



GHP/GMP CRITERIA FOR LICENSING FEED MILLS

Bhutan Agriculture and Food regulatory Authority
Ministry of Agriculture and Forests
Thimphu

Version 1, 2022

Contents

1. Objective	1
2. Scope.....	1
3. Design and Facilities.....	1
3.1 Location.....	1
3.2 Premises and rooms.....	1
3.2.1 Design and layout.....	1
3.2.2 Internal structures and fittings.....	2
3.3 Equipment.....	2
3.4 Containers for waste and inedible substances	3
3.5 Facilities.....	3
3.5.1 Water supply	3
3.5.2 Drainage and waste disposal.....	3
3.5.3 Cleaning and washing.....	3
3.5.4 Temperature control.....	4
3.5.5 Air quality and ventilation	4
3.5.6 Lighting	4
4. Control of Operations	4
4.1 Microbiological cross contamination	4
4.2 Physical and chemical contamination.....	5
4.3 Incoming materials requirements.....	5
4.4 Packaging.....	5
4.5 Water and steam	5
4.6 Management and supervision of operations.....	6
4.7 Documentation and records.....	6
4.8 Product recall and traceability.....	6
4.9 Storage.....	7
5. Maintenance, Cleaning and Sanitation.....	8
5.1 Maintenance.....	8
5.2 Pest Control	8

5.3	Waste management	8
6.	Personal Hygiene	9
7.	Quality Control	9
8.	Transportation	9
9.	Product Information, Consumer Awareness and Complaints.....	10
10.	Feed Formulation	10
11.	Complaint Management	10
12.	Competence and Training	10
13.	Self-Evaluation.....	11
13.1	Internal audits and inspections	11
14.	Annexure 1: Checklist for GHP/GMP Criteria.....	11

1. Objective

The objective of this document is to define a set of basic Good Hygienic and Manufacturing Practices (GHP/GMP) that Feed Mills (FM) need to implement for production of suitable and safe animal feeds. This document shall be used for Licensing of Feed Mills. It shall be the responsibility of the FMs to ensure compliance to GHP/GMP Criteria for Licensing of FM. This document can also be used for the purpose of internal and/or external evaluation of compliance to these requirements.

2. Scope

This document specifies the basic Good Hygienic and Manufacturing Practices for production of safe and suitable feeds. The requirements as given in this document apply to all commercial FM except home-based feed formulations for self-consumption. The document has specified requirements described as 'shall' where compliance to the Criteria is essential.

3. Design and Facilities

3.1 Location

- a. Establishment shall have clearly defined boundaries; be away from Toxic chemical producing industries; approach road to the site shall be concreted; surrounding areas shall be clean with no garbage accumulation and stagnant water; and not prone to pest infestation and flooding.
- b. Open drains, garbage dumps, water logging; open spaces, such as yards, streets, and roof tops shall not be used for storage of feed.

3.2 Premises and rooms

3.2.1 Design and layout

- a. Basic infrastructure appropriate to the operations shall be in place. The buildings shall provide sufficient space to allow a logical flow of materials, products and personnel through the production process. Entry and exit points for materials and

personnel shall be separate as far as possible. Feed flow shall be in one direction, as far as possible.

- b. Adequate space shall be provided for various activities such as raw material receipt and storage, processing, packing, final product storage, toilets which do not open directly into the processing, packing and storage areas.
- c. There shall be adequate separation between storage areas (raw material, packaging material and finished goods), processing area, packing area, utility area etc.
- d. There shall be a provision of appropriate loading and unloading points which facilitate movement of material and such points shall be suitably covered to provide adequate protection from pests, rain, etc.
- e. Openings intended for transfer of materials and products (e.g. transport hoses, conveyors) shall be designed to prevent entry of foreign matter and pests.

3.2.2 Internal structures and fittings

- a. Flooring shall be concreted, impervious, with no crevices or damages. Floors shall be constructed to allow adequate drainage.
- b. Roof shall be constructed so as to be gap free, water resistant, and finished so as to minimize build-up of dirt and shedding of particles. Overhead fixtures, if any, shall be constructed and finished to minimize the build-up of dirt and condensation and the shedding of particles.
- c. Walls and partitions shall have a smooth surface. Wall paint shall not be flaking off. There shall be no crevices to harbor pests.
- d. Windows and ventilators shall be easy to clean, and where necessary fitted with cleanable insect-proof screens. Window glasses shall be protected to ensure that feed is not contaminated in the event of glass breakages. Mesh on windows and ventilator shall not have cuts or damages to avoid entry of pest.
- e. Doors shall have smooth non-absorbent surfaces.

3.3 Equipment

- a. Equipment/machines shall be located so that it permits adequate maintenance and cleaning, functions in accordance with its intended use and facilitates good hygienic practices, including monitoring, if required.
- b. Equipment and re-usable containers coming into contact with feed shall be durable, designed and constructed to ensure that they can be adequately cleaned, disinfected where necessary, and maintained to avoid the contamination of feed. Where necessary, equipment shall be movable or capable of being disassembled to allow for maintenance, cleaning, disinfection, monitoring, etc.
- c. Equipment shall be made of materials that are impervious, non-reactive, with no toxic effect in intended use and do not pass colors, odors or taste to feed.
- d. Feed products and process monitoring and measuring devices shall be periodically calibrated and records maintained. The feed mills shall have documented procedure for calibration of equipment specifying frequency.

3.4 Containers for waste and inedible substances

- a. Containers for waste, by-products or dangerous substances shall be identifiable, suitably constructed and where appropriate made of impervious material. Those used to hold dangerous substances shall also be lockable and access restricted to authorized personnel.

3.5 Facilities

3.5.1 Water supply

- a. An adequate supply of potable water with appropriate facilities for its storage, and distribution, shall be available (if necessary). In case water is stored in tanks, the tanks shall be such that they prevent contamination of water. They shall be suitably covered to prevent the access by animals, birds, pests and other extraneous matters.
- b. The water pipes shall be made of material that is non-toxic, corrosion resistant, free from cracks, impervious and shall be sealed.

- c. Separate non-potable water systems (e.g. fire control, steam production, sanitary conveniences) shall be identified and shall not connect with or allow reflux into, potable water systems.

3.5.2 Drainage and waste disposal

- a. Drainage and waste disposal systems as relevant to the operations shall be appropriately designed and constructed.
- b. Drainage shall flow from clean to contaminated areas.
- c. Drains, if any, in the processing area shall be made of impervious rust proof material and shall be covered. These shall have adequate trapping devices to avoid entry of pests. Drains shall allow for effective cleaning as relevant and shall not allow any stagnation or backflow of water.
- d. Waste bins of adequate size for different types of wastes shall be made available.

3.5.3 Cleaning and washing

- a. Adequate facilities, suitably designated, where necessary, shall be provided for cleaning working areas, storage rooms, walkways etc.
- b. Adequate means of washing hands including wash basins and supply of adequate water of potable quality shall be provided.
- c. Toilets of appropriate hygienic design at suitable location with adequate ventilation, lighting and hand washing facilities shall be provided.

3.5.4 Temperature control

- a. If any of the operations require heating, cooling, and refrigerating, adequate facilities shall be available for the same.

3.5.5 Air quality and ventilation

- a. Adequate ventilation as appropriate to the feed/ingredients and the operations shall be provided for controlling ambient temperatures and humidity where necessary which might affect the safety and suitability of feed.

- b. Processing areas where operations result in release of steam or any vapour shall be equipped with an exhaust system or ventilation that can efficiently and effectively remove these.
- c. Ventilation systems shall ensure that air does not flow from unclean to clean areas and, where necessary, they can be adequately maintained and cleaned.

3.5.6 Lighting

- a. Natural and / or artificial lighting shall be provided for various operations and other activities within the facility (e.g. sanitary conveniences). The intensity of lighting shall be adequate for the nature of operations. (e.g. sorting, cleaning, grading, inspection and testing require greater intensity of light). Where necessary, lighting shall be such that the resulting colour is not misleading.
- b. Lighting fixtures shall, especially in feed processing areas and open hoppers where feed/ingredients are exposed, be shatter proof or protected with shatter-proof covers to ensure that feed is not contaminated in the event of breakages.

4. Control of Operations

4.1 Microbiological cross contamination

- a. When processing feed, adequate steps shall be taken to prevent the same from microbiological cross contamination.
- b. Raw, unprocessed feed ingredients shall be effectively separated.
- c. Unauthorized access to processing areas shall be restricted. Appropriate foot dipping facilities shall be provided at the main entrance gate to disinfect foot-wares of visitors and employees.

4.2 Physical and chemical contamination

- a. Feeds shall not be contaminated by foreign bodies such as glass, metal particles from machinery, plastic, dust, harmful fumes and hazardous chemicals.

4.3 Incoming materials requirements

- a. Only sound, suitable incoming material like raw materials, ingredients and semi processed products viz. additives, concentrates, mineral mixtures shall be used.
- b. Raw materials shall be inspected, tested or covered by Certificate of Analysis at appropriate frequencies for verifying conformance to specified requirements prior to acceptance or use.
- c. No raw material or ingredient shall be accepted by an establishment if it is known to contain undesirable substances, microorganisms, pesticides, veterinary drugs, heavy metals, radioactive substance or toxic, decomposed or extraneous substances which would not be reduced to an acceptable level by normal sorting and or processing.
- d. Records of raw materials, feed additives and ingredients as well as their source of procurement shall be maintained.

4.4 Packaging

- a. Packaging materials shall provide adequate protection for feed to minimize contamination, prevent damage and accommodate proper labeling. The materials shall be appropriate for the feed to be packed and sufficiently durable to withstand handling, storage and transportation.
- b. Packaging materials shall be stored and handled under hygienic conditions away from raw materials and finished products.
- c. Re-usable packaging, if used, shall be suitably durable, easy to clean and where necessary, disinfect.

4.5 Water and steam

- a. Water, if used in feed processing shall be potable water and be stored to protect them from contamination.
- b. For steam production, fire control and other similar purposes not connected with feed may not require the use of potable water.
- c. Water pipes shall be maintained in good condition and order at all times to prevent leakage or defects that would result in contamination of feed. Water storage tanks for potable water shall be regularly cleaned and disinfected at least once in 6 months to prevent contamination.

4.6 Management and supervision of operations

- a. All operations shall be monitored and supervised appropriately. The type of control and extent of supervision needed will depend on the size.

4.7 Documentation and records

- a. Different aspects of operations shall be documented in the form of protocol/SOP /instruction manuals along with appropriate forms/ formats/ check lists for implementation.
- b. Appropriate records of material reception, processing, production, storage and distribution shall be kept and retained for a period equal to one month beyond the shelf life of particular batch of feeds.
- c. At a minimum, records for the following processes shall be maintained:
 - Incoming material checks
 - Inspection and test
 - Product recall and traceability
 - Sanitization of the mill
 - Pest control
 - Training
 - Calibration
 - Complaint and customer feedback
 - Corrective and preventive action

4.8 Product recall and traceability

- a. Raw materials, ingredients and finished products shall be clearly identified during all stages of receipt, production, storage, and dispatch.
- b. The responsibility and methods used to trace product shall be documented and implemented to ensure:
 - Finished product is traceable at least one step forward to the customer and provides traceability at least one step back to the supplier of raw materials;

- The effectiveness of the product tracing system is reviewed at least annually as part of the product recall and withdrawal review.
- Records of raw material receipt and use, and finished product dispatch and destination shall be maintained.
- c. The responsibility and methods used to withdraw or recall product shall be documented and implemented. The procedure shall:
 - Identify those responsible for initiating, managing, and investigating a product withdrawal or recall;
 - Describe the management procedures to be implemented including sources of legal, regulatory, and expert advice and essential traceability information;
 - Outline a communication plan to inform site personnel, customers, consumers, authorities, and other essential bodies in a timely manner appropriate to the nature of the incident;
 - Ensure that all the relevant stakeholders are listed as essential organizations and notified in instances of a feed safety incident requiring product recall.
- d. The procedure in place shall ensure complete and rapid recall of any implicated lot/ batch of finished feed. Where a product has been withdrawn, other products which are produced under similar condition shall be evaluated for safety and may need to be withdrawn.
- e. Recalled products shall be held under supervision until they are destroyed, or, determined to be safe for animal feeding.
- f. Records shall be maintained of recall feeds incidents, root cause investigations into actual withdrawals and recalls, and corrective and preventative actions applied and the action taken on recalled feeds.

4.9 Storage

- a. Feed storage facilities shall be designed and constructed to enable maintenance of cleanliness, ventilation, avoid pest access and harborage; prevent contamination and where necessary, provide suitable conditions of temperature and humidity for minimizing deterioration of feed.
- b. Adequate facilities for storage of feed, ingredients/raw materials, packaging material, non conforming material and non-feed chemicals (e.g. cleaning materials, lubricants, fuels) shall be provided, and segregated appropriately.
- c. Feeds shall be stored under conditions that prevent spoilage, protect against contamination and minimize damage. Feeds shall be stored away from the wall and not directly on the floor. It shall be stored preferably either on pallets / racks or any other manner to facilitate cleanliness, avoid ingress of moisture, etc. Feed shall be stored in clean areas and stacked in a manner that facilitates ease of movement.
- d. All products in storage shall be clearly identified.
- e. Stocks of raw materials (including packaging material) and ingredients shall be subject to effective stock rotation.
- f. Cleaning materials and hazardous chemical substances shall have restricted access and only to authorized personnel.

5. Maintenance, Cleaning and Sanitation

5.1 Maintenance

- a. Establishment and equipment shall be maintained under an appropriate state of repair and condition to;
 - Facilitate all sanitation procedures
 - Function as intended particularly at critical steps
 - Prevent contamination of feed
- b. Maintenance programmes shall be in place which shall cover maintenance schedule, responsibilities, methods, tools and gadgets, etc. and appropriate records maintained.

- c. Consumables like lubricants that come in contact with feed shall be food grade, and spares parts of equipment which directly come in contact with feed shall be non-toxic, non-reactive and impervious.

5.2 Pest Control

- a. Suitable pest control programme shall be in place and effective to ensure there are no signs of pest infestation including flies, cockroaches, lizards, rats, etc. The pest control programme shall identify the pests to be controlled, the area / locations where control is to be applied, the method of control e.g. physical or chemical and responsibilities, etc. These shall include use of traps and baits as appropriate.
- b. The pest control activities shall be performed by trained personnel. These shall be continuously monitored for their effectiveness. It shall be ensured that pest control chemicals do not contaminate feed.
- c. The measures shall be documented and records maintained.

5.3 Waste management

- a. Suitable waste management system including waste disposal shall be in place. Waste shall not accumulate in feed processing and storage areas. Waste shall be periodically cleared avoiding a build-up in the premises. Waste bins and areas shall be identified, covered and kept appropriately clean.

6. Personal Hygiene

- a. Personnel while working in a feed processing area shall maintain personal cleanliness and shall wear clean uniform.

7. Quality Control

- a. The responsibility and procedure for selecting, evaluating, approving, and monitoring an approved supplier shall be documented and implemented. A current record of approved suppliers, receipt inspections, and supplier audits shall be maintained.

- b. Verification of raw materials shall include certificate of analysis, or sampling and testing on receipt.
- c. The quality control programme shall include inspection and testing of incoming, in process and finished product and records maintained
- d. Infrastructure shall be available for carrying out testing. In case the same is not available, a proper system for testing in an accredited external laboratories shall be in place.
- e. The laboratory shall have
 - Competent manpower,
 - Appropriate equipment ,
 - Methods of sampling and testing,
 - Quality assurance through in-house or external programme
 - Records of testing, calibration, manpower competence, Quality Assurance programme.

8. Transportation

- a. Feeds shall be adequately protected during transport to ensure feed safety.
- b. The transportation or transport containers shall be designed and constructed so that they do not contaminate feed (including ingredients). Feeds and non-feed shall be suitably segregated during transportation where the same conveyance or container is used for transportation.

9. Product Information, Consumer Awareness and Complaints

- a. All incoming, in process and finished products shall be suitably identified for final product (batch/lot) identification. All statutory requirements shall be clearly given on the label of the final product as per the Food Rules and Regulations of Bhutan (2017). All finished products shall be given a unique Batch number. Any special

requirements of handling, transportation and storage by customer etc. shall be clearly indicated on labels.

10. Feed Formulation

- a. The methods and responsibility for feed formulations and manufacturing processes shall be documented and implemented.
- b. Feed formulations and manufacturing processes for products shall be reviewed when there are changes in materials, ingredients, or equipment.
- c. Records of feed formulations, process flows, shelf life trials, and approvals for all new and existing products shall be maintained.
- d. Specifications for all raw materials and packaging including ingredients, additives, hazardous chemicals, and packaging that impact finished product safety shall be documented and implemented.

11. Complaint Management

- a. The methods and responsibility for handling, investigating, and resolving feed safety complaints from customers and authorities arising from products manufactured on-site shall be documented and implemented.
- b. All customer complaints shall be investigated and analyzed and the root cause established about the incidents.
- c. Corrective and preventative action shall be implemented based on the seriousness of the incident and the root cause analysis.
- d. Records of customer complaints, their investigation, and resolution shall be maintained.

12. Competence and Training

- a. Managers and supervisors shall have appropriate knowledge of feed hygiene principles and practices. Suitable training shall be given to all persons to enable them to have the required knowledge and skills in GHP and GMP for the tasks to be performed by them effectively to ensure a safe feed.

13. Self-Evaluation

13.1 Internal audits and inspections

- a. The methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of application of GMP and GHP criteria for feed safety enhancement shall be documented and implemented. Internal audits shall be conducted in full and at least annually. The methods applied shall ensure:
 - All applicable requirements of the GMP and GHP criteria for feed safety enhancement for Animal Feed Manufacturing are audited as per the checklist of the criteria;
 - Objective evidence is recorded to verify compliance and/or non-compliance;
 - Corrective and preventative actions of deficiencies identified during the internal audits are undertaken; and
 - Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective and preventative actions.
- b. Staff conducting internal audits shall be trained and competent in internal audit procedures. Where practical, staff conducting internal audits shall be independent of the function being audited.
- c. Records of internal audits and inspections and any corrective and preventative actions taken as a result of internal audits shall be recorded.

14. Annexure 1: Checklist for GHP/GMP Criteria

BASIC COMPLIANCE CHECKLIST
GHP/GMP Criteria for Licensing of Feed Business

Name of The Feed Mill:	Registration Number:
Address :	Name of the Responsible Person:
Type of Inspection:	Date of Inspection:
Products:	Inspection Team:

Design and Facilities

Clause #	Requirements	Yes	No	Remarks
3.1 Location				
3.1.a	Establishment with clearly defined boundaries away from toxic chemical industries and clean surrounding			
3.1.b	Open drains, garbage dumps, water logging; open spaces, such as yards, streets and roof tops are not used for storage of feed.			
3.2.1 Design and layout				
3.2.1 a	The buildings have sufficient space to allow a logical flow of materials, products and personnel and maintain flow of products in one direction			
3.2.1 b	Adequate space for raw material receipt and storage, processing, final product storage, toilets which do not open directly into the processing, packing and storage areas.			
3.2.1 c	There is adequate separation between storage areas (raw			

	material, packaging material and finished goods), processing area, packing area, utility area, etc.			
3.2.1 d	There is a provision of appropriate loading and unloading points suitably covered to provide adequate protection from pests, rain, etc.			
3.2.1 e	Openings intended for transfer of materials and products (e.g. transport hoses, conveyors) are designed to prevent entry of foreign matter and pests.			
3.2.2 Internal Structures and Fittings				
3.2.2 a	Floorings are concreted, impervious, with no crevices or damages to allow adequate drainage			
3.2.2 b	Roof is gap free, water resistant, and finished with no build-up of dirt and shedding of particles			
3.2.2 c	Walls and partitions have smooth surface without wall paint flaking off and no crevices to harbor pests.			
3.2.2 d	Windows and ventilators shall be easy to clean and mesh on windows/ventilator have no cuts or damages to avoid entry of pest.			
3.2.2 e	Doors shall have smooth non-absorbent surfaces.			
3.3 Equipment				
3.3 a	Equipment/machines are located to permit adequate maintenance and cleaning, functions in accordance with its intended use			
3.3b	Equipment and re-usable containers coming into contact with feed are durable, designed and constructed to ensure that they can be adequately cleaned, disinfected and maintained to avoid the			

BAFRA GHP/GMP Criteria for Licensing Feed Mills

BAFRA GHP/GMP Criteria

Version 1, 2022

	contamination of feed. The equipment shall be movable or capable of being disassembled to allow for maintenance, cleaning, disinfection, monitoring, etc.			
3.3c	Equipment are made of materials that are impervious, non-reactive, with no toxic effect in intended use and do not pass colors, odors or taste to feed.			
3.3d	The feed product and process monitoring and measuring devices are periodically calibrated and records maintained based on the type of equipment, criticality of the measurement, location and extent of usage.			
3.4 Containers for waste and inedible substances				
3.4a	Containers for waste, by-products or dangerous substances are identifiable, suitably constructed and made of impervious material.			

Facilities

Clause #	Requirements	Yes	No	Remarks
3.5.1 Water supply				
3.5.1.a	An adequate supply of potable water with appropriate facilities for its storage and distribution are available.			
3.5.1.b	The water pipes are made of material that is non-toxic, corrosion resistant, free from cracks, impervious and sealed.			
3.5.1.c	Separate water system is identified that does not connect with or allow reflux into, potable water systems.			
3.5.2 Drainage and waste disposal				
3.5.2.a	Drainage and waste disposal systems are appropriately			

	designed and constructed.			
3.5.2 b	Drainage flow from clean to contaminated areas.			
3.5.2 c	Drains in the processing area are made of impervious rust proof material and are covered that does not allow any stagnation or backflow of water.			
3.5.2 d	Waste bins of adequate size for different types of wastes are provided.			
3.5.3 Cleaning and washing				
3.5.3 a	Adequate facilities are provided for cleaning working areas, storage rooms, walkways etc.			
3.5.3 b	Adequate means of washing hands including wash basins and supply of adequate water of potable quality are provided.			
3.5.3 c	Toilets of appropriate hygienic design at suitable location with adequate ventilation, lighting and hand washing facilities are provided.			
3.5.4 Temperature control				
3.5.4 a	If any of the operations require heating, cooling, and refrigerating, adequate facilities shall be available for the same.			
3.5.5 Air quality and ventilation				
3.5.5 a	Adequate ventilation for feed/ingredients are provided for controlling ambient temperatures and humidity			
3.5.5 b	Processing areas are equipped with an exhaust system or ventilation for steam/vapour			
3.5.5 c	Ventilation systems ensure that air does not flow from unclean to			

	clean areas and they can be adequately maintained and cleaned.			
3.5.6 Lighting				
3.5.6 a	Lighting is provided for various operations adequate for the nature of operations			
3.5.6 b	Lighting fixtures are protected with shatter-proof covers to ensure that feed is not contaminated in the event of breakages.			

Control of operations

Clause #	Requirements	Yes	No	Remarks
4.1 Microbiological cross contamination				
4.1 a	When processing feed, adequate steps shall be taken to prevent the same from microbiological cross contamination.			
4.1 b	Raw, unprocessed feed ingredients shall be effectively separated			
4.1 c	Unauthorized access to processing areas are restricted. Appropriate foot dipping facilities are provided at the main entrance gate to disinfect foot wares of visitors.			
4.2 Physical and chemical contamination				
4.2 a	Feeds are not contaminated by foreign bodies such as glass, metal particles from machinery, plastic, dust, harmful fumes and hazardous chemicals.			
4.3 Incoming materials requirements				
4.3 a	Only sound, suitable incoming material like raw materials, ingredients and semi processed products are used.			

4.3 b	Raw materials are inspected, tested or covered by Certificate of Analysis at appropriate frequencies for verifying conformance to specified requirements prior to acceptance or use.			
4.3 c	No raw material or ingredient are accepted by an establishment if it is known to contain undesirable substances, microorganisms, pesticides, veterinary drugs, heavy metals, radioactive substance or toxic, decomposed or extraneous substances			
4.3 d	Records of raw materials, feed additives and ingredients as well as their source of procurement are maintained.			
4.4 Packaging				
4.4 a	Packaging materials shall provide adequate protection for products to minimize contamination, prevent damage and accommodate proper labeling			
4.4 b	Packaging materials are stored and handled under hygienic conditions away from raw materials and finished products			
4.4 c	Re-usable packaging are suitably durable, easy to clean and disinfect.			
4.5 Water and steam				
4.5 a	Water, if used in feed processing are potable and are stored to protect them from contamination			
4.5 b	Water (not potable) for steam production, fire control and other similar purposes are not connected with feed processing.			
4.5 c	Water pipes are maintained in			

	good condition and order at all times. Water storage tanks for potable water are cleaned and disinfected at least once in 6 months			
4.6 Management and supervision of operations				
4.6 a	All operations are monitored and supervised appropriately depending on the size.			
4.7 Documentation and records				
4.7 a	Different aspects of operations are documented in the form of protocols/SOPs/instruction manuals etc. along with appropriate forms/formats/check lists			
4.7.b	Appropriate records of material reception, processing, production, storage and distribution are kept and retained for a period one month beyond the shelf life of the batch of product.			
4.7 c	Records for the following processes are maintained: <ul style="list-style-type: none"> · Incoming material checks · Inspection and test · Product recall and traceability · Sanitization of the mill · Pest control · Training · Calibration · Complaint and customer feedback · Corrective and preventive action 			
4.8 Product recall and traceability				
4.8 a	Raw materials, ingredients and finished products are clearly identified during all stages of receipt, production, storage, and dispatch.			

4.8 b	<p>The responsibility to trace product are documented and implemented to ensure:</p> <ul style="list-style-type: none"> · Finished product is traceable at least one step forward to the customer and at least one step back to the supplier; · The effectiveness of the product trace system is reviewed at least annually. · Records of raw material receipt and use, and finished product dispatch and destination are maintained. 			
4.8 c	<p>The responsibility to withdraw or recall product are documented and implemented. The procedure shall:</p> <ul style="list-style-type: none"> · Identify person responsible for initiating, managing, and investigating a product recall; · Describe the management procedures to be implemented; · Outline a communication plan to inform site personnel, customers, consumers, authorities, and other essential bodies in a timely manner; · Ensure that all the relevant stakeholders are listed as essential organizations and notified in instances of a feed safety incident requiring product recall. 			
4.8 d	<p>The procedure in place to ensure complete and rapid recall of any</p>			

	implicated lot/ batch of finished feed.			
4.8 e	Recalled products are held under supervision until they are destroyed, or, determined to be safe for animal feeding.			
4.8 f	Records are maintained of recalled feeds incidents, root cause investigations into actual withdrawals and recalls, and corrective and preventative actions applied and the action taken on recalled feeds.			
4.9 Storage				
4.9 a	Feed storage facilities are designed and constructed to enable maintenance of cleanliness, ventilation, avoid pest access and harborage; prevent contamination and provide suitable conditions of temperature and humidity for minimizing deterioration of feed.			
4.9 b	Adequate facilities for storage of feed, ingredients, packaging material, nonconforming material and non-feed chemicals are provided, and segregated appropriately.			
4.9 c	Feeds are stored under conditions that prevent spoilage, protect against contamination and minimize damage. Feed stored: <ul style="list-style-type: none"> · away from the wall, · not directly on the floor, · on pallets/racks or any other manner to facilitate cleanliness, avoid ingress of moisture, etc. · in clean areas and stacked in a 			

BAFRA GHP/GMP Criteria for Licensing Feed Mills

BAFRA GHP/GMP Criteria

Version 1, 2022

	manner that facilitates ease of movement.			
4.9 d	All products in storage are clearly identified.			
4.9 e	Stocks of raw materials (including packaging material) and ingredients are subjected to effective stock rotation.			
4.9 f	Cleaning materials and hazardous chemical substances have restricted access and only to authorized personnel.			

Maintenance, cleaning and sanitation

Clause #	Requirements	Yes	No	Remarks
5.1 Maintenance				
5.1.a	Establishment and equipment are maintained under an appropriate state of repair and condition to; <ul style="list-style-type: none"> · Facilitate all sanitation procedures · Function as intended particularly at critical steps · Prevent contamination of feed 			
5.1 b	Maintenance programmes are in place which shall cover maintenance schedule, responsibilities, tools and gadgets, etc. and appropriate records maintained.			
5.1 c	Consumables like lubricants that come in contact with feed are food grade, and spares parts of equipment which directly come in contact with feed are non-toxic, non-reactive and impervious			
5.2 Pest Control				

BAFRA GHP/GMP Criteria for Licensing Feed Mills

BAFRA GHP/GMP Criteria

Version 1, 2022

5.2 a	Suitable pest control program are in place			
5.2 b	The pest control activities are performed by trained personnel and are continuously monitored for their effectiveness			
5.2 c	The measures are documented and records maintained.			
5.3 Waste management				
5.3 a	Suitable waste management and waste disposal system are in place. Waste are not accumulated in feed processing and storage areas. Waste bins and areas are identified, covered and kept clean.			

Personal hygiene

Clause #	Requirements	Yes	No	Remarks
6 a	Personnel while working in a feed processing area shall maintain personal cleanliness and shall wear clean uniform.			

Quality Control

Clause #	Requirements	Yes	No	Remarks
7 a	The responsibility and procedure for selecting, evaluating, approving, and monitoring an approved supplier are documented and implemented. A current record of approved suppliers, receipt inspections, and supplier audits are maintained.			
7 b	Verification of raw materials shall include certificate of analysis, or sampling and testing.			
7 c	The quality control programme			

BAFRA GHP/GMP Criteria for Licensing Feed Mills

BAFRA GHP/GMP Criteria

Version 1, 2022

	includes inspection and testing of incoming, in process and finished product and maintenance of records.			
7 d	Infrastructure are available for carrying out testing. In case the same is not available, a proper system for testing in an accredited external laboratories are in place			
7 e	The laboratory have <ul style="list-style-type: none"> · Competent manpower, · Appropriate equipment , · Methods of sampling and testing, · Quality assurance through in-house or external program, · Records of testing, calibration, manpower competence, quality assurance program. 			

Transportation

Clause #	Requirements	Yes	No	Remarks
8 a	Feeds are adequately protected during transport to ensure feed safety			
8 b	Transport containers are designed and constructed so that they do not contaminate feed. Feeds and non-feed shall be suitably segregated during transportation where the same conveyance or container is used for transportation.			

Product information, consumer awareness and complaints

Clause #	Requirements	Yes	No	Remarks
9 a	All incoming, in process and			

BAFRA GHP/GMP Criteria for Licensing Feed Mills

BAFRA GHP/GMP Criteria

Version 1, 2022

	<p>finished products are suitably identified for product (batch/lot) identification. All statutory requirements are clearly given on the label of the final product as per the Food Rules and Regulations of Bhutan (2017). All finished products are given a unique batch number. Any special requirements of handling, transport and storage by customer etc. are clearly indicated on labels.</p>			
--	--	--	--	--

Feed Formulation

Clause #	Requirements	Yes	No	Remarks
10 a	The methods and responsibility for feed formulations and manufacturing processes are documented and implemented.			
10 b	Feed formulations and manufacturing processes for products are reviewed when there are changes in materials, ingredients, or equipment.			
10 c	Records of feed formulations, process flows, shelf life trials, and approvals for all new and existing products are maintained.			
10 d	Specifications for all raw materials and packaging including ingredients, additives, hazardous chemicals, and packaging that impact finished product safety are documented and implemented.			

Complaint Management

BAFRA GHP/GMP Criteria for Licensing Feed Mills

BAFRA GHP/GMP Criteria

Version 1, 2022

Clause #	Requirements	Yes	No	Remarks
11 a	The methods and responsibility for handling, investigating, and resolving feed safety complaints from customers and authorities arising from products manufactured on-site are documented and implemented.			
11 b	All customer complaints are investigated and analyzed and the root cause established about the incidents.			
11 c	Corrective and preventative action are implemented based on the seriousness of the incident and the root cause analysis done.			
11 d	Records of customer complaints, their investigation, and resolution are maintained.			

Competence and Training

Clause #	Requirements	Yes	No	Remarks
12 a	Managers and supervisors have appropriate knowledge of feed hygiene principles and practices. Suitable training are given to all persons to enable them to have the required knowledge and skills in GHP and GMP for the tasks to be performed by them effectively to enable a safe feed.			

Self-Evaluation

Clause #	Requirements	Yes	No	Remarks
13.1 Internal audits and inspections				
13.1 a	The responsibility for scheduling and conducting internal audits to verify the effectiveness of application of GMP and GHP criteria are documented and implemented. Internal audits are conducted in full and at least annually.			
13.1 b	Staff conducting internal audits are trained and competent in internal audit procedures. Staff conducting internal audits are independent of the function being audited.			
13.1 c	Records of internal audits and inspections and any corrective and preventative actions taken as a result of internal audits are recorded.			

Name & Signature of Inspection Team: