Notification Number: 2000/607/F

SOOS - Draft Decree concerning medical devices which must be subject to a declaration before their placing on the market and amending Book V of the Public Health Code (second part: Decrees in the Council of State).

Date received	:	10/10/2000
End of Standstill	:	Closed
Issue of comments by	:	Denmark,Italy
Issue of detailed opinion by	:	Ireland

Message

Departement of Trade and Industry - Stan dards and Technical Regulations - Dir 2
Mrs Brenda O'Grady

EFTA Surveillance Authority
Ms Solveig Georgsdottir

ELOT
Mr E. Melagrakis

European Free Trade Association
Ms Anne-Lise Bakke-D'Aloya

Kauppa-ja teollisuusministeriö
Mr Petri Kuurma

Kommerskollegium
Fru Kerstin Carlsson

Min. of Industry, Energy & Technology
Mr K. Polychronidis

Ministerie van Financiën - Belastingsdie nst - Douane / CDIU
De Heer IJ.G. van der Heiden

NSAI
Mr Tony Losty

Représentation Permanente de l'Irlande
.

Représentation Permanente du Royaume-Uni

.

Message 002

Communication from the Commission - SG(2000) D/52208
Directive 98/34/EC
Translation of the message 001
Notification: 2000/607/F

(MSG: 200002208.EN)

1. Structured Information Line
MSG 002 IND 2000 0607 F EN 10-10-2000 F NOTIF

2. Member State
FRANCE

3. Department Responsible
Secrétariat général du Comité interministériel pour les questions de coopération économique européenne - 2, Bd Diderot 75012 Paris

Délégué interministériel aux Normes -64-70 allée de Bercy-télédoc 811
75574 paris cedex 12

3. Originating Department
Ministère de l'emploi et de la Solidarité
Direction générale de la santé
Sous-direction de la politique des produits de santé
Madame Hélène Sainte-Marie
8, avenue de Ségur
75350 Paris 07 SP

4. Notification Number
2000/0607/F

5. Title
SOOS - Draft Decree concerning medical devices which must be subject to a declaration before their placing on the market and amending Book V of the Public Health Code (second part: Decrees in the Council of State).

6. Products Concerned
Medical device.

7. Notification Under Another Act
No

8. Main Content
Article L. 5211-4 of the Public Health Code provides that after certification of conformity with the basic requirements of the health and safety of patients, operators and third parties, medical devices whose design or manufacture could be the cause of special health risks shall only be operated, made available freely or for a fee, or used if they have been the subject of a declaration at least three months before their placing on the market by AFSSAPS (French Agency for safety of health products).

This draft lays down the classes of medical devices subject to this procedure (devices liable to present risks from identified emerging risks or in the light of published scientific literature) and specifically states that the list of these classes is laid down by an order that is reviewed every two years. AFSSAPS shall also be informed of any amendments to the initial certificate of conformity.

Any natural or legal person not complying with the procedures shall be fined.

9. Brief Statement of Grounds
Law No 98-535 of 1 July 1998 on the strengthening of the health care monitoring and the inspection of the safety of products for humans has added new provisions laying down that new medical devices whose design or manufacture could be the cause of special health risks shall only be operated, made available, or used if, after having obtained the CE marking, they have been the subject of a declaration made at least three months before their placing on the market by the AFSSAPS.

This draft Order lays down the conditions for applying these provisions that intend to ensure the protection of public health by allowing the French health authorities responsible (AFSSAPS) to have prior information allowing them to put into place health policy measures that they have at their disposal, by way of a precaution, for specific groups of products.

This procedure is only intended for the classes of device for which health risks have been identified and is to be used to rectify the risk factors.

These devices "presenting special health risks" are defined by this draft as devices for which the identification of emerging risks or published scientific literature give rise to concern over risks to health and safety or risks that undermine public health requirements.

By way of example:

- the appearance of a new strain of Creutzfeldt-Jakob Disease, which raises the issue of the potential risk of transmission of the agent of bovine spongiform encephalopathy to humans, should lead to the investigation on possible restrictions on the placing on the market of medical products containing bovine tissue.

- likewise, a lack of published scientific literature on the long term effects of certain medical devices (endocoronary brachytherapy, aortic endoprotheses, carotid stents, lasers intended for transmyocardiac revascularisation etc) means that it is necessary to reassess the data collected by the manufacturer in order to show they have these risks under control.

The list of medical devices presenting health risks is therefore by its very nature constantly updated. This is why the provision used by this draft Decree comprises the creation of a list of classes of the medical devices concerned, by Order of the Minister responsible for health, this Order needing to be completely re-examined in its entirety at least every two years. These Orders will be the subject of a notification to the European Commission.

In addition, the registering of a class of medical devices in the above-mentioned Order will be included within the framework of special health measures laid down in the provisions of Article 14b of Directive 93/42/EEC of 14 June 1993 concerning medical devices, introduced by Article 21(d) of Directive 98/79/EC of 27 October 1998.

This Article states that a Member State can undertake interim measures with the aim of banning, restricting or ascribing particular conditions to the offering of a product or group of products when it considers that these measures are necessary to protect public health and safety and/or to ensure compliance with public health requirements. Unlike the restrictive situations provided for in Article 8 of Directive 93/42/EEC (safeguard clause), the measures in Article 14b can be invoked in situations where there remains some uncertainty with regard to the actual risk involved.

The first draft Order laying down the list of classes of medical devices which must be the subject of a declaration before their placing on the market is also appended to this notification.

The declaration made by the manufacturer to AFSSAPS consists of elements taken from the file established in view of the conformity assessment with regard to the basic requirements of the competent body and certificates issued by the latter, proving this conformity. These elements allow AFSSAPS to assess the risks that the medical device may possibly involve and its design and manufacturing conditions.

AFSSAPS has three months from the receipt of these elements during which it may, under current legislation, ask the manufacturer to provide any other element for appraisal and if need be adopt necessary measures to restrict the placing on the market or the scope of use of the device.

In the absence of a reply from AFSSAPS at the end of the three-month period, the manufacturer can freely introduce the device subject to the declaration, on the market without needing to take additional steps.

10. Reference Documents - Basic Texts
Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

Public Health Code, in particular Articles L. 5211-4 and L. 5211-6 (5)

11. Invocation of the Emergency Procedure
Yes

12. Grounds for the Emergency
It is necessary to adopt this Decree and this Order swiftly in the interests of protecting public health. According to the information provided by AFSSAPS, the likely measures to be taken, in application of these texts, may for example, relate to the potential risk of human transmission of the BSE agent (see explanations supplementing the notification sheet).

13. Confidentiality
No

14. Fiscal measures

No

David O'Sullivan
General Secretary
European Commission