John Gilmore April 18, 2008
Science Information Specialist
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Floor 2, Room 2321 W
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Ottawa, Ontario K1A 0Y9

Re: Draft Policy for the regulation of distillers' grain derived as by-products from the ethanol production process

Dear Mr Gilmore:

The expansion of fuel ethanol production in Canada due to various provincial and federal regulations and financial incentives is resulting in a parallel increase in the quantity of distillers grains produced. The rising price of grain, a result in part of the increase in demand from ethanol production, has reduced the profitability of ethanol plants and has severely affected the profitability of grain-based livestock production. Feeding ethanol by-product to livestock is at once a way to dispose of the distillers' grains and provide an alternative feed source to livestock producers. The desire is for ethanol producers to find a market for their by-product so as to create a second revenue stream for their operations.

In the context of expanding ethanol production, feeding the waste product to livestock looks like a way to solve two problems at once. However, the price of distillers grain is not cheap, the product is not consistent, and furthermore, it does not currently meet the legal requirements for livestock feed in Canada. The CFIA's draft policy appears to be an attempt to avoid new regulation by bending the law enough to make it possible for ethanol plants to continue disposing of their waste through the bodies of animals. The BSE crisis in the UK was brought about by a similar approach, using rendering waste as animal feed. The implications of feeding byproducts of the ethanol fuel production system for the health of the animals, the humans who will consume the meat/milk/eggs from the animals and for the environment which will receive the manure from the animal feeding operations raise many questions that we believe should be answered.

In our brief we would like to raise these questions, and ask the CFIA to consider the interaction between the proposed feed policy and the impacts of increased feeding of distillers' grains from fuel ethanol production on human health and the environment.

Issues identified by CFIA as problematic:

Antibiotics are used in fuel ethanol production that are not approved for use in livestock feed. These antibiotics are routinely used to limit the bacteria growing in the warm, wet, non-sterile grain mixture, displacing the desired yeast that produces alcohol via fermentation. Residues of the antibiotics remain in the distillers' grain. These antibiotics contribute to the development of antibiotic resistant microbes.

Unapproved drugs, unapproved methods

Under Canada's Food and Drugs Act and Regulations, licensed veterinarians have the right to prescribe antimicrobials within the framework of valid Veterinarian-Client-Patient Relationship. Antimicrobials listed under Food and Drug Regulations Part II of Schedule F require a prescription for human use, but do not require a prescription for veterinary use *if so labelled* or if in a form unsuitable for human use. Furthermore, provincial laws and regulations may be more restrictive. Quebec, for example, requires prescriptions for all antibiotics administered to livestock.

Monensin sodium, virginiamycin and penicillin are commonly used in fuel ethanol production. When these drugs are administered to livestock by means of distillers' grain, they are neither prescribed by a veterinarian, nor labelled as such.

Monensin does not appear in Part F, Schedule II. Monensin sodium is used as a growth promoter in cattle, and to treat Coccidiosis, and thus requires a prescription for veterinary use. Virginiamycin appears in Part F, Schedule II but is not approved for use in livestock feed in Canada. Penicillin and its salts and derivatives, (except amoxicillin, ampicillin, azlocillin, benzathine penicillin, carbenicillin, cloxacillin, dicloxacillin, hetacillin, mecillinam, methicillin, mezlocillin, nafcillin, oxacillin and ticarcillin and their salts and derivatives) appears in Part F, Schedule II. Penicillin is approved for use as a growth promoter in chickens, swine, and turkeys and to treat Enteritis, Dysentery, stress, and Rhinitis in swine.

The current practice of feeding unprescribed and unlabelled DG from fuel ethanol production containing antibiotics clearly violates the Feeds Act and the Food and Drugs Act, and appears to evade provincial laws regarding veterinary medicine.

According to the Final Report of the Advisory Committee on Animal Uses of Antimicrobials and Impact on Resistance and Human Health, an ideal system for distributing the antimicrobial drugs used in food animals, as laid out by the World Health Organization[1] would have the following characteristics:

- antimicrobials manufactured to GMP or another clear, transparent standard;
- antimicrobials evaluated by regulatory authorities for safety (including resistance) and efficacy;
- the person deciding when and how to use the antimicrobial would be trained, licensed, held to professional standards and not in a conflict of interest (i.e. veterinarian);
- the person distributing the antimicrobial would be trained, licensed, held to professional standards and not in a conflict of interest (e.g. pharmacist or veterinarian);
- a strong system to ensure compliance and traceability;
- antimicrobials available only under prescription; and
- antimicrobials readily available to producers at an economical price

Having unknown amounts and kinds of antimicrobials present in distillers grain being fed to livestock would move Canada away from this ideal, and increase health risks to Canadians.

Increase in antibiotic resistance

The development of antibiotic resistant strains of typical bacterial infecting ethanol facilities, has already been recorded[2]. A percentage of the livestock being fed will have pathogens in their gut, which will then be able to exchange genes with the antibiotic resistant strains from the DG. The rise in community acquired methicillin-resistant *Staphylococcus aureus* (MRSA)[3] and antibiotic resistant *clostridium difficile* has been linked to the handling and consumption of contaminated meat[4]. Canada recognizes the problem of food borne antibiotic resistant *Salmonella enterica* and *Campylobacter jejuni*, and tracks it, albeit in a very limited fashion, via the Canadian Integrated Program for Antimicrobial Resistance Surveillance[5].

The Report of the Advisory Committee to Health Canada on Animal Uses of Antimicrobials and Impact on Resistance and Human Health, June 2002 stated: "Even resistance in animal bacteria that are harmless to humans is important to public health because these bacteria are a pool of resistance genes available to be transferred from animal bacteria to human pathogens.[6]"

Bacteria evolve quickly and are able to transfer DNA that provides antibiotic resistance within a population of bacteria, and also between different types of bacteria. The routine use of antibiotics in fuel ethanol production provides an evolutionary pressure on microbes to develop antibiotic resistance. These resistant microbes will be present in the DG used as feed, and will contribute to increasing incidence of food borne resistant pathogens.

Virginiamycin is similar to Pristinamycin, which is used in human medicine to treat MRSA and erythromycin-resistant staphylococci and strepcococci[7]. The implications of creating an environment for the development of MRSA resistant to virginiamycin through feeding livestock already known to be a reservoir of MRSA on DG feed containing virginiamycin-resistant bacteria would be foolish, and immoral.

Antibiotic resistance is a serious public health concern. The World Health Organization has called upon all countries to address the problem of antibiotic resistance due to feeding sub-therapeutic levels to livestock. Using DG from facilities that use antibiotics would be contrary to that global public health goal.

Feed derived DG produced with genetically modified feedstock and genetically modified microbes

Approximately 65% of corn grown in Canada is genetically modified for herbicide tolerance, insect resistance, or both. The potential for introducing a genetically modified wheat designed for ethanol production has been raised. Genetically modified crops contain not only the novel trait, but also transgenes that code for traits used as markers, such as antibiotic resistance, and transgenes that function as switches to ensure the plant expresses the novel trait. The switch genes are commonly derived from a virus, such as the cauliflower mosaic virus.

Recombinant DNA is being used to create new yeasts designed for ethanol production.

The fermentation process, using enzymes, yeasts and antibiotics, with other unwanted microbes contaminating the mixture as well, is a recipe for horizontal gene transfer between the recombinant yeasts, transgenic corn, and potentially, wheat and the microbes in the DG. This would tend to increase the odds of horizontal transfer of transgenes between the proteins in the transgenic feedstcok and both the gut bacteria and the livestock animals themselves, when fed as DG. The implications of such horizontal transfer for animal health, human health and the introduction into the environment via manure spreading and water contamination are unknown.

Sulphur

Ethanol DG contains high concentrations of sulphur. Current research indicates that sulphur is likely the first factor to limit the amount of DG that can be added to feed, however Iowa State University extension research indicate that maximum tolerable levels in place in the US is based on limited research. Polioencephalomalacia is a disorder of the nervous system of cattle and can be caused by sulphur toxicity and salt toxicity, both contaminants to be found in DG.

CFIA documents propose up to 50% of ration for beef, swine; 40% for dairy; 30% for broilers and turkeys; and 15% for layers. Most of the literature recommends no more than 40% for beef and 20% for dairy ration be DG. Swine rations are in the same neighbourhood at around 20%, depending on the specific qualities of the DG. Current research at the Prairie Swine Centre indicates that DG digestibility is low, resulting in higher quantities of manure excreted. Poultry is generally lower, in the 15% range. Feeding higher proportions may result in digestive and metabolic problems for the animals, leading to health and animal welfare problems. Feeding at higher rates would indicate that animals are being used as a means of waste disposal, rather than DG being used as a legitimate feed source.

Phosphorus

Distillers' grain also contains higher levels of nutrients and especially phosphorus than does the feedstock. Benson [8] found that phosphorus intake in feedlot steers increased from 18.6 to 27.8 g/day as the DG inclusion level increased from 0% to 36% in a rolled-corn ration. Trenkle [9] reported that feeding 20 to 40 percent DG with solubles increased feedlot phosphorus in manure by 60 and 120 percent respectively compared to feeding no DGS. This substantial increase of phosphorus will have major implications for nutrient planning and water quality in a number of regions in Canada, which are already stressed with nutrient imbalances. Lake Winnipeg, with its vast watershed, is currently in a state of eutrophication due to phosphorus overloading and resulting blue-green algae growth. Southern Lake Huron is in a similar state, suffering from excessive agricultural nutrient run-off, as is the surface water systems in southeastern Quebec.

Mycotoxins

Mycotoxins which are produced by fungus, bacteria and yeast are already a major concern when feeding livestock a regular grain diet. While ruminants can be least sensitive to mycotoxin contamination, swine are the most sensitive to these compounds. The fusarium mold can produce the mycotoxins, vomitoxin and zearalenone. Vomitoxin can cause diminished feed consumption, while zearalenone can cause infertility. CFIA has identified research that demonstrates that there can be a 2 to 4 fold increase concentration of mycotoxins in DG, which will only compound any health impacts to the animal.

The FAO/WHO Expert Meeting on “Animal Feed Impact on Food Safety” (October 2007) stress that more research is needed to determine the fate and residual concentration of aflatoxin B1. Aflatoxin is a potent chemical liver carcinogen which can be transferred to the meat and milk of the animal to humans.

Wet DG is only good for 5 to 7 days before it begins to spoil, thus livestock proximity to ethanol plant is required. Dried DG with Soluables (which is not that dry at 35% moisture) is subject to spoilage, which results from bacterial and fungal infection. Such infection may not only make the product unpalatable to animals, but can also result in toxicity.

The infrastructure costs related to safe storage of Wet DG means that shifting livestock feeding to wet DG will have the effect of increasing feedlot size, and thus concentrating manure production and disposal problems in a smaller area, or increasing proximity of feedlots of ethanol plants so that storage is not required, thus contributing to issues around the cattle and ethanol processes having high requirements for water, and water contamination due to manure runoff and leaching.

Emerging Issues

Recent research at Kansas State University[10] has found that cattle fed 25% dried distillers grain had increased prevalence of E. coli 0157 in their hindgut by 50%. This poses an added health risk to humans who can acquire it through undercooked meat, raw dairy products and produce and ground meat contaminated with cattle manure. The positive association between dried distillers grain and E-coli have important ramifications for food safety.

USDA sponsored research by Varel indicates that feeding cattle wet distillers grains with solubles at 20, 40 and 60 percent rates of inclusion increases the release of methane, thereby increasing greenhouse gas emissions, and increases odorants in manure slurries and extends the persistence of generic E. coli.

USDA Agricultural Research Services has initiated a long term study to evaluate the metabolic variables (rates of absorption, tissue and microbial biotransformation and excretion) affecting the efficacy, safety and fate of agricultural chemicals in food animals within an intensive setting. Their researchers report that data are not available to support or refute the safe use of new chemical entities and the impacts of some established chemicals (antibiotic feed additives) and endogenous hormones (steroids) on soils and water systems are unknown.

Similar “groundbreaking” research is also underway in Canada, where there has been little research into the use of wheat distillers’ grain as a feed additive, the crop of choice for ethanol in western Canada.

Conclusion

With the rapid expansion of the ethanol industry in Canada and the US (and elsewhere), it is becoming evident that no thought was placed on what to do with the waste by-product (DG). A quick internet literature search reveals that a tremendous amount of research has recently been initiated to determine the impacts of using this by-product at different percentages as feed rations in cattle, swine and poultry. The bulk of the research focuses on the health and performance of the animal as well as the characteristics of the meat. However, it is clear that the evidence that does exist, suggests that using DG derived from the ethanol process as a feed additive can cause harm to the animal, humans and the environment.

CFIA uses a risk management approach to regulation. Instead of safeguarding against hazards, risk management allows for the weighing of risk of harm against economic benefit. Unknown and uncertain hazards are discounted as matters to be solved in the future, pending the collection and analysis of more data if deemed significant. Furthermore, those subject to being harmed by the risks are not the same people that benefit economically, nor do they have the power to reduce their personal risk of harm resulting from such decisions.

In contrast to the risk management approach, precautionary decision-making has been summarized as follows, in the Wingspread Statement on the Precautionary Principle:

> *Where an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.*
>
> *In this context the proponent of an activity, rather than the public bears the burden of proof.*

The process of applying the Precautionary Principle must be open, informed and democratic, and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action.

The *Lowell Statement on Science and Precaution* states that precautionary decision-making is consistent with sound science because of the large areas of uncertainty and even ignorance that persists in our understanding of biological systems, in the interconnectedness of organisms, and in the potential for interactive and cumulative impacts of multiple hazards.

We recommend that a precautionary approach be taken on this issue. Thus, we are calling for a moratorium to be placed on utilizing DG derived from the industrial fuel ethanol production process as a feed additive for livestock.

Additional requests

1) We are aware that CFIA routinely inspects and samples ethanol producing plants to obtain an overview of the manufacturing process, the ingredients used and chemical and biological contaminants which may be found in the residue of DG. We wish to receive this data and/or any reports derived from CFIA's monitoring program.

2) We are aware that the Veterinary Drugs Directorate still requires additional baseline data in order to complete their risk assessment. Can you provide us the data VDD currently houses on this issue?

3) Can you provide us copies of the safety assessments of the new and novel ingredients currently used in the ethanol producing process that are not referenced or listed?

Sincerely,

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[1] World Health Organization (WHO) (1998). Use of quinolones in food animals and potential impact on human health. WHO, Geneva, Switzerland.

[2] Bischoff, Kenneth M., Kelly A. Skinner-Nemec and Timothy D. Leathers. *Antimicrobial susceptibility of Lactobacillus species isolated from commercial ethanol plants,* Journal of Industrial Microbiology and Biotechnology. Volume 34, Number 11 / November, 2007

[3] Branswell. Helen. *Staph superbug found in commercial pork products*., Fort McMurray Today Wed 19 Mar 2008, page A9

[4] Duffield, Todd; Rodriguez-Palacios, Alexander; Staempfli, Henry R.; Weese, J. Scott. *Clostridium difficile in retail ground meat, Canada*., Emerging Infectious Diseases. Date: 3/1/2007 http://www.encyclopedia.com/doc/1G1-161011318.html

[5] Public Health Agency of Canada. *Canadian Integrated Program for Antimicrobial Resistance Surveillance* (CIPARS) http://www.phac-aspc.gc.ca/cipars-picra/index_e.html

[6] Health Canada. *Summary of the Final Report of the Advisory Committee on Animal Uses of Antimicrobials and Impact on Resistance and Human Health* http://www.hc-sc.gc.ca/dhp-mps/pubs/vet/amr-ram_backgrounder-documentation_e.html

[7] http://en.wikipedia.org/wiki/Virginiamycin and http://en.wikipedia.org/wiki/Pristinamycin

[8] Benson, C.C., Wright, J. McCarthick, and R. Pritchard 2006 Effect of Dietary Concentrations of Dried Distillers Grains plus Solubles on Phophorus Balance in Finishing Steers" 2006 South Dakota State University Beef Report

[9] Trenkle, A. 2006. With increasing availability of distillers grain will phosphorus be a problem for Iowa livestock producers? A.S Leaflet R 2124, Iowa State University Animal Industry Report

[10] Jacob, M.E., Fox, J.T., Drouillard, J.S., Renter, D.G., and Nagaraja, T.G., Applied and Environmental Microbiology 74, 2008, 38-43