

Tracking Federal Regulatory Initiatives

Regulatory Affairs

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| | |
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| Circulate to: | HIGHLIGHTS |
| 1. | Proposed Regulations |
| 2. | Allergy nasal spray medicine to be available without prescription. 1 |
| 3. | Exempt from Prepublication and Approved |
| 4. | Only certain U.S. fishing vessels to be allowed into Canadian ports 2 |
| 5. | Prepublished and Approved |
| | Import controls on feeder cattle eased. 2-4 |

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

Food and Drug Regulations, amendment

Food and Drugs Act

The proposed amendment would remove flunisolide nasal solution in concentrations of 0.025 percent (25µg flunisolide per spray) from Schedule F of the *Food and Drug Regulations*. Schedule F lists drugs that must be sold on prescription.

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Flunisolide is indicated for the relief of (nasal) symptoms due to seasonal allergies. The maximum daily dose of flunisolide 0.025 percent nasal spray is limited to four sprays in each nostril daily.

Flunisolide 0.025 percent nasal spray has been marketed as a prescription drug in Canada for approximately 19 years. It is being used by approximately 21.9 million patients worldwide, and is available without a prescription, in the United Kingdom and South Africa. The post market surveillance data support the safe use of this drug with nonprescription status.

Contact: Karolyn Lui, Policy Division, Bureau of Policy and Coordination, Therapeutic Products Programme, Health Protection Building, Address Locator 0702B1, Tunney's Pasture, Ottawa, Ontario K1A 0L2, or by Internet at karolyn_lui@hc-sc.gc.ca

Exempt from Pre-Publication and Approved

Statutory Authority

Coastal Fisheries Protection Regulations, amendment (SOR/98-410, OIC 1998-1366)

Coastal Fisheries Protection Act, section 6

These amendments allow the Minister of Fisheries and Oceans to issue licences to U.S. fishing vessels, other than fishing vessels involved in the Pacific hake or salmon fisheries, to enter Canadian ports for the purpose of effecting repairs and obtaining supplies.

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The Regulations list 36 nations whose vessels may be granted a licence to enter Canadian fisheries waters/ports for a number of purposes, including the effecting of repairs and obtaining supplies. The countries listed cooperate with Canada on international fisheries conservation objectives including the sound conservation and management of fish stocks off Canada's coasts.

According to the Fisheries Department, the United States is absent from the list of nations whose vessels may be granted licences to enter Canadian ports because the U.S. does not cooperate with Canada on a number of fishery issues (e.g., the U.S. failure to reach long-term arrangements on Pacific salmon interceptions, its unwillingness to agree to catch allocations for the transboundary Pacific hake stocks, and its refusal to proceed in a timely manner to finalize arrangements for Yukon salmon).

There are some exceptions in the Regulations which allow the Minister to issue Licences to U.S. fishing vessels. Licences may be issued to albacore tuna and Pacific halibut fishing vessels as provided for in treaties with the U.S. which grant reciprocal port access for Canadian vessels. Licences may also be issued to U.S. fishing vessels that either unload salmon or herring at Canadian ports on the Pacific coast, or herring or menhaden on the Atlantic coast, in light of the historical trade in these species.

Under the amendment, only U.S. fishing vessels which have not been used in the Pacific hake or salmon fisheries in the two years prior to the application, are eligible to obtain licences for the purpose of effecting repairs or obtaining supplies at Canadian ports. The licence applicant would be required to provide documentation, such as fishing licences, to the Minister to this effect. As a number of fisheries conservation problems remain with the United States, the other elements of the port access policy towards the United States are retained.

Contact: A.J. Sarna, Director, Multilateral Relations Division, International Directorate, Department of Fisheries and Oceans, 200 Kent Street, Ottawa, Ontario, K1A 0E6. Tel: 613-993-1897; Fax: 613-993-5995, E-mail: sarnaa@dfo-mpo.gc.ca.

Pre-Published and Approved With comments or changes

Statutory Authority

Health of Animals Regulations, amendment (SOR/98-409, OIC 1998-1365)

Health of Animals Act, subsection 64(1)

These amendments introduce a number of changes with respect to the controls on animal and animal products being imported into Canada.

The changes include:

- reducing the import controls on feeder cattle;
- requiring at least a 60-day quarantine for bison imported from the United States, to allow for testing for brucellosis, tuberculosis, bluetongue and anaplasmosis;

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Statutory Authority

- allowing certificates and other documents to be sent by facsimile in order to speed processing of animals and their products being imported into Canada;
- allowing manufacturers to quote in the cautionary statement on the labels of veterinary biologics the time periods before animals can be slaughtered, similar to those in the United States;
- allowing newborn animals accompanying their mother to enter Canada from the United States on the basis of their mother's certification;
- closing several ports of entry in Quebec which have not been used for some time, as part of that Region's switch to the use of electronic means of clearing agricultural products;
- requiring everyone who conducts a public sale or auction to keep records of the names and addresses of the buyers and sellers of poultry and game farm animals in order to help trace back exposed animals when there is a disease outbreak.

With respect to restricted feeder cattle, the amendments would:

- remove the requirement that individual identification of restricted feeders and all other livestock on a permitted premises be recorded at slaughter;
- allow imported feeder cattle to be moved for purposes other than slaughter after the treatment period is complete; and
- allow other livestock on the permitted premises to be moved for purposes other than slaughter.

The restricted feeder regulations allow the importation of feeder cattle from American herds from those States that meet control criteria for bovine tuberculosis and from those that have achieved freedom from brucellosis under the U.S. national eradication program. Importation of restricted feeder cattle is seasonally restricted to limit the risk associated with vector-borne bluetongue and anaplasmosis. To further mitigate the risk of introducing anaplasmosis to Canada, restricted feeders must be treated with antibiotics as specified in the import protocol. The risk assessment indicates that the risk of importing disease in treated cattle is equivalent or less than importing disease in tested cattle.

Three technical changes were made at the suggestion of Canadian Food Inspection Agency staff to the proposals prepublished June 20, 1998:

- item 6(2), subsection 22.12(5) was changed to allow "restricted feeders" to be removed from a feedlot provided they are licensed by an inspector to a place where they can be destroyed. This change will allow permit holders to dispose of "restricted feeders" in a manner that is safe, where for some reason, the owner feels the restricted feeder cannot continue to be kept in the feedlot.
- item 15. The ports of entry - Noyan, Trout River, and Stanhope - will remain available. As Revenue Canada maintains staff at these locations, they will still be considered ports of entry for presentation of animals or other things as required by section 16 of the *Health of Animals Act*.
- the amendment to section 8 of the regulations which allows the use of electronic means to send certificates and other import documents was modified. It will now allow the Agency to require importers who do not produce the original documents within the required two weeks, to provide the originals at the time of importation.

Pre-Published and Approved With comments or changes

Statutory Authority

As a result of consultations following the prepublication of the amendments, a concern was raised by the Canadian Veterinary Medical Association (CVMA) regarding the change to the regulation that will permit the acceptance of copies of import certificates (i.e. facsimile) for animals and animal products. According to the CVMA, this amendment may result in the submission of fraudulent documents. The proposed regulation has been amended such that the CFIA may refuse to accept copies of import documents from importers who do not produce the original documents in the required 14 days. The acceptance of copies of original import documents will not be instituted until proper procedures are in place to verify that the original documentation has been submitted within the required time allotted (14 days). The requirement to produce originals is felt to be sufficient to prevent fraudulent documents from being presented.

Many of the changes would make it easier for U.S. feeder cattle to move from northern states such as Montana into the prairie provinces instead of more southern states.

Contact: Dr. P. Greenwood, Animal Health and Production Division, Canadian Food Inspection Agency. Tel: 613-225-2342; Fax: 613-228-6630.

Ministerial Orders Approved

Statutory Authority

Domestic Substances List, amendment (SOR/98-411)

The amendment adds 6 substances to Part I of the *Domestic Substances List*.

More specifically, the additions to Schedule I are: 34041-09-3; 61524-93-4; 68133-01-7; 68610-47-9; 176227-30-8; 192526-10-6.

The Order comes into effect on August 10, 1998.

Contacts: Martin Sirois, A/Head, New Substances Notification Section, New Substances Division, Commercial Chemicals Evaluation Branch, Department of the Environment, Hull, Quebec, K1A 0H3. Tel: 819-953-9348; Arthur Sheffield, A/Director, Regulatory and Economic Assessment, Regulatory Affairs and Program Integration Directorate, Department of the Environment, Hull, Quebec, K1A 0H3. Tel: 819-953-1172.

Canadian Environmental Protection Act, subsection 30(1)

To be published in Canada Gazette September 2, 1998

Domestic Substances List, amendment (SOR/98-412)

The amendment adds 9 substances to Part I, and adds 12 substances to Part II of the *Domestic Substances List* (DSL).

The additions to Schedule I are: 77-71-4 T; 31605-22-8 N; 55636-49-2 N; 66071-35-0 N; 68083-84-1 T; 68334-73-6 N; 70983-64-1 T; 74347-33-4 T; 121912-39-8 N.

The Order comes into effect on August 10, 1998.

Contacts: Martin Sirois, A/Head, New Substances Notification Section, New Substances Division, Commercial Chemicals Evaluation Branch, Department of the Environment, Hull, Quebec, K1A 0H3. Tel: 819-953-9348; Arthur Sheffield, A/Director, Regulatory and Economic Assessment, Regulatory Affairs and Program Integration Directorate, Department of the Environment, Hull, Quebec K1A 0H3. Tel: 819-953-1172.

Canadian Environmental Protection Act, subsection 30(1)

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