

Tracking Federal Regulatory Initiatives

Regulatory Affairs

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Air Services Charges Regulations, amendment

The proposed amendments would increase landing, general terminal and/or aircraft parking charges at 37 airports, as part of the shift to local ownership and financial self-sufficiency by way of increases in user charges.

The changes in user fees are expected to generate an additional \$5.3-million in annual revenues, representing about a 12.85% increase over existing levels; the increases have been capped at any airport at \$2.50 per enplaned/deplaned passenger (for more than half of the airports, the increase is less than half the \$2.50 cap).

The one exception to the capping of increases is Schefferville Airport which shows an impact of \$3.12 per enplaned/deplaned passenger. A doubling of the landing charges was agreed to by airlines if the Department agreed to restore the runway.

Several other changes are also proposed:

- the special landing charges applicable to international flights making refueling stops at Gander would be increased to \$6.11 from \$5.68 on the first 30 000 000 kg in accumulated weight landed, to \$5.14 from \$4.71 on the next 14 800 000 kg in accumulated weight landed, and to \$4.75 from \$4.32 on any weight in excess of 44 800 000 kg in accumulated weight landed;

Aeronautics Act, subsection 4.4(2); *Ministerial Regulations Authorization Order*, section 2

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Proposed Regulations

for Pre-Publication in Part I, Canada Gazette

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- the loading bridge charge at Québec (Jean-Lesage) Airport would increase to \$80 from \$61 for each connection of an aircraft to the loading bridge;
- the loading bridge charge at Regina Airport would increase to \$60 from \$54 for each 90-minute period or portion thereof that an aircraft is connected to the loading bridge; and
- references to Kamloops, Kapuskasing, Moncton, Springbank, Sydney, Thunder Bay and Yarmouth airports have been removed from the Regulations as these airports have been transferred to local control and as such are no longer subject to these Regulations.

Contact: Dan Cogliati, Director, Cost Recovery, Department of Transport, Place de Ville, Tower C, 22nd Floor, Ottawa, Ontario K1A 0N5. Tel: 993-5769; Fax: 991-4410.

Processed Products Regulations, amendment

The proposed amendment will establish new standard container sizes for frozen French fried potatoes in the range between 2 kilograms and 20 kilograms; they will also deregulate standard container requirements for frozen potatoes other than frozen French fried potatoes.

Currently, the largest container size currently prescribed in the Regulations for frozen French fried potatoes is 2 kilograms.

This proposed change will allow manufacturers and importers to market this product more efficiently and economically and will harmonize the Regulations with industry standards in both Canada and the United States.

The larger containers are generally intended for food service customers and may qualify for certain labelling exemptions.

Several other amendments are also proposed:

- the definition of “container” is being amended to accommodate the larger food service sizes;
- the definition of “package” is being deleted because the current definition is ambiguous and it will become redundant with the new definition of “container”;
- a labelling provision is being amended to clearly show that the labelling requirements apply equally to Canadian and imported products;
- a new labelling provision is being introduced to require that the unlabelled inner units of a food service product must be labelled in accordance with the Regulations if those units are removed from the larger container and offered for sale separately;
- to deregulate standard containers for ripe or black olives. This product is not packed in Canada and importers have indicated that the existing standard container requirement was intended for green olives which are imported in bulk and repacked in Canada. Black (ripe) olives are imported as prepackaged products.
- the declaration of net quantity requirement for all food products is being amended to require only metric units; however, other equivalent units of measurement will be permitted to be shown along with the metric units provided the other units of measurement are not more prominently displayed than are the metric units; and
- the existing standard containers prescribed for frozen potatoes other than frozen French fried potatoes and for unspecified frozen vegetables are being deleted because the industry no longer sees any advantage in maintaining standard container sizes for these products.

*Canada Agricultural
Products Act, section 32*

Published in Canada
Gazette March 7, 1998

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

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Contact: J. F. Standish, Associate Director, Processed Products Section, Dairy, Fruit and Vegetable Division, Canadian Food Inspection Agency, 59 Camelot Drive, Nepean, Ontario K1A 0Y9. Tel: 225-2342, Extension 4725; Fax: 228-6632; e-mail: jstandish@em.agr.ca

Exempt from Pre-Publication and Approved

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Special Appointment Regulations, No. 1998-4 (SOR/98-151, OIC 1998-343)

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 appointee is in the position:

- Huguette Labelle as Deputy Head of the Millenium Bureau of Canada, effective March 12, 1998.

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

Public Service Employment Act, subsection 37(1)

Not included in Federal Regulatory Plan

To be published in Canada Gazette April 1, 1998

Honey Regulations, amendment (SOR/98-153, OIC 1998-346); Honey Fees Order, amendment (SOR/98-163)

The Honey Regulations have been amended to clarify the grading and packer registration requirements and to simplify the wording of the Regulations respecting interprovincial shipment of honey and exemptions for the shipment of bulk honey.

Details of these changes (although not the actual proposed amendments) were pre-published on August 9, 1997, along with amendments to the *Honey Fees Order*.

The fees Order introduces a new compliance assistance fee, at a rate which is the greater of \$87 or \$21.75 per quarter hour, rounded to the nearest quarter hour. The service will be provided, as resources permit, when a client requests the presence of an inspector to meet the requirements of the relevant inspection regulations.

More specifically, the amendments:

- repeal a provision that permitted grade names to be used on packages of honey if the honey was packed, classified and graded in accordance with the written authority of an inspector. This provision pre-dated the current *Canada Agricultural Products Act* and is considered an improper sub-delegation of authority under this statute. This regulation has been repealed and replaced by a provision that permits the grades to be used only for honey that is prepared in a registered establishment. This change reflects the grading requirements found in other food regulations administered by Food Inspection Agency.
- prescribe requirements respecting the interprovincial shipment of honey. Under international trade agreements, the principle of national treatment requires that imported products be treated the same as domestically traded products. The absence of specific interprovincial trade provisions in the Regulations created an ambiguous situation with respect to imports. This has been clarified with the introduction of requirements for the interprovincial shipment of honey that mirror the export and import requirements, including exemptions for the shipment of bulk honey.

Plant Protection Act, S.C., 1990, c. 22; *Financial Administration Act*, paragraphs 19(1)(b) and 19.1(b)

To be published in Canada Gazette April 1, 1998

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- remove a restriction which limited producer-graders to packing only honey produced at their own apiaries. This was not compatible where producer-graders had an opportunity to expand their business to pack honey produced by other apiaries. This restriction has been removed to expand market access opportunities for all producers.

Contact: J. F. Standish, Associate Director, Processed Products Section, Dairy, Fruit and Vegetable Division, Canadian Food Inspection Agency, 59 Camelot Drive, Nepean, Ontario K1A 0Y9. Tel: 225-2342, Extension 4725; Fax: 228-6632; e-mail: jstandish@em.agr.ca.

Fresh Fruit and Vegetable Regulations, amendment (SOR/98-155, OIC 1998-348); Fresh Fruit and Vegetable Fees Order, amendment (SOR/98-162)

The amendments deregulates the grading and inspection of fresh fruits and vegetables for export. This change will allow the Canadian produce industry to be more flexible and innovative in their export marketing approach.

Food inspection and certification for export purposes will continue to be available on request, particularly when an importing country requires Canadian government inspection.

The heading before section 31 and sections 31 and 32 are repealed.

The fees Order introduces a new compliance assistance fee, at a rate which is the greater of \$87 or \$21.75 per quarter hour, based on the program hourly rate. The service will be provided, as resources permit, when a client requests the presence of an inspector to meet the requirements of the relevant inspection regulations.

The fees Order also increases the fee for verification of an import declaration to \$14 per shipment from \$11.

The regulations come into effect March 12, 1998.

Contact: R. Cardinal, A/Associate Director, Dairy, Fruit and Vegetable Division, Canadian Food Inspection Agency, 59 Camelot Drive, Nepean, Ontario K1A 0Y9. Tel: 613-225-2342, ext. 4640; Fax: 613-228-6632; e-mail: rcardinal@em.agr.ca.

Maple Products Regulations, amendment (SOR/98-154, OIC 1998-347); Maple Products Fees Order, amendment (SOR/98-164)

The amendments exempt smaller maple producer establishments from the export certification requirements if they are operated under the terms and conditions of the Canadian Food Inspection Agency (CFA) Quality Management System (QMS) for Canadian Maple Products Exporters, published by the Agency on September 1, 1997.

The fees Order introduces a new compliance assistance fee, at a rate which is the greater of \$87 or \$21.75 per quarter hour, based on the program hourly rate. The service will be provided, as resources permit, when a client requests the presence of an inspector to meet the requirements of the relevant inspection regulations.

The regulations come into effect March 12, 1998.

Contact: J. F. Standish, Associate Director, Processed Products Section, Dairy, Fruit and Vegetable Division, Canadian Food Inspection Agency, 59 Camelot Drive, Nepean, Ontario K1A 0Y9. Tel: 225-2342, Extension 4725; Fax: 228-6632; e-mail: jstandish@em.agr.ca

Canada Agricultural Products Act, R.S., c. 20 (4th Supp.); *Financial Administration Act*, paragraphs 19(1)(b) and 19.1(b)

To be published in Canada Gazette April 1, 1998

Canada Agricultural Products Act, R.S., c. 20 (4th Supp.); *Financial Administration Act*, paragraphs 19(1)(b) and 19.1(b)

To be published in Canada Gazette April 1, 1998

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Town of Jasper Zoning Regulations, amendment (SOR/98-167, OIC 1998-369)

The amendments, which come into effect March 13, 1998, rezone three areas in that town to permit increased residential densities on the specified lots.

The amendment will help address a general housing shortage in the Town of Jasper, allow the existing, limited land base to be used more efficiently, and provide more affordable housing for residents of the town.

More specifically:

- on Block 25, Lots 1 and 20, the zoning will change from R1, one-family dwelling district, to R2, two-family dwelling district. The zoning change will permit the construction of a duplex which will provide part of the staff accommodation required by a commercial enterprise currently under development on Block 9, Lots 14 and 15.
- on Block A, Lot 9 and Block 37, Lots 12 to 18, lands previously zoned as public open space will be rezoned to R3, multiple-family dwelling district. The zoning of these areas to R3 will permit the development of a nonprofit, co-operative housing project which will consist of two multiple-family townhouse complexes.

The proposed zoning changes were recommended by independent planning studies and conform with the objectives and guidelines contained in the residential development section of the 1988 Jasper Town Plan.

Contact: Sharon Budd, Project Manager, Regulatory Development, National Parks, Parks Canada, Department of Canadian Heritage, 4th Floor, 25 Eddy Street, Hull, Québec, K1A 0M5 Tel: 819-994-2698; Fax: 819-994-5140.

National Parks Act, paragraph 7(1)(o)

To be published in Canada Gazette April 1, 1998

Pre-Published and Approved With comments or changes

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Plant Protection Fees Regulations, repeal (SOR/98-152, OIC 1998-345); Plant Protection Cost Recovery Fees Order (SOR/98-161)

The Government has repealed the *Plant Protection Fees Regulations*, effective March 12, 1998, and replaced them with the *Plant Protection Cost Recovery Fees Order*. The fees order was enacted under the authority of the *Financial Administration Act* instead of the *Plant Protection Act*.

The fees Order increases the fees stipulated in the *Plant Protection Fees Regulations* from 34% to 50%.

New fees for domestic inspection services are introduced and are calculated on a basis of 25% cost recovery. All other new fees are calculated at 50% for those import and export inspection services for which the Canadian Food Inspection Agency cost recovers.

The fees Order includes fees for such services as laboratory tests and related services, designation of inspectors (i.e., accreditation), inspection services for domestic facilities (e.g., lumber mills, flour mills, field crop inspections) and conveyances (e.g., used containers). These services include re-inspection and follow-up actions (e.g., an inspection to verify the effectiveness of a treatment, release from detention).

Plant Protection Act, S.C., 1990, c. 22; *Financial Administration Act*, paragraphs 19(1)(b) and 19.1(b)

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In addition to the fees for the issuance of an import permit or phytosanitary certificates, a fee is charged for the issuance of a Movement Certificate. The fees Order also contains a payment provision stipulating when the fees are payable.

All overtime fees, including the overtime inspection for grain, contains a payment provision stipulating when the fees are payable.

All overtime fees, including the overtime inspection for grain vessels, are specified in the FPI Branch Overtime Fees Order.

Both the proposed repeal and the replacement fees Order were republished in the Canada Gazette Part I, on September 6, 1997.

Following the republication, a number of changes were made, including:

- postponement of fees under the Seed Potato Certification Program;
- establishment of a \$100 inspection fee for Christmas tree yards where the cut trees are collected at one location prior to export; Christmas tree industry representatives disagreed with the fee category proposed for field inspection of such products.
- lowering the specific fees for imported shipments of fresh fruits and vegetables, based on the estimated number of shipments presented for entry into Canada. As a result, the fee for fresh fruits and vegetables, where the lot consists of not more than 250 boxes or bags, is \$28. Where the lot consists of more than 250 boxes or bags, the fee is \$48.
- amending the proposed fees for the apple ermine moth nursery field inspection to reflect the fee per hectare as requested by industry.
- clarifying that the laboratory fees will only apply to testing, done at the Centre of Expertise Laboratories at Sidney, B.C., at Nepean, Ontario, and at Charlottetown, PEI.

The Food Inspection Agency has said it will explore alternative delivery arrangements for inspection services within the various industry sectors affected by the fees Order.

Contact: Dr. Jean Hollebhone, Director Plant Protection Division, Canadian Food Inspection Agency, 59 Camelot Drive, Nepean, Ontario, K1A 0Y9. Tel: 613-225-2342, extension 4316; Fax: 613-228-6606.

Industrial Hemp Regulations (SOR/98-156, OIC 1998-352); Amendment to Schedule II of the Controlled Drugs and Substances Act (SOR/98-157, OIC 1998-353); Narcotic Control Regulations, amendment (SOR/98-158, OIC 1998-354)

The *Industrial Hemp Regulations* will permit the legal production and processing of hemp for commercial purposes while providing compliance and enforcement mechanisms to prevent diversion of Cannabis to the illicit drug market.

Cultivation of hemp is currently permitted for scientific studies only under licenses issued by Health Canada under the *Controlled Drugs and Substances Act* (CDSA).

Hemp refers to varieties of the Cannabis plant that have a low content of delta-9-tetrahydrocannabinol (THC) which are generally cultivated for fibre. Varieties with a high content of THC are referred to as marihuana. The psychoactive ingredient in marihuana is THC.

The Regulations define industrial hemp as the plants and plant parts of the Cannabis plant, the leaves and flowering heads of which do not contain more than 0.3 per cent THC. It includes the derivatives of the plant, and plant parts such as the oil derived from hemp seeds.

Controlled Drugs and Substances Act, subsection 55(1) and section 60

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The Regulations define seed as “any part of an industrial hemp plant that is represented, sold or used to grow a plant”.

Industrial hemp does not include non-viable Cannabis seed, other than its derivatives, or mature Cannabis stalks. Leaves, flowers, seeds or branches, or fibre derived from those stalks are included.

Hemp seed oil, and seed cake, regardless of the viability of the seed source, are considered derivatives of Cannabis and are therefore controlled under the CDSA. To make this clear, these Regulations modify Schedule II to the CDSA and the Schedule to the *Narcotic Control Regulations* to clarify the status of derivatives.

More specifically, under the *Industrial Hemp Regulations*:

- Importers and exporters of industrial hemp, in the form of seed or viable grain, will be licensed. In addition to holding a licence they will also be required to obtain a permit for each shipment.
- The importer must ensure that shipments of viable grain are accompanied by foreign certification. A list will be published by Health Canada indicating which countries are designated as having equivalent controls on the production of grain. Grain may only be imported from listed countries. This will ensure that grain imported will not produce a plant containing more than 0.3% THC.
- Seed growers will be restricted to a 0.4 hectare minimum plot size and will be required to demonstrate current membership with the Canadian Seed Growers Association as part of their licence application. Seed growers will be required to provide the number of hectares grown in the previous two years as part of their licence application.
- Plant breeders will not be restricted by minimum plot sizes. Persons applying for a licence as a plant breeder must be registered with the Canadian Seed Growers Association and may only cultivate industrial hemp under this regulatory framework. The pedigreed seed restriction which applies to growers in the year 2000 does not apply to plant breeders nor does the limitation to the “List of Approved Cultivars”
- Growers for fibre or grain will require a licence before they can purchase seeds from a distributor or cultivate industrial hemp. Growers will be required to provide the number of hectares grown in the previous two years as part of their licence application.
- Only approved varieties of industrial hemp seeds, as listed on Health Canada's “List of Approved Cultivars” may be planted. Commencing January 1, 2000, only pedigreed seeds of approved varieties may be planted. Growers will be required to identify their fields, and maintain records of production and distribution.
- Licences and audit trail requirements will also be required for processing activities such as pressing seeds into oil. All parties licensed or authorized will be required to identify a person resident in Canada who will be responsible for the licensed activities.
- To obtain a licence for the importation, exportation, production, or sale of industrial hemp, applicants will be required to produce a police security check.
- Derivatives of seed or grain, such as oil and seed cake, will be exempted from the Regulations if there is evidence that the derivatives contain no more than 10 micrograms of delta-9-tetrahydrocannabinol per gram and carry appropriate labelling statements.

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- Products made from derivatives of seed or grain will be exempted if there is evidence that each lot or batch contains no more than 10 micrograms of delta-9-tetrahydrocannabinol per gram.
- Importers and exporters of derivatives will be required to provide proof with each shipment that the shipment contains no more than 10 micrograms of delta-9-tetrahydrocannabinol per gram for each lot to ensure that the product is within the limit.
- Similarly products made from the derivatives of seed or grain must be accompanied with evidence that each shipment contains no more than 10 micrograms of delta-9 tetrahydrocannabinol per gram.
- No person will be permitted to import or export a derivative or a product produced from a derivative that contains more than 10 micrograms of delta-9-tetrahydrocannabinol per gram.
- No person will be permitted to import or sell whole plants, including sprouts or the leaves, flowers or bracts of industrial hemp; or import, sell, or produce any derivative or any product made from a derivative of the above.
- Authorizations will be required for transportation, when products are transported outside the direction or control of a licence holder, or for possession for the purpose of testing for viability.
- No person shall advertise to imply that a derivative or product is psychoactive.
- Testing for the level of THC in leaves or in derivatives must be done by a competent laboratory according to standards defined by Health Canada.
- Growers will be required to identify the coordinates of their field by using global positioning system (GPS) and provide a legal description of the location of the land to be cultivated.

The proposed Regulation was published with a 45 day comment period in Canada Gazette Part I on December 27, 1997.

As a result of the republication and other consultations, several changes were made to the proposed Regulations, including:

- the inclusion of a Ministerial list of approved varieties along with administrative guidelines to provide information concerning compliance action where the crop produced from approved varieties exceeds the 0.3% THC limit. The guidelines will provide flexibility for crops which exceed the 0.3% THC limit. Enforcement options range from immediate harvesting to destruction depending on the THC level.
- provision of criteria by which the Minister may designate certain varieties which are suitable for Canadian use. This list will include some OECD varieties but will also include other varieties which meet the criteria set out in the Regulations. The change to the Regulations to permit the use of seeds contained on the Ministerial list should help to reduce the cost to growers; however, only approved cultivars will be permitted on the list to ensure a low THC starting point for the crop.
- addition of a requirement that documentation accompany each imported shipment to certify that the shipment contains no more than 10 micrograms/g of THC. This certification can then be presented to Customs prior to release in Canada and will ensure that all derivatives, whether produced domestically or imported, all meet the same requirements.

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- inclusion of a sunset clause to permit growers to cultivate uncertified approved cultivars until December 31, 1999. The Regulations have also been modified to require official seed certification rather than an OECD seed tag. In addition, the varietal status of the imported seed must be validated by a designated authority in the country of origin. To allow the use of seeds of non-certified varieties during the sunset period, the Regulations have been modified to provide an exemption until January 1, 2000. Efforts are also underway to support the modification of Schedule III to the *Seeds Regulations* to include Cannabis and establish a variety registration system for Canada.
- introduction of a 0.4 hectare minimum for seed growers while retaining, the 4 hectares minimum for producers of fibre or grain. This change resulted in numerous changes within the Regulations to provide a specialized framework for plant breeders and seed growers while ensuring more efficient enforcement.
- allowance of small divisions within a single site, hence balancing the need to maintain control of locations with the need to adapt to the environmental conditions present.
- clarifications with respect to packaging, including a definition for package which is consistent with the definition in the *Seeds Act*. The definition of package “includes a sack, bag, barrel, case, or any other container in which seed, viable grain or its derivatives are placed or packed”. The Regulations were also modified to clarify the requirement to fasten the package in a manner which harmonizes the requirements with the *Seeds Regulations*: fastened with respect to “package” means sealed in such a manner that it is impossible to open the package easily without leaving evidence of it having been opened.
- a requirement for a licence amendment for changes in field location. In addition, the Regulations have been amended to include a requirement for a legal description of the land to facilitate inspection.
- addition of an advertising provision to prohibit the promotion of industrial hemp products to produce a psychotropic effect.

The associated amendment to Schedule II of the *Controlled Drugs and Substances Act* replaces subitem 1(8) with “non-viable Cannabis seed, with the exception of its derivative.” The same change is made to subitem 17(8) of the schedule to the *Narcotic Control Regulations*.

The regulations come into force March 12, 1998.

Contact: Lauraine Bégin, Policy Division, Bureau of Policy and Coordination Therapeutic Products Directorate, Health Protection Building, Address Locator 0702B1, Tunney's Pasture, Ottawa, Ontario, K1A 0L2. Tel: 613-957-0372; Fax: 613-941-6458; e-mail: lauraine-begin@hcsc.gc.ca

Motor Vehicle Restraint Systems and Booster Cushions Safety Regulations (SOR/98-159, OIC 1998-355); Motor Vehicle Safety Regulations (Restraint Systems Consequential Amendments), amendment (SOR/98-160, OIC 1998-356)

The new regulations govern restraint systems and booster cushions that are installed after purchase by users and replace the requirements governing “add-on” restraint systems and booster cushions contained in sections 213, 213.1, 213.2, and 213.3 of the *Motor Vehicle Safety Regulations*.

Motor Vehicle Safety Act,
S.C., 1993, c. 16

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Consequently, sections 21-31, 21-3.1, 213.2, and 213.3 of the *Motor Vehicle Safety Regulations* are being repealed. Since built-in child restraint systems and built-in booster cushions are integral parts of the motor vehicle, section 213.4, which governs these components, will remain in the *Motor Vehicle Safety Regulations*.

Due to new requirements imposed by the revised *Motor Vehicle Safety Act*, which came into force on April 12, 1995, several provisions of a non-technical nature have been added relating the use of the national safety mark and the keeping of records; the maintenance of a registration system by manufacturers; the issuance of Notices of Defect; and the keeping of records by importers as evidence of conformity.

Several additional changes have been made by the Department in order to clarify certain provisions. In addition, the requirements of two other proposed regulatory initiatives have been incorporated, including the requirement for a statement to be placed on infant restraint systems that warns against installing them in the front seat of a vehicle equipped with a passenger-side air bag.

The proposed regulations were prepublished in the *Canada Gazette*, Part I, July 13, 1996 and again on January 18, 1997.

The new Regulations come into effect March 15, 1998.

Contact: France Legault, Road Safety and Motor Vehicle Regulation, Department of Transport, 330 Sparks Street, Place de Ville, Tower C, Ottawa, Ontario, K1A 0N5. Tel: 613-998-1963; Fax: 613-990-2911; e-mail: LEGAULF@tc.gc.ca

Patented Medicines (Notice of Compliance) Regulations, amendment (SOR/98-166, OIC 1998-366)

Patent Act, section 5 and
subsection 55.2(4)

The amendments would introduce a number of improvements to the Regulations designed to make the Regulations fairer and more effective, and reduce unnecessary litigation.

To be published in *Canada Gazette* April 1, 1998

More specifically, the changes include:

- reducing the length of stay to 24 months from 30 months, whereby the Minister is prevented from issuing a Notice of Compliance (NOC) while patent issues are resolved;
- modifying court discretion to lengthen or shorten a stay, based on the diligence of the patentee in pursuing its application;
- specifying circumstances in which damages or costs can be awarded, including allowing the court to award costs to either a generic manufacturer or a patentee, including solicitor and client costs;
- requiring patentees to certify that the patents submitted on a patent list are relevant to the particular version of a drug;
- authorizing the Minister of Health to audit the patent list and to remove ineligible patents from the patent list;
- clarifying the court's capacity to order disclosure to the patentee of a generic manufacturer's NOC submission, as well as to require that documents disclosed be treated confidentially;
- requiring a generic manufacturer to indicate to the patentee the version of the drug it intends to market (with respect to a notice of allegation (NOA) relating to non-infringement);
- preventing a NOA relating to non-infringement being submitted without a generic manufacturer having first filed a submission for NOC approval with the Minister of Health;

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- imposing the burden of proof of proving that a patent would not be infringed on a generic manufacturer seeking to make a version of a patentee's drug and alleging non-infringement of a product-by-process patent on the patent list; and
- providing for a generic manufacturer to be able to have the patentee's case dismissed at an early stage, in certain circumstances.

The proposed changes respond to the April 1997 report of the Standing Committee on Industry reviewing the *Patent Act Amendment Act, 1992*.

The government has indicated its willingness to bring the proposed regulations into force on a stage basis, in order not to give either patentees or generic manufacturers any strategic advantage.

The proposed amendments were prepublished in the Canada Gazette Part I on January 24, 1998.

Changes to the regulations come into force on March 12, 1998. Specific transitional rules deal with how the amended regulations will apply to existing and new proceedings.

Contact: Vinita Watson, Director General, Corporate Governance Branch, Industry Canada, 235 Queen Street, West Tower, 5th Floor, Ottawa, Ontario, K1A 0H5. Tel: 613-952-0211; Fax: 613-952-1980; E-mail: watson.vinita@ic.gc.ca

Ministerial Orders Approved

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Canadian Turkey Marketing Quota Regulations, 1990, amendment (SOR/98-169)

Farm Products Agencies Act, paragraph 22(1)(f)

This amendment, which comes into force on March 17, 1998, revises the limitations to be applied when determining the market allotment of a producer or when issuing a new market allotment of a turkey producer or when issuing a new market allotment with a province during the control period beginning March 1, 1998 and ending April 30, 1999.

To be published in Canada Gazette April 1, 1998

The new limits are as follows (in pounds of turkey): Ontario, 121,008,298; Quebec, 61,702,691; Nova Scotia, 7,800,148; New Brunswick, 5,377,462; Manitoba, 20,400,727; British Columbia, 32,207,936; Saskatchewan, 10,254,206; Alberta, 24,332,325. The overall total is 283,083,793 pounds.

Farm Debt Mediation Regulations (SOR/98-168)

Farm Debt Mediation Act

The Regulations define the number and constitution of the Appeal Boards, designation of members and the appeal procedures under procedures for providing mediation between insolvent farmers and their creditors.

To be published in Canada Gazette April 1, 1998

The regulations also:

- provide a definition of the term "related" for the purposes of Section 20 and Subsection 22(2) of the *Farm Debt Mediation Act*.
- define methods of service that are available to creditors for serving Notice of Intent to Realize on Security under Section 21.
- require the establishment of five Appeal Boards: in British Columbia/Yukon/Alberta/Northwest Territories; in Saskatchewan/Manitoba; in Ontario; in Quebec; and in the Atlantic Provinces.

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- limit appeals to applications made under Section 5(1)(a) of the Act and only with respect to the eligibility of the farmer (S. 15(2)(a) or the extension or termination of a stay of proceedings (S. 15(2)(b)).
- permit the farmer and all creditors of the farmer to appeal the Stay of Proceedings, Extensions of the Stay of Proceedings and Termination of the Stay of Proceedings. In appealing a Stay of Proceedings or an Extension of a Stay of Proceedings, the farmer or creditor will have 15 calendar days to file an appeal with the administrator, in the prescribed form, containing the prescribed information, from the date the notice is sent to them by the administrator.
- give 48 hours for farmers appealing a decision to terminate a Stay pursuant to subsection 14(2)(c) or 14(2)(d) to have the appeal to the administrator from the time he is notified by the administrator of the intent to terminate.
- provide, in all other cases, 7 days for a farmer to appeal to the administrator, in the prescribed form, from the time that the administrator notifies the farmer of the intent to terminate.
- in defining related person, covers the various relationships from family to business partners, shareholders, cooperatives.
- provide a reasonable period of time for the farmer to receive the notice and at the same time allow the creditor to serve the notice if for some reason he has difficulty in reaching the farmer or any adults residing at the farmer's residence or in the case of a partnership, corporation or cooperative association, time to reach a partner, an officer, a director or agent or any adult residing at the residence of the partner, officer, director or agent. In both cases, after a notice has been served, the farmer still has 15 business days from date of service to make an application to the administrator before any action to realize on security can be taken by a creditor.

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