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INDUSTRIAL DEVELOPMENT ORGANIZATION



INTEGRATION OF RISK-BASED APPROACH RELATED TO THE LIVESTOCK SECTOR

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WORLD BANK GROUP

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Integration of Risk-Based Approach Related to the Livestock Sector

Work Package 74, Sub-activity 3.8

This report is submitted in response to Workpackage 74 and Sub-activity 3.8. “Provide leadership and assist in the development and strengthening of risk-based, integrated national systems for food safety”

Prepared by

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Department of Livestock Services

Ministry of Fisheries and Livestock

Bangladesh

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Abbreviations and Acronyms

AMR	Antimicrobial Resistance
AS & MQC	Animal Slaughter and Meat Quality Control (Act)
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
GAP	Good Agricultural Practices
GHP	Good Hygiene Practice
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis and Critical Control Point
IARCC	Interagency Regulatory Coordination Committee
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 AND OBJECTIVES

This report offers a review and recommendations regarding the Governance Structure associated with the regulatory oversight exercised with respect to the management of the Livestock sector in Bangladesh.

This review is based on the results of a mission executed from 5-8 March 2023 by Prof. Samuel Godefroy and Dr. Gabor Molnar.

At the request of partners and stakeholders, and based on the commitments made by the project implementation team for the “Food Safety Component” of the Project, additional recommendations have been assembled to support the implementation of a risk-based approach in planning and delivering food regulatory oversight for foods of animal origin, at the domestic level and, additionally, to manage imports and exports.

REVIEW OF THE GOVERNANCE STRUCTURE AND PROPOSED ENHANCEMENTS

1. Approach Followed and Methodology

A mission to the People’s Republic of Bangladesh was carried out from 5-8 March 2023, as part of efforts to enhance the food regulatory oversight on foods of animal origin, with a particular emphasis on areas pertaining to the oversight of the Department of Livestock Services (DLS), whose responsibility is focused on the primary production of food of animal origin.

The mission targeted the delivery of a workshop to key directors and managers of the DLS over 1.5 days and involved Prof. Samuel Godefroy, Senior Food Safety Regulatory Expert, and Mr. Michael Barry, Food Safety Expert.

The objective of the workshop organised during the mission was to:

- (1) Continue discussions on current governance, inter-agency coordination and management approaches associated with the development of standards, technical requirements and rules with regards to foods of animal origin, with the involvement of the various food regulatory partners in Bangladesh.
- (2) Review best practices in food safety governance associated with:
 - a. Standard setting, rulemaking and technical regulation development related to foods of animal origin.
 - b. Compliance verification and enforcement measures.

- (3) Recommend a better understanding of roles and responsibilities among food regulatory partners, in particular DLS, BFSA and BSTI, as well as, other partner organizations (for example: data providers, research institutes).
- (4) Recommend an enhanced governance and interagency coordination approach for strengthened operations of food regulatory functions, including situations pertaining to food safety incident management and foodborne illness outbreak management.

The proposed agenda of the workshop is appended to this report under Annex 1.

The workshop included discussions between senior directors of DLS, enabling better characterization regarding the role of DLS as a regulatory authority in key food regulatory functions, with emphasis on standard setting, food safety rule making, compliance verification and enforcement.

2. Mapping of Current Responsibilities and Interagency Management

Workshop participants mapped the current food standard setting roles and responsibilities of various food regulators, with emphasis on foods of animal origin and a focus on primary production.

Based on the current legislation and regulations in place and the empowerment provided by these texts, the main authority in charge of food regulatory oversight was identified, along with supporting agencies working in the same field and intended to provide support or additional oversight on a given sector or value chain.

Authorities were identified for the key functions of standard setting and rulemaking as well as enforcement (Table 1).

Questions were raised for food produced from primary production and with minimum processing. It was agreed that the regulatory authority **should remain with DLS** for these products, with involvement of other regulators as required.

The food regulatory capacity of DLS was discussed and it was agreed that although DLS enjoys a high technical and veterinary capacity, the capability of the department in generating scientific information and assessments to support the development of rules and standards was limited. This function should be assumed through collaborative mechanisms with other regulators, such as BFSA, whose mandate includes this function and the “support function” to other regulators.

It was also concluded that a prioritization of DLS food regulatory functions be conducted, with a possible focus on the development of guidance and rules on the hygienic conditions of production of foods of animal origin, as part of the primary production cycle.

Table 1: Findings of Relevance Related to Shared Roles and Responsibilities and Oversight on Food of Animal Origin

Rule / Standard	Authority Empowered to Set the Rule / Standard in General	Authority involved in Setting the Rule / Standard for Primary Production of Food of Animal Origin	Corresponding Enforcement Agency for Primary Production of Food of Animal Origin
Horizontal Standards: Contaminants in Food	BFSA in collaboration with DLS and BSTI	BFSA with consultation of DLS	DLS
Horizontal Standards: Additives	BFSA in collaboration with DLS and BSTI	BFSA with consultation of DLS	DLS
Horizontal Standards: Microbial Criteria	BFSA in collaboration with DLS and BSTI	BFSA with consultation of DLS	DLS
Horizontal Standards: Methods of Analysis and Sampling	BFSA in collaboration with DLS and BSTI	BFSA with consultation of DLS	DLS
Horizontal Standards: Maximum Residue Limits of Pesticides in Food	BFSA / BSTI	BSTI/BFSA in collaboration with DLS	DLS
Horizontal Standards: Maximum Residue Limits of Veterinary Substances in Food	BFSA / BSTI (with the involvement of the Drugs Directorate, Ministry of Health for the approval)	BSTI/BFSA in collaboration with DLS	DLS
Horizontal Standards: Labeling	BSTI	BSTI/BFSA	DLS
Rules Supporting Sanitary Conditions of Production: Pre-requisite Programs (PRPs), Preventive Controls, Traceability These rules should underpin Licensing of Establishments	BFSA	BFSA, City Corporation and DLS This function needs to shift entirely to DLS	DLS
Licensing	BFSA (Some authority exercised)	DLS / City Corporation	DLS

3. Major Recommendations

The consultation process that resulted from this workshop led to the identification of the following recommendations:

A. Recommendation 1:

It is recommended that an Interagency Committee on Food Regulatory Decisions, gathering DLS, BFSA and BSTI be created.

This Committee would act to support the formulation of recommendations related to approvals of substances and applications used in food of animal origin and subject to oversight.

The Committee would also be tasked to review and clarify roles and responsibilities in food standard setting functions and support the follow-up on agreed collaborative activities between the involved agencies.

B. Recommendation 2:

It is recommended that the MoU between DLS and BFSA be broadened to enable BFSA to play the role of the Food Risk Assessment Body for decisions requiring such assessments (in a manner that is similar to EFSA's mandate in Europe) with the relevant development of Procedural Measures.

C. Recommendation 3:

It is recommended that a Procedural Manual be developed, led by DLS, to include process maps related to the development and promulgation of food regulatory measures / decisions pertaining to food of animal origin, e.g. approval of substances and processes related to food of animal origin or measures to manage contaminants in food of animal origin, as well as other horizontal provisions.

This task would be led by the DLS Admin Group.

D. Recommendation 4:

It is recommended that food regulatory priorities be clearly identified for DLS with emphasis on rule-making pertaining to hygienic conditions of production.

E. Recommendation 5:

It is recommended that DLS technical teams have stronger engagement in international standard setting processes, in particular in work carried out by the Codex Committee on Residues of Food of Animal Origin.

4. Next Steps

The proposed, agreed-upon next steps would involve:

- A. Engagement between DLS leadership and BFSA, as well as BSTI, to discuss and agree on the creation of the Interagency Regulatory Coordination Committee (IARCC) with the relevant scope and terms of reference.
- B. Convene the IARCC and develop priorities of its agenda of work, starting with the clarification and adoption of formal agreements on the manner in which shared responsibilities would be exercised, including the way collaborative efforts would be planned and executed (e.g. risk assessment in support of rule making).
- C. DLS (through the admin group) to proceed with the development of the process map for key food regulatory functions that DLS is entrusted with, along with the development of the relevant procedural manuals.

INITIAL CONSIDERATIONS FOR THE IMPLEMENTATION OF RISK-BASED OVERSIGHT ON FOOD OF ANIMAL ORIGIN – FOCUSING ON INSPECTION RESOURCES

This section of the report will attempt to address initial considerations given for the inclusion of a risk lens in the development and administration of food regulatory oversight on food of animal origin in Bangladesh, with an emphasis on factors related to compliance verification and enforcement through inspection.

With the important number of production establishments, primarily made of artisanal and small-scale businesses and fresh markets, in addition to, the limited resources deployed to carry out the inspection activities related to food of animal origin, traditional food inspection systems tend to be reactive in nature, inspecting (or enhancing the inspection activities) of an establishment or import in response to food safety incidents (i.e., recalls, outbreaks, international alerts).

A risk-based inspection tends to be more proactive and preventive in nature, collecting and analyzing historical data from the inspection activities in order to identify high-risk conditions. Directing the inspection effort toward the high-risk situations (establishments, food products and inherent hazards) would render efficient use of available resources, while protecting public health.

The main goal of a risk-based inspection is to drive more resources (i.e., higher inspection frequency and/or inspection intensity) toward the high-risk establishments and imports.

The risk based inspection approach (Figure 1) is based on guidance from the Codex Alimentarius

Commission and encompasses components of:

- **Assessment:** identification of risk-profiles and assignment of the level of risk,
- **Management:** Decision on the assignment of the level of inspection (frequency, intensity) based on risk and,
- **Communication** of the decision to stakeholders.

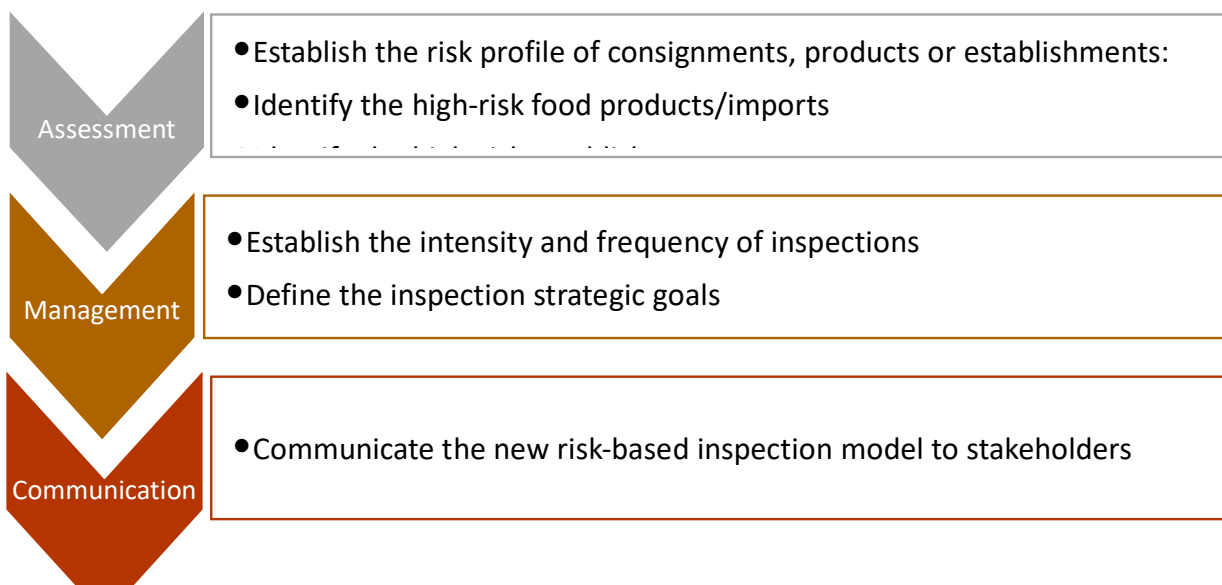


Figure 1: Risk analysis principles applied to a risk-based inspection

The implementation of a risk-based inspection system has several benefits for regulators, including:

- **Predictability:** Ability to analyze the historical inspection records and anticipate future potential risks.
- **Efficiency:** Inspection resources are optimized and aligned with the food safety risks.
- **Training:** Highly skilled inspection personnel with a clear understanding of food safety risks and the risk analysis process.
- **Customization:** Inspection systems are tailored to the specific country's reality.
- **Harmonization:** Favorable conditions for adopting harmonized regional food inspection systems.
- **Documentation:** Registration databases enable a record of all domestic food facilities and/or importers, including historical food inspection profiles.

1. Challenges and Needs

The implementation of a risk-based inspection system imposes the reliance upon several pre-requisites including:

- **Databases and data collection procedures** need to be created with the intent to contain:
 - o Information about the domestic facilities within the oversight of the regulator, of different activities, i.e. slaughterhouses, processing facilities or retail facilities.
 - o Information related to the importers, country of origin and type of products imported in order to manage imports.
 - o Historical data on the results and types of inspections performed including non-compliances observed by inspectors or enforcement agents.
- **IT solutions:** Creation of online platforms (Figure 2) and databases are a must:
 - o Cloud-based databases that include all the historical data related to the inspections performed for imports and domestic food production.
 - o Dynamic risk algorithm(s) that allows to assign the intensity and inspection frequency based on the historical data and risk posed by a given facility.
- **Training:** Inspection personnel need to be trained in risk analysis principles and risk-based inspection.
- **Culture of Risk-Based Interventions:** Risk-based inspection systems need to be part of a decision-making framework adopted by the regulator on an on-going basis.
- **Roadmap for the implementation of an import-export risk-based food inspection system**

Where possible a clear legislation and regulation should empower the regulator to apply the risk-based approach, including with the ability to collect and maintain / analyze data, supporting the decision-making process (establishment information and performance).

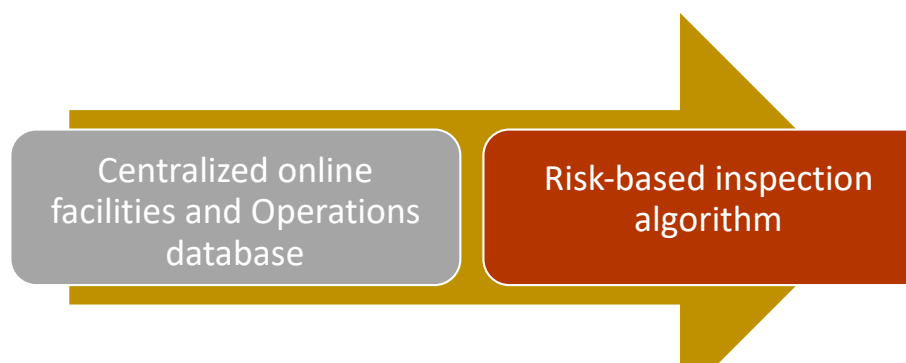


Figure 2: Technological requirements for the implementation of a risk-based inspection system

2. Inspection manuals and procedures

Inspectors assigned to implement the risk-based enforcement approach need to follow a standardized procedure to conduct the inspection of facilities based on the level of intensity assigned (guided by the risk determination).

Inspection manual procedures should describe (adapted from Codex, 2012):

- Organizational chart of the official inspection system.
- Job functions and responsibilities of the inspector.
- Operating procedures on how to conduct an inspection including technical requirements, infrastructure, and equipment.
- Types of inspections to conduct.
- Decisions to be made upon the finding(s) of a non-conformity.

If inspectors from several authorities are carrying out inspections, a standardized unique inspector manual should be developed to harmonize inspection procedures among all authorities.

Inspectors need to follow a standardized procedure to conduct the inspection of an establishment.

Typically, different types of inspection exist:

- **Continuous:** Permanent inspection. This is carried out by the official veterinary inspector at the slaughterhouses.
- **Periodic:** Verify Good Manufacturing Practices (GMP), Good Agricultural Practices (GAP), and Hazard Analysis and Critical Control Points (HACCP).
- **Follow-up:** In response to a serious non-compliance that affected the safety of the product.
- **Response:** In response to an outbreak or alert.

Depending on the type of inspection, the inspector should follow a checklist that will contain a list of factors that can impact the safety of the product. Usually, the inspector will inspect compliance with GMPs for all food establishments and the presence of preventive controls or HACCP in those establishments that would pose a higher risk.

Although generic checklists are useful for uniformity, some specificity may be introduced depending on the food of animal origin that is targeted (e.g., dairy, meat or other).

It is also recommended that the checklists be quantitative (using a score system) that allows the determination of a final inspection score and facilitates comparison of the establishment's performance over time and movement of the percentage of compliance.

This can also serve as a communication tool with the establishment being made aware of their score.

3. Risk Algorithm and Decision Trees

Risk categorization is a risk assessment process where facilities are categorized based on the risk level of the products they carry, the operations they perform and their level of performance with regards to food safety management and compliance with regulatory requirements.

The risk is evaluated based on the potential hazards present and several parameters including the degree of processing, the control that the food undergoes, the annual volume of production per food category, historical performance of the operation in complying with food safety management requirements, including regulatory requirements and the possible product recalls from a given establishment.

It is possible to have this risk assignment (for a facility) and the associated decision of inspection (frequency and intensity) result from a program set in the form of an algorithm.

It is also possible to reach these decisions as part of decision trees and risk matrices.

The use of these different tools will depend on the data and expertise available for the regulators involved.

It is recommended that the approach follows an incremental process from simple to more complex tools.

Decision trees are simple visual tools to provide an objective approach for conducting risk categorization exercises. The tool consists of a flow chart with a series of simple questions (typically with yes/no answers). It is important that each node of the tree results in a clear yes or no decision (e.g., does product support pathogen growth?). Due to its simplicity, decision trees are easy to customize and can be as generic or specific depending on the food chain or specific products. The output from decision trees are risk categories (e.g., high, moderate, or low risk) that can be used by the regulator to decide on **inspection intensity and frequency**.

An example of decision-tree is shown in Figure 3 for illustrative purposes. This example shows how to develop a decision on categorizing a product based on the microbiological risks and how they may be managed.

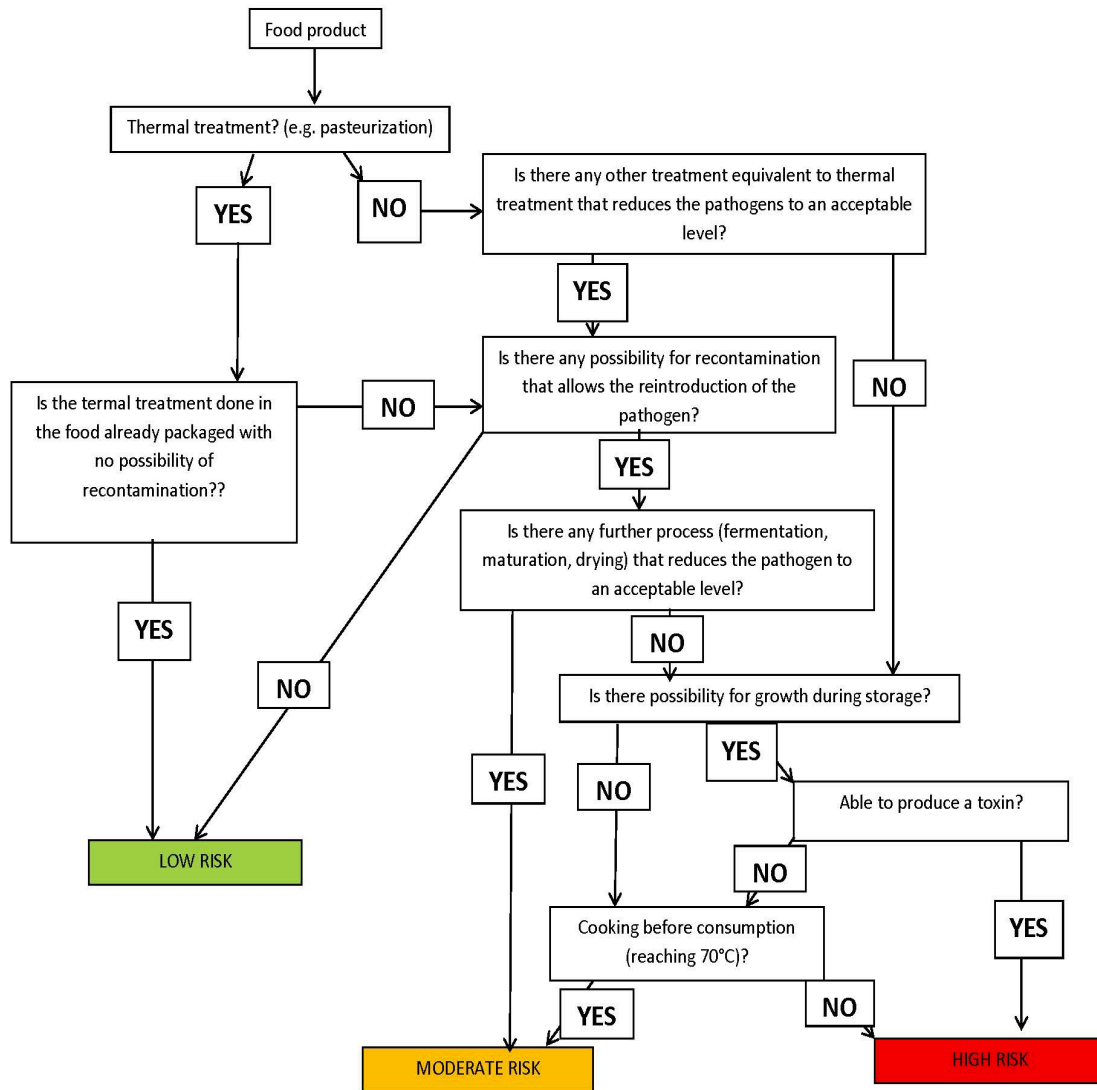


Figure 3: Decision tree to categorize food products based on the microbiological risk.

For imports, categorization of the risk (figure 4) is based upon several parameters including the inherent food safety risk of the food imported, the country of origin, the importer’s performance and the facility’s performance (facility involved in the production of the food):

- **Country of origin** (based on information related to international alerts, lack of trade agreements, assessment of the official inspection system).
- **Importer performance** (% of noncompliance).
- **Facility of origin** (compliance with regulations by the official regulatory agency at the country of origin, third party certifications).

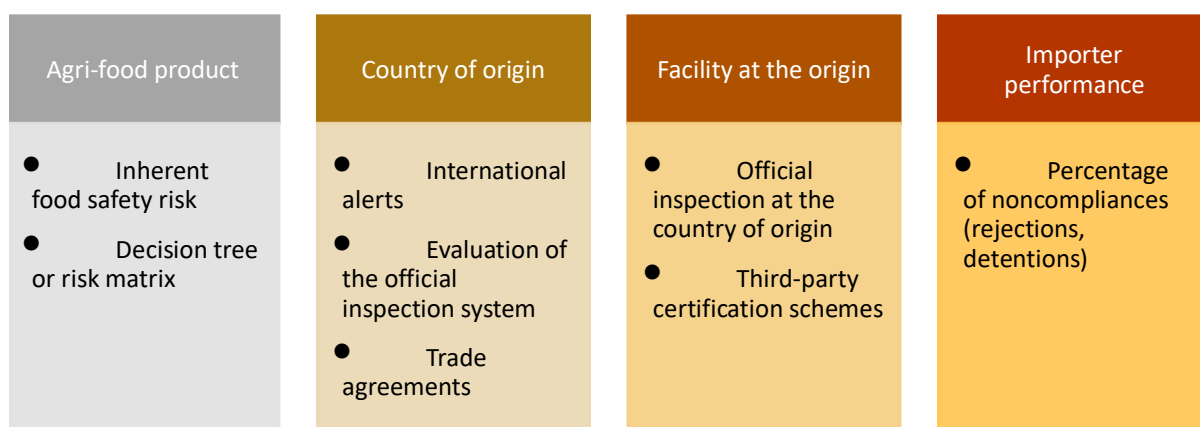


Figure 4. Risk factors to include in the risk algorithm

4. Communication and Continuous improvement

Once the risk-based inspection system has been designed, a timetable for implementation and enforcement must be established. For this purpose, internal review of procedures and meetings should be held within the organization to ensure that inspectors know and understand the new risk-based inspection system.

Communication channels should also be established with the industry and other actors in the production chain to explain the new model and establish a staggered implementation schedule (Table 2).

Table 2: Examples of communication of the new risk-based inspection system.

Communication Channel	Purpose
Website	Publish the new inspection model on the website (including compliance dates)
In-Person / Virtual Meeting	Explain the new risk-based inspection system to industry and producers allowing time for a Q&A session
Letter	Send letters to industry/producers concerning the new risk-based inspection system

It is also important that the regulator periodically evaluates its performance (at least annually) to identify potential improvements and adjustments.

Once the results of the inspections are obtained for the period considered (e.g., annual), the team in charge of the operation plan must analyze the risk scores obtained from the system to assess the performance of each establishment and the situation of the entire sector or production chain, in order to set new inspection objectives and reformulate controls.

To this end, those establishments that were identified with poor performance may be subject to more scrutiny in the subsequent period, including more frequent inspection.

A “traffic light” color code (e.g., red, yellow and green) can also be established by categorizing establishments according to their risk score. The % of worst, intermediate and best performing establishments can be calculated for the whole sector in order to set new targets within the operation plan for the following years. For example, an official entity may identify as a target: “to reduce the percentage of high-risk establishments by 50% over a two-year period”. Figure 5 shows an example of the traffic light a regulatory agency may use to understand the level of risk among the food establishments.

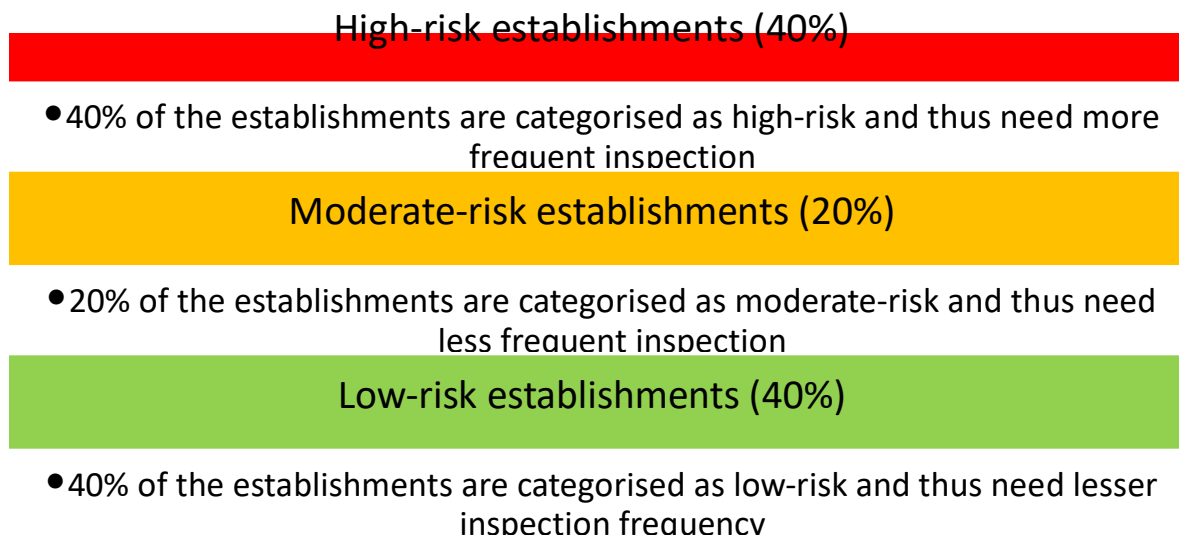


Figure 5: ‘Traffic light’ indicating the food safety performance of establishments

In turn, analysis of the results of the new system can indicate trends (improvement or worsening) in the performance of each facility over time, allowing the frequency of inspection to be varied according to compliance results. An analysis of the results can also reveal differences in assessment attributable to the inspector during the inspection (which should be minimized by exchanging technical criteria) or “weak points” common to all establishments in the sector, which can be used by inspectors to emphasize areas for improvement and thus reduce the risk of the establishments.

Periodically, it is advisable to review the inspection checklist to check that all risk factors are included, and to include new regulatory aspects. At the same time, it is important to update the weighting or “weight” to be given to each factor in the establishment’s risk matrix. For example, new aspects related to emerging hazards such as history of non-compliance findings in finished product and pathogen verification programs on **food contact surfaces** are some of the risk factors that can be considered for inclusion in the risk matrix for categorization of the establishment.

Finally, it is important to highlight that taking into account the experiences of countries with implemented risk-based inspection systems, it has been possible to observe a better performance of small establishments, as inspectors are present more frequently than before, which in itself represents a great achievement in the new risk-based inspection system.

CONCLUSION

The review of the shared responsibility of oversight on food of animal origin in Bangladesh, is a crucial step to establish the relevant coordination mechanisms between the DLS and other regulators involved in the operations of food regulatory programs.

Recommendations for the development of standing committees of coordination between the DLS and the other regulators in particular BFSA and BSTI were made and are being initiated through the organisation of bilateral meetings between DLS and these entities.

Considering the importance of effective management of food regulatory resources, in particular those devoted to compliance verification and enforcement, a risk based approach was discussed, with initial considerations of conditions of achievement. The proposed approach is far from comprehensive and needs to be complemented by a practical development supported by the actual realities of the food regulatory operations of DLS and informed by the type of establishments targeted as well as the current workforce and resources in place and to be foreseen by the DLS and its partners.

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ANNEX 1

Workshop Agenda

DAY ONE – Monday 07 March 2023

Objective of the day:

The aim of the day is to review key food regulatory functions subject to further review and enhancement and to initiate proposals for re-engineered operations of such functions supported by an updated collaborative approach.

Moderator: *Prof. Samuel Godefroy, Senior Food Safety Regulatory Expert*

9:30 – 10:00 Inaugural session

1. *Welcome address:*
 - a. *By Dr. Md. Ainul Haque, National Project Coordinator*
 - b. *Dr. Gabor Molnar, Industrial Development Expert, UNIDO*
2. *Speech by Special guest Md. Abdur Rahim Project Director, LDDP*
3. *Inaugural Speech and opening of workshop by Special guest:*
 - a. *Director General, Department of Livestock Services*
 - b. *by Chief guest Dr. Mohammad Yamin Chowdhury, Secretary, MoFL*
4. *Concluding Statement by Dr. Zaki Uz Zaman, UNIDO Country Representative in Bangladesh*

10:00 – 10:30 Tea break

10:30 - 11:30 Review of the Key Food Regulatory Functions Targeted by Enhancement of Operations and Enhancement of Governance/ inter-agency coordination: Standard Setting, Rulemaking, Compliance Verification and Enforcement – Prof. Samuel Godefroy, Professor Food Risk Analysis and Regulatory Policies, Laval University, Quebec, Canada - Food Safety Regulatory Expert, UNIDO

11:30 – 13:00 First Facilitated Roundtable Discussions on Current Governance / inter-agency coordination and Practices in the Operation of the First Set of Targeted food regulatory function:

**Operation of Establishments Involved in the Production of Food of Animal Origin
Rulemaking, Compliance Verification and Enforcement**

13:00 – 14:00 Lunch and prayer break

14:00 – 16:00 Second Facilitated Roundtable Discussions on Current Governance / interagency coordination and Practices in the operation of the Second Targeted food regulatory function:

Standard Setting: Substances used in conjunction with food of animal origin

Management of Contaminants in Food: Chemicals and Microbiological

**Other Requirements (e.g., quality attributes and methods of production) :
Halal/Local**

16:00 – 16:30 Closing remarks of the day and reflection for day two by *Dr. Md. Ainul Haque* and *Dr. Gabor Molnar, UNIDO*

DAY TWO – Tuesday 07 March 2022

Objective of the day:

Review Findings of Day 1 and Recommendations of Next Steps

Review of Codex guidance on management of food safety emergencies and foodborne illness outbreaks

9:30 – 10:30 **Review of day One activities and Modalities for day two workshop** by *Prof. Samuel Godefroy*, Professor Food Risk Analysis and Regulatory Policies, Laval University, Quebec, Canada - Food Safety Regulatory Expert, UNIDO

Review of Findings of Day 1 Discussions:

Mapping of current operations and practices and

Recommendations of enhancement of food regulatory operations and interagency coordination

10:30 – 11:00 Tea break

11:00 – 12:00 **Presentation on Codex Guidance Related to: Food Emergency Preparedness/Management and Management of Foodborne Illness Outbreaks**

Prof. Samuel Godefroy, Professor Food Risk Analysis and Regulatory Policies, Laval University, Quebec, Canada - Food Safety Regulatory Expert, UNIDO

12:00 – 12:45 **Group Discussion**

Discussion of Additional Requirements of Enhancements Stemming from the Codex Guidance Proposals:

Reviewed and Updated Roles and Responsibilities in the operation of the targeted food safety regulatory functions, applied to food of animal origin

- Enhanced Governance and interagency coordination: Enhanced coordination mechanisms, New / additional support mechanisms / tools
- Enabling environment
- Presentation of the outcomes from each group and proposals for a way forward

12:45 – 13:00 **Closing remarks of the day and Review of Workshop Outputs and Next Steps** by Dr. Md. Ainul Haque and *Dr. Gabor Molnar*, UNIDO

13:00 – 14:00 Lunch break



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