

STATUTORY LAW MANDATING THE ROLE OF COMPETENT AUTHORITIES OVERSEEING FOOD OF ANIMAL ORIGIN IN BANGLADESH

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Statutory Law Mandating the Role of Competent Authorities Overseeing Food of Animal Origin in Bangladesh

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The following report has been drafted as part of work package 74 and specifically in response to sub activities 2.2 "Based on the legislation on food safety, develop policies or rules for establishing a Competent Authority for veterinary services in the country, based on the food safety legislation" and 2.3 "Establish a legal mandate to veterinary services to implement regulations on quality and safety requirements for animal products before they can be imported, exported or placed in markets, in order to ensure public health through control on licensing, registration, inspection, food hygiene, processing and storage, transportation, labelling, use of food additives and veterinary medicinal products, use of laboratory tests at production and processing levels"

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Abbreviations and Acronyms

AMR Antimicrobial Resistance

AS & Animal Slaughter and Meat Quality Control (Act)

MQC

BAB Bangladesh Accreditation Board

BFSA Bangladesh Food Safety Authority

BSTI Bangladesh Standards and Testing Institute

CA Competent Authority

DGDA Directorate General for Drug Administration

DLS Department of Livestock Services

FBO Food Business Operator

GAHP Good Animal Husbandry Practices

GHP Good Hygiene Practice

HACCP Hazard Analysis and Critical Control Point
LDDP Livestock and Dairy Development Project

SPS Sanitary and Phytosanitary (Agreement of the WTO)

TAHC Terrestrial Animal Health Code

UNIDO United Nations Industrial Development Organisation

WHO World Health Organisation
WTO World Trade Organisation

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INTRODUCTION

The review of the food legislative and regulatory framework related to the oversight of food of animal origin in Bangladesh has identified various pieces of legislation and regulations whose scope extend from farm to retail, including the management of imported / exported commodities.

The legislations and regulations include:

- The Diseases of Animals Act (2005)
- The Disease of Animals Rules (2008),
- The Animal and Animal Product Quarantine Act, 2005
- The Animal Slaughter and Meat Quality Control Act (2011)
- The Animal Slaughter and Meat Quality Control Rules (2021)
- The City Corporation Act (2009)
- The Fish and Animal Feed Act (2010)
- The Animal Feed Rules (2013)
- The Animal Feed Production and Marketing Guideline (2020)
- The Import Policy Order (2021-2024), in relation with importation of veterinary substances

Other legislation is involved and is related to the role of other food competent authorities in Bangladesh in particular the Bangladesh Food Safety Authority Act and the Bangladesh Standards and Testing Institute Act, which govern the intervention of the respective organizations also involved in the oversight of food of animal origin.

The various provisions related to the safety and quality of food of animal origin, including the oversight of the various steps of production from the farm to the market/consumer, are scattered throughout these pieces of legislation.

While continued efforts are underway to review, simplify and strengthen the regulatory oversight on food from whichever source, this project has identified opportunities to streamline the legislation and associated regulations pertaining to food of animal origin.

Changes to these provisions, could then be integrated in a larger reform of food legislation and regulation in Bangladesh as may be required.

PRINCIPLES GOVERNING THE PROPOSED REFORM OF FOOD LEGISLATION AND REGULATION FOR FOOD OF ANIMAL ORIGIN

The principles followed to develop the proposed legislative and regulatory reform were identified as follows:

- **Principle 1:** Aim to simplify and streamline the legislative and regulatory requirements associated with the production and handling of food of animal origin with the possibility for such requirements to reside in a minimum number of texts, such that there is minimum reliance on multiple texts.
- Principle 2: Aim to maintain the current roles and responsibilities identified and
 defined in the various competent authorities (Figure 1), in relation to the oversight of
 food of animal origin, with the intent to support collaboration and coordination
 between food regulatory partners. A change in these roles and responsibilities would
 imply a major policy shift which can only be developed as a result of a political
 decision.
- Principle 3: Aim to reduce the confusion, duplication and to address gaps in the
 coverage of the current legislation and regulation, with the intent to create a "one
 Stop Shop" for the regulatory requirements and obligations of Food Business
 Operators (FBOs) for Food of Animal Origin, until principal legislation is amended
- Principle 4: Aim to develop texts in legislation (requiring parliamentary approval) that
 include high level requirements and principles, while providing the regulatory
 authority to develop the relevant technical rules, through regulatory provisions that
 are based on evidence and scientific assessments as may be relevant.
- Principle 5: Aim to have the legislation and regulatory rules that are in line with the
 principles set by the international standard setting bodies including the World
 Organisation for Animal Health Codex and the Alimentarius Commission, promoting
 preventive approaches and food safety interventions at the earliest stage of
 production, rather than mitigation strategies

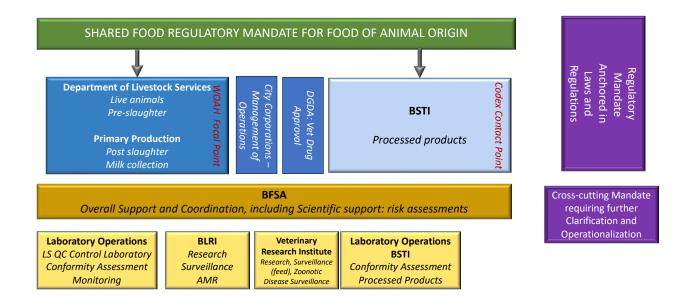


Figure 1: Shared roles and responsibilities for food regulatory oversight applied to food of animal origin in Bangladesh

PROPOSED STRUCTURE OF THE LEGISLATIVE AND REGULATORY PROVISIONS IN THE REFORMED LEGAL FRAMEWORK FOR FOOD OF ANIMAL ORIGIN

The proposed legislative and regulatory structure to be adopted will attempt to include the various requirements associated with the various steps of production of food of animal origin from the farm to the retail, including to foreign markets.

It will be important that new texts of legislation be developed to cover the following items with the proposed structure outlined in Figure 2, where a possible text of legislation for example: the Safety of Food of Animal Origin Act, be the prominent document, supported by regulatory provisions and rules that are developed under the Authority of this Act.

Under this Act, the Department of Livestock Services (DLS) will be the prominent regulator, with the collaboration of:

- BSTI,
- BFSA.

- City Corporations,
- Directorate General of Drug Administration (DGDA).

The structure proposed in Figure 2 includes general requirements of safety and quality that need to be fulfilled, which should generally be included in food legislation, requiring producers at any level of production to not sell or make available contaminated and/or adulterated products, nor to have their operations performed under unsanitary conditions. Standard setting functions need to be supported by the relevant powers and authority given to regulators. In the case of foods of animal origin, this would cover food, feed, and veterinary substances including feed additives. Powers and authority should be given to regulators to oversee production establishments, including setting the relevant rules of safety to be fulfilled, observance of pre-requisite programs, preventive controls, and hygienic practices. These requirements are generally the foundation used by regulators to underpin licensing or registration of food production operations from farm to the retail. Licensing production premises generally goes beyond the simple identification of the establishment through "administrative registration" and would include the need to comply with the safety and quality requirements of operations. Authority to set requirements of operations

(supporting licensing or not) are also generally accompanied by the authority to verify compliance and enforce the relevant provisions with a set of sanctions included in the Act and / or regulations.



Figure 2: Proposed structure of the legislative and regulatory provisions in the reformed legal framework of food for animal origin

PROPOSED COMPOSITION OF THE REFORMED LEGAL FRAMEWORK FOR FOOD OF ANIMAL ORIGIN

The following paragraphs offer a descriptor of the elements composing the newly proposed framework:

1. General Requirements of Food Safety Management Applicable to Food of Animal Origin

These provisions may refer to other requirements that are already listed in other food legislation, and should create general prohibitions against:

- Availability / sale of food of animal origin that is contaminated, adulterated, or harmful to human health,
- Availability/sale of food of animal origin that is mis-represented/mislabelled as to its composition, with the intent to deceive clients or consumers,
- Availability / sale of food of animal origin that was produced under unsanitary conditions,

The provisions should also prescribe the requirements to adopt hygienic production practices along the supply chain, including the requirements of safety of inputs such as feed, with the obligation to apply and document preventive controls in all aspects of production.

A general provision should also be developed to provide powers to competent authorities, with oversight on any segment of production of food of animal origin, to develop the required technical regulations or rules supporting the achievement of the principles listed above

2. Standard Setting Provisions

These provisions should refer to other provisions in food legislation and regulations related to the setting requirements of safety of additives, pesticides or the way contaminants should be limited in food of animal origin, including microbiological criteria.

If required, dedicated requirements for microbiological criteria could be developed incrementally for products of animal origin, applying the risk analysis principles as a foundation, and guided by international standards (codex standards).

Specific requirements could be considered for veterinary drug management and the availability / use of medicated feed.

The requirements of approval of veterinary substances in conjunction with food producing animals are to be well defined in the regulatory provisions, identifying the:

· Process of submission of requests for approval of new substances and their use,

- Management of veterinary substances in conjunction with their availability and sale,
- Conditions of use and the requirements to observe Maximum Residue Levels in food of animal origin.

This pre-market standard setting should cover all aspects related to the review, the sale and use of veterinary medicines and biologicals; identifying conditions of "prescription only sales" of antimicrobials and other medicines for treatment of food producing animals, also specifying the requirements of setting and respecting withdrawal periods, setting conditions of prophylactic use of antimicrobials if any, as well as regulating dry cow therapy of dairy animals.

These regulatory provisions should cover the management of the residues in food destined to humans by specifying the conditions of setting up MRLs.

The regulatory provisions should also be clear as to the roles and responsibilities of the various regulators involved in this process, including:

- The Directorate General of Drug Administration (DGDA),
- BSTI and BFSA,
- DLS.

The governance structure (e.g., committees, technical working groups) related to the decision-making about these technical provisions should also be explicitly defined in the regulations, leaving minimum discretion to the required level of collaboration and concertation between the competent authorities involved (identified above) to reach such decisions.

Regulatory provisions should also be developed to mandate the post-market surveillance of the antimicrobial use (AMU), along with the set-up of a residue monitoring program, the result of which should be periodically published.

It is also recommended that the regulations require the examination of the data generated from the surveillance and monitoring activities, with the relevant data exchange between all food competent authorities involved and to support the review and change of policies related to AMU and management of antimicrobial resistance.

Roles and responsibilities as well as resource allocation related to these activities should also be identified in these rules / regulations, with the intent to limit to the level of discretion on such interventions.

3. Set-up of Safety Requirements of Production Operations

Regulatory provisions should be set to define safety requirements that need to be fulfilled for specific steps of production or facilities of production of animal derived food, including:

• On-farm safety requirements, (Biosafety, animal health, prevention and control of zoonotic diseases that may be transmitted to humans via PoAO)

- · Animal Husbandry requirements,
- Animal welfare conditions to be fulfilled,
- · Requirements of transportation of live animals and food of animal origin,
- Good Hygienic Practices that need to fulfilled by operations of production of food of animal origin.

Where required and for specific establishments, such as:

- Slaughterhouses,
- · Butcher shops,
- Meat processing facilities,
- Wet markets
- Milk collection centres.,
- · Milk processing facilities

Requirements of operations for these establishments to fulfil the safety conditions need to be specified, including Ante-mortem and Post-mortem inspection of animals and meat where relevant.

Requirements of traceability, at least at n-1 / n+1 level, meaning with the obligation to keep records of at least the most immediate supplier(s) and the most immediate client(s), would need to be envisaged to support the preventive approach and a better response time in managing food safety incidents.

These requirements will be the basis for regulatory compliance, administered through the registration or licencing of the said establishments as a condition to qualify for such registration / licencing and to maintain it.

4. Management of Food Production Operations for Food of Animal Origin

One of the key components of the food regulatory oversight on food of animal origin is to enable the registration /licensing of premises that operate various steps of production of food of animal origin. This would include:

- Registration of farms (including livestock and poultry farms)
- Registration of milk collection centres,
- Registration of all premises handling animals destined for human consumption

(slaughterhouses, butcher shops, processing facilities)

- Registration of feed production and mixing / handling operations

Some provisions, currently in place in section 16 of the Diseases of Animals Act (2005) would be consolidated with these provisions. Similarly provisions under Rule 18, Schedule 6 of the Disease of Animals Rules, (2008), would be consolidated to define all the conditions that need to be fulfilled for such facilities to meet registration/licensing requirements. Consolidation of the provisions related to licensing of abattoirs and slaughter facilities currently scattered between the Animal Disease Act (2005) & Rules (2008) and the Animal Slaughter & Meat Quality Control (AS & MQC) Act (2011) & Rules (2021), will be achieved through these provisions.

The authority of the registration/licensing of each type of facility will need to be clarified, with a clear emphasis on the leadership of DLS for farms and all facilities handling primary production.

All registration/licensing provisions will be conditioned by meeting the requirements of operations defined in the paragraph above (4.3 - Set-up of Safety Requirements of Production Operations).

Gaps related to the registration/licensing of transportation facilities / vehicles, of privately owned slaughter facilities and or import/export operations will be addressed through these consolidated provisions. Similarly, duplication or confusion in the application of some provisions, such as those related to the conditions of management of facilities operated by government and city corporations will need to be addressed following the principle that no exception should exist in the standards of safety requirements to be applied / followed by such operations.

Although the terms of "Licensing" and "Registration" have been used in this paragraph interchangeably, they can be differentiated in legislation and regulation, where registration is generally a simple mechanism of identification of who does what – identifying the operations with minimum prerequisites; on the other hand licensing of operations is generally conditions by fulfilling requirements of safety and quality, in the way the establishment is designed and operated.

5. Management of Import Export Operations

Dedicated and consolidated provisions should be developed to cover the import/export of live animals and animal products, which cover both sanitary and trade considerations.

The clarification of the roles and responsibilities of DLS in issuing and enforcing rules related to these operations, in collaboration with other government parties (Customs, Ministry of Finance) will need to be clarified.

Export control provisions should include the power (to DLS) to issue certificates of compliance or suitability with the provisions of the importing country.

Import control provisions should be reviewed with the intent to be risk-based and to remove unnecessary technical burdens that may be historical or inherited from previous international situations (e.g., requirements of testing of milk for Cs137 which would not be justified for regions

not subject to nuclear accidents).

Import and export control provisions should also cover feed and feed products (inputs).

6. Requirements of Collaboration and Cooperation – Governance Structure

With the current roles and responsibilities remaining the same i.e., shared responsibilities between several government organisations, it will be important to ensure that the relevant coordination mechanisms be identified and be mandated in legislation. These could include high level steering committees, taskforces and working groups between the relevant parties and in particular DLS, BFSA and BSTI. Coordination with DGDA will also be required for aspects pertaining to the management of veterinary substances and AMR.

The governance and coordination structures should be set, such that they are amenable to operationalization, i.e., are workable structures with a representation from the Working / Technical level (bottom-up approach), meeting frequently and a direction / steering provided by the senior leadership of the organisations to enable empowerment and endorsement of decisions.

Enshrining these requirements of coordination in legislation and regulatory texts will limit the level of discretion as to their importance and the requirements of their operationalization by the relevant groups.

The way these coordination and collaboration efforts are to be developed is being currently discussed through the organisation of bilateral roundtables, between the various food competent authorities in Bangladesh, sharing the responsibility of oversight on food of animal origin. These bilateral meetingsl aim to identify both the "working" mechanism of coordination as well as the steering functions to be set to ensure the sustainability of the collaboration between the relevant regulatory partners.

CONCLUSION

The development of a consolidated set of legislation and regulatory texts supporting the control of and the oversight over food of animal origin along the entire production chain is a necessity to enhance such level of oversight and address some of the challenges and gaps identified in the legislative and regulatory review.

While most of the powers and the requirements of oversight are already present in the current legislation, the scattered nature of these requirements (in different texts and provisions, dating to different periods) and their uneven distribution, as well as their reliance on principles different from the preventive approach and the application of the risk-based lens in setting regulatory programs provide for opportunities of improvement through the development of this new legislation and the associated regulatory texts. By addressing the requirements of coordination and collaboration between competent authorities in these texts, direction will be given to exercise the shared responsibilities of oversight with a stronger complementarity and reliance on the expertise and mandate of each organisation: e.g., BFSA for risk assessment and scientific / technical direction, DLS for regulatory development and enforcement.

Developing updated and modernized legislative and regulatory provisions will only be effective if accompanied by the development and deployment / operationalisation of the relevant regulatory programs as well as the development of a capacity of compliance verification and enforcement that embraces the spirit and principles of the revised legislation (risk-basis, preventive approach) aiming to develop a culture of compliance amongst food business operators, along with a strong capacity of enforcement, governed by decisions applying the risk analysis principles and commensurate with the level of risk.



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