For Immediate Release: **April 20, 2000**

Comment on the CFIA's Proposed Regulations Respecting the Making of Medicated Feed

Kevin Grier, Senior Market Analyst and Larry Martin, CEO
George Morris Centre

Animal feeds and the safety of those feeds are one of the key foundations of the Canadian livestock and meat industry. The importance of animal feeds to both animal and human health cannot be overemphasized. Nothing is more important to any food sector than consumer confidence in the safety of its products. Any endeavour which seeks to continue to build on Canada's exemplary record must be taken seriously. As such, we commend the Canadian Food Inspection Agency for its foresight in seeking to ensure the future safety of animal feeds. Furthermore, we know, based on the thoroughness with which CFIA approaches food safety measures such as HACCP, that any proposal undertaken by the Agency will be done in an exhaustive and serious manner. It is in that spirit that we examine the Canadian Food Inspection Agency's proposed regulations governing the mixing of medicated feed for livestock and poultry.

Before we begin, we think that there are a few questions that need to be addressed in order to frame this discussion. These questions include the following:

1. What is the problem and are the proposed regulations going to address the problem?
2. Do the regulations impact on all sectors in a fair manner?
3. Will the regulations have the desired results? Will they move us in the right direction?
4. Are the regulations cost effective? Are they practical?

Conceptually, the most critical question relates to current industry initiatives with regard to quality, safety and standards. The specific question that we must ask is: will the industry programs be as effective in protecting the public and will they be as cost effective as what CFIA is recommending?

Background

As noted by the CFIA notes in the "Regulatory Impact Analysis Statement," feed-additive medications are commonly administered to livestock in Canada to prevent or treat disease conditions or accelerate animal growth as part of conventional livestock production programs. Administering medications via feeds is considered a practical and cost-effective way to treat groups of animals being raised for breeding or food production. This has been the case for many years.

Health Canada evaluates and approves medications for use in animals including those to be administered via feeds. Evaluations consider the effectiveness of the drug at preventing or treating specific disease conditions, the safety of the drug to treated animals as well as any potential safety implications on human food products derived from treated animals. The "Impact Statement" notes that, "Generally speaking, approved feed-additive medications may be purchased by commercial and farm-based feed manufacturers on an "over-the-counter" basis without need of any permit, licence or approval by any regulatory agencies, veterinarians or self-regulating bodies and used according to labelled instructions."

The Canadian Food Inspection Agency (CFIA), using the authority of the federal *Feeds Act*, monitors the use of feed-additive medications primarily through facility inspection, label inspection and feed sampling and testing programs at feed mills and farms in Canada. These programs seek to verify that the use of medications complies with conditions of each drug approval or with exceptions provided in the federal *Food and Drug Regulations* and the *Feeds Regulations*. As part of the *Feeds Regulations*, detailed conditions and instructions respecting the use of feed-additive medications are set out in the *Compendium of Medicating Ingredients Brochures* (CMIB), maintained and published by the CFIA.

CFIA asserts that the use of medications in food-producing animals, including those used in feeds, has come under increased scrutiny by academics, public health organizations, government regulators, the media and consumers for several reasons. It contends that the use of medications in food-producing animals poses certain potential health and economic risks to animals, livestock producers and consumers. If animal feeds are over-medicated, they pose a threat to the health of animals as excess medication may be harmful. In addition, CFIA states that the safety of food products derived from animals may also be affected as drug residues may remain in animal tissues and end up in meat, milk and eggs. Feeds that are under-medicated or those that contain drug residues arising from imprudent manufacturing practices may prove ineffective at preventing or treating the disease condition for which the medication is intended. In addition, under-medicated feeds or drug residues in feeds may contribute to the emergence of antibiotic resistant bacteria in animals that are passed on to humans.

The *Feeds Act* and Regulations have provided the authority to regulate feeds for the major food-producing species of livestock (beef and dairy cattle, swine, chickens, turkeys, sheep, goats and fish) as well as horses and other minor species. To be in compliance with the *Feeds Regulations*, feeds are required to meet standards for composition, drug and nutrient content and freedom from specific deleterious substances, drug residues and other contaminants that might otherwise adversely affect animal health or the safety of animal products (meat, milk and eggs) destined for human food.

The Proposal

CFIA is concerned that this current regulatory approach does not consider how feeds are manufactured. There is also concern that the current regulations do not advocate having manufacturing controls in place that serve to improve the assurance that finished products meet regulatory standards. Under what CFIA calls this "product-based approach," compliance with regulatory requirements can largely only be verified by sampling and analysis of feeds after manufacture. CFIA asserts that this approach is inefficient and costly inasmuch as it only detects problems after manufacturing errors have been made and does not serve to identify where specifically such errors may have occurred.

As a result of these concerns, the CFIA devised a series of regulations governing the mixing of medicated feed. The regulations were published in the Canada Gazette on February 5. Once implemented, these regulations will require that any operator, commercial or on-farm, wishing to mix medicated feeds must have a license. In order to obtain a license, operators including on-farm operators, will need to demonstrate that they are controlling the critical areas of mixing. Any operator submitting an application for a license must be inspected by an inspector to verify that the information submitted about the operation meets the requirements of the regulations. These requirements include the following:

- **Scale and Metering**
  All scale and metering devices must be tested for accuracy not less than once a year. Operators must have written procedures for the calibration of scales and metering

- **Mixer Performance**
  The performance of all mixers must be verified not less than once a year. Every operator must have written procedures.

- **Handling**
  All medicated feeds and medicating ingredients for the making of animal food must be received, inspected, identified, handled and stored in a manner to preserve potency and purity.

- **Mixing**
  Medicated feed must be made by sequential production and every licensed operator must have written procedures. Every operator must have written procedures that ensure that medicated feed contains its intended level of medicating ingredient.

- **Inventory**
  On each day that an operator uses medicating ingredients or medicated feed in the making of medicated feed, the operator must complete an inventory that demonstrates that the current medicating ingredients or medicated feed in the correct quantities are being used. If the inventory shows a discrepancy between the actual amounts of medicating ingredients used and the amounts that should have been used, and further to investigation there is evidence of likely contamination, then the operators must stop selling lots of animal foods that are likely to be contaminated, and promptly conduct an investigation and take necessary corrective measures.

- **Record Keeping**
  Every licensed operator must keep the required records for three years.

Once the regulations are passed, they will come into effect on April 1, 2001 for commercial mills, on June 30, 2002 for livestock producers who use concentrated drug sources and on December 31, 2002 for all remaining producers using any kind of drug source to make medicated feeds.

CFIA have provided estimates of the cost of implementing the regulations. For the Agency, it is estimated that it will cost $10.3 million over the first three years to get the program up and running, and then $5 million each year thereafter. For the industry, CFIA is estimating $22 million. The cost to industry would cover feed testing based on a minimum of 4 samples per year and other costs related to getting equipment and procedures up to regulatory requirements.

The cost for feed tests range widely from $80 to $400. *At this point* the Agency is not planning to introduce cost recovery fees on inspection. This is based on the fact the operators will need to bear the costs associated with having equipment and procedures up to regulatory requirements. Once the initial three-year phase-in is completed, cost recovery may be considered.

Commentary on the Regulations

In this section, we will try to answer the questions that we asked at the beginning of this paper. Once again, those questions are:

1. What is the problem and are the proposed regulations going to address the problem?
2. Do the regulations impact on all sectors in a fair manner.
3. Will the regulations have the desired results? Will they move us in the right direction?
4. Are the regulations cost effective? Are they practical?
5. Will current industry programs be as effective in protecting the public, and will they be as cost effective as what CFIA is recommending?

First of all, we must emphasize that producer groups representing the Canadian livestock industry have shown a great deal of leadership in addressing safety and quality assurance throughout their production practices. At the same, time, livestock producer organizations have also taken the lead in questioning the merits of the CFIA's approach in regard to these licencing regulations. No one disputes the need for control with regard to the manufacture of medicated feeds. In fact the Canadian Cattlemen's Association states in their comments on the regulations that "The Canadian beef cattle industry does not dispute the need for comprehensive guidelines on the use and mixing of medicated feeds."

With that said, there is a need to delve deeper into the impact and results of these regulations.

The first and most important question that must be addressed is whether or not there is a problem with residues in meat products? The answer to that question, is that we are dealing with a potential issue, not an existing problem. In that regard, CFIA deserves credit for foresight. We state that it is not an existing problem because we note in the hog industry, for example, that CFIA testing shows that more than 99% of all hog carcasses show no sign of medication residues. This is ultimately the bottom line issue.

As an additional argument to that point, we note that the hog industry has had a program in place for at least 10 years that does random tests for sulfa residue. In the case of a positive test, the farmer is not paid for the hogs and cannot ship again until the problem is sorted out and a negative test is achieved. Today violations are negligible. The are also similar rigorous standards in the beef industry.

As such, it is important to emphasize that producers and the Canadian meat industry in general, are subject to thorough safeguards when they market animals as a result of the direct testing for the presence of medications in the animal carcasses.

A second critical issue with regard to the potential problem, is that CFIA states that one of the objectives of the proposed regulations is to prevent the build up of anti-microbial resistance. These regulations are geared towards manufacturing processes. Based on the science of this issue, quite bluntly, the regulations will not achieve this objective. There is nothing in the regulations, which pertain

to manufacturing procedures, that will accomplish this objective of preventing anti-microbial resistance. As a related issue, there is no scientific basis for the inclusion of products that science has already deemed to be no risk, such as ionophores and products with a zero withdrawal period. These should be exempted from the regulations.

We are also not clear as to where the weakness is with *Feeds Act.* CFIA says it is concerned that its current approach does not consider how feeds are manufactured. It says that under its current product-based approach, compliance with regulatory requirements can largely only be verified by sampling and analysis of feeds after manufacture. CFIA asserts that this approach is inefficient and costly inasmuch as it only detects problems after manufacturing errors have been made and does not serve to identify where specifically such errors may have occurred. Why is CFIA concerned about that? There has been no demonstrated problem with the current system. If a manufacturer does not comply with current regulations and therefore must correct the errors, that is the manufacturer's problem. Why should the entire industry bear a cost burden to deal with this?

Another issue suggested by the CFIA is the need to adopt similar requirements as those in Europe with regard to medicated feeds. In other words, if Canada does not adopt similar regulations, there may be trade implications. Is this really an issue? We do not view this as a compelling reason to adopt these regulations for a variety of reasons. One reason of course is the fact that our meat industry exports very little to Europe. In any event, European roadblocks to trade in meat products have long since been seen for what they really are - non-tariff barriers. A change in medicated feed regulations will not impact that fact.

The cost burden of these regulations is another issue. The CFIA estimates that the industry compliance cost of the regulations will be $22 million. We believe that the CFIA has seriously underestimated the size of the task at hand. The Agency has stated that "some 30,000" farms across Canada may require inspection. Instead, it is probable that the number could be one and a half times that figure. For example the Canadian Pork Council states that the regulations will apply to the vast majority of hog producers. There are about 17,000 hog farms in Canada. The regulations will likely apply to nearly 20-30,000 cattle farms.

The licencing regulations and therefore the cost will have the greatest impact on livestock producers. Due to the sheer number of the on-farm manufacturers, versus the 500 or so commercial manufacturers, the on-farm sector will have a significantly larger share of the total industry costs. In addition, as noted by Alberta Pork, commercial mills have the ability to pass along any additional costs to the purchaser, but on-farm operators have no method to further pass along the additional cost burden. It is also felt that many smaller operators will simply decide to purchase complete feeds rather than jump through the regulatory hoops for licensing, thus throwing off the competitive balance that currently exists in the sector.

Finally, another concern with regard to the regulations relates to enforcement. Even CFIA, with the well deserved respect it has acquired for thoroughness, cannot be expected to be able to effectively enforce these regulations. This is a fundamental test for regulatory effectiveness. This in turn will result in a false sense of security when resources simply are being mis-directed. The number of farms, even on a 3-year basis, will overwhelm CFIA's resources or cause them to seek costly contracting arrangements.

When combining the concepts that these regulations may not be enforceable and that producers may conclude that the regulations make them uncompetitive, it leads to a concern regarding unintended consequences. That is, these regulations may encourage people to ignore the regulations because of the cost disincentive of following the regulations.

Another unintended consequence is its impact on the family farm. Consider the fact that the cost impact of these regulations is largely fixed. That means that the overhead or fixed costs will not be very different between a large scale operation and a smaller operation. In effect, these regulations will place a disproportionate negative impact on small family farms.

Another point that needs to be noted is that industry groups are well along the way in Hazard Analysis Critical Control Point (HACCP) quality assurance programs that will address the concerns of feed quality and safety, as well as many other aspects of production. The $10.3 million that CFIA is spending in the first three years, and the $5 million each year after that could be better spent in enhancing current quality assurance and HACCP programs that are already underway.

The reason behind that statement is that producer and industry organizations have developed new, comprehensive, effective, and advanced meat safety systems. We, along with hog producer organizations across Canada, endorse the *Canadian Quality Assurance Program* that is designed to assure hog producers are following production protocols based on HACCP principles. In Ontario the program has been in effect for less than two years and already nearly half the producers are enrolled in it. Eventually all will have to be enrolled or packers will not buy their hogs.

In the cattle industry, the situation is similar. The CCA states that the record keeping and verification requirements prescribed by this regulation are not at issue. The requirements are compliant with the record keeping recommended by the cattle industry's *Quality Starts Here* program and will, in fact, be part of the accreditation program for Quality Starts Here as one of the good production practices standards for food safety assurance. While the Quality Starts Here program will be initially implemented as a voluntary program, it will lead to an industry and market place standard. The 2-year phase-in period accommodates this.

These on-farm quality assurance programs provide Good Production Practices for mixing medicated feeds. Pork producers who have enrolled in the Canadian Quality Assurance Program should be exempted from these proposed Regulations regarding medicated feeds. Ontario Pork is correct in noting that as this QA program evolves and gains acceptance, the CFIA may be able to recognize such programs in lieu of strict adherence to some or all mandatory regulatory requirements in the future. The same exemption should be in place for cattle producers in the Quality Starts Here program.

As a final point, we also want to emphasize that we have only addressed what we consider to be the larger scale issues of principle. This paper has not even begun to address industry specific concerns with regard to regulatory methodology and compliance. In other words, at the farm or feedlot level, when the rubber hits the road, there are still many other problems that must be addressed a from practical perspective.

Conclusion/Recommendation

We conclude that there are several serious issues that need to be addressed before this proposal moves any further. Those issues include:

- the actual costs of the regulations
- effectiveness in dealing with the targeted concern
- enforcement
- impact on the family farm
- recognition of current industry programs

In other words, these regulations appear to be tackling a problem that does not exist, in a manner that would not be successful even if it ever does exist. Since it does not benefit the industry or the consuming public, we have to note that the only beneficiaries are the bureaucrats who thought up this idea in the first place.

Even though CFIA appears to be reluctant to certify producer-industry quality assurance programs, we challenge CFIA to work with these producer groups to alleviate their concerns within the framework of existing quality assurance programs. At the same time, we also challenge producer groups to ensure that feed manufacturing receives the attention and detail it deserves in their QA programs. Why can't the CFIA be the third party in certifying compliance with the industry programs?

In summary, we ask that CFIA reconsider this new regulatory measure. A few years from now, if this measure goes forward, it will be regarded as a classic example of over-regulation for no added value. It is respectfully suggested that the CFIA refocus its efforts on the meat safety issues associated with animal feeds as opposed to the process of manufacturing those feeds. We believe that in this way, CFIA can continue to make the most positive and effective contribution to the safety of the Canadian meat industry.

For further information, please contact one of the authors.

Larry J. Martin, Ph.D.
C.E.O.
George Morris Centre
#102-150 Research Lane
Guelph, ON N1G 4T2
Tel: 519-822-3929, ext 208
Fax: 519-837-8721
Email: larry@georgemorris.org

Kevin Grier, M.A.
Senior Market Analyst
George Morris Centre
#102-150 Research Lane
Guelph, ON N1G 4T2
Tel: 519-822-3929, ext 202
Fax: 519-837-8721
Email: kevin@georgemorris.org