The Commission considers that no argument justifies the existence of the prior authorisation procedure at issue. First, it cannot be justified by concern to ascertain that the medicinal product has been manufactured according to the good practices laid down by Community legislation. The imported medicinal product has been authorised or registered in the Member State of export, which is responsible for ensuring compliance with those good practices. Any additional check carried out in France would be contrary to the principle of mutual recognition and the objective of ensuring the free movement of medicinal products. Secondly, with regard to possible justification on other grounds of protection of health, it is necessary, in the Commission's view, to distinguish between three types of medicinal products:

— medicinal products authorised pursuant to amended Directive 65/65, then pursuant to Directive 2001/83/EC, both in France and in the Member State where they are purchased (or covered by an authorisation to place them on the Community market (marketing authorisation)). The French authorities have acknowledged that an import authorisation was required in the case of personal importation of medicinal products covered by a marketing authorisation in France. However, in view of the advanced state of harmonisation achieved in the pharmaceutical products sector, in that type of case important guarantees of protection of the health of patients are satisfied. In addition, there is the fact that importation will take place only following the issue of a lawful medical prescription and in quantities not exceeding the needs of the treatment. It follows that the prior authorisation procedure at issue is not justified.

— homeopathic medicinal products registered in a Member State pursuant to Directive 92/73/EEC, replaced by Directive 2001/83/EC. When a homeopathic medicinal product is registered in a Member State, it does not in principle pose any risk to health, especially given the fact that the rules on the manufacture, control and inspection of that type of medicinal product have been harmonised. In addition, Directive 92/73/EEC has liberalised patients' access to the medicinal products of their choice. A prior authorisation procedure for personal importation of registered homeopathic medicinal products is therefore manifestly unjustified.

— medicinal products not authorised in France, but authorised in the Member State where they are purchased. The prior authorisation procedure at issue does not constitute a measure necessary for the purpose of combating the risk of fraud or misuse of the marketing authorisation mechanism, since the general legislation making the importation of medicinal products to be marketed subject to prior authorisation, as well as the on-the-spot checks, are sufficient to combat illegal imports of medicinal products. However, from the point of view of the protection of public health, the case of imports relating to medicinal products not authorised in France may justify a more qualified approach than the case of medicinal products authorised in France or in the Member State of export or than in the case of homeopathic medicinal products registered in a Member State. Nevertheless, while acknowledging that a prior authorisation procedure may be justified, in principle, in the case of personal imports of such products, that procedure should be easily accessible, carried out within a reasonable period and culminate in an authorisation for the importation of medicinal products not posing any risk to public health. However, the prior authorisation procedure applied by France to personal imports of medicinal products does not comply with those criteria and is therefore disproportionate to the objective to be attained.

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(1) 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).

(2) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(3) Council Directive 92/73/EC of 22 September 1992 widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homeopathic medicinal products (OJ L 297, 13.10.1992, p. 8).

Reference for a preliminary ruling by the Cour de cassation (France), First Civil Chamber, by order of that court of 6 May 2003 in the case of Syndicat professionnel coordination des pêcheurs de l'Etang de Berre et de la région against Électricité de France

(Case C-213/03)

(2003/C 158/30)

Reference has been made to the Court of Justice of the European Communities by order of the Cour de cassation (Court of Cassation) (France), First Civil Chamber, received at the Court Registry on 19 May 2003, for a preliminary ruling in the case of Syndicat professionnel coordination des pêcheurs de l'Etang de Berre et de la région (Trade association coordinating fishermen of the Etang de Berre and the area) against Electricité de France on the following questions:

1. Must Article 6(3) of the Athens Protocol of 17 May 1980 for the protection of the Mediterranean Sea against pollution from land-based sources (the Barcelona Convention), which has become Article 6(1) in the revised version, be held to have direct effect, so that any interested party may rely on it before the national courts in an action to halt discharges of water which are not authorised in accordance with the procedure and criteria which it prescribes?

2. Must the same provision be interpreted to mean that it prohibits the discharge into a saltwater marsh communicating with the Mediterranean Sea of substances which, although not toxic, adversely affect the oxygen content of the marine environment, without an authorisation issued by the competent authorities of the Member States, taking into account the provisions of the abovementioned Protocol and of Annex III C thereto (now Annex II)?

Action brought on 19 May 2003 by the Commission of the European Communities against the Republic of Austria

(Case C-214/03)

(2003/C 158/31)

An action against the Republic of Austria was brought before the Court of Justice of the European Communities on 19 May 2003 by the Commission of the European Communities, represented by Josef Christian Schieferer and Gregorio Valero Jordana, of the Commission's Legal Service, acting as Agents, with an address for service in Luxembourg.

The applicant claims that the Court should:

I. Rule that:

1. by laying down in paragraph 22(1) of the Luftreinhalteverordnung für Kesselanlagen (regulation on air purity for boiler plants) (LRV-K) a definition of 'multi-fuel firing unit' that departs from Article 2.8 of Council Directive 88/609/EEC of 24 November 1988 on the limitation of emissions of certain pollutants into the air from large combustion plants, as amended ([1]);

2. by failing to include in the relevant Austrian legal provisions (Luftreinhaltegesetz für Kesselanlagen — LRG-K and LRV-K) (law on air purity for boiler plants) the definitions of 'new plant' and 'existing plant' as set out in Article 2.9 and 2.10 of the directive;

3. by failing fully, in particular by reason of the divergence of the Austrian definition of fuel from that set out in Article 2.6 of the directive, to incorporate in the relevant air-purity legislation the emission limit values for sulphur dioxide, oxides of nitrogen and dust laid down in Article 4.1 in conjunction with Annexes III to VII to the directive;

4. by failing correctly to transpose in the LRG-K and LRV-K Article 9(2) and (3) of the directive concerning the calculation of the emission limit value in multi-fuel firing units which use distillation and conversion residues from crude-oil refining for own consumption, alone or with other fuels,

the Republic of Austria has failed to fulfil its obligations under Articles 2.6, 2.8, 2.9, 2.10 and 10(4)(1) of Directive 88/609, in conjunction with Annexes III to VII thereto and Article 9(2) and (3) of that directive;

II. Order the Republic of Austria to pay the costs of the proceedings.

Pleas in law and main arguments

The Commission finds that the Republic of Austria has failed to fulfil its obligations by failing to bring its national law into line with the directive, which was thus improperly and incompletely transposed, in so far as:

— it failed correctly to transpose Article 2.8 of the directive relating to the term 'multi-fuel firing unit' by restricting the term, in a manner not envisaged in the directive, to units in which the percentage of additional fuels contributing to the thermal input amounts to at least 20 % and thus restricting the scope of the directive in that regard;

— it failed to transpose Article 2.9 and 2.10 of the directive with regard to the definitions of 'new plant' and 'existing plant';

— it failed fully to give effect to the emission limit values for sulphur dioxide, oxides of nitrogen and dust in accordance with Article 4(1) in conjunction with Annexes III to VII, particularly in light of the definition of fuel, which in the Austrian legal provisions is confined to 'conventional fuels', as a result of which only partial effect is given to the scope of the directive;

— it failed correctly to transpose Article 9(2) and (3) of the directive with regard to the calculation of the limit values for multi-fuel firing units in refineries.

([1]) OJ 1988 L 336, p. 1.