

WORLD TRADE ORGANIZATION

RESTRICTED

G/TBT/Notif.95.85

28 March 1995

(95-0717)

Committee on Technical Barriers to Trade

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 National Health and Welfare
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): Colouring agents
5.	Title and number of pages of the notified document: Proposed Amendment to the Food and Drug Regulations (pages 708-711)
6.	Description of content: <p>This Amendment adds anthocyanin pigments derived from the juice expressed from fresh edible fruit or vegetables to paragraph C.01.040.2(3)(a) to the list of colouring agents permitted in drugs for internal and external use. This addition is consistent with Part B, Division 16, Table III of the Food and Drug Regulations which includes anthocyanins as food additives that may be used as colouring agents. Additionally, fruit and vegetable juices are also permitted for use as food colorants in the United States.</p> <p>In view of these permitted uses, and the fact that ingestion of the colouring agent from drugs would be negligible in comparison to foods, the Working Party on Drugs and Cosmetic Colours has recommended that anthocyanin pigments derived from juice expressed from fresh edible fruit or vegetables be added to the list of permitted colorants in drugs for internal or external use.</p> <p>This amendment also adds the following colorants to the list of colouring agents permitted in drugs for external use only:</p> <p>Annatto (C.I. No. 75120) Bismuth Oxychloride (C.I. No. 77163) Chromium Hydroxide Green (Pigment Green 18 (C.I. No. 77289)) Dibromofluorescein (Solvent Red 72 (C.I. No. 45370:1); Orange No. 5 (D & C Orange No. 5)) Guanine (C.I. No. 75170) Manganese Violet (C.I. No. 77742) Mica (C.I. No. 77019) Zinc Oxide (C.I. No. 77947)</p>

7.	Objective and rationale: Protection of health
8.	Relevant documents: Canada Gazette, Part I, 11 March 1995
9.	Proposed date of adoption and entry into force: Not stated
10.	Final date for comments: 10 April 1995
11.	Texts available from: National enquiry point <input checked="" type="checkbox"/> or address and telefax number of other body: