Guidelines for Regulating Feed Additives and Supplements

Developed in collaboration with
Drug Regulatory Authority (DRA)
&
Bhutan Agriculture & Food Regulatory Authority
(BAFRA), MoAF

FIRST EDITION

DOL

Department of
Livestock
Ministry of Agriculture and Forests **2020**

FOREWORD

Almost over a century, the animal production sector around the world witnessed a tremendous growth and productivity fuelled by advancement in animal nutrition. The feed additives & supplements played a vital role in enhancing productivity manifold, changing the scenario of availability of animal proteins across the globe. Similarly, Bhutan is witnessing rapid increase in livestock productivity due to use of various forms of feed additives & supplements in livestock nutrition.

As Bhutan depends on import of all such technological nutrients, there is an ever-increasing threat to local famers and feed millers from utilizing unintended nutrients which could cause unforeseen repercussions. One such example could be the use of feed additives and supplements containing antibiotics banned for prophylactic use. With limited regulatory tools in place and many feed agents importing more and diverse products (feed types, feed additives and supplements), the regulatory agencies are hindered from imparting adequate regulation on the import of authentic and standardized products. Further, to enable farmers enjoy the benefit of feeding a well-balanced and safe diet to their livestock, the need to distinguish feed additives from feed supplement and their ease of access, was observed as a requirement.

This requirement entailed the development of a standard guideline that would ensure the availability of safe, quality and efficacious products in the country. The need was also felt to prescribe roles and

responsibilities to the importers and product manufacturers besides delineating roles for Drug Regulatory Authority (DRA) and Bhutan Agriculture and Food Regulatory Authority (BAFRA) in regulating the import of feed additives and supplements.

Consequently, as recommended by the Drug Technical Advisory Committee (DTAC), the Animal Nutrition Section (ANS) of the Department of Livestock developed "The Guidelines for Regulating Feed Additives and Supplements" in consultation and collaboration with DRA and BAFRA. The guideline adequately describes the principles for regulating feed additives and supplements and provides Recommended Daily Allowances for feed additives/ premixes.

We are confident that this guideline will serve as a useful resource in providing information to the feed manufactures, importers, distributors and manufacturers of feed additives and supplements, regulatory agencies, technical departments and farmers in the country in understanding and implementing their roles with regard to feed additives and supplements.

I would like to congratulate the core team members, technical advisors and in particular Ms. Ganga Maya Rizal, Deputy Chief Feed and Fodder Officer, ANS, LPD for coordination in production of this booklet.

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1. Introduction

With livestock production geared towards self-sufficiency and economy, a wide range of feed additives and supplements are being imported by the local suppliers. Due to uncontrolled import of such products, the 32nd and 33rd meeting of Drug Technical Advisory Committee (formed under Medicines Act of the Kingdom of Bhutan 2003) recommended for instituting a standard to ensure the availability of safe, quality and efficacious products in the country. Thus, this guideline has reference to Bhutan Medicine Rules and Regulations 2019 and Livestock Rules and Regulations 2017.

For purpose of clarity in regulation and in our context, distinction has been made between Feed Additives and Feed Supplements. Feed Additives are intentionally added ingredients in animal feed by the manufacturers/feed millers as to compensate for the nutrients lacking in the normal feeding and it includes feed premixes as well, whereas Feed Supplements are concentrated sources of nutrients (i.e. minerals and vitamins) found in the level above the recommended daily allowances (RDA) or other substances with a nutritional or physiological effect that are marketed in "dose" form. For deducing the limits for daily intake by the farm animals, this guideline draws reference from "Bhutan Standards for Animal Feeds" as adopted and published by the Bhutan Standard Bureau (BTS 47: 2018).

This document aims to establish an understanding of the roles between the Bhutan Agriculture and Food Regulatory Authority

(BAFRA) and the Drug Regulatory Authority (DRA) in regulating Feed Additives and Feed Supplements respectively. This guideline also provides guidance to the clients (manufacturers/importers) on the principles, roles and duties pertaining to import, sale and distribution of the Feed Additives and Feed Supplements including the documentation requirement. It also mentions about the additional role of Food and Drug Interface Committee (FDIC) formed under Bhutan Medicines Board under this guideline.

For uniformity of the application forms for acquiring various permits/authorizations from the regulatory authorities, the formats are annexed to this guideline. The RDA and maximum tolerable level (MTL) for some animals are also made available to provide guidance on segregation between Feed Additives and Feed Supplements. This document may be updated as and when required depending on the needs and reforms of the national and international regulatory norms.

2. Scope

This guideline shall apply to both natural & synthetic feed additives and feed supplements as follows:

a) Feed Supplements

Feed supplements containing concentrated sources of nutrients (i.e. mineral and vitamins) found in the level above the recommended daily allowances (RDA) or other substances with a nutritional or

physiological effect that are marketed in “dose” form (e.g. pills, tablets, capsules, liquids, powders in measured doses) in concurrence with Table 1 (Minerals with a maximum tolerable level (MTL).

b) Feed additives

Products generally containing enzymes, micro-organism products, acidifiers, antioxidants, mould inhibitors, digestibility enhancers, pigments, vitamins, amino acids, minerals, flavors, processing aids meant for formulation of feeds in concurrence with RDA specified in **Table 2**.

c) Out of scope

This guideline shall not apply to animal feed and medicated animal feed.

3. Objectives

This guideline will serve as:

- **A.** Guidance document to regulatory agencies (DRA and BAFRA) to regulate import, sale and distribution and manufacture;
- **B.** Reference document for the Department of Livestock;
- **C.** Guidance document to clients for processing import, distribution and manufacturing authorizations.

4. Definitions

Feed additive Substances, micro-organisms or preparations, other

than feed material and premixes, which are intentionally added to feed or water in order to improve the quality of feed and the quality of food from animal origin, or to improve the animal's performance and health (e.g providing enhanced digestibility of feed materials. Feed additive includes terms such as premix, base-mixes, blends, which are commonly used as synonyms and reflect the large variety of products. These additives are usually used in micro quantities and require careful handling and mixing to prevent avoidable nutritional disorders in farmed animals. While absence of some additives may not be necessary in feed, some are essential and must be part of feed formulation fulfilling the standard requirement.

Feed Supplement

A "concentrated" or "dosed" form of specific nutrients used with normal feed to improve the nutritive balance or performance of the total feed and intended to be: (i) fed undiluted as a supplement to other feeds; or (ii) offered free choice with other parts of the ration separately available; or (iii) further diluted and mixed to produce a complete feed (FAO, 2000). The supplements are

	usually used in case of nutritional deficiencies and are prescribed by Veterinary Health Practitioner to remedy the nutritional deficiency.
Client	It refers to importers, manufacturers, distributors and end-users
Product	It refers to feed additive and feed supplements
Import Authorization	It refers to a permit issued by the regulatory agency for importing the products.
Antimicrobials	Substances which destroys or inhibits the growth of other micro-organisms.
Coccidiostats	It refers to synthetic substances intended to inhibit protozoa growth.
Listing	It refers to listing or registration carried out by regulatory agencies after completion of the assessment of the product.
Market Authorization Holder	It refers to any firm in whose name the product is listed or registered.
Medicated Feed	A mixture of animal feed and veterinary medicinal product containing one or more active medicinal ingredients Any feed which contains drug ingredients intended or presented for the cure, mitigation, treatment, or

prevention of disease of animals other than man or which contains drug ingredients intended to affect the structure or any function of the body of animals other than man (FAO, 2000).

Feed Edible materials(s) which are consumed by animals and contribute energy and/or nutrients to the animals diet (FAO, 2000).

5. Acronyms

DRA	Drug Regulatory Authority
BAFRA	Bhutan Agriculture and Food Regulatory Authority
MAH	Market Authorization Holder
DTAC	Drug Technical Advisory Committee
DoL	Department of Livestock
FDIC	Food and Drug Interface Committee
cGMP	Current Good Manufacturing Practices
HACCP	Hazard Analysis Critical Control Point
RDA	Recommended Daily Allowance

6. Principles for regulating feed additives and supplements

6.1 Roles of Agencies and categorization

- Feed additives shall be regulated by BAFRA while feed supplements will be regulated by DRA
- Product shall be categorized as a feed additive or supplement depending on the product label claims or the ingredients present in it
- Feed supplements shall be further categorized based on the risk to the consumer and product claims
- For the purpose of product categorization, the Maximum Tolerable Limit (MTL) and the Recommended Daily Allowance (RDA) tables, adopted from the National Research Council (NRC), listed in the Annexure (1 & 2), will be used
- The manufacturer shall be subject to inspection from time to time by the concerned authorities to ensure compliance with the regulatory requirements
- The products listed or registered by the respective agencies will be made publicly available
-

6.2 Duties of Market Authorization Holder

- Feed additives and feed supplements shall require registration/ listing and import authorization from BAFRA and DRA, respectively.

- Importer and manufacturer shall be responsible for ensuring safety, quality, effectiveness of the product and timely recall from Bhutanese market in case of product recalls.
- The market authorization holder shall notify DRA or BAFRA within a period of one month in case of any changes in the product label.
- Any adverse reactions or side effects related to the use of feed supplements and feed additives shall be reported to DRA/ BAFRA/ DoL using the prescribed form
- Any suspected product defect shall be reported to DRA/ BAFRA/ DoL and investigated
- Approval for product advertisement shall be sought from the respective authorities (DRA for BAFRA)
- The manufacturer of feed additives and feed supplements shall seek approval from BAFRA provided the proponent and premises for manufacturing is the same
- For import and export of the product, the proponent shall seek import/ export authorization from concerned agencies as per section 15 of this guideline
- The manufacturer of feed additives and feed supplements shall follow Bhutan Standards for Animal Feeds

7. Rejection of application

An application for listing or registration of the product shall be

rejected on the following grounds:

a. If the product label contains medicinal ingredients such as antibiotics and/ or coccidiostats that are not approved

b. If the product label indicates objectionable terms as per the **Table 3**.

c. If the applicant fails to submit evidence to substantiate claims within six months from the date of inspection.

8. Labeling requirements

Feed additives and Feed supplements shall be labelled with the following minimum information:

a. Product name
b. Presentation/ dosage form
c. Target animal (including development stage)
d. Dose
e. Name and strength of active ingredients
f. Manufacturing date (if any)
g. Expiry date
h. Batch number
i. Direction of use
j. Indication or indented use
k. Storage conditions
l. Name and address of the manufacturer
m. Pack size
n. Warning or precaution (if any)
o. Authorization number (if any)

- Feed Supplement and Feed additives shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any aspect.
- Label must not contain Objectionable terms listed in the following **Table 3**
- The feed additive shall not have any medicinal claims on the labels.
- The label information should be in English and / or Dzongkha.
- Principal display panel shall be large enough to accommodate all the mandatory label information required to be placed with clarity.

9. Market Accessibility

Feed additives shall be made available only to local Feed manufacturers. Only Feed Supplements, and not the Feed Additives, shall be allowed for sale through general stores or Pharmacies depending on the categories assigned by the DRA.

a. **Category 1:** General Store and Pharmacies
b. **Category 2:** Only through Pharmacies

10. Technical Committee

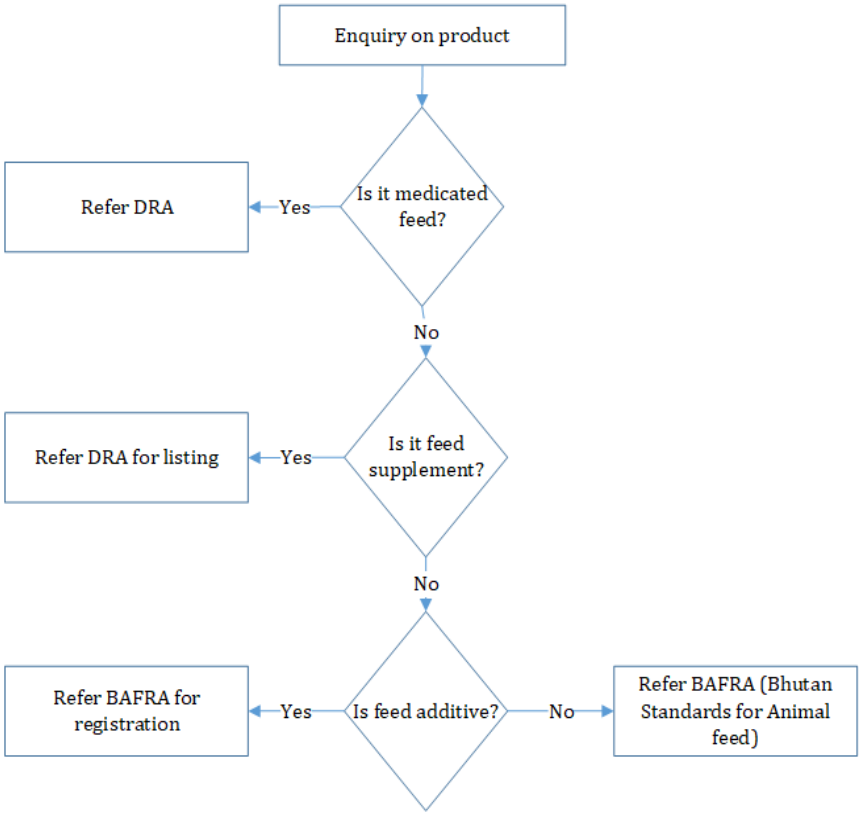
The Food Drug Interface Committee formed under Bhutan Medicines Board shall serve as a technical committee with the following Terms of Reference:

1. Categorization of the products in the event of lack of clarity on the product
2. Review any technical guidelines related to interface products
3. Provide guidance to regulatory agencies for making informed decisions on related products

11. Procedures for regulating feed additives and supplements

a) The process for categorization and listing or registration shall be followed as described below in figure 1.

Figure 1: Process flow for listing of Feed additives and Feed supplements



b) The applicant shall approach either of the agencies along with the product query form to determine the category of the product as

per annexure form.

c) Upon confirmation of the product category, the applicant shall approach the concerned agency.

12. Feed Supplements

The applicant shall apply for listing with DRA using application form as annexure of this guideline accompanied by the following documents:

a. Letter of authorization from the manufacturer/ dealer indicating the list of the product
b. Product profile/ product sample indicating the information on Name, Brand name, Dosage form, Strength of the product, Ingredients, Commercial presentation
c. Evidence to substantiate the claims as per the category determined by the DRA.

Category 1. Nutritional/ General claims- evidence to be provided shall be from any authoritative reference text. Example of this category is VETBIOMIN which can be added on feed or mixed with feed ingredients to formulate the feed.

Category 2. Functional Claims - Scientific evidence from animal studies or monographs or scientific opinions, or scientific organization or regulatory authorities. Example, Safemin AB2D3K Powder, SAFEMOVIT-Forte, etc. which are clearly indicated as feed

supplements.

d. The regulatory approval shall be issued within 30 working days excluding the period when the application is kept on hold pending clarification or submission of evidence.

e. Validity of the certificate/ approval shall be three years from the date of issuance.

13. Feed Additives

1. The applicant shall apply for registration to BAFRA using application form as annexure ii of this guideline accompanied by the following documents:

a. Letter of authorization from the manufacturer/ dealer indicating the list of the product

b. Product profile/product sample indicating the following information:

i. Name/ Brand name

ii. Dosage form

iii. Strength of the product

iv. Ingredients

v. Commercial presentation

2. In addition to the above requirements, for imported products, the applicant shall submit HACCP Certificate and Veterinary Health Certificate issued by Competent Authority of the country of origin.

3. For local products, the proponent shall submit trade license, GMP certificate and other technical documents notified by BAFRA at the time of application.

4. The regulatory approval shall be issued within 30 working days excluding the period when the application is kept on hold pending clarification or submission of evidence.

14. Validity and Renewal

1. Validity of the certificate/ approval shall be three years from the date of issuance.
2. The proponent shall apply for renewal three months before the expiry of the certificate/ approval.

15. Import and Export Authorization

For import of the feed additives, the applicant shall comply with the following procedures.

1. An applicant requesting for import permit shall submit the duly filled application form to the nearest BAFRA office at least two weeks prior to importation of animal feed additives.

2. BAFRA shall issue import permit with the requirement and conditions to be met for feed additives for import within 15 working days upon submission of application form.

3. The feed additives must originate from a manufacturing plant approved by the veterinary authority of the exporting country.

4. The end product is packed in the plant in new or sterilized packages.

5. That appropriate precautionary measures had been taken to prevent the contamination of the end product.

6. The packaging of the feed additives must be clearly labelled in English or Dzongkha with the following information.

7. The consignment shall be accompanied by official veterinary certificate certifying that:

a. Product was not contaminated by pathogens of animal or contagious diseases during manufacturing, packing and storage processes.

b. Feed additives preparations which contain ingredients derived from cloven-hoofed animals from a country (or area) with foot and mouth disease, rinderpest, bovine contagious pleuropneumonia or African swine fever, or which contain ingredients derived from poultry from a country (or area) with Newcastle disease or highly pathogenic avian influenza, it shall be heat-treated with the core of the product reaching a temperature of 700 °C for at least 30 minutes, or 800 °C for at least 9 minutes, or 1000 °C for 1 minute.

c. Ingredients derived from cattle, sheep, goat or other animals susceptible to bovine spongiform encephalopathy were not from a

bovine spongiform encephalopathy infected country and the product and raw materials were not contaminated by pathogen of bovine spongiform encephalopathy while manufacturing and processing.

8. The imported feed meets the standards of Bhutan in terms of their nutritive value and safety.

9. That all appropriate measures are taken en-route to avoid cross-contamination with infectious agents or toxic substances.

10. All information and documentation requested by the BAFRA Officials of the Ministry of Agriculture and Forests as to their ownership and content is provided.

11. Upon entry into Bhutan, the consignment must be declared to Regulatory and Quarantine Inspectors of BAFRA.

12. These requirements will be amended as and when deemed necessary depending on the risk associated with the products and the disease status of the exporting country.

13. Failure on the part of the importer to meet the prescribed conditions in the import permit shall result in the returning of the consignment to exporting country at the importer's expense or destruction/disposal without payment of compensation.

14. At the point of entry of products, the importer shall produce required documents for verification.

16. Certification by the exporting country

The requirements for certification shall be as follows:

a. Certificates are issued for the particular risk goods by authorized official of the exporting country;
b. Country shall be consistent with national requirements if not the relevant to OIE;
c. Terrestrial Animal Health Code or Aquatic Animal Health Code is in effect;
d. Only certificate written in English, Dzongkha or translated in either of the two languages shall be accepted; and
e. Only original certificates shall be accepted.

17. Manufacturing Authorization

Following process for issuance of manufacturing authorization shall be applicable:

1. The applicant shall submit the proposal to BAFRA for manufacturing authorization containing the following information:

a. Introduction of the project with scope of activities;
b. Source of raw materials;
c. Target Market (mention the intended countries if for export);
d. Technology collaboration (if any);
e. Proposed site detail - Bird's eye view or Sketch map/Pictorial

f. Product presentation, size of the proposed site, location and immediate environment and other manufacturing activities on the site (if available).

2. The layout design of the proposed manufacturing area should be appended with site plot, covered/uncovered land area ratio, activities being conducted in adjoining areas and environmental aspects;
3. Technical Aspects - Brief description of the Quality Management System, arrangement on production and quality control activities (mention any services to be outsourced), Engineering and maintenance, Project Management, Type of products intended for manufacture with therapeutic categories, List of intended manufacturing equipment to be procured, Intended size of the employees; and
4. Waste Management Plan - Detailed plan for the management of wastes generated from the manufacturing plant.

18. Sampling and Quality Testing for Animal Feed Additives and Supplements

The Animal Nutrition Laboratory (ANL) under National Research and Development Centre (NRDCAN), Bumthang shall be responsible for post marketing sampling and quality control of animal feed additives and supplements for laboratory testing.

In case of inadequate capacity to test the samples, the Department of Livestock shall identify reference laboratory for enabling testing of samples.

In case of medicated feed and interface substances, National Drug Testing Laboratory (NDTL) shall take lead to ensure quality of such substances.

19. Annexures

Annexure 1. Maximum Tolerable Limits (MTL) of feed additives for various livestock types

Table1a. **Maximum Tolerable Limits of Minerals for cattle**

Mineral	**Health Concern** [2]	**MTL**[3]	**Mineral**	**Health Concern** [2]	**MTL**[3]
Excessive exposure possible			**Excessive exposure is rare**		
Calcium (Ca)	Medium	1.5%	Aluminum (Al)	Low	1000 ppm
Cobalt (Co)	Low	25 ppm	Boron (B)	Medium	150 ppm
Copper (Cu)	High	40 ppm	Bromine (Br)	Medium	200 ppm
Iodine (I)	Low	50 ppm	Cadmium (Cd)	High	10 ppm
Iron (Fe)	Medium	500 ppm	Chromium (Cr)	Low	100 ppm
Magnesium (Mg)	Low	0.6%	Lead (Pb)	High	100 ppm
Manganese (Mn)	Low	2000 ppm	Lithium (Li)	Low	25 ppm
Molybdenum (Mo)	High	5 ppm	Mercury (Hg)	High	2 ppm

Phosphorus (P)	Medium	0.7%	Nickel (Ni)	Low	100 ppm
Potassium (K)	Medium	2%	Silicon (Si)	Low	0.2%
Selenium (Se)	High	5 ppm	Strontium (Sr)	Low	2000 ppm
Salt (NaCl)	High	3.0%	Tin (Sn)	Low	100 ppm
Sulfur (S)	High	0.4%	Tungsten (W)	Low	20 ppm
Zinc (Zn)	Medium	500 ppm	Vanadium (V)	Low	500 ppm

[1]The NRC established MTL for antimony, barium, bismuth, rare earth elements, rubidium, silver, titanium, and uranium for some species of animals but not cattle.
[2]Concern considers both the likelihood of a toxic exposure (including accidental) and severity of animal response.
[3]The MTLs are for cattle and are on a dry matter basis. Numerous factors affect MTLs, including bioavailability of mineral, duration of exposure, animal factors, and water concentrations. Data in this table should not be the sole source of information; readers should consult the appropriate section of NRC (2005).

Table1b. **Maximum Tolerable Limits for Poultry**

Based on 88% Dry Matter of feed

A. Macro Minerals

Macro Minerals	**MTL % of feed**	**Remarks**
Calcium (Ca)	1.5	Requirements vary based on stage of production. Pre-Layer / Pre-Layer Breeder require 4% while Broiler Breeder/ Layer/ Layer Breeder MTL is 5%. **Source:** NRC 2005, Hurwitz et al 1995, Pelicial *et al,* 2011, Bar *et al,* 2002.
Phosphorus (P)	1	Requirements vary based on stage of production. Pre-Layer / Pre-Layer Breeder Breeder/ Layer/ Layer Breeder MTL is 0.8%. **Source:** NRC 2005, Harms *et al,* 1965; Charles and Jensen, 1975.
Magnesium (Mg)	0.5	Requirements vary based on stage of production. Layer/ Layer Breeder MTL is 0.75%. **Source:** NRC 1994 and NRC 2005.
Sodium (Na)	0.45	Rationale is for animal health reasons. Same for all stages. **Source:** NRC, 2005, Leeson, S. 2006, Smith *et al,* 2000.
Potassium (P)	2.0	Same for all stages. **Source:** NRC 2005, Smith and Teeter (1987); Smith *et al,* 2000.
Sulfur (S)	0.4	Rationale is for animal health reasons. Same for all stages. **Source:** NRC 2005, NRC 1994, Bobeck *et al*, 2013.

B. Trace Minerals

Based on 88% Dry Matter of feed
Mg/ Kg, at 88% DM

Mineral	**MTL, % of feed**	**Remarks**
Cobalt (Co)	1	Same for all stages. Source: **Source:** NRC 2005, EFSA 2009.
Copper (Cu)	125	Same for all stages. **Source:** NRC 2005, EFSA 2016, EC.No. 1334/2003.
Iodine (I)	5	Same for all except Layer/ layer breeder whose MTL is 3mg/ Kg. **Source:** NRC 1994, EFSA 2005 and 2013.
Iron (Fe)	450	Same for all stages. **Source:** NRC 2005, EFSA 2015 and 2014.
Manganese (Mn)	150	Same for all stages. **Source:** NRC 1994, EFSA 2016, ATSDR 2012, EC No. 1334/2003.
Selenium (Se)	0.5	0.5mg/ Kg feed should be in total. This includes Se from both additives and feed ingredients. **Source:** NRC 2005, 1994.
Zinc (Zn)	150	Same for all stages except 100 mg/ Kg for Layer/ Layer Breeder. **Source:** NRC 2005, EC No. 1334/2003, EFSA 2014, Leeson, S. 2006.

C. Vitamins (IU/Kg, at 88% DM)

IU = International Units
Based on 88% Dry Matter of feed

Vitamin	**MTL, % of feed**	**Remarks**
Vitamin A	10,000	Same for all stages except for starter whose MTL is 20,000 IU. **Source:** Leeson, S, 2006, NRC 1994, EFSA 2008 and 2014.
Vitamin D	6,500	Same for all stages. **Source:** Leeson, S, 2006, NRC 1987.
Vitamin E	200	NRC 1987, EFSA 2010, Leshchinsky and Klasing 2001.
Vitamin C	No limit	Ascorbic acid as source of Vitamin C requires no limit to ensure animal/ human safety. **Source:** EFSA 2013.

Table1c. **Maximum Tolerable Limits for Piggery**

A. Macro Minerals

%, at 88% DM

Macro Minerals	**MTL % of feed**	**Remarks**
Calcium (Ca)	1	Same for all stages of production. **Source:** NRC 2005, Hall *et al* 1991.
Phosphorus (P)	1	Same for all production stages.
Magnesium (Mg)	0.2	Same for all stages of production. **Source:** NRC 2005 and Tarsitano *et al,* 2013.
Sodium (Na)	1.1	Same for all stages.
Potassium (P)	3% for 3-5 kg starter; 2.8% for 6-10kg starter; 2.6% for 11-20kg starter; 2.3% for 21-50kg grower; 1.9% for 51-80 kg grower; 1.7% for >80kg finisher; 2.0% for dry and lactating sows.	Different for all stages. **Source:** NRC 2005.
Sulfur (S)	0.40	Same for all stages except starter (3-5kg) with 0.2% MTL. **Source:** NRC 2005, Perez *et al,* 2011.

B. Micro/ Trace Minerals

Mg/ Kg, at 88% DM

Mineral	**MTL, % of feed**	**Remarks**
Cobalt (Co)	1	Same for all stages. **Source:** NRC 2005, EFSA 2009.
Copper (Cu)	250	Same for all stages. **Source:** NRC 2005, Health Canada's Veterinary Drugs Directorate
Iodine (I)	4	Same for stages. **Source:** Li et al, 2011, Frank et al, 2008.
Iron (Fe)	750	Same for all stages. **Source:** Porres *et al,* 1999.
Manganese (Mn)	125	Same for all stages. **Source:** EC No. 1334/2003, Matrone *et al,* 1959.
Selenium (Se)	0.5	0.5mg/ Kg feed should be in total. This includes Se from both additives and feed ingredients. **Source:** NRC 2005.
Zinc (Zn)	1,000	Same for all stages. **Source:** NRC 2005, EC No. 1334/2003, EFSA 2014, Leeson, S. 2006.

C. Vitamins (IU/Kg, at 88% DM)

IU = International Units
%, at 88% DM

Vitamin	MTL, IU of feed	Remarks
Vitamin A	Different for different stages. Starter at 16,000; Grower at 6,500; Finisher at 6,500; Dry sows at 12,000; Lactating Sows at 7,000 IU.	Same for all stages except for starter whose MTL is 20,000 IU. **Source:** NRC 1987, EFSA 2008 and 2014.
Vitamin D	2,200	Same for all stages. **Source:** NRC 1987.
Vitamin E	1,000	**Source:** NRC 1987.
Vitamin C	No limit	Ascorbic acid and sodium calcium ascorbyl phosphate as source of Vitamin C requires no limit to ensure animal/ human safety. **Source:** EFSA 2013, NRC 1987.

Table 1d. **Maximum Tolerable Limits for Fishery**

A. Macro Minerals

Macro Minerals	**% of feed**	**Remarks**
Calcium (Ca)	0.03% - 0.07%	Requirements vary based on species of fish and stage of production. **Source:** Halver and Hardy (2002) & NRC (2011).
Phosphorus (P)	0.33% - 1.5%	Depends on species of fish, rearing condition and stage of production
Magnesium (Mg)	0.02% - 0.07%	(“)
Sodium (Na)	1.2%	(“)
Potassium (P)	0.20% - 0.80%	(“)
Sulfur (S)	-	(“)

B. Trace Minerals

Minerals	**Mg/kg of feed**	**Remarks**
Cobalt (Co)	0.05 – 1.0 mg/kg	Vary on fish species, rearing condition and production stage. **Source:** Watanable *et al*, 1997; Webster and Lim (2002); NRC, 2011.
Copper (Cu)	1.5 – 10.0 mg/kg	(“)
Iodine (I)	0.6 – 5.0 mg/kg	(“)
Iron (Fe)	30.0 – 199.0 mg/kg	(“)
Manganese (Mn)	2.0 – 20.0 mg/kg	(“)
Selenium (Se)	0.15 – 0.5 mg/kg	(“)
Zinc (Zn)	15.0 – 150.0 mg/kg	(“)

C. Vitamins

Vitamins	Mg/kg of feed	Remarks
Vitamin A	0.3 – 31.0 mg/kg	Depending on fish species, rearing condition & stage of production. **Source:** NRC (2011).
Vitamin C	5.0 – 750.0 mg/kg	(“)
Vitamin D	6.25 – 40.0 mg/kg	(“)
Vitamin E	25.0 – 500.0 mg/kg	(“)

Annexure 2: Recommended Daily Allowance (RDA) of Feed Additives for Livestock

Table 2a. **RDA of Essential Amino Acids for Pigs**

Category	**Lysine (%)**		**Methionine (%)**	
	Max	**Min**	**Max**	**Min**
Piglet (1 to 5 kg)	1.28	1.41	0.76	0.84
Piglet (5 to 10 kg)	0.95	1.05	0.56	0.62
Pig (10-20 kg)	0.79	0.87	0.51	0.56
Pig (20-35 kg)	0.70	0.77	0.45	0.50
Pig (35-60 kg)	0.61	0.67	0.40	0.44
Pig (60-100 kg)	0.57	0.63	0.30	0.33
Gilt, sow and boar	0.43	0.52	0.23	0.25

Source: NRC 2004 and 2005

Table 2b. **RDA of Vitamins for Pigs**

Live weight, kg	**1-5**	**5-10**	**10-20**	**20-35**	**35-60**	**60-100**	**Bred gilts, sows boars**	**Lactating gilts & sows**
Vitamin A, IU	2200	2200	1750	1300	1300	1300	4000	2000
Vitamin D, IU	220	220	200	200	150	125	200	200
Vitamin E, IU	11	11	11	11	11	11	10	10
Vitamin K, mg	2	2	2	2	2	2	2	2
Riboflavin, mg	3	3	3	2.6	2.2	2.2	3	10
Niacin, mg	22	22	18	14	12	10	10	10
Pantothenic acid, mg	13	13	11	11	11	11	12	12
Vitamin B_{12}, µg	22	22	15	11	11	11	15	15
Choline, mg	1100	1100	900	700	550	400	1250	1250
Thiamin, mg	1.3	1.3	1.1	1.1	1.1	1.1	1	1
Vitamin B_6, mg	1.5	1.5	1.5	1.1	1.1	1.1	1	1
Biotin, mg	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Folacin, mg	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6

Source: NRC 2004 and 2005

Table 2c. **RDA of Minerals for pigs**

Live weight, kg	**1-5**	**5-10**	**1-20**	**20-35**	**35-60**	**60-100**	**Bred gilts, sows boars**	**Lactating gilts and sows**
Calcium, %	0.90	0.80	0.65	0.60	0.55	0.50	0.75	0.75
Phosphorous, %	0.70	0.60	0.55	0.50	0.45	0.40	0.6	0.5
Sodium, %	0.1	0.1	0.1	0.1	0.1	0.1	0.15	0.2
Chlorine, %	0.13	0.13	0.13	0.13	0.13	0.13	0.25	0.3
Potassium, %	0.30	0.26	0.26	0.23	0.20	0.17	0.2	0.2
Magnesium, %	0.04	0.04	0.04	0.04	0.04	0.04	0.04	0.04
Iron, mg	150	140	80	60	50	40	80	80
Zinc, mg	100	100	80	60	50	50	50	50
Manganese, mg	4	4	3	2	2	2	10	10
Copper, mg	6	6	5	4	3	3	5	5
Iodine, mg	0.14	0.14	0.14	0.14	0.14	0.14	0.14	0.14
Selenium, mg	0.15	0.15	0.15	0.15	0.15	0.10	0.15	0.15

Source: NRC 2004 and 2005

Table 2d. **RDA of Essential Amino Acids for Poultry**

Amino acid Requirement (%)	**Chick**	**Grower**			**Pre-lay**		**Breeder**	
	Min	**Max**	**Min**	**Max**	**Min**	**Max**	**Min**	**Max**
LAYER (PARENT STOCK)								
Lysine	1.10	1.21	0.90	0.99	0.72	0.79	0.90	0.96
Methionine	0.45	0.50	0.44	0.44	0.35	0.39	0.40	0.44
COMMERCIAL LAYERS								
Lysine	1.10	1.21	0.86	0.90	0.72	0.79	0.93	0.96
Methionine	0.45	0.50	0.35	0.40	0.37	0.39	0.45	0.47
BROILER (PARENT STOCK)								
Lysine	1.07	1.11	0.62	0.65	0.65	0.74	0.65	0.70
Methionine	0.40	0.45	0.25		0.30	0.35	0.30	0.37

Amino acid Requirement (%)	**Starter**		**Grower**		**Broiler finisher**	
	Min	**Max**	**Min**	**Max**	**Min**	**Max**
Commercial Broiler						
Lysine	1.15	1.20	1.00	1.10	0.85	0.87
Methionine	0.48	0.50	0.38	0.42	0.32	0.35

Source: NRC 2004 and 2005

Table 2e. **RDA of Vitamins for Poultry (Layer and Broiler)**

Vitamins	**Starter**	**Grower**	**Pre-lay**	**Layer**
Vitamin A, IU	1420	1420	1420	1420
Vitamin D, ICU	190	190	190	280
Vitamin E, IU	10	4.7	4.7	4.7
Vitamin K, mg	0.47	0.47	0.47	0.47
Riboflavin, mg	3.40	1.70	1.70	1.70
Pantothenic acid, mg	9.4	9.4	9.4	9.4
Niacin, mg	26	10.3	10.3	10.3
Vitamin B12, mg	0.009	0.003	0.003	0.003
Choline, mg	1225	850	470	470
Biotin, mg	0.14	0.09	0.09	0.09
Folacin, mg	0.52	0.23	0.23	0.23
Thiamin, mg	1.00	1.00	0.80	0.80
Pyridoxine, mg	2.8	2.8	2.8	2.8

Source: NRC 2004 and 2005

Table 2f. **RDA of Minerals for Poultry**

Minerals	**Starter**	**Grower**	**Pre-lay**	**Layer**
Calcium, %	0.9	0.8	0.8	1.8
Avail. phosphorus, %	0.4	0.35	0.3	0.35
Potassium, %	0.25	0.25	0.25	0.25
Sodium, %	0.15	0.15	0.15	0.15
Chlorine, %	0.12	0.11	0.11	0.11
Magnesium, mg	570	470	370	370
Manganese, mg	56	28	28	28
Zinc, mg	38	33	33	33
Iron, mg	75	56	56	56
Copper, mg	5	4	4	4
Iodine, mg	0.33	0.33	0.33	0.33
Selenium, mg	0.14	0.10	0.10	0.1

Source: NRC 2004 and 2005

Table 3. Objectionable Terms

Drastically improves health, fertility and production	No side effects
Ensures biosecurity	100% safe
Results in fastest growth & production	Guaranteed
Miraculous solution to any livestock problem	Boosts immunity
The only product to use	Enhances immunity
World's best	Hormone releaser/ enhancer/ amplifier
Regulate hormone	

Annexure 3. Application for import permit of feed additive

ས་ནམ་དང་ནགས་ཚལ་ལྷན་ཚན།

འབྲུག་ས་ནམ་དང་ཟ་ཆས་ཁྲིམས་དོན་དབང་འཛིན།

Royal Government of Bhutan
Ministry of Agriculture and Forests, Bhutan
Agriculture and Food Regulatory Authority (BAFRA)

APPLICATION FOR ISSUANCE OF IMPORT PERMIT FOR FEED ADDITIVES

The Director General
BAFRA, MoAF
Thimphu.

The undersigned here by applies for a permit authorizing the import of poultry and animal feeds as per the details given below:
(Please type/write in BLOCK LETTERS)

Name and Address of
Applicant……
Citizenship ID No. ……..Passport No……..Trade license No*……..

(Attach a copy of CID, Passport and Trade License No)

Details of consignment to be imported

Sl. No.	***Particulars***	***Company/ Manufacturer***	***Description of the supply/package***	***Quantity (No./weight)***
1.				
2.				

Use additional sheet if required

Purpose of importation……Origin or source of commodity……..Means of conveyance…… Place of entry……Final destination…….. Expected date of arrival……

Signature of applicant:
Place: Seal:
Date:

 # if expatriate, attach recommendation letter from the concerned employer.
* *If the consignment is for commercial purpose, valid trade license is required.*

……

Thimphu: Bhutan, Post Box No. 1071; Tel. PABX 975-2-327031/325790/325993; fax No. 975-2-327032/335540

Annexure 4. Application Form for Product Query

Product Query Form			
Form Number	**Effective Date**	**Review Date**	**Version No**

To
……DRA / BAFRA……..

I, …….. hereby would like to make an enquiry about the following product if it requires listing with the Authority:

Product details	
Product Name:	
Main Ingredients:	
Manufacturer Details:	
Product label/ Leaflet claims:	
Importer/Trader details	
Applicant:	Name: Signature & date: Contact no.:
Type/Scope of Trade License:	

XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Leave this blank: For Official's use only:

Preliminary classification of the Product:

1. Feed ☐ 2. Feed Additive ☐ 3. Feed Supplement ☐ 4. Not sure, refer to FDIC ☐

Reviewed by:	**Signature:**	**Date of Review:**

Annexure 5. **Application Form for Product Defects**

Product Defect Complaint Form (Feed Additives & Supplements)			
Document Number	**Effective Date**	**Review Date**	**Version Number**

Instructions:
i. This Form is used to report deficiencies/defects of Feed additives and Feed Supplements.
ii. Use a separate form for each product reported
iv. ***Return the completed form to BAFRA or DRA***

1. Reporter (i.e Person reporting the Defect/Problem)	
Name:	
Occupation/Position:	
Institution/Organization:	
Address:	Telephone:
2. Complainant (i.e patient, customer, and client): **[IF ANY] or Leave it Blank**	
Name:	
Address:	Telephone:
3. Product Details	
Name of the product:	
Batch no.	
Name & Address of the Manufacturer:	
Expiry Date:	
4. Details of the Product Defect:	
Description of the Defect/Problem:	
6. Details on Stock Balance and Storage:	
Do you have Stock Balance of the same batch product:	Please circle one: YES/ NO If Yes: How many? ……..
Where was the product stored?	Please circle one: Closed Store Room/Open shed? If Others, give details: ……

Leave this blank: For Official's use only:

1. Categorization of the type of Product Defect:

Critical ☐ Major ☐ Minor ☐ Not sure ☐

Alert Recall Committee YES ☐ NO ☐

Complaint reviewed by:	**Signature:**	**Date of Review:**

20. References

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2. Bhutan Standards for Animal Feeds. BTS 47: 2018.
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5. Food Safety and Standards (Health Supplements, nuetraceuticals, food for special dietary use, food for special medical purpose, functional food and novel food)
6. Regulations 2016, Food Safety & Standards Authority of India.
7. Health Supplements Guidelines, Revised August 2017, Health Sciences Authority, Singapore.
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9. National Research Council (NRC). 2004 and 2005.
10. https://www.inspection.gc.ca/animals/feeds/consultations/maximum-nutrient-values-in-swine-feeds/eng/1478095052728/1478095178247
11. https://www.inspection.gc.ca/animals/feeds/consultations/proposal/eng/1519151188110/1519151188699

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