

# Appendix 1 Regulations

## A. Federal Legislation

The federal and provincial governments are both committed to the production of safe food. Health Canada is the federal department responsible for helping Canadians maintain and improve their health. In partnership with provincial and territorial governments, Health Canada provides national leadership to develop health policy, enforce health regulations, promote disease prevention and enhance healthy living for all Canadians ([www.hc-sc.gc.ca](http://www.hc-sc.gc.ca)). The Minister of Health has total or partial responsibility for the administration of the following acts related to beef safety.

- *Canadian Food Inspection Agency Act*
- *Food and Drugs Act*
- *Pest Control Products Act*
- *Feeds Act*

The Canadian Food Inspection Agency (CFIA) provides inspection and related services to four federal government departments, including Health Canada and Agriculture and Agri-Food Canada. The CFIA ([www.inspection.gc.ca](http://www.inspection.gc.ca)) administer and enforce the following Acts related to beef safety:

- *Feeds Act*
- *Food and Drugs Act (as it relates to food)*
- *Health of Animals Act*
- *Meat Inspection Act*

The Veterinary Biologic Section (VBS) is a division of CFIA which is responsible for the licensing of veterinary biologics (vaccines) in Canada. The VBS licenses biologics to ensure they are safe and efficacious in animals, and pose no threat to humans and the environment. The regulations for licensing veterinary biologics are part of the Health of Animals Act.

The Pest Management Regulatory Agency (PMRA) administers the *Pest Control Products Act* (PCPA) for the federal Minister of Health ([www.hc-sc.gc.ca/pmra-arla](http://www.hc-sc.gc.ca/pmra-arla)). The *Pest Control Products Act* regulates products used for the control of pests and the organic functions of plants and animals. The Act and Regulations prescribe standards for registration, manufacturing, storing, displaying and use of pesticides to ensure their efficacy and safety. A copy of the Act and Regulations can be found on the Department of Justice Canada web site ([laws.justice.gc.ca/en/p-9/90918.html](http://laws.justice.gc.ca/en/p-9/90918.html)). Provincial governments may require pesticide training and licensing requirements for producers. Contact Alberta Agriculture, Food & Rural Development and Alberta Environment to find out what provincial regulations are in place for producer use of pesticides and disposal requirements for empty containers, unwanted or expired pesticides.

The Veterinary Drugs Directorate (VDD) is part of the Health Products and Food Branch of Health Canada. ([www.hc-sc.gc.ca/vetdrugs-medsvet](http://www.hc-sc.gc.ca/vetdrugs-medsvet)). The VDD ensures safety of food from animals treated with veterinary drugs. As well, VDD ensures that veterinary drugs sold in Canada are safe and effective for animals.

The *Food and Drugs Act* provides the conditions and standards under which drugs are manufactured and offered for sale. The Act ensures drugs on the Canadian market are safe and effective and that labels contain all necessary warnings, such as toxicity, contraindications and withdrawal periods.

Different types of drugs are classified in various Schedules of the *Food and Drugs Act*. Schedule G drugs are controlled drugs, such as barbiturates. Schedule N drugs are narcotics and these drugs can not be sold over the counter, under any circumstances.

Schedule F drugs are of primary interest to cattle producers. Schedule F, Part I veterinary drugs are prescription drugs for animals. These drugs are restricted to sale and use on the order of a licensed veterinarian and can only be sold under the confines of a valid veterinary-client-patient relationship (VCPR).

Prescription drugs can be differentiated from nonprescription drugs by the Pr symbol which is on the label of the drug. Prescription drugs are not available on demand from producers, can not be sold over the counter by non-professional staff and must be adequately labeled with specific instructions for use. Examples of prescription drugs are Micotil, Nuflor, Excenel, and oxytocin.

Schedule F, Part II veterinary drugs are not prescription drugs. These drugs can be sold “over the counter” (OTC) provided the label indicates “For Veterinary or Agricultural Use Only” or the product is in a dosage form unsuitable for humans. The producer must understand what the product is for and how to use it. This includes understanding label directions (including correct calculation of label dosages), contraindications and withdrawal periods. Examples of some nonprescription drugs are penicillin and tetracycline.

In the national beef on-farm food safety program, producers are required to have an annually signed processing protocol and treatment protocol from a licensed veterinarian to ensure that all drug use is under a valid VCPR and the veterinarian has provided adequate information for the safe and prudent use of these products.

Any extra-label drug use (i.e., used other than as stated on the manufacturer’s label, such as increasing the dosage, different route or frequency, different animal species) can only be done through the written order of a licensed veterinarian and a copy of the signed, written veterinary prescription should be provided by the veterinarian to the producer for his records.

Within the *Food and Drugs Act*, Part C Drugs, regulations (C.08.012) exist for the sale of medicated feeds. Any medications used in feeds other than as described on the manufacturer’s label (reference: Compendium of Medicating Ingredients Brochure) require a written medicated feed prescription from a licensed veterinarian. A copy of the written medicated feed prescription must be given to the producer by the veterinarian and the veterinarian is responsible for ensuring that the producer understands how to feed the medicated feed to his cattle.

The *Health of Animals Act* includes regulations respecting the health of animals. A copy of it can be found at the Department of Justice Canada web site [laws.justice.gc.ca/en/H-3.3/C.R.C.-c.2961/129597.html](http://laws.justice.gc.ca/en/H-3.3/C.R.C.-c.2961/129597.html). The regulation contains parts and schedules related to eradication of diseases (Part IX), animal identification (Part XV), prohibited materials in ruminant feed (Part XIV), and veterinary biologics (Part XI).

It is within the *Health of Animals Act* where the proposed Regulations Respecting the Making of Medicated Feed is described. These regulations are currently being revised with stakeholder input. The regulations include standards that cattle producers will have to follow when making medicated feed on farm. The regulations will include licensing requirements of operations, standards on-farm for making medicated feeds e.g., mixer and scale verification, procedures to prevent drug cross-contamination and carry-over, procedures in case of discrepancy or contamination, and records.

The Canadian Cattle Identification Agency (CCIA) ([www.canadaid.com/](http://www.canadaid.com/)) follows the legislation for animal identification under the *Health of Animals Act*. These regulations describe identification requirements, prohibitions, tagging sites, losses of an approved tag, animal death or slaughter, export and import requirements. Animal identification is an important tool in an animal health and food safety programs.

Under the Health of Animals Regulations, prohibited material is defined as “anything that is, or that contains any, protein that originated from a mammal, other than a porcine or an equine. It does not include milk, blood, gelatin, rendered animal fat or their products.” The regulations define importation and rendering requirements of animal protein products to ensure that they do not contain prohibited material which could potentially include agents that cause transmissible spongiform encephalopathies i.e. bovine spongiform encephalopathy. The regulations specify in section 164 “that no person shall feed prohibited material to a ruminant.” Producers who have pigs and poultry on the same farm as cattle must have storage and equipment clean-out procedures to prevent feed cross contamination, since pig and poultry feed currently can contain ruminant bone and meat meal. CFIA has recently proposed new regulations that would remove all SRMs from animal feed to reduce the potential on-farm cross contamination of prohibited materials between ruminant and pig/poultry feed.

The CFIA is responsible for the administration of the meat hygiene program to ensure that meat and poultry products leaving federally-inspected establishments are safe and wholesome. The CFIA enforces the *Meat Inspection Act* and Regulations. The *Meat Inspection Act* covers the import and export of and inter-provincial trade in meat products, the registration of establishments, the inspection of animals and meat products in registered establishments and the standards for those establishments and for animals slaughtered and meat products prepared in those establishments. The standards under the regulations discuss some issues as ante and post mortem inspections, how to handle meat products with *Cysticercus bovis* (beef measles), and allowable food additives, e.g., maximum drug residue limits (authorized by these Regulations or the Food and Drug Regulations). The CFIA monitors on a regular basis carcasses for drug residues. Any carcasses found with residues above tolerance levels are condemned and the producer contacted to investigate the problem and prevent reoccurrences. Currently, drug residues in beef carcasses are <1%.

CFIA activities also include HACCP. All federal packing plants in Canada must have HACCP implementation and their HACCP programs are regularly inspected by CFIA for compliance. Information on the Food Safety Enhancement Program (FSEP) and HACCP can be found at CFIA’s web site ([www.inspection.gc.ca](http://www.inspection.gc.ca)). As well, CFIA is responsible for the administrative and technical recognition of the commodity specific on-farm food safety programs ([www.inspection.gc.ca/english/fssa/polstrat/reco/conte.shtml](http://www.inspection.gc.ca/english/fssa/polstrat/reco/conte.shtml)), such as Canadian Quality Milk and Quality Starts Here Verified Beef Production.

Under the authority of the federal *Feeds Act*, CFIA administers a national livestock feed program to verify that livestock feeds manufactured and sold in Canada or imported into Canada are safe, effective and labeled appropriately. A copy of the *Feeds Act* and Regulations can be found at ([laws.justice.gc.ca/en/F-9/57123.html](http://laws.justice.gc.ca/en/F-9/57123.html)).

CFIA conducts such activities as

- Evaluating and approving ingredients for use in livestock feeds
- Monitoring feeds via random sampling and analysis for the presence of residues of chemicals, pesticides, contamination by heavy metals, mycotoxins, and salmonella and verifying drug guarantees in feeds
- Undertaking investigations in response to detections of contamination of meat and producer complaints related to feed, conducted at both commercial feed mills and on farm
- Reviewing labels of medicated feeds for accuracy to verify that the proper level of medication is provided and that all applicable cautions and warnings are provided to enable safe use of the feed as directed. ([www.inspection.gc.ca/english/anima/feebet/feebete.shtml](http://www.inspection.gc.ca/english/anima/feebet/feebete.shtml))

Under the Feed Regulations, a “medicated feed” is defined as a mixed feed that contains a medicating ingredient. A “medicating ingredient” is defined as:

- a substance that is intended for use in the prevention or treatment of disease in livestock or
- a substance, other than a feed, that is intended to affect the structure or any function of the body of the livestock,
- and that has assigned to it a drug identification number pursuant to the *Food and Drugs Act*.

Medicating Ingredients Permitted in Cattle Feed – When used according to the label. Compounding of drugs may alter withdrawal times.

[www.inspection.gc.ca/english/anima/feebet/mib/drguse1e.shtml](http://www.inspection.gc.ca/english/anima/feebet/mib/drguse1e.shtml)

Review the CFIA website regularly for changes below in CMIB.

## 2005 Medicating Ingredient List

Cattle-Calves Nutritional Uses	Withdrawal (days)	Medicating Ingredient Brochure (MIB)
<b>Growth Promotion and Improved Feed Efficiency</b>		
1) chlortetracycline hydrochloride	0	10.1
2) lasalocid sodium	0	66
3) melengestrol acetate	2	46
4) monensin sodium	0	57
<b>Improved Feed Efficiency</b>		
1) salinomycin sodium	0	69
<b>MEDICINAL USES</b>		
<b>Calf diarrhea</b>		
1) chlortetracycline hydrochloride	5	34
2) oxytetracycline hydrochloride	5	35
<b>Stress</b>		
1) chlortetracycline hydrochloride/sulfamethazine	10	49
2) oxytetracycline hydrochloride/neomycin sulfate	7	55
<b>Coccidiosis</b>		
1) amprolium	7	27
2) decoquinate	0	50
3) lasalocid sodium	0	66
*4) monensin sodium	0	57
<b>Foot rot</b>		
1) chlortetracycline hydrochloride	5	34
<b>Bloat</b>		
*1) oxytetracycline hydrochloride	5	35
*2) poloxalene	0	56
<b>Suppression of Estrus</b>		
1) melengestrol acetate	2	46
<b>Liver Abscesses</b>		
1) tylosin phosphate	0	43
<b>Worms</b>		
*1) fenbendazole	13	72
*2) levamisole	10 (meat) 2.5 (milk)	54
*3) morantel tartrate	30	61
<b>*includes lactating dairy cattle</b>		

## B. Provincial Legislation

Alberta legislation consists of the *Pharmaceutical Profession Act*, the *Veterinary Professions Act*, the *Livestock Diseases Act*, and the *Environmental Protection and Enhancement Act*. Copies of the Acts can be found at [www.gov.ab.ca/qp](http://www.gov.ab.ca/qp).

The *Pharmaceutical Profession Act* is the primary provincial legislation regulating the sale of all drugs in the Province of Alberta. This Act is administered by the Alberta College of Pharmacists. This Act lists a number of activities which are defined as “exclusive scope areas of the practice of pharmacy”. The Act states that only a pharmacist can engage in the exclusive scope areas of the practice of pharmacy. Exceptions in this provision include “registered veterinarians” and the sale of livestock medicine pursuant to the Production Animal Medicine Regulation.

The *Veterinary Profession Act* is administered by the Alberta Veterinary Medical Association. The Act defines the requirements of a “registered” veterinarian and states that only such a veterinarian can engage in the practice of veterinary medicine which includes but is not restricted to prescribing and dispensing of drugs. Specific exemptions regarding who can engage in the practice of veterinary medicine are listed in the Act (Part 1 (2)) under exclusive scope of practice. January 2004, the AVMA implemented a new policy requiring veterinarians to treat all antimicrobials, including OTC, as prescription drugs in terms of prescribing and dispensing.

Under the *Livestock Diseases Act*, certain provisions exist, where persons other than those under the *Pharmaceutical Profession Act* and *Veterinary Profession Act*, may sell medicine. The Production Animal Medicine (PAM) Regulations provide for the licensing of a person to sell medicine, specifying which medicine may be sold and prescribing any other conditions concerning the sale and handling of medicine. [www1.agric.gov.ab.ca/\\$department/deptdocs.nsf/all/acts301](http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/acts301)

The Animal Industry Division of Alberta Agriculture, Food & Rural Development is responsible for administering PAM regulations. Section 13 of PAM regulations lists the drugs that are allowed for sale through PAM outlets and these would be referred to as “over the counter” drugs. Schedule F of the Food and Drug Act is the main guide as to which drugs will or will not be allowed for sale through a PAM outlet. All drugs under Schedule F Part I of the *Food and Drugs Act* are prohibited drugs for PAM outlets. Producers take possession of the drug at a licensed PAM outlet.

The *Livestock Diseases Act* also contains the regulations for disposal of dead animals under the Destruction and Disposal of Dead Animals Regulations [www1.agric.gov.ab.ca/\\$department/deptdocs.nsf/all/acts299?opendocument](http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/acts299?opendocument). The regulations require that all dead animals be disposed of within 48 hours by incineration, burying, rendering, composting or natural disposal (scavenging). See Section IX for further details.

The *Environmental Protection and Enhancement Act* of Alberta contains the Environmental Code of Practice for Pesticides which regulates the use, application, handling and disposal of pesticides. Some animal health products we use in cattle are pesticides, e.g., Lysoff, Spotton, fly tags. If unsure of whether the product is a pesticide, look for a Pest Control Product number on the container and read the label for indications that the product is regulated under the *Pest Control Act*. Pesticide concentrate must be disposed of in accordance with the Waste Control Regulation. See Section IX and contact Alberta Environment for further information [www3.gov.ab.ca/env/](http://www3.gov.ab.ca/env/) on proper pesticide disposal.

The *Agricultural Operation Practices Act* (AOPA) of Alberta came into effect January 1, 2002 to provide the industry with a framework for socially and environmentally sustainable livestock production in Alberta. The Act ensures the safe and sustainable handling of manure through regulation of the expansion and construction of confined feeding operations (CFOs) and the storage, application and incorporation or injection of manure. Alberta Agriculture, Food and Rural Development is responsible for the Act, and it takes the lead role in delivery of extension services and technology transfer to the livestock industry. The Natural Resources Conservation Board (NRCB) is responsible for administering the Act. More information can be obtained at [www.agric.gov.ab.ca/\\$department/deptdocs.nsf/all](http://www.agric.gov.ab.ca/$department/deptdocs.nsf/all).