OPINION OF ADVOCATE GENERAL LÉGER

delivered on 13 January 2000 *

1. Are national measures which, in order to comply with Directive 86/469/EEC, [1] prohibit the administration of growth promoting products to fattening cattle, and the keeping, stocking, buying or selling of cattle to which such products have been administered, contrary to Articles 30 and 36 of the EC Treaty (now, after amendment, Articles 28 EC and 30 EC)?

That is the question which the Arrondissementsrechtbank te Arnhem (Netherlands) refers to the Court of Justice for a preliminary ruling in the context of criminal proceedings against farmers who have used those products in breach of the national provisions referred to above.

Legal background

Community legislation

2. Under Article 30 of the Treaty, quantitative restrictions on imports and measures having equivalent effect are prohibited between Member States.

3. For the purposes of Article 30, measures having equivalent effect are defined as obstacles to free movement of goods which, in the absence of harmonisation of legislation, are the consequence of applying to goods coming from other Member States where they are lawfully manufactured and marketed, rules that lay down requirements to be met by such goods (such as those relating to designation, form, size, weight, composition, presentation, labelling, packaging), even if those rules apply without distinction to all products, unless their application can be justified by a public-interest objective taking precedence over the free movement of goods. [2]

4. According to the first sentence of Article 36 of the Treaty, prohibitions or restrictions on imports between Member States which are justified, in particular, on

* Original language: French.

1 — Council Directive 86/469/EEC of 16 September 1986 concerning the examination of animals and fresh meat for the presence of residues (OJ 1986 L 275, p. 36).

2 — See, in particular, Joined Cases C-267/91 and C-268/91 *Keck and Mithouard* [1993] ECR I-6097, paragraph 15.

grounds of protecting the health and life of humans and animals are authorised.

5. However, according to the second sentence of Article 36 of the Treaty, those prohibitions or restrictions may not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

6. Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations [3] as amended by Council Directive 88/182/EEC of 22 March 1988 [4] is aimed at preventing any technical barriers to intra-community trade in products resulting from diversity between the legislation of the various Member States. [5] The third recital in the preamble to Directive 83/189 therefore states that a procedure requiring Member States to notify the Commission of technical standards and rules prior to their adoption is established.

7. Article 8 of Directive 83/189 provides that Member States must send to the Commission any draft technical regulation and, if necessary, the underlying legislative provisions or regulations. However, the first subparagraph of Article 8(1) permits derogation from that principle 'where such technical regulation merely transposes the full text of an international or European standard ...'. In that case, information regarding the relevant standard will suffice.

8. Article 10 of Directive 83/189, amended by Directive 88/182, provides that a draft technical regulation does not need to be either notified to or sent to the Commission where '... Member States honour their obligations arising out of Community Directives'.

9. Directive 86/469 [6] is designed to facilitate the free movement of goods by approximating the divergent rules of the Member States which lead to obstacles in intra-Community trade and to a distortion in the conditions of competition between products that are the subject of common organisations of the market.

10. To that end, common control measures in order to ascertain and eliminate the causes of residues in animals and fresh meat, and to ensure that meat showing residues which exceed the permitted level is excluded from consumption, [7] have been adopted.

3 — OJ 1983 L 109, p. 8.

4 — OJ 1988 L 81, p. 75.

5 — First and second recitals in the preamble to Directive 83/189.

6 — See, in particular, the third and fourth recitals in its preamble.

7 — Ninth recital.

11. For the purposes of Directive 86/469, 'residue' means residue of substances having a pharmacological action and of conversion products thereof and other substances transmitted to meat and which are likely to be dangerous to human health'. [8]

12. Article 9(3)(b) of Directive 86/469 requires the competent authorities to ensure that, if the examination of an official sample 'reveals the presence of prohibited substances, the animals may not be placed on the market for human or animal consumption'.

13. Directive 86/469 lists in Annex I the groups of residues which fall within the scope of Article 9, referred to above. Clenbuterol falls within Point B of Annex I, headed 'Specific Groups', Group I: 'Other medicines', sub-group (c): 'Other veterinary medicines'.

The Netherlands legislation

14. Article 1 of the Verordening Stoffen met sympathico mimetische werking (PVV) 1991 (Regulation on sympathicomimetic substances; referred to below as 'the Netherlands Regulation') defines sympathicomimetic substances as '... substances with the effect of stimulating growth, beta-agonist in character or not, save for substances with hormonal effect, as referred to in the "Verordening verbod toediening bepaalde stoffen met hormale werking" (PPV) of 1987 [regulation prohibiting the administration of certain substances with hormonal effects]'.

15. Article 2 of the Netherlands Regulation provides that it is prohibited 'to administer sympathicomimetic veterinary medicines containing Clenbuterol to fattening cattle over 14 weeks old or to authorise the administration of such veterinary medicines to such fattening cattle'.

16. Article 3(1) provides: 'It is prohibited to keep or to have in stock, to buy or to sell fattening cattle to which sympathicomimetic substances referred to therein have been administered contrary to Article 2'.

Factual and procedural background

17. The order for reference shows that the presence of clenbuterol was recorded in urine samples taken from four cattle at the

8 — Article 2(c) of Directive 86/469.

farms of the defendants in the main proceedings, Berendse-Koenen M.G. and Berendse H.G. Maatschap. They were therefore prosecuted for infringement of the Netherlands Regulation.

18. At the hearing, citing the judgment in Case C-194/94 *CIA Security* v *Signalson and Securitel*, [9] the defendants argued that the Netherlands Regulation contained technical standards that had not been notified to the Commission. They inferred therefrom that the regulation could not be used against them.

19. They also argued that clenbuterol is a substance used in certain veterinary medicinal products such as Ventipulmin which, prescribed for therapeutic purposes, allows the effective treatment of certain illnesses specific to cattle. [10] They maintain that the cattle under investigation had undergone that type of veterinary treatment, so that the presence of clenbuterol in the urine samples was due to the administration of that medicinal product prescribed precisely for the purposes of treating the illness from which the animals were suffering.

20. They have further stated that the Netherlands Regulation has the effect of prohibiting the use of that type of veterinary medicinal product, whereas other Member States do not impose such a prohibition. In their submission, that inequality of treatment between Netherlands operators and other Community operators has the effect of creating distortions in competition prohibited by Community law.

21. Concerning the first plea, the Arrondissementsrechtbank te Arnhem differs from the defendants in its analysis and presentation of the Netherlands legislation. [11] According to the national court, the Netherlands Regulation constitutes the measure whereby the Netherlands complied with the obligations imposed by Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products. [12] That directive, which places anabolic products under a special regime, while not prohibiting all transactions concerning cattle and meat to which anabolic substances have been administered, does not, in the national court's view, require Member States to notify the Commission of the transposition measures adopted in order to comply with the obligations laid down by the directive. It concludes that the Netherlands Regulation did not have to be notified to the Commission in accordance with Directive 83/189 in order to produce effects in

9 — [1996] ECR I-2201.

10 — It is common ground that the veterinary medicinal product called 'Ventipulmin' contains clenbuterol, and that, when lawfully prescribed in authorised doses, it can effectively treat asthmatic illnesses of cattle.

11 — Page 4, paragraph 2 of the English translation of the order for reference.

12 — OJ 1981 L 317, p. 1.

relation to the defendants. However, the court wishes to obtain confirmation of its proposed interpretation of Directive 83/189 for the purposes of ruling on the compatibility of its national law with the latter.

22. Concerning the defendants' second plea, the national court expresses no opinion, but questions whether it is well founded.

23. Considering itself unable to determine the dispute in the main proceedings without obtaining the reply of the Court of Justice to its questions, the Arrondissementsrechtbank te Arnhem has formulated the following questions which it refers for a preliminary ruling:

'1. Does the Verordening Stoffen met sympathico mimetische werking (PVV) 1991 and, more particularly, Articles 2 and 3 thereof, contain technical regulations which, pursuant to Article 8 of Directive 83/189/EEC, as it stood when the Verordening came into force, should have been notified to the Commission beforehand?

2. Does the Verordening Stoffen met sympathico mimetische werking (PVV) 1991 and, more particularly, Articles 2 and 3 thereof, contain provisions which constitute obstacles to freedom of trade for the purposes of Article 30 of the EC Treaty?'

24. By letter of 11 June 1999, the national court indicated to the Court of Justice that, in the light of the judgment of 11 May 1999 in Case C-425/97 *Albers and Others*, [13] it no longer wished to proceed with the first question.

25. In that judgment, the Court of Justice held that 'in issuing the prohibition on administering clenbuterol to fattening cattle over 14 weeks old and holding, having in stock, buying or selling fattening cattle over 14 weeks old to which that substance has been administered, the Netherlands Government honoured its obligations under Directive 86/469'. [14] It concluded that, although Articles 2 and 3 of the Netherlands Regulation were to be regarded as technical regulations within the meaning of Directive 83/189, as amended by Directive 88/182, Article 10 of the same directive exempted them from the notification obligation laid down by Article 8 thereof. [15]

13 — [1999] ECR I-2947.
14 — Paragraph 23.
15 — Paragraph 24.

Answer to the question referred for a preliminary ruling

26. The wording of the question referred by the national court shows that the Court of Justice is not being asked to rule on the validity of Directive 86/469 in the light of Article 30 of the Treaty, [16] but has to assess the compatibility, with regard to that Treaty provision, of a rule of domestic law such as that laid down by Article 3(1) of the Netherlands Regulation read in combination with Article 2 thereof.

27. It might legitimately be asked what need there is to reformulate the second question in so far as the national court decided to withdraw the first, having taken cognisance of the *Albers* judgment which — it should be remembered — held that the national measures in dispute did not constitute measures adopted unilaterally by the Netherlands State but were internal measures for transposing Directive 86/469 which, in accordance with Article 10 of Directive 83/189, escape the notification obligation laid down by Article 8 of that directive. [17] Therefore, review of the compliance of that directive with Article 30 of the Treaty might have been asked for. [18]

28. It is settled case-law that measures having equivalent effect to quantitative restrictions on imports within the meaning of Article 30 of the Treaty are defined as obstacles to free movement of goods which, *in the absence of harmonisation of legislation*, are the consequence of applying to goods coming from other Member States, where they are lawfully manufactured and marketed, conditions with which such goods must comply, even if those rules apply without distinction to all products, unless their application can be justified by a public-interest objective taking precedence over the free movement of goods. [19]

29. Measures such as those adopted by the disputed national provisions were, as already mentioned, regarded by the Court

16 — That is confirmed by the reasons given for the decision to refer (see p. 4 of the English translation of that decision), by the letter of 11 June 1999 in which the national court indicated to the Court of Justice that it was withdrawing its first question, by the written observations submitted in these preliminary ruling proceedings (paragraphs 43 to 49 of the Commission's observations, paragraph 46 of the Netherlands Government's observations; paragraphs 29 to 31 of the Irish Government's observations), by the further arguments of the latter and of the parties to the main proceedings at the hearing before the Court of Justice, and by the replies given to the Court's questions during that hearing.

17 — Paragraphs 23 and 24.

18 — It is settled case-law that 'the prohibition of quantitative restrictions and of all measures having equivalent effect applies not only to national measures but also to measures adopted by the Community institutions' (Case C-284/95 *Safety Hi-Tech* v *S & T* [1998] ECR I-4301, paragraph 63).

19 — *Keck and Mithouard*, cited above.

of Justice in *Albers* as measures whereby the Netherlands State honoured its obligations to transpose the provisions of Directive 86/469. It is clear from the third and fourth recitals in the preamble to that directive that its aim is to harmonise common measures for controlling residues and to fix common maximum tolerance levels for those residues in fresh meat, the exceeding of which by itself entails prohibition on such meat being marketed. [20] That directive therefore pursues a dual aim, which is both to ensure the protection of human health [21] and to facilitate the free movement of goods.

30. It must be concluded that provisions such as those in Article 3(1) of the Netherlands Regulation, read in combination with Article 2 of that regulation, do not constitute unilateral measures designed to protect the own interests of the Member State enacting them, but were adopted to comply with the decision of the Council in the general interest of the Community.

31. Therefore, the question of the compatibility of those national measures with Article 30 [22] or Article 36 of the Treaty no longer arises. [23]

32. For the sake of completeness, it should be noted that the defendants in the main proceedings have produced no evidence to support their claims that the Netherlands legislation has the effect of extending prohibitions on the marketing in national territory of goods which comply with Directive 86/469 beyond what the directive requires. [24]

33. It follows from the above that, in so far as rules such as those laid down by the Netherlands Regulation, and in particular by Articles 2 and 3 thereof read in combination, have been enacted by Member States not to protect interests of their own but in order to comply with the decision of the Council in the general interest of the Community, the question of the compatibility of those national rules with Articles 30 and 36 of the Treaty no longer arises.

20 — See Article 9(3)(b) of Directive 86/469.

21 — I emphasised in my Opinion in *Albers* (footnote 5) how the presence of clenbuterol in excess of the authorised doses presents real dangers for human health.

22 — See the judgment in *Keck and Mithouard*, referred to above.

23 — See, for example, Case 72/83 *Campus Oil* v *Minister for Industry and Energy* [1984] ECR 2727, paragraph 27; Case 148/85 *Direction Générale des Impôts* v *Forest* [1986] ECR 3449, paragraph 14; Case C-5/94 *R* v *MAFF* ex parte *Hedley Lomas* [1996] ECR I-2553, paragraph 18; Case C-1/96 *R* v *MAFF* ex parte *Compassion in World Farming* [1998] ECR I-1251, paragraph 41.

24 — They claim, in particular, that the legislation effectively prohibits the marketing in national territory of cattle to which medicines prescribed for therapeutic purposes and containing clenbuterol in authorised doses have been administered.

Conclusion

34. I therefore propose that the Court should rule as follows:

A rule such as that in Article 3(1) of the Verordening Stoffen met sympathico mimetische werking (PVV) 1991, read in combination with Article 2 of that same regulation, whereby the Member State adopting it honoured obligations arising from Council Directive 86/469/EEC of 16 September 1986 concerning the examination of animals and fresh meat for the presence of residues, and in particular from Article 9 thereof, does not constitute a unilateral national measure hindering intra-Community trade prohibited by Article 30 of the EC Treaty (now, after amendment, Article 28 EC).