

Regulations Respecting the Making of Medicated Feed

September, 2004

Background

The Canadian Food Inspection Agency received funding early in 2004, to administer, deliver, and enforce the proposed Medicated Feed Regulations. These regulations have been in development for several years, and will apply to everyone who manufactures medicated feed for food producing animals. The regulations set out standards for the manufacture and mixing of medicated feeds to better protect animal health and food safety. On-farm feed mixing will be included in these regulations. There are three main topics covered under the regulations; weigh scales, mixer verification and flushing and cleaning of mixers. A three-year phase-in process has been proposed. By January 2005 feed mills must come into compliance, by January 2006 farms mixing raw product with a Drug Identification Number (DIN) must come into compliance, and by January 2007 all farms using less concentrated medicated supplements or premixes will need to be licensed. This includes supplements containing ionophores.

Licensing will require:

1. Annual mixer performance testing which confirms a coefficient of variation that meets the standard set in the regulation.
2. Annual verification of the accuracy of scales and metering devices.
3. Annual drug guarantee verification tests on at least four feed samples representative of the feed produced at that facility.
4. An annual drug residue test on each piece of manufacturing equipment that verifies that clean out procedures are effective, when mixing concentrated feeds.
5. Records of investigation reports if sample results are out of compliance.

The regulations also demand that feeds must be made by sequential production unless equipment is cleaned or flushed using validated procedures.

Regulations are to go back to Gazette 1 sometime this fall for a 60-90 day comment period.

Following that the regulations will likely go to Gazette 2 for finalization in January 2005.

Issues

A. Zero Withdrawal Medications

Many livestock producers use zero-withdrawal medications such as ionophores as the only medication mixed in feed on their farms. Livestock commodity groups have suggested that zero-withdrawal medications should not be included under these regulations. Health Canada has responded that a zero-withdrawal on a drug does not mean the drug is inherently safer and therefore these regulations will apply to all medicating feed ingredients regardless of whether withdrawal is required or not.

B. Dilute Medicated Ingredients

Feeds have been designed and recommended inclusion rates determined by commercial feed mills. Once in dilute form (complete mineral premixes, such as those used at 25kg/tonne concentrate or pelleted supplement), the several-fold mixing error required to induce toxicity/residue is nearly impossible. This process is usually one of low-technology on-farm so equipment verification goes beyond a reasonable expectation.

C. Cost

CFIA has confirmed that there is no cost recovery proposed for the administration and inspection process related to licensing under these regulations. However, there will be costs to the licensee in the form of annual drug guarantee and drug residue testing. Costs could range up to \$300 per sample. A minimum of five samples (4 annual drug guarantee samples and 1 drug residue test) would mean an annual cost for testing alone could be as high as \$1500. In addition there will be costs for annual mixer verification testing and for verification of the accuracy of scales and metering devices.

OCA Position

OCA's primary concern has been that of the inclusion of ionophores in the Medicated Feed regulations. It is OCA's position that ionophores should be removed from the proposed medicated feed for the following reasons:

- zero withdrawal time
- no proven evidence of anti-microbial resistance
- the active ingredient is not significant in human medications
- no threat to animal health when fed at label dose to prescribed species

In fact, when fed to the prescribed species, the label dose would have to be exceeded by several times to create an animal health concern. The sheer economic impact of overfeeding ionophores provides a deterrent.

OCA would like to see a re-consideration of the definition of medicated feed manufacture to help in addressing the issue of dilute medicated ingredients (i.e. complete mineral premixes or pelleted supplements). These are normally mixed on farm and the several-fold mixing error required to induce toxicity/residue is nearly impossible.

OCA feels that producers mixing small quantities of feed should not be required to bear the full cost of testing 5 samples per year. Either base sampling levels on quantity of feed produced (i.e. reduce sampling requirements to 2 per year for low volume on farm mixing) or ensure cost of tests does not exceed a certain level (i.e. \$100/test).