

# Tracking Federal Regulatory Initiatives

# Regulatory Affairs

VOL. 3, No. 45

December 9, 1997

Circulate to:	<b>HIGHLIGHTS</b>
1.	<b>Proposed Regulations</b>
2.	Tougher safety rules proposed for recreational boating. . . . . 2
3.	<b>Exempt from Prepublication and Approved</b>
4.	Terfenadine and astemizole anti-histamines to be sold only by prescription . 5
5.	<b>Pre-Published and Approved</b>
	New civil aviation fees established . . . . . 6-7

<b>Proposed Regulations for Pre-Publication in Part I, Canada Gazette</b>	<b>Statutory Authority &amp; Regulatory Plan Listing</b>
<p><b>Laurentian Pilotage Tariff Authority Regulations, amendment</b></p> <p>The proposed amendment would eliminate the criteria relating to tonnage and substitute the length of ships with respect to the classes of licences and pilotage certificates. The change to section 15 follows substantial changes to the <i>Tonnage Regulations</i> in 1994.</p> <p>As well, a minor editorial change would be made to repeal the definition of “dead weight tonnage” and substitute a definition for “deadweight tonnage.”</p> <p>The proposed regulations will come into effect on the day they are approved by the federal cabinet.</p> <p>Contact: Jean-Claude Michaud, Chairman, Laurentian Pilotage Authority, Stock Exchange Tower, Suite 600, 715 Victoria Square, P.O. Box 680, Montreal, Quebec, H4Z 1J9. Tel: 514-496-1501; Fax: 514-496-2409.</p>	<p><i>Pilotage Act</i>, paragraph 20(1)(e)</p> <p>TC/97-6-L</p> <p>Published in Canada Gazette November 29, 1997</p>

*Regulatory Affairs* is published weekly when Cabinet meets by J-K Carruthers Limited  
 © 1997 J-K Carruthers Limited All Rights Reserved. Visit our Web Pages at [www.carruthers.com](http://www.carruthers.com).

# Proposed Regulations

## for Pre-Publication in Part I, Canada Gazette

### Statutory Authority & Regulatory Plan Listing

#### **Small Vessel Regulations, amendment**

The proposed amendments would offer recreational boaters choices with respect to the safety equipment they must carry, while at the same time eliminating the use of life-saving cushions as a substitute for lifejackets or personal flotation devices.

The proposals would introduce some new safety precautions, including requiring exhaust muffling systems on engines operating within five nautical miles of shore, extending the rules for water-skiing to barefoot skiing, tubing and surfboarding, and a prohibition against careless operation.

The proposals would increase the fees for capacity plates (\$5 from \$2.50) and for conformity plates (\$5 from \$1).

Capacity plates would be required for vessels less than 6 metres (compared to 5 metres) in length capable of being fitted with a motor or motors of 10 hp or more. All vessels capable of being fitted with a motor of any power would have to have a conformity plate stating that it is constructed in accordance with applicable construction standards.

The proposals would also require all boating accidents involving five or fewer fatalities, or injury requiring medical attention beyond first aid, or damage affecting the seaworthiness of the boat (estimated damage of \$2,500 or more) to be reported to local police authorities.

The proposals would also extend the powers of Enforcement Officers to require boat owners to provide personal identification on request and to allow the Enforcement Officers to examine the vessel and its equipment, ask pertinent questions and seek assistance from the owner or operator of a vessel.

Contact: Edith Dussault, Senior Project Officer (Regulatory Development), Office of Boating Safety, Department of Fisheries and Oceans, Canada Building, 9th Floor, 344 Slater Street, Ottawa, Ontario, K1A 0N7. Tel: 613-990-6412.

#### **Food and Drug Regulations, amendment (Schedule No. 873)**

This amendment establishes an updated standard for conjugated estrogens in Division 6 of the Regulations.

Conjugated estrogen preparations consist of a mixture of naturally occurring or synthetically-produced estrogens; they are used for the relief of menopausal symptoms and for the prevention of osteoporosis which may occur after menopause.

The proposed regulations conjugated estrogens sold in Canada to meet the requirements set out in the United States Pharmacopoeia 23, except with respect to composition.

The proposed amendment lists the requirements on composition which must be met.

The proposal also revokes section C.06.003. As a result, conjugated estrogens for injection must meet requirements for professed standards as do combination drugs and vaginal creams.

Contact: Joan Korol, Risk Management and Regulatory Affairs Division, Bureau of Drug Policy and Coordination, Drugs Directorate, Health Protection Building, Postal Locator 0702B1, Tunney's Pasture, Ottawa, Ontario, K1A 0L2. Tel: 613-957-1487; Fax: 613-941-6458; e-mail: joan.korol@isdtcp3.hwc.ca.

Canada Shipping Act, sections 338, 405, 478 and 562

Not included in Regulatory Plan

Published in Canada Gazette November 29, 1997

*Food and Drugs Act*, subsection 30(1); Hazardous Products Act, section 15

HCan/R-7-I

Published in Canada Gazette November 29, 1997

# Proposed Regulations

## for Pre-Publication in Part I, Canada Gazette

### Statutory Authority & Regulatory Plan Listing

#### **Food and Drug Regulations, amendment (Schedule No. 1042)**

This amendment would provide for the use of milk coagulating enzyme from the source *Aspergillus oryzae* RET-1 (pBoel777) in the production of cheese, cottage cheese and sour milk.

Contact: The Director, Bureau of Food Regulatory, International and Interagency Affairs, Department of Health, Address Locator 0702C, Tunney's Pasture, Ottawa, Ontario, K1A 0L2. Tel: 613-957-1828; Fax: 613-941-3537.

*Food and Drugs Act*, subsection 30(1); Hazardous Products Act, section 15

Not included in Regulatory Plan

Published in Canada Gazette November 29, 1997

#### **Food and Drug Regulations, amendment (Schedule No. 1066)**

This amendment would require fortification of flour and enriched pasta with folic acid and would harmonize the Canadian levels of nutrient addition to flour and enriched pasta to the U.S. levels.

The required level of added nutrients would be specified as a single level per 100 grams of flour rather than a range as part of the harmonization.

Contact: The Director, Bureau of Food Regulatory, International and Interagency Affairs, Department of Health, Address Locator 0702C, Tunney's Pasture, Ottawa, Ontario, K1A 0L2. Tel: 613-957-1828; Fax: 613-941-3537.

*Food and Drugs Act*, subsection 30(1); Hazardous Products Act, section 15

Not included in Regulatory Plan

Published in Canada Gazette November 29, 1997

#### **Food and Drug Regulations, amendment (Schedule No. 1072)**

This amendment would allow the use of iron oxide as a colouring agent in edible collagen film used on Black Forest ham.

This change would make it easier to produce the traditional black exterior on Black Forest Ham.

Contact: The Director, Bureau of Food Regulatory, International and Interagency Affairs, Department of Health, Address Locator 0702C, Tunney's Pasture, Ottawa, Ontario, K1A 0L2. Tel: 613-957-1828; Fax: 613-941-3537.

*Food and Drugs Act*, subsection 30(1); Hazardous Products Act, section 15

Not included in Regulatory Plan

Published in Canada Gazette November 29, 1997

#### **Food and Drug Regulations, amendment (Schedule No. 1078)**

This amendment would allow the use of 4-hexylresorcinol as a melanosis inhibitor in fresh and frozen crustaceans at levels consistent with "good manufacturing practice", with residues in the edible portion of the uncooked product not to exceed 1.0 parts per million.

The proposed use is permitted in the United States and Australia.

Contact: The Director, Bureau of Food Regulatory, International and Interagency Affairs, Department of Health, Address Locator 0702C, Tunney's Pasture, Ottawa, Ontario, K1A 0L2. Tel: 613-957-1828; Fax: 613-941-3537.

*Food and Drugs Act*, subsection 30(1); Hazardous Products Act, section 15

Not included in Regulatory Plan

Published in Canada Gazette November 29, 1997

## Exempt from Pre-Publication and Approved

### Statutory Authority & Regulatory Plan Listing

#### **Prohibition of Entry on Certain Lands in the Yukon Territory (1997-No. 11) (SOR/97-539, OIC 1997-1791); Prohibition of Issuance of Interests at Rampart House, in the Yukon Territory (SOR/97-540, OIC 1997-1792)**

The Prohibition of Entry Order ensures that no new third-party interests are created on Lots numbered 1 and 2, Group 1301 (The Rampart House Historic Site).

Pursuant to Chapter 13, Schedule B, Clause 2.1 of the Vuntut Gwitchin First Nation Final Agreement of May 29, 1993 made between Her Majesty the Queen in Right of Canada, the Government of the Yukon Territory and the Vuntut Gwitchin First Nation, the Government of the Yukon Territory has also requested that the administration and control of the Rampart House Historic Site be transferred to the Commissioner of the Yukon Territory.

In addition to the transfer of administration and control to the Commissioner of the Yukon Territory, Chapter 13, Schedule B, Clause 6.1 of the Vuntut Gwitchin First Nation Final Agreement requires the Government of Canada to prohibit entry onto the said lots for the purposes of locating a claim or prospecting for gold or other precious minerals or stones under the *Yukon Placer Mining Act* and locating a claim or prospecting or mining for minerals under the *Yukon Quartz Mining Act*.

The same clause provides that the Government of Canada prohibit the issuance of interests, pursuant to the *Canada Petroleum Resources Act*, to ensure that no new third-party interests are created on these lands. Therefore, a Prohibition of Entry Order pursuant to sub-section 10(1) of the *Canada Petroleum Resources Act* is also being issued to ensure that no new third-party interests are created on the lots.

The two Prohibition Orders are effective on the date of their registration (December 4, 1997) and have no expiry date, as permanent protection is required on the said lots.

Contact: Chris Cuddy Chief, Land & Water Management Division, Department of Indian Affairs and Northern Development, Les Terrasses de la Chaudière, 10 Wellington Street, Hull, Quebec, K1A 0H4. Tel: 819-994-7483; Fax: 819-953-2590.

#### **Contraventions Regulations, amendment (SOR/97-541, OIC 1997-1794)**

This amendment to the Regulations modifies an existing parking contravention made under the *Government Property Traffic Regulations* to reflect a recent amendment to those Regulations.

More particularly, it replaces item 12 of Part II of Schedule III relating to parking in reserved areas other than disabled persons and parking in an area for disabled persons without a required permit. The fines are \$25 and \$50 respectively.

The amendments come into effect December 4, 1997.

Contact: Michel Gagnon, Director, Contraventions Project, Department of Justice, 344 Wellington, Ottawa, Ontario, K1A 0H5; Tel: 613-998-5669; Fax: 613-998-1175.

*Yukon Placer Mining Act*, section 98, *Yukon Quartz Mining Act*, section 14.1; *Canada Petroleum Resources Act*, subsection 10(1)

INAC/97/R-1-I

To be published in Canada Gazette December 24, 1997

*Contraventions Act*, section 8

Jus/97-1-I

To be published in Canada Gazette December 24, 1997

## Exempt from Pre-Publication and Approved

## Statutory Authority & Regulatory Plan Listing

### **Food and Drug Regulations Medical Devices Regulations Controlled Products Regulations Miscellaneous Amendments Regulations, 1997-1 (Schedule No. 1019) (SOR/97-543, OIC 1997-1798)**

This amendment corrects and updates certain sections of the *Food and Drug Regulations*, the *Medical Devices Regulations* as well as *Controlled Products Regulations*. These corrections consist of clarifications, additions, deletions, corrections of typographical and spelling errors, and other inconsistencies inadvertently introduced in these regulations.

Among the changes are:

- a change in the definition “serious adverse drug reaction” in subsection C.01.001(1) of the Food and Drug Regulations;
- changes to Part I and II of Schedule F of the *Food and Drug Regulations*, to add folic acid, vitamin A and vitamin D in specified oral dosages;
- the repeal of subsection 8(3) of the *Medical Devices Regulations*, along with changes to subsections 11(1), 11(4) and 12;
- the repeal of section 8.1 and section 15.1 of the *Controlled Products Regulations*, along with changes to subsections 12(3) and 3(3), sections 25 and 27, section 1 of Schedule V, and paragraphs 33(3)(a), 39(c), 57(2)(a), 60(a), 60(b), 62(b), and paragraph 1(d) of Schedule IV.

The amendments come into effect Dec. 4, 1997.

Contact: Joan Korol, Risk Management and Regulatory Affairs Division, Bureau of Drug Policy and Coordination, Drugs Directorate, Health Protection Building, Postal Locator 0702B1, Tunney’s Pasture, Ottawa, Ontario, K1A 0L2. Tel: 613-957-1487; Fax: 613-941-6458; e-mail: joan.korol@isdtcp3.hwc.ca.

### **Food and Drug Regulations, amendment (Schedule No. 1103), Schedule F Update (SOR/97-544, OIC 1997-1809)**

This amendment will require terfenadine and astemizole to be sold only by prescription for both human and veterinary use. These drugs are second generation antihistamines used for treating symptoms associated with seasonal and perennial allergic rhinitis (hayfever and allergies) and chronic urticaria (hives).

The Health Department has concluded that the potential risks associated with these antihistamines and the number of drugs and/or foods that have been reported, or have the potential, to interact with terfenadine and astemizole no longer justify their nonprescription status.

Terfenadine and astemizole have been available in Canada as nonprescription drugs since the early 1980’s. Since 1992, it has become apparent that there was a growing list of drugs and foods that can interact with these antihistamines and cause rare but possibly fatal cardiovascular reactions. At that time, these antihistamines were moved from the nonprescription self-selection sections of pharmacies to nonprescription “behind the counter” sections to ensure Canadian consumers received appropriate counselling from a pharmacist at the time of purchase. In addition, consumer labelling information was modified to carry explicit warning statements regarding these risks. Health Canada also issued Dear Doctor/Pharmacist letters to alert health professionals to the potential risks.

Contact: Karolyn Lui, Policy Division, Bureau of Policy and Coordination, Therapeutic Products Directorate, Health Protection, Building Address Locator 0702B1, Tunney’s Pasture, Ottawa, Ontario K1A 0L2. Tel: 613-941-3693; Fax: 613-941-6458; e-mail: karolyn\_lui@inet.hwc.ca.

*Food and Drugs Act*, subsection 30(1); Hazardous Products Act, section 15

HCan/R-16-I

To be published in Canada Gazette December 24, 1997

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

HCan/R-7-L

To be published in Canada Gazette December 24, 1997

## Exempt from Pre-Publication and Approved

### Statutory Authority & Regulatory Plan Listing

#### **Vince Wagner Remission Order (SI/97-138, OIC 1997-1795)**

The Order remits \$2,242.59 of GST. The taxpayer in question became disentitled to a rebate for the amount because he failed to apply on time due to illness and death in his family.

Under the Order, a claim for a remission must be made in writing to the Minister within two years of the approval of the Order.

*Financial Administration Act*, subsection 232(2)  
Not included in Regulatory Plan  
To be published in Canada Gazette December 24, 1997

## Pre-Published and Approved With comments or changes

### Statutory Authority & Regulatory Plan Listing

#### **Canadian Aviation Regulations (Part I), amendment (SOR/97-542; OIC 1997-1796)**

This regulatory amendment increases, reduces or eliminates existing fees for aviation regulatory services and create some new fees, effective January 1, 1998, two months later than originally proposed when prepublished on August 2, 1997.

The fees established in the Schedule (Sections 104.01, 104.02 and 104.03) to the regulations cover aircraft registration, aircraft leasing, personnel licensing and training, aeronautical product approvals, maintenance and manufacturing, air operations, and general fees.

As a result of the amendments, fees will increase overall by some \$6.2-million.

In response to comments made after Canada Gazette, Part I prepublication, these regulations have been rewritten and reorganized for simplification and clarification and changes have been made to a number of proposals.

The proposed regulations also set out a transition regime to handle the calculation of fees for applications made on or before January 1, 1998.

As a result of the initial consultations and comments received, a number of revisions had been made to the proposals.

These revisions, reflected in the prepublished version, included:

- changing flat fees to hourly fees with a maximum cap, for many aeronautical product approvals. This was done to respond to concerns that the costs of aeronautical product approvals is highly variable and not conducive to recovery by use of flat fees per approval.
- reducing the examination fees. Entry-level examination fees were considered to be too high and could be a deterrent to new applicants wanting to enter the aviation industry as either a pilot or an aircraft maintenance engineer.

Among the changes resulting from comments received after prepublication are:

- fees for Aircraft Maintenance Engineer (AME) written examinations (Schedule IV, items 9 & 10) have been restructured to recognize changes in the process of issuing AME licences.
- fees for issuing a type certificate following a Level I Airworthiness Review, for manned free balloons, airships and propellers that are the responsibility of an airworthiness authority other than the Department of Transport (Schedule V, items 2 & 6), have been reduced to reflect the workload of processing such applications which is relatively lower than that for other aeronautical product approvals.

*Aeronautics Act*, subsection 4.4(2)

TC/R-3-M

To be published in Canada Gazette December 24, 1997

## Pre-Published and Approved With comments or changes

Statutory Authority  
&  
Regulatory Plan Listing

- fees for the validation authority for amateur-built foreign aircraft to operate in Canada (Schedule VI, item 5) have been decreased as compared to those for other foreign aircraft operating in Canada to allow for the lesser workload in validating such flight authorities.
- the proposed fee for Other Special Flight Operations (previously Schedule VII, item 2(e)), which would have applied to parachuting and to some other miscellaneous flight activities, has been eliminated. The workload associated with issuing certificates for these activities, which occur rarely, is less than that for similar Special Flight Operations certificates.
- instead of the higher fees were initially proposed for the issuing of air operator certificates for operators from foreign countries, other than the United States, as compared to United States certificated air operators, no distinction will be made by country among applications for foreign air operator certificates (Schedule VII, item 9). This recognizes the fact that no standard to identify different workload requirements for the two types of application has not yet been developed.

Contacts: Dan Cogliati, Director Cost Recovery (AFTR), Transport Canada, Place de Ville, Ottawa, Ontario, K1A 0N5. Tel: 613-993-5769; Fax: 613-991-4410. Chief, Regulatory Affairs, Civil Aviation (AARBH), Transport Canada Safety and Security, Place de Ville, Tower "C", Ottawa, Ontario K1A 0N8. Tel: 613-993-7284; Fax: 613-990-1198.

## Ministerial Orders Approved

Statutory Authority  
&  
Regulatory Plan Listing

### **Canadian Broiler Hatching Egg and Chick Orderly Marketing Regulations, amendment (SOR/97-536)**

The amendments replaces section 13 of the Regulations to extend the expiry date to December 31, 1998.

The amended regulations came into force on December 2, 1997.

*Farm Products Agencies Act*, paragraph 22(1)(f); *Canadian Broiler Hatching Egg Marketing Agency Proclamation*, subsections 5(2) and 6.1(2) of the schedule  
Not included in Regulatory Plan  
To be published in Canada Gazette December 24, 1997

### **Canadian Broiler Hatching Egg Marketing Agency Quota Regulations, amendment (SOR/97-537)**

This amendment establishes the final 1997 limits for broiler hatching eggs in the signatory provinces, as set out in a revised schedule to the Regulations.

The new limits for the period Jan. 1, 1997 through Dec. 31, 1997, by province and in number of broiler hatching eggs, are set as follows: Ontario, 166,637,839; Quebec, 164,766,457; Manitoba, 24,596,816; British Columbia, 92,420,934; and Alberta, 70,385,029. The Column II amounts for export trade are zero for all provinces.

The amended regulations came into force on December 2, 1997.

*Farm Products Agencies Act*, paragraph 22(1)(f); *Canadian Broiler Hatching Egg Marketing Agency Proclamation*, subsection 5(1) of the schedule  
Not included in Regulatory Plan  
To be published in Canada Gazette December 24, 1997

# Ministerial Orders Approved

## Statutory Authority & Regulatory Plan Listing

### Canadian Broiler Hatching Egg Marketing Levies Order (SOR/97-538)

The amendments change the levies imposed on producers in signatory and non-signatory provinces for broiler hatching eggs marketed in interprovincial or export trade. The expiration date of the Order is also extended to Dec. 31, 1997.

More specifically, the levies are changed as follows: for producers in Ontario (decrease to \$0.005078 from \$0.00772 per broiler hatching egg produced), Quebec (unchanged at \$0.0034), for producers in Manitoba, (unchanged at \$0.0075 per broiler hatching egg produced), British Columbia (decrease to \$0.0048 from \$0.00483) and in Alberta (increase to \$0.0051 from \$0.0045), and decrease to \$0.0046 from \$0.0054 for producers, dealers or hatchery operators in a non-signatory province marketing the eggs in interprovincial trade into a signatory province.

The amended regulations came into force on December 2, 1997, except section 1, which comes into force January 1, 1998.

*Farm Products Agencies Act*, paragraph 22(1)(f);  
*Canadian Broiler Hatching Egg Marketing Agency Proclamation*, subsection 5(1) of the schedule

Not included in Regulatory Plan

To be published in Canada Gazette December 24, 1997

### Regulatory Affairs

ISSN 1201-0715

© 1997 J-K Carruthers Ltd.



9 771201 071007

Editor: Mary Ferguson

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without the prior written permission of the publisher.

Please send any questions or comments c/o the Editor, J-K Carruthers Ltd., R.R. #1, Perth, Ontario, K7H 3C3, Telephone (613) 267-3890, Fax (613) 267-6727. Visit our Web Pages at [www.carruthers.com](http://www.carruthers.com).