

# Feed Quality and On-Farm Feed Mills

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## ■ Background

Federal Feeds legislation has regulated the manufacture and marketing of livestock feed in Canada since the early 1900's. The current Feeds Act and Regulations allows the Canadian Food Inspection Agency (CFIA) to verify that livestock feeds manufactured, sold or imported into Canada are safe, efficacious and are labelled to avoid fraud. The feed program has in the past been predominantly a program based on pre-sale ingredient/product evaluation and registration. As a result of deregulation activities in the 1980's, 95% of feeds are currently exempt from the requirement to be registered. As a result of these changes, the focus has shifted toward post-sale compliance monitoring and the national feed inspection program, which includes an on-farm feed inspection component. When conducting on-farm inspections, CFIA staff confirm that livestock feeds:

- contain only approved ingredients listed in Schedules IV and V of the Regulations;
- contain only approved medications at the correct levels, for the intended purpose and for the intended species/class of livestock; and
- do not contain harmful levels of chemical and biological contaminants, including drug residues.

For more information on which ingredients are approved and the feed registration process check out the Feed Page on the CFIA website at: <http://www.inspection.gc.ca/english/anima/feebet/feebete.shtml>

## ■ Introduction

There are two federal regulatory initiatives being developed that may impact on the way feed is manufactured on farms and in commercial feed mills in the

future: the proposed process-based Regulations Respecting the Making of Medicated Feeds (MFRs) and amendments to the Health of Animals Regulations, specifically the Mammalian to Ruminant Feeding Ban, to further strengthen Canada's safeguards against bovine spongiform encephalopathy (BSE).

The MFRs contain a set of minimum manufacturing standards to better protect animal health and food safety and will apply to all manufacturers of medicated feeds for food-producing animals. This regulatory initiative will have direct implications for the Canadian swine industry, especially those swine operations that manufacture medicated feeds on their farms that will in the future require a license to continue doing so.

Changes to the Mammalian to Ruminant Feeding Ban, including the removal of bovine specified risk material (SRM) from the animal feed chain may not have direct implications for most swine operations but will affect all livestock sectors to some extent and operations in many commercial feed mills. SRM are tissues that, in infected cattle, harbour the BSE agent.

This paper provides details of the regulatory proposals and their implications for you.

## ■ **Proposed Regulations Respecting the Making of Medicated Feeds**

To ensure that the regulations developed for the manufacture of medicated feeds are effective and practical, the CFIA has been consulting with the Canadian commercial feed industry, livestock producer groups, provincial governments, and the U.S. Food and Drug Administration since 1991. The new regulatory proposal reflects the consensus position achieved at the March 2004 stakeholder meetings and takes into consideration comments received to the initial regulatory proposal and during the recent consultations.

## ■ **Highlights of the Proposed Regulations**

The MFRs have two basic objectives:

- All medicated feeds should contain the intended level of medications; and
- Carryover during manufacture of medicated feeds should be managed such that there are no detectable residues present in "high-risk" feeds.

The following is a review of the controls to be included in the proposed regulations.

## ■ **Hitting your Medication Targets**

Health Canada approves medications for use in food-producing animals. These approvals are for a particular specie or class of animals at specific levels and for a particular purpose. Over-medicated feeds may pose a threat to animal health or result in residues in the food products produced from these animals that can be harmful to humans. Under-medicated feeds can prove ineffective at preventing or treating the livestock disease conditions for which the medication was intended and may contribute to the development of antimicrobial resistance.

The proposed regulations contain two manufacturing controls that are intended to help manufacturers obtain the target level of medication in every batch of medicated feed:

- Scale and Metering Device Performance Testing; and
- Mixer Performance Testing.

## ■ **Scale and Metering Device Performance Testing**

The accurate measurement of feed ingredients is a critical step to ensure that medicated feeds contain the target level of medication. Errors in measurement in the making of a particular feed would be impossible to correct elsewhere in the manufacturing process for that batch of feed. In addition to being calibrated and accurate, scales and metering devices must be suitable for the range of weights or volumes to be measured.

The proposed regulations require that all scales and metering devices used in the manufacture of medicated feed be tested at the time of installation for new equipment and afterwards at least once a year. Licensed operators must follow written procedures describing an approved testing procedure and keep records to demonstrate the written procedures were followed that show that the equipment is accurate within the critical limit.

Scales are considered to be accurate when the variance from true weight is 0.1% of the capacity of the scale or  $\pm 1$  graduation, whichever is greater, for new scales. Scales which have been in operation should have a maintenance tolerance of 0.2% of the capacity of the scale or  $\pm 1$  graduation, whichever is greater. Metering devices are considered to be calibrated properly when the variance from target output is 5 % of target output or  $\pm 1$  graduation, whichever

is greater. Where critical limits are exceeded, corrective actions must be taken and documented.

### ■ **Mixer Performance Testing**

The mixing process is a critical step in the manufacture of medicated feeds. Performance of the mixing equipment is key to manufacturing quality feeds and obtaining the correct drug level in medicated feeds. The purpose of mixer performance testing (mixer validation) is to determine whether the mixing equipment is capable of producing feeds of uniform consistency.

The proposed regulations require that all mixers used in the manufacture of medicated feed be tested at the time of installation for new equipment and afterwards at least once a year. Licensed operators must document that they are following written procedures describing an approved testing protocol. The test methodology requires that a pre-established number of feed samples be selected from a batch of mixed product, tested for the level of one or more substance in each sample and the coefficient of variation (CV) calculated for the batch. The mixer is considered to be producing homogenous feeds when the coefficient of variation for the test batch is:

- no greater than 5% for dilute drug premixes;
- no greater than 10% for micro or macro premixes and supplements; &
- no greater than 15% for complete feeds and total mixed rations.

### ■ **Managing Carryover and Drug Residues**

It is important that medicated feeds contain the correct medication level. It is equally important that carryover and residues are managed properly. The proposed regulations contain two manufacturing controls that are intended to help ensure that unintended residues are directed to lower-risk feeds reducing the potential for negative impacts on animal health or food safety:

- Sequencing Practices; and
- Appropriate Use of Flush Material

### ■ **Sequencing Practices**

The current sequencing guidelines recognize that enforcing an umbrella zero-tolerance policy on drug residues in feeds is neither completely necessary nor practical. The sequencing guidelines identify the highest risk situations, e.g.,

the presence of certain drug residues in feeds for “market-ready” animals and the presence of residues of drugs not approved for a particular species or class of animals in feeds intended for these animals. Sequences where residues are targeted to these feeds are considered unacceptable without the use of an effective flush or other additional validated clean-out procedure to reduce the residues to an acceptable level. At this time, the limit of detection (e.g., the lowest level that can be quantified by official laboratory tests) defines acceptable but industry representatives are collecting scientific evidence, which may support the safety of trace levels of medications in these high-risk feeds.

### ■ **Use of Flush Material**

Health Canada and CFIA do not condone the intentional addition of flush material containing medication residues to feeds not intended to contain that medication as this is not a sound management practice and must not be permitted. Rather the flush material should be used as an ingredient in a feed intended to contain that medication or disposed of in accordance with local environmental regulations.

### ■ **End Product Testing**

As a final verification that your manufacturing system is functioning properly, the proposed regulations will require that a minimum of four samples a year be submitted for drug residue analysis or drug guarantee verification. Either approved analytical methods or approved indirect tests may be used.

### ■ **Implementation**

Once finalized, the MFRs will be phased-in over three years to allow commercial feed mills and on-farm mixers to adapt their operations. In the first year, all commercial feed mills (including any farm that sells feed) will be required to obtain a license. In the second year, all farms using concentrated drug premixes that bear a Drug Identification Number (DIN) will require a license. And, in the third year all farms using less concentrated medicated premixes and supplements or other medicated feeds requiring additional mixing prior to consumption will require a license.

## ■ Strengthening the Feed Ban

The Government of Canada implemented a mammalian-to ruminant feeding ban (with exceptions) in 1997 by amending and adding provisions to the federal Health of Animals Regulations. The current ban prohibits the feeding of ruminant animals with most proteins derived from mammals (excluding proteins derived from solely swine and equines as well as milk, gelatin and blood products from all species). It also requires manufacturers, users, retailers and feeders of animal proteins and feeds to have procedures and records in place to demonstrate:

- segregation of animal proteins prohibited from being fed to ruminants is maintained and cross-contamination of ruminant feeds with prohibited proteins is prevented;
- labels of products comprising or containing prohibited proteins carry warnings about not feeding them to ruminants; and,
- records of distribution for proteins and feeds are being kept to facilitate tracing throughout the animal feed and animal production chain.

Since detecting BSE in North America last year, the Government has taken significant steps to strengthen Canada's BSE safeguards. For example, Canada has excluded SRM from human food, is enhancing animal identification and intensifying BSE surveillance. The addition of new feed controls will further strengthen the future health of the national herd and complete Canada's response to the key domestic recommendations of the international team of animal health experts that reviewed the Canadian BSE situation.

The report of the international team strongly endorsed the removal and redirection of SRM from the animal feed chain. A similar recommendation was made by the team that reviewed the United States BSE experience. The Government of Canada announced on July 9, 2004, that it will introduce new animal feed restrictions to further strengthen Canada's safeguards against BSE. The Government intends to require the removal of SRM from the animal feed chain. These tissues are already removed from all animals slaughtered for human consumption.

Preventing these potentially infectious materials from entering the entire feed production chain at the start diminishes the effects of potential cross-contamination of ruminant animal feeds that could occur as feed is produced and distributed, as well as any inappropriate on-farm use. Based on risk analyses, removing SRM from animal feed will more quickly reduce the incidence of BSE in North America by preventing future disease spread.

The CFIA intends to pre-publish a package of proposed regulatory amendments in Part I of the Canada Gazette in the fall of 2004 that will feature

requirements regarding the removal and redirection of SRM and dead and downer cattle from all animal feed, including pet food. Given the importance of this measure, the Government has been carefully considering various options in consultation with provincial and territorial representatives, stakeholders and international counterparts, including from the U.S. Food and Drug Administration. The Government is continuing to consult widely on the scope, implementation timetable, and other operational details for this measure as it is further developed.

### ■ **Summary**

In summary, the CFIA has found it necessary to enhance our controls over feed manufacturing respecting the use of medications and the BSE agent. The CFIA recognizes the need for quality control throughout the entire food production chain as do the livestock production sectors. This is evidenced by your participation in on-farm food safety programs. We look forward to continuing to work with you to protect animal health, human health and food safety and ensure that Canadian food products remain among the safest in the world.