Comments on CFIA's August 2017 proposal

Contaminant Standards for Aflatoxins, Deoxynivalenol, Fumonisins, Ergot Alkaloids and *Salmonella*

Submitted by the Animal Nutrition Association of Canada

September 22, 2017

The following comments are submitted by the Animal Nutrition Association of Canada (ANAC) and were developed with a team of Canadian experts from ANAC's Nutrition Committee and general membership.

For almost 90 years, ANAC has represented the interests of Canada's livestock and poultry feed sector. Our 160 members include feed and ingredient manufacturers and distributors, as well as suppliers of a wide range of goods and services to the feed industry. Taken together, ANAC's membership represents 90 percent of commercial feed manufactured in Canada. The sector is an important component of the agri-food chain and intersects with everyone from grain growers to suppliers of nutrient supplements to producers of meat, eggs, and milk. In 2016, animal feed and animal feed ingredients generated more than C$3.5 billion dollars in cross-border trade between Canada and the United States and more than C$230 million between Canada and the European Union. During the same period, cross-border trade in animal products such as meat, dairy products, eggs, and seafood – all of which rely directly on animal feed – totalled C$12.8 billion between Canada and the United States and C$920 million between Canada and the European Union.

Since its creation, ANAC has worked with its members and partners from other industry segments to ensure the Canadian agriculture and agri-food sector reaches its full potential. ANAC also works closely with its American and European counterparts on industry issues and hopes that the Canadian government continues to focus on harmonizing regulations and policies to maintain smooth trading relationships between the three regions.

ANAC and our team of experts look forward to discussing our comments with CFIA.

GENERAL COMMENTS

Firstly, ANAC and its members recognize that the limits being proposed are intended as maximum levels and do not represent target levels for an optimal diet. However, consideration for poor crop years with high mycotoxin load needs to be incorporated into the proposed maximum limits. The reality for the livestock industry is that animals still need to be fed despite raw material challenges. In these situations, emphasis should be on impact to human food safety and animal health rather than animal growth and performance. Consequently, for deoxynivalenol (DON) and fumonisins, which have minimal transmission

and impact on human health and food safety, we recommend utilizing the terminology “action levels” whereby action needs to be taken to reduce the symptoms of mycotoxicosis, rather than “maximum limits”. This would provide regulatory flexibility while ensuring that animal and human health is maintained.

Rapid tests for mycotoxins at feed mills are very useful for accepting/rejecting loads of grain or segregating contaminated grains. When asked about variability in mycotoxin testing, CFIA responded that the inherent variability in testing should not impact the proposed standards as it does not impact the industry practices of testing for biological contaminants in their feed products. On the contrary, variability in mycotoxin distribution, sampling and testing pose significant challenges when assessing mycotoxin levels in a shipment and for regulating mycotoxins. Results from in-house testing and ring tests from ANAC member companies can be shared to illustrate this point. Testing from an external or certified laboratory can be limited by poor sampling procedures as well as sample preparation and methodology. In a scientific opinion published by the EFSA Panel on Contaminants in the Food Chain, it was suggested that “considerable analytical variability exists in the determination of DON (levels)” and that we need greater “standardization of lab analyses and validation procedures to make more reliable conclusions about risk levels” (Knutsen et al., 2017). Analytical testing also has limited value for feed mills due to slow turn-around times. Loads of grain are often used in the manufacturing of feed before results are available.

Apart from aflatoxins, the mycotoxins in the proposal have minimal or no human food safety risk. In years when the levels of mycotoxins are high, nutritionists routinely balance animal health and performance with financial considerations. For these reasons, setting overly restrictive mycotoxin levels, especially for single ingredient feeds, does not justify the significant potential loss of agricultural output and negative impact to the economic feasibility of livestock production.

In order to reduce the risks of mycotoxins, the feed industry employs a number of tools including analytical testing, segregation of contaminated grains and incorporation at different inclusion levels. Currently, feed additives that mitigate the risk of mycotoxins on animal health and performance are a critical tool that are not acknowledged in the CFIA proposal. The evolution of mycotoxin “binding” technology should be considered, as products with repeatable data are being developed to improve the usability of contaminated feedstuffs (Loi et al. 2017). Further, future monitoring of livestock exposure by biological matrices will be more applicable once these techniques are in place (for diagnostics if not for feed quality control) (Lauwers et al. 2016). Additionally, extensive research funding is supporting the development of new detoxification strategies that would not be available in Canada if proposed maximums were enforced (Zhu et al., 2017). The approval of additional mycotoxin binders will aid in mitigating the risks. Enforcing maximum limits without acknowledging the feed industry’s tools for reducing risk is not helpful for managing mycotoxin challenges that occur across Canada every year in specific locations and provinces. In summary, reducing the risk of mycotoxins at a feed mill level is more complicated than looking at maximum limits and setting those for regulatory compliance.

Regardless of the final outcome of CFIA’s consultation on maximum biological contaminant levels, it should be recognized that standards in foreign jurisdictions (including Canada’s major trading partners such as the US and EU) may differ. Consequently, to facilitate trade, maximum contaminant levels for feed and feed ingredients designated for export should be subject to the regulations of the importing

country. For example, if a load of grain is judged by a CFIA inspector to be out of compliance due to a mycotoxin contaminant, but the levels found do not contravene US levels, this shipment of grain should be allowed to be exported to the US. CFIA's consolidated proposal stipulated that feeds and feed ingredients for export need to meet Canadian regulations; however, this is impractical and must be addressed in the new regulations.

Finally, ANAC recommends that the limits be re-evaluated, at a maximum, two years following implementation. This is especially appropriate for ergot alkaloids as there is a significant body of relevant research that is currently in progress.

In the following sections, please find our comments on specific contaminants proposed as well as our rationale for the levels we have recommended.

LIMITS FOR SINGLE INGREDIENT FEEDS

CFIA is proposing maximum limits for aflatoxins, DON, fumonisins and ergot alkaloids for single ingredient feeds. Except for aflatoxins, whose concentrations may increase with storage and which have potential food safety concerns, ANAC does not support setting maximum limits for single ingredient feeds as described in the proposal.

Although the commercial feed industry in Canada has long advocated shared responsibility of feed and food safety across the value chain, the proposal fails to account for years when crops have high mycotoxin levels in various parts of the country due to weather and other factors which are outside the control of producers. Furthermore, there are significant complexities related to accountability, monitoring, and enforcement when maximum limits are exceeded.

Commercial feed facilities are typically multi-species and the majority do not have the storage or bin capacity to segregate ingredients based on different levels of mycotoxins. It is impractical to set different maximum levels for single ingredients based on species. Similarly, setting relatively conservative limits discounts the importance of analytical testing and feed formulation in mitigating mycotoxin risk. We thus put forward that single ingredient feeds should have relatively high tolerances that are the same regardless of species.

For DON and fumonisins, ANAC recommends the highest levels proposed by CFIA for any given species be adopted for all species. In the case of DON, this value was lower than the limit we proposed in total diet for a couple of species, based on a review of scientific literature. As this seems illogical, the level of the highest target species was recommended. For single ingredient feeds, ANAC therefore proposes an action level of 20 ppm for DON and 100 ppm for fumonisins.

Finally, we recommend that the Agency explore alternative policy tools to reduce mycotoxins entering the feed chain (e.g. via Canadian Grain Commission). Continued surveillance of single feed ingredients coupled with action levels whereby industry can work towards desired levels and still offer flexibility could also be considered.

AFLATOXINS

ANAC supports the maximum limit of aflatoxins as proposed (20 ppb in single ingredient feeds and in total diet).

DEOXYNIVALENOL (DON) – LIMITS IN TOTAL DIET

Deoxynivalenol (DON) has a high prevalence (68-80%) in North America (Schatzmayr and Streit 2013, Biomin 2017). During cool, wet crop years, DON levels in grain and grain by-products (i.e. distillers' grains, corn gluten meal, mill run, screenings, etc.) can be quite high. A significant amount of data from routine data collection of member companies is available for further discussion if required. The natural occurrence of DON in grains used for animal feeds is normally between 0 and 5 mg/kg, although concentrations can be higher (Chaytor et al. 2011). In grain by-products, the level is magnified, and can be as high as three times these levels in corn DDGs and even higher in corn gluten feed. Consequently, it is possible to have crop growing years whereby a significant proportion of the Canadian domestic grain crop would be unavailable to the feed industry because of CFIA's proposed maximums on DON. This would have a negative impact on the economic viability of both Canadian processor groups and crop growers.

Despite potential damaging effects on animal health and performance, DON is not significantly incorporated into body tissues or fluids when consumed by animals, and thus will not be transferred to humans consuming animal products (Chaytor et al. 2011). Deoxynivalenol that is excreted from the body into the urine or feces is primarily in the form of de-epoxy-deoxynivalenol (DOM-1), which is a nontoxic metabolite due to an altered ring structure (Chaytor et al. 2011).

Beef

Ruminants are considered to have relatively high tolerance to deoxynivalenol (Seeling and Danicke 2005; DiCostanzo et al. 1995). DON undergoes extensive conjugation in the liver, resulting in rapid clearance from the body via urine (Seeling and Danicke 2005). In an EFSA Scientific Opinion related to the risks of DON on animal and human health (Knutsen et al., 2017), the "no observed adverse effect levels" (NOAEL) were 10 and 18 ppm for heifers and steers, respectively. It has been demonstrated that finishing feedlot steer performance was not impacted by DON levels up to 21 mg/kg diet dry matter (DiCostanzo et al. 1995). While DON residue in tissue has not been well investigated, little carryover into milk has been found, even after long term exposure (Charmley et al. 1993; DiCostanzo et al. 1995). Given these data, we suggest an action level of 20 ppm for DON for beef cattle.

Dairy

Response to DON in dairy cow diets has been variable. Dry matter intake and milk production of dairy cows exposed to DON levels up to 14.6 mg/kg for short term (3 weeks; Ingalls 1996) or lower levels (3.6 mg/kg) for longer term (56 days; Korosteleva et al 2007) was not different from the control; milk composition and somatic cell count (SCC) were evaluated in the longer-term study also without differences to the control. Conversely, Charmley et al. (1993) found a tendency for reduced milk production when diets contained 2.6 to 6.5 mg/kg DON. Likewise, Diaz et al. (2001) found dairy cows consuming diets containing 2.5 mg/kg DON (in combination with other mycotoxins) produced more milk when a clay mycotoxin sequestering product was included in the diet, indicating that DON does impact

milk production. The EFSA scientific panel on the risks of DON on human and animal health (Knutsen et al., 2017) reported a NOAEL of 5.2 ppm for dairy cattle. Current FDA advisory levels for DON for the total ration for ruminating beef and feedlot cattle older than 4 months is 10 ppm DON. The total ration for ruminating dairy cattle older than 4 months is 5 ppm DON (FDA 2010). As safety and not animal performance should be the priority of this proposal, we propose an action level of 5 ppm DON for both lactating dairy cattle and calves less than 4 months of age. Consequently, all dairy cattle would have an action level of 5 ppm DON.

Swine

A maximum of 1 ppm DON in the total daily diet for swine as proposed by the CFIA will be too restrictive, given the natural occurrence of DON in grain, and the concentration of DON in by-products commonly used in the Canadian swine industry, as previously referenced (Chaytor et al., 2011). Furthermore, there is a lack of evidence demonstrating risk to environment or human health to support a max of 1 ppm on DON in swine feed.

In field case reports and controlled studies of DON levels, variation exists in the impact on swine health and performance (Friend et al., 1986; Foster et al., 1986). The effects of feeding DON-contaminated grains to swine (including reduced average feed intake and daily gain, vomiting, immune system suppression, and organ damage) have been observed at low and high levels of DON (Chaytor et al. 2011; Friend et al., 1986; Foster et al., 1986). Several factors are known to explain this variation: nutritional status of the animals (adequate vs nutrient deficiency), sex (gilt vs barrow), naturally contaminated vs inoculated diets, presence of other mycotoxins, and improper sampling and methodology (Friend et al., 1986). The effects of DON can also vary depending whether naturally-contaminated material (which may contain other unidentified toxic compounds) or pure toxin is used (Friend et al., 1986; Foster et al., 1986; Rotter et al, 1995).

Chavez and Rheaume (1986) found that performance was maintained in grower/finisher pigs fed a high-density diet (to compensate for reduced feed intake) when contaminated cereals were fed in total diets that contained 3 ppm or less of DON. In this study, the authors found no difference in the biochemical analysis of plasma samples from animals in different dietary treatments. There are numerous trials showing no evidence of a negative effect on growth performance or various animal health measures when feeding DON past 2 ppm, and up to 3.7 ppm (Danicke et al., 2004). There is evidence of DON negatively impacting animal performance and other measures at higher levels (> 6 ppm).

For nursery pigs, the data set is variable and there seems to be some influence of the nature of contamination (naturally contaminated grain vs. cultured toxin) on performance, even at low concentrations. Artificial toxin application seems to produce more drastic toxin response. Evidence of DON having a negative impact on growth performance at lower levels is not consistent or even widespread. There was also evidence of piglets being able to maintain statistically similar gain at 6 ppm DON (Wu et al, 2015) and numerous examples of piglets maintaining statistically similar gain at 3 ppm DON.

For gilts, Alma et al. (2006) demonstrated the dangers of feeding diets contaminated with high levels of DON to reproductive gilts. However, in combination with the data from Danicke et al. (2005) and

Gutzwiller et al. (2009), there appears to be no affect of feeding up to 2 or 3 ppm DON on numerous reproductive measures or indicators of proper gilt development.

For sows, there is evidence of elevated DON levels causing decreased feed intake in both gestating and lactating sows. However, in numerous trials, DON had no negative effect on sow reproductive performance, subsequent reproductive performance or piglet performance. In recent trials (Gutzwiller, 2010 and Herkelman et al., 2017) DON was fed up to 3 ppm with no negative effect on lactating sow reproductive performance.

In summary, the data referenced provides a wide range of evidence that deoxynivalenol can be fed to swine above 1 ppm with no observed negative effect on pigs at various stages of production. Due to even less consistency of results in young pigs and the sensitive nature of nursery production, perhaps there is more reason to be cautious with regulations for nursery piglets (< 20 kg BW). However, the research discussed clearly demonstrates that pig performance and health in other stages of production are not compromised by feeding upwards of 3 ppm DON. Therefore, increasing the maximum to 3 ppm for all classes of swine would be a practical maximum that would allow nutritionists to formulate to a level of DON based on experience and field conditions.

Others

ANAC proposes higher limits for ducks/geese, sheep, and equine with levels of 7, 16, and 20 respectively. These values are based on the no observed adverse effects levels from the recently-published EFSA Scientific Opinion entitled "Risks to human and animal health related to the presence of deoxynivalenol and its acetylated and modified forms in food and feed" (Knutsen et al., 2017). (Note that the NOAEL for equine reported was 36 ppm; however, we feel that setting the tolerance at 20 ppm will provide sufficient manufacturing flexibility.) Although these levels appear high compared to European and US thresholds, this scientific opinion likely includes new developments that were not considered by these jurisdictions in their evaluations of maximum limits.

Table 1 summarizes CFIA's proposed maximum limits for deoxynivalenol compared to ANAC's proposed levels.

Table 1: Proposed limits for Deoxynivalenol from CFIA and ANAC

	Current Action Level (as per RG-8)	CFIA Proposed Max Limit		ANAC Proposed Action Level	
Species/Class of Animal	**Complete diets (ppm)**	**Single ingredient feeds (ppm)**	**Total diet (ppm)**	**Single ingredient feeds (ppm)**	**Total diet (ppm)**
Cattle – calves (<4 mo)	1	5	1	20	5
Cattle – Beef	5	10	5	20	20
Cattle – Dairy	5	10	5	20	5
Lactating Dairy Animals	1	5	1	20	5
Swine	1	5	1	20	3
Poultry: chickens, turkeys, ducks	5	10	5	20	Chickens 5
					Ducks/geese 7
Other animals incl sheep, equine, rabbits	None	10	5	20	Sheep 16 Equine 20
					Rabbits 5

FUMONISINS – LIMITS IN TOTAL DIET

There is support for the proposed levels for fumonisins in the total diet for swine and adult ruminants. We are proposing a higher limit for horses, rabbits, breeding/lactating ruminants and poultry. In a review documented by the European Food Safety Authority (EFSA) research has shown there are no observed adverse effects at the following levels of fumonisins: Pigs/Horses/Rabbits 5 mg/kg, Poultry/Calves 20 mg/kg, Adult Ruminants 50 mg/kg (EFSA 2005).

Table 2 summarizes CFIA's proposed maximum limits for fumonisins compared to ANAC's proposed levels.

Table 2: Proposed limits for Fumonisins from CFIA and ANAC

	Current Action Level (as per RG-8)	**CFIA Proposed Max Limit**		**ANAC Proposed Action Level**	
Species/Class of Animal	**Complete diets (ppm)**	**Single ingredient feeds (ppm)**	**Total diet (ppm)**	**Single ingredient feeds (ppm)**	**Total diet (ppm)**
Horses	None	5	1	100	4
Rabbits	None	5	1	100	4
Swine	None	20	10	100	10
Ruminants (beef cattle, dairy cattle, sheep and goats & other ruminants >4 mo old & fed for slaughter	None	60	30	100	30
Ruminants (breeding – bulls, lactating dairy cattle)	None	30	15	100	20
Poultry (Turkeys, chickens, ducklings & other poultry fed for slaughter)	None	100	50	100	50
Poultry (Laying hens & roosters for breeding stock)	None	30	15	100	20

ERGOT ALKALOIDS (EA)

The Canadian feed industry has long recognized the difficulties related to ergot in feed and continues work on minimizing the impact on our industry. ANAC strongly believes that it is premature to regulate maximum ergot alkaloids in feed. Ongoing research projects, the results of which will be published over the next several years, will contribute greatly to the current knowledge. Consequently, ANAC urges CFIA to remove this category of contaminants from the document and reconsider its regulation at a later date; or at the minimum, maintain the current action levels in total diets. We recommend that CFIA continue to extensively monitor the levels of ergot alkaloids in feed and feed ingredients in Canada so that appropriate and achievable maximum levels of ergot alkaloids can be considered in regulation for the future. For single ingredient feeds, implementing an action level based on ergot bodies (consistent with Canada Grain Guide method of assessing quality) could be considered to minimize the amount of ergot entering animal feed.

In the following section, we have detailed the reasons we do not support setting maximum targets for ergot alkaloids in feed at this time.

There is no rapid test.
There is no rapid test for ergot alkaloids (unlike the other mycotoxins in the proposal). The only method is visual, which reflects the percentage of ergot bodies rather than ergot alkaloid content. There is currently no way for the grain or feed industries to test for ergot alkaloids in real time which creates significant challenges for compliance if they were regulated. ANAC member companies have been advocating for the development of a similar test for ergot from the suppliers of mycotoxin quick testing methods but realistically, this is several years away.

Industry practices related to the sale of seed or the trade of grains are not based on ergot alkaloids.
The Official Grain Grading Guidelines regulates ergot in grain by calculating the percentage of ergot in a set amount of grain. This method or that of the Canadian Seed Regulations (counting ergot bodies) are commonly used by the feed industry, not only in Canada, but around the world. Newly published work from Canada shows that the relationship between these two measurements and ergot alkaloid content is weak when feed grain (in this case wheat) contained less than 350 ppb (Grusie et al., 2017). The relationship was stronger between both weight/count when total ergot content (no epimers considered) was >350 ppb but error of estimation was high. (If grains were included with more than 350 ppb, the correlation was higher, but the error was large.) These authors concluded “the data indicate(s) that ergot count and weight were not predictive of diagnostically relevant ergot concentrations.” We would therefore put forward that the feed industry cannot be regulated to a standard of total ergot alkaloid concentration, when a) other important grain industries in Canada are regulated by weight or count and b) weight and count are the only indices available to operate in real time, but research has shown they are not strongly related to total ergot alkaloid content.

Analytical methodologies have not been standardized and results are highly variable.
Currently, the quantity of ergot alkaloids can only be determined by commercial laboratories. The analytical variability between commercial laboratories in Canada is quite significant and well documented. (Neither of the two labs offering ergot alkaloid analysis are accredited for ergot analysis.) Disparity in results between laboratories is a major roadblock in setting maximum limits. In some cases, the difference between the labs on split samples can be three times the standard being proposed. ANAC member companies have data supporting this that can be shared. Simple factors such as grind size and sample volume used in analysis can greatly affect the quantification of total ergot alkaloid content (Grusie et al, 2017). Setting limits for ergot alkaloids in light of these inconsistencies is unworkable.

The issue of accredited/certified laboratories available for chemical determination of ergot alkaloids in Canada should be addressed prior to setting maximum limits in feeds. First, there is no official method of determination of ergot alkaloids in feeds. Secondly, the only lab “certified” on an international basis to perform ergot analysis in Canada is the Canadian Grain Commission. If incorporated into regulation, the number of labs accredited should either increase or methodology should be standardized so that more labs can manage the potential increase in demand for analysis. Neither commercial laboratory offering total ergot alkaloids analysis (TEA) for *Claviceps purpurea* in Canada currently includes the epimers. The number of ergot alkaloids and the specific epimers should be defined.

There is limited data showing that ergot alkaloids impact animal safety.
The proportion of individual alkaloids, including ergotamine, ergocristine, ergosine, ergocornine, and ergocryptine is extremely variable within ergot bodies and the relative toxicity of these alkaloids has yet to be determined. To further complicate matters, the total alkaloid content in ergot varies depending on geographic region, harvest year, cereal species, variety, and genotype. Variability in alkaloid content and profile among samples is an important variable that needs to be recognized when applying the results of ergot feed research. This has led researchers in the field to conclude that current recommendations on safe levels of ergot in feeds may be unreliable.

Maximum limits on animal and human safety should be based on literature that shows cause and not association. There is little data that shows this. EFSA concluded in a report in 2005 that "[d]ata on the sensitivity of agricultural animal species towards ergot alkaloids are incomplete and do not allow the establishment of tolerance levels for individual ergot alkaloids and mixtures thereof". EFSA 2012 indicates that "[r]isk characterization/conclusion reported by EFSA (2005) can only be updated with new information for pigs". The committee felt that information for cattle, sheep and poultry was incomplete.

Arcella et al. (2017) reported on the dietary exposure levels of ergot alkaloids in the EU between 2011 and 2016. Dietary exposure estimates for animals, assuming a mean concentration scenario, varied between 0.31–0.46 lg/kg bw per day in beef cattle and 6.82–8.07 lg/kg bw per day (LB–UB) in piglets, while exposure estimates assuming a high concentration scenario (95th percentile) varied between 1.43–1.45 lg/kg bw per day and 16.38–16.61 lg/kg bw per day (LB–UB) in the same species. Animal exposure was calculated based on data from grain cereals, forages, and roughages as ergot alkaloids in feed are scarce (low number of samples available for each target species/category) and do not allow a reliable exposure estimate to be made.

Key trading partners are not currently regulating ergot alkaloids.
Ergot alkaloids are not regulated in feed in most jurisdictions. In fact, the only countries currently regulating ergot alkaloid content in feed (not grain) are Uruquay and Canada (Scott, 2009). The EU has been monitoring ergot alkaloid levels for several years with the view of potentially setting maximum targets. The results of a human and animal dietary exposure study was published in May 2017 (Arcella, 2017). New levels in regulation were to be adopted by August 2017, but have been delayed. At a minimum, we recommend better understanding of the European position prior to setting maximum levels in Canada, especially given the many challenges related to ergot (e.g. variable results, limited studies on safe levels, lack of rapid test methods). In the meantime, it is recommended that monitoring of ergot alkaloids in feed continue so that the levels set are appropriate and achievable.

New and relevant research is in progress and will be soon ready for publication.
Recommended limits for ergot in literature vary considerably and can be confusing as they may be reported as percentage of total ergot bodies or by total levels of alkaloids. The University of Saskatchewan has recently submitted four papers for publication on ergot and animal feeding. Likewise, Dr. Kim Stanford from Alberta Agriculture is completing a three-year study with sheep that could be useful in determining levels of ergot alkaloids for growing versus lactating sheep, and the effect of binders on ergot toxicity. In addition, there is a significant amount of research poised for publication in

the next couple of years, which would add greatly to our understanding of what ergot is shown to cause, rather than just associations.

Data on endophyte-fescue ergot (ergovaline, forage only) should not be used to determine tolerances for rye ergot (*Claviceps purpurea*), which is more relevant for Canadian livestock. Much of the literature referencing sheep is based on ergovaline. Klotz (2007) reported that while ergot alkaloids from *Claviceps* elicited a contractile response at a similar dose to ergovaline, the latter was more potent (68.5% versus 45.5, 42.9 and 57.2% for ergovaline versus ergocryptine, ergocrostine and ergocornine, respectively). Likewise, there are several studies based on feeding sorghum ergot (mainly dihydroergosine). The potency of this ergot alkaloid compared to that from rye ergot is unclear. Some literature reports that dihydroergosine is much less toxic to laboratory animals than is ergot alkaloids from rye (*Claviceps purpurea*) while other Australian research disagrees. This complicates any decision regarding establishment of maximum limits. It would be prudent to review research specifically related to rye ergot (*Claviceps purpurea*). Should insufficient relevant research be available, increased monitoring of rye ergot should be considered until appropriate and achievable levels can be established.

CFIA states in its proposal that "processing has no impact on toxicity". Whether or not this is the case, processing may impact the ability of a laboratory to extract ergot alkaloids. There is some data suggesting that heat treatment can decrease toxicity of ergot alkaloids. Mainka et al. (2005) published a study where steam (95 degrees) was applied for 2 minutes, followed by expanding (5 sec, 120 Degrees C, pressure) to 4 batches of rye ergot. They found that the hydrothermal treatment decreased total ergot alkaloids by approximately 10%, increasing the -inine isomers which are shown to be less toxic. The food industry has published studies showing that the baking process decreases ergot alkaloid toxicity. Further research on ways to decrease ergot toxicity along with the impact of potential binders should be considered in setting maximum limits.

Table 3 summarizes CFIA's proposed maximum limits for ergot alkaloids compared to ANAC's proposed action levels.

Table 3: Proposed limits for Ergot Alkaloids from CFIA and ANAC

	Current Action Level (as per RG-8)	**CFIA Proposed Max Limit**		**ANAC Proposed <u>Action</u> Level**	
Species/Class of Animal	**Complete diets (ppm)**	**Single ingredient feeds (ppm)**	**Total diet (ppm)**	**Single ingredient feeds (ppm)**	**Total diet (ppm)**
Weaned piglets	4	3	1	No level	No level or 4
Growing-finishing pigs & sows	4	6	2	No level	No level or 4
Poultry	6	6	2	No level	No level or 6
Cattle	2	2	1	No level	No level or 2
Sheep	2	0.6	0.3	No level	No level or 2
Horses	2	0.3	0.15	No level	No level or 2

SALMONELLA

ANAC does not support CFIA's proposal to amend Section 19 of the *Feeds Regulations* to indicate that "…a feed shall not contain…(xx) *Salmonella* that presents a risk of harm to human or animal health or the environment", essentially formalizing CFIA's longstanding policy on zero tolerance for *Salmonella*. We propose that the regulation reference restriction of serotypes pathogenic to animals, with specific serovars, scientific rationale and risk classification, described in a document that is incorporated by reference in the regulation.

There are over 2,400 different serotypes or strains of *Salmonella enterica* (Murray et al., 2009). *Salmonella* are ubiquitous in nature. The expectation of zero tolerance for *Salmonella* considering its prevalence in the supply chain and without referencing specific high-risk serovars is impractical and unworkable. The industry believes that suitable control of the organism and safeguarding of human health can be achieved and does not necessarily mean absolute absence.

Alignment with the United States is imperative with regards to *Salmonella* policy given the high volume of cross-border trade in feed and feed ingredients. FDA's Compliance Policy Guide is widely viewed by American feed ingredient and animal feed manufacturing industries (excluding pet food) as the practical operating procedure for industry which would provide predictability when challenged with a potential non-compliance incident. The Canadian feed industry requests that CFIA identify serovars of specific concern based on high risk and further engage in dialogue with FDA regarding rationale on serovar exclusions. Since 2012, the Canada-US Regulatory Cooperation Council has been engaged in facilitating closer regulatory cooperation between the two countries on a number of files in order to enhance economic competitiveness by aligning our regulatory systems where appropriate, while maintaining high levels of protection for health, safety and the environment.

ANAC and its members support CFIA evaluating on a case-by-case basis the corrective actions and control measures in the event of a positive Salmonella result; however, we request that the process be documented and more predictable. Industry would welcome the opportunity to work with the Agency to produce a guidance document(s) that would incorporate a decision tree/flowchart, providing a measure of predictable outcomes when assessing contamination risks.

It should be recognized that controlling *Salmonella* at the feed mill is nearly impossible if present in incoming ingredients and is difficult to eliminate once detected due to high potential for cross-contamination once in the manufacturing facility. Focusing enforcement of *Salmonella* policy at this stage in the supply chain has limited effectiveness if decreasing *Salmonella* in the food supply chain is the ultimate objective. There is no rapid assay for *Salmonella*, which limits preventive controls on incoming ingredients. Additionally, there are only a limited number of local suppliers for certain feed ingredients. Inactivation of the organism by heat treatment is not always possible, practical, or desirable. Due to the numerous challenges related to *Salmonella* control, feed manufacturing operations rely heavily on their suppliers to lower the risk of contamination. To reduce the prevalence of Salmonella in the food chain, an integrated farm to fork approach should be considered.

Chemical treatment may be effective in reducing *Salmonell*a occurrence; however, no commercial *Salmonella*-control products have yet been recognized in Canada despite being approved in other

jurisdictions. This limits the tools available to the feed industry to manage *Salmonella* if it enters a facility. CFIA must start recognizing feed ingredients (additives) which have the ability to control pathogens, such as *Salmonella*, both in feed and in-vivo. This approach is considerably more practical and realistic to minimize the risk of *Salmonella* both to livestock and humans than CFIA's current zero tolerance policy with no tools to enable industry to come into compliance.