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CgFARAD – the Canadian Food Animal Residue Avoidance Database

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Food animal production in Canada is dependent on drugs and other chemicals to protect the health and welfare of animals. Food animals may also be exposed to environmental contaminants or possibly become objects of bioterrorism. To protect Canadian public health, the Canadian Food Inspection Agency (CFIA) screens for chemical and drug residues in foods of animal origin. However, not all products are tested and detection programs are not available for all drugs and chemicals used in livestock production. To proactively reduce residue risks, veterinarians must provide producers with science-based withdrawal interval recommendations for extralabel drug use or chemical exposures. Practitioners may lack information with which to make such recommendations. With financial support from the Agriculture and Agri-Food Canada's Canadian Adaptation and Rural Development Fund (CARD Fund), veterinary medical and livestock producer groups, Canada joined a global food animal residue avoidance databank program known as gFARAD in the fall of 2002. Based at the Western College of Veterinary Medicine in Saskatoon, SK, and the Faculté de médecine vétérinaire at St Hyacinthe, QC, the Canadian gFARAD provides information on residue avoidance to veterinarians.

Historical background

The FARAD concept was established in 1982 as a cooperative project between four United States (US) veterinary colleges and the US Department of Agriculture's Food Safety and Inspection Service as a way to reduce the rate of residue violations in animal products through education and information.¹ The founding philosophy of FARAD was that information about residue avoidance from all sources should be immediately available from a scientific source. The FARAD was developed to contain not only information related to approved animal drugs, but also to include information on extralabel drug use and environmental toxins. For this "one-stop shopping" information service to work, the FARAD information was collated into a searchable computer database, with residue and pharmacokinetic data analyzed and interpreted by veterinary pharmacologists and toxicologists. Currently, the FARAD database includes over 1200 drugs and chemicals and over 20,000 pharmacokinetic records extracted from over 9000 citations. For 20 years, the US FARAD centres have been providing accurate and timely information to veterinarians to protect the US food supply.²

The global FARAD

For many years, the US FARAD centres provided limited consultation on residue avoidance to Canadian veterinarians. With the disappearance of trade barriers, however, it was apparent that an international clearinghouse of residue information was needed. In 1998, 11 countries, including Canada, embraced the concept of global FARAD (gFARAD) centres with multinational cooperative sharing of data on food animal drugs and residue avoidance.² Member countries receive web-based access to the FARAD database along with customized software and technical training from the original US centres.



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In return, gFARAD members share all relevant drug and chemical information and tolerance data from their countries. This global partnership provides a web-accessible compendium of drug information and tolerance data, to which only member countries have access. This pooling of data greatly augments efforts to ensure that withdrawal recommendations and interspecies extrapolations are based on the best scientific information available. The gFARAD system also aids in the harmonization of acceptable international standards of veterinary drug use.

The Canadian gFARAD

With the development of the gFARAD system, the US FARAD centres discontinued consultations with Canadian veterinarians and limited residue avoidance information was provided by veterinary pharmacologists and toxicologists at Canadian veterinary colleges. In order to bring Canada into the gFARAD cooperative, Dr. Tim Blackwell of the Ontario Ministry for Agriculture, Food, and Rural Affairs and Dr. Patricia Dowling of the Western College of Veterinary Medicine petitioned the federal CARD program for start-up funding for a Canadian program. Dr. Michèle Doucet of the Faculté de Médecine Vétérinaire joined in February 2000. In July of 2001, the Agriculture and Agri-Food Minister announced the funding of the Canadian gFARAD program. Canada has now joined the United States, Great Britain, France, and Spain as a full gFARAD member country.

The Canadian, CgFARAD is composed of 2 regional centres: the Western College of Veterinary Medicine in the west and the Faculté de Médecine Vétérinaire in the east. The western CgFARAD centre is directed by Patricia Dowling, DVM, MS, and supported by Chris Clark, VetMB, MVetSc, Barry Blakely, DVM, PhD, and Mark Wickstrom, DVM, PhD of the Toxicology Centre. The eastern CgFARAD centre is directed by Michèle Doucet, DMV, DVSc, and Sylvie Fortier, DMV, MSc is the CgFARAD administrator who maintains the database, researches residue information, and ensures adequate follow-up of all inquiries. Graduate veterinary students also participate in the activities of the centres.

CgFARAD Services

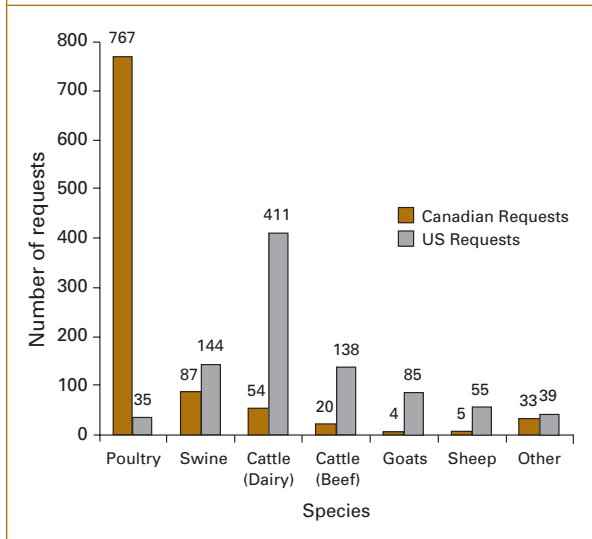
The CgFARAD became operational on October 1, 2002. The centres provide expert-mediated decision support for any inquiry related to drug or chemical residues in food animals. CgFARAD personnel also assist veterinarians or government agencies with inquiries related to animal exposures to environmental contamination. Extralabel drug withdrawal information is only provided to veterinarians authorized to practice in Canada because of their privilege and responsibility in using or prescribing drugs in an extralabel manner. The purpose of the CgFARAD is not to promote extralabel drug use, but to protect the food supply when it is necessary for veterinarians to use drugs in an extralabel manner. Accurate information regarding the health of the affected animals is critical

in determining residue depletion. Because of the impact of physiology and disease on drug disposition, all CgFARAD personnel are veterinarians and neither the Canadian nor the US gFARAD publishes lists of extralabel drug withdrawal times. Because a CgFARAD withdrawal recommendation is not an official withdrawal time and is based on data that has not been reviewed or approved by the Veterinary Drugs Directorate, responsibility for residue violations rests with the prescribing veterinarian. In the unfortunate event where a residue results from extralabel drug use, it is still advantageous for a veterinarian to have recommended a withdrawal interval that is based on the best scientific evidence available.

Requests to the CgFARAD can be submitted via the CgFARAD website (www.cgfarad.usask.ca). Practitioners are asked for their contact information and provincial license number. After the first inquiry, the database remembers the contact information, but it can be changed and the database keeps a historical record. A CgFARAD inquiry is considered a medical record and all personal information is kept confidential. If the inquiry is related to a licensed veterinary drug, the veterinarian can select the generic and corresponding trade name of the drug from a drop-down menu of entries from the Canadian Veterinary Compendium. For each specific drug, the veterinarian is directed to provide information regarding species, number of animals treated, dosage, route of administration, and disease. There is a box for additional information relevant to the situation. Requests are submitted directly to a secure SQL server at the University of Saskatchewan and stored in a temporary file. CgFARAD personnel review submissions for legitimacy and then transfer requests into the database. For requests involving chemicals or environmental contaminants or if the person making the request is not a veterinarian, the CgFARAD can be contacted by phone (1-866-CGFARAD) or email (cgfarad@umontreal.ca).

When a new request is submitted to the CgFARAD, Dr. Sylvie Fortier conducts a systematic review of the Canadian database, other gFARAD databases, and the available scientific literature for background information on the drug or chemical. The database is searchable by drug or chemical name, case number, province, veterinarian, and species, so centre personnel can easily review past inquiries and update with new information. Dr. Fortier then sends a report to Dr. Dowling, Dr. Clark, or Dr. Doucet for final analysis. The information is reviewed along with the Maximum Residue Limits (MRLs) in Canada,³ the acceptable daily intake and tolerance limits in other countries, and the limits of detection for the CFIA. If depletion data are available, CgFARAD personnel conduct a pharmacokinetic analysis to determine the time at which the concentration in meat, milk, honey, or eggs, is expected to be undetectable.⁴ Additional time may be added to account for variables (eg, disease) that affect how individual animals eliminate drugs or chemicals. In some situations, there simply is not enough data upon which to base a recommendation. In these cases, either the product should not be used in food animals or

Figure 1: Global FARAD requests by species (Canadian n=970 from October 1, 2002 – December 31, 2003), US n=1002 from January 2000 to December 2002⁴)



testing should be carried out to insure that such products do not have detectable residues. The CgFARAD also provides information on rapid milk-screening tests and laboratories available to carry out such testing.

When to call the CgFARAD

Most calls to the CgFARAD are for withdrawal recommendations for extralabel drug use. Veterinarians who intend to use a drug in an extralabel manner should contact the CgFARAD first to obtain advice on a safe withdrawal interval. If data are available, centre personnel will provide science-based withdrawal recommendations or advise the practitioner that such information is not available and discourage the drug use. The practitioner will also be advised if the extralabel drug use is permitted in Canada, but banned in other countries, such as the extralabel use of fluoroquinolones in the US.⁵ CgFARAD personnel also assist in determining safe withdrawal times when animals are accidentally exposed to pesticides, heavy metals, or other chemicals.

CgFARAD: The first year

Because of the obvious similarities between the 2 countries, it was anticipated that the CgFARAD caseload would resemble the US caseload. However, just prior to startup, the CFIA and the poultry industry developed a policy aimed at preventing drug residues from extralabel drug usage in poultry products. According to the policy, if extralabel drugs are used in a flock, such use must be declared in writing on a “flock sheet.” The flock sheet is to be sent ahead of the birds to the slaughter facility along with the veterinarian’s prescription for the extralabel drug use and a reference from the CgFARAD with a withdrawal recommendation. If there is no CgFARAD withdrawal recommendation, then the birds are subject to

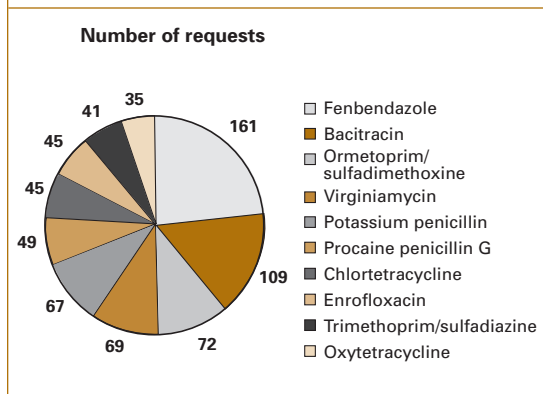
Figure 2: Number of inquires to the CgFARAD by province.



“hold and test” for the administered drug(s) at the producer’s expense. Therefore, as soon as CgFARAD became operational, personnel were deluged with requests from poultry practitioners and it became apparent that the CgFARAD caseload would differ significantly from the US. Under the rules of the Animal Medicinal Drug Use Clarification Act in the United States, extralabel drug use is not permitted in feed.² In Canada, such use is permitted and the pharmaceutical companies have not had an incentive to seek label approvals for a number of drugs and drug combinations routinely used in poultry production. As a result, the CgFARAD personnel had to find residue depletion information for these drugs and drug combinations without assistance from the US centre. It also was apparent that the relational database received from the US was not adequate for Canadian needs. Therefore, information technology services at the University of Saskatchewan were contracted to make a database accessible from both CgFARAD centres that would allow practitioners to submit requests via the web. The new database became operational in October 2003 and has greatly increased the efficiency and consistency in withdrawal recommendations.

The US gFARAD recently published a review of their caseload from 2000 to 2002.⁶ They received 1,145 inquiries during that time. In contrast, from October 1, 2002 until December 31, 2003, the CgFARAD received 970 inquiries for 1084 drugs (some requests involved more than one drug). The Canadian caseload by species is very different from the US caseload (Figure 1). In the US, the majority of inquiries relate to dairy cattle, followed by swine, and beef cattle.⁶ The CgFARAD caseload is led by poultry as a group, followed by swine, dairy cattle, and beef cattle. In the US, the majority of inquires were from the states with high dairy production (California, Ohio, Alabama, Wisconsin, and Texas), while the CgFARAD inquires were predominantly from the poultry producing provinces of Ontario, Quebec, and British Columbia (Figure 2).

Figure 3: Top ten drug requests (out of a total of 970 inquiries involving 1084 drugs)



As a group, withdrawal recommendations were requested most frequently for antimicrobials in both countries. However, the single most frequent extralabel use of a drug in Canada was the anthelmintic, fenbendazole, with 161 requests (Figure 3). In the US, the most frequent antimicrobial requests were for aminoglycosides, penicillins, and tetracyclines.⁶ In Canada, after fenbendazole, the most frequent requests were for bacitracin, ormetoprim/sulfadimethoxine, virginiamycin, and penicillin. In both countries, after antimicrobials, the most common inquiries were for information on anti-inflammatory and analgesic drugs, anthelmintics, and endectocides.⁶

The CFIA policy on extralabel drug use in poultry and the ability of Canadian veterinarians to prescribe extralabel drugs in feed and water are responsible for the request volume and predominantly avian caseload of the CgFARAD. The database “searchability” allows the analysis of extralabel drug use that previously had not been possible. The widespread extralabel use of fenbendazole in poultry was unknown to the manufacturer and the scientists at the CFIA’s Centre for Veterinary Drug Residues (CVDR). Fenbendazole is approved for use in the US for turkeys at a dose of 15 ppm in feed. It is not approved for any species of poultry in Canada, but requests have been received for turkeys, broilers, broiler breeders, layers, and eggs, with a wide variation from 15 ppm to 110 ppm in prescribed dosages. When questioned about the dosages and withdrawal intervals previously followed by poultry veterinarians, a practitioner supplied the CgFARAD with a much-copied sheet of paper listing extralabel drug dosages and withdrawal times for the meat and eggs of chickens, turkeys, and ratites. This document contained no identifying information as to its source and CgFARAD has not been able to substantiate either the suggested dosages or the withdrawal times from any of its global resources. The widespread acceptance of unreferenced material is a concern and it highlights the benefits of a national database with withdrawal information. Every record in the CgFARAD database contains the informa-

tion used to make a withdrawal recommendation and the identity of the person who answered the inquiry. As the database is relational, it is simple to review and update recommendations. The frequent use of fenbendazole clearly indicates the need for an approved product and appropriate dosage regimen in poultry, and a surveillance program for residues. In this way, the CgFARAD serves as an independent, academic intermediary between the commodity groups and the federal agencies for veterinary drug use information.

Interesting cases from the CgFARAD Files

Dipyron in swine and cattle

The CgFARAD received inquiries regarding dipyron administered intramuscularly as an anti-inflammatory drug in swine and cattle. It is banned for use in food animals in the US and any animal treated with dipyron can never enter the US food chain.^{5,7} Dipyron has historically been used in humans and animals as an antipyretic, anti-inflammatory, and analgesic. However, its use is associated with serious toxic effects in humans, including dose-independent teratogenicity, reduced clotting times, and a potentially fatal agranulocytosis.⁵ Due to these concerns, the US Food and Drug Administration (FDA) removed approval for all dipyron-containing human medical products in 1977. Dipyron products labeled for horses and small animals continued to be sold in the US, even though they had never been formally approved by the FDA. Extralabel drug use surveys indicated that dipyron was being used in food animals. This use, along with the lack of animal safety, residue, and efficacy data, as well as the lack of an assay method for residues, caused the FDA to ban the sale of all dipyron products in the US in 1995.⁷ However, dipyron continues to be sold labeled for use in horses and dogs in Canada. In the US, any use of dipyron in food animals receives the same regulatory priority as chloramphenicol and clenbuterol.⁵

The analytical chemists from the CVDR recently developed an accurate detection method with an extremely low detection limit.⁸ In the project component involving residues, it was apparent that intramuscular injections of dipyron are highly irritating to muscle tissue and such use is not consistent with beef and pork quality assurance guidelines (Figure 4). Since a depletion study was not performed, there is still no information to establish a withdrawal recommendation for food animals in Canada.

The CgFARAD has played a vital role in bringing these issues to the attention of bovine and swine practitioners, and decreasing this unacceptable extralabel drug use.

Swine and cattle exposed to chemical and environmental contaminants

The Canadian gFARAD was contacted about 2 cases where cattle and feeder pigs were accidentally fed seed grain treated with terbufos, an organophosphate pesticide.

Figure 4: Intramuscular injection site lesion in a calf caused by dipyrone⁸



In both cases, the intoxication was identified following the acute deaths of a number of animals in the herd. The question was when (if ever) would the surviving animals be fit for human consumption. As terbufos is a licensed pesticide, it has been extensively tested and its toxicity and disposition are well defined. The US gFARAD shared their Joint Expert Committee on Food Additives (JECFA) report on terbufos in food animals. While terbufos is highly toxic, it is also rapidly metabolized and eliminated. In sublethal doses, residues are undetectable 24 hours after exposure. As a result, the CgFARAD was able to assure the parties involved in these cases that the surviving cattle and swine were fit for human consumption at their regular marketing times.

In another case, the CgFARAD was consulted about a group of cows and calves exposed to a natural gas desiccant product in water due to containment system overflow from heavy rains. The product contained a number of compounds known to be carcinogens, initiators of aplastic anemia, and a cause of blindness. CgFARAD consulted with Jim E. Riviere, DVM, PhD, a Director of the US gFARAD, as well as the Director of the Centre for Chemical Toxicology Research and Pharmacokinetics at North Carolina State University, and concluded that the exposed animals should never be used for human consumption.

Glucocorticoids in swine and cattle

The CgFARAD has received inquiries regarding dexamethasone in swine and cattle. Dexamethasone products in Canada and the US were approved for use in food animals many years ago without withdrawal recommendations on their labels. The lack of a label withdrawal time is often interpreted by practitioners as a “zero” withdrawal; however, there is no legal MRL for dexamethasone in meat or milk in Canada.³ The European Union considers glucocorticoid residues a high priority in food animals

because they are synergistic with illegal growth promoters such as beta-agonists or anabolic steroids.⁹⁻¹¹ Product withdrawal times in Europe range from 14 days to 2 months. In a recent analytical methodology study, dexamethasone concentrations in calf liver were 15 times as high as the European MRL, 72 hours after injection.⁹ Since this was not a depletion study, the CgFARAD does not have depletion data with which to predict a suitable meat withdrawal interval for cattle. For swine, the CgFARAD has been unable to find any published scientific information regarding the depletion of dexamethasone from swine tissues. In the dexamethasone summary report of the European Agency for the Evaluation of Medicinal Products, there is a comment that after a 0.06 mg/kg IM dose of dexamethasone phosphate, residues in all sample tissues were below the limits of detection within 4 days. No source is given for this information and the CgFARAD is unable to determine its validity. If administration of dexamethasone is declared, the CFIA now subjects the tissues of treated animals to “hold and test” at the producer’s expense. For milk, both the US and Canadian gFARAD have found data to support a 48-hour withdrawal interval when dosed at 0.06 mg/kg IM.¹²

A similar situation exists for flumethasone in dairy cattle. Flumethasone is not labeled for use in food animals in the US and, while the Canadian label states that it is indicated for the treatment of ketosis and milk fever in cattle, it does not specifically indicate lactating dairy cattle. Although there is a 4-day meat withdrawal time on the flumethasone label, there is no recommendation for milk withdrawal time and there are no Canadian MRLs for meat or milk.³ When dairy cattle are dosed with flumethasone at 0.014 mg/kg, the US and Canadian gFARAD’s have found data to support a 48-hr milk withdrawal interval.¹²

Conclusions

Consumers are increasingly demanding a safe food supply and food animal veterinarians have an important role in this process. To avoid politically-mandated, top-driven regulation of food animal production, veterinarians must work with producers in on-farm food safety programs using the best available information. The number of inquiries received by the US and Canadian gFARAD centres indicates the need for expert-mediated advice on residue avoidance issues. The CgFARAD database is now easily accessible to Canadian veterinarians and the data can be used to identify trends in drug use and the pharmaceutical needs of the commodity groups. The centralized database provides an accurate historical record and national consistency on withdrawal recommendations. International cooperation facilitates the gFARAD model in other countries for the global enhancement of food safety and animal welfare.

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