

# Tracking Federal Regulatory Initiatives

# Regulatory Affairs

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July 2, 1997

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**Food and Drug Regulations, amendment (Schedule F)**

The proposed amendment would permit nizatidine, a histamine H<sub>2</sub> receptor antagonist, to be made available without a prescription for concentrations equivalent to 75 mg of nizatidine or less per oral dosage unit. The Health Department has given notice that it proposes to request an exemption from prepublication of the proposal in the Canada Gazette, Part I.

The department has concluded that retention of nizatidine on Schedule F of the *Food and Drug Regulations* is no longer necessary, since it unnecessarily restricts the availability of the drug.

The drug, marketed in Canada since 1988, is available without prescription in the United States. The maximum daily dose of nizatidine is limited to 150 mg; recommended duration of treatment without medical supervision is two weeks.

Comments should be provided to the Health Department within 45 days.

Contact: Karolyn Lui, Risk Management and Regulatory Affairs Division, Therapeutics Directorate, Health Protection Branch Building, Address Locator 0702B1, Tunney's Pasture, Ottawa, Ontario, K1A 0L2. Tel: 613-957-0372; Fax: 613-941-6458; e-mail: karolyn\_lui@inet.hwc.ca.

*Food and Drugs Act*, subsection 30(1)

HCAN/97-R-15-L

Published in Canada Gazette June 28, 1997

## Exempt from Pre-Publication and Approved

## Statutory Authority & Regulatory Plan Listing

### **Regulations amending Certain Regulations Administered and Enforced by the Canadian Food Inspection Agency (SOR/97-292, OIC 1997-883)**

The amendments updates references in a number of regulations to reflect the creation of the Canadian Food Inspection Agency.

Amended are: *Egg Regulations*; *Fresh Fruit and Vegetable Regulations*; *Honey Regulations*; *Maple Products Regulations*; *Processed Egg Regulations*; *Processed Products Regulations*; *Dairy Product Regulations*; *Licensing and Arbitration Regulations*; *Livestock and Poultry Carcass Grading Regulations*; *Feeds Regulations, 1983*; *Fertilizers Regulations*; *Health of Animals Regulations*; *Meat Inspection Regulations, 1990*; *Plant Protection Regulations*; and the *Seeds Regulations*.

The amendments come into effect June 20, 1997.

Contact: Ron Doering, Executive Vice-President, Canadian Food Inspection Agency, 59 Camelot Drive, Room 128 B East, Nepean, Ontario, K1A 0Y9. Tel: 613-952-8000, ext. 3737; Fax: 613-228-6608.

### **Information Technology Agreement Order, 1997 (SOR/97-294, OIC 1997-839)**

This Order implements tariff reductions in accordance with Canada's commitment under the Information Technology Agreement (ITA) which was acceded to by Canada and 38 other governments on March 26, 1997. The agreement provides for the staged elimination of Most-Favoured-Nation Tariffs on a broad range of information technology products, with the first stage of cuts being on July 1, 1997.

The Information Technology Agreement will eliminate the tariffs on over 92% of the US \$500 billion-a-year global trade in information technology products and open these markets to Canadian exporters.

The Order amends: Schedule I to the *Customs Tariff* (Parts 1 to 4 of the Order); Schedule II as set out in Part 5 of the schedule to the Order; and the Customs Duties Reduction or Removal Order, 1988 (Part 6 of the schedule to the Order).

The Order comes into effect July 1, 1997.

Contact: Randy Freda, International Trade Policy Division, Department of Finance, Ottawa, Ontario, K1A 0G5. Tel: 613-992-6355.

### **Marine Navigation Services Fees Regulations, revocation (SOR/97-295, OIC 1997-840)**

The revocation, effective July 1, 1997, will eliminate the authority to charge the Marine Navigation Services Fees under the *Financial Administration Act* (something that is currently being challenged in court). Instead, the Canadian Coast Guard intends to impose the Marine Navigation Services Fees under the *Oceans Act*.

The fees in question are controversial. On June 1, 1996, the government imposed the fees to help recover the costs of marine navigation services provided by the Coast Guard. The initial fees were set at a level of \$20-million for nine months in 1996-97. In 1997-98, the Marine Navigation Services Fees are expected to generate some \$26.7-million, or about 27% of the estimated \$99-million in full costs of providing marine aids to navigation and vessel traffic services to commercial shippers.

While the fees are a small percentage of marine transportation, they do not hit all sectors equally. Hardest hit include the gypsum and aggregate industries and the Miramichi area; mitigative measures for these are scheduled for 1997-98 implementation by the Coast Guard.

*Canada Agricultural Products Act*, section 32; *Feeds Act*, section 5; *Health of Animals Act*, section 64; *Meat Inspection Act*, section 20; *Plant Protection Act*, section 47; and *Seeds Act*, section 4

Not included in Regulatory Plan

To be published in Canada Gazette July 9, 1997

*Customs Tariff*, section 12.1 and 62

Not included in Regulatory Plan

To be published in Canada Gazette July 9, 1997

*Financial Administration Act*, paragraph 19(1)(a)

F&O/97-4-M

To be published in Canada Gazette July 9, 1997

## Exempt from Pre-Publication and Approved

## Statutory Authority & Regulatory Plan Listing

The final rate structure for the fees will be published in Part I of the Canada Gazette within 30 days, for comment.

Contact: Suzanne Shirreff, Director, Marine Services Fees, Canadian Coast Guard, Canada Building, Minto Place, 344 Slater Street, Ottawa, Ontario, K1A 0N7. Tel: 613-993-6943; Fax: 613-990-3480.

### **Immigration Regulations, 1978, amendment (Investor Program) (SOR-97-296, OIC 1997-841)**

This amendment removes the restriction on the number of allowable extensions for approved investor funds under the Immigrant Investor Program, to enable all existing funds to continue to be marketed until the expiry of the Program.

The effect of this change will be to allow the provinces of Ontario and British Columbia, whose funds had already been extended twice, to continue to be active in attracting investment. All other Program requirements remain unchanged.

On April 24, 1997, the current Immigrant Investor Program was extended until December 31, 1997 to allow more time to consider input received following the recent pre-publication of regulations on Program redesign. Under the Program, only government-administered funds can accept subscriptions (investors' capital). When funds are initially approved by Citizenship and Immigration they can accept subscriptions for a maximum of eighteen months, which is also known as the offering period: funds can apply for two extensions of the offering period for up to six months each.

The amendment introduced in April of 1997 simply extended the provisions of the Program then in effect; it did not take into account the fact that some provincially administered funds had already taken advantage of the maximum number of extensions of offering periods possible under the interim Program. The new change eliminates this restriction on extensions by authorizing the Minister to approve requests from government administered investment funds for a six month extension of their offering period, regardless of the number of previous extensions that the fund had already been granted. The change replaces a part of subsection 6.13(3) of the Regulations, before paragraph (a); they come into effect June 25, 1997.

Contact: Don Myatt, Director Business, Immigration Division, Citizenship and Immigration Canada, 7th Floor, Jean Edmonds Tower North, 300 Slater Street, Ottawa, Ontario, K1A 1L1. Tel: 613-957-0001; Fax: 613-941-9014.

### **Prohibition of Entry on Certain Lands in the Yukon (1997-No. 2, Fishing Branch Ecological Reserve, Y.T.) (SOR/97-297, OIC 1997-843); Withdrawal from Disposal of Certain Lands in the Yukon Territory (Fishing Branch Ecological Reserve) (SI/97-83, OIC 1997-844)**

The Prohibition of Entry on Certain Lands Order, 1992, No. 3, made by Order in Council P.C. 1992-1041 of May 14, 1992, prohibits entry on certain lands (approximately 166 square kilometers) to facilitate the establishment of the Fishing Branch Ecological Reserve, located in the vicinity of the Fishing Branch River and Bear Mountain, in the Yukon Territory until June 30, 1997.

Pursuant to Chapter 15, Clause 15.3.4.3 of the Vuntut Gwitchin First Nation Final Agreement of May 29, 1993 made between the Government of Canada, the Yukon Territorial Government (YTG) and the Vuntut Gwitchin First Nation, the Yukon Government has requested an extension to the existing Order in Council until the Settlement Land Committee defines the boundaries of the ecological reserve.

*Immigration Act*, paragraphs 114(1)(a)

CIC/95-3-M

To be published in Canada Gazette July 9, 1997

*Yukon Placer Mining Act*, section 98; *Yukon Quartz Mining Act*, section 14.1; *Territorial Lands Act*, paragraph 23(a)

INAC/R-1-I

To be published in Canada Gazette July 9, 1997

## Exempt from Pre-Publication and Approved

Statutory Authority  
&  
Regulatory Plan Listing

The new Prohibition of Entry Order will continue to ensure that no new third party interests are created on the proposed Fishing Branch Ecological Reserve. The Order in Council, effective on June 26, 1997, will end on June 30, 2002; the earlier Order is revoked.

The purpose of the second Order is to repeal the Withdrawal of Certain Lands (Fishing Branch Ecological Reserve, Y.T.) from Disposal Order, made by Order in Council P.C. 1992-1048 of May 14, 1992 and to make in substitution therefor the Order Respecting the Withdrawal from Disposal of Certain Lands in the Yukon Territory, for the period beginning June 26, 1997 and ending on June 30, 2002, to facilitate the establishment of the Fishing Branch Ecological Reserve.

Contact: Ian Sneddon, Chief, Land Management Division, Department of Indian Affairs and Northern Development, Les Terrasses de la Chaudière, 10 Wellington Street, Ottawa, Ontario, K1A 0H4; Tel: 819-997-9090; Fax: 819-953-2590.

## Pre-Published and Approved With comments or changes

Statutory Authority  
&  
Regulatory Plan Listing

### **Food and Drug Regulations, amendment (Schedule 624) (SOR/97-298, OIC 1997-845)**

This regulatory amendment will delay the coming into force of the licensing provisions of the Establishment Licensing Regulatory Framework for drug manufacturers until January 1, 1998.

This action will allow industry more time to understand and meet the licensing requirements. It will also provide Health Canada with additional time to assess the impact of the licensing framework on drug manufacturers, especially small businesses, and make adjustments where necessary.

The other provisions of the Establishment Licensing Framework which came into force on January 1, 1997 will remain. These include the machinery for making application for a license, amendments to licenses, expiry dates, definitions, and the application of Good Manufacturing Practices (GMP) for Schedule C (radiopharmaceuticals) and D (biological) drugs. The licensing provisions for Schedule C and D drugs will also remain and the existing licenses for these products will be extended to December 31, 1997.

The proposal for an Establishment Licensing Framework has been the subject of a broad consultation exercise with industry beginning in November 1995. A Regulatory Impact Analysis Statement was published in Canada Gazette on January 8, 1997. Health Canada has received substantial feedback on the licensing proposal, many asking for additional time to prepare for compliance with the requirements and conditions of the licensing scheme.

Contact: Chantal Trepanier, Policy Division, Bureau of Policy and Coordination, Therapeutic Products Directorate, Health Protection Building, Address Locator 0702B3, Tunney's Pasture, Ottawa, Ontario, K1A 0L2. Tel: 613-957-1487; Fax: 613-941-6458; e-mail: chantal\_trepanier@inet.hwc.ca.

*Food and Drugs Act, section 30*

HCan/R-33-I

To be published in Canada Gazette July 9, 1997

# Ministerial Orders Approved

## Statutory Authority & Regulatory Plan Listing

### **Canadian Chicken Marketing Levies Order, amendments (SOR/97-293)**

These amendments set the levy rates to be paid by producers engaged, in the provinces of Ontario, Nova Scotia and Manitoba, in the marketing of chicken in interprovincial or export trade, effective July 1, 1997.

More specifically, the rates are changed as follows: Ontario, 1.39 cents; Nova Scotia, 1.12 cents; and Manitoba, 1.34 cents.

*Farm Products Agencies Act*, paragraph 22(1)(f);  
*Canadian Chicken Marketing Agency Proclamation*, section 12 of the Schedule  
Not included in Regulatory Plan  
To be published in Canada Gazette July 9, 1997

### **Rules of the Supreme Court of Canada, amendment (SOR/97-299)**

Under the amendments, subsection 11(4) of the *Rules of the Supreme Court of Canada* is replaced by the following:

“(4) The month of July shall not be included in the computation of the times appointed or allowed by these Rules for the doing of any act, except for the filing of the case as provided in subsection 34(1) and factums as provided by Rule 38 and for the purpose of determining the date set out in subsection 44(2).”

In addition, paragraph 16(3)(b) of the English version of the Rules before subparagraph (i) is replaced by the following:

“(a) on the next day after it was received that is not a Saturday or holiday, if it was received”.

The amended rules come into force June 27, 1997.

*Supreme Court Act*, section 97  
Not included in Regulatory Plan  
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