

# WORLD TRADE ORGANIZATION

G/TBT/N/FRA/22  
14 March 2003

(03-1505)

Committee on Technical Barriers to Trade

Original: French

## NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

<b>1.</b>	<b>Member to Agreement notifying:</b> <u>FRANCE</u> <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
<b>2.</b>	<b>Agency responsible:</b>  Interministerial Director for Standards SQUALPI 64-70 Allée de Bercy Télédoc 811 – 75574 PARIS Cedex 12 Tel.: 01 53 44 97 04 Fax: 01 53 44 98 88 E-mail: <a href="mailto:suzanne.piau@industrie.gouv.fr">suzanne.piau@industrie.gouv.fr</a> or <a href="mailto:syrte@industrie.gouv.fr">syrte@industrie.gouv.fr</a>  Ministry of Health, the Family and Disabled Persons Directorate-General of Health Office of Health Products of Human Origin 8, avenue de Ségur - 75700 PARIS <b>Name and address (including telephone and fax numbers and E-mail and Web site addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:</b>
<b>3.</b>	<b>Notified under Article 2.9.2 [ X ], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
<b>4.</b>	<b>Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Ancillary therapeutic products (ATP): products coming into contact with organs, tissues, cells or products of human or animal origin during storage, preparation, processing, treatment or transportation before use in human therapy, and any product coming into contact with embryos in the sphere of medically-assisted reproduction.
<b>5.</b>	<b>Title, number of pages and language(s) of the notified document:</b> Draft Order on the Rules of Good Practice for Manufacturing, Treating, Storing, Importing, Transporting and Distributing ATPs (19 pages).
<b>6.</b>	<b>Description of content:</b> The order sets rules of good practice by specifying basic requirements in terms of staff, premises, equipment, procedures and documentation to guarantee the quality of these products. It comprises four parts on: quality control; the preparation of ATPs; their storage, distribution and transportation; and import, respectively.

<b>7.</b>	<b>Objective and rationale, including the nature of urgent problems where applicable:</b> The aim of the rules established under the draft order is to ensure the quality and safety of these products. It seemed essential for the French authorities to provide a regulatory framework - based very largely on the existing controls applying to medicines - for ATPs of chemical or organic origin that come into contact with human products intended for transplantation or embryos for implantation, in order to guarantee their safety and therapeutic effectiveness.
<b>8.</b>	<b>Relevant documents:</b> The Articles of the Public Health Code upon which the decree and the decision are based : Article L.1263-1 to L.1263-4.
<b>9.</b>	<b>Proposed date of adoption:</b> June 2003  <b>Proposed date of entry into force:</b> 1 January 2004 (the order will enter into force six months after publication)
<b>10.</b>	<b>Final date for comments:</b> End of May 2003
<b>11.</b>	<b>Texts available from: National enquiry point [ X ] or address, telephone and fax numbers and E-mail and Web site addresses, if available, of other body:</b>  National Enquiry Point CINORTECH AFNOR 11, avenue Francis de Pressensé 93571 SAINT-DENIS LA PLAINE Cedex  FRANCE