

GENERAL AGREEMENT
ON TARIFFS AND TRADE

RESTRICTED
TBT/Notif.94.495
22 December 1994
Special Distribution

(94-2934)

Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.4.

1.	Party to Agreement notifying: <u>CANADA</u>
2.	Agency responsible: Department of National Health and Welfare
3.	Notified under Article 2.5.2 [X], 2.6.1 [], 7.3.2 [], 7.4.1 [], other:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Menstrual tampons
5.	Title and number of pages of the notified document: Proposed Amendment to the Medical Devices Regulations
6.	<p>Description of content: These amendments delete the requirement for receipt and review of submissions for tampons other than those claiming higher absorbency. It is no longer useful to subject menstrual tampons of absorbency of 15 grams or less per tampon to pre-market review. Technology has advanced to the point that menstrual tampons are no longer new or of questionable stability. These amendments remove menstrual tampons of up to and including 15 grams of absorbency from the Table to Part V. Only high absorbency tampons, which absorb more than 15 grams of fluid per tampon, and which pose the greatest risk of Toxic Shock Syndrome (TSS), will remain on the Table to Part V.</p> <p>Menstrual tampons with absorbency of 15 grams or less per tampon will continue to be subject to the safety and efficacy requirements of the Food and Drugs Act and the Medical Devices Regulations.</p> <p>In addition, these amendments create a new Schedule XIV in the Medical Devices Regulations, which will address the labelling of menstrual tampons packaging and provides a standard test method to determine the absorbency of tampons. The Health Protection Branch has developed standardized absorbency designations for menstrual tampons. Standard labelling will enable consumers to compare the absorbency of one brand and style of tampons with the absorbency of all other brands and styles.</p>

7.	Objective and rationale: Protection of health
8.	Relevant documents: Canada Gazette, Part I, 17 December 1994, pages 4748-4757
9.	Proposed date of adoption and entry into force: 1 October 1995
10.	Final date for comments: 2 March 1995
11.	Texts available from: National enquiry point [X] or address and telefax number of other body: