

# Tracking Federal Regulatory Initiatives

# Regulatory Affairs

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<b>for Pre-Publication in Part I, Canada Gazette</b>	

**Competency of Operators of Pleasure Yachts Regulations; Boating Restriction Regulations, amendment**

*Canada Shipping Act*, section 562

The proposed regulations would immediately introduce firstly age and power restrictions on unaccompanied and unsupervised operators of motorized pleasure craft (*Boating Restriction Regulations*), as well as mandatory operator proficiency for operators of all power-driven pleasure yachts, with the new requirements to be phased in over a period of ten years (*Competency of Operators of Pleasure Yachts Regulations*).

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The new competency requirements would not apply to operators who are 55 years of age or older when the regulations come into force or who are non-Canadian residents whose pleasure yacht is in Canada for less than 45 consecutive days.

The proposed age restrictions would:

- prohibit anyone under 12 years of age to operate in Canadian waters a pleasure yacht propelled by a motor with engine power greater than 7.5 kW;
- prohibit anyone under 16 years of age to operate in Canadian waters a pleasure yacht propelled by a motor with engine power greater than 30 kW;

# Proposed Regulations

for Pre-Publication in Part I, Canada Gazette

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- prohibit anyone under 16 years of age to operate in Canadian waters a personal watercraft (i.e., a specified water-jet-drive pleasure craft);
- allow anyone 12 years of age or older, but under 16, to operate in Canadian waters a personal watercraft (i.e., a specified water-jet-drive pleasure craft) as long as the person is accompanied and directly supervised by a person 16 years of age or older.

Comments: Michel Berthiaume, AWEF, Small Vessel Partnerships Project, Rescue, Safety and Environmental Response, Canadian Coast Guard, Department of Fisheries and Oceans, 344 Slater Street, 9th Floor, Ottawa, Ontario, K1A 0N7. Tel: 613-991-5725; Fax: 613-991-3444.

## Fees to be Paid in Respect of Medical Devices Regulations

The proposed Regulations would revoke the current fees Regulations for medical devices and prescribe new client fees for:

- the service provided by the Therapeutic Products Program (TPP) for the examination of an application for a medical device licence,
- the right or privilege to import or sell a medical device in Canada conferred by granting a medical device licence to manufacturers of class II, III and IV medical devices, and
- the right or privilege to import or sell a medical device in Canada conferred by granting an establishment licence to importers and distributors of class I, II, III and IV medical devices and to manufacturers of class I medical devices who do not have a licensed Canadian importer or distributor.

The proposed Regulations constitute the second phase of the medical devices cost recovery initiative. Client fees are to be charged for an expanded pre-market review program and a number of additional services that will be provided by the TPP as the result of proposed changes to the *Medical Devices Regulations*.

The *Medical Devices Regulations* set out a system for classifying medical devices into one of four classes, class I representing the lowest risk devices (e.g. surgical instruments) and class IV representing the highest risk devices (e.g. test kit used for the detection of infectious agents such as Human Immune Deficiency Virus [HIV] and hepatitis viruses). These Regulations, which have been under development since 1992, were published in the Canada Gazette, Part I, on February 15, 1997, and are targeted to come into effect on July 1, 1998. The introduction of these fees was delayed until Phase II to allow for the implementation of the new *Medical Devices Regulations*.

The proposed Regulations will establish fees for services based on the requirements set out in the new *Medical Devices Regulations* and will replace the existing *Medical Devices Fees Regulations*.

Proposed are three types of fees:

- fees for examination of applications for medical device licences;
- annual medical device licensing fees; and
- establishment licensing fees.

The proposed medical devices fees would not apply to devices which are:

- custom-made;
- imported or sold under the special access program (emergency use);
- imported or sold for investigational testing; or
- which fall into class I.

*Financial Administration Act*, section 4.9

Published in Canada Gazette June 13, 1998

# Proposed Regulations

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

Statutory Authority

The proposed establishment licensing fees also do not apply to the following establishments:

- retailers;
- health care facilities; or
- manufacturers of class II, III or IV medical devices.

As an example, the proposed Therapeutic Products Program (TPP) fees would increase from a range of \$125 to \$11,000 to a range of \$200 to \$15,000.

The establishment registration fees would be \$2,530 for each establishment for the initial registration and \$2,120 for each renewal.

The proposed regulations include transitional provisions.

The proposed Regulations, except sections 11 to 14, are to come into effect September 1, 1998, with section 11 (Fee to be Paid for the Right or Privilege to Sell a Medical Device Conferred by Registration) and section 12 (sales records) coming into force November 1, 1999. Sections 13 and 14 (Establishment Registration Fees) are to come into force January 1, 2000.

Contact: Nancy Shadeed or Julie Gervais, Policy Division, Bureau of Policy and Coordination, Therapeutic Products Program, Health Protection Building, Address Locator 0702B1, Tunney's Pasture, Ottawa, Ontario, K1A 0L2. Tel: 613-957-0372; Fax: 613-941-6458; e-mail: nancy\_shadeed@hc-sc.gc.ca or julie\_gervais@hc-sc.gc.ca.

### **Schedule A to the Food and Drugs Act (hepatitis), amendment**

The Health Department has given notice of its intention to specify that liver disease, which is listed on Schedule A of the Act does not include hepatitis.

Subsection 3(1) of the Food and Drugs Act prohibits the advertising of any food, drug, cosmetic or device to the general public as a treatment, preventative, or cure for any disease, disorder or abnormal physical state referred to in Schedule A. Liver disease is listed on Schedule A to the Act and includes hepatitis.

Consequently, without the amendment, the advertisement and promotion of hepatitis vaccines to the general public would continue to be prohibited. Health Canada has concluded that this unduly restricts health promotional advertisements which are beneficial to groups at risk of contracting hepatitis.

Vaccines are currently available for Hepatitis A and B.

Contact: Andrew Adams, Bureau of Policy and Coordination, Therapeutic Products Program, Health Canada, Address Locator 0702B1, Tunney's Pasture, Ottawa, Ontario, K1A 0L2. e-mail: andrew\_adams@hc-sc.gc.ca.

### **Regulations Exempting Certain Precursors and Controlled Substances from the Application of the Controlled Drugs and Substances Act**

The Health Department has given notice of its intention to undertake a review of the Regulations to identify the substances for which regulatory changes are necessary to bring the control of certain substances, including benzodiazepines, into compliance with Canada's obligations under international drug control conventions.

The review will be followed by the development of regulations for these substances to give effect to the mandatory control provisions of the Conventions.

Contact: Karen Reynolds, Project Manager, Bureau of Policy and Coordination, Therapeutic Products Program, Health Canada, Address Locator 0702B1, Tunney's Pasture, Ottawa, Ontario, Canada K1A 0L2. e-mail: karen\_reynolds@hc-sc.gc.ca.

*Food and Drug Act*

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*Controlled Drugs and  
Substances Act*

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## Exempt from Pre-Publication and Approved

### Statutory Authority

#### **Alaska Marine Lines, Inc. Remission Order (SOR/98-338, OIC 1998-1015)**

*Customs Tariff*, section 115

This Order remits approximately \$52,000.00 in customs duties to Alaska Marine Lines, Inc. (AML) for vessels imported into Canada during the period commencing after September 30, 1996 and ending before January 1, 1998.

To be published in Canada Gazette June 24, 1998

AML transports Canadian consumer goods to the Yukon. These goods are initially delivered by truck from Vancouver to Seattle, then shipped by vessel from Seattle to Alaska and then delivered by truck to the Yukon. While AML currently receives duty relief on a 1/120th basis interchangeably on a tug and a barge, only approximately 3 per cent of the volume carried on the vessels is designated for Canadian coasting trade. The remaining 97 percent represents U.S. goods in transit to a U.S. port. This Order would remit the proportion of duties levied on the vessel in proportion to the freight service that is not destined for Canada.

Recognizing that the Yukon has no similar service providers, and that the United States tariff on these vessels was reduced to zero on January 1, 1998, remission of duties has been granted based on the percentage of cargo that is not destined for Canadian ports.

Contact: Catharine Tait, Secretary, Interdepartmental Remission Committee, Department of National Revenue, 6th Floor, Connaught Building, 555 MacKenzie Avenue, Ottawa, Ontario, K1A 0L5. Tel: 613-952-7915.

## Ministerial Orders Approved

### Statutory Authority

#### **Senate Sessional Allowance (Deductions for Non-Attendance) Regulations (SOR/98-337)**

*Parliament of Canada Act*, section 59

The regulation increases to \$190 per day the deduction from the sessional allowance of a senator for every sitting day beyond 21 on which the senator does not attend a sitting of the Senate.

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The deduction is pursuant to subsection 57(1) of the Act.

The Regulations come into effect July 1, 1998.

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