended, and in particular Article 9m. In the third recital in the preamble, the Council refers to the opinions of the 'Joint FAO/WHO Expert Committee on Food Additives' and the

Community 'Committee for Veterinary Medicinal Products' issued between 1990 and 1995 relating to the use of veterinary medicinal products 'in food-producing animals of the group of substances known as nitrofurans', according to which, because of the genotoxicity and carcinogenicity of those substances, it was not possible to determine an ADI. The fourth and fifth recitals refer to the Commission's request that SCAN re-examine the risks presented by Nifursol and to SCAN's unfavourable opinion of 11 October 2001. The Council concluded, as stated in the sixth recital, that 'it cannot be guaranteed that Nifursol does not present a risk for human health'. In the seventh and eighth recitals it states that the conditions laid down in Article 3a(b) are no longer met and that the use of Nifursol should no longer be permitted.

36 Accordingly, under Article 1 of the contested regulation, the reference to additive E769 Nifursol in the annexes to Regulation No 2430/1999 and Directive 70/524 are withdrawn; Article 2 provides that the withdrawal is to apply from 31 March 2003.

Proceedings before the Court of First Instance

37 By document lodged at the Court Registry on 26 December 2002, the applicant brought an action under the fourth paragraph of Article 230 EC for the annulment of the contested regulation and for an order for costs against the Council.

38 By separate document lodged at the Court Registry on the same day, the applicant applied for its application for annulment to be decided under an expedited procedure, in accordance with Article 76a of the Rules of Procedure of the Court of First Instance.

39 In its observations lodged on 21 January 2003 on the application for an expedited procedure, the Council claimed that the Court should dismiss the application.

40 By application lodged at the Court Registry on 22 January 2003, the Commission submitted an application to intervene in the main proceedings in support of the form of order sought by the Council.

41 The Second Chamber of the Court of First Instance, to which the main action was assigned by decision of 22 January 2003, dismissed the application for an expedited procedure by decision of 4 February 2003, of which the parties were notified on the following day.

42 Since the applicant, despite bringing its action, had had further tests carried out on Nifursol, it informed the Commission of the results on 6 and 10 February 2003.

43 At a meeting held on 17 February 2003 between the applicant's representatives and the Commission, the head of division responsible for the file at the Commission's Directorate-General for Health and Consumer Protection confirmed to the former that those new reports had already been sent to SCAN and to the Member States, which had been asked to examine them quickly.

44 On 24 February 2003 the applicant learned from the Secretary of SCAN that the committee would not meet before 26 March 2003, that is, after the last meeting of the Standing Committee — planned for 20 March 2003 — before the withdrawal of Nifursol came into effect on 31 March 2003.

45 By document lodged at the Court Registry on 5 March 2003, the applicant made an application for suspension of the operation of Articles 1 and 2 of the contested regulation and an application for urgent suspension under Article 105(2) of the Rules of Procedure.

46 On 11 March 2003, the President of the Court put certain questions to the Commission and asked it to produce certain documents in accordance with the second paragraph of Article 24 of the Statute of the Court of Justice, applicable to the Court of First Instance by virtue of the first paragraph of Article 53.

47 On 14 March 2003 the Commission replied to those questions and provided the documents requested. It also lodged an application for leave to intervene in the interlocutory proceedings in order to make oral submissions.

48 By order of 17 March 2003 of the President of the Second Chamber of the Court, the Commission was granted leave to intervene in the main action in support of the form of order sought by the Council. Since interlocutory proceedings are incidental in nature, it follows that the Commission is also permitted to intervene in these proceedings.

49 The Council lodged its written observations on the application for interim relief on 24 March 2003.

50 The parties presented oral argument and replied to the questions put at the hearing on 27 March 2003 before the President of the Court.

Law

51 Under Article 242 EC in conjunction with Article 243 EC, and Article 255(1) EC, the Court may, if it considers that the circumstances so require, order suspension of operation of the contested measure or adopt the necessary interim measures.

52 Article 104(2) of the Rules of Procedure provides that applications for suspension of operation must state the circumstances giving rise to urgency and the pleas of fact and law establishing a *prima facie* case for the relief applied for. These conditions are cumulative, so that an application for suspension of operation must be dismissed if either of them is not fulfilled. The Judge hearing the application will also, where appropriate, balance the competing interests (orders of the President of the Court of Justice in Case C-445/00 R *Austria* v *Council* [2001] ECR I-1461, paragraph 73, and of the President of the Court of First Instance of 27 March 2003 in Case T-398/02 R *Linea GIG* v *Commission* [2003] ECR II-1139, paragraph 16).

53 It is settled case-law that, in principle, the issue of the admissibility of the action before the bench adjudicating on the substance should not be examined in interlocutory proceedings, so as not to prejudge the case in the main action. It may nevertheless appear necessary, when it is contended that the main application to which the application for interim relief relates is manifestly inadmissible, to establish whether there are any grounds for concluding prima facie that the main application is admissible (orders of the President of the Court of Justice in Case 376/87 R *Distrivet* v *Council* [1988] ECR 209, paragraph 21, and in Case 160/88 R *Fédération européenne de la Santé Animale and Others* v *Council* [1988] ECR 4121, paragraph 22; order of the President of the Court of First Instance in Case T-13/99 R *Pfizer Animal Health* v *Council* [1999] ECR II-1961, paragraph 121, 'the order in *Pfizer*', confirmed on appeal by order of the President of the Court of Justice in Case C-329/99 P(R) *Pfizer Animal Health* v *Council* [1999] ECR I-8343).

Admissibility

54 The applicant claims that its application is admissible. It submits that the contested regulation is a measure of general application only in its form, because in substance it is a disguised decision taken against the applicant.

55 Although it has not formally raised a plea of inadmissibility in respect of the main action, the Council, in its defence lodged on 10 March 2003, nevertheless expresses doubts in that regard. However, it stated at the hearing that, for the purposes of these proceedings, it did not object to a finding that the action was not manifestly inadmissible.

56 The fourth paragraph of Article 230 EC gives individuals the right to challenge any decision which, albeit in the form of a regulation, is of direct and individual concern to them. The particular objective of that provision is to prevent the Community institutions from being able, merely by choosing the form of a regulation, to preclude an individual from bringing an action against a decision which concerns him directly and individually and thus to make it clear that the nature of a measure cannot be changed by the form chosen (see, *inter alia*, Joined Cases 789/79 and 790/79 *Calpak and Società Emiliana Lavorazione Frutta* v *Commission* [1980] ECR 1949, paragraph 7; Case T-298/94 *Roquette Frères* v *Council* [1996] ECR II-1531, paragraph 35; Case T-13/99 *Pfizer Animal Health* v *Council* [2002] ECR II-3305, paragraph 81, and Case T-70/99 *Alpharma* v *Council* [2002] ECR II- 3495, paragraph 73).

57 Given that the sole aim of the contested regulation is to withdraw the authorisation, of which the applicant is the sole holder, to place the additive Nifursol on the market, and given that the applicant is also — as is apparent from Annex I to Regulation No 2430/1999 — the 'person responsible for putting it into circulation' (see paragraphs 6, 7 and 10 above), it seems *prima*

facie, even if that regulation were to be regarded as a measure of general application, that the applicant must be considered as directly and individually concerned by it (see, to this effect, the judgments in *Pfizer Animal Health* v *Council*, cited above, paragraphs 81 to 106, and *Alpharma* v *Council*, cited above, paragraphs 73 to 98).

58 Accordingly, it is impossible to say with certainty that the main action is clearly inadmissible, and therefore this application for interim relief is admissible.

Prima facie *case*

59 The Council, having only conceded at the hearing that the pleas raised in support of the main action show, at most, an arguable case, denies that there is an adequate *prima facie* case. It is therefore necessary, first of all, to examine whether the condition for a *prima facie* case is met in the present case; this requires an examination of whether the pleas in law put forward by the applicant are *prima facie* well founded (Case C-440/01 P(R) *Commission* v *Artegodan* [2002] ECR I-1489, paragraph 64).

60 The applicant raises three pleas in its application, alleging, first, infringement of Article 9m, second indent, and Article 3a(b) of Directive 70/524, as amended, and, in the alternative, of the 'precautionary principle', second, of Article 9m, fifth indent, of the directive, as amended, and of the principle of equality of treatment, and, third, of the principles of legal certainty, good faith and sound administration in the procedure which led to the adoption of the contested regulation.

61 Although all three pleas are contested by the Council, at the hearing the Commission essentially supported the Council's submissions only with regard to the third plea. Since the first two pleas are closely linked, as is shown in particular by the oral observations of the main parties, they should, at this stage, be examined together.

Arguments of the parties

62 The applicant claims, in substance, that, by justifying — in the sixth recital in the preamble to the contested regulation — the withdrawal of the authorisation of Nifursol on the ground that it was no longer possible to guarantee that the additive was harmless, the Council significantly altered the test referred to in Articles 9m and 3a(b) of Directive 70/524, as amended. Under the latter provision, an authorisation already granted can be withdrawn only where it appears that the additive in question has an adverse effect on human health. However, in the present case, the withdrawal of the authorisation is not based on such an impact but on a risk which, as regards Nifursol, is purely hypothetical.

63 The Council cannot rely on the precautionary principle, because no reference is made thereto in the contested regulation. If it had to be accepted that the Council did take that principle as a basis, it misapplied it by choosing a purely hypothetical risk criterion which is irreconcilable with the judgments in *Pfizer Animal Health* v *Council* and *Alpharma* v *Council*, both cited above. The opinions referred to in the third recital in the preamble to the contested regulation does not concern the nitrofurans group as such but only some nitrofurans, which do not include Nifursol. Since Nifursol has been authorised since 1982 and in view of the fact that its authorisation was renewed by Regulation No 2430/1999 on the basis of Article 9h of Directive 75/524, as amended (see paragraphs 10 and 11 above), there is, according to the applicant, a presumption that it meets the conditions of Article 3a of that directive. Accordingly, in order to show that the condition in Article 3a(b) is no longer met, the Community authorities would have to establish the presence of a serious risk.

64 The applicant points out that the Council merely referred to the opinions cited in the third recital in the preamble to the contested regulation and to SCAN's opinions of 11 October 2001 and 18 April 2002. The latter are based mainly on an *in vitro* test according to which a risk of mutagenicity cannot be ruled out and from which it is concluded that an ADI cannot be determined. As for the former opinions, although they have been available since the beginning of the 1990s, the Commission did not react to them until July 1998 and the contested regulation, which was adopted more than four years later, in September 2002, provided for the withdrawal of the authorisation concerned only from the end of March 2003. These facts show that the risk invoked is slight.

65 As regards the second plea, the applicant claims that the conclusion drawn from SCAN's opinions is based essentially on an alleged lack of information or data necessary for determining an ADI. However, notwithstanding the fact that there is a specific provision in Directive 70/524, as amended, namely the fifth indent of Article 9m, enabling the Commission to be provided with such information or data, it never called on the applicant, as holder of the authorisation in question, to provide it. The applicant insists that it never received a precise indication from the Commission as to the nature of the information or data allegedly missing.

66 The Council submits, with regard to the first plea, that Directive 70/524 is based on a 'positive list' system, according to which additives are prohibited unless the manufacturer provides evidence of compliance with the conditions listed in Article 3a of that directive, as amended. It is for the manufacturer to show that the risks are acceptable. The contested regulation is correctly based on the precautionary principle, which originates in the rules of evidence applicable to the procedures laid down by Directive 70/524 (Joined Cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00 *Artegodan and Others* v *Commission* [2002] ECR I-4945, paragraph 188). There is no difference between the test required by Article 3a of the directive, as amended, and that carried out by the Council in the present case, to which the sixth recital in the preamble to the contested regulation refers. In any event, it is certainly permissible for the

Community legislature to have a 'zero tolerance' policy with regard to certain risk factors for which the manufacturer cannot adduce proof that they are acceptable (judgment in Case C-121/00 *Hahn* [2002] ECR I-9193, and the Opinion delivered by Advocate General Geelhoed in that case, ECR I-9195, point 29).

67 The Council, supported on this point by the Commission, claims that the risk presented by Nifursol is far from hypothetical. Nifursol belongs to a class of substances whose use for food-producing animals is generally considered in the Community, and at international level, as unacceptable, which is confirmed by the *in vitro* experiments. At the hearing its Agent stated that, according to SCAN's opinions, Nifursol should be regarded as potentially genotoxic owing, in particular, to the results of certain *in vitro* tests. That explains why an ADI cannot be determined by the committee, which is the most negative conclusion which may be drawn from the assessment of the risks presented by an additive. It follows that, in the absence of any contrary proof at the time when the contested regulation was adopted, the Council rightly ordered the withdrawal in the light of the nature of the risk identified by SCAN.

68 The fact that the withdrawal in question was made quite some time after the use of nitrofurans as veterinary medicinal products was prohibited in 1990 stems from the fact that the procedure which had to be followed in the present case required not only contacts between the Commission and the applicant but also continual exchanges with the Member States.

69 As for the second plea, the Council insists that the validity of the contested regulation cannot be called in question on the ground that the Commission did not exercise an alleged power to instruct the applicant to provide it with the missing data. The Council maintains that it is clear from Article 9m of Directive 70/524, as amended, that an authorisation may be withdrawn at any time if the manufacturer is unable to provide data showing that the conditions laid down in Article 3 continue to be met.

Findings of the President of the Court

70 It appears that, by its first plea, the applicant seeks, in essence, to challenge the application in the contested regulation of the term 'adversely affect' to which reference is made in Article 3a(b) of Directive 70/524, as amended. It maintains that, since the additive Nifursol has been used since 1982 without any adverse effect on human health being detected, the withdrawal of its authorisation is unjustified. Consequently, it is necessary to carry out an assessment, albeit provisional, of the scope of the risk required by that term.

71 It must be stated at the outset that the lack of an express reference to the precautionary principle in the recitals in the preamble to the contested regulation is not enough to preclude the relevance of that principle to the interpretation, in the present case, of the term 'adversely affect'. Since the contested regulation was adopted pursuant to Directive 70/524, as amended, it should be noted that this Court has already held that, in accordance with Article 174 EC, the precautionary principle is one of the principles on which Community policy on the environment is based; this includes the policy relating to the protection of human health (*Pfizer Animal Health* v *Council*, cited above, paragraph 114, and *Alpharma* v *Council*, cited above, paragraph 135). The principle is also established in Article 152 EC as forming a constituent part of the Community's other policies, amongst them the common agricultural policy. Its importance has also been recognised by well-established case-law thereafter (see in that regard the case-law cited in *Pfizer Animal Health* v *Council*, cited above, paragraph 115, and *Alpharma* v *Council*, cited above, paragraph 136).

72 It follows *prima facie* that the Community institutions may, in the course of applying Directive 70/524, as amended, adopt measures on the basis of Article 3a(b), which take account of that principle, but are not necessarily required, when they adopt them, to make express reference to it. Since the judgments in *Pfizer Animal Health* v *Council* and *Alpharma* v *Council*, both cited above, confirm that the precautionary principle expresses the requirement to seek a high level of protection, the fact that the Council only referred, in the sixth

recital in the preamble to the contested regulation, to the fact that 'it cannot be guaranteed that Nifursol does not present a risk for human health', is not enough, at first sight, to call in question the validity of that regulation.

73 It is therefore necessary to examine whether the applicant's arguments as to the Council's alleged misapplication of the principle in the present case and, above all, the claim that the Council actually took as its basis a hypothetical risk, are so weighty that they cannot be dismissed in this application for interim relief (order of the President of the Court of Justice in Case C-149/95 P(R) *Commission* v *Atlantic Container Line and Others* [1995] ECR I-2165, paragraph 26, and order in *Pfizer*, paragraph 132).

74 In that regard, it does not seem, at least *prima facie*, irrelevant that the use of the additive Nifursol has been authorised in the Community for over 20 years and that that authorisation has recently been renewed by the Commission in November 1999, without re-evaluation, pursuant to Article 9h of Directive 70/524, as amended, for a period of 10 years (see paragraphs 10 and 11 above). As the applicant points out, not without reason, if the existence of a serious risk of genotoxicity, in particular, had really been feared since the publication of the opinions cited in the third recital in the preamble to the contested regulation, it is very unlikely that the Community legislature would have provided for a new authorisation without re-evaluation in 1996. It is also somewhat surprising that the Commission granted that authorisation three years later, by Regulation No 2430/1999, at a time when the re-evaluation, made on the basis of Article 9m and initiated by the VMD's letter of 20 July 1998, was already well under way (see paragraph 18 above).

75 Although it is true, as the Council and the Commission point out, that in the fifth recital in the preamble to Regulation No 2430/1999 it is stated that the authorisations granted by that regulation 'may be withdrawn at any time in accordance with Article 9m... of Directive 70/524', it must be pointed out that the recital states that '[i]n particular, authorisations of additives may be withdrawn as a result of the re-evaluation carried out under Article 9g of Directive 70/524', a

provision which is not applicable to Nifursol. In any event, the new authorisation without re-evaluation provided for by Article 9h of Directive 70/524, as amended, is *prima facie* significant in view of the fact that Regulation No 2377/90, as amended, had prohibited, between 1993 and 1995, the administration as veterinary medicinal products, of all nitrofurans (including Nifursol) to animals intended for human consumption (see paragraph 16 above).

76 The weight of the plea must nevertheless be assessed principally in the light of the risks identified by SCAN, on which, as the oral observations made by the Council and the Commission confirm, the contested regulation is essentially based.

77 In that regard, it should be pointed out, first of all, that SCAN itself, in its opinion issued at the meetings of 5 and 6 February 2002, ruled out the risk of carcinogenicity (see paragraph 30 above). The reference nevertheless made to that risk by the Council in the fifth recital in the preamble to the contested regulation does not therefore seem able to justify the withdrawal ordered.

78 As regards, secondly, the risk of genotoxicity, it is apparent from the written pleadings and oral observations that there is a very significant difference between the interpretations, on the one hand, of the applicant and, on the other, of the Community institutions party to these proceedings, as to the appropriate interpretation of SCAN's opinion of 11 October 2001, as maintained at the various meetings of 5 and 6 February 2002 and 17 and 18 April 2002, which, in fact, provides the basis of the serious risk invoked by the Council in the contested regulation. According to the applicant, that risk exists only in theory in the *in vitro* tests or studies carried out, above all those on the marrow. In response, the Community institutions point out not only the very serious nature of the scientific doubts as to the potential genotoxicity of nitrofurans but also the inconclusive nature of some of the *in vivo* tests carried out for the applicant, above all those involving liver tissues.

79 Thirdly, as regards the fact that SCAN was unable to determine an ADI for Nifursol, it need only be observed that, although the Council is certainly right to point out the very serious nature of such a conclusion, the applicant's argument that that conclusion stems directly from the position taken by the committee particularly with regard to the alleged inconclusive nature, or simply the absence, of certain tests relating to the alleged risk of genotoxicity produced by the applicant does not seem wholly unfounded.

80 In that regard, it should be noted that, according to case-law, a preventive measure may be taken only if the risk, although the reality and extent thereof have not been 'fully' demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time the measure was taken (judgments in *Pfizer Animal Health* v *Council*, cited above, paragraph 144, and *Alpharma* v *Council*, cited above, paragraph 157). Since a 'zero risk' cannot actually exist (judgments in *Pfizer Animal Health* v *Council*, paragraphs 145 and 146, and *Alpharma* v *Council*, paragraphs 158 and 159), it follows that 'the precautionary principle can therefore apply only in situations in which there is a risk, notably to human health, which, although it is not founded on mere hypotheses that have not been scientifically confirmed, has not yet been fully demonstrated'.

81 If, in connection with the application of Articles 3a(b) and 9m of Directive 70/524, as amended, the precautionary principle justifies — as the Council suggests by analogy with the judgment in *Hahn*, cited above — having a tolerance equal (or close) to zero as being the only acceptable level for a certain risk, that would presuppose, at least *prima facie*, that the risk in question is well established. Although it is clear from that judgment (see, in particular, paragraph 45) that the fact that the scientific data concerning the extent of a risk are uncertain does not, in Community law, preclude the risk from being regarded as established, it seems that, even if that judgment were capable of being applied to the circumstances of this case, a minimum level of scientific knowledge is still required. As the applicant stated at the hearing, while the serious health problems which may be caused by the variant of listeria at issue in this case to a certain number of groups of individuals, such as pregnant women or immunodeficient

persons, were well documented, the reality of the risk of genotoxicity presented by Nifursol, unlike the serious nature of such a risk if it were established, remains uncertain.

82 Adopting in the present proceedings the same approach as that taken in the judgments in *Pfizer Animal* Health v *Council* and *Alpharma* v *Council*, cited above, it seems, in the light of all the documentation and the submissions made at the hearing, that the applicant has raised weighty arguments as to the reality of the risk of genotoxicity for turkey-meat consumers arising out of the use of Nifursol as a feedingstuff additive. Although, admittedly, it is settled case-law that where a Community institution is called upon to make complex assessments it enjoys a wide measure of discretion, the exercise of which is subject to a restricted judicial review (judgments in Case C-405/92 *Mondiet* [1993] ECR I-6133, paragraph 32; Case C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265, paragraph 97, and Case C-120/97 *Upjohn* [1999] ECR I-223, paragraph 34), the fact remains that the applicant appears to be relying on weighty evidence that the Council exceeded the bounds of its discretion in this case.

83 The plea alleging that the Council committed an infringement when applying Articles 9m and 3a(b) of Directive 70/524, as amended, in the present case therefore warrants a thorough examination which only the bench adjudicating on the substance may carry out.

84 In any event, the second plea, raised by the applicant likewise does not seem wholly unfounded. The Council concedes that the contested regulation is based mainly on SCAN's opinions. However, it seems that specific additional information or tests were never requested from the applicant, either before that committee began to re-examine the Nifursol file in 1999 at the request of the Commission and/or the VMD or, subsequently, during the procedure which led to SCAN's confirmatory opinion adopted at the hearings of 17 and 18 April 2002.

85 The interpretation of the second and fifth indents of Article 9m, and of Article 3a(b), on the one hand, and of Article 9h, on the other, of Directive 70/524, as amended, does not justify precluding, at first sight, that, when the Commission re-evaluates an additive which is expressly not made subject to re-evaluation by the Community legislature in Directive 96/51 and subsequently renews the authorisation for a period of 10 years pursuant to the amendments introduced by that directive, it should be required — except in urgent cases in which a new, clear and serious risk suddenly appears — by itself, or through the Member State which is the rapporteur of the file, to send formal notice to the person responsible for putting the additive concerned into circulation. Such a notice should contain a short but specific indication of the scientific doubts justifying re-evaluation and be sent during the re-evaluation procedure or, at least, before the Commission proposes the withdrawal of the authorisation of the additive.

86 In the present case, the applicant states that at no time did it receive a letter similar to such a formal notice. The Community institutions which are party to these proceedings, while not conceding that the Commission is required to send a formal notice, strongly contest the applicant's statement. They maintain that the applicant was provided, particularly in SCAN's opinions, with adequately precise indications as to the additional information and studies required.

87 It is established that the applicant's arguments, in the particular circumstances of the withdrawal of an authorisation of an additive expressly not made subject to re-evaluation are, *prima facie*, of a weighty nature. Accordingly, the President of the Court cannot preclude that the contested regulation is unlawful owing to an infringement of the fifth indent of Article 9m of Directive 70/524, as amended, during the procedure which preceded its adoption.

88 As it is apparent from the first two pleas raised by the applicant that the condition for a *prima facie* case is satisfied in this instance, it is necessary to examine the other conditions for granting the suspension of operation sought.

Urgency and the balancing of interests

Arguments of the parties

— Urgency

89 The applicant pleads, in essence, that it risks losing the market for its Nifursol production, 96% of which is intended for the Community and 4% for neighbouring countries.

90 It claims that, since Nifursol is currently the only means in the European Union available to turkey-farmers for protecting their farms effectively against the risks of histomoniasis, it is foreseeable that there will be an increase in the cases of this parasitic disease from the time when the ban on marketing the product is implemented. In those circumstances, it argues, the European turkey-farming market, for which Nifursol is specifically and exclusively intended, will shrink very significantly, even disappear, both in the Community and in the other European countries in which the additive is used and which align themselves with the Community position. Such an outcome is as likely as it is irreparable. Even if the market remained of a sufficient size to envisage a resumption of sales after the possible annulment of the contested regulation, the withdrawal of the authorisation would seriously and irremediably harm the product's reputation and, in so doing, that of the applicant.

91 In that regard, the applicant stresses that the prohibition, for a long period, against marketing Nifursol would make it very difficult to overcome consumer mistrust, even after the annulment of the contested regulation. The inability of information campaigns to restore lost confidence is shown by studies carried out

by the United Kingdom's Food Standards Agency to which the applicant refers (namely its monitoring reports Nos 212 and 217 entitled 'Monitoring and Modelling Consumer Perception of Food-related Risks' and 'Eliciting and Modelling Consumers' and Experts' Perception of Food-related Risks').

92 As the applicant was well aware of that risk, it asked for an expedited procedure in order to reduce the period between the commencement of the main action and the delivery of the judgment. The regrettable dismissal of that application makes it even more urgent to grant the suspension of operation requested in these proceedings.

93 According to the Council, there is no risk that serious and irreparable harm will be caused to the applicant if the requested suspension of operation is not granted.

94 The Council points out, first of all, that the burden of proving the likelihood that serious and irreparable harm will occur lies with the party requesting the interim measure. In the present case, it is clear that there is no risk that, following the implementation of the contested regulation, the applicant will suffer irreparable financial harm, that is to say, that its very survival will be at risk. Referring to the applicant's statements, contained in its application for an expedited procedure, that interlocutory proceedings are inappropriate when the applicant is a legal person forming part of a large group which, in order to protect financial interests, seeks suspension of a measure based on a risk to human health, the Council notes that the applicant actually acknowledged that an interim measure would not be appropriate. At the hearing, it added that the risk of the Solvay group to which the applicant belongs going into liquidation is highly unlikely in the light of its annual turnover of approximately EUR 8 thousand million.

95 As for the losses which turkey-farmers might suffer, such loss suffered by third parties cannot justify granting the requested suspension of operation (see the order in *Pfizer*, paragraph 136). The harm to the farmers would not inevitably have an irreversible impact on the market for the sale of Nifursol if the contested regulation were annulled. That consequence appears even less likely in the light of the applicant's claims that Nifursol is essential in turkey-farming. In any event, according to the Council, a similar but more certain loss of market (given that the prohibited substances were partly replaceable by competing products) was rejected by the President of the Court in his order in *Pfizer*.

96 With regard to the arsenic-based product used in the United States, it is very unlikely that, even if an application for its authorisation were made to the Community authorities, it would be granted before judgment is given in the main proceedings.

— Balancing of interests

97 The applicant claims that the immediate implementation of the contested regulation would have harmful consequences from the point of view of the protection of animal health and would entail irreversible harmful consequences in financial terms for the whole Community turkey-farming sector. That is all the more the case owing to the fact that, since the withdrawal of Dimetridazole as a veterinary medicinal product on 1 July 2002, Nifursol has become essential for preventing histomoniasis in turkeys. The possible hygiene measures which could be taken to combat that disastrous disease would be totally inadequate to control the risk, unless they were combined with the administration of Nifursol.

98 At the hearing the applicant stressed the fact that such measures would be particularly ineffective in so-called 'alternative' farming in the light of the roles of hosts and carriers of the parasite played by worms and insects. The small and medium-sized undertakings, often family concerns, involved in turkey-farming, and, above all, the owners of alternative farms which are often small, would be very exposed to the risk of histomoniasis occurring on their farms. It is only in the Scandinavian countries where the production of turkey-meat is relatively small that these methods are currently considered to be appropriate.

99 The applicant maintains that the implementation of the prohibition would considerably weaken Community production in relation to the competition resulting from the importation of turkey-meat from non-member countries, where production is subject to less strict rules concerning the use of therapeutic products or prophylactic additives. In that regard, the applicant refers to a letter from a German undertaking (Annex RA12 to its application for interim relief) in which it is stated that, in the German turkey market, the level of imports is almost 50%, comprising in part imports from non-member countries where the use of medicinal products already prohibited in the Community is still possible and subject to little control. At the hearing, it was claimed that there would probably be an increase in imports from the United States, the world's leading turkey-meat producer, where histomoniasis is controlled by a product based *inter alia* on arsenic.

100 The contested regulation is not justified by the established existence of a considerable or significant risk to human health but by an alleged lack of adequate data on which to conclude that there is no risk. However, nothing has changed since Nifursol was first included in Annex I to Directive 70/524 in 1988. The fact that the Community legislature took more than four years in the present case, since the opening in July 1998 of the alleged re-evaluation of Nifursol, to react to an allegedly serious risk shows that the risk was not of a serious nature. If the requested suspension of operation were granted and if the hypothetical risk

currently feared by the Community authorities became a reality, the Council could always ask the President of the Court, under Article 108 of the Rules of Procedure, to revoke the suspension immediately. It follows, according to the applicant, that the requirements connected with the protection of public health are not so imperative that they preclude the grant of the requested suspension.

101 In any event, the President of the Court may authorise interim measures if evidence of a manifest error is revealed or if it appears that a misuse of powers has been committed by the Community authorities (order of the President of the Court of Justice in Case C-471/00 P(R) *Commission* v *Cambridge Healthcare Supplies* [2001] ECR I-2865). That is the position in this case, according to the applicant, since the reason for the contested regulation is in reality the shortage of available data, although the Commission could have called on the applicant, as the person responsible for putting Nifursol on the market, to provide those data within a specific period, failing which its authorisation would be withdrawn.

102 The Council maintains that, even if the risk of irreparable harm is established, neither the applicant's financial interest nor that of the turkey-farmers can prevail over the general interest inherent in protecting the public against a substance suspected of being genotoxic. It points out that the applicant appears to share that opinion in its application for an expedited procedure.

103 According to the Council, there are alternative methods of combating histomoniasis, in particular by the use of certain hygienic practices in farming. Furthermore, turkey-farming became viable in Europe only after the first authorisation of the additive Nifursol in 1982. Supported by the Commission, the Council pointed out at the hearing that in Finland, Sweden and Denmark, at least, these alternative methods are used effectively enough. There is therefore no real risk for the future of turkey-farming in the Community. The fact of the matter is that manufacturers will have to agree to finance production methods

which are more costly but do not present risks for consumer health. If large French, Italian and German producers, in particular, risked being affected by more frequent outbreaks of histomoniasis after the withdrawal of Nifursol, the protection of animal health could still not override the paramount general interest which requires human health to be protected.

Findings of the President of the Court

104 It should be observed, as a preliminary point, that the fact that the Court of First Instance (Second Chamber) decided, on 22 January 2002, to reject the applicant's request that the Court adjudicate on the substance of the action under an expedited procedure cannot influence either the assessment of urgency or, should it prove necessary, the balancing of the interests concerned by the Judge hearing the application for interim measures. The relevant criteria for the existence of a 'particular urgency' which, under Article 76a(1) of the Rules of Procedure, is to be satisfied if the Court is to adjudicate under an expedited procedure and those which, according to the case-law, govern the assessment of the condition of urgency that must be satisfied before the Judge hearing an application for interim measures is able to adopt such measures are only partly the same (see the order of the President of the Court of First Instance in Joined Cases T-195/01 R and T-207/01 R *Government of Gibraltar* v *Commission* [2001] ECR II-3915, paragraph 94). Furthermore, the grant of an application for a case to be decided under an expedited procedure lies within the discretion of the Court, as is apparent from the use of the word 'may' in the first subparagraph of Article 76a(1) of the Rules of Procedure and requires that account also be taken of other circumstances, including the impact which the grant will have on the length of the proceedings in other cases.

105 Since the Council pointed out in its observations on the application for an expedited procedure that, if new scientific data submitted by the applicant confirm that Nifursol complies with the conditions for being authorised, a new application for authorisation could be submitted, it is necessary to note, also as a preliminary point, that the existence of that possibility cannot affect the urgency

of this application for interim relief. Since that application relates to the main action brought by the applicant against the contested regulation, it is necessary to assess its urgency only in relation to the possible need to suspend provisionally the withdrawal of authorisation ordered by that regulation.

106 It is clear from well-established case-law that damage of a purely pecuniary nature cannot, save in exceptional circumstances, be regarded as irreparable or even as being reparable only with difficulty, if it can ultimately be the subject of financial compensation (order of the President of the Third Chamber of the Court of Justice in Case 141/84 R *De Compte* v *Parliament* [1984] ECR 2575, paragraph 4; order in *Commission* v *Cambridge Healthcare Supplies,* cited above, paragraph 113, and order in *Pfizer*, paragraph 137).

107 Under that principle, the suspension sought could be justified only if it appeared that, if the measure were not granted, the applicant would be placed in a situation which would endanger its very existence or irremediably affect its market share (order in *Pfizer*, paragraph 138).

108 As regards the first of these hypotheses, it need only be noted that, for the purposes of assessing the economic circumstances of an applicant, consideration may be given, in particular, to the characteristics of the group of which, by virtue of its shareholding structure, it forms part (orders of the President of the Court of Justice in Case C-12/95 P *Transacciones Marítimas and Others* v *Commission* [1995] ECR I-467, paragraph 12, and Case C-43/98 P(R) *Camar* v *Commission and Council* [1998] ECR I-1815, paragraph 36; and order in *Pfizer*, paragraph 155). In the present case, having regard to the group to which the applicant belongs (see paragraph 94 above), it cannot be presumed that it risks going into liquidation before judgment is given on the substance owing to losses, even though those may potentially be large, which it may suffer following the withdrawal ordered by the contested regulation. It is therefore not surprising that the applicant does not invoke the risk of irreparable harm of a purely financial nature.

109 As regards the second hypothesis, the applicant claims, in essence, that there is a risk that almost all the market for the sale of Nifursol, namely that in the Community, will disappear or be significantly and irremediably reduced before judgment is given on the substance. As for the other European countries in which there is currently authorisation to put Nifursol on the market, the applicant claims that the authorities will soon follow the example of the contested regulation and prohibit it.

110 With regard to the alleged risk of the introduction of a prohibition against putting Nifursol on certain markets in non-member European countries, as the Council rightly pointed out, referring in particular to the order in *Pfizer* (paragraph 160), that risk cannot validly be invoked to establish the urgency for suspending a Community measure such as the contested regulation, without evidence that the grant of the requested suspension of operation will prevent the materialisation of the harm feared. No evidence of that kind was adduced by the applicant, particularly with regard to the position which would be adopted by the Hungarian, Polish, Slovak and Czech authorities if the suspension requested in these proceedings were refused. It therefore cannot be concluded that the order in the present case will directly and definitely influence the decision-making process in those countries, at least before their possible accession to the European Union as from 1 May 2004.

111 It is therefore necessary to examine the scope of the alleged risk that the Community turkey-farming market will be seriously and irremediably adversely affected between now and the judgment on the substance.

112 In that regard, it must be stated that the evidence adduced by the applicant in the annexes to its application for interim relief (in particular, the letters produced in Annexes RA3, RA6, RA10, RA11, RA12 and RA15) tends to prove satisfactorily the likelihood of the risk that the Community turkey-meat production industry

will be not insignificantly reduced. Although it is true that the Community institutions party to these proceedings claim that all producers may, in principle, use the hygiene practices used in the Scandinavian Member States, that claim disregards the fact that the level of production in those countries is very low in relation to that of the other Member States in which Nifursol was widely used until the contested regulation came into force. It therefore seems unlikely that the use of those practices is enough to protect the Community market against the serious consequences of the withdrawal of the authorisation of Nifursol.

113 The Council, supported by the Commission, claims that that reduction is not irreversible. Since the additives in the feedingstuffs given to turkeys are not stated on the labels on the end product which the consumer finds on the shelves at sales outlets and since there is no doubt as to the effectiveness of Nifursol for the producers of that meat, it would not too difficult, if the contested regulation were annulled, for the applicant to relaunch Nifursol. Furthermore, the Council points out that, according to settled case-law, if there are no obstacles of a structural or legal nature preventing the manufacturer of a product, who is required to have a marketing authorisation, from regaining a significant proportion of its market share with the help *inter alia* of appropriate publicity measures, it cannot be ruled out that the loss caused by a withdrawal of its authorisation is essentially of a financial nature (*Commission* v *Cambridge Healthcare Supplies*, cited above, paragraphs 111 and 113, and *Pfizer*, cited above, paragraphs 160 and 161).

114 In the light of that case-law, these arguments appear persuasive. At the present time, Nifursol is the only sure means of combating histomoniasis available to farmers in the European Union. The reputation it enjoys amongst them for effectiveness does not seem to be seriously undermined by the contested regulation and, indeed, is clearly evidenced by the various documents in the annexes to this application for interim relief. Furthermore, it should be pointed out that, since July 2002, it has not had any real competition in the Community turkey-farming market.

115 Moreover, the Council, when questioned at the hearing about the tests carried out on turkey-meat imports from non-member countries, stated *inter alia* that residues of arsenic were not found. There is therefore no reason to suppose that the probable reduction in the level of Community turkey-meat production following the implementation of the contested regulation will not be offset to a large extent by an increase in the Community market share of the sale of that meat represented by the imports from non-member countries, above all those from the United States, the world's leading turkey-meat producer.

116 Since the validity of the Council's statement, which was made with the support of the Commission at the hearing, that the arsenic-based competing product used in the United States will probably not be authorised in the Community between now and judgment on the substance was not seriously challenged by the applicant, it seems that there is very little risk that the use of that product will replace the use of Nifursol amongst the European turkey-meat producers who, until now, were the applicant's customers and who will manage in the meantime to avoid outbreaks of histomoniasis on their farms.

117 In those circumstances, notwithstanding the probable reduction in the number of Community turkey-meat producers, it appears that this will not be — at least not wholly — irremediable. If the contested regulation is annulled, it seems likely that at least a significant number of the producers still in the market, perhaps with a level of production which is lower because of fear of histomoniasis outbreaks, will return easily enough to using Nifursol, in view of its effectiveness and the lack, within the Community, of a real alternative product. That will, in all probability, also be the case for producers who, having stopped producing turkey-meat because of the risk of histomoniasis when Nifursol is not available, will always be able to return to it after the annulment. Although the applicant's fear that certain supermarket chains, in particular, may prefer to sell 'Nifursol-free turkey-meat', in spite of the annulment of the contested regulation, is not

unfounded, it is difficult to believe that that sales policy will be pursued by all or some of the large retailers in the Community. In any event, no evidence of the intentions of the large retailers in that regard has been adduced before the President of the Court.

118 However, the President of the Court cannot wholly preclude that the Council's arguments underestimate the difficulties which the applicant would have, probably at each level of the production chain and above all at the levels of the farmers and large retailers, in relaunching its product in two years at least. In that regard, it should be added that independent studies carried out by the Food Standards Agency (see paragraph 91 above) demonstrate, in the light of all the recent food scares, how difficult it is for the manufacturer of a product used in the food chain to restore consumers' lost confidence. The loss of market suffered by the applicant might therefore be partly irremediable.

119 Furthermore, and more significantly, it is difficult to preclude that the structure of the Community market for the sale of turkey-meat will not be permanently and not insignificantly altered between now and the date on which judgment is given on the substance. In the meantime, importers from non-member countries will have risen to a higher position in that structure than the one they have occupied up to now. It may be difficult, if not almost impossible, for the applicant to oust them subsequently (see, to this effect, the orders of the President of the Court of First Instance in Case T-65/98 R *Van den Bergh Foods* v *Commission* [1998] ECR II-2641, paragraph 66, and in Case T-184/01 R *IMS Health* v *Commission* [2001] ECR II-3193, paragraph 129).

120 In those circumstances, it has to be concluded that the risk of damage which is serious and partly irreparable or reparable only with difficulty following the withdrawal of Nifursol during the course of the main proceedings cannot be ruled out in the present case. It is therefore necessary to balance the interests in question.

121 In that regard, the applicant's interest in obtaining the suspension of the operation of the contested regulation cannot prevail in the present case over the Community's interest in withdrawing the authorisation of Nifursol with a view to protecting public health.

122 It is important to point out, in the first place, that, as a rule, there can be no question but that the requirements of the protection of public health must take precedence over economic considerations (order of the Court of Justice in Case C-180/96 R *United Kingdom* v *Commission* [1996] ECR I-3903, paragraph 93; orders of the President of the Court of Justice in Case C-459/00 P(R) *Commission* v *Trenker* [2001] ECR I-2823, paragraph 109; Case C-474/00 P(R) *Commission* v *Bruno Farmaceutici and Others* [2001] ECR I-2909, paragraph 112; *Commission* v *Cambridge Healthcare Supplies*, cited above, paragraph 121, and the order in *Pfizer*, paragraph 171). It follows that, where a serious risk to human health is invoked by a defendant Community institution, the Judge hearing the application for interim relief, notwithstanding his formal discretion in balancing the interests, will almost inevitably lean in favour of protecting public health.

123 Secondly, it should be pointed out that that is the case even if the urgency justifying the grant of the interim measure requested is, unlike in the present case, obvious (see the order in *Commission* v *Artegodan*, cited above, in particular paragraphs 75 to 77, by which *inter alia* the order of the President of the Court of First Instance in Case T-74/00 R *Artegodan* v *Commission* [2000] ECR II-2583 was revoked).

124 When balancing the interests, the Judge hearing the application for interim relief has to determine whether the annulment of the contested measure by the bench hearing the main action would enable the situation brought about by its immediate implementation to be reversed and, conversely, whether suspension of the operation of that measure would be such as to prevent its being fully effective in the event of the main application being dismissed (orders in *Commission* v *Atlantic Container Line and Others* cited above, paragraph 50, and *United Kingdom* v *Commission*, cited above, paragraph 89).

125 In the present case, apart from its own interest in avoiding a non-quantifiable economic loss arising from the probable bankruptcy of a large number of Community turkey-meat producers and the irreversible increase in the imports of turkey-meat from non-member countries, the applicant pleads other economic and social interests, namely those of the Community producers and above all the risk of bankruptcy for a large number of small and medium-sized undertakings involved in alternative turkey-farming. However, the protection of those interests, although commendable, cannot outweigh the damage which might be caused by the suspension of the contested regulation if the reality of the risk on which the Council based the regulation is confirmed (order in *United Kingdom* v *Commission,* cited above, paragraph 91, and the order in *Pfizer*, paragraph 170).

126 In that regard, the fact that the Council (or the Commission) may have recourse to Article 108 of the Rules of Procedure, should the requested suspension be granted and should more scientific data be available before the judgment on the substance, in order to justify the withdrawal ordered by the contested regulation, is not enough to eliminate the risks presented in the meantime by the transmission to consumers of potentially genotoxic residues.

127 As for the protection of animal health, also invoked by the applicant, although it is true that an increase in morbidity and mortality in Community turkey-farming caused by more frequent and disastrous outbreaks of histomoniasis is foreseeable from now on, the protection of animal health — the importance of which is, admittedly, acknowledged in Community law, particularly in Article 30 EC — cannot outweigh the pre-eminent nature of the requirements related to human health (see, with regard to the limits on protecting animal health, *inter alia*, the judgments of the Court of Justice in Case 40/82 *Commission* v *United Kingdom* [1982] ECR 2793, paragraph 44, and Case C-1/96 *Compassion in World Farming* [1998] ECR I-1251, paragraph 66).

128 It follows from all the foregoing considerations that all the conditions for granting the suspension of operation of the contested regulation requested in the present case are not satisfied. The President of the Court must therefore dismiss this application for interim measures.

On those grounds,

THE PRESIDENT OF THE COURT

hereby orders:

1. **The application for interim measures is dismissed.**

2. **Costs are reserved.**

Luxembourg, 11 April 2003.

H. Jung — Registrar

B. Vesterdorf — President