Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Proposal - Maximum Nutrient Values in Fish (Freshwater and Marine) Feeds

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Canada

Purpose

As part of a comprehensive, multi-year regulatory modernization process, the Canadian Food Inspection Agency (CFIA) has initiated the renewal of the federal *Feeds Regulations* (Regulations) as one of several priorities identified for modernization.

The goal of renewing the Regulations is to develop a modernized risk- and outcome-based regulatory framework for feeds which:

- safeguards feeds and the food production continuum;
- attains the most effective and efficient balance between fair and competitive trade in the market; and
- minimizes regulatory burden.

Modernization of the Regulations provides the opportunity to review feed controls, standards, labelling and other regulatory requirements. The purpose of this proposal is to:

- review the nutrient content standards for fish feeds set out in Table 4 of Schedule I of the current Regulations which the CFIA has used to exempt complete feeds and some supplements from registration; and
- recommend possible updates or amendments to the current requirements.

Background and Current Situation

Table 4 of Schedule I was created and incorporated into the *Feeds Regulations* in the 1980s as a mechanism to exempt certain groups of feeds from mandatory registration. The original Table 4 established nutrient ranges (minimums and maximums) as exemption criteria for feeds for chickens, turkeys, swine, beef and dairy cattle, and sheep. In 1990, via two regulatory amendments, the table was first expanded to include horses, goats, ducks, and geese; and then for rabbits, mink, and salmonid fish. Since that time, there have been no other substantive changes to the table or to any of the nutrient ranges.

Currently, if

- a complete feed provides nutrients which fall within the ranges listed in Table 4; or
- a supplement has directions for use which would result in a complete feed that provides nutrients which fall within the Table 4 ranges,

then the feed can be exempted from registration. Feeds that provide nutrients which fall outside the ranges listed in Table 4, and that do not meet any additional exemption criteria, require assessment and registration by the CFIA prior to manufacture and sale.

In the case of fish feeds, Table 4 of the Regulations currently establishes nutrient ranges only for salmonid species, e.g. salmon and trout. The Feed Regulatory Renewal Consolidated Modernized Framework Proposal – November 2015 (Consolidated Proposal) proposed that the scope of the species to which the *Feeds Regulations* apply would be expanded to include feeds for animals that are raised for human consumption. In addition, the Consolidated Proposal suggested clarification would be provided regarding which species of fish would be subject to the Regulations. As such, the species of fish has been expanded to include those raised commercially in Canada.

As indicated in the Consolidated Proposal, both the CFIA and stakeholders recognize that some of the values in Table 4 may no longer have the same nutritional relevancy that they did when the table was first introduced. Stakeholders have also indicated that they feel that Table 4 prevents innovation for new feed products. However, many of the maximum nutrient levels which are currently set out in Table 4 have health and safety implications that must be considered.

Proposal

It is proposed that:

1. Table 4 be removed from the Regulations and no longer serve as a trigger to register feeds based on specified ranges of nutrient content; and,
2. maximum nutrient levels be established for fish (freshwater and marine) feeds.

This proposed approach addresses stakeholder concerns regarding Table 4 and its relevance in current industry practices, as well as claims that the nutrient ranges provided in Table 4 impede new products from entering the marketplace. Furthermore, it addresses concerns regarding the harmful impact that higher levels of certain nutrients may have on livestock or the resulting food products, and underscores the modernized regulatory framework's focus on health and safety for humans, animals, and the environment. It is further proposed that:

- minimum levels for nutrients will no longer be established, however, feeds will still be required to be suitable for their intended purpose and must meet an animal's nutritional requirements;
- maximum levels for nutrients will be established initially for families of finned fish raised commercially for human consumption; and,
- nutrient maximum levels will be incorporated by reference in the *Feeds Regulations* to facilitate updating, as necessary.

Considerations

The domestic feed industry considers that the Table 4 nutrient ranges are out of date, and that this table is no longer an appropriate regulatory tool for feeds. However, there remains a continued need for an enforceable regulatory framework regarding maximum nutrient concentrations in livestock feeds for health and safety reasons. For instance,

levels of certain vitamins in livestock rations (e.g., vitamins A, D, and E) in excess of nutritional requirements can be harmful to livestock or can be concentrated into tissues that are used for human consumption, thus posing potential risk to human health. Similarly, certain minerals (e.g., copper, iodine, phosphorus and zinc) fed in excess of livestock requirements can also contribute to increased human and environmental risks.

A significant proportion of minerals fed in excess of requirements are excreted into the environment via urine and feces. Consequently, even though the maximum tolerable level (MTL) of a given mineral may be significantly greater than the nutritional level, feeding at the maximum tolerable level may result in negative impact on the environment.

An analysis of fish nutritional requirements and maximum tolerable dietary nutrient levels was conducted by the CFIA with the following scope:

- to determine those nutrient levels that may impact the health and safety of the respective livestock, humans, and environment;
- to determine those nutrient levels that support a nutritional purpose as opposed to a therapeutic purpose; and,
- to determine those nutrient levels that may produce residues in the resulting food that could be harmful to those consuming the products.

Information sources used in the review and development of nutrient maximums in fish (marine and freshwater) feeds included:

- recommendations and formal opinions provided by other national authorities and food safety agencies (e.g., the National Research Council of the National Academies, the European Food Safety Authority, etc.);
- research published in peer-reviewed literature (e.g., Journal of the World Aquaculture Society and Aquaculture Nutrition); and,
- Academic text books, (e.g. Nutrient Requirements and Feeding of Finfish for Aquaculture, Ed. By C.D. Webster and C.E. Lim, 2002; Fish Nutrition, 3rd Edition. Ed. By J. E. Halver and R. W. Hardy, 2002).

Appendix I sets out the proposed maximum nutrient values for fish (marine and freshwater) feeds.

Anticipated Outcomes

This modernized regulatory approach to the oversight of maximum nutrient content in fish (marine and freshwater) feeds would:

- give regulated industry the flexibility to manufacture feeds with nutrient contents that meet their customers' needs without requiring pre-market assessment and authorization;

- allow the CFIA to maintain regulatory oversight for hazards that may negatively impact human or animal health or the environment;
- allow for timely updates to the standards as new information concerning specific nutrients is provided; and,
- reduce the regulatory burden on industry wishing to get innovative products into the marketplace.

Stakeholders are being provided with an opportunity to comment on all proposals, including the maximum nutrient values being suggested for each species or class of species, before they are incorporated into a regulatory framework.

References: A complete bibliography is available upon request.

Have your say

The CFIA is seeking feedback on the proposal to modify the regulatory requirements related to maximum nutrient content in livestock feed:

- Do you have any concerns with the proposal to remove the Table 4 nutrient levels from the *Feeds Regulations* and no longer exempting feeds from registration based on the nutrient content of the feeds?
- Do you have any concerns with the proposal to establish maximum nutrient values for livestock feeds?
- Do you have any concerns with the proposed maximum nutrient values outlined in Appendix I for fish feeds?
- Would the proposed amendments to the *Feeds Regulations* be effective in protecting human and animal health and the environment?
- Are there options not mentioned in this proposal that should be explored?
- Any additional feedback?

We strongly encourage you to provide your input and feedback, which is critically important to the success of the regulatory modernization initiative. Please send written comments by XXXXXX to:

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Appendix I – Proposed Maximum Nutrient Values for Fish Feeds

List of Regulated Fish Families

Current	Proposed
Salmonids (Salmon, Trout, etc.)	Salmonids (Salmon, Trout, etc.) Cichlids (Tilapia, etc.) Anoplopomatids (Sablefish, etc.) Pleuronectids (Halibut, Sole, etc.) Percids (Perch, etc.) Other (remaining commercially raised fish species)

Considerations:

- List expanded to include those fish raised commercially for human consumption.

Macro-minerals

Calcium (Ca)

Class	Current (% of complete feed, as fed)	Proposed (%, at 88% dry matter [DM])
Fish (All)	3.0	NRS (No requirement specified)

Considerations:

- Calcium (Ca)-rich water is essential for successful fish culture (National Research Council (NRC), 2011).
- As such, metabolic requirements for Ca are often met through the absorption of ions from the aquatic environment (NRC, 2011).
- In the absence of waterborne Ca sources, dietary Ca requirements vary between 0.03% and 0.70% of the total diet based on the species of fish and stage of production (Halver and Hardy, 2002; NRC, 2011).
- NRC (2011) identifies 7 types of fish meal with Ca levels ranging from 2.2 to 7.86% (as-fed basis) and NRC (2016) characterizes Ca levels in fish meal on a dry matter basis of 5.2 ± 2.41% (n=143) giving an upper 95% confidence limit of 9.9%. From this upper level, fish meal alone used at 40 – 70% of fish diets would contribute 4 - 7 % Ca to the diet (DM) equivalent to 3.5 - 6.1% on an 88% DM basis.

Phosphorus (P)

Class	Current (% of complete feed, as fed)	Proposed (%, at 88% DM)
Fish (All)	2.5	3.5

Considerations:

- Phosphorus (P) concentrations are low in both freshwater and saltwater; therefore, fish rely primarily on their diet to meet their P requirements.
- P requirements are 0.33% to 1.5% of total diet depending on species of fish, rearing conditions, and stage of production (NRC, 2011).
- Increasing total phosphorus to greater than 2.0% of the diet results in poor feed conversion ratios, reduced growth, and increased mortalities (Skonberg et al., 1997; Fontagne et al., 2009).
- NRC (2011) identifies 7 types of fish meal with P levels ranging from 1.67 to 4.21% (as-fed basis) and NRC (2016) characterizes P levels in fish meal on a dry matter basis of 2.9 ± 1.07% (n=146) giving an upper 95% confidence limit of 5%. From this upper level, fish meal alone used at 40 – 70% of fish diets would contribute 2 – 3.5 % P to the diet (DM) equivalent to 1.8 - 3.1% on an 88% DM basis.
- P supplied in excess of dietary needs is excreted in the urine and/or feces, contaminates the water and the environment, and leads to eutrophication; a significant environmental concern (NRC, 2005).

Magnesium (Mg)

Class	Current (% of complete feed, as fed)	Proposed (%, at 88% DM)
Fish (All)	0.3	0.3

Considerations:

- Magnesium (Mg) is readily absorbed from the water to satisfy the nutritional requirements of fish.
- When water Mg is insufficient, dietary Mg requirements vary between 0.02% and 0.07% of the total diet (NRC, 2011).
- NRC (2005) indicates the maximum tolerable limit of Mg to be 0.30%.

Sodium (Na)

Class	Current (% of complete feed, as fed)	Proposed (%, at 88% DM)
Fish (All)	1.2	NRS

Considerations:

- Sodium (Na) is abundant in the aquatic environment and present in substantial amounts in typical feedstuffs.
- Requirements for Na have only been recorded in tilapia (0.15% of diet DM) and channel catfish (0.06% diet DM) (NRC, 2011).
- Diets containing up to 4.8% Na have been fed to fish without adverse effects (Shaw et al., 1975).
- However, excessive Na supplementation may lead to disturbances in acid-base balance and osmoregulation.

Potassium (K)

Class	Current (% of complete feed, as fed)	Proposed (%, at 88% DM)
Fish (All)	1.3	NRS

Considerations:

- Potassium (K) is abundant in feedstuffs and readily absorbed from the water to satisfy the nutritional requirements of fish.
- Dietary K requirements have only been reported in freshwater fish; marine fish can obtain sufficient K from the aquatic environment.
- Requirements for freshwater fish vary between 0.20-0.80% of total diet depending on species of fish, rearing conditions, and stage of production (NRC, 2011).
- Excessive K supplementation may lead to disturbances in acid-base balance and osmoregulation.

Sulfur (S)

Class	Current (% of complete feed, as fed)	Proposed (%, at 88% DM)
Fish (All)	NRS	NRS

Considerations:

- There are no available reports indicating that fish have a dietary requirement for sulfur, nor are there reports of toxicosis resulting from the presence of high levels of dietary sulfur in fish feeds.

Trace Minerals

Cobalt (Co)

Class	Current (mg/kg of complete feed, as fed)	Proposed (mg/kg of diet at 88% DM)
Fish (All)	NRS	3.0

Considerations:

- Fish require cobalt (Co) for the intestinal synthesis of cyanocobalamin (Vitamin B_{12}) and red blood cells.
- Requirements for dietary Co vary between 0.05 to 1.0 mg/kg depending on the species of fish, rearing conditions, and stage of production (Watanabe et al., 1997; Webster and Lim, 2002).
- Co and Co compounds pose a risk to workers during mixing and feeding, due to their dusting potential and presumed carcinogenicity after inhalation (Agency for Toxic Substances and Disease Registry (ATSDR), 2004; European Food Safety Authority

(EFSA), 2009; EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), 2012; EFSA, 2012).

- The need to supply Co as trace mineral salts in fish feeds is very low since nutritional requirements can probably be derived from major feeding components (Watanabe et al., 1997).
- The European Union authorizes a maximum content of 2.0 mg Co/kg diet noting the need to maintain this level based on higher background Co levels in fish meal, a major component of fish diets (The Commission of the European Communities, 2003).
- NRC (2016) characterizes Co levels in fish meal on a dry matter (DM) basis of 1.24 ± 0.68 mg/kg (n=3) giving an upper 95% confidence limit of 4 mg/kg. From this upper level, fish meal alone used at 40 – 70% of fish diets would contribute 1.6 – 2.8 % Co to the diet (DM) equivalent to 1.4 – 2.5% on an 88% DM basis.

Copper (Cu)

Class	Current (mg/kg of complete feed, as fed)	Proposed (mg/kg of diet at 88% DM)
Fish (All)	75.0	30.0

Considerations:

- Copper (Cu) requirements vary between 1.5 and 10.0 mg/kg depending on the species of fish, rearing conditions, and stage of production (NRC, 2011).
- The maximum tolerable level for dietary copper is 100.0 mg/kg and 500.0 mg/kg for Atlantic salmon and rainbow trout, respectively (NRC, 2005). However, Clearwater et al. (2002) reviewed the dietborne toxicity of Cu and reported toxicity in:
    - Atlantic salmon Parr at 34 mg Cu/kg diet, and
    - Channel catfish fingerlings at 40 mg Cu/kg diet.
- Elevated levels of dietary Cu may contribute to excessive Cu in the aquatic environment.
- The use of Cu supplements (greatly exceeding requirements) in fish feed also threatens food safety through the potential emergence and spread of antibiotic resistance pathogens.
- The European Union authorizes a maximum content of 25.0 mg Cu/kg diet (The Commission of the European Communities, 2003).
- Characterization of the intrinsic Cu content of feed ingredients supplying macro nutrients was reviewed (Watanabe et al., 1997; NRC, 2011). Considering the typical use of these ingredients in fish feeds meeting the nutrient requirements of fish, the toxicity of Cu to some species, and keeping in mind efforts to limit environmental excess, a limit of 30 mg/kg on an 88% DM basis appears to be achievable without impeding the use of available feed ingredients.

Iodine (I)

Class	Current (mg/kg of complete feed, as fed)	Proposed (mg/kg of diet at 88% DM)
Fish (All)	20.0	70.0

Considerations:

- Iodine (I) is widely available in the aquatic environment.
- Freshwater species of fish are more dependent on dietary I supplementation to meet their metabolic requirements than marine species.
- I requirements vary between 0.6 and 5.0 mg/kg total diet depending on species of fish, rearing conditions, and stage of production (NRC, 2011).
- Marine plants and animals are rich sources of I with some seaweeds containing up to 1000 mg/kg. While most animal and plant protein sources contain negligible amounts of I, fish meals such as normal herring and capelin meal have 5-10 mg/kg and Atlantic white fish meal may contain up to 60-90 mg/kg (Watanabe et al., 1997).
- Fish tolerance to iodine in feed is high (up to 86 mg I/kg feed), tissue deposition of iodine at this level resulted in fish fillets with 0.90±0.37 mg/kg (Julshamn et al., 2006). Based on a reasonable daily intake of 100 g/d of fish, this would result in human exposure of 90±37µg/d which meets the Recommended Dietary Allowance and does not exceed the Tolerable Upper Intake Levels.
- The European Union authorizes a maximum content of 20.0mg I/kg diet to ameliorate consumer risk (EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), 2005).

Iron (Fe)

Class	Current (mg/kg of complete feed, as fed)	Proposed (mg/kg of diet at 88% DM)
Fish (All)	500.0	750.0

Considerations:

- Iron (Fe) requirements in fish vary between 30.0 and 199.0 mg/kg depending on species of fish, rearing conditions, and stage of production (NRC, 2011).
- Elevated levels of Fe are metabolically stressful to fish.
- Although there is limited data, a level of 750.0 mg Fe/kg seems to be protective of animal and human health (EFSA FEEDAP, 2016a).

Manganese (Mn)

Class	Current (mg/kg of complete feed, as fed)	Proposed (mg/kg of diet at 88% DM)
Fish (All)	150.0	150.0

Considerations:

- Manganese requirements vary between 2.0 and 20.0 mg/kg depending on species of fish, rearing conditions, and stage of production (Webster and Lim, 2002; NRC, 2011).

- Limited data prevents the establishment of a maximum tolerable limit for manganese in fish feed.
- The European Union authorizes a maximum content of 100.0mg Mn/kg diet. At this level of supplementation, there is sufficient margin of safety for animal, consumer and environmental health (EFSA FEEDAP, 2016b).
- Proposing to maintain the current level.

Selenium (Se)

Class	Current (mg/kg of complete feed, as fed)	Proposed (mg/kg of diet at 88% DM)
Fish (All)	0.1 (total)	2.0 (total)

Considerations:

- Uptake of selenium (Se) through the gills of fish via the aquatic environment is very effective.
- Dietary Se requirements vary between 0.15 and 0.5 mg/kg depending on species of fish, rearing conditions, and stage of production (Watanabe et al., 1997; NRC, 2011).
- The maximum tolerable level of Se in fish feed is 2.0 mg/kg diet (NRC, 2005).
- Hilton et al (Hilton et al.) found that Se uptake and accumulation in tissues of trout reared on diets containing in excess of 3 mg/kg may ultimately be toxic to trout.
- NRC (2011) identifies 7 types of fish meal with Se levels ranging from 1.36 to 4.30 mg/kg (as-fed basis) From this range and fish meal alone being used at 40 – 70% of fish diets would contribute 1.7 – 3 mg/kg Se to the diet.
- Given the high background concentrations in fish meal, its toxicity to fish, the proposed maximum accommodates animal health, consumer health, and industry practices.

Zinc (Zn)

Class	Current (mg/kg of complete feed, as fed)	Proposed (mg/kg of diet at 88% DM)
Fish (All)	300.0	250.0

Considerations:

- Fish have the ability to absorb zinc via the water but obtain the majority of zinc (Zn) through their diet.
- Zn requirements for fish are estimated to be between 15.0 and 150.0 mg/kg diet based on species, rearing conditions, and stage of production (NRC, 2011).
- However, the use of Zn supplements (greatly exceeding requirements) in fish feed threatens food safety through the potential emergence and spread of antibiotic resistance pathogens.
- EFSA FEEDAP, 2014 suggests a reduction in the allowable zinc in feed to 150.0 mg/kg for salmonids and 100.0 mg/kg for other fish species in order to reduce environmental health and consumer health risks.
- The maximum tolerable level of zinc in fish feed is 250.0 mg Zn/kg feed (NRC, 2005).

Vitamins

Vitamin A

Class	Current (IU/kg)	Proposed (IU/kg of diet at 88% DM)
Salmonids	25,000	100,000
Cichlids	N/A	10,000
Anoplopomatids	N/A	25,000
Pleuronectids	N/A	25,000
Percids	N/A	25,000
Other	N/A	25,000

Considerations:

- Requirements of vitamin A are reported as 0.3 to 31.0 mg/kg (999 to 103 230 IU/kg) depending on species of fish, rearing conditions, and stage of production (NRC, 2011).
- The presumed upper safe levels established by the NRC (NRC, 1987) are 25 000 IU/kg for salmon and trout, and 33 330 IU/kg for catfish.
- Studies indicate salmonid species (Atlantic salmon and rainbow trout, specifically) can tolerate dietary levels of vitamin A up to 400 000 IU/kg and in some instances, as much as 900 000 IU/kg (Hilton, 1983; Ornsrud et al., 2002; Fontagné-Dicharry et al., 2010; Ørnsrud et al., 2013)
- Tilapia fingerlings are more sensitive to dietary vitamin A levels. A slight reduction in growth occurred at 10 000 IU/kg and signs of hypervitaminosis occurred at 40 000 IU/kg (Saleh et al., 1995), while juvenile tilapia tolerated up to 17 534 IU/kg (Guimarães et al., 2014).

Vitamin C

Class	Current (mg/kg)	Proposed (mg/kg of diet at 88% DM)
Fish (All)	NRS	NRS

Considerations:

- Requirements of vitamin C are reported as 5.0 to 750.0 mg/kg depending on species of fish, rearing conditions, and stage of production (NRC, 2011).

Vitamin D

Class	Current (IU/kg)	Proposed (IU/kg of diet at 88% DM)
Fish (All)	10,000	10,000

Considerations:

- Requirements of vitamin D are reported as 6.25 to 40.0 µg/kg (250 to 1,600 IU/kg) depending on species of fish, rearing conditions, and stage of production (NRC, 2011).
- The NRC (NRC, 1987) estimated safe upper dietary levels of vitamin D_3 of 20 000 IU/kg for catfish and 1 000 000 IU/kg for rainbow trout.
- The EU authorized maximum content for vitamin D_3 in complete fish feed is 3000 IU/kg and D_2 of 2000 IU/kg and they cannot be used concurrently (European Union, 2004). There are currently no sources of Vitamin D_2 approved for use in livestock feeds.
- Fish is an important dietary source of vitamin D for humans. Fillets from different species of fish have been found to contain between 26 and 319 µg/kg fresh weight (Mattila et al., 1999).
- Increasing the maximum could result in fortification of fish with vitamin D. As fish is not a food for which mandatory or voluntary fortification of vitamins is allowed we are proposing to maintain the current maximum. The requirements and voluntary permissions for fortification are set out in food standards under Part B and Part D, Division 3 of the *Food and Drugs Regulations*.
- We are proposing to maintain the current maximum level of vitamin D in fish feeds for all species at 10, 000 IU/kg.

Vitamin E

Class	Current (IU/kg)	Proposed (mg/kg of diet at 88% DM)
Fish (All)	NRS	NRS

Considerations:

- Requirements of vitamin E are reported as 25.0 to 500.0 mg/kg (25.0 to 500.0 IU/kg) depending on species of fish, rearing conditions, and stage of production (Webster and Lim, 2002; NRC, 2011).
- Vitamin E hypervitaminosis is possible but has not been described in fish.
- Elevated levels of vitamin E (5000 to 10 000 IU/kg) in the diet may result in a reduction of the erythrocyte concentration in the blood or have negative effects on lipid peroxidation in fish (NRC, 2011). These factors can negatively impact fish health and production.
- Feeding levels greater than 200 IU vitamin E/kg of complete feedingstuffs is considered to be an undesirable feeding practice in the EU (EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), 2010).