

Tracking Federal Regulatory Initiatives

Regulatory Affairs

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Proposed Regulations	Statutory Authority
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<p>Medical Devices Regulations, amendment (Schedule 1088: Diagnostic Products Related to Blood Screening)</p> <p>The Therapeutic Products Programme of Health Canada is withdrawing a proposal (Schedule 1088) to amend the old <i>Medical Devices Regulations</i>.</p> <p>The intent of this amendment was to subject the following products to the requirements of Part V of the old Medical Devices Regulations: blood grouping reagents, including red blood cell (A and B), kits and automated analysers; tissue typing (HLA) reagents, kits and automated analysers; and kits for the detection of infection by: cytomegalovirus (CMV), Epstein Barr virus (EBV), hepatitis B viruses (HBV), hepatitis C viruses (HCV), human T-lymphotropic viruses (HTLV) and <i>Treponema pallidum</i>.</p> <p>With new <i>Medical Devices Regulations</i> in effect since July 1, the amendment is no longer required.</p> <p>Contact: Julie Gervais, Regulatory Associate, Policy Division, Bureau of Policy and Coordination, Therapeutic Products Programme, Health Protection Building, Address Locator 0702B1, Tunney's Pasture, Ottawa, Ontario, K1A 0L2. E-mail: julie_gervais@hc-sc.gc.ca</p>	<p style="text-align: center;"><i>Food and Drugs Act</i></p> <p style="text-align: center;">Published in Canada Gazette October 10, 1998</p>
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Proposed Regulations

for Pre-Publication in Part I, Canada Gazette

Statutory Authority

Food and Drug Regulations, amendment (Schedule 733: Changes to Marketed New Drugs)

Food and Drugs Act

The Therapeutic Products Programme (TPP) of Health Canada is withdrawing a regulatory proposal (Schedule 733) to amend the *Food and Drug Regulations*. The intent of the proposal was to introduce in the Regulations a graduated system of regulatory requirements for changes to new drugs marketed in Canada. This proposal was republished in the Canada Gazette, Part I, on March 1, 1997.

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The Therapeutic Products Programme has developed and refined over the past few years a policy entitled "Changes to Marketed New Drug Products". The amendments proposed in Schedule 733 would have incorporated this policy into the Regulations. However, with international standards rapidly evolving, the proposed amendments are being withdrawn.

Instead, the Therapeutic Products Programme will modify its Changes to Marketed New Drug Products policy within the current regulatory authority. The revisions will reflect comments received from stakeholders including those received following the publication of the proposal in the Canada Gazette, Part I, on March 1, 1997.

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Radiocommunication Regulations, amendment

Radiocommunication Act,
section 6

The proposed amendments would broaden the eligibility requirements for licensing earth stations in the fixed and mobile satellite services, to meet Canada's General Agreement on Trade in Services Agreement on Basic Telecommunications (GATS-ABT) commitments.

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The existing regulations require that radiocommunication carriers be Canadian owned and controlled in terms of voting shares, board membership and control of the corporation.

A new provision would be added to the Regulations such that Canadian ownership and control provisions to complement provisions under the Telecommunications Act.

The new provision would remove the requirement for Canadian ownership and control of licence holders for earth stations in fixed satellite service (FSS) and mobile satellite service (MSS) that provide telecommunications services by means of satellites.

The new section of the Regulations would allow a service provider that is not Canadian owned and controlled to be eligible to hold a radio licence as a radiocommunication carrier for earth stations in the fixed satellite service and the mobile satellite service.

The new provision would exclude:

- services, i.e. over-the-air television, radio, and cable television, regulated under the Broadcasting Act and measures affecting such services, and
- telecommunications services supplied for the transmission of services, i.e. direct-to-home and direct-broadcasting Satellite, regulated under the Broadcasting Act where such services are intended for direct reception by the public.

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In the case of the exclusions, in each case, the applicable Canadian ownership and control requirements made under the *Broadcasting Act*, *Telecommunication Act* or *Radiocommunication Act* still apply. This is consistent with Canada's GATS-ABT commitments.

Contact: Ronald Amero, Director, Space and International Regulatory Activity Directorate, Radiocommunication and Broadcasting Regulatory Branch, Industry Canada, 300 Slater Street, Ottawa, Ontario, K1A 0C8. Tel: 613-998-3759; Fax: 613-952-9871; e-mail: Amero.Ron@ic.gc.ca.

General Nuclear Safety and Control Regulations; Radiation Protection Regulations; Class I Nuclear Facilities Regulations; Class II Nuclear Facilities and Prescribed Equipment Regulations; Uranium Mines and Mills Regulations; Nuclear Substances and Radiation Devices Regulations; Packaging and Transport Regulations; Nuclear Security Regulations; and Nuclear Non-proliferation Import and Export Control Regulations

Nuclear Safety and Control Act

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The proposed amendments would introduce the new regulatory regime under the *Nuclear Safety and Control Act* (NSC Act), which was passed on March 20, 1997. Once the new regulatory regime is put in place, the new legislation would establish the Canadian Nuclear Safety Commission (CNSC) and replace the existing Atomic Energy Control Board (AECB). With the exception of the ex officio position on the Board, the members and staff of the AECB will become the members and staff of the CNSC.

In order to simplify the transition from the current regulatory system to the new regulatory system under the NSC Act, the AECB has minimized the number of substantive changes in the new regulations.

For the most part, the new regulations consist of the requirements that currently exist in the *Atomic Energy Control Act* (AEC Act) of 1946, regulations or licence conditions, but in a format compatible with the new Act.

Some new regulatory requirements have been added, as follows:

- under the *General Nuclear Safety and Control Regulations*, a requirement to provide information on financial guarantees has been added. Licence applicants will be required to describe their financial guarantees and their plans for decommissioning at the end of the life of the nuclear facility.
- Under the *Radiation Protection Regulations*, new dose limits and action levels would be established as follows: for nuclear energy workers, 100 mSv for five years (i.e., an average of 20 mSv/year); for pregnant nuclear energy workers, 4 mSv; and for members of the public, 1 mSv/year.
- under the *Class I Nuclear Facilities Regulations*, which specify the requirements for major facilities, such as reactors, high energy accelerators and uranium processing plants, a five-year recertification period is being introduced. Under this new regulation, nuclear reactor operators will need to have continuing training and testing to the same standard as demonstrated for initial certification. Compliance verification will consist of monitoring the licensee's program, rather than having recertification exams given by the Commission.
- under the *Class II Nuclear Facilities and Prescribed Equipment Regulations*, which cover low energy accelerators, irradiators and radiation therapy installations, a requirement for servicing licences would be introduced.

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- under the *Uranium Mines and Mills Regulations*, certain licence conditions would be added.
- under the *Nuclear Substances and Radiation Devices Regulations*, servicing licences would be added and exemption values called “scheduled quantities” would be generally smaller based upon current radiation protection knowledge and new dose limits.
- under the *Packaging and Transport Regulations*, the major change is the requirement for carriers to have a radiation protection training program.
- under the *Nuclear Security Regulations*, three new security measures would be required at reactor sites in order to bring them up to international standards. For example, licensees will be required to continuously maintain, and in some cases, install additional surveillance equipment in order to provide accurate and timely alarm assessment. As well, an alarm assessment system would be required for inner areas where sensitive nuclear material are stored; more specifically, a surveillance system would be required in the inner area to allow the immediate assessment of the cause of an alarm. Finally, licensees would be required to search, or otherwise monitor, every person and thing entering and leaving the protected area; these searches can be carried out by technical means and are similar to the standard of security provided at Canadian airports.
- under the *Nuclear Non-Proliferation Import and Export Control Regulations*, the number of items for which import licences are required would be increased.

Contact: Ross Brown, Manager, New Act Implementation Group, Atomic Energy Control Board, 280 Slater Street, P.O. Box 1046, Ottawa, Ontario, K1P 5S9. Tel: 613-995-1357; Fax: 613-995-5086; e-mail: brown.r@atomcon.gc.ca.

Minority Investment (Banks) Regulations, amendment; Minority Investment (Cooperative Credit Associations) Regulations; Minority Investment (Insurance Companies) Regulations; Minority Investment (Trust and Loan Companies) Regulations

Bank Act, section 474

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The amendments rectify an omission in earlier amendments, as well as make few minor technical changes requested by the Standing Joint Committee for the Scrutiny of Regulations.

On July 28, 1997, the Government promulgated revised Minority Investment Regulations, which enhanced the ability of federally regulated financial institutions (FRFIs) to make less than controlling investments in permitted entities. The revised Regulations enhanced the ability of financial institutions to form alliances, enter new markets, and compete more effectively in Canada and abroad.

The promulgation of Bill C-82, among other things, extended the list of permitted entities to include multi-activity type entities. However, the authority to make less than controlling investments in multi-activity type entities was omitted from the revised *Minority Investment Regulations*. As a result, the Government is amending the July 28, 1997, Minority Investment Regulations to rectify this situation.

The Regulations amending the Minority Investment Regulations also include a few minor technical changes which were requested by the Standing Joint Committee for the Scrutiny of Regulations.

Contact: Charles P. Johnston, Regulations Officer, Legislation and Precedents Division, Office of the Superintendent of Financial Institutions, 255 Albert Street, Ottawa, Ontario, K1A 0H2. Tel: 613-990-7472; Fax: 613-998-6716.

Exempt from Pre-Publication and Approved

Statutory Authority

Tobacco Regulations, amendment (SOR/98-509, OIC 1998-1804)

The proposed amendments revise the schedules to the Regulations, which list the brands of tobacco products and cigarettes eligible for exemption from marking requirements, to respect changes to sales and marketing practices relating to brands and volumes, in the tobacco industry. Several products have been removed from the lists, while only one tobacco product has been added.

The brands listed in the Schedule I (tobacco products) are: Aspen, Bronco, Canadian, Canadian Natural, Dickens and Grant, Doral, Dorchester, Excel, Gauloises Blondes, Gitanes, Gold Coast, GPC Approved, Imperial Special Blend, Islands, Kent, Lucky Strike, Magna, Marathon, Mercer, Mild Seven, Monte Carlo, Montreal Blend, River, and Viceroy.

The brands of cigarettes listed in Schedule III are: Canadian Gold, Old Port, and Vantage.

The amendment comes into effect on October 8, 1998.

Contact: Bill Anderson, Project Officer, Excise Duties & Taxes Directorate, Vanier Towers, Tower C, 7th Floor, 25 McArthur Road, Vanier, Ontario, K1A 0L5. Tel: 613-957-7593; Fax: 613-954-2226.

Retirement Compensation Arrangements Regulations, No. 1, amendment (SOR/98-510, OIC 1998-1810)

The amendments ensure transitional pension coverage for that portion of an employee's benefits no longer allowed under a registered pension plan under income tax rules.

The amendments are the companion pieces to the provisions of the *Regulations Respecting Transitional Coverage in the Case of Divestiture of Service* made pursuant to the *Public Service Superannuation Act* that provide for pension coverage under the Act for a maximum period of one year following the divestiture of a service.

These Regulations come into force on October 1, 1998.

Contact: Joan M. Arnold, Director, Pensions Legislation Development Group, Pensions Division, Treasury Board Secretariat, Ottawa, Ontario, K1A 0R5. Tel: 613-952-3119.

Order Amending the Schedule to the Family Orders and Agreements Enforcement Assistance Act (SOR/98-511, OIC 1998-1813)

The *Schedule to the Family Orders and Agreements Enforcement Assistance Act*, which became effective on May 1, 1997, lists the licences which are subject to the licence denial provisions of Part III of the Act. This Order is a technical update of the references in the list for aviation and marine licences.

Currently the Schedule also includes passports but they are not affected by this Order.

The licence denial scheme is a tool to facilitate enforcement of support orders by the provinces and territories. At the request of a provincial or territorial enforcement agency, the federal government will withhold, refuse to renew or suspend specific licences issued to an individual who has failed to meet support obligations for three payment periods or has accumulated arrears of a least \$3000. Licence denial is a measure of last resort when other enforcement actions by the provincial or territorial support service have not succeeded.

Excise Tax Act, sections 60, 127 and 202

To be published in Canada Gazette October 28, 1998

Special Retirement Arrangements Act, subsections 4(2) and 16(1) and paragraph 28(1)(i)

To be published in Canada Gazette October 28, 1998

Family Orders and Agreements Enforcement, section 63

To be published in Canada Gazette October 28, 1998

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The technical changes include:

- with respect to aviation licences, an update of references to take into account the changes to the licensing scheme which occurred as the result of the coming into effect of the *Canadian Aviation Regulations*, under the *Aeronautics Act*;
- the deletion of certain marine and aviation licences which are no longer required to be on the list;
- with respect to marine certificates, proposed changes to the licensing regime to ensure that licence denial action may be taken in respect of licences that continue to be valid and that were issued under regulations repealed by the *Crewing Regulations* and the *Marine Certification Regulations* under the *Canada Shipping Act* in 1997.

The amendment comes into effect October 8, 1998.

Contact: Ken Duford, Director, Family Law Assistance Section, Department of Justice, Ottawa, Ontario, K1A 0H5. Tel: 613-998-5670.

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