OPINION OF ADVOCATE GENERAL LÉGER

delivered on 17 December 1998 *

1. Are national provisions prohibiting the administration to fattening cattle of products which stimulate growth technical regulations which must be notified to the Commission before adoption pursuant to Article 8 of Directive 83/189/EEC, [1] as amended by Council Directive 88/182/EEC [2] (hereinafter 'the Directive')? That is the question referred to the Court by the Gerechtshof (Regional Court of Appeal), 's-Hertogenbosch, Netherlands, for a preliminary ruling in three sets of criminal proceedings against farmers charged with breaching that prohibition.

Facts and procedure

2. Following a check by the AID (general inspection service) which revealed the presence of prohibited residues [3] in the urine of cattle, their owners, Mr Albers, Mr Van den Berkmortel and Mr Nuchelmans (hereinafter 'the defendants in the main proceedings'), cattle breeders in the Netherlands, were sentenced to fines for breaching the Verordening Stoffen met sympathico mimetische werking (PVV) 1991 (Regulation concerning sympathicomimetic substances — hereinafter 'the national regulation').

3. On appeal to the Gerechtshof, 's-Hertogenbosch, the defendants in the main proceedings argued that the national regulation is a technical regulation under Community law which should have been notified to the Commission as such. Since it was not so notified, and in accordance with the judgment of 30 April 1996 in *CIA Security International*, [4] that regulation could not be enforced against them.

4. In some doubt as to the relevance of the legal argument advanced, the Gerechtshof, 's-Hertogenbosch, has referred the following question to this Court for a preliminary ruling:

'Does the Verordening Stoffen met sympathico mimetische werking (PVV) 1991, in particular Article 3(1) thereof, contain technical regulations which, pursuant to Article 8 of Directive 83/189/EEC, as it stood at the time when the Verordening came into force,

* Original language: French.

1 — Council Directive of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ 1983 L 109, p. 8).

2 — Council Directive of 22 March 1988 (OJ 1988 L 81, p. 75).

3 — Namely Clenbuterol.

4 — Case C-194/94 [1996] ECR I-2201.

should have been notified to the Commission beforehand?'

The relevant Netherlands legislation

5. Article 1 of the national regulation defines sympathicomimetic substances as '... beta-agonal or other substances promoting growth, apart from substances with hormonal effect within the meaning of the "Verordening verbod toediening bepaalde stoffen met hormonale werking" (PVV) of 1987 (regulation prohibiting the administration of certain substances with hormonal effect)'. [5]

6. Article 2 provides: '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.'

7. 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.'

The relevant provisions of the Directive

8. The aim of the Directive is to remove all technical obstacles to intra-Community trade resulting from differences in national legislation. [6] To that end it introduces a procedure requiring Member States to notify the Commission of all technical standards and regulations before they are adopted. [7]

9. Article 1(5) defines such regulations as 'technical specifications, including the relevant administrative provisions, the observance of which is compulsory, *de jure* or *de facto*, in the case of marketing or use in a Member State or a major part thereof, except those laid down by local authorities.'

5 — Without going into technical and scientific detail, it is clear from the pleadings, and is not disputed, that such substances are considered an effective treatment for specific cattle diseases (treatment of asthmatic diseases etc.) and, in prescribed doses, can be supplied legally. However, the administration of this substance to young cattle in amounts exceeding the prescribed dose reduces the quantity of lipids and promotes an increase in the amount of muscle. It has the same effects as a growth hormone and can therefore increase the value of a carcass. The use of this substance for that purpose may pose a serious threat to the health of consumers of animal products. It is found in animals in the form of residues and the secondary effects of Clenbuterol may therefore also affect consumers of meat from such animals (vasodilation, bronchiectasis, problems with heart rate and muscular fibrillation).

6 — First and second recitals of Directive 83/189.

7 — Third recital.

10. Article 1(1) defines 'technical specification' as 'a specification contained in a document which lays down the characteristics required of a product such as levels of quality, performance, safety or dimensions, including the requirements applicable to the product as regards terminology, symbols, testing and test methods, packaging, marking or labelling and the production methods and procedures for agricultural products as defined in Article 38(1) of the [EC] Treaty [8] and for products intended for human and animal consumption and for medicinal products as defined in Article 1 of [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], [9] as last amended by Directive 87/21/EEC.' [10]

11. Article 8 of the Directive requires Member States to communicate to the Commission any draft technical regulation, and, where appropriate, the basic legislative or regulatory provisions. However, the first subparagraph of Article 8(1) provides for a derogation from that principle, 'where such technical regulation merely transposes the full text of an international or European standard.' In such a case information regarding the relevant standard suffices.

12. Finally, Article 10 of the Directive provides that a draft technical regulation need be neither notified nor communicated to the Commission 'where Member States fulfil their obligations as arising out of Community directives and regulations.'

Ruling on the question referred

13. By the question it refers to this Court, the national court seeks a ruling as to whether national provisions, such as those contained in the national regulation, under which it is prohibited to keep or to have in stock, to buy or to sell fattening cattle to which sympathicomimetic substances been administered or to administer sympathicomimetic veterinary medicines, in this case Clenbuterol, to fattening cattle over 14 weeks old, fall within the scope of the obligation to notify laid down by Article 8 of the Directive.

To answer that question, it must first be ascertained whether the provisions of the national regulation are technical regulations within the meaning of Article 1 of the Directive. If they are, I can go on to consider whether the obligation to notify implied by such a definition could be waived in the present case.

8 — Which defines agricultural products as 'the products of the soil, of stockfarming and of fisheries and products of first-stage processing directly related to these products.'

9 — OJ, English Special Edition 1965-66, p. 20.

10 — OJ 1987 L 15, p. 36.

Definition as a technical regulation

14. The Court has been asked to rule on the components of this definition on many occasions. It has, for instance, been asked to rule as to whether the following provisions can be taken to be technical regulations within the meaning of the Directive: the approval granted by the Direction Générale des Télécommunications, pursuant to the French Postal and Telecommunications Code, in respect of equipment complying with the specifications set out in the list annexed to the notice; [11] Article 12 of the Belgian Law of 10 April 1990 on caretaking firms, security firms and internal caretaking services, which provided that prior approval granted by the committee established for that purpose by that law and by royal decree was necessary for the marketing or use of alarm systems and their components on Belgian territory; [12] the Belgian Ministerial Order of 24 December 1993 concerning products subject to environmental tax, [13] which imposed a requirement that a distinctive sign obtained from the Belgian Ministry of Finance must be affixed to all disposable products to be marketed on Belgian territory; [14] the Decree of 9 November 1993 of the Government of the Region of Metropolitan Brussels concerning standards of quality and safety in furnished accommodation, [15] which provides that equipment for protection against fire, natural-gas installations or natural-gas appliances must bear the mark 'BENOR' if they are to be marketed on Belgian territory; [16] the Regeling Ademanalyse (Regulation on breath analysis) of 25 September 1987, [17] which sets out the characteristics which breath-analysis apparatus must exhibit, in particular so far as concerns quality, performance, testing and test methods as well as the procedures for assessing conformity, in order to be capable of being used by the police for measuring alcohol content. [18] In a case currently pending before the Court it is asked to rule as to whether the Belgian Law of 14 July 1991 on trade practices and consumer information [19] which provides that, in order to be marketed on Belgian territory, products such as foodstuffs, cosmetics, detergents and petfood must carry labelling in the language of the region, in that instance, Dutch, must be considered to be a technical regulation within the meaning of the Directive. [20]

15. Unlike the interveners in this case, I take the view that the term 'technical regulation' as used in the Directive has already been defined by the Court. [21]

16. To define the term the Court has consistently cited Articles 1(1) and 1(5) of the Directive verbatim. That approach was self-evident since that article was drafted in sufficiently clear, precise and general terms to be applied

11 — Judgment in Case C-69/91 *Decoster* [1993] ECR I-5335.

12 — *CIA Security International*, cited above.

13 — *Moniteur Belge* of 29 December 1993, p. 28903.

14 — Case C-13/96 *Bic Benelux* [1997] ECR I-1753.

15 — *Moniteur Belge* of 31 December 1993, p. 29194.

16 — Case C-145/97 *Commission* v *Belgium* [1998] ECR I-2643.

17 — Dutch Ministerial Decree of 1987 on breath analysis (*Stcrt.* 187).

18 — Case C-226/97 *Lemmens* [1998] ECR I-3711.

19 — *Moniteur Belge* of 29 August 1991.

20 — See the Opinion of Advocate General Cosmas in Case C-33/97 *Colim* pending before the Court.

21 — To that effect, see Lecrenier, S., 'Le contrôle des règles techniques des États et la sauvegarde des droits des particuliers' (The monitoring of technical regulations of States and the protection of individual rights), *Journal des Tribunaux de Droit Européen*, 1997, p. 1.

to the perforce varied circumstances which give rise to references to the Court for preliminary rulings. [22] It covers all the matters to be taken into account, the essential nature and the specific characteristics which define the term.

17. The Court's judgments in *CIA Security International* and *Bic Benelux*, cited above, further clarified certain aspects of the definition.

18. Those judgments and the Directive essentially pinpoint not only the aspects of the definition of the term 'technical regulation' to be taken into account, but also criteria concerning its originator and the system of which it is part (legal effect and penalty for failure to observe the specifications imposed by the standard in question).

19. As regards the essential nature and specific characteristics which enable the term, its originator and the system of which it is part to be defined, it is clear from Article 1(1) and (5) of the Directive and the judgments in *CIA International* and *Bic Benelux*, cited above, read in conjunction, that:

— as regards the content of a standard which must be classified as a technical regulation: there must be a collection of formal requirements relating to the characteristics of a product (for instance, the production methods and procedures for an agricultural product as defined in Article 38(1) of the Treaty);

— as regards its originator: it must not be issued by a local authority (it must therefore be issued by a national authority);

— as regards its effect: it must be binding *de facto* or *de jure* and have legal effects of its own; [23]

— as regards the penalty for failure to observe the regulation: such failure must give rise to a ban on marketing or using the product in a Member State or a major part thereof; in other words, only a provision 'capable of *hindering*, directly or indirectly, actually or potentially, *intra-Community trade*

22 — See point 14 of this Opinion.

23 — *CIA Security International*, cited above, paragraphs 29 and 30.

in goods' [24] can be classified as a technical regulation within the meaning of the Directive.

20. The Court has, moreover, made clear that, if those criteria are fulfilled, 'a directive applies to technical regulations irrespective of the grounds on which they were adopted.' [25]

21. Fattening cattle are the products of stock-farming and are thus agricultural products within the meaning of Article 38(1) of the Treaty which expressly mentions such products.

22. The national regulation requires breeders of fattening cattle to produce stock without using substances to promote growth such as Clenbuterol. Accordingly it lays down a specific production method and procedure for an agricultural product.

23. That regulation was issued by the Netherlands legislature and thus by a national authority.

24. Finally, there is no doubt that the national regulation at issue is binding and that failure to observe it gives rise to a prohibition on marketing cattle to which substances to promote growth have been administered on the national territory. Consequently it is capable of hindering directly intra-Community trade in goods.

25. It must therefore be concluded that the national regulation is a technical regulation within the meaning of Article 1(1) of the Directive.

The obligation to notify that technical regulation to the Commission

26. Noting that the national regulation was not notified to the Commission pursuant to Article 8 of the Directive, the defendants in the main proceedings, citing *CIA Security International*, cited above, claim that the referring court is bound to hold that the regulation at issue is unenforceable against them. Although the question is not put formally, it is clear from the grounds of the order for reference that it falls to the Court to determine the scope of the direct effect of Article 8 of the Directive and to rule as to whether the defendants in the main proceedings can, in

24 — *Bic Benelux*, cited above, paragraph 19, emphasis added.

25 — *Lemmens*, cited above, paragraph 20. Accordingly, the Directive covers fiscal accompanying measures such as the requirement to affix a specific mark on certain products in order to monitor the collection of an environmental tax (*Bic Benelux*, cited above) or products intended for uses falling with the prerogatives of public authority (breath-analysis equipment used only by the police, *Lemmens*, cited above).

the circumstances of the case, rely on the Court's judgment in *CIA Security International.*

27. In that judgment the Court ruled that Article 8 of the Directive had direct effect and that individuals can rely on it before the national courts which must decline to apply a national technical regulation which has not been notified in accordance with the Directive. In *Lemmens*, cited above, the Court clarified the scope of that decision.

28. In that case it fell to the Court to determine the effect of failure to give prior notification of a draft national order laying down the required characteristics of breath-analysis apparatus used by the police to measure alcohol content on criminal proceedings instituted against drivers charged with driving with excess alcohol, evidence of whose level of alcohol had been adduced using apparatus to measure alcohol approved in accordance with the national order at issue.

29. In that judgment the Court ruled: 'While failure to notify technical regulations, which constitutes a procedural defect in their adoption, renders such regulations inapplicable inasmuch as they hinder the use or marketing of a product which is not in conformity therewith, it does not have the effect of rendering unlawful any use of a product which is in conformity with regulations which have not been notified.' [26]

30. The Court pointed out that the national regulations applied to the defendants in that case differ from those which, not having been notified to the Commission in accordance with the Directive, are unenforceable against individuals and that 'the use of the product by the public authorities, in a case such as this, is not liable to create an obstacle to trade which could have been avoided if the notification procedure had been followed.' [27] The regulations in question were those which prohibit and penalise driving while under the influence of alcohol and require a driver to exhale his breath into an apparatus designed to measure the alcohol content, the result of that test constituting evidence in criminal proceedings.

31. It must therefore be inferred from *Lemmens*, cited above, that the effects of the judgment in *CIA Security International*, cited above, are limited to individuals who can prove an *interest* in ensuring that the technical regulations contained in national legislation which is not notified to the Commission were monitored on the basis of the Directive.

26 — *Lemmens*, cited above, paragraph 35.

27 — Ibid., paragraph 36.

32. In the case currently before the Court the national legislation at issue prohibits the marketing of cattle whose growth has been promoted through the administration of prohibited substances. Accordingly it constitutes a direct obstacle to the free movement of goods. Nor is there any doubt that the defendants are cattle breeders who used those substances in contravention of the provisions of the national legislation at issue. It must be concluded that they have an interest in having the technical regulations contained in that legislation monitored on the basis of the Directive if that legislation falls within the scope of the obligation to notify laid down by Article 8 of the Directive.

33. It therefore remains to be ascertained whether the national legislation falls within the scope of Article 8 or whether it is covered by the derogations provided for by Articles 8(1) or 10 of the Directive.

34. According to the first subparagraph of Article 8(1) of the Directive, Member States need merely provide information regarding the relevant standard to the Commission where a draft technical regulation merely transposes the full text of an international or European standard.

35. However, under Article 10 of the Directive, Member States are not under an obligation to notify the Commission of a draft technical regulation nor under an obligation to provide information where they fulfil their obligations as arising out of Community directives.

36. Like the Commission and the intervening governments, I consider that the national legislation at issue does not fall within the scope of the obligation to notify provided for by Article 8. In introducing the prohibition on keeping, having in stock, buying or selling fattening cattle to which sympathicomimetic substances have been administered or in prohibiting the administration of veterinary medicines with sympathicomimetic effect, in this case Clenbuterol, to fattening cattle over 14 weeks old, the Netherlands Government fulfilled obligations as arising from two Directives.

37. It is clear from Article 4 of Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products, [28] as amended by Council Directive 90/676/EEC, [29] that no veterinary medicinal product may be placed on the market in a Member State or *administered to animals unless authorisation has previously been granted by the competent authority of that Member State*.

28 — OJ 1981 L 317, p. 1.

29 — Directive of 13 December 1990 (OJ 1990 L 373, p. 15).

38. Moreover, under Council Directive 86/469/EEC of 16 September 1986 concerning the examination of animals and fresh meat for the presence of residues, [30] Member States are to submit to the Commission a plan setting out the national measures to be taken to achieve the stated objective of that Directive which is to examine animals, their excrement and body fluids and tissues and fresh meat for the presence of residues. Under that directive, in accordance with the final part of its Article 18, the national measures at issue were notified to and examined by the Commission which approved them on 30 March 1989 by Decision 89/273/EEC. [31] There would be no point whatsoever in requiring that the national legislation at issue be notified a second time under the Directive.

39. Furthermore, Article 9 of Directive 86/469 requires Member States to prohibit the marketing of such animals for both human and animal consumption if prohibited substances are found in the animals examined. The national legislation at issue therefore merely transposed the penalty laid down clearly and precisely by Directive 86/469.

40. Finally, Clenbuterol is amongst the residues whose presence above a certain limit in animals intended for human or animal consumption is prohibited [32] by that Directive.

41. Accordingly, although it can be classified as a technical regulation under the Directive, the national legislation adopted by the Netherlands authorities is not subject to the requirement to notify which the Directive imposes generally.

Conclusion

42. For the reasons given above, I propose that the Court should reply to the question referred by the Gerechtshof, 's-Hertogenbosch, as follows:

Rules such as those in the Verordening Stoffen met sympathico mimetische werking (PVV) 1991 (Regulation concerning sympathicomimetic substances), in particular

30 — OJ 1986 L 275, p. 36.

31 — Decision approving the plan relating to the examination for residues of substances other than those having a hormonal action submitted by the Netherlands (OJ 1989 L 108, p. 28).

32 — Annex I to Directive 86/469 contains a classification of all the residues concerned, including Clenbuterol, which is included under heading B, Group I(c) 'Other veterinary medicines'.

Article 3(1) thereof, constitute technical regulations within the meaning of 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, as amended by Council Directive 88/182/EEC of 22 March 1988, in the version applicable at the time of entry into force of the Verordening, which, under Article 10 of that Directive, do not have to be notified to the Commission beforehand.