WORLD TRADE ORGANIZATION

G/TBT/N/EEC/405
4 October 2011

(11-4785)

Committee on Technical Barriers to Trade Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** EUROPEAN UNION **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** European Commission **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above**: European Commission EU-TBT Enquiry Point Fax: +(32) 2 299 80 43 E-mail: mailto:eu-tbt@ec.europa.eu Website: http://ec.europa.eu/enterprise/tbt/
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [X], 5.7.1 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medical devices manufactured utilising tissues of animal origin
5.	**Title, number of pages and language(s) of the notified document:** Draft Commission Regulation concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (14 pages, in English)
6.	**Description of content:** The draft Regulation shall replace existing requirements regarding medical devices manufactured utilising tissues originating of bovine, ovine or caprine species, deer, elk, mink or cats (i.e. TSE-susceptible species). It shall extend the scope of the current requirements (Directive 2003/32/EC) to active implantable medical devices. The text sets out the aspects to be taken into account by manufacturers during their risk analysis and risk management in order to minimise the risk of transmitting animal spongiform encephalopathies to patients or other persons via medical devices. The text also makes provision for the aspects to be taken into account by designated conformity assessment bodies (i.e. Notified Bodies) in the context of the conformity assessment procedure.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Maintaining a high level of safety and health protection against the risk of transmitting animal spongiform encephalopathies to patients or other persons via medical devices.

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8.	**Relevant documents:** - Council Directive 90/385/EEC http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0385:EN:HTML - Council Directive 93/42/EEC http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0042:EN:HTML - Commission Directive 2003/32/EC http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:006:0010:0010:EN:PDF
9.	**Proposed date of adoption:** **Proposed date of entry into force:** } April 2012. Date of application: one year later.
10.	**Final date for comments:** 60 days from date of notification.
11.	**Text available from: National enquiry point [ ], or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:** European Commission EU-TBT Enquiry Point Fax: +(32) 2 299 80 43 E-mail: mailto:eu-tbt@ec.europa.eu The text is available on the EU-TBT Website: http://ec.europa.eu/enterprise/tbt/ http://members.wto.org/crnattachments/2011/tbt/EEC/11_3197_00_e.pdf