Food Safety

Veterinary Drugs Requirements Summary

The primary goal of the Food Safety program (previously known as the Canadian Quality Milk program) is to ensure that farmers are implementing best management practices to produce safe milk and meat. The program requirements related to veterinary drugs are designed to ensure that farmers use veterinary drugs responsibly and in a manner that will not compromise food safety for the milk or meat their cattle produce.

What does the Food Safety program require regarding veterinary drugs?

The program requires strict best management practices regarding medicines and chemicals used on dairy cattle. Regarding drug choice, the program can only address the acceptability of products through the regulatory authorities, as approved drugs have undergone scrutiny to ensure their safety for food producing animals and human health.

The Food Safety program's requirements related to veterinary drug usage are:

1. Farmers must only use veterinary drugs approved in Canada for use in dairy cattle according to the label or written veterinary directions.

   Workbook, September 2015, Section B: Question 27: Do you use ***only*** livestock medicines (including medicated foot baths):

   - Approved in Canada for use in dairy cattle?
   - According to the label?
   - According to written veterinary directions, which must be available for every treatment administered not according to the label (extra-label drug use (ELDU)) and for every veterinary drug used that is not approved for use in Canada? (Record 8)

   Farmers are permitted by Health Canada to purchase and use over-the-counter (OTC) veterinary drugs approved in another country for use in dairy cattle, as long as the OTC drugs are designated as OTC by Canadian definition. For food safety, farmers must obtain written veterinary directions from their Canadian veterinarian for each product.

   It is illegal, under Health Canada regulations, for farmers to import veterinary drugs designated as Prescription into Canada by any means (e.g. mail, courier, in-person) unless the farmer is a veterinarian or is only importing a single course of treatment needed for an animal with which the farmer is travelling (i.e. the cow is with you).

Canadian Drug Definitions:

Prescription drug: a drug is classified as a prescription drug if any of its medicinal ingredients are listed on the Prescription Drug List, which is accessible on Health Canada's website. The Prescription Drug List replaced Schedule F in the Food and Drugs Regulation in December 2013.

A prescription drug has the **Pr** symbol on its label and a Drug Identification Number (DIN). However, prescription or OTC designations differ from country to country. As a result, the lack of a Pr symbol on a label of a drug from another country does NOT mean that it is classified as OTC in Canada. You need to check to make sure that the medicinal ingredients are not on the Canadian Prescription Drug List.

Over-The Counter drug: a drug is classified as OTC if none of its medicinal ingredients are listed on the Prescription Drug List. An OTC drug does not have a special symbol on its label, but it does have a DIN.

If a farmer routinely uses a product in a manner that requires written veterinary directions for use each time, the veterinarian may be able to provide a treatment protocol (valid for up to one year) to allow for consistent use on multiple animals. An example could be the routine treatment of a cow with metritis using higher than label dosage of penicillin.

The Food Safety program recognizes that the herd veterinarian has the professional expertise, access to information databases, and knowledge of the particular farm situation that would permit him/her to determine the risks to food safety of using unapproved drugs or extra-label applications. This does not mean that the Food Safety program expects veterinarians to provide written directions. Veterinarians have professional and legal obligations that restrict the situations where they can provide written directions. They must first be faithful to these requirements.

2. Canadian Organic Production Systems Standards: In January 2008, the Food Safety program accepted the use of products listed in Section 5 of the Permitted Substances Lists (PSL) for Livestock Production (CAN/CGSB-32.311-2015) according to the specifications indicated. Any product on the PSL used in a manner that is not described on the PSL needs written veterinary directions, as this is considered extra-label use.

   The PSL is published on the Canadian General Standards Board website.

3. March 2010, the Food Safety program accepted the use of veterinary Natural Health Products (vNHPs) as listed on the list of Animal Health Care Products and Production Aids.

   The list of Animal Health Care Products and Production Aids is published on the CFIA webpage (click on "Food" and then "Organic Products," and it is listed under "Standards").

What is the risk related to 2 drugs administered at the same time?

The Food Safety program considers two or more drugs administered at the same time an extra-label treatment. Even if each drug is administered according to its label, if the two drugs have the same active ingredient, their use in combination increases the effective dose to the animal and the withdrawal time for each individual drug may not be long enough. However, many drugs can be given in combination with very low risk of impacting the withdrawals. As a result, the Food Safety program has narrowed the requirements to the following:

- Farmers must obtain written veterinary directions for the on-label use of any two antimicrobial treatments administered at the same time by any route.

  Examples of two antimicrobials given at the same time that would require written veterinary directions:

  - Intramammary antimicrobial treatment plus an intramuscular antimicrobial treatment.
  - Intrauterine antimicrobial treatment plus any other antimicrobial treatment (IM, IMM, IV, SQ).
  - An intravenous antimicrobial treatment plus any other antimicrobial treatment (IM, IMM, SQ).

- Examples of two treatments given at the same time that would NOT require written veterinary directions:

  - Antimicrobial treatment plus a vaccine.
  - Antimicrobial treatment plus a reproductive hormone.
  - Antimicrobial treatment plus an anti-inflammatory.
  - Antimicrobial treatment plus a de-wormer.

Please note: the Food Safety program is concerned with both milk and meat withdrawals associated with drugs used in combination.

Please further note: another potential risk is administering a second antimicrobial treatment before the completion of the withdrawal time of the first antimicrobial treatment. Please talk to your veterinarian to ensure that you are applying sufficient withdrawal times for both milk and meat if you do this.

Can farmers use an unapproved drug or chemical?

Farmers can only use an unapproved drug or chemical if they obtain written veterinary directions for it.

What is the risk associated with unapproved veterinary drugs?

Unapproved drugs present a great potential food safety risk, as they have not been evaluated for food safety, quality or efficacy by Health Canada. The requirement for written veterinary directions ensures that a veterinarian has evaluated the risks associated with the product, as veterinarians either have the knowledge or have access to sources of information that permit them to evaluate the need for the use of unapproved drugs and the measures necessary to mitigate any safety risk for the milk and meat produced from treated cattle.

Do teat dips need to be approved?

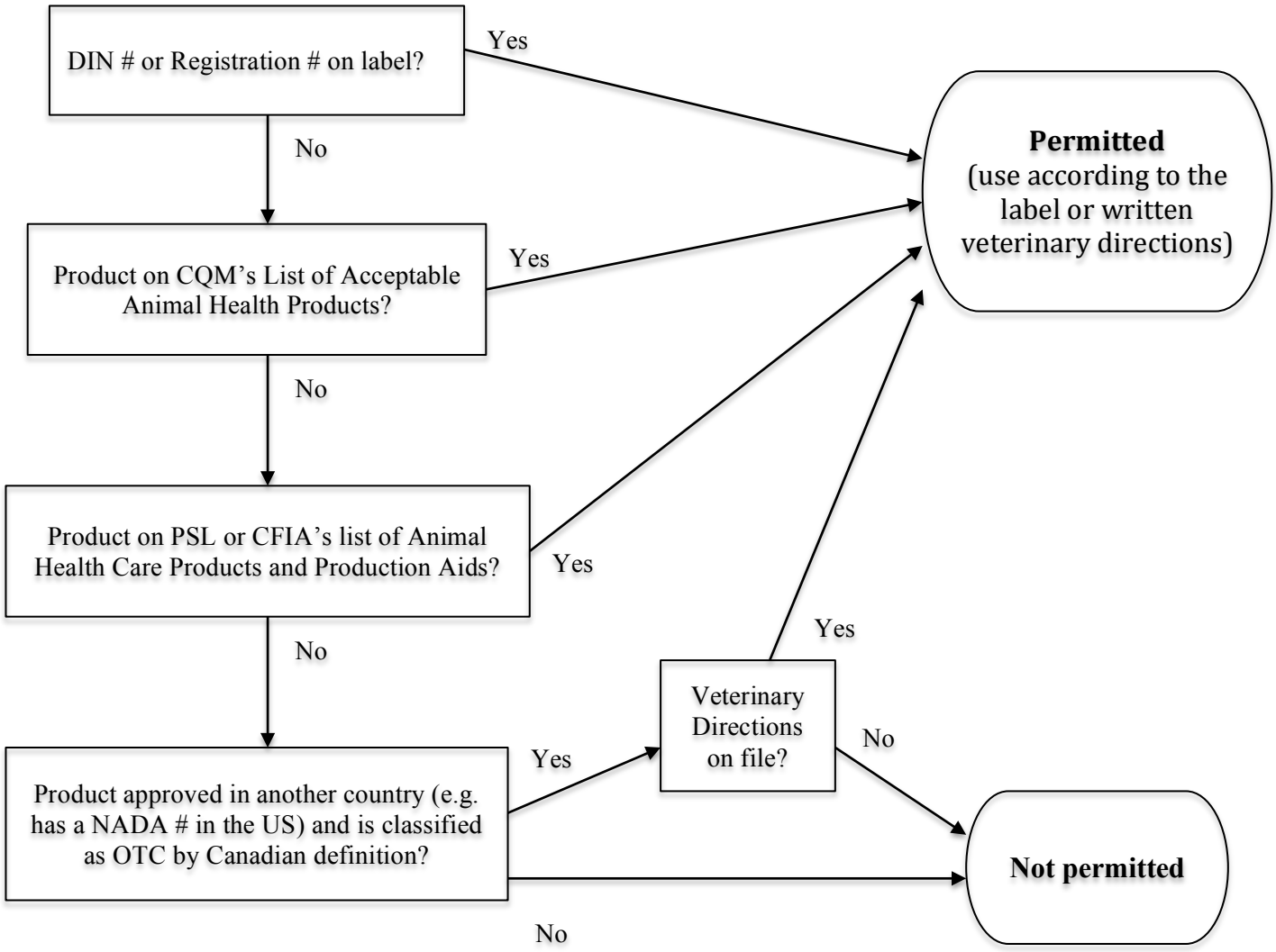
Yes, teat sanitizing products are classified as drugs, and must have a DIN (Drug Identification Number). Some teat cleansing products are included in the organic program documents and are considered to be low-risk to use, but please note that without a DIN, they are not sanitizers, and, therefore, do not meet the sanitizing teats requirement.

How will a validator score unapproved veterinary drug usage?

The use of unapproved veterinary drugs without written veterinary directions is a major nonconformance on a validation report under Question 27. Farmers have to correct major nonconformances before their registration can be issued or continued.

How can farmers or validators determine if a product is permitted?

Farmers and validators can determine if a product is permitted by following this decision tree:



Who can I contact for more information?

1. Your provincial producer association
2. Visit: www.dairyfarmers.ca/proAction