

# Tracking Federal Regulatory Initiatives

# Regulatory Affairs

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March 1, 1997

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**Pacific Fishery Regulations, 1993, amendment**

The proposed amendment would introduce a new minimum size mesh for gill nets used in Pacific salmon fisheries.

As a result of conservation concerns for Fraser River wild coho stocks, which have been in marked decline since the 1970s because of fishing pressures and habitat loss, fisheries managers, in consultation with salmon fishers, have determined that 158 mm is the minimum gill net mesh size that would allow for the harvest of chum salmon on the Fraser River, while minimizing incidental catches of coho, chinook and steelhead.

According to the Fisheries Department, fishers will benefit from the proposed amendment, through stronger Fraser River coho and chinook stocks. Steelhead, important to Aboriginal and sport fishers, will also benefit. Commercial salmon fishers will benefit from fishing opportunities for chum salmon. This action would reduce the need for future additional harvest restrictions.

Contact: Frances Dickson, Area Chief, Fisheries Management, Fraser River Division, Department of Fisheries and Oceans, 400-555 West Hastings Street, Vancouver, British Columbia, V6B 5G3. Tel: 604-666-6509; Fax: 604-666-7112.

*Fisheries Act*

Not included in Regulatory Plan

To be published in Canada Gazette March 1, 1997

## **Proposed Regulations** for Pre-Publication in Part I, Canada Gazette

### **Statutory Authority & Regulatory Plan Listing**

#### **Food and Drug Regulations, amendment (Schedule No. 733)**

The proposed amendment would optimize filing requirements for drugs intended for human use by categorizing the changes on the basis of risk, so that changes involving a greater or lesser degree of safety and efficacy will require the filing of an appropriate level of information and material.

Four levels would be established for drugs intended for human use:

- changes detailed in the first level require the submission of a Supplemental New Drug Submission (S/NDS);
- changes detailed in the second level involve a notification process (called a notifiable change) with a maximum 90 day default approval mechanism;
- changes detailed in the third level require only that the manufacturer immediately records the change so that it is available on site in the event of an inspection, and files annually with the Drugs Directorate before October 1st, a notice of all the changes that have taken place between July 1 of the previous year and June 30th of the current year;
- changes detailed in the fourth level outline involve changes that may be made without notification but for which a record of the change must be maintained by the manufacturer for the purpose of inspection. Subsequent to an inspection, the manufacturer may be requested to submit additional information should it be warranted. Changes not listed in Sections C.08.003.1, C.08.003.2, C.08.003.3 are considered to be fourth level changes.

The overall effect of the proposed change would be a substantial reduction in, or elimination of the information to be submitted to the Drugs Directorate, especially for fourth level changes which are considered to be low risk changes

The amendment would also refine filing requirements, based on experience gained with the *Changes to Marketed New Drug Products* policy and a review of filing practices in other countries. These changes will now be established in law with the promulgation of this regulation. A broad interpretation of the existing regulatory scheme has allowed the Drugs Directorate, in cooperation with industry, to develop and refine over the past few years an appropriate policy for implementing the new classification system for drugs intended for human use.

Current regulations for new drug submissions and supplements require the filing of a submission certificate whereby the manufacturer certifies the information and material filed is accurate and complete. The requirement to file a submission certificate in respect of a notifiable change and notice of change will now also be specified in regulation. Should subsequent to an inspection, the submission of additional information relating to a fourth level change be required, a submission certificate would also be required.

The amendment would also enable the senior executive officer of the manufacturer in Canada to designate an appropriate corporate officer in Canada with the legal responsibility of certifying the accuracy and completeness of all information filed by the manufacturer with the Drugs Directorate of the federal Health Department.

The amendment would put into regulation the requirement to submit a certified product information document (CPID) for chemistry and manufacturing changes.

Finally, this initiative would revoke a specific provision related to expiration date for anterior pituitary extracts, which would be made possible through accommodation of new technological advances.

*Food and Drugs Act*, sub-section 30(1)

HCan/96-8-L

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Subsection C.08.003.3(3) will be revoked once Schedule 624, Establishment Licencing has been promulgated since this provision will be covered under licence requirements.

Product specific information would still be required as part of a drug submission but whenever possible information submitted as part of the establishment licence will be cross-referenced in order to reduce duplication in the filing of information. Guidances will be provided to assist industry with their submission requirements.

A guidance document, Guidance Document: Schedule 733, has been prepared to assist in the interpretation of this regulatory amendment and is available on the Drugs Directorate Electronic Bulletin Board under Policies. Access may be obtained via the World Wide Web at <http://www.hwc.ca/drugs.html>.

The Drugs Directorate intends to charge fees for the evaluation of Notifiable Changes. Currently the *Food and Drug Regulations* do not provide for various levels of filing information based on the degree of risk, and all significant changes to the new drug submission necessitate a supplemental new drug submission. Evaluation fees for S/NDSs have been in place since September 1, 1995. Stakeholders will be consulted on the fee structure for the evaluation of notifiable changes.

Contact: Joan Korol, Risk Management and Regulatory Affairs Division, Bureau of Drug Policy and Coordination, Drugs 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: [joan\\_korol@isdtcp3.hwc.ca](mailto:joan_korol@isdtcp3.hwc.ca).

### **Hazardous Products (Ice Hockey Helmets) Regulations, amendment**

The proposed amendment would update the Canadian Standards Association (CSA) ice hockey helmet standard mandated in the Regulations from the one amended in June 1984 to the one amended in 1990 (*CAN/CSA-Z262.1-M90, Ice Hockey Helmets*).

Among the changes made to the standard are:

- the ear opening is reduced from 50 mm to 38 mm;
- a helmeted headform is dropped onto an anvil versus dropping a weight onto the helmeted headform.
- the impact failure criterion is measured in units of acceleration, i.e., 275 g; and
- helmet impacts are measured in terms of energy, i.e., 40 joules.

Failing to mandate the requirements of the 1990 CSA ice hockey helmet standard would counter the progress made in head protection since 1984 and render the current Regulations virtually unenforceable, thus going against the kind of progress that has, in the past, virtually eliminated serious head injuries associated with ice hockey.

Contact: Georges Desbarats, Product Safety Bureau, Health Protection Branch, Health Canada, Vanier Building, 8th Floor, Address Locator 4608A, 222 Nepean Street, Ottawa, Ontario, K2P 0B8. Tel: 613-954-3948; Fax: 613-952-1994.

### **Ship-sourced Oil Pollution Fund Regulations, amendment**

This amendment would reinstate a requirement for persons receiving contributing oil to complete an information return reporting such oil shipped in bulk as cargo of a ship from a place in Canada or from a Canadian offshore oil installation to a terminal or port in Canada.

This requirement was inadvertently repealed from the Regulations in an amendment registered and published as SOR/95-372 in the Canada Gazette Part II on August 9, 1995.

*Hazardous Products Act*,  
S.C. 1987, c. 30, s. 1

Not included in Regula-  
tory Plan

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*Canada Shipping Act*,  
section 719

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tory Plan

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At that time, rather than simply adding a new required item as paragraph 3(1)(c), the new item was instead made as paragraph 3(1)(a) and resulted in the repeal of the requirement in the old subsection 3(1)(a). This was not intended and the requirement for the reporting of coastal movements is being reintroduced.

As well, the proposed amendment would correct French wording in two sections of the Regulations.

The Regulations were established as a result of Canada, in 1989, acceding to the 1971 International Convention on the Establishment of an International Fund for Compensation for Oil Pollution damage. The *Ship-source Oil Pollution Fund Regulations* comply with the requirements of the International Convention and contributions are made to the Fund on an annual basis.

Contacts: F.A.S Millar, Office of the Administrator, Ship-source Oil Pollution Fund, 8th Floor, 90 Elgin Street, Ottawa, Ontario. K1A 0N5. Tel: 613-990-5420; Fax: 613-990-5423; or D. Dagenais, Marine Regulatory Coordinator and Analyst, (AMBCA), Marine Safety Directorate, Safety and Security Group, Transport Canada, Ottawa, Ontario. K1A 0N7. Tel: 613-990-3092; Fax: 613-991-5670.

### Ship Station Technical Regulations, amendment

The proposed amendments are consequential to the *Radiocommunication Regulations* published in Part II of the Canada Gazette on 27 November 1996 by Industry Canada (SOR/96-484) (See *Regulatory Affairs*, Vol. 2, No. 43, pp. 4-6, November 9, 1996). These regulations contain a provision that gives effect to a new radio operator certificate called the "Restricted Operator Certificate (Maritime)" (ROC) which will replace the Restricted Radiotelephone Operator's (RRO) Certificate. This new certificate ensures that maritime radio operators will have basic knowledge of the Global Maritime Distress and Safety System (GMDSS) and be capable of operating the appropriate GMDSS radio equipment. A provision in the *Ship Station Technical Regulations* (SSTR) describes the type of radiocommunications equipment that a person holding an RRO Certificate is allowed to operate. By amending this provision holders of the new ROC will be allowed to operate the same equipment.

The proposed amendments would also give effect to new performance standards that will apply to portable survival craft VHF radiotelephones carried on or after 23 November 1996 for Safety Convention ships and 1 June 1997 for Non-Safety Convention ships. The SSTR currently incorporate by reference the International Maritime Organization (IMO) Assembly Resolution A.762(18) entitled "Performance Standards for Survival Craft Two-Way VHF Radiotelephone Apparatus." These standards have been revised by IMO and new standards were adopted by Assembly Resolution A.809(19) on November 23, 1995. The changes that have been made to the standards primarily refer to the source of energy for these devices and ensure that in the event of a distress situation, each portable device will be equipped with a battery charged to full capacity.

Survival craft VHF radiotelephones are required on Safety Convention ships and on certain Non-Safety Convention ships that operate more than 20 miles from shore. In Canada, approximately 85 Non-Safety Convention ships are presently required to carry either two or three of these devices depending on the type and size of ship. The impact of this initiative on these ships will be minimal. Survival craft VHF radiotelephones already carried that comply with Assembly Resolution A.762(18) may continue to be carried until they become damaged or inoperative.

*Canada Shipping Act*,  
section 343

Not included in Regula-  
tory Plan

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In addition, as a result of comments received from the Standing Joint Committee for the Scrutiny of Regulations, two subsections have been deleted. The provisions contained in these subsections address radio inspectors and their inspection procedures. As these provisions were not intended to apply to the owner or master of a ship, it was decided that they would be deleted.

Contacts: Robert Turner, AMBC-E, Marine Surveyor, Ship Equipment, Marine Safety, Department of Transport, Canada Building, 344 Slater Street, Ottawa, Ontario, K1A 0N7. Tel:613-991-3134; Fax: 613-991-5670.

## Exempt from Pre-Publication and Approved

**Statutory Authority  
&  
Regulatory Plan Listing**

### **Special Appointment Regulations, No. 1997-1 (SOR/97-125, OIC 1997-269); Special Appointment Regulations, No. 1997-2 (SOR/97-126, OIC 1997-271)**

*Public Service Employment Act*, subsection 37(1)

The regulations make the following appointments and exempt the appointments from the application of the Public Service Employment Act, except sections 32, 33 and 34, while the appointees are in the position:

Not included in Federal Regulatory Plan

- Arthur Olson of Ottawa, Ontario as Special Advisor to the Minister of Agriculture and Agri-Food, and President designate of the Canadian Food Inspection Agency;
- Ronald Doering of Ottawa, Ontario as Special Advisor to the Minister of Agriculture and Agri-Food, and Executive Vice-president designate of the Canadian Food Inspection Agency.

To be published in Canada Gazette March 19, 1997

Contact: Senior Personnel Management, Privy Council Office, Postal Station B Building, Ottawa, Ontario K1A 0A3. Tel: 613-957-5288

## Ministerial Orders Approved

**Statutory Authority  
&  
Regulatory Plan Listing**

### **Canada Communication Group Divestiture Regulations (SOR/97-127)**

These regulations will provide automatic pension protection for transferring employees affected by the sale of Canada Communication Group (CCG) to a private corporation, Canada Communication Group, Inc. (CCGI)

*Public Service Superannuation Act*, paragraph 42.1(1)(u); *Financial Administration Act*, paragraph 7(2)(a)

Under the regulations, service with the new employer will be used for *Public Service Superannuation Act* (PSSA) threshold purposes when an affected former CCG employee eventually cease to be employed by CCGI.

Not included in Regulatory Plan

In the sale of the CCG to CCGI, employees receiving and accepting offers of "contiguous employment" with CCGI will have the availability of regular pension termination options from CCG deferred under the PSSA until they cease to be employed with the St. Joseph Corporation. The regulations will provide automatic pension protection for transferring employees so that service with CCGI, the new employer, will be used for PSSA threshold purposes when they eventually cease to be employed by the CCGI.

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# Ministerial Orders Approved

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&  
Regulatory Plan Listing

The regulations are limited to the employees of the CCG who cease to be employed in the Public Service as a result of the sale of that organization to a private sector corporation.

The regulations come into force March 7, 1997.

Contact: Joanne Lee, Director, Pensions Legislation Development Group, Pensions Division, L'Esplanade Laurier, West Tower, Ottawa, Ontario, K1A 0R5. Tel: 613-952-3233.

## **National Energy Board Pipeline Crossing Regulations, Part I, amendment (SOR/97-128)**

The amendment to these regulations corrects non-substantive problems identified by the Standing Joint Committee for the Scrutiny of Regulations.

More specifically, the amendment replaces a portion of section 4, before paragraph (a), with the following:

“4. Leave of the Board is not required for any construction or installation of a facility, other than the installation of an overhead line referred to in section 5, if”

The Standing Committee's concern was that section 4 of the Regulations had the effect of converting a legislative discretion into an administrative power.

The amended regulations come into force February 26, 1997.

Contact: P. Noonan, Counsel, National Energy Board, 311-6th Ave. S.W., Calgary, Alberta, T2P 3H2. Tel: 403-299-3552; Fax: 403-292-5503; e-mail: pnoonan@neb.gc.ca.

*National Energy Board Act*, subsection 112(5)

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