OPINION OF MRS ADVOCATE GENERAL ROZÈS DELIVERED ON 19 JANUARY 1983 [1]

Mr President,
Members of the Court,

This is an action brought by the Commission of the European Communities for a declaration that the Kingdom of Belgium has failed to fulfil its obligations under the Treaty by imposing a requirement that a person applying for authorization to market phyto-pharmaceutical products and pesticides for non-agricultural use be established in Belgium.

I — 1. The action was brought as a result of a complaint submitted by the Government of the Federal Republic of Germany to the Commission in 1979. The Court was informed at the hearing that the product in question is a lotion which is intended to protect horses and ponies against insect bites and the general discomfort caused by insects, in particular flies. According to its manufacturer, established in Germany, the use of the product, which is widely distributed in the Community, has not once resulted in an accident during the 13 years in which it has been marketed.

The Commission therefore sent a first letter to the Belgian Government dated 5 November 1979, which set out the problems raised by the requirement imposed by the Belgian legislation in respect of Article 30 et seq. of the Treaty. In its reply dated 31 December 1979, the Belgian Government claimed that the requirement was justified by the need to protect public health, in view of the risks connected with the use of the products concerned.

The preliminary procedure provided for by Article 169 of the Treaty was officially commenced on 27 March 1981. In its formal letter of notice, the Commission alleged that the Belgian legislation constituted an infringement of Article 30 of the Treaty inasmuch as it rendered the marketing of imported products more difficult than that of domestic products and could not be justified under Article 36. In its observations of 21 May 1981, the Belgian Government conceded that its legislation might "certainly have the apparent effect of rendering the marketing of imported goods more difficult than that of domestic goods". However, it justified the legislation by reference to the dangerous nature of the products, which necessitated the imposition of extremely strict rules, particularly in relation to inspections. In its view, the requirement that a national representative with responsibility for the quality of each product be nominated ensured the protection of users in a manner which was appropriate and not excessive.

Nevertheless, the Commission issued on 23 October 1981 a reasoned opinion, notified to the Belgian authorities on 30 October 1981, in which it asked the Belgian Government to take the necessary measures to rectify its alleged failure to fulfil its obligations under the Treaty within a period of two months. The Belgian Government did not comply with that request. On the contrary, by a letter of 18 February 1982, it emphasized that in its opinion the disputed requirement was indispensable for the protection of public health.

1 — Translated from the French.

Those were the circumstances which led the Commission to bring an action before the Court, which was lodged at the Court Registry on 17 May 1982.

2. The provision which is said to conflict with Community law is contained in the Royal Decree of 5 June 1975 on the storage, marketing and use of pesticides and phyto-pharmaceutical products. That measure essentially provides that:

No phyto-pharmaceutical product or pesticide may be marketed without prior authorization;

Packaging and labelling are subject to strict requirements in order to ensure that any person who may handle the products is both protected and provided with the necessary information;

The marketing and, in certain cases, the use of the products regarded as the most dangerous, which are listed in the annex to the Royal Decree, are restricted to persons who are qualified and are subject to special provisions.

Article 12 of the Royal Decree states that:

The application for approval or authorization, the application for a renewal of the approval or the authorization and the application for supplementary approval or authorization are to be submitted on a form, a model of which is included in Annex I to this decree.

The application is to be submitted in triplicate to the competent minister by the person *established* in Belgium who is responsible for the marketing of the phyto-pharmaceutical product or the pesticide for non-agricultural use, whether he is a manufacturer, importer, proprietor or concessionnaire.

According to the Belgian Government, as a result of Article 12, "the person who has knowledge of the total composition and of all the physico-chemical and biological properties of such products becomes the holder of the official certificate of authorization or approval issued for the product in question". The requirement that the holder be established in Belgium is justified by the need to ensure that he is held liable for all the consequences which result from the fact that the product is on the market and in particular those consequences which affect public health.

Article 12 applies to the two categories of products which are defined in Article 1 of the Royal Decree: phyto-pharmaceutical products and pesticides for non-agricultural use. The former include pesticides for agricultural use and must be approved by the Minister for Agriculture. The latter are subject to authorization by the Minister for Public Health. If the person making the application is established in Belgium, his actual status is irrelevant, as the last words of the second paragraph of Article 12 show. Moreover, in the course of these proceedings the Belgian Government stated that such a person might equally be a local representative of the importer, a wholesaler, or even a retailer.

In reply to one of the questions which the Court put to it, the Belgian Government pointed out that a similar requirement was imposed by its legislation relating to pharmaceutical products and to explosives. The representative of the Commission informed the Court at the hearing that the

Commission would not fail to take any necessary action in that regard.

Finally it should be noted that similar proceedings have been brought, are at present being brought and should constantly be brought in respect of legislation comparable to the Belgian legislation. Thus the Commission took action against the Federal Republic of Germany where the Law on the protection of plants (Pflanzenschutzgesetz), in particular Article 12 thereof, provided that the packages of products should state the name of the producer, importer or distributor *"established in the territory in which the Law applies"*. As a result of the Commission's action, Germany amended the wording to *"established in a Member State of the EEC"* and the Commission was able to suspend its action. In the same way, the Commission commenced a procedure against the French Republic in which a reasoned opinion had been issued at the time of the hearing in this case. It concerns an order of the Minister for Agriculture of 7 October 1974 on the procedure for the approval of products listed in Article 1 of the Law of 11 November 1943 relating to the organization of inspections of anti-parasitic products. The order provides that "the applications for approval ... must be submitted, for each specialized product, to the Minister for Agriculture by the licenced distributor residing in France".

Finally, as a result of information provided by the Belgian Government in the course of these proceedings, the existence of a similar situation in Italy has been brought to the Commission's notice, and it intends to initiate the procedure under Article 169 against that Member State in the very near future.

3. The only existing Community legislation which relates specifically to pesticides and phyto-pharmaceutical products is a Council harmonizing directive relating to the classification, packaging and labelling of dangerous substances.[1]

In addition, mention should be made of the proposal for a Council directive concerning the placing of EEC-accepted plant protection products on the market submitted by the Commission to the Council on 4 August 1976.[2] That proposal envisages in particular that each applicant for "EEC-acceptance" of a plant protection product shall be required to have a permanent office within the Community.[3] However, that Community solution to the question of establishment has met with resistance from certain Member States, including Belgium, who prefer a national solution of the kind which is the subject of these proceedings. At present it is impossible to foresee the date at which the Council is likely to complete its examination of that proposal.

II — 1. The two parties agree that the practical effect of the action is relatively limited.

On the one hand, the Commission accepts that the requirement imposed by the existing legislation is satisfied in the large majority of cases, since the firms in question often have a local representative as a matter of sales policy. However, at the same time it emphasizes that the requirement may represent an obstacle to small and medium-sized undertakings

1 — Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (Official Journal, English Special Edition 1967, p. 234).

2 — Official Journal 1976, C 212, p. 3.

3 — Article 5 (2).

wishing to export their products to Belgium. That seems to me to be an important consideration. Indeed it may be said that the particular characteristics of national legislation and practices have a much greater effect on small undertakings and are, therefore, especially discriminatory in relation to them.

On the other hand, the parties agree that the disputed products may be dangerous and that the marketing thereof may be subjected to prior authorization. Thus the label of the apparently harmless "fly repellent lotion", the product which gave rise to the present proceedings, states, as the Court was informed at the hearing:

"Toxic for bees and fish. For animals only. Keep out of the reach of children. For external use only. Not to be used in the proximity of feed. Inflammable."

The action, therefore, is concerned only with the requirement that the applications for authorization be submitted by a person established in Belgium, whether he be the producer, importer, concessionaire, wholesaler or retailer.

The Commission takes the view that the requirement renders the marketing of imported goods more difficult than that of domestic goods. It therefore constitutes a measure having an effect equivalent to quantitative restrictions on imports, as prohibited by Article 30 of the Treaty. Moreover, the exemptions to that prohibition in Article 36 of the Treaty do not apply.

2. In the first place it is correct that Article 30 of the Treaty applies to this case. There are no common or harmonized Community rules relating to the marketing of phyto-pharmaceutical products and pesticides for non-agricultural use. It is therefore for the Member States to decide what degree of protection of the health and life of humans they intend to assure.[1] However, they must have regard "to the fact that their freedom of action is itself restricted by the Treaty", in particular by Article 30 et seq.[2]

It must then be established whether the disputed measure is in fact contrary to Article 30. Generally, as the Court has repeatedly held, it is sufficient that the measure in question should be likely "to hinder, directly or indirectly, actually or potentially, imports between Member States." [3]

It should further be noted that, if the disputed legislation had existed when the Treaty came into force, Belgium would have been under a duty to amend it in accordance with Article 4 (1) of Commission Directive 70/50/EEC of 22 December 1969 based on the provisions of Article 33 (7), on the abolition of measures which have an effect equivalent to quantitative restrictions on imports and are not covered by other provisions adopted in pursuance of the EEC Treaty (Official Journal, English Special Edition 1970 (I), p. 17). It would in fact have been contrary to Article 2 (3) (g) of that directive, which refers to measures which "make access of imported products to the domestic market conditional upon having an agent or representative in the

1 — Judgment of 20 May 1976, Case 104/75 *de Peijper* [1976] ECR 613, paragraph 15 of the decision, at p. 635; judgment of 17 December 1981, Case 272/80 *Frans-Nederlandse Maatschappij voor Biologische Producten* [1981] ECR 3277, paragraph 12 of the decision at p. 3290.

2 — Paragraph 12 of the decision in *Biologische Producten* at p. 3290.

3 — Most recently: judgment of 9 June 1982 in Case 95/81 *Commission* v *Italian Republic*, paragraph 24 of the decision.

territory of the importing Member State". For that reason alone, it would seem difficult to argue that, because it was adopted after the Treaty had come into force, the disputed measure was compatible with Community law. Indeed, to adopt a measure contrary to Community law after, rather than before, the entry into force of the Treaty, as Belgium has done in this case, would seem a more serious breach of Community law.

Quite apart from that consideration, it may be thought that the disputed measure constitutes a restriction on imports in view of the special obligations which it imposes on the person applying for authorization. As the Commission remarked following the Belgian Government's explanation, those obligations seem severe, because, in particular, the applicant must verify that the products are in conformity with the information contained in the authorization documents and, in case of accident, incurs civil and criminal liability.

Finally, the Belgian Government itself concedes that Article 12 of the Royal Decree is contrary to Article 30 and merely emphasizes that its legislation has a limited effect on trade and that the majority of legislative provisions indirectly restrict the free movement of goods.

III — Therefore, the effect of Article 36 is the essential problem in this case. In the view of the Belgian Government, the requirement that the person applying for authorization be established in Belgium is indispensable in order to ensure the protection of public health. That is one of the grounds, mentioned in the first sentence of Article 36, on which restrictions on imports may be justified and indeed it ranks first among the property or interests protected by Article 36.[1]

1. Before examining the submissions of the parties on that aspect of the case, I would point out that, "in accordance with the settled case-law of the Court, Article 36 must be strictly interpreted".[2] Moreover, according to that article, in order to be lawful restrictions on imports must be *"justified* on grounds of . . . the protection of health and life of humans . . .". The word "justified" means that the measures must be *necessary* for the protection of health[3] and further that there is no other means of affording such protection which places less of a restriction on trade.[4] In other words, as the Belgian Government has acknowledged, "the measures adopted by States under Article 36 must be compatible with the principle of proportionality".

Finally it should be recalled that, in cases concerning Article 36, the onus of establishing that the national legislation is in fact justified by one of the

1 — Judgment of 20 May 1976, *de Peijper,* cited above, paragraph 15 of the decision at p. 635.

2 — Judgment of 9 June 1982, Case 95/81 *Commission* v *Italian Republic,* cited above, paragraph 27 of the decision.

3 — Judgment of 8 November 1979, Case 251/78 *Denkavit* [1979] ECR 3369, paragraph 21 of the decision at p. 3391.

4 — Most recently, judgment of 10 November 1982, Case 261/81 *Rau:* "If a Member State has a choice between various measures to attain the same objective it should choose the means which least restricts free movement of goods" (paragraph 12 of the decision).

exceptions referred to in the article rests on the government which seeks to rely on that exception.[1]

2. The Belgian Government emphasizes the dangerous nature of insecticides and phyto-pharmaceutical products. It points out that the improper handling thereof may have serious, if not disastrous, consequences for public health. The danger is particularly acute in view of the enormous increase in the use of such products over the last few years. The risk is increased by the fact that the products are used not only by professionals but also by domestic users, less skilled in handling them with the proper care. The Belgian Government maintains finally that the harmful effects of such products may sometimes manifest themselves in the long term.

The Commission accepts that in the sector in question it is both necessary and lawful to impose a system of monitoring, inspection and checks and to adopt such protective measures as are necessary to safeguard public health. However, it suggests that Member States are sometimes tempted to exploit the potentially dangerous nature of a product as an excuse for protecting their market against imports of identical products from other Member States. In that respect, it cites the example of a Member State which attempted to plead the dangerous nature of mopeds in order to justify the requirement that person applying for authorization be established in its territory, so that such a person might, if necessary, be prosecuted in the criminal courts.

It emphasizes that its action is intended solely to contest the proposition that the potentially dangerous nature of some of the products concerned justifies the requirement that the applications for approval or authorization be submitted by a person *established* in Belgium.

Ultimately, then, the case rests on a single question, namely whether the requirement under Belgian legislation that a person applying for authorization be established in Belgium is indispensable for the protection of public health and whether there exists an alternative means of affording the same protection to public health which places less of a restriction on trade.

3. The Belgian Government maintains, in the first place, that the requirement that the holder of the authorization be established in Belgium is the best safeguard for preventing accidents and also for alleviating the consequences thereof.

In its view a holder of the authorization established in Belgium is in a better position than a holder based in another country to assist the administration in the process of verifying, after the initial authorization has been granted, that the products actually on sale conform to the requirements of the legislation. In order to carry out the inspections required for that purpose, for example inspections of the composition and labelling of consignments, it is essential to be able to contact the authorization holders quickly. As such inspections help to prevent accidents, the requirement that the holder be established in Belgium is indispensable.

That would seem to carry the argument too far. Even if it is accepted that the presence in Belgium of the authorization holder may facilitate the inspections to

1 — Judgment of 8 November 1979, *Denkavit*, cited above, paragraph 24 of the decision at p. 3392.

which the Belgian Government refers, it is questionable whether that presence is indispensable for the prevention of accidents resulting from the improper use of pesticides and phyto-pharmaceutical products. If inspections to ensure the conformity of the products after they have been marketed are indeed indispensable, the principal responsibility for such inspections must be assumed by the administration itself. It seems to me in particular that the administration's laboratories are capable of checking the conformity of the consignments which are analysed with the description of the composition of the product which appears in the authorization documents, without requiring the assistance of the person who is responsible for its marketing. Furthermore, I fail to see why any person who is responsible for the sale of the product would not be able to provide the necessary information. In other words, the requirement imposed by the Belgian legislation would seem to be inconsistent with the principle of proportionality.

The Belgian Government also sets out the safeguards provided by the presence in Belgium of the holder of the authorization in the event of an accident. According to the Government, it is essential in such a case that the user or the doctor in attendance should be in a position to contact the holder, as the person who has knowledge of the composition of the product and its toxic properties. That is clearly easier, continues the Government, in the case of a person established in Belgium whose name and address appear on the label of each of the products than in that of a person established in a place within the Community which is much further away from the scene of the accident.

The Commission rightly replies that there is an alternative system which would be more efficient, in view of the fact that the holder is not required to be qualified in biology, chemistry or agriculture, as the Belgian Government has itself pointed out. Under that alternative system, the authorities who were informed of the composition and toxic properties of the authorized products would communicate that information to the specialized emergency centre, the Poisons Information Centre.

4. The main contention of the Belgian Government is that the protection of health requires the holder of the approval to be established in Belgium because he is the person who incurs liability, including criminal liability, in connection with the marketing of the product. If criminal penalties are to be effective the person to whom they apply must be established in the country in which they are imposed. The Belgian Government must therefore establish three propositions:

1. Criminal penalties are necessary for the protection of public health;

2. To be effective those penalties must apply to a person established in Belgium;

3. To be effective the penalties must apply only to the holders of the approval or the authorization.

In the opinion of the defendant government, the protection of public health requires that the infringement of rules relating to the marketing of the products in question be subject to criminal penalties. Such penalties are not only punitive in nature but also have a deterrent effect on persons who may be tempted to bring on to the market goods which do not conform to the requirements. Moreover, to be effective the criminal penalties imposed by the courts must be enforceable against

persons established in Belgium. In the present state of affairs, international agreements relating to cooperation in matters of criminal law (extradition, exchange of information and the enforcement of criminal judgments) are ineffective; prison sentences are completely unenforceable, as, indeed, are fines when the person convicted has no property in Belgium.

The Commission does not seriously dispute the first two elements of the Belgian Government's argument. It expresses some doubt as to whether punitive action has in practice the effects attributed to it by the Belgian Government, but it does not formally contest the necessity thereof or, ultimately, the relative ineffectiveness of criminal judgments in relation to persons established abroad.

In that respect it should be emphasized that, although I share the view taken by both the parties, criminal penalties, that is to say in practice usually fines, have in my opinion much less deterrent value than administrative sanctions such as the temporary or permanent prohibition of carrying out independent activities in the sector of the products concerned.

The essential question in this dispute is, therefore, whether it is necessary, in order for criminal penalties to be effective, that they be enforceable against the holder of the authorization alone.

The Belgian Government takes the view that it is logical to hold only the person who applies for authorization liable for the accuracy of the authorization documents and for the conformity of the product marketed with the registered formula and the provisions relating to packaging and labelling. If the persons offering the product for sale on national territory were held liable, that would weaken the liability and reduce the effectiveness of the legislation. If several persons were liable, they would doubtless try to escape liability by attempting to put it on each other. In addition they would be expected to have the same knowledge of all the details in the authorization documents as the holder. To make such an obligation effective it would be necessary to introduce a system at least as restrictive as the present one. Finally, the inspections would be much less effective in view of the fact that it cannot reasonably be suggested that they be carried out in respect of all potential buyers of the products.

That line of argument does not seem to me to be wholly successful.

It may be noted that the most dangerous products (those included in lists A, B and C in the annex to the disputed Royal Decree) "may not be imported, purchased or stocked for sale, offered for sale, sold or transferred free of charge except by persons duly authorized by the minister with responsibility for public health and recognized as approved dealers". It would seem therefore that criminal proceedings for the offering for sale of goods which do not satisfy the requirements may be brought just as easily against those persons as against the holders of the authorization. Again, it may be thought that the withdrawal of their approved status would have a greater deterrent value than the imposition of a fine.

The same argument applies to those products which must not be sold by approved dealers. It is difficult to appreciate why the effectiveness of the Belgian system of criminal law enforcement would be lessened, since nothing prevents criminal liability from being imposed on the importer or the dealer or, if necessary, on both, as both of them are necessarily established in Belgium.

Consequently I consider that the requirement that the person applying for approval or authorization for the marketing of pharmaceutical products or pesticides be established in Belgium amounts to a restriction on imports into that country which is not justified on the ground of the protection of public health within the meaning of the first sentence of Article 36 of the Treaty.

5. I shall nevertheless briefly consider whether the disputed measure fails to meet the conditions imposed by the second sentence of Article 36, which provides that measures justified on one of the grounds listed in the first sentence of the article are unlawful if they constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

In that respect it may be accepted that the disputed requirement is indeed designed to protect public health and not domestic production. The good faith of the Belgian Government is illustrated by its statement, which has not been contradicted, that more than 95 % of the products in question marketed in Belgium are imported products.

On the other hand, I am not convinced that the requirement of being established in Belgium is not discriminatory. It is true that the requirement applies to any applicant for authorization whether he is a Belgian or foreign national. However, whilst the requirement is automatically satisfied by Belgian producers, it may create problems for producers from other Member States, as is shown by the complaint which gave rise to this case. In reality, therefore, it is not a measure which applies without distinction to domestic and foreign products.

In those circumstances, I propose that the Court declare that, by providing that applications for the approval and authorization of phyto-pharmaceutical products and pesticides may be submitted only by a person established in Belgium, the Kingdom of Belgium has failed to fulfil its obligations under Articles 30 and 36 of the EEC Treaty and that the Court order the Kingdom of Belgium to pay the costs.