

WORLD TRADE ORGANIZATION

G/TBT/N/CAN/34

7 May 2002

(02-2562)

Committee on Technical Barriers to Trade

Original: English/
French

NOTIFICATION

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

1.	Member to Agreement notifying: <u>CANADA</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: Department of Health Name and address (including telephone and fax numbers, 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: Canadian Enquiry Point, 200-270 Albert Street, Ottawa, Ontario, Canada, K1P 6N7 Tel.: +1 613 238 3222, ext. 491, Fax.: +1 613 569 7808, E-mail: info@scc.ca
3.	Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 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): Human plasma (ICS: 11.120)
5.	Title, number of pages and language(s) of the notified document: Proposed Amendment to the Food and Drug Regulations (Schedule No. 1100) (pages 1150-1152; English and French)
6.	<p>Description of content: This notice is to advise the public of our intention to proceed with the amendment of the regulatory provisions respecting Human Plasma Collected by Plasmapheresis located in Part C, Division 4 of the <i>Food and Drug Regulations</i> (FDR or the Regulations). This proposed initiative will, among other things, bring the regulatory requirements up to date to reflect current practices and advances in technology.</p> <p>Human plasma is collected by plasmapheresis either for transfusion purposes or as a bulk process intermediate used in the manufacturing of blood products (e.g., products used to treat burn victims or patients with life threatening infections).</p> <p>This regulatory initiative only applies to human plasma collected by plasmapheresis for further manufacturing. Requirements for plasma intended for transfusion will be incorporated into a separate regulatory initiative for blood and blood components which is currently under development.</p> <p>The intent of the plasmapheresis regulatory requirements are two-fold:</p> <p>(1) To contribute towards maintaining the health of the plasma donor; and</p> <p>(2) to contribute to the goal of ensuring the quality and safety of human plasma collected by plasmapheresis for further manufacturing.</p>

7.	Objective and rationale, including the nature of urgent problems where applicable: Protection of human health
8.	Relevant documents: Canada Gazette, Part I, 27 April 2002
9.	Proposed date of adoption: Proposed date of entry into force: } Not stated
10.	Final date for comments: 26 June 2002
11.	Texts available from: National enquiry point [X] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body: The electronic version of this document can be downloaded at: http://canada.gc.ca/gazette/part1/pdf/g1-13617.pdf