JUDGMENT OF THE COURT OF FIRST INSTANCE (Second Chamber)

1 December 1999 *

In Joined Cases T-125/96,

Boehringer Ingelheim Vetmedica GmbH

and

C.H. Boehringer Sohn,

companies incorporated under German law, established in Ingelheim am Rhein (Germany), represented by Denis Waelbroeck and Denis Fosselard, of the Brussels Bar, with an address for service in Luxembourg at the Chambers of Ernest Arendt, 8-10 Rue Mathias Hardt,

applicants,

supported by

Fédération Européenne de la Santé Animale (Fedesa), an association incorporated under Belgian law, established in Brussels, represented by Alexandre Vandencasteele, of the Brussels Bar, with an address for service in Luxembourg at the Chambers of Ernest Arendt, 8-10 Rue Mathias Hardt,

and

United Kingdom of Great Britain and Northern Ireland, represented by Lindsey Nicoll, of the Treasury Solicitor's Department, acting as Agent, and by David

* Language of the case: English.

Lloyd Jones, Barrister, of the Bar of England and Wales, with an address for service in Luxembourg at the Embassy of the United Kingdom, 14 Boulevard Roosevelt,

interveners,

v

Council of the European Union, represented by Moyra Sims-Robertson and Ignacio Díez Parra, Legal Advisers, acting as Agents, with an address for service in Luxembourg at the office of Alessandro Morbilli, Manager of the Legal Affairs Directorate of the European Investment Bank, 100 Boulevard Konrad Adenauer,

defendant,

supported by

Stichting Kwaliteitsgarantie Vleeskalverensector (SKV), a foundation incorporated under Netherlands law, established in The Hague, represented by Gerard van der Wal, advocate before the Hoge Raad der Nederlanden, and Laura Paret, of the Brussels Bar, with an address for service in Luxembourg at the Chambers of Aloyse May, 31 Grand-Rue,

and

Commission of the European Communities, represented by Xavier Lewis, of its Legal Service, acting as Agent, with an address for service in Luxembourg at the

office of Carlos Gómez de la Cruz, also of its Legal Service, Wagner Centre, Kirchberg,

interveners,

APPLICATION for the partial annulment of Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ 1996 L 125, p. 3) together with a claim for compensation,

and T-152/96,

Boehringer Ingelheim Vetmedica GmbH
and
C.H. Boehringer Sohn,

applicants,

supported by

Fedesa,

intervener,

Commission of the European Communities,

defendant,

supported by

SKV

and

Council of the European Union,

interveners,

APPLICATION for the partial annulment of Commission Regulation (EC) No 1312/96 of 8 July 1996 amending Annex III of Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ 1996 L 170, p. 8),

THE COURT OF FIRST INSTANCE
OF THE EUROPEAN COMMUNITIES (Second Chamber),

composed of: A. Potocki, President, C.W. Bellamy and A.W.H. Meij, Judges,
Registrar: B. Pastor, Principal Administrator,

having regard to the written procedure and further to the hearing on 12 May 1999,

gives the following

Judgment

Factual and legislative background

1 Beta-agonists are substances used primarily for the treatment of respiratory problems in both humans and animals.

2 Clenbuterol hydrochloride (hereinafter 'clenbuterol') is a chemical compound in the beta-agonist category, used as the active ingredient in certain medicines. In veterinary medicine, its therapeutic effects are as follows:

— bronchospasmolysis action (dilation of the bronchial tracts in order to ease breathing in the event of an infection of the upper respiratory tracts);

— cardiac stimulation of equines and bovines;

— induction of tocolysis in cows when calving (relaxation of the uterus to facilitate parturition).

3 The first applicant, Boehringer Ingelheim Vetmedica GmbH (hereinafter 'BI Vetmedica'), develops and markets veterinary medicinal products. It is a wholly owned subsidiary of the second applicant, C.H. Boehringer Sohn (hereinafter 'Boehringer'), which is one of the leading twenty pharmaceutical companies in the world.

4 With the exception of Agraria Pharma GmbH (hereinafter 'Agraria'), BI Vetmedica is the only pharmaceutical company within the European Union to produce and market veterinary medicinal products containing a beta-agonist, namely clenbuterol, for the treatment of respiratory disorders in production animals (those intended for commercial purposes and whose flesh and products are consumed by humans). Since, however, Agraria markets its medicinal product containing clenbuterol in Germany only, its turnover for that product is very low. The applicants claim to account for 'almost 97% of the sales of the veterinary medicinal products affected by the prohibition of beta-agonists' provided for in Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ 1996 L 125, p. 3), and 'about 99% of sales in the European Union of the veterinary medicinal products concerned' by Commission Regulation (EC) No 1312/96 of 8 July 1996 amending Annex III of Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ 1996 L 170, p. 8). According to the information provided by the applicants in reply to the written questions of the Court of First Instance, their

sales of veterinary medicinal products containing clenbuterol in Member States (taking all uses and products together) represented a turnover of DEM 13 528 063 in 1995.

5 BI Vetmedica and its subsidiaries manufacture and distribute those veterinary medicinal products in most of the Member States, pursuant to authorisations granted by the competent national authorities, under the trade marks Ventipulmine, Spasmobronchal, Ventipulmine-TMPS and Planipart, which have also been registered in most Member States. Planipart, however, which is designed to induce tocolysis in bovines, remains authorised and is not at issue in these proceedings. The patent held by the applicants, and which gave them a monopoly in marketing clenbuterol, expired in 1988.

6 Although beta-agonists are not growth hormones, they have also been known for their anabolic action since the 1980s. When used in high doses, well above those prescribed for therapeutic purposes, they provoke a considerable 'repartitioning effect', consisting of reduced synthesis of fat tissue and a reduction in protein degradation. Their use by farmers therefore makes it possible to obtain animals with a high flesh-to-fat ratio. It is estimated that the meat content of an animal may increase by between 10 and 26%, whilst its fat content may fall by between 10 and 30%.

7 It is not disputed that, in practice, the clenbuterol-based veterinary medicinal products marketed by the applicants cannot profitably be used in order to obtain that 'repartitioning effect', in view of their packaging and low clenbuterol content in relation to their cost.

8 Nor is it disputed, however, that certain firms and individuals market clenbuterol and other beta-agonists as bulk chemicals, in the form of highly concentrated powders and liquids, as low cost products, for the purposes of artificially fattening bovines.

9 The administration of beta-agonists in doses higher than those prescribed for therapeutic purposes can provoke certain side-effects harmful to the health of the animals, in particular, disturbances in temperature regulation and the endocrine systems, an increase in heart rate and sweating, muscle tremors and a reduction in resistance to stress. Furthermore, the meat is of lower quality; it becomes darker, is less tender and has impaired taste because of the reduction in intra-muscular fat.

10 Although the beta-agonists which are authorised in the European Community are safe products when used for therapeutic purposes on humans or animals, their use as growth factors in food-producing animals has been shown to involve certain risks for human health. Beta-agonist residues found in the meat of animals treated with very high, non-therapeutic, doses have, in particular, caused food poisoning in a number of cases in humans, the main symptoms being an increase in heart rate, severe headaches, tremors and palpitations, nervousness, a reduction in blood pressure and muscle tetany for several days. According to the information provided by the Council, the countries most affected are Spain (135 cases of poisoning in 1990, 200 in 1992 and 136 in 1994), France (22 cases in 1990) and Italy (62 cases in 1996).

11 According to the information provided by the parties in reply to the written questions of the Court of First Instance, even before the adoption of Directive 96/22, the marketing and use of veterinary medicinal products containing clenbuterol for the treatment of respiratory problems of bovines were not authorised in a number of Member States (Denmark, Finland, France, Greece and Sweden) and non-member countries (Argentina, Australia, Canada, the United States and New Zealand). The applicants have stated, however, that, for various reasons, they never sought to obtain such authorisation in those countries. As regards Argentina, its aim was to preserve its access to the Community market.

12 Public opinion in Member States has shown itself to be very concerned by the effects on human health of beta-agonist residues in meat intended for human

consumption. Many articles have appeared in the press, both in specialised journals and in daily newspapers, and various reports have been published, including, in October 1993, an information report drawn up by Schuman Associates under the auspices of the European Parliament.

13 In the context of a widespread enquiry carried out in the Member States between 1990 and 1992 on the misuse of beta-agonists, the Commission stated, *inter alia*, that, in practice, the detection of fraud, especially involving the use of clenbuterol, had been rendered more difficult by the existence of the medicinal products marketed by the applicants. Indeed, whenever clenbuterol was found to have been administered to animals, the farmers claimed that that was only as a result of the legal use of one of those products.

14 On 21 April 1993 the Commission submitted its findings in a Communication to the Council and the European Parliament on control of residues in meat (COM(93) 167 final), in which, *inter alia*, it expressed the following view (at paragraph 30):

'The question arises as to whether control of the misuse of beta-agonists would be substantially improved by their total prohibition, including for therapeutic uses. The broad consensus among those charged with control in the Member States is that the misuse of beta-agonists has become a serious problem and that a prohibition would greatly ease the difficulty of proving illegal intent. While normally reluctant to propose removal from the market of a product with therapeutic uses, the Commission has come to the conclusion that a total ban on beta-agonists, except for the therapeutic treatment of horses and pet animals, would be a significant help to control. In taking this view, the Commission is influenced also by indications that replacement products are generally available for therapeutic purposes'.

15 On 14 October 1993 the Commission submitted to the Council a proposal for an EEC regulation concerning the prohibition on the use in stockfarming of certain

substances having a hormonal or thyrostatic action and of beta-agonists (OJ 1993 C 302, p. 8) which provided, *inter alia*, for a total ban on the placing on the market of beta-agonists intended to be administered to all species of animals, with the exception of therapeutic use for equines and domestic carnivorous animals.

16 In various letters to the members and departments of the Commission and to the competent authorities of the Member States, the applicants submitted that banning their veterinary medicinal products containing clenbuterol would harm animal welfare and deprive BI Vetmedica of its officially recognised right to manufacture and market those medicinal products. Furthermore, they claimed that other less restrictive measures than the total ban advocated, in particular the practical implementation by the Member States of the control measures already provided for by Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States concerning veterinary medicinal products (OJ 1981 L 317, p. 1), as amended by Council Directive 90/676/EEC of 13 December 1990 amending Directive 81/851/EEC (OJ 1990 L 373, p. 15) would be sufficient to combat the misuse of clenbuterol and other beta-agonists.

17 In that regard, the applicants have referred more particularly to Article 50c of Directive 81/851, as amended by Directive 90/676, according to which:

'Member States shall ensure that the owners or keepers of food-producing animals can provide proof of purchase, possession and administration of

veterinary medicinal products containing the substances set out in Article 1(5) [these include beta-agonists in particular] [...]

In particular, Member States may require the maintenance of a record giving at least the following information:

(a) date;

(b) identity of the veterinary medicinal product;

(c) quantity;

(d) name and address of the supplier of the medicinal product;

(e) identification of the animals treated.'

18 The applicants have also referred to Article 1(5) of Directive 81/851, as amended by Directive 90/676, whereby:

'Member States shall take all measures necessary to ensure that only persons empowered under their national legislation in force possess or have under their

control veterinary medicinal products or substances which may be used as veterinary medicinal products that have anabolic [...] properties.

Member States shall maintain a register of producers and dealers permitted to be in possession of active substances which may be used in the manufacture of veterinary medicinal products having the properties referred to in the first subparagraph. Such persons must maintain detailed records of all dealings in substances which may be used in the manufacture of veterinary medicinal products and keep these records available for inspection by the competent authorities for a period of at least three years.'

19 By letter of 28 October 1993, the Council consulted the Parliament pursuant to Article 43 of the EC Treaty (now, after amendment, Article 37 EC) on that proposed regulation.

20 In its report of 1 March 1994, the Committee on Agriculture, Fisheries and Rural Development of the European Parliament proposed that the placing on the market of beta-agonists for administration by a veterinarian for therapeutic purposes be permitted. The Committee on the Environment, Public Health and Consumer Protection of the European Parliament did not, however, support that view and proposed only minor amendments to the proposed Council regulation.

21 Without further consultation of the Parliament, the Council adopted, on 29 April 1996, on the basis of Article 43 of the Treaty, Directive 96/22/EC, Article 2(b) of

which provides that Member States are to prohibit 'the placing on the market of beta-agonists for administering to animals the flesh and products of which are intended for human consumption'. The fifth to ninth recitals in the preamble to Directive 96/22 state as follows:

'(5) whereas the results of an enquiry conducted by the Commission in the Member States from 1990 to 1992 show that beta-agonists are widely available in the livestock-rearing sector, leading to their illegal use;

(6) whereas the improper use of beta-agonists can be a serious risk to human health; whereas, in the interests of the consumer, the holding, administering to animals of any species and the placing on the market for that purpose of beta-agonists should be prohibited;

(7) whereas, however, the administering of medicinal products based on beta-agonists may be authorised for well-defined therapeutic purposes, in the case of certain categories of bovine animals, equidae and pets;

(8) whereas, moreover, it is necessary to ensure that all consumers are able to acquire meat and foodstuffs derived therefrom under the same conditions of supply and that those products correspond as closely as possible to their concerns and expectations; whereas, given consumer sensitivity, this can only bring about an increase in the consumption of the products in question;

(9) whereas the prohibition on the use of hormonal substances for fattening purposes should continue to apply; whereas the use of certain substances for

therapeutic or zootechnical purposes may be authorised but must be strictly controlled in order to prevent any misuse'.

22 Article 3 of Directive 96/22/EC provides that Member States are to prohibit:

'(a) the administering to a farm [...] animal [...] of beta-agonists;

(b) the holding, except under official control, of animals referred to in (a), on a farm, the placing on the market or slaughter for human consumption of farm animals [...] which contain the substances referred to in (a) or in which the presence of such substances has been established, unless proof can be given that the animals in question have been treated in accordance with Articles 4 or 5;

[...]

(d) the placing on the market of meat of the animals referred to in (b);

(e) the processing of the meat referred to in (d).'

23 Article 4(2) of Directive 96/22/EC provides that, by way of derogation from Articles 2 and 3, Member States may authorise:

'2. the administering for therapeutic purposes of authorised veterinary medicinal products containing:

(i) allyl trenbolone, administered orally, or beta-agonists to equidae and pets, provided they are used in accordance with the manufacturer's instructions;

(ii) beta-agonists, in the form of an injection to induce tocolysis in cows when calving.

Such substances must be administered by a veterinarian or, in the case of the veterinary medicinal products referred to in (i), under his direct responsibility; treatment must be registered by the veterinarian responsible, who shall record at least the details referred to in point 1.

Farmers shall be prohibited from holding veterinary medicinal products containing beta-agonists which may be used for induction purposes in the treatment of tocolysis'.

24 Article 1(2)(b) of Directive 96/22 defines 'therapeutic treatment' as 'the administering — under Article 4 of this directive — to an individual farm animal of an authorised substance to treat, after examination by a veterinarian, a fertility

problem [...] and, in the case of beta-agonists, to induce tocolysis in cows when calving and to treat respiratory problems and to induce tocolysis in equidae raised for purposes other than meat production'.

25 According to Article 14, Directive 96/22 was to be transposed into national law before 1 July 1997. In the meantime, the relevant national rules continued to apply in compliance with the general provisions of the Treaty.

26 In order to strengthen the controls carried out by and in the Member States, the Council also adopted Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ 1996 L 125, p. 10). According to Article 3, the production process of animals and primary products of animal origin must be monitored 'for the purpose of detecting the presence of the residues and substances listed in Annex I'. Beta-agonists are included in that annex. Council Regulation (EC) No 894/96 of 29 April 1996 amending Regulation (EEC) No 805/68 on the common organisation of the market in beef and veal, with regard to penalties (OJ 1996 L 125, p. 1), also provides for the imposition of more stringent penalties on producers where unauthorised substances, or authorised substances used illegally, are detected on inspection of an animal or found on a farm.

27 Council Regulation (EEC) No 2377/90 of 26 June 1990 lays 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).

28 Pursuant to that regulation, the Commission establishes the maximum residue limit ('MRL'), defined in Article 1(1)(b) as the maximum concentration of residue resulting from the use of a veterinary medicinal product 'which may be accepted by the Community to be legally permitted or recognised as acceptable in or on a food'.

29 Regulation No 2377/90 provides that, after assessment of the risks which they represent for public health, pharmacologically active substances used in veterinary medicinal products are to be included in one of the four lists provided for in the following annexes:

— Annex I, for substances in respect of which an MRL may be established (see Article 2);

— Annex II, for substances in respect of which it does not appear to be necessary to establish an MRL (see Article 3);

— Annex III, for substances already used on the date of the entry into force of Regulation No 2377/90, or, by way of exception, which are not yet used, in respect of which it is not possible definitively to establish an MRL but which, providing their residues at the level proposed present no hazard for human health, may be given a provisional MRL (see Article 4);

— Annex IV, for substances in respect of which no MRL can be established, by reason of their hazardous nature (see Article 5).

30 Pursuant to Article 14 of Regulation No 2377/90, with effect from 1 January 1997, the administration to food-producing animals of veterinary medicinal

products containing pharmacologically active substances which are not mentioned in Annexes I, II or III is, in principle, prohibited within the Community.

31 Article 6 of Regulation No 2377/90 lays down the procedure for including a new pharmacologically active substance in Annexes I, II or III.

32 Regulation No 2377/90 also lays down, in Article 7, the procedure applicable to pharmacologically active substances which are authorised for use in veterinary medicinal products on the date of its entry into force. The persons responsible for marketing the veterinary medicinal products concerned must ensure that all necessary information is submitted to the Commission before expiry of the relevant time-limit (Article 7(2)). After verification, within a period of 30 days, that the information is presented in correct form, the Commission submits it forthwith for examination to the Committee for Veterinary Medicinal Products (the 'CVMP'), which must deliver its opinion within a period of 120 days (Article 7(3)). Having regard to the observations of the CVMP, the Commission prepares, within a maximum period of 30 days, a draft of the measures to be taken. It may, if necessary, request the person responsible for marketing the product to supply further information to the CVMP (Article 7(4)). That draft is communicated 'forthwith' to the Member States and to the person responsible for marketing who may, at the request of the CVMP, supply it with written or oral explanations (Article 7(5)). The Commission submits the proposed measures 'forthwith' to the Committee for the Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products (Article 7(6)), which is composed of representatives of the Member States and presided over by a representative of the Commission. Under Article 8 of Regulation No 2377/90, that committee must deliver an opinion on the draft within a time-limit set by the chairman. The Commission adopts the measures envisaged where they are in accordance with the opinion of the committee (Article 8(3)(a)). Where the measures envisaged are not in accordance with that opinion, or if no opinion is adopted, the Commission refers the matter to the Council, which acts by qualified majority (Arti-

cle 8(3)(b)). If, after a period of three months of the proposal being referred to it, the Council has not acted, the proposed measures are adopted by the Commission, unless the Council votes against them by a simple majority (Article 8(3)(c)).

33 Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 214, p. 1), establishes a centralised procedure for the grant of marketing authorisation for a veterinary medicinal product.

34 According to Article 31(3)(b) of that regulation, in the case of a medicinal product intended for administration to food-producing animals, a statement of the MRL which may be accepted by the Community in accordance with Regulation No 2377/90 is a prerequisite for the grant of marketing authorisation.

35 Pursuant to Article 34(2) of that regulation, the refusal of marketing authorisation constitutes 'a prohibition on the placing on the market of the veterinary medicinal product concerned throughout the Community'.

36 In accordance with Article 7 of Regulation No 2377/90, BI Vetmedica applied to the Commission on 20 July 1994 for the establishment of MRLs for clenbuterol as regards bovines and equidae. In an opinion of 3 January 1996, the CVMP recommended, for reasons of scientific methodology, the adoption of provisional MRLs, expiring on 1 July 2000.

37 On 8 July 1996 the Commission adopted Regulation (EC) No 1312/96, in which it established provisional MRLs for clenbuterol, but exclusively for the therapeutic purposes authorised under Directive 96/22/EC, namely, in the case of bovines, solely for inducing tocolysis in cows when calving and, in the case of equines, for inducing tocolysis and treating respiratory ailments. The sixth, seventh and ninth recitals in the preamble to Regulation No 1312/96 state as follows:

'Whereas, in order to allow for the completion of scientific studies, clenbuterol hydrochloride should be inserted into Annex III to Regulation (EEC) No 2377/90;

Whereas Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, prohibits the use of clenbuterol in all farm animals with the exception of some specific therapeutic purposes in equines and in cows;

[...]

Whereas the measures provided for in this regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products.'

Procedure

38 By application lodged at the Registry of the Court of First Instance on 9 August 1996, the applicants brought an action, registered as Case T-125/96, seeking partial annulment of Directive 96/22 and compensation for damage.

39 By application lodged at the Registry of the Court of First Instance on 27 September 1996, the applicants brought an action, registered as Case T-152/96, seeking primarily the partial annulment of Regulation No 1312/96.

40 By a separate application lodged at the Registry on 31 October 1996, the Council raised a plea of inadmissibility in Case T-125/96, pursuant to Article 114 of the Rules of Procedure.

41 By order of 13 June 1997 in Case T-125/96, the Court of First Instance granted leave to intervene, on the one hand, to Fedesa and the United Kingdom, in support of the forms of order sought by the applicants and, on the other, to the Commission and SKV, in support of the form of order sought by the defendant. By an order of the same date in Case T-152/96, the Court gave Fedesa leave to intervene in support of the applicants, and SKV and the Council leave to intervene in support of the defendant.

42 In Case T-125/96 the interveners submitted their written observations, initially limited to the admissibility of the action pursuant to paragraph 4 of the operative part of the aforementioned order, on 8 October 1997 (United Kingdom), 10 October 1997 (Fedesa and Commission) and 24 October 1997 (SKV) respectively. Following an informal meeting between the parties on 9 November 1998, the Court of First Instance asked the parties to clarify certain points of fact and, by order of 19 November 1998, joined the plea of inadmissibility raised by

the Council to the substance of the case. Fedesa, SKV and the Commission lodged their written observations on the substance on 5 March 1999. The United Kingdom waived its right to lodge such observations. By a letter received at the Registry of the Court of First Instance on 10 March 1999, the applicants waived their right to lodge a reply. The written procedure was therefore closed.

43 In Case T-152/96 the interveners submitted their written observations on 8 October 1997 (Council), 10 October 1997 (Fedesa) and 27 October 1997 (SKV) respectively.

44 On hearing the report of the Judge-Rapporteur, the Court of First Instance (Second Chamber) decided to open the oral procedure in both cases and to put certain written questions to the applicants, the Commission and the Council pursuant to Article 64 of the Rules of Procedure. Those parties replied by letters of 28 and 30 April 1999. The parties presented oral argument and replied to the oral questions of the Court at the public hearing on 12 May 1999.

45 In response to a letter from the Registry of 3 June 1999, in accordance with Article 50 of the Rules of Procedure, the parties stated that they had no objection to Cases T-125/96 and T-152/96 being joined for the purposes of the judgment.

Forms of order sought by the parties in Case T-125/96

46 The applicants claim that the Court should:

— annul Articles 1, 2, 3 and 4 of Directive 96/22/EC in so far as they prohibit the placing on the market of veterinary medicinal products containing beta-agonists intended to be administered for therapeutic purposes to animals the flesh and products of which are intended for human consumption;

— order the Community to make good the damage suffered by them as a result of the adoption of the contested measure;

— order the parties to produce to the Court, within a reasonable period from the date of the judgment, the figures corresponding to the amount of compensation agreed on between the parties;

— in the absence of any such agreement, order the parties to produce to the Court, within the same period, details of the sums claimed;

— order that interest at the annual rate of 8% be paid on the amount payable from the date of judgment;

— order the Council to pay the costs.

47 The defendant contends that the Court should:

— dismiss the application as manifestly inadmissible or, in the alternative, as unfounded;

— order the applicants to pay the costs.

48 Fedesa supports the pleas and forms of order sought by the applicants and requests that the Council be ordered to pay the costs of its intervention.

49 The United Kingdom claims that the Court should dismiss the Council's plea of inadmissibility as to the claim for compensation.

50 SKV supports the form of order sought by the defendant and requests that the applicants be ordered to pay the costs of its intervention.

51 The Commission supports the form of order sought by the defendant.

Forms of order sought by the parties in Case T-152/96

52 The applicants claim that the Court should:

— declare, in accordance with Article 184 of the EC Treaty (now Article 241 EC), that Directive 96/22/EC, in so far as it prohibits the placing on the market of veterinary medicinal products containing beta-agonists for administration for therapeutic purposes to farm animals, is illegal and therefore cannot serve to justify the restrictions contained in Regulation No 1312/96;

— annul Regulation No 1312/96 in so far as it restricts the validity of the MRLs established for clenbuterol to certain specific therapeutic purposes;

— order the Commission to pay the costs.

53 The defendant contends that the Court should:

— dismiss the application as inadmissible or, in the alternative, as unfounded;

— order the applicants to pay the costs.

54 Fedesa supports the pleas and forms of order sought by the applicants and requests that the Commission be ordered to pay the costs of its intervention.

55 SKV supports the form of order sought by the defendant and requests that the applicants be ordered to pay the costs of its intervention.

56 The Council contends that the Court should:

— dismiss the plea of illegality raised against Directive 96/22 as inadmissible or, in the alternative, as unfounded;

— dismiss the application as inadmissible or, in the alternative, as unfounded;

— order the applicants to pay the costs.

Preliminary observations concerning the subject-matter of the dispute and the procedure

57 The application for the partial annulment of Regulation No 1312/96 in Case T-152/96 is essentially based on the plea of illegality raised against Directive 96/22, the partial annulment of which forms part of the subject-matter of the action in Case T-125/96. Moreover, the arguments used by the applicants to challenge the legality of that directive are substantially the same in both cases.

58 In those circumstances, the Court considers it appropriate to rule first on the question of the legality of Directive 96/22, which is common to both cases, before examining the other issues of admissibility and substance raised by each of them.

The legality of Directive 96/22

59 For the purpose of establishing the illegality of Directive 96/22, the applicants raise four pleas in law. The first alleges breach of the principle of proportionality, the second, breach of the principles of legal certainty and protection of legitimate expectations, the third, breach of the principle of sound administration and the fourth, infringement of Article 43 of the EC Treaty.

The first plea, alleging breach of the principle of proportionality

Arguments of the parties

60 Whilst conceding that Directive 96/22 as a whole could have the effect of protecting human health and consumer expectations, the applicants submit that the sole purpose of the contested provisions is to make it easier for the national authorities to check on the illegal use of beta-agonists, by preventing farmers from justifying the residual presence of those substances in animals by reference to the fact that they administered to them veterinary medical products containing beta-agonists.

61 The applicants concede that clenbuterol may be used for the illicit purpose of fattening cattle. They emphasise nevertheless that only clenbuterol in the form of

a bulk chemical may be used for such purposes and that their veterinary medical products cannot be used in an abusive manner (see paragraph 7 above).

62 Furthermore, the applicants highlight the universally acknowledged safety, quality and efficacy of their veterinary medical products containing clenbuterol. They maintain that Ventipulmine, in particular, is considered by specialists in veterinary medicine to be an indispensable medicinal product for the treatment of respiratory diseases in bovines and equines, and that there is no substitute product with equivalent properties.

63 In the circumstances of the present case, the applicants submit that it is contrary to the principle of proportionality to jeopardise in this way the health of animals, which is protected by the Community legal order (see Article 36 of the EC Treaty, now, after amendment, Article 30 EC), when there is no risk to human health, simply because it would facilitate the work of national bodies. It would also be contrary to the principle of proportionality, in the same circumstances, to inflict upon the applicants severe financial losses such as to affect their rights to property and their right to pursue trade or professional activities (see Case 44/79 *Hauer* v *Land Rheinland-Pfalz* [1979] ECR 3727, paragraph 32; Case 265/87 *Schräder* v *Hauptzollamt Gronau* [1989] ECR 2237, paragraph 15; and Case C-177/90 *Kühn* v *Landwirtschaftskammer Weser-Ems* [1992] ECR I-35).

64 Furthermore, the applicants submit that the restrictions to fundamental rights, to which the contested measures give rise, are not necessary in order to achieve the aim pursued. They refer, first, to the Community procedure for establishing MRLs and, secondly, to Articles 1(5) and 50c of Directive 81/851, as amended by Directive 90/676 (see paragraphs 17 and 18 above), strict application of which in all Member States would make it easy to verify whether an animal had actually been therapeutically treated in accordance with the instructions of a veterinarian, who would himself be obliged to record the details in a register placed at the disposal of the competent authorities.

65 In that respect, the applicants point out that, as of the period between 1990 and 1992, most Member States had not yet adopted the implementing measures required by Directive 90/676. It was therefore impossible at that time to ascertain whether strict control measures were sufficient to combat effectively the illegal use of beta-agonists. In 1993 the Commission itself admitted before the European Parliament that it had 'detected a considerable improvement in the application of controls in the internal market since its enquiry in 1990-92' (see COM(93) 167 final of 21 April 1993, cited above). In addition, a significant reduction in the number of positive tests had been observed in several Member States.

66 Furthermore, the applicants point out that an efficient system of control, based on Directive 81/851, as amended by Directive 90/676, already existed in the United Kingdom, under which the owner of an animal found to contain residues of beta-agonists had to produce, within five days, written confirmation from the veterinarian who authorised its use. The effectiveness of that system is shown by the fact that the national authorities did not detect any clenbuterol residues under their monitoring scheme. The applicants also refer to the opinion of 5 August 1993 of the Veterinary Medicines Directorate (Executive Agency of the UK Ministry of Agriculture, Fisheries and Food), according to which the British system of control constitutes 'the way to resolve the present difficulties over the illegal use of beta-agonists'.

67 The applicants also submit that Directive 96/22 itself, and in particular Articles 8, 9 and 10 thereof, provides for such a system of control in cases where the administration of beta-agonists has been authorised (for example, for inducing tocolysis in cows when calving). The Community institutions have not explained why such a system of control was considered sufficient in some instances but not in others.

68 They also maintain that, in normal cases, legal therapeutic use of their products containing clenbuterol will not interfere with the work of the control agencies. It

is easy in most cases to ascertain whether illegal use has been made of beta-agonists simply by analysing the concentration of clenbuterol in the residues detected when monitoring the animals concerned.

69 Fedesa essentially supports the arguments of the applicants, and adds that, in accordance with the third recital in the preamble to Regulation No 2309/93, it is necessary, in the interest of public health, that decisions on the authorisation of medicinal products for human or veterinary use should be based solely on objective scientific criteria of quality, safety and efficacy, to the exclusion of economic or other considerations.

70 According to Fedesa, to allow a veterinary medicinal product to be withdrawn from the market for reasons not unconnected with those three criteria would result in a disincentive for companies in the pharmaceutical sector to invest in the development and improvement of their products.

71 Furthermore, in this case, veterinarians would themselves be deprived of an effective medicinal product, for which no real substitute exists. Fedesa refers in that respect to the opinion of Professor Ungemach of the Faculty of Veterinary Medicine at the University of Leipzig, to the effect that a serious therapeutic lacuna would arise from the prohibition on the use of beta-agonists.

72 At the very least, Fedesa submits that, even if the Council was entitled to prevent the use of a given substance for specific therapeutic use which does not present any risk to public health, that should be allowed only in exceptional cases where it appears that such a prohibition is the only way to prevent other uses which

present a risk for public health. In its view, those conditions are not satisfied in the present case.

Findings of the Court of First Instance

73 The principle of proportionality has been recognised in settled case-law as one of the general principles of Community law. According to that principle, measures of the Community institutions must not go beyond what is appropriate and necessary for achieving the objectives legitimately pursued by the measure in question, it being understood that, where there is a choice between several appropriate measures, recourse must be had to the least restrictive and that the disadvantages caused must not be disproportionate to the aims pursued (Case C-331/88 *The Queen* v *Minister for Agriculture, Fisheries and Food and Secretary of State for Health, ex parte Fedesa and Others* [1990] ECR I-4023, paragraph 13, and Case C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265, paragraph 96).

74 With regard to judicial review of those conditions, in matters concerning the common agricultural policy, the Community legislature has a discretionary power corresponding to the political responsibilities entrusted to it by Article 40 of the EC Treaty (now, after amendment, Article 34 EC) and Article 43 of the EC Treaty. Consequently, the legality of a measure adopted in that sphere can be affected only if the measure is manifestly inappropriate having regard to the objective which the competent institution is seeking to pursue (*Schräder*, cited above, paragraph 22; *Fedesa and Others*, cited above, paragraphs 13 and 14; *United Kingdom* v *Commission*, cited above, paragraph 97; and Joined Cases T-481/93 and T-484/93 *Exporteurs in Levende Varkens a.O.* v *Commission* [1995] ECR II-2941, paragraphs 119 and 120).

75 In this case, the applicants are not challenging the validity of the prohibition on using beta-agonists for the purpose of fattening cattle, having regard to the public health objective pursued by the institutions within the general framework of

Directive 96/22. They consider, however, that the Council infringed the principle of proportionality by also prohibiting, solely for the purpose of facilitating controls, the use of those substances with a view to their administration to cattle for therapeutic purposes.

76 Since Directive 96/22 falls within the scope of the common agricultural policy, it is necessary to ascertain, first, what is the aim of the measures in question; second, whether those measures are manifestly inappropriate in relation to that aim; third, whether they are necessary for the attainment of that aim and whether any alternative, less restrictive, measures could have been envisaged; and finally, fourth, whether the disadvantages caused are disproportionate in relation to that aim.

77 As regards, first, the objective pursued by the measures in question, the sixth and eighth recitals in its preamble show that Directive 96/22 is concerned both with the protection of public health and with the attainment of the aims of the common agricultural policy within the framework of a common organisation of the markets, by ensuring that all consumers are able to acquire meat and foodstuffs derived therefrom under the same conditions of supply and that those products correspond as closely as possible to their concerns and expectations. It is in the light of that dual objective that the legality of the measures in question must be assessed.

78 As regards, secondly, the assessment as to whether the measures in question are clearly inappropriate, it must be held that, from the point of view of the objective of protecting public health referred to in the sixth recital in the preamble to Directive 96/22, a measure prohibiting a product by reason of the risks which its use may involve is, by definition, suited to preventing the dangers connected with such use. The same holds true, in this case, from the point of view of the objective

set out in the eighth recital in the preamble to Directive 96/22, since its attainment is closely connected to the concerns and expectations of consumers in public health matters.

79 Moreover, in a case like the present, where the product in question has two uses, one as a veterinary medicinal product which does not endanger public health and the other for the purpose of fattening cattle which is harmful to humans, the question whether the prohibition should extend to both uses cannot be assessed in the abstract but must take account of all the relevant circumstances, in particular the possibilities for abuse and evasion, the risks connected therewith and the effectiveness of control measures.

80 Thirdly, with regard to the assessment as to whether the measures in question are necessary and whether alternative less restrictive measures may exist, it should first be remembered that the provisional MRLs were fixed for beta-agonists, and in particular for clenbuterol, by Regulation No 1312/96.

81 It follows that use of that substance may be regarded as being without danger for human health below a certain residue level. Under Article 1 of Regulation No 2377/90, an MRL 'is based on the type and amount of residue considered to be without any toxicological hazard for human health'. Under Article 4 of that regulation, a provisional MRL may be established only if 'there are no grounds for supposing that residues of the substance concerned at the level proposed present a hazard for the health of the consumer'.

82 In the circumstances of this case, however, the establishment of an MRL for clenbuterol is not sufficient to ensure the protection of public health. It would be

necessary, to that end, for the presence of residues of that substance to be systematically analysed in each foodstuff of animal origin entering the food chain.

83 Since establishment of a systematic screening system of that kind is excluded in practice, if only because of the prohibitive cost, the argument that simply fixing an MRL for beta-agonists makes the adoption of any other measure regulating their use unnecessary must be rejected.

84 It must be borne in mind, moreover, that the Council had to exercise its discretion and assume its political responsibilities in the face of a particularly complex and delicate situation.

85 On the one hand, a number of considerations linked with the health and welfare of animals argued in favour of maintaining the authorisation for the therapeutic use of beta-agonists, including their use for bovines. Those considerations were expressed not just by the applicants but also by Fedesa, the Fédération des Vétérinaires Européens, the Union Européenne des Vétérinaires Practiciens, the Deutsche Tierarztegeschäfte e.V., Professor Lekeux of the faculty of veterinary medicine of the University of Liège and Professor Ungemach of the faculty of veterinary medicine of the University of Leipzig, the permanent veterinary committee, the Committee on Agriculture, Fisheries and Rural Development of the European Parliament, and the Economic and Social Committee, which, in its Opinion of 21 December 1993 (OJ 1994 C 52, p. 30), expressed reservations concerning the Commission's proposal for a regulation of 14 October 1993, referred to in paragraph 15 above.

86 In particular, the existence of substitute products of equivalent quality, safety and efficacy to those of beta-agonists, for the treatment of respiratory problems in bovines, does not appear to have been established in this case (see the letter of the Fédération des Vétérinaires Européens to Mr Steichen, Member of the Commission, of 12 October 1993, the letter from the Union Européenne des Vétérinaires Practiciens to Mr Steichen of 20 October 1993, and the letter from the president

of Deutsche Tierärztegeschäft e.V. to Mr Bangemann, Member of the Commission, of 21 April 1993, and the opinions of Professors Lekeux and Ungemach).

87 On the other hand, the Council had to take account of the growing use of beta-agonists and other anabolic substances in the raising of livestock in place of conventional growth hormones, following the adoption of prohibition and supervisory measures in respect of those products throughout the 1980s; the new risks for public health posed thereby; the request by various Member States as early as 1988 for Community action in this field; the enquiry carried out by the Commission in the Member States from 1990 to 1992 concerning the application of Community legislation, the results of which indicated the existence of serious risks to public health, linked to the widespread availability of anabolic agents; the opinion of the Parliament, whose Committee on the Environment, Public Health and Consumer Protection considered in 1994 that beta-agonists should be banned as soon as possible for overriding reasons related to public health; the opinions of those responsible for monitoring in the Member States, and the opinions of certain experts (see the report by Schuman Associates, referred to in paragraph 12 above, and the report of the scientific conference on growth agents in meat, of 17 January 1996, produced by the Council at the request of the Court of First Instance, according to which the use of beta-agonists was not appropriate because of their potential risks to human and animal health.

88 In assessing the possibilities for action open to it, the Council had to focus its assessment in particular on the question whether authorisation to use beta-agonists for therapeutic purposes, coupled with control measures of the type proposed by the applicants, was sufficient to prevent the clandestine use of substances whose harmfulness in massive doses for fattening purposes is universally acknowledged, or whether only a prohibition coupled with very strict derogations could be effectively monitored and should therefore be imposed, even though the Commission was 'normally reluctant to propose removal from the market of a product with therapeutic uses'.

89 In that respect, the applicants argue more particularly that it is possible, by establishing appropriate controls, to distinguish easily between the use of beta-agonists for the purposes of fattening cattle and their use for therapeutic purposes, so that the prohibition of the one, with a view to attaining the objective pursued by the Council, need not necessarily have entailed the prohibition of the other. For the institutions, on the other hand, it is precisely the impossibility or the difficulty of distinguishing between those two uses, without establishing a system of controls the cost of which would be prohibitive, that justifies the near-total prohibition on the use of beta-agonists in the raising of bovines imposed by Directive 96/22, since the protection of human health and the restoration of consumer confidence have to take priority in this case over all other considerations, and in particular those concerning animal welfare or the property rights of the applicants.

90 In the light of the scientific documentation produced before the Court, it must be acknowledged that current detection techniques do not make it possible to determine with certainty whether beta-agonist residues found when monitoring an animal or derivative foodstuffs come from a dose administered for therapeutic purposes the day before the control or from a dose administered for the purpose of artificial fattening several days before.

91 Moreover, it is not clear that the measures put into effect within the framework of Directive 81/851, as amended by Directive 90/676 (see paragraphs 17 and 18 above) are sufficient to prevent any misuse of the products in question.

92 In that respect, the Court finds that the applicants' proposed solution, which is, as they stated at the hearing, to allow farmers themselves to administer clenbuterol-based veterinary medicinal products to cattle on the prescription of a veterinarian but without his actually being present, would, by the very fact of presupposing and justifying the habitual, large-scale presence of those products on farms, make it more difficult to identify the origin, lawful or unlawful, of any clenbuterol residues found on inspection.

93 Directive 96/22 provides, moreover, in cases where it authorises the administration of substances having a hormonal action to farm animals for therapeutic purposes or of medicinal products containing beta-agonists to cows when calving (see Article 4(1) and (2)), that treatment is to be administered by a veterinarian and must be subject to detailed registration.

94 All the parties agree in acknowledging that, as regards the treatment of respiratory problems in bovines, such a system would be prohibitive to the point of discouraging farmers from using it. In the first place, treatment does not normally consist of a single injection but requires the oral administration of one or more daily doses over a period of several days. Moreover, intensive rearing conditions prevailing in the Community and the infectious nature of the most frequent respiratory problems require simultaneous treatment of a large number of animals.

95 Furthermore, any possibility on inspection of justifying the presence of beta-agonist residues by reference to administration for therapeutic purposes facilitates misuse of those substances by unscrupulous farmers. Although the obligatory involvement of a veterinarian undeniably reduces the risk of such use, it is not capable of eliminating it altogether.

96 In any event, the control measures which would be warranted by the application of less restrictive provisions, such as those advocated by the applicants, would entail a significant cost for the public purse. That cost must also be balanced against the loss caused to the applicants by the prohibition of their clenbuterol-based veterinary medicinal products. The information in the documents placed before the Court does not support the conclusion that, in that assessment, the balance of interests is in favour of the applicants, taking into account the relatively small loss they have suffered following the implementation of Directive 96/22 (see paragraph 107 below).

97 Having regard to the above considerations, the Court finds that the applicants have not succeeded in demonstrating that the Council made a manifest error of assessment in holding that the general prohibition constituted the preferable solution from the point of view of protecting public health.

98 Furthermore, even if protection of public health takes priority over all other considerations, the protection of consumer confidence is equally important.

99 It is undisputed that at least a section of the public and the professions involved together with many Members of the European Parliament were in favour of an outright ban on beta-agonists, and that their anxieties would not have been allayed by the establishment of control mechanisms, however effective they might have been in purely operational terms. It is also undisputed that, in many Community countries, information campaigns going so far as to issue calls for the boycott of meats containing hormones were launched by consumer associations in the past.

100 In those circumstances, and taking into account the growing use of beta-agonists for the purpose of fattening cattle artificially, the Council cannot be regarded as having committed a manifest error of assessment in holding that only a general prohibition was capable of restoring consumer confidence.

101 Moreover, the argument based on the traditional practice of the Community in regard to the authorisation of pharmaceutical products (see the preamble to Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 20), Directive 81/851, cited above, Council Directive 81/852/EEC of 28 September

1981 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products (OJ 1981 L 317, p. 16), and the third recital in the preamble to Regulation No 2309/93) is irrelevant, since the safety, quality and efficacy of the applicants' veterinary medicinal products if used under normal conditions are not in any way called in question.

102 As to the fourth point, proportionality in the narrow sense of the term, that is to say the weighing of damage to individual rights against the benefits accruing to the general interest, the Court finds that the importance of the aims pursued, namely the protection of public health and the restoration of consumer confidence, is such as to justify adverse economic consequences, even of a substantial nature, for individual traders (see *Fedesa and Others*, paragraph 17), and that the maintenance of public health must take precedence over all other considerations (see the Opinion of Advocate General Mischo in *Fedesa and Others*, p. I-4051), and in particular those relating to the welfare of animals or the applicants' property rights.

103 As regards, more particularly, the impact of the measures in question on the economic interests of the applicants, the Court held in Case T-113/96 *Dubois* v *Council and Commission* [1998] ECR II-125, paragraphs 74 and 75, that, whilst the freedom to pursue a trade or profession forms part of the general principles of Community law, that principle does not constitute an unfettered prerogative, but must be viewed in the light of its social function. Consequently, that freedom may be restricted, provided that those restrictions do in fact correspond to objectives pursued by the Community in the public interest and that, in the light of the aim pursued, they do not constitute a disproportionate and intolerable interference which would adversely affect the very substance of the right so guaranteed (see also Case 4/73 *Nold* v *Commission* [1974] ECR 491, paragraph 14; Case C-280/93 *Germany* v *Council* [1994] ECR I-4973, paragraph 78; and Case C-183/95 *Affish* v *Rijksdienst voor de keuring van Vee en Vlees* [1997] ECR I-4315, paragraph 42).

104 In this case, the partial forfeiture of the marketing authorisations held by the applicants, which is a consequence of the implementation of Directive 96/22, does not affect the very substance of their property right over their products and trade marks.

105 Moreover, the forfeiture of those authorisations is limited both geographically and materially. In the first place, the applicants have never obtained or even applied for marketing authorisation in respect of their clenbuterol-based products in a number of Member States (Denmark, Finland, France, Greece and Sweden: see paragraph 11 above). Moreover, they remain free to market those products outside the Community, and within it for all the therapeutic uses not prohibited by Directive 96/22.

106 It should be noted in that respect that the applicants misinterpret Directive 96/22 where they maintain that it entails, *de facto*, a prohibition on the administration of any beta-agonists for the treatment of respiratory problems in equines, on the ground that the latter are all to be regarded as farm animals and are thus covered by Article 2(b) of the directive. That interpretation, which is rejected by both the Commission and the Council, is incompatible with Articles 1(2)(b) and 4(1)(2) of Directive 96/22. Those provisions show that the prohibition on administering beta-agonists does not concern the treatment of respiratory problems in equines which are not raised specifically for meat production. By contrast, the fact that horses are included within the list of species fit for human consumption for the purposes of Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-Community trade in fresh meat (OJ, English Special Edition 1963-1964, p. 185), as amended, is entirely irrelevant for the purposes of the present question.

107 It is also apparent from the information provided by the applicants in reply to the written questions of the Court of First Instance that the total turnover achieved by them in their sales of veterinary medicinal products containing clenbuterol in the Member States (taking all uses and products together) fell from DEM 13 528

063 in 1995 to DEM 12 283 756 in 1998, a decrease of 9.2%, representing DEM 1 244 307. That relatively modest decrease can be explained, according to the applicants, by a rise in sales of their clenbuterol-based products for equines.

108 In the circumstances of the case, the restrictions thus imposed on the economic exploitation of products developed by the applicants more than twenty years ago, and no longer protected by a patent, do not amount to a disproportionate or intolerable sacrifice in relation to the objectives pursued by the Community legislature in the public interest.

109 It follows from all of the foregoing considerations that the plea alleging breach of the principle of proportionality must be dismissed.

The second plea, alleging breach of the principles of legal certainty and protection of legitimate expectations

Arguments of the applicants

110 The applicants consider that they were entitled to expect that the Council would not deprive them of their right to market the veterinary medicinal products in question, and submit that the contested provisions are contrary to the fundamental principles of protection of legitimate expectations and legal certainty.

111 The Community institutions have always stressed that the sole criteria relevant when deciding whether a medicinal product should be granted marketing

authorisation are the quality, safety and efficacy of the product (see Article 41 of Directive 81/851/EEC), and have refused, to date, to introduce supplementary criteria of a socio-economic nature.

112 Likewise, in Case 301/82 *Clin-Midy* [1984] ECR 251, paragraph 10, the Court stated that, when adopting Directive 65/65/EEC, cited above, the Council intended to restrict the grounds for refusal, suspension or revocation of such authorisation solely to the considerations of public health expressly mentioned in the directive (see also Case C-83/92 *Pierrel* [1993] ECR I-6419).

113 The applicants submit that the same is true for veterinary medicinal products. They refer in particular to the seventh and eighth recitals in the preamble to Directive 81/851/EEC, which indicate the situations in which marketing authorisation is to be refused, and the third recital in the preamble to Council Directive 93/40/EEC of 14 June 1993 amending Directives 81/851/EEC and 81/852/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products (OJ 1993 L 214, p. 31), according to which a Member State may refuse to recognise the authorisation issued by another Member State only if it considers that the product concerned may present a risk to human or animal health or to the environment. They also refer to Articles 5 and 8a of Directive 81/851, as amended by Directives 90/676 and 93/40, both cited above, the latter article providing that the risk to human or animal health or the environment must be assessed exclusively in the light of the quality, safety and efficacy of the products. In their reply in Case T-152/96, the applicants also refer to a speech delivered in December 1995 by Mr Fischler, Member of the Commission and to Commission Document COM(93) 220 final, in which the Commission explained that it was obliged to reject an amendment to its proposal for a Council directive amending Directives 81/851/EEC and 81/852/EEC of 28 September 1981 (cited above) proposed by the European Parliament, because that amendment would have introduced 'into the five yearly re-examination of the authorisation of a veterinary medicinal product concepts that are not clear and which appear to move away from the three customary criteria of authorisation (quality, safety and efficacy)'.

114 The applicants therefore submit that the Council infringed the principle of legal certainty, also known as '*patere legem quam ipse fecisti*', by departing from the usual criteria for authorisation and adopting the contested provisions for the sole purpose of facilitating checks by the competent national authorities, even though that cause was not dictated by any overriding matter of public interest.

Findings of the Court of First Instance

115 The principle of legal certainty aims *inter alia* to ensure that situations and legal relationships governed by Community law remain foreseeable (Case C-63/93 *Duff and Others* [1996] ECR I-569, paragraph 20; Case T-229/94 *Deutsche Bahn* v *Commission* [1997] ECR II-1689, paragraph 113; Case T-105/96 *Pharos* v *Commission* [1998] ECR II-285, paragraph 63).

116 In this case, Directive 96/22 does not give rise to any doubt as to the law that will apply upon its implementation. The plea alleging infringement of the principle of legal certainty must therefore be dismissed as unfounded.

117 As for the principle of protection of legitimate expectations, it can be relied on by any individual whom a Community institution has caused to entertain justified expectations (see, for example, Case T-489/93 *Unifruit Hellas* v *Commission* [1994] ECR II-1201, paragraph 51). Nevertheless, it must also be borne in mind that traders cannot have a legitimate expectation that an existing situation which is capable of being altered by the Community institutions in the exercise of their discretion will be maintained, particularly in an area such as the common organisation of the markets (Case 245/81 *Edeka* v *Germany* [1982] ECR 2745, paragraph 27; Case C-350/88 *Delacre* v *Commission* [1990] ECR I-395, paragraph 33; Case T-521/93 *Atlanta and Others* v *Council and Commission* [1996] ECR II-1707, paragraph 55). Moreover, in the absence of specific

assurances given by the administration, it is not open to anyone to plead breach of the principle of protection of legitimate expectations (*Atlanta*, paragraph 57; *Pharos*, paragraph 64).

118 In this case, the matters put forward by the applicants cannot constitute assurances of that kind. Since the Council remained within the limits of its discretion, as the Court has found in its examination of the first plea, it was entitled to impose a prohibition such as the one at issue for the future (see also paragraph 101 above).

119 The plea alleging infringement of the principle of protection of legitimate expectations must therefore also be dismissed.

The third plea, alleging breach of the principle of sound administration

Arguments of the applicants

120 The applicants submit that the Community institutions infringed the principle of sound administration (see Case 179/82 *Lucchini* v *Commission* [1983] ECR 3083), by adopting in 1996 a measure taken on the basis of the result of an enquiry carried out in 1990 to 1992, at a time when the Member States had not yet implemented Directive 90/676, even though the Commission had noted in its Communication of 21 April 1993, cited above, that, following implementation of that directive, the situation had improved.

121 According to the applicants, the Community institutions should have attempted to correct the deficiencies identified in the 1990 to 1992 enquiry as far as the efficacy of control measures was concerned and should have carried out a new enquiry to assess the effect of the improvement in those measures on the state of the market before taking such extreme measures in the contested directive.

Findings of the Court of First Instance

122 In the first place, the results of the enquiry carried out by the Commission between 1990 and 1992, referred to in the fifth recital in the preamble to Directive 96/22, constitute just one of the factors which the Council took into account when adopting that measure. In particular, the Council also took account of the opinion and the resolution of the Parliament, of 19 April 1994 and 18 January 1996 respectively, as is shown by the 16th recital in the preamble to Directive 96/22.

123 The Council also had other information at its disposal, and in particular the results of the scientific conference organised by the Commission from 29 November to 1 December 1995, concerning growth promoters in meat production.

124 Moreover, the statistics concerning cases of intoxication show that these persisted in 1994 and even in 1996 (see paragraph 10 above), so that implementation of Directive 90/676 in the various Member States had obviously not resolved all the public health problems connected with the use of beta-agonists for the purpose of fattening cattle. Thus, even on the assumption that national procedures enabling the use of beta-agonists to be controlled had been improved, it still appeared justified in 1996 to harmonise the national rules governing authorisation of those products at Community level, in order to improve not only the overall level of protection of human health, but also the free movement of meat and products derived from animals to which those substances have been administered (see Articles 7, 8, 10 and 11 of Directive 96/22).

125 In those circumstances, the Council was entitled to decide that a ban was the most appropriate means of protecting human health and allaying consumer anxieties. The third plea must therefore be dismissed.

The fourth plea, alleging infringement of Article 43 of the Treaty

Arguments of the parties

126 The applicants submit that, in the present case, the Council failed to fulfil its duty under Article 43 of the Treaty to consult the European Parliament anew whenever the text finally adopted, taken as a whole, departs substantially from the text on which the Parliament has already been consulted, except where the amendments essentially correspond to the wishes of the Parliament itself (see Case C-388/92 *Parliament* v *Council* [1994] ECR I-2067).

127 In the first place, the applicants claim that the text on which the European Parliament was consulted provided for the adoption of a regulation, and not a directive, the choice being justified by the need to ensure the immediate and uniform application of the prohibitions envisaged. By subsequently turning the proposal into a directive, the Council changed a significant element of the proposal.

128 The consequences of the choice of a directive are numerous, in particular in so far as it leaves a discretion to the Member States. The applicants submit that Article 4 of the initial proposal provided for certain exceptions to the prohibition on administering beta-agonists, which would have been applicable throughout the European Union, whilst Article 4 of Directive 96/22 provides only that Member States may authorise in certain circumstances the administering of beta-

agonists to animals the flesh and products of which are intended for human consumption. There is no certainty that all the Member States will implement that possibility of exemption in the same manner. Likewise, there is no certainty as to the homogenous character of the transposition measures with regard to the system of penalties (see Article 14(1) of Directive 96/22), whilst, in the proposal submitted to the European Parliament, it was provided that detailed rules for the application of the proposed regulation would be adopted at Community level.

129 Second, the applicants submit that the initial proposal for a regulation authorised the administering of beta-agonists to horses in order to treat cardio-respiratory disorders, whilst, according to them, Directive 96/22/EC results *de facto* in a prohibition on doing so.

Findings of the Court of First Instance

130 Due consultation of the Parliament in the cases provided for by the Treaty constitutes an essential procedural requirement, breach of which renders the measure concerned void. Effective participation of the Parliament in the Community's legislative process, in accordance with the procedures laid down by the Treaty, represents an essential factor in the institutional balance intended by the Treaty. This function reflects the fundamental democratic principle that the peoples should take part in the exercise of power through the intermediary of a representative assembly (see, in particular, Case C-392/95 *Parliament* v *Council* [1997] ECR I-3213, paragraph 14; Case C-408/95 *Eurotunnel and Others* v *Seafrance* [1997] ECR I-6315, paragraph 45).

131 It is settled law that the requirement to consult the European Parliament in the legislative procedure, in the cases provided for by the Treaty, means that it must be consulted again whenever the text finally adopted, taken as a whole, departs substantially from the text on which the Parliament has already been consulted,

except where the amendments essentially correspond to the wishes of the Parliament itself (*Parliament* v *Council*, paragraph 15; *Eurotunnel*, paragraph 46).

132 In this case, the Parliament was consulted on a proposal for a regulation, whereas the text finally adopted, without fresh consultation, is a directive.

133 However, that amendment to the form of the measure does not entail any alteration in the actual substance of the text on which the Parliament was consulted, for the purposes of the case-law referred to above, nor has it been called into question by the Parliament itself.

134 The proposal for a regulation submitted to the Parliament for its opinion laid down the principle that the placing on the market of beta-agonists for administering to animals of all species, with the exception of equidae and domestic carnivorous animals, should be prohibited (Article 2(2)). More particularly with regard to farm animals, namely animals, including equines, raised on a holding (Article 1), the proposal for a regulation provided, *inter alia*, that the administering to them of beta-agonists should be prohibited (Article 3), subject to the possibility left open to Member States of authorising the administration of such substances to equines to treat cardio-respiratory disorders, by a veterinarian or on his direct responsibility (Article 4(3)).

135 Directive 96/22 in turn lays down the principle that the placing on the market of beta-agonists for administering to animals whose flesh and products are intended for human consumption for purposes other than those provided for in point 2 of Article 4 is to be prohibited (Article 2(b)). Farm animals are defined as in the proposal for a regulation (Article 1) and are subject to the same prohibitions on the administering of beta-agonists (Article 3). By way of derogation, Member States may authorise the administration of beta-agonists, for therapeutic purposes

and by a veterinarian or under his direct responsibility, first, to equidae, provided those products are used in accordance with the manufacturer's instructions, and, secondly, in the form of an injection, to induce tocolysis in cows when calving (Article 4(2)). Therapeutic treatment is defined, in the case of equidae raised for purposes other than meat production, as the administering of beta-agonist substances for treating respiratory problems and inducing tocolysis (Article 1(2)(b)). However, therapeutic treatment of production horses remains prohibited (Article 4(2)).

136 A comparison of the proposal for a regulation and Directive 96/22 shows that the only real difference between their respective provisions lies in the power left to Member States by the directive to authorise the administering of beta-agonists for inducing tocolysis in cows when calving. By contrast, no discernible difference appears concerning equidae.

137 The inclusion in the directive of a derogation envisaging the induction of tocolysis in cows when calving does not constitute a substantial amendment for the purposes of the case-law cited above.

138 Moreover, the proposal for a regulation also left Member States the power to provide for certain exemptions or derogations from the prohibition which applied in principle (see Article 4), so that in this case the applicants' argument based on the difference between a regulation and a directive is irrelevant.

139 Furthermore, neither the proposal for a regulation nor Directive 96/22 lays down a uniform system of penalties at Community level. Besides, the Council rightly observes that the penalties concerned are harmonised more precisely by Regulation No 894/96 of 29 April 1996, cited above.

140 Finally, the applicants' argument that all horses are, *de facto*, covered by the prohibition imposed by Directive 96/22 has already been found by this Court to be inaccurate (see paragraph 106 above).

141 The plea alleging infringement of Article 43 of the Treaty cannot therefore be upheld.

142 It follows from the above considerations as a whole that the four pleas in law, raised by the applicants for the purpose of establishing that Directive 96/22 was unlawful, must be dismissed as unfounded.

The claim for annulment in Case T-125/96

143 Since the applicants' four pleas in support of their claim for the annulment of Directive 96/22 have been dismissed, this claim must be declared unfounded in any event, without there being any need to rule on the objection of inadmissibility raised by the Council.

The claim for compensation in Case T-125/96

144 The applicants consider that the Community has incurred non-contractual liability by reason of the adoption and implementation of the contested provisions of Directive 96/22 and claim compensation for the damage which they have sustained as a result.

145 It is settled case-law that the Community can incur non-contractual liability only if a set of conditions relating to the illegality of the conduct alleged against the institutions, the occurrence of actual damage and the existence of a causal link between the conduct complained of and the harm alleged are fulfilled. As regards liability arising from legislative measures, the Community conduct complained of must also constitute a breach of a superior rule of law for the protection of individuals. If the institution has adopted the measure in the exercise of a wide power of assessment, as is the case in relation to the common agricultural policy, that breach must also be sufficiently serious, that is to say manifest and grave (see, for example, *Exporteurs in Levende Varkens*, paragraph 81; Joined Cases T-195/94 and T-202/94 *Quiller and Heusmann* v *Council and Commission* [1997] ECR II-2247, paragraphs 48 and 49; *Pharos*, paragraphs 47 and 62).

146 In this case, the Court has already held, in its examination of the pleas put forward by the applicants for the purpose of establishing the unlawfulness of Directive 96/22, that the latter does not infringe any of the rules of law relied upon. Since the claim for compensation is based on the alleged infringement of those rules, it must be dismissed as unfounded in any event, without there being any need to rule on the objection of inadmissibility raised by the Council.

The claim for annulment in Case T-152/96

Admissibility

Arguments of the parties

147 As a preliminary point, the Commission raises the question why Boehringer is an applicant in this case as well as its subsidiary BI Vetmedica. It does not appear

from the description given by Boehringer that it is engaged directly in the production and marketing of veterinary medicinal products containing clenbuterol.

148 The Commission then contends that the application is inadmissible, since, in its view, the applicants have no interest in the action and are neither individually nor directly concerned by Regulation No 1312/96.

149 First, the Commission submits that Regulation No 1312/96 does not interfere with any legally protected right of the applicants, or their registered trade marks or patents. In particular, that regulation does not result in the forfeiture of any authorisations to manufacture and market the product concerned, held by the applicants, but, on the contrary, has the effect of maintaining them in force after 1 January 1997, by including clenbuterol in Annex III to Regulation No 2377/90. The Commission therefore submits that, after the adoption of Regulation No 1312/96, the applicants remain entirely free to carry on their business of producing and marketing clenbuterol.

150 Furthermore, it submits that the interests which the applicants are seeking to protect are affected not by Regulation No 1312/96, but by Directive 96/22/EC, which limits the therapeutic use of beta-agonists as laid down in Article 4(2). In its view, the applicants cannot, under Article 173 of the EC Treaty (now, after amendment, Article 230 EC), seek the annulment of one act by invoking the alleged effects on their position caused by another.

151 Secondly, the Commission argues that the applicants are not individually concerned by Regulation No 1312/96, since that regulation is, in its view, a measure of general application which addresses a situation assessed objectively.

152 The fact that the applicants hold a large market share for clenbuterol products does not in itself distinguish them from others affected by the measure in question, such as Agraria. Furthermore, since patent protection for clenbuterol has expired, other undertakings could legally manufacture it and obtain marketing authorisation, in which case Regulation No 1312/96 would apply to them in the same manner as it applies to the applicants. In relation to the contested regulation, therefore, the applicants are not in a situation which distinguishes them from any other trader (see Case T-298/94 *Roquette Frères* v *Council* [1996] ECR II-1531, paragraph 42).

153 Thirdly, the Commission submits that the applicants are not directly concerned by Regulation No 1312/96 since there is no causal link between that measure and the damage allegedly caused to their rights. By establishing MRLs, that regulation directly affected only farmers and veterinarians. By contrast, its effect on the applicants' market position and the profitability of their products was only indirect and hypothetical.

154 Finally, the Commission considers that the applicants, who are in effect seeking the annulment of Regulation No 1312/96 on the ground that it does not establish MRLs for the treatment of respiratory ailments in bovines, should have brought proceedings for failure to act under Article 175 of the EC Treaty (now Article 232 EC).

155 The Council and SKV essentially support the arguments put forward by the Commission.

156 As regards the question whether the applicants are individually concerned, SKV argues more specifically that the fact that the applicants have obtained authorisation to market certain veterinary medicinal products containing

clenbuterol is not sufficient to confer upon them certain specified rights which differentiate them from others, who can also acquire such authorisation. In particular, the applicants are not in the highly exceptional situation of the applicant in Case C-309/89 *Codorniu* v *Council* [1994] ECR I-1853.

157 The applicants maintain that their action for the annulment of Regulation No 1312/96 is admissible, since it is aimed at challenging measures which are of direct and individual concern to themselves.

Findings of the Court of First Instance

— The interest of BI Vetmedica in bringing an action

158 According to settled case-law, any measure which produces binding legal effects such as to affect the interests of an applicant by bringing about a distinct change in his legal position is an act or decision which may be the subject of an action under Article 173 of the Treaty for a declaration that it is void (see, for example, Case T-274/97 *Ca'Pasta* v *Commission* [1998] ECR II-2927, paragraph 24).

159 In this case, the contested provisions of Regulation No 1312/96 produce such effects in relation to BI Vetmedica, since, having regard to the legislation in force (see Article 14 of Regulation No 2377/90), the restriction on the validity of MRLs for clenbuterol to certain precise therapeutic indications is equivalent to a

prohibition on the use of that product for any other therapeutic indication, and thus to a partial withdrawal of the marketing authorisations which that applicant holds in a number of Member States.

160 The Court also rejects the Commission's argument that BI Vetmedica's interests are affected by Directive 96/22 rather than by Regulation No 1312/96. According to the Commission's argument, Regulation No 1312/96 produces legal effects independent of those entailed by Directive 96/22. As BI Vetmedica rightly points out, moreover, the relevant provisions of that regulation, in so far as they restrict the validity of the MRLs which they establish to certain specified therapeutic indications, would continue to affect its legal position even in the event of annulment, withdrawal or non-implementation of Directive 96/22. Furthermore, Regulation No 1312/96 entered into force on the sixtieth day following that of its publication in the *Official Journal of the European Communities*, on 9 July 1996, whereas the time-limit communicated to Member States for the transposition of Directive 96/22 into domestic law was 1 July 1997. It follows that BI Vetmedica has a distinct interest in obtaining the annulment of Regulation No 1312/96.

— The question whether BI Vetmedica is individually concerned

161 Under the fourth paragraph of Article 173 of the Treaty, any natural or legal person may institute proceedings against decisions which, although in the form of a regulation, concern that person directly and individually. According to settled case-law, the criterion for distinguishing between a regulation and a decision must be sought in the general application or otherwise of the act in question. A measure is of general application if it applies to objectively determined situations and produces legal effects with respect to categories of persons envisaged in general amd abstract terms (order in Case C-87/95 P *CNPAAP* v *Council* [1996] ECR I-2003, paragraph 33; judgments in Case T-482/93 *Weber* v *Commission* [1996] ECR II-609, paragraph 55, and Case T-158/95 *Eridania* v *Council* [1999] ECR II-2219, paragraph 54).

162 In this case, Regulation No 1312/96 lays down provisional MRLs for clenbuterol, whilst restricting their validity to certain specified therapeutic indications. Such provisions apply to objectively determined situations and produce legal effects with respect to categories of persons envisaged in general and abstract terms, namely the pharmaceutical undertakings which produce clenbuterol and those who prescribe and use that substance. By its nature and scope, therefore, Regulation No 1312/96 is legislative in character and does not constitute a decision within the meaning of Article 189 of the EC Treaty (now Article 249 EC).

163 Nevertheless, it is possible that a provision which, as a result of its nature and scope, is general in character may be of individual concern to a natural or legal person where that person is affected by reason of certain attributes peculiar to him or by reason of factual circumstances differentiating him from all other persons and, as a result, distinguishing him individually in like manner to the addressee of a decision (Case C-209/94 P *Buralux* v *Council* [1996] ECR I-615, paragraph 25; Case T-135/96 *UEAPME* v *Council* [1998] ECR II-2335, paragraph 69; and *Eridania*, paragraph 56).

164 It therefore needs to be determined in this case whether BI Vetmedica is affected by the disputed regulation by reason of certain attributes peculiar to it or by reason of factual circumstances differentiating it, as far as that regulation is concerned, from all other persons.

165 In that respect, it is important to note that Regulation No 1312/96 was adopted after a formal request by BI Vetmedica that an MRL be fixed for clenbuterol (see paragraph 36 above), on the basis of its file in accordance with Regulation No 2377/90. The latter expressly provides, moreover, that, as the undertaking responsible for the marketing of the veterinary medicinal products concerned, BI Vetmedica should be involved in the procedure for establishing MRLs (see, by analogy, Case T-96/92 *Société Générale des Grandes Sources* v *Commission* [1995] ECR II-1213, paragraphs 30 and 31, and the order in Case T-189/97

Société Française de Production v *Commission* [1998] ECR II-335, paragraphs 36 and 37). Thus the draft measures to be taken were notified to BI Vetmedica and the CVMP was entitled to ask it for additional information (see paragraph 32 above).

166 Furthermore, whilst the inclusion of a substance in one of the annexes to Regulation No 2377/90, at the request of the person responsible for marketing it, takes the form of a regulation (see Article 8(3) of that regulation), the rejection of such an application, in the Commission's practice, takes the form of a decision [see, for example, Commission Decision C(96) 1374 final of 22 May 1996 rejecting the application of Lilly Industries Ltd for the inclusion of somidobove, a recombinant bovine somatotrophin (BST), in Annex II to Regulation No 2377/90].

167 In its judgment in Case T-120/96 *Lilly Industries* v *Commission* [1998] ECR II-2571, the Court of First Instance held that the applicant had standing to challenge such a decision, despite the case-law of the Court of Justice to the effect that, if an individual requests the Commission to adopt a regulation and it refuses to do so, the adverse decision containing the refusal must be regarded for purposes of annulment as a legislative measure of general application, even though the refusal is addressed solely to the person concerned (Case 42/71 *Nordgetreide* v *Commission* [1972] ECR 105; Case C-87/89 *Sonito and Others* v *Commission* [1990] ECR I-1981; and Joined Cases C-15/91 and C-108/91 *Buckl and Others* v *Commission* [1992] ECR I-6061). In *Lilly* (paragraph 59 of the judgment), the Court of First Instance took the view that that case differed from those in which the above judgments were given in that the Commission had no discretionary power to decide whether or not to take action on the request for the adoption of a regulation, but was obliged to rule on the request by virtue of Article 6 of Regulation No 2377/90.

168 It should be noted that the person who is responsible for placing a product on the market, and who has made an application for an MRL to be fixed, is just as concerned by the provisions of a regulation setting certain limits on the validity of those MRLs, as in this case, as he would be by a refusal.

169 BI Vetmedica has thus established the existence of a series of factors constituting a particular situation which, as regards the measure in question, differentiates it from all other traders, and it may therefore be regarded as individually concerned by that measure.

— The question whether BI Vetmedica is directly concerned

170 The Court's case-law shows that, for a person to be directly concerned by a Community measure, the latter must directly affect the legal situation of the individual and leave no discretion to the addressees of that measure who are entrusted with the task of implementing it, such implementation being purely automatic and resulting from Community rules without the application of other intermediate rules (see, for example, Case C-404/96 P *Glencore Grain* v *Commission* [1998] ECR I-2435, paragraph 41).

171 Those conditions are met in this case, since the contested regulation does not require any measures for its transposition into national law and directly affects all the traders concerned.

172 Moreover, the Court rejects the Commission's argument that the applicants should have brought proceedings for failure to act rather than an action for annulment. The case-law of the Court of Justice shows that Article 175 of the Treaty refers to a failure to act in the sense of failure to take a decision or to define a position, and not to the adoption of a measure different from that desired or considered necessary by the persons concerned (Case 8/71 *Deutscher Komponistenverband* v *Commission* [1971] ECR 705, paragraph 2; *Nordgetreide*, cited above; and order of the Court of Justice in Case C-250/90 *Control Union* v *Commission* [1991] ECR I-3585, paragraph 16).

173 It follows from the above considerations as a whole that the action brought by BI Vetmedica is admissible.

— Boehringer's capacity to bring an action

174 It is true that Boehringer, which is joined 'in so far as necessary' (see page 2 of the application) to the action brought by its subsidiary BI Vetmedica, neither produces nor markets any of the veterinary medicinal products concerned by Regulation No 1312/96.

175 However, since a single action is involved, it is not necessary to examine whether Boehringer has the capacity to bring proceedings, since the action brought by BI Vetmedica is admissible in any event, as is shown by the foregoing considerations (see Case C-313/90 *CIRFS and Others* v *Commission* [1993] ECR I-1125, paragraph 31; Case T-435/93 *ASPEC and Others* v *Commission* [1995] ECR II-1281, paragraph 72; and Joined Cases T-374/94, T-375/94, T-384/94 and T-388/94 *European Night Services and Others* v *Commission* [1998] ECR II-3141, paragraph 61).

Substance

Arguments of the parties

176 In their action, the applicants raise two pleas in law in support of their application for the annulment of Regulation No 1312/96. The first alleges unlawful interference in the exercise of their property rights and the freedom to pursue trade and professional activities, while the second alleges insufficient statement of reasons. Those two pleas are underpinned by a single objection to the effect that Directive 96/22 is unlawful, leaving the restriction imposed by Regulation No 1312/96 on the validity of the MRLs fixed for clenbuterol without a sufficient legal basis or statement of reasons.

177 In its statement in intervention, Fedesa argues, moreover, that by limiting the validity of the MRLs for a veterinary medicinal product to certain specified therapeutic indications, the Commission exceeded the power conferred upon it by Regulation No 2377/90, which does not provide for such a possibility.

178 In reply to that argument, the Commission maintains in its defence that it had to take account of the prohibitions on marketing and use and of the derogations set out in Directive 96/22.

179 When invited by the Court of First Instance to express a view on what consequences might be drawn in the present case from the *Lilly* judgment, the applicants effectively put forward, in their reply of 28 April 1999, an argument identical to that used by Fedesa in its statement in intervention. As for the Commission, it argued *inter alia* in its reply of 28 April 1999, first, that the *Lilly* judgment was not relevant for the purposes of this case, and secondly, that the applicants had not raised any plea in their action alleging infringement of Regulation No 2377/90.

Findings of the Court of First Instance

180 The Court has already held that the various pleas in law raised by the applicants for the purpose of establishing the illegality of Directive 96/22 cannot be accepted. It follows that their objection of illegality must be dismissed as unfounded in any event, without there being any need to rule on the submission by the Commission and the Council that the objection is inadmissible.

181 The two pleas on which the applicants base their action for the annulment of Regulation No 1312/96 must therefore also be dismissed as unfounded, in so far as they are based on the alleged illegality of Directive 96/22.

182 Nevertheless it remains to be examined whether the Commission exceeded the power conferred upon it by Regulation No 2377/90 by limiting the validity of the MRLs for a veterinary medicinal product to certain specified therapeutic indications, as is argued by Fedesa in its statement in intervention and by the applicants in their replies to the written questions of the Court.

183 That line of argument cannot be regarded as inadmissible on the ground that it was not initially raised by the applicants. The case-law of the Court of Justice and the Court of First Instance shows that the third paragraph of Article 37 of the EC Statute of the Court of Justice and Article 116(3) of the Rules of Procedure of the Court of First Instance do not preclude the intervener from advancing arguments which are new or which differ from those of the party he supports, provided those arguments do not alter the context of the dispute and the intervention is always intended to support the form of order sought by the latter (see Case 30/59 *Steenkolenmijnen* v *High Authority* [1961] ECR 1, p. 18; Case C-245/92 P *Chemie Linz* v *Commission* [1999] ECR I-4643, paragraph 32; Case T-459/93 *Siemens* v *Commission* [1995] ECR II-1675, paragraph 21; and Case T-37/97 *Forges de Clabecq* v *Commission* [1999] ECR II-859, paragraph 92).

184 In this case, the line of argument put forward by Fedesa does not alter the context of the dispute as defined in the application. If the misuse of power alleged in that line of argument were established, it would necessarily follow that there had been an unlawful interference in the applicants' exercise of their property rights and their freedom to pursue trade and professional activities, as they maintain in their first plea for annulment. That line of argument therefore has a bearing on the pleas raised by the applicants, and as such it must be examined by this Court.

185 In order to assess whether that line of argument is well founded, it should be borne in mind that the administering of veterinary medicinal products to food-producing animals may result in the residual presence of pharmacologically active substances in the foodstuffs obtained from animals treated (see the first recital in the preamble to Regulation No 2377/90). Therefore, in order to protect public health, Community legislation lays down a procedure for establishing permissible MRLs for those medicinal products (see the second recital in the preamble to Regulation No 2377/90). According to Article 1(1)(b) of Regulation No 2377/90, the MRL is defined as:

'the maximum concentration of residue resulting from the use of a veterinary medicinal product (expressed in mg/kg or microgrammes/kg on a fresh weight basis) which may be accepted by the Community to be legally permitted or recognised as acceptable in or on a food.

It is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the acceptable daily intake (ADI), or on the basis of a temporary ADI that utilises an additional safety factor. It also takes into account other relevant public health risks as well as food technology aspects.'

186 It appears from Articles 2 to 7 of Regulation No 2377/90 that the procedure for fixing MRLs, which may be provisional, for a pharmacologically active substance depends solely on the question whether residues of the substance in question, at the proposed level, constitute a risk to the health of consumers.

187 By contrast, Article 6(1) of Regulation No 2377/90 does not make the inclusion of a substance in one of the Annexes (I to III) to that regulation subject to the condition that the product containing that substance must be capable of being directly used and marketed.

188 In that respect, the Court has already held, in *Lilly*, that the procedure for the establishment of an MRL under Regulation No 2377/90 is independent of, and distinct from, the procedures for the issue of the marketing authorisations laid down in Directive 81/851 and Regulation No 2309/93 (see paragraph 88 of the *Lilly* judgment).

189 The Court has also pointed out (in paragraph 89 of the *Lilly* judgment) that those two measures, which govern respectively the issue of national and Community authorisations for the marketing of veterinary medicines, expressly provide that marketing authorisation for a product will be refused where its use is prohibited under other provisions of Community law (see point 3 of the first paragraph of Article 11 of Directive 81/851 and point 3 of the first paragraph of Article 33 of Regulation No 2309/93).

190 However, Regulation No 2377/90 contains no provision authorising the Commission to take account of a ban on marketing in refusing to establish an MRL (paragraph 90 of the *Lilly* judgment).

191 The Court concluded (at paragraph 92 of the *Lilly* judgment) that the Commission was not legally entitled to base its decision refusing to establish an MRL for somidibove, a recombinant bovine somatotrophin (BST), on the existence of the moratorium on BST.

192 Similarly, in this case, under the procedure for establishing an MRL for clenbuterol pursuant to Regulation No 2377/90, the Commission was not legally entitled to base the limitation on the validity of that MRL on the provisions of Directive 96/22.

193 That consideration is not affected by the fact that, like Regulation No 2377/90, Directive 96/22 is designed to protect public health, whereas, in *Lilly*, the moratorium on BST was introduced for socio-economic reasons. By commenting incidentally on that fact in paragraph 91 of *Lilly*, it was not the intention of the Court to find that there was an implicit derogation from the principle laid down in paragraph 90 of the judgment.

194 In that respect, it must be emphasised once again that the procedure for establishing MRLs laid down by Regulation No 2377/90 is strictly limited to the determination of the threshold below which residues of a given product, present in or on foodstuffs, may be regarded as posing no danger to human health. If the institutions nevertheless consider that they have other reasons for prohibiting the marketing of the product in question, they are under a duty to act by the appropriate means, as they did in this case by adopting Directive 96/22.

195 Besides, Article 15 of Regulation No 2377/90 provides that the regulation is in no way to prejudice the application of Community legislation prohibiting the use in livestock farming of certain substances having a hormonal action, and that nothing in the regulation is to prejudice the measures taken by Member States to

prevent the unauthorised use of veterinary medicinal products. Thus the limitation in question, introduced by Regulation No 1312/96, was not at all necessary to ensure or preserve the effectiveness of Directive 96/22, since that regulation could not in any event prejudice the measures taken by the Member States for the implementation of that directive.

196 Furthermore, there is no provision in Regulation No 2377/90 authorising the Commission to limit the MRLs of a veterinary medicinal product permissible in foodstuffs of animal origin to certain therapeutic indications. Nor can such a limitation be justified by the requirements inherent in safeguarding public health on which Regulation No 2377/90 is based. Those requirements are limited to determining the maximum permissible threshold for the concentration of residues of a substance in food intended for human consumption, whatever the therapeutic indication in respect of which that substance was prescribed. It is self-evident that residues of a pharmacologically active substance which are present in food of animal origin are neither more nor less dangerous for health, at a certain level of concentration, according to whether that substance was administered in respect of a particular therapeutic indication. It follows that the MRLs for a given pharmacologically active substance cannot be determined by reference to the therapeutic properties or indications of that substance, which may be numerous (see, by analogy, Case C-293/97 *The Queen* v *Secretary of State for the Environment and MAFF ex parte Standley and Others* [1999] ECR I-2603, paragraph 34).

197 In addition, Regulation No 1312/96 prejudges the measures to be taken by Member States to prevent unauthorised use of veterinary medicinal products, in breach of Article 15(2) of Regulation No 2377/90, since the limits to the validity of the MRLs for clenbuterol which it imposes would continue to exist even in the event of annulment, withdrawal or amendment of the relevant provisions of Directive 96/22.

198 It follows from the foregoing that, by limiting the validity of the MRLs established for clenbuterol to certain specified therapeutic indications for bovines

and equidae, in Regulation No 1312/96, the Commission exceeded the powers exercised by it under Regulation No 2377/90.

199 Therefore, in accordance with the forms of order sought by the applicants, Regulation No 1312/96 must be annulled in so far as it restricts the validity of the MRLs which it establishes for clenbuterol to certain specified therapeutic indications for bovines and equidae.

Costs

200 Under Article 87(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Under Article 87(3), the Court may order that the costs be shared or that each party bear its own costs where each party succeeds on some and fails on other heads. Since the action in Case T-125/96 has been dismissed, as has the objection of illegality raised in Case T-152/96, it is proper for those provisions to be applied to the main parties and for the applicants to be ordered to bear, in Case T-125/96, the costs of the Council in addition to their own, and, in Case T-152/96, one-half of their own costs. In the latter case, the Commission is ordered to pay one-half of the applicants' costs in addition to its own.

201 The United Kingdom, the Commission and the Council are ordered to bear the costs incurred by them as interveners, pursuant to the first subparagraph of Article 87(4) of the Rules of Procedure.

202 Fedesa is ordered to pay the costs of its intervention in Case T-125/96 and one-half of the costs incurred by it in Case T-152/96, the other half to be borne by the Commission.

203 As to SKV, the Court considers that it is proper to apply the second subparagraph of Article 87(4) of the Rules of Procedure and order SKV to bear its own costs.

On those grounds,

THE COURT OF FIRST INSTANCE (Second Chamber)

hereby rules:

1. **Cases T-125/96 and T-152/96 are joined for the purposes of this judgment.**

2. **Commission Regulation (EC) No 1312/96 of 8 July 1996 amending Annex III of Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin is annulled, in so**

far as it restricts the validity of the MRLs which it establishes for clenbuterol to certain specified therapeutic indications for bovines and equines.

3. For the rest, the applications are dismissed.

4. In Case T-125/96, the applicants and Fédération Européenne de la Santé Animale (Fedesa), as regards its intervention, are ordered to bear their own costs and those of the Council. The United Kingdom, the Commission and Stichting Kwaliteitsgarantie Vleeskalverensector (SKV) are ordered to bear their own costs.

5. In Case T-152/96, the Commission is ordered to bear its own costs and to pay one-half of the costs of the applicants and Fedesa, the other half to be borne by them. The Council and SKV are ordered to bear their own costs.

Potocki Bellamy Meij

Delivered in open court in Luxembourg on 1 December 1999.

H. Jung A. Potocki

Registrar President