



SPRING 2021

PROTECTING ANIMALS AND OUR FOOD SUPPLY

What is extra label drug use?

The simplest definition of extra label drug use is a use that is any way different from the exact label instructions for the product including: species, age, route of administration, dose and duration.

How are drug labels created?

Drug labels are submitted from a manufacturer with supporting documentation to a national regulatory body for approval. This means that for each drug there must be an approved label for every country or regulatory region in which it is sold.

Why is extra label drug use so important in veterinary medicine?

If you imagine all of the pharmaceutical products and all of the countries in which they could be registered and then try to imagine a label for every species of animals with which veterinarians work from antelope to zebras, you can imagine the size of label and the cost and length of that imaginary registration submission! When we understand the process, it makes sense that most pharmaceuticals will not be registered and labeled for most species. This is why extra label drug use is an essential aspect of veterinary medicine.

**CgFARAD™ responded to
2,557 withdrawal requests in
2020-2021 covering 24
different livestock and poultry
commodities.**

If veterinarians must use drugs in an extra label manner to do their jobs, how can we ensure that it is done safely and that there are no residues in food animals or their products?

The answer in Canada is CgFARAD™! The Canadian Global Food Animal Residue Avoidance Databank assists veterinarians in protecting animals and our food supply.

CGFARAD™ YEAR IN REVIEW

Veterinarians are legally permitted to prescribe drugs in an extra label manner (i.e. for disease indications, or doses or duration of treatments that are different than the approved drug labelling). But, using a drug in an extra label manner means the label withdrawal time for meat, milk or eggs, no longer applies. Unlike human medicine, when drugs are used in veterinary medicine, the labels cannot and will never include all of the species and uses on the label. By definition then, many uses of pharmaceuticals in veterinary medicine are extra label.

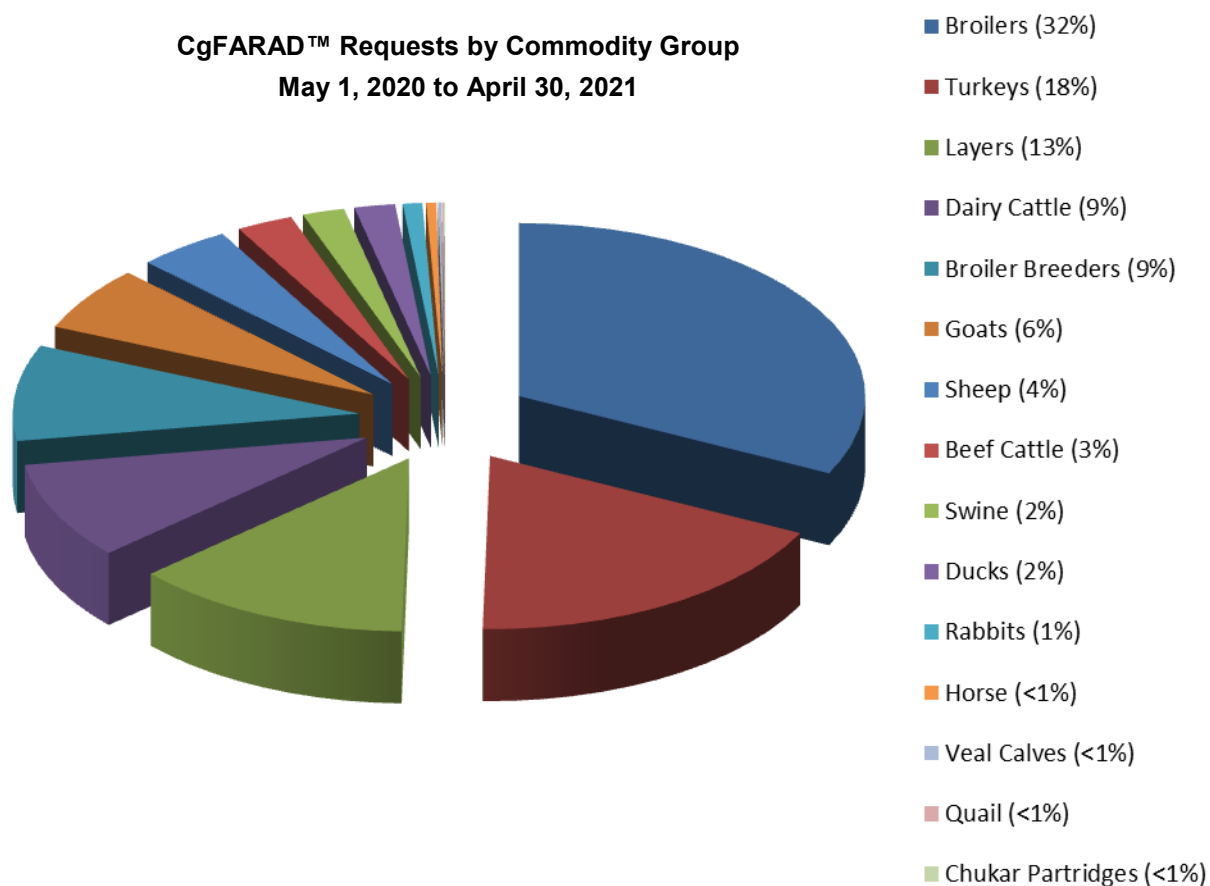
The Canadian global Food Animal Residue Avoidance Databank (CgFARAD™) provides veterinarians with unbiased veterinary pharmacology expertise on withdrawal times. CgFARAD™ also undertakes research where insufficient information exists. This ensures food safety when drugs are used extra label in food producing animals. In addition to extra label use, the nature of delivering treatments and the number of points of contact for veterinary treatments result in errors and also accidental exposures. These occurrences must be addressed to ensure that violative residues in animal food products. Dangerous levels of prescribed or compounds to which food animals have been accidentally exposed, must not enter the human and animal food supplies and CgFARAD™ is an essential frontline service which helps to perform this critical safety function for public health.

In our spring newsletter each year, we provide graphs illustrating requests by pharmaceutical product and by disease for each commodity group. Several graphs depicting this summary data by species are shown on the following pages. This is valuable information as it illustrates the health challenges with which veterinarians are dealing and highlights where there may be limited registered label options. The CgFARAD™ pharmacologists also use this knowledge to identify where drug residue research and depletion studies are needed.

The fiscal year of the CgFARAD™ (May 1, 2020 to April 30, 2021) has been an unusual time for us, reflecting the impact of the COVID pandemic on food production in Canada. Changes in consumer buying habits greatly impacted the meat, dairy and poultry industries as the amount of products needed by restaurants, grocery stores, and schools decreased. With limitations on the size of family gatherings, consumers suddenly required small sized turkeys for holiday dinners, requiring changes in production schedules. For chickens, there were interesting changes in the demand for specific parts. For example, the majority of chicken wing consumption occurs outside of the home. For eggs, the industry had to adjust to a drop in demand for liquid eggs from the hospitality sector with an increase in table egg demand for home baking. In the early days of the pandemic, closure of schools and restaurants caused a dramatic drop in demand for milk and need for different packaging, resulting in on-farm dumping of milk and early culling of cows. The meat processing industry in Canada was hit by virus outbreaks in processing plants that forced closures of some and disruption in others. Animals ready for slaughter that were “back logged” experienced disease and treatment challenges. There were cases of slaughter weight animals being euthanized for lack of processing options. When shopping for home consumption, consumers tended to buy cheaper cuts of meat and hamburger and grocery store shortages occurred as consumers hoarded frozen products. Fluctuation in prices for feed and fuel with the pandemic recovery also impact food animal production in Canada.

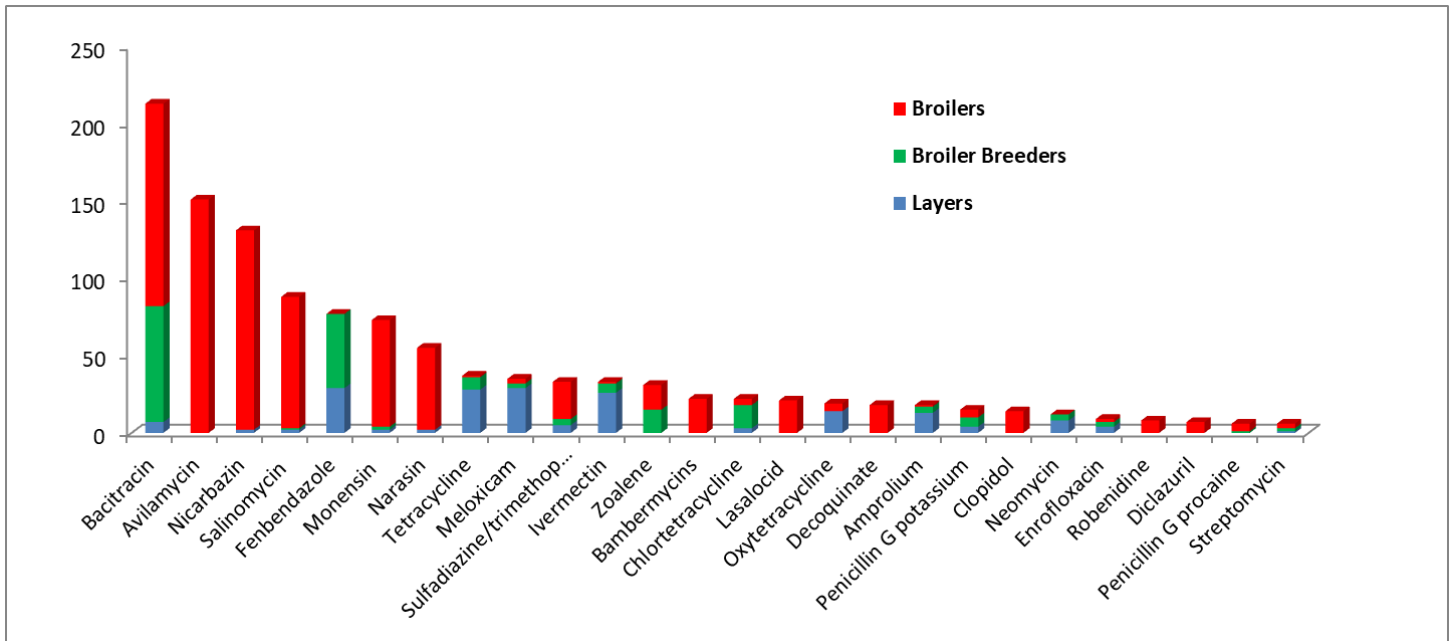
The COVID-19 pandemic has also impacted the reliance on the CgFARAD™ service. Animals held on farms longer due to processor shutdowns has led to increased animal health issues. As well, some animals have been sent to alternate slaughter facilities in the U.S. While drug labels and withdrawal times are appropriate for animals and their products that remain in Canada, there are important differences in federal drug regulations between the two countries that can impact animals heading south for processing.

The number of requests received by CgFARAD™ continues to grow by approximately 200 inquiries a year however the relative proportions of the animal groups were very similar.

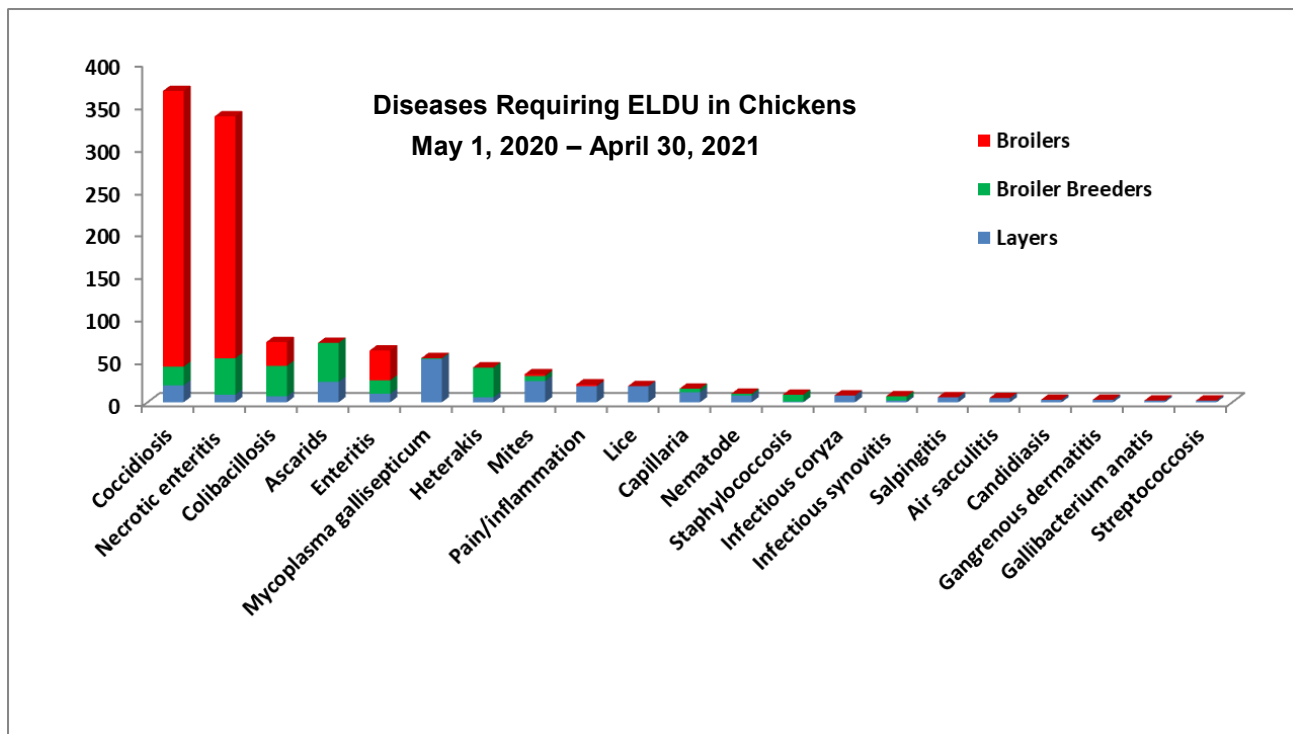


In all types of chickens, coccidiosis and necrotic enteritis continue to be the predominant diseases that require extra-label drug use (ELDU). The changes in federal regulations, removing all growth promotion claims for antimicrobials, continue to impact the use of a number of antimicrobials in layers. There has been a significant increase in the number of requests involving avilamycin. While many requests are due to combinations with other drugs in the same batch of feed, others involve treatment duration beyond the approved 21 days. The CMIB has now included this statement regarding avilamycin: "This livestock feed contains a medically important antibiotic. To reduce the development of antimicrobial resistance and maintain effectiveness, use this antibiotic prudently." Due to concerns regarding antimicrobial resistance, the Veterinary Drugs Directorate will no longer approve antimicrobials for continuous use throughout the production cycle and they strongly discourage extended durations of therapy. As such, we suggest that extended treatments with avilamycin should be avoided whenever possible, but the realities of feed milling sometimes make it difficult to follow such specific treatment durations.

ELDU Requests for Chickens by Product
May 1, 2020 – April 30, 2021



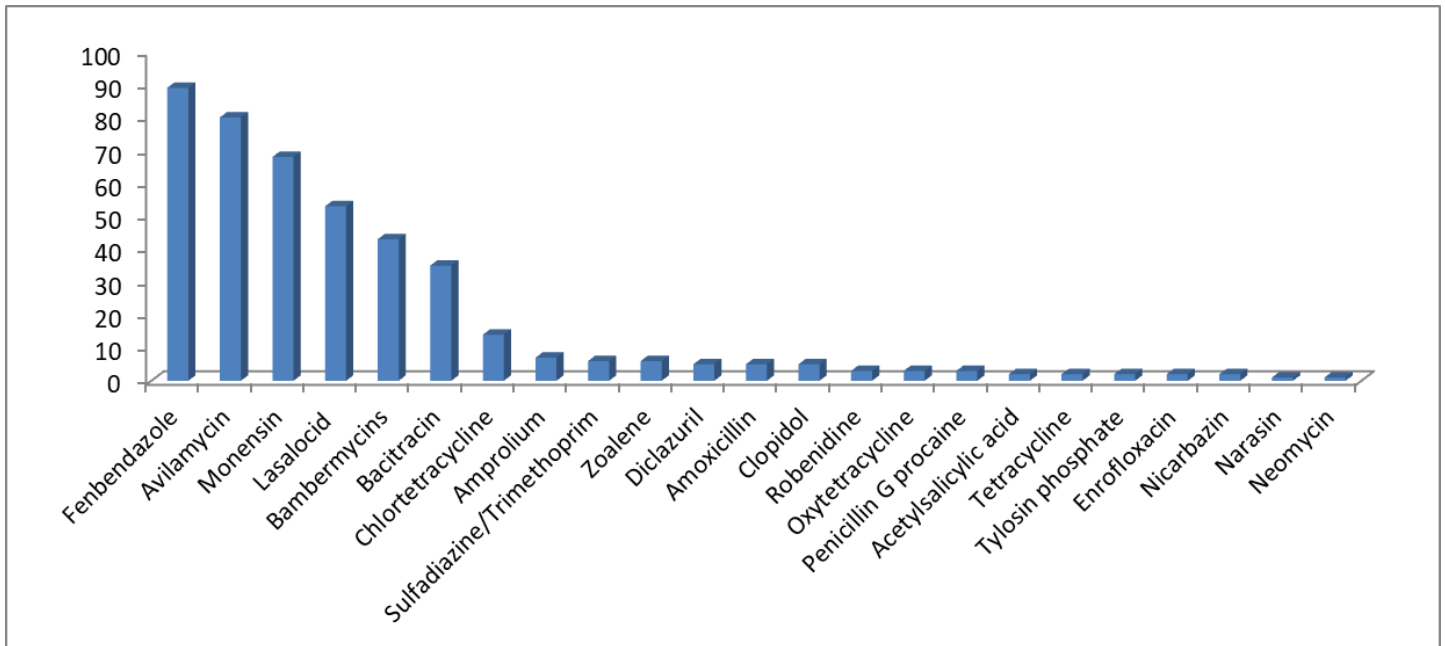
Mites and lice are problematic both in commercial birds and backyard flocks. We do a lot of educations for veterinarians for small flock owners, as pesticides cannot be used in an extra-label manner and we must tell them that the CgFARAD™ cannot give withdrawal recommendations for an illegal pesticide use. Currently, we only have residue depletion information for the use of ivermectin in the water, so we direct veterinarians to this treatment. We hope that fluralaner (Exzholt®) will soon be approved for mite control in poultry in Canada. It is currently approved in the European Union with a zero day egg withdrawal time and a 14 day meat withdrawal time. We continue to receive requests for backyard poultry being treated by small animal practitioners for respiratory disease and injuries. Unfortunately, these practitioners often request withdrawal information for small animal approved products such as meloxicam and amoxicillin/clavulanic acid. We often do not have residue depletion information for these drugs. As well, amoxicillin/clavulanic acid is a Category I antimicrobial and as such, the Chicken Farmers of Canada has eliminated the on-farm use of this category of antimicrobials. The CgFARAD™ staff do our best to educate the veterinarians seeing backyard poultry on appropriate ELDU.



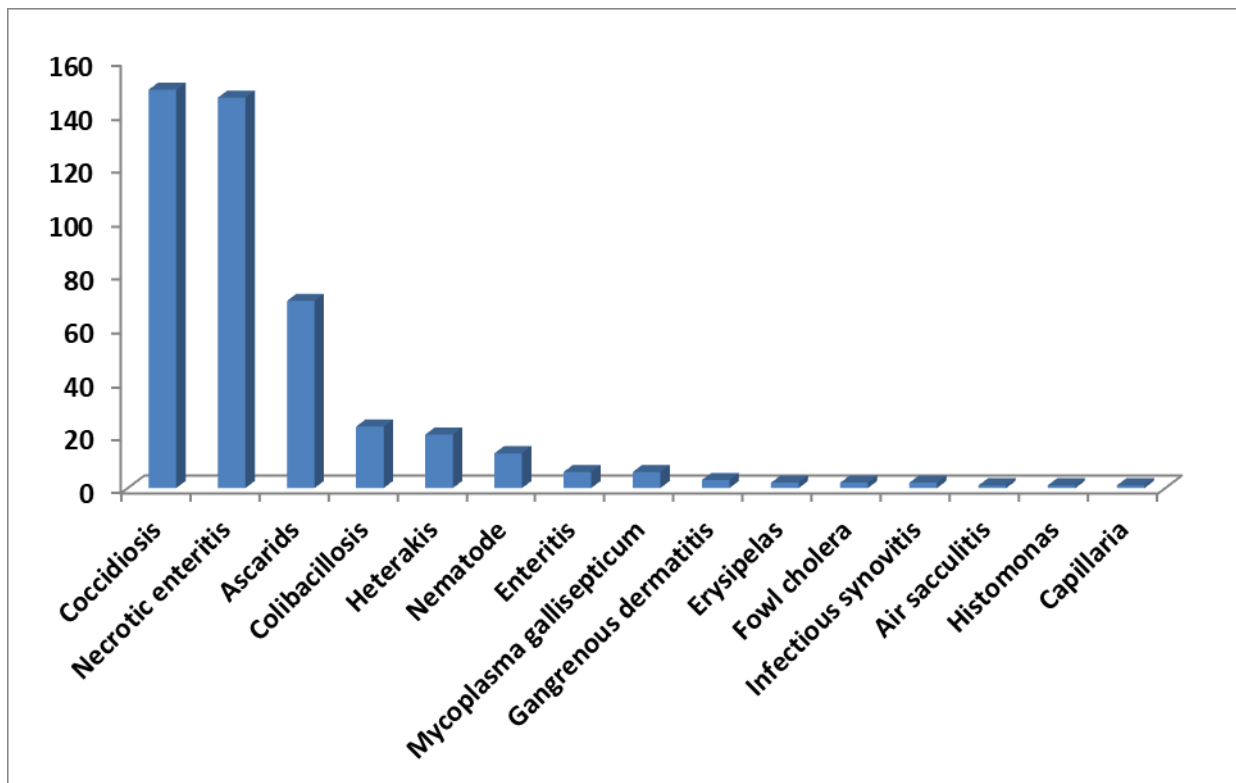
With the approval of Panacur AquaSol for all classes of chickens with no meat or egg withdrawal needed, our requests for ELDU in chickens has decreased. There are still occasions where use of this water product is not feasible, so we do still receive some requests in chickens. Backyard poultry requests are typically for small animal or equine formulations of fenbendazole.

As this product was not approved for turkeys, requests for the use of Safe-Guard Premix had continued at a similar rate. But with the very recent approval of this premix for turkeys with a 24 hr withdrawal time, we expect to see a reduction in these requests. However, the approved dosage and duration of 16 ppm and six days does not match how it was being used by poultry practitioners. The most common dosage and duration have been 30 ppm and seven days and still require an ELDU withdrawal recommendation. But now that we have Maximum Residues Limits for fenbendazole in turkeys (they are the same as for chickens), we can provide a much shorter withdrawal recommendation based upon the published CgFARAD™ fenbendazole depletion study. As previously mentioned, the restrictions on holiday gatherings due to the COVID pandemic impacted Canadian turkey production which subsequently impacts bird health and medication usage.

ELDU Requests for Turkeys by Product
May 1, 2020 – April 30, 2021



Diseases Requiring ELDU in Turkeys
May 1, 2020 – April 30, 2021

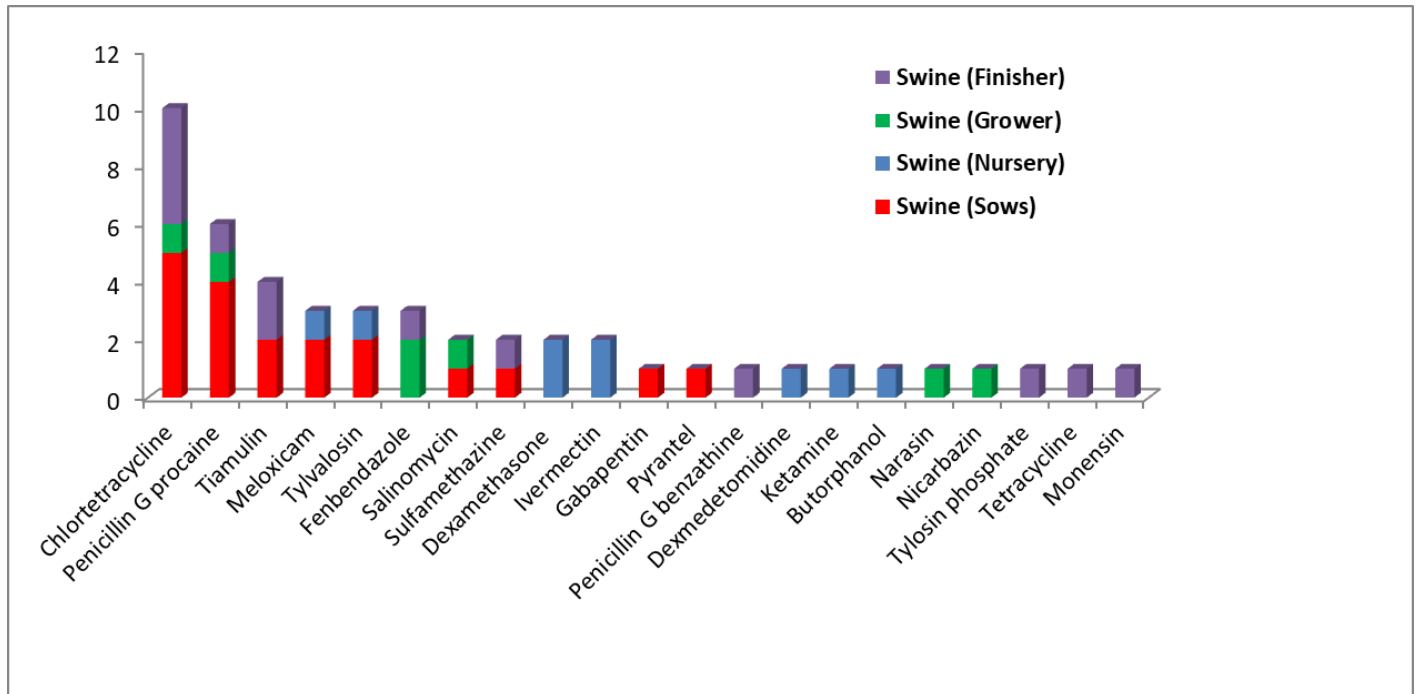


The primary reason for ELDU in swine continues to be antimicrobial treatments for infectious diseases, especially respiratory and gastrointestinal infections. We were frequently consulted for advice on drugs used for anesthesia and pain control. The swine veterinarians have few on-label treatment options in this area and one of the only

approved products was in a back order situation. It is difficult for Canadian veterinarians to meet the requirements of the Code of Practice for the care and handling of pigs with so few treatment options.

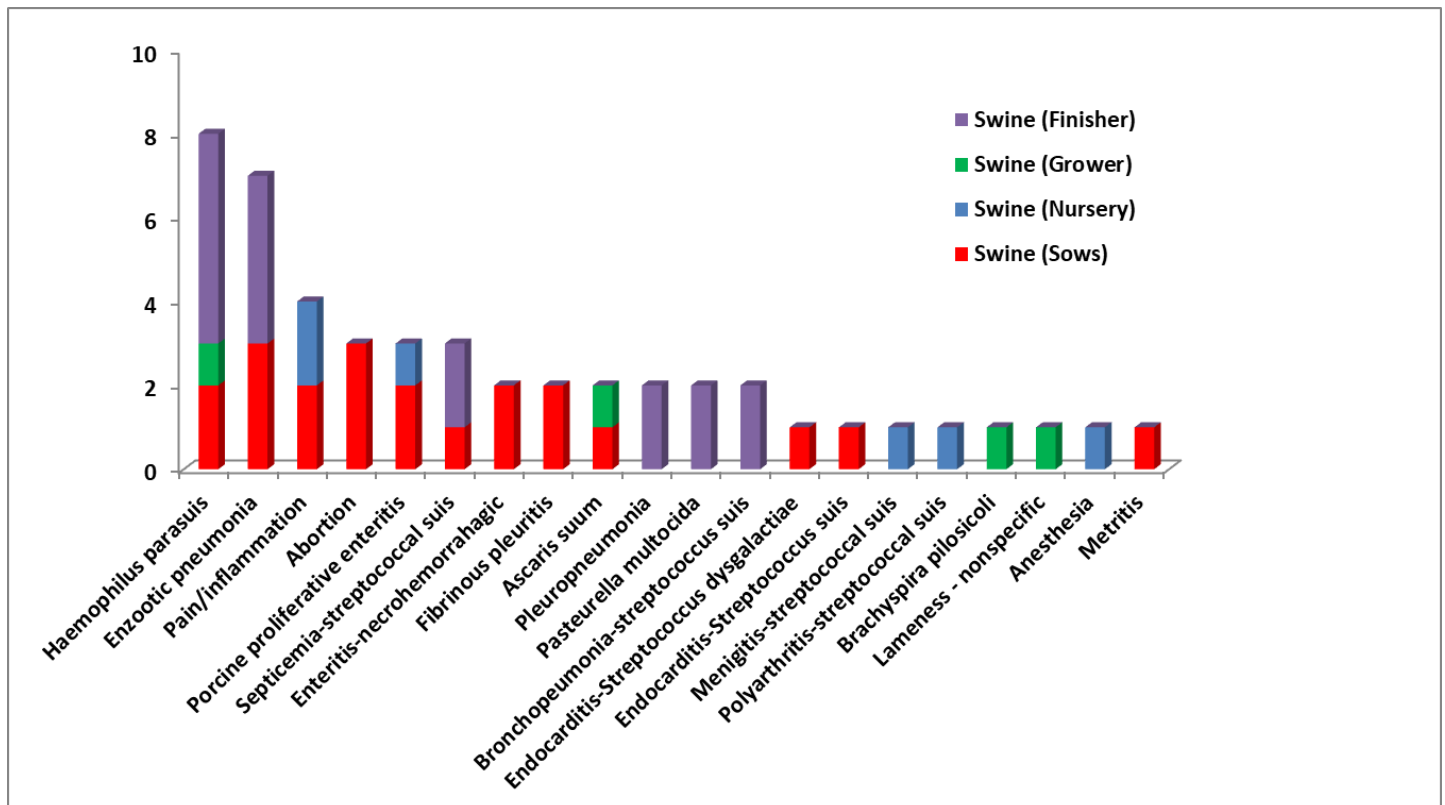
ELDU Requests for Swine by Product

May 1, 2020 – April 30, 2021



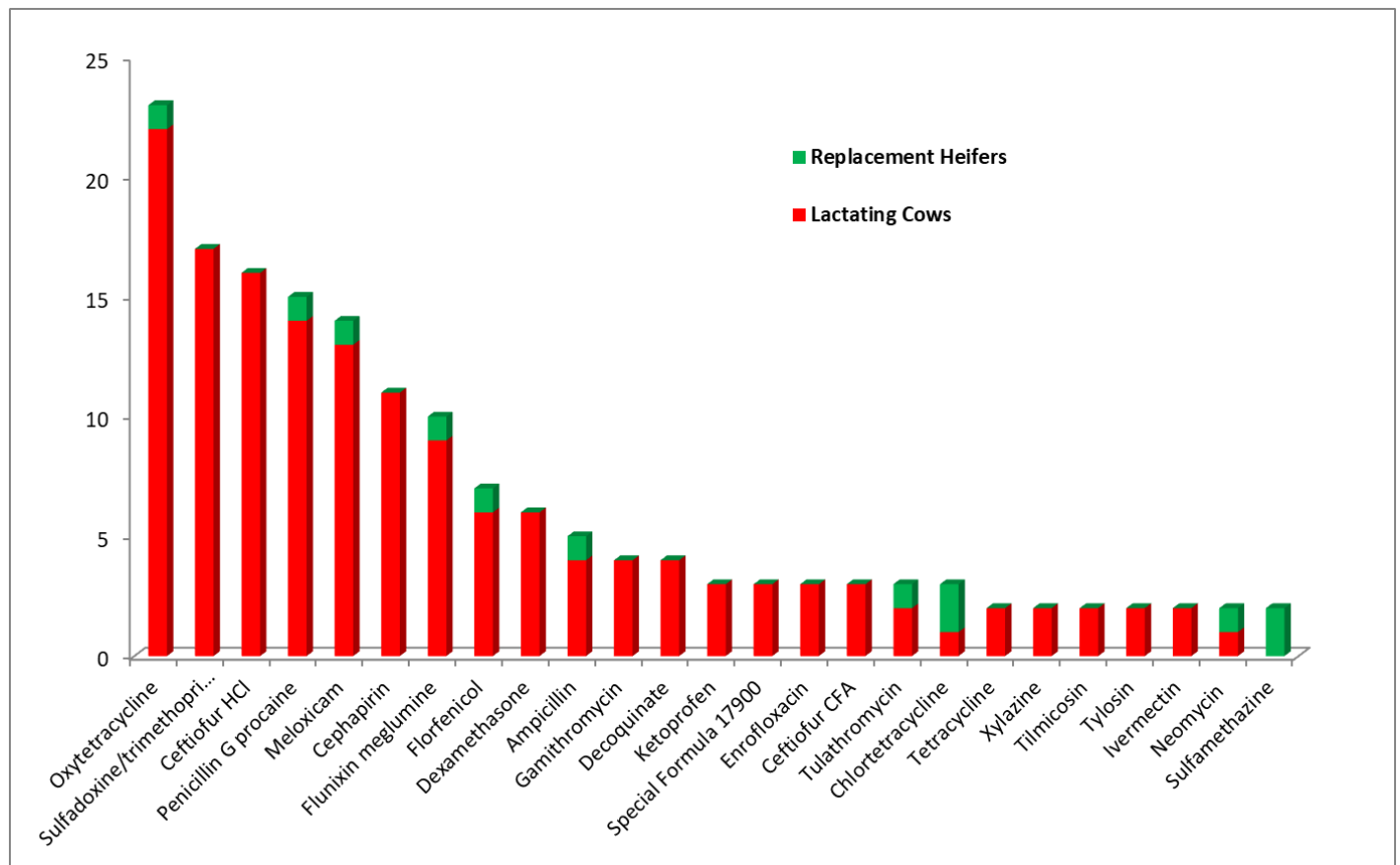
Diseases Requiring ELDU in Swine

May 1, 2020 – April 30, 2021



In dairy cattle, treatment of bovine respiratory disease (BRD) and mastitis continue to be the most common reasons for ELDU. Treatment of digital dermatitis and pain and inflammation are also important reasons for ELDU. Drug availability for the on label treatment of mastitis continues to be a problem. Special Formula 17900, while approved for bovine mastitis, was frequently used with extra-label treatment regimens (e.g. twice daily and for more than two days). This product contained penicillin G procaine, dihydrostreptomycin, novobiocin and polymyxin B. It is no longer available from the manufacturer. Cefa-Lak (cephapirin, a first generation cephalosporin) was on back order for a period of time. The loss of these two products left dairy veterinarians with few treatment choices. It appears to be increasing the use of Spectramast LC (ceftiofur). As a third generation cephalosporin, it is a Category I antimicrobial. Feed mill errors and accidental exposures are always given emergency priority for dairy cattle. The most common accidental exposure is decoquinatate (Deccox), a coccidiostat intended for use in calves. If given a chance, dairy cows will knock down gates to get in to the calf ration! For these situations, CgFARAD™ personnel provide information on drug residue testing in milk and laboratories with the capability of rapid testing in order to get the impacted producer back on line as fast as possible. CgFARAD™ personnel were also consulted regarding herd treatments for a multi-farm leptospirosis outbreak that required treatment of the lactating cows.

ELDU Requests for Dairy Cattle by Product May 1, 2020 – April 30, 2021

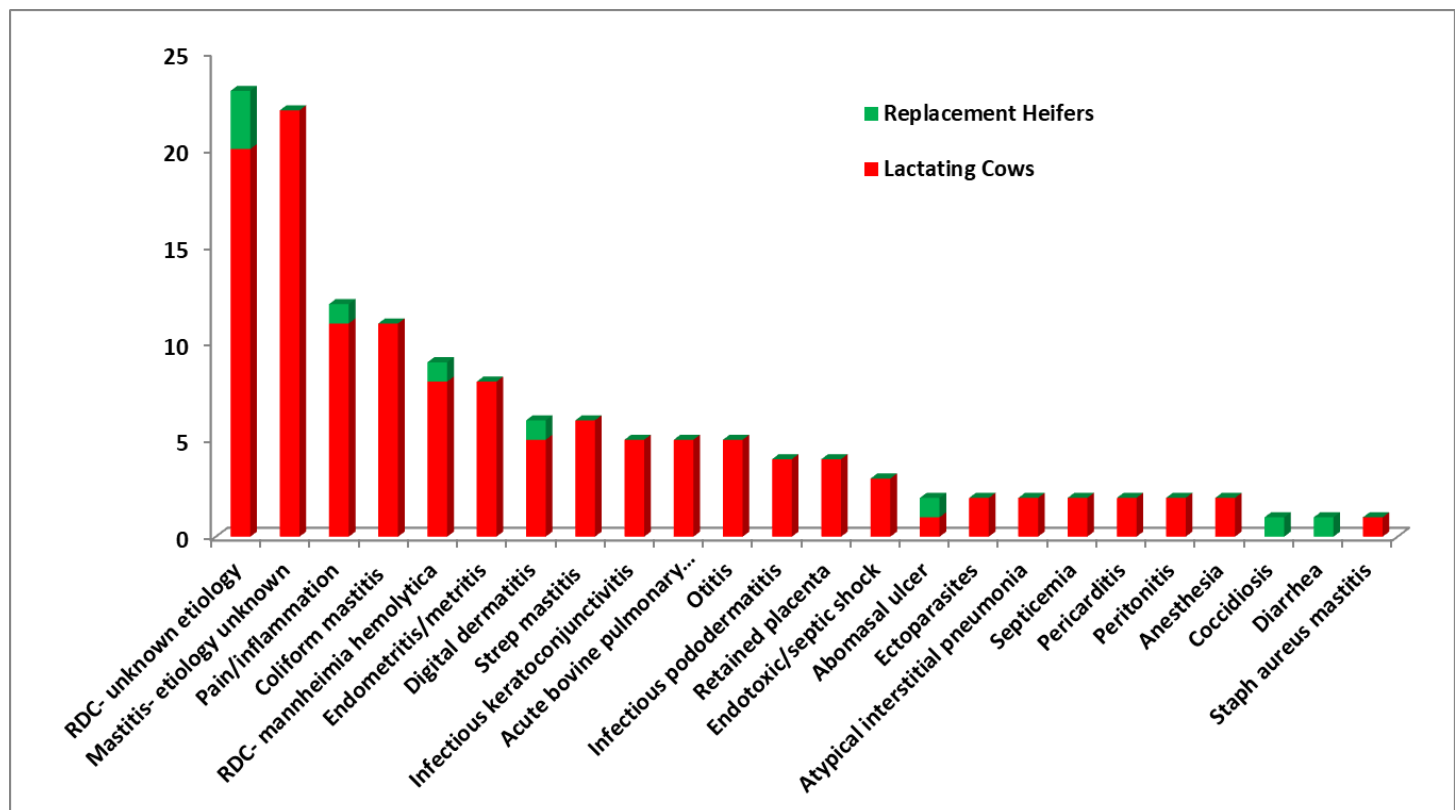


Due to the COVID 19 pandemic, there was a reduced need for milk in schools and restaurants, and the Canadian dairy industry initially struggled to reduce production. One of their strategies was to rapidly cull marginal lactating cows. But many of these dairy cows are to be sent for slaughter in the United States. These cows are then

subject to the US laws regarding ELDU. We saw requests for meloxicam (Metacam) and ketoprofen (Anafen), which are not approved for use in food animals in the US but they are not banned drugs. Therefore, cattle treated with any of these drugs must not have detectable residues. Boehringer-Ingelheim has been kindly providing the CgFARAD™ with depletion data for both of these drugs to help us with this process. The list of drugs that may be an issue with Canadian food animals can be found at <http://www.farad.org/prohibited-and-restricted-drugs.html>.

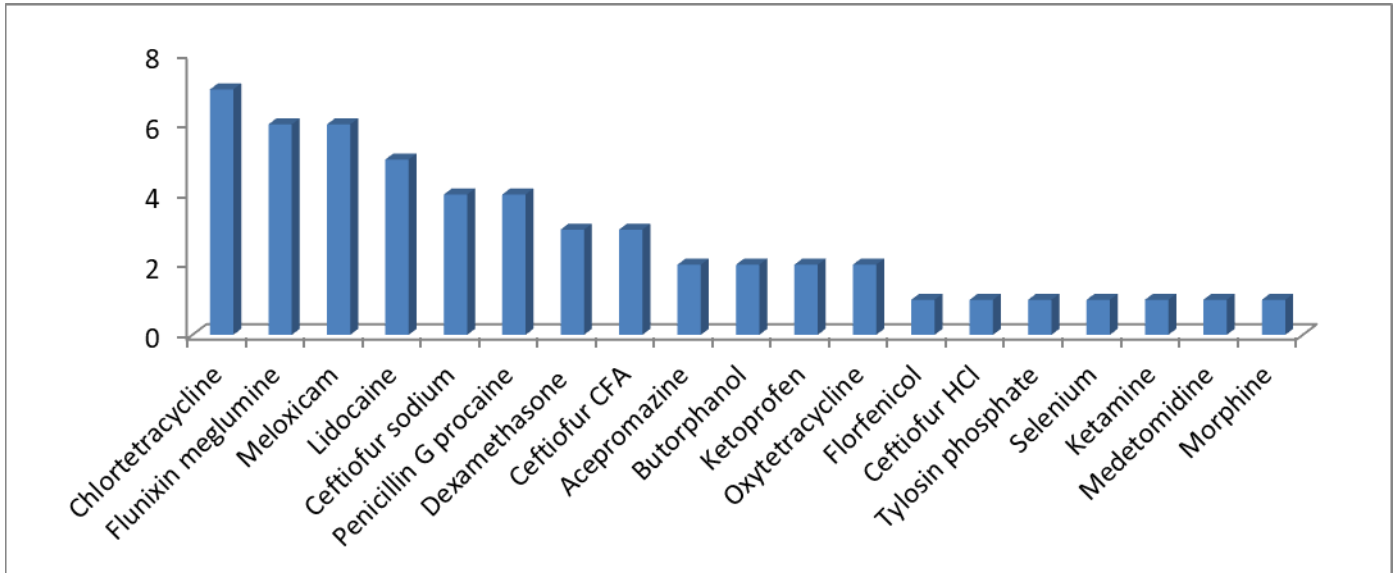
A more serious issue is the use of drugs that are banned or restricted in the US. The US has not had injectable trimethoprim/sulfadoxine (e.g. Trimidox, Borgal) for decades. The use of non-approved sulfonamide drugs is not permitted in dairy cows over 20 months of age. Therefore, Canadian lactating dairy cows treated with these drugs cannot be sent for slaughter in the US. It is not an issue of detectable residues; cattle treated with banned drugs must not EVER be slaughtered in the US. Other drugs of concern include Baytril (enrofloxacin) or A180 (danofloxacin). We occasionally get requests for these drugs as it is legal to use them in an extra-label manner in Canada. No ELDU of fluoroquinolones is permitted in the US; so again, treated dairy cattle must NOT enter the US food supply. Ceftiofur can be used extra-label but only under specific circumstances. The CgFARAD™ staff worked to provide this information to dairy veterinarians and associations.

Diseases Requiring ELDU in Dairy Cattle May 1, 2020 – April 30, 2021

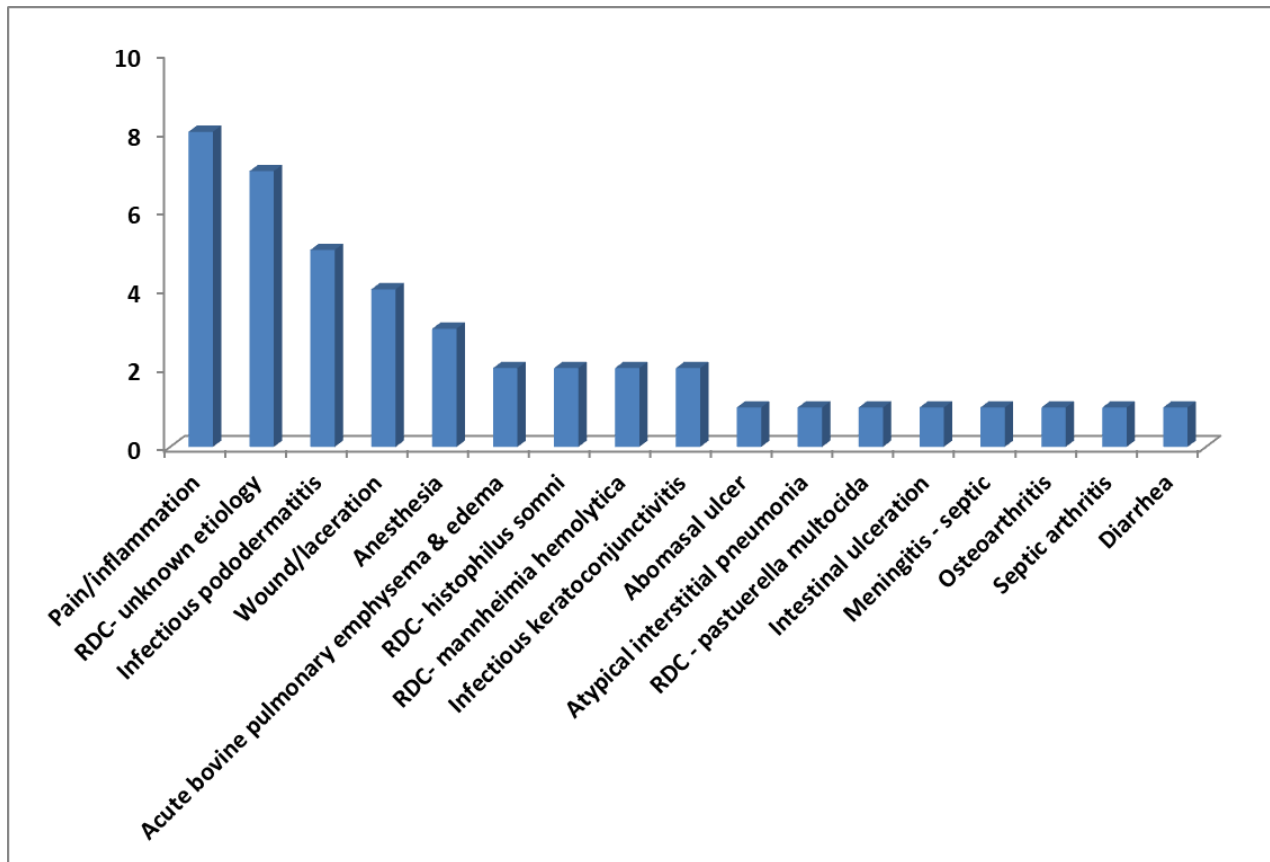


Requests for withdrawal information for ELDU in beef cattle are traditionally low. Cow/calf operations have animals that are far from the time of slaughter and feedlot operations typically do not use drugs in an ELDU manner. But the COVID pandemic impacted the beef slaughter facilities and created a back log of slaughter ready cattle that suffered some disease challenges that generated requests to the CgFARAD™.

ELDU Requests for Beef Cattle by Product
May 1, 2020 – April 30, 2021



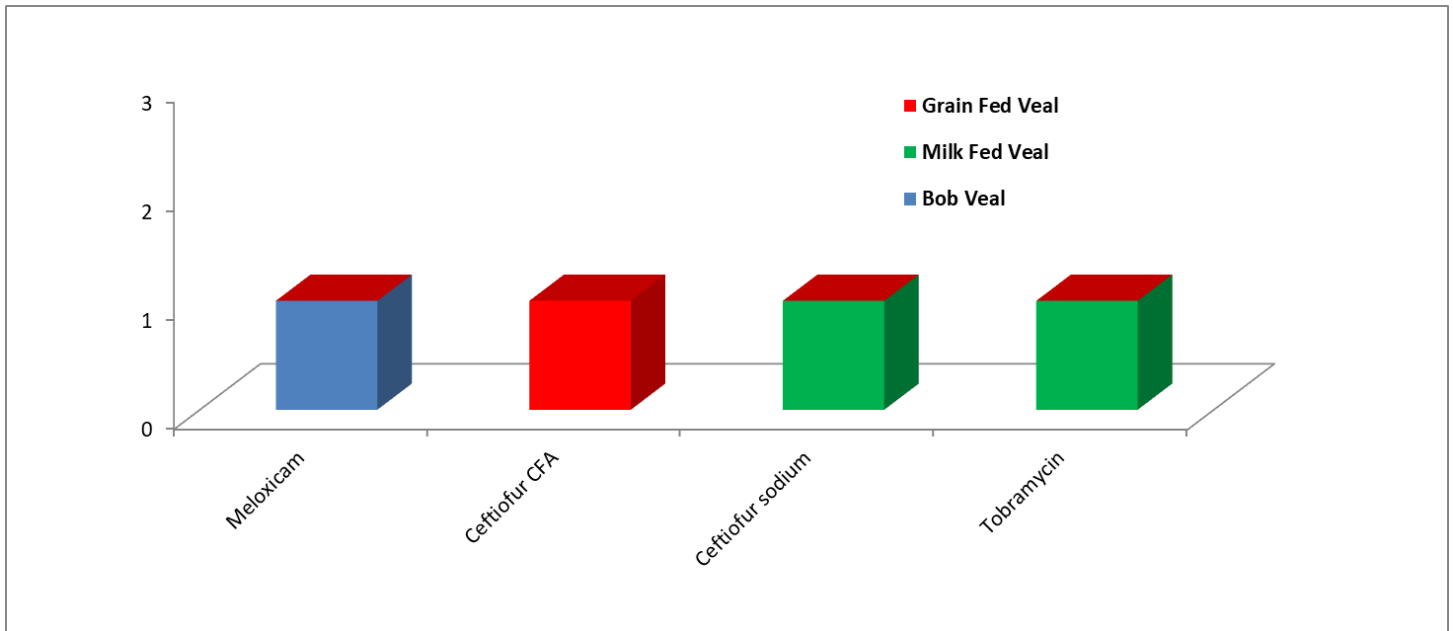
Diseases Requiring ELDU in Beef Cattle
May 1, 2020 – April 30, 2021



The veal sector seems to be impacted similarly to other meat production sectors. The number of ELDU requests for veal was down significantly last year to just four requests. The greatest number of requests came in 2017-2018 and was stable the last two years.

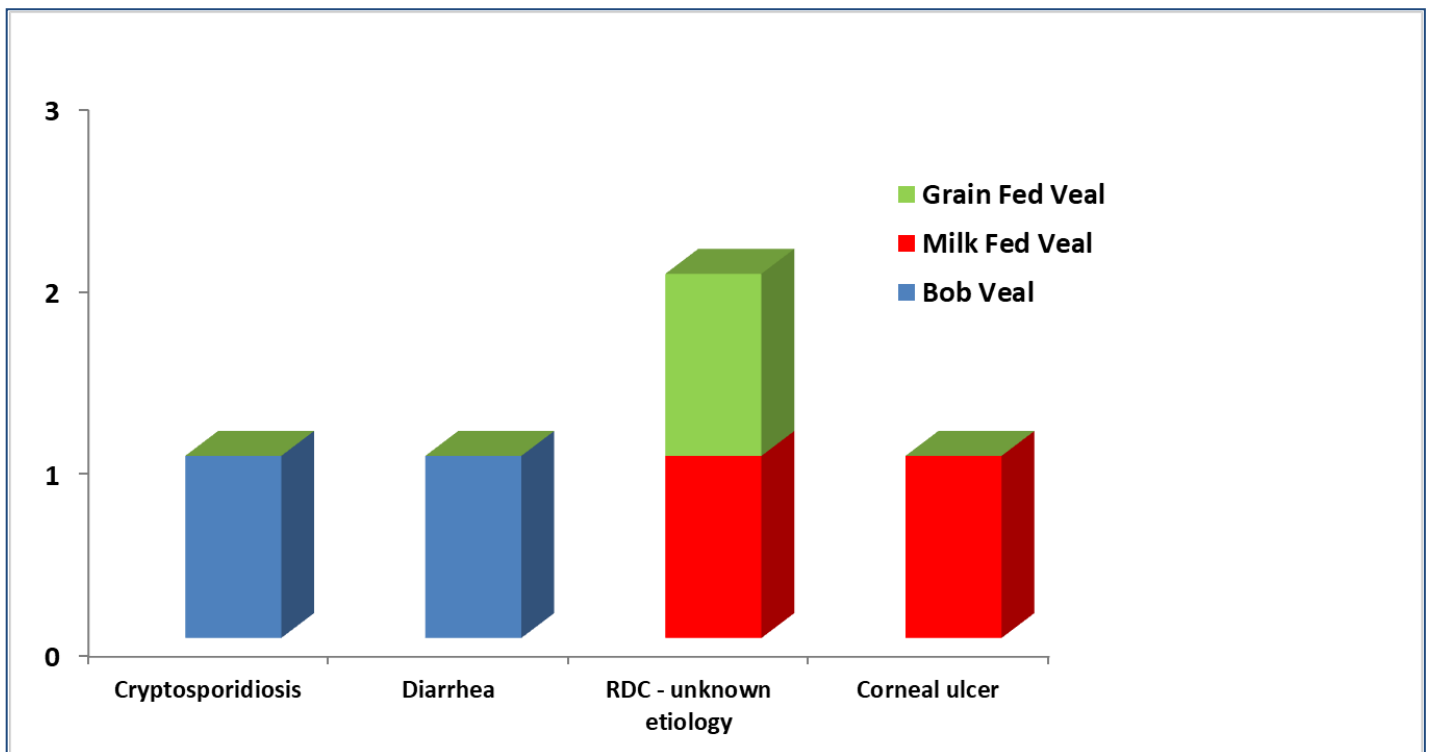
ELDUs Requests for Veal by Product

May 1, 2020 – April 30, 2021

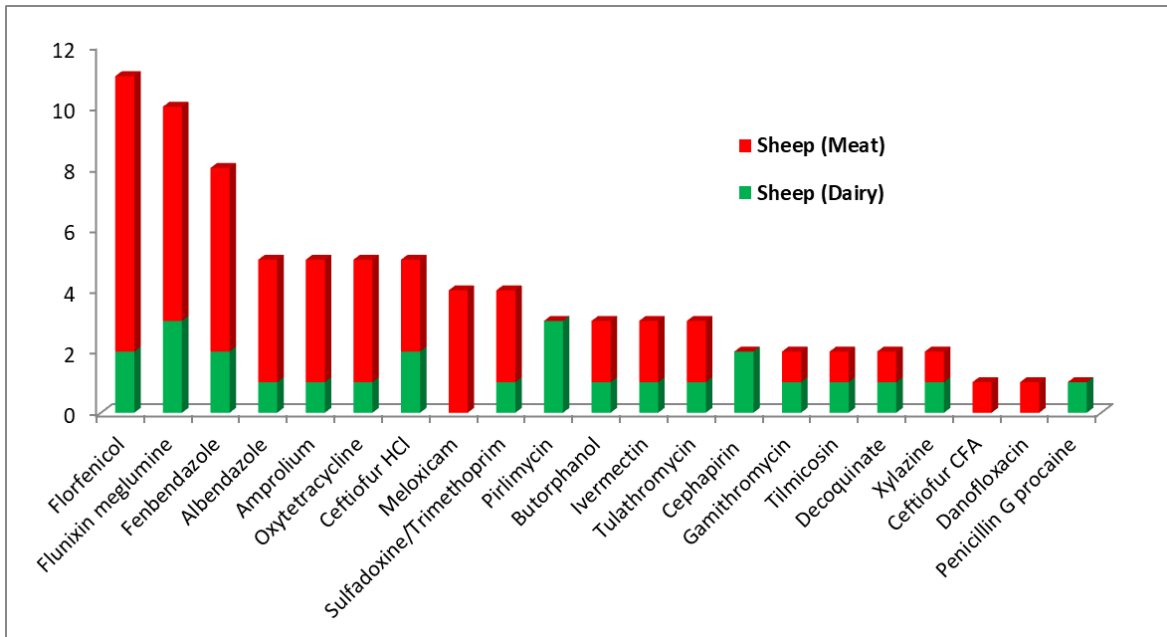


Diseases Requiring ELDU in Veal

May 1, 2020 – April 30, 2021

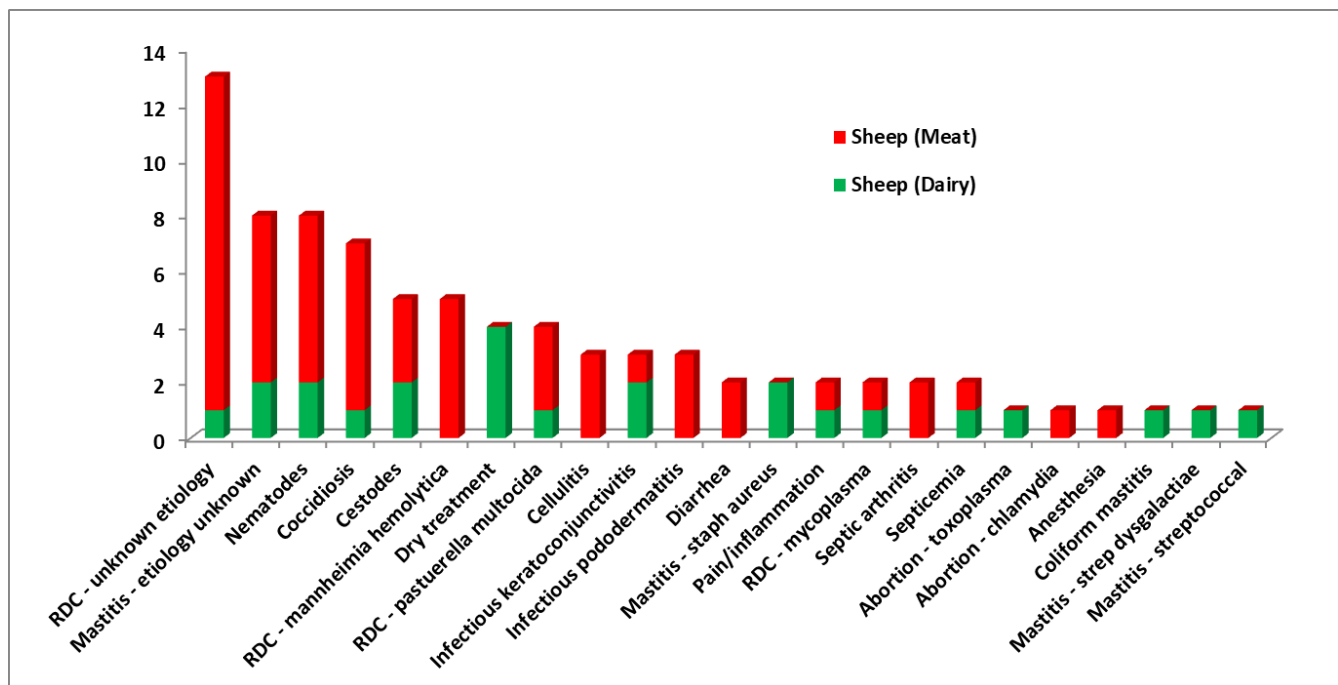


ELDU Requests for Sheep by Product May 1, 2020 – April 30, 2021



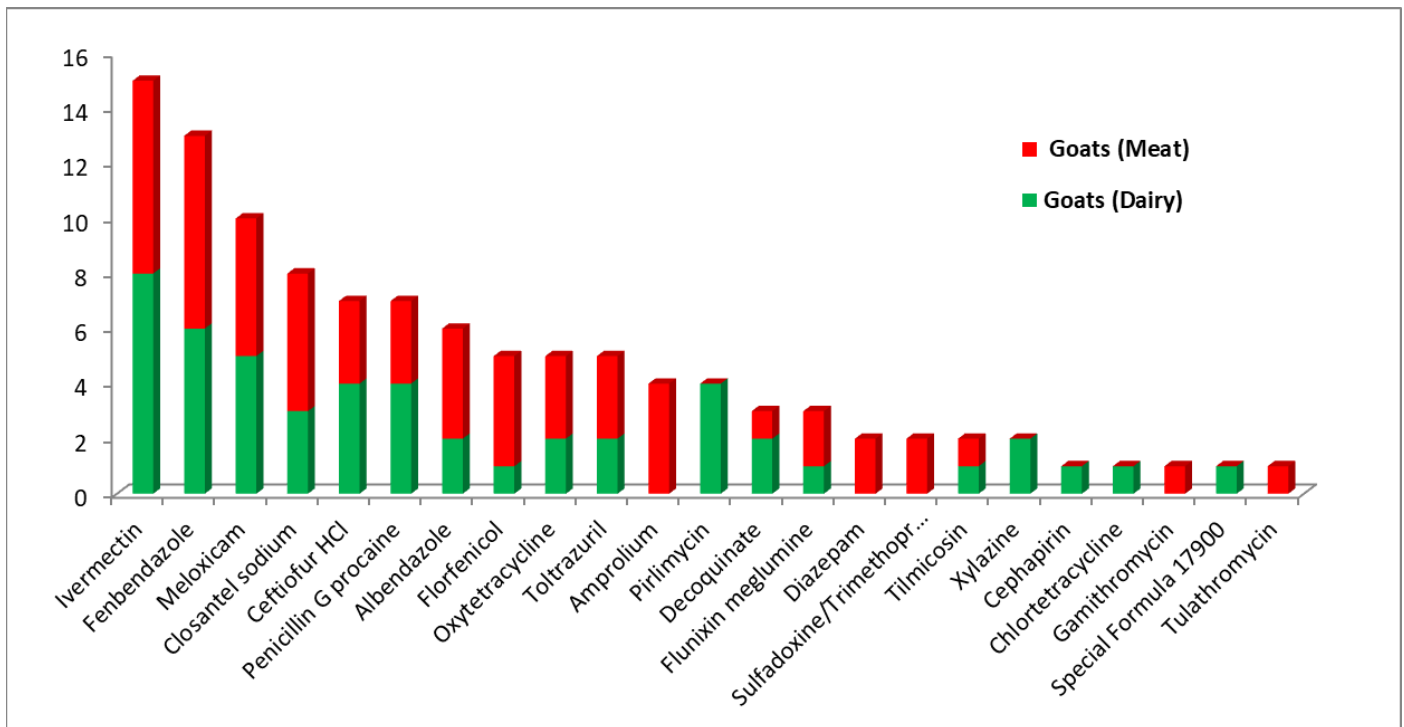
Due to limited drug approvals and bacterial and parasite resistance, antimicrobials, coccidiostats and dewormers are the most commonly used products for ELDU in sheep and goats. Even if parasite resistance is not present, residues in milk of lactating sheep and goats can be very problematic due to persistence and very sensitive detection methods used by regulators.

Diseases Requiring ELDU in Sheep May 1, 2020 – April 30, 2021



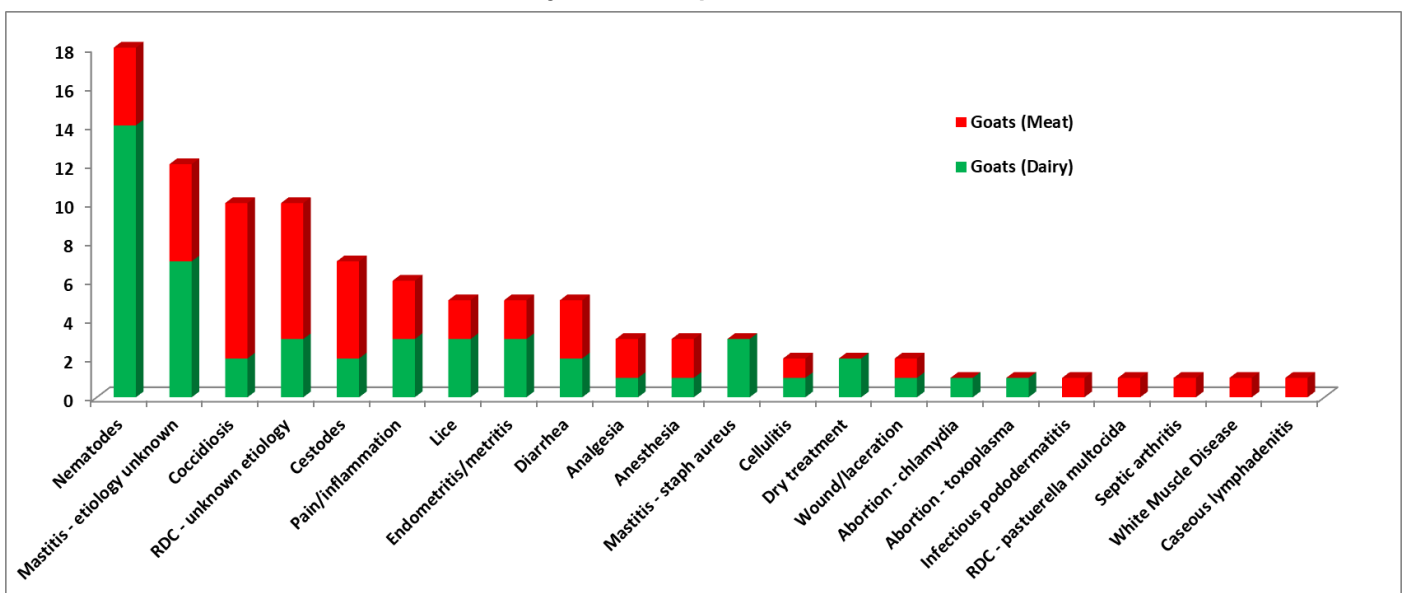
ELDU Requests for Goats by Product

May 1, 2020 – April 30, 2021



Diseases Requiring ELDU in Goats

May 1, 2020 – April 30, 2021



The chart to the right shows a comparison of ELDU requests by commodity over the past five years. Requests in 2020-2021 were up by 164 as compared to 2019-2020 but still lower than the all-time high of 2,640 in 2018-2019. Layer requests were noticeably higher than normal. There were relatively high numbers of duck requests as well..

The “other” category in 2020-2021 was comprised of four alpaca and one ostrich requests. The CgFARAD™ team is asked to provide advice on a wide variety of species but the vast majority of requests are for the major farmed animal species.

Species	2020-2021 request	2019-2020 requests	2018-2019 requests	2017-2018 requests	2016-2017 requests
Chickens/Broilers	819	866	796	756	825
Turkeys	455	399	380	512	482
Dairy Cattle	230	274	266	261	232
Broiler Breeders	227	228	259	119	79
Chickens/Layers	330	145	144	137	92
Goats	153	134	241	189	196
Sheep	110	80	170	164	125
Beef Cattle	67	72	82	64	88
Swine	50	62	171	38	40
Rabbits	23	24	24	22	21
Bison	5	22	11	13	11
Horses	12	19	23	21	10
Ducks	48	16	20	5	6
Veal Calves	4	14	15	45	23
Deer	0	7	0	1	1
Chukar Partridges	1	6	10	6	8
Elk (Wapiti)	2	5	5	4	N/A
Quail	2	4	5	10	5
Geese	2	3	2	5	N/A
Pigeons	3	2	3	14	N/A
Guinea Fowl	1	2	2	8	1
Pheasants	7	2	6	6	6
Fish	1	0	1	4	1
Other	5	7	4	N/A	5
Total	2557	2393	2640	2404	2257

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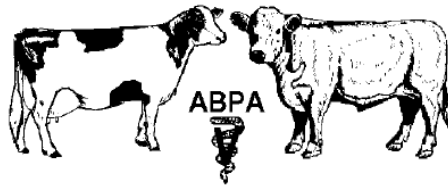
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