INSPECTION PROCEDURE– Licensing Process for Food Businesses

1. Objective

The objective of this document is to regulate the operation of the BFDA Licensing Process and promote uniformity in its operation and the interaction between BFDA and the Food Businesses (FBs) as required by the Food Act of Bhutan (2005).

2. Scope

This document explains the process of Licensing of food business operations in Bhutan except for street food vendors and temporary mass catering services during events under the Food Act of Bhutan and lays down the requirements that shall be followed in order to obtain, operate and maintain the BFDA Food Safety License for Food Businesses.

3. Scope of Licensing

The scope of the BFDA Licensing Process for Food Businesses covers Food Businesses (FBs) processing food products in Bhutan as per the BFDA Licensing Criteria which is the BFDA Criteria for Good Hygienic and Manufacturing Practices. Food businesses processing livestock-related products shall also comply with requirements specified in the Livestock Rules and Regulations of Bhutan 2017.

4. Licensing Process Requirements

4.1 In addition to the requirements specified in the applicable Licensing Criteria, the requirements specific to Licensing Process as described in this document shall also apply.

4.2 **Licensing Terms & Conditions–** The Licensing terms and conditions describe the requirements which the FB is required to abide by after the Food Safety License is granted. The details of the requirements are also available on the BFDA website. These terms and conditions also cover requirements with respect to use of the Food Safety License number by FB.

4.3 BFDA does not outsource any of the Licensing activities, and all activities are carried out by personnel who are employees of BFDA. BFDA does not use any external personnel in the conduct of its Licensing activities.

5. Licensing Process

5.1 Application

5.1.1 BFDA shall provide the applicant Food Business (FB) with an up-to-date detailed description of the evaluation including inspection, Licensing process and the documents containing the requirements for Licensing, the applicants' rights and the duties. The above information along with the application format shall be made available on the BFDA website.

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5.1.2 The application format for the Licensing of Food Businesses, obtains at least the following information:

a) the general features of the FB, including its name, size & address of its physical location, contact details, number of employees, legal entity status, its functions and relationship in a larger corporation, if any;

b) the Licensing Criteria against which Food Safety License is being sought; c) the product(s) that are to be/being processed by the FB at the site mentioned in a) above;

d) information about judicial proceedings relating to its operations/product, any proceedings by any Regulatory body or suspension/cancellation/withdrawal of any relevant Licensing/approvals under any Regulations;

e) in case of new establishments, copy of the Project Proposal providing general information about the applicant FB's activities, description of production processes, details of manufacturing facilities, technological context, facility layout, food safety systems, its human and technical resources (Internal as well as external, contracted, etc.), number of shifts of operation, information on in-house laboratory, if any, accessibility to external testing facilities,
expected date of commissioning etc.,;

f) information concerning all processes outsourced by the applicant FB that have potential to affect the hygiene and safety of the food products. If the FBis outsourcing or intends to outsource such processes then the information regarding what processes being outsourced / being planned to outsource, the name and address of the outsourced organization, the BFDA license it
holds, the basis on which they are approved by the FB, the controls FB exercises / plans to exercise for controlling the quality (including safety) of such materials, etc., is required to be submitted at the application stage itself;

g) the current status of functioning of the Food Business (project stage, already commissioned food business); and

h) name of the licensed food handler along with a copy of the Food Handlers License issued by BFDA, if any.

5.1.3 The prospective applicant organization shall declare whether it has been an applicant/licensed by BFDA, and if yes, then shall provide the previous inspection and product test reports to BFDA. BFDA may verify the information provided in the application by reviewing their own records.

5.1.4 License is granted only against the current relevant BFDA Criteria for granting licenses. The FB shall submit the application either to the BFDA District Office or Head Office. The District Office shall review the application received by them for completeness and forward it to the Head Office.

5.2 Application Review

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5.2.1 BFDA Head Office shall assign a reviewing officer to undertake an Application Review for ensuring the following:

a) the information about the FB and its human resources, the type of product being manufactured and other details are sufficient for the conduct of the application review and the subsequent Licensing Process;

b) any known difference in understanding between BFDA and FB are resolved, including agreement regarding the Licensing Criteria.

5.2.2 Application Reviews shall be done by the identified Technical Reviewing Officer. Based on the review of applications, and deficiencies observed, requirement of additional information if any, shall be informed to applicant FB within three working days. Records of review shall be maintained.

5.2.3 Only applications found to be completely filled and supported with all documents sought shall be accepted and registered in order of receipt with a unique identification number, acknowledged and records maintained. The applications shall be registered within 3 days of receipt of the application from the FB.

5.2.4 The application with complete supporting documents is forwarded to the concerned District Office for undertaking inspections. Copy of all the documents are also retained as records at the BFDA Head Office.

5.2.5 Antecedents of the applicants shall be checked in relation to the BFDA Licensing Process. If the BFDA Food Safety License has been suspended and cancelled during the last one year, the application from the same FB shall not be entertained till they provide evidence of having taken suitable corrective action.

5.2.6 Applications from FBs, who have earlier been implicated due to food safety related issues, or whose earlier Food Safety License was cancelled because of violation of terms & conditions of Licensing, shall not be re-registered for three years from the date of cancellation of the Food Safety License by BFDA.

5.2.7 Applications from food businesses found to be violating/misusing the provisions of the Food Act of Bhutan (2005) and the Food Rules and Regulations of Bhutan (2017), while their application is being processed for grant of License shall not be processed any further and rejected after a due notice of 10 days.

Fresh applications from them shall be treated as per clause 5.1 given above. Requests for grant of Food Safety License from ex applicants shall be processed like a fresh applicant and the entire procedure for grant of license be adhered to subject to clauses 5.2.5, 5.2.6 and 5.2.7 given above.

5.3 Evaluation

5.3.1 BFDA undertakes evaluation of FBs which includes carrying out inspections as per relevant Licensing Criteria and testing of product samples drawn from the factory as per applicable product standards in National Food Testing Laboratory (NFTL) or any other ISO 17025 accredited laboratories or recognized laboratories.

5.3.2 BFDA requires the applicant FB to undergo a Feasibility Inspection prior to commissioning of the

food establishment and once the establishment is commissioned, an announced Preliminary Inspection to check the preparedness of the establishment for licensing and Factory Inspection for obtaining the Food Safety License is planned. Post Licensing, BFDA generally conducts unannounced surveillance inspections. Follow-up inspections are announced inspections conducted as and when required for verification of actions taken by the FB for ensuring compliance to the Licensing Criteria.

5.3.3 **Tentative Work Plan for the Month -** For managing all the inspections being conducted, the Officer In-charge at the District Office of BFDA in consultation with the Food Inspector develops a Tentative Work Plan for the month identifying the FBs, along with details of the Inspection teams and the Inspection dates. The Work Plan for the month shall include Feasibility Inspections, Preliminary Inspections, Factory Inspection, Follow-up Inspections and Surveillance Inspections. The Tentative Work Plan for the Month is developed on a risk-based approach. The tentative Work Plan for the Month shall cover the following Food Businesses in the District:

a) Applications received for Licensing need to be scheduled for a Feasibility Inspection preferably within 5 working days of registration of application.

b) For already commissioned FBs, a preliminary Inspection to grant/not to grant Conditional Food Safety Clearance may preferably be planned within 5 working days from date of receiving of application.

c) Preliminary Inspection for fresh FBs may preferably be planned within 6 months of grant of Conditional Food Safety Clearance and

d) FBs whose last Inspections had identified non compliances need to be verified within the defined time frame agreed with the FB through Follow up Inspection.

5.3.3.1 The Tentative Work Plan for the Month is updated as and when any new applications, inspections report for inspections conducted during the month in which noncompliance have been raised that require a follow-up within a defined time frame and when complaints are received.

5.3.4 **Risk based Inspection Planning -** For each food business, the Food Inspector shall determine the risk associated with the business and this shall form the basis for the prioritization of Inspections to be planned and conducted during the month.

5.3.4.1 Determination of risks associated with each food business shall be done on the following basis:

a) The risks associated with the food being produced:

i) Physical risks (risk score 1)

ii) Chemical risks (risk score 2)

iii) Microbiological risks (risk score 3)

b) The intended use of the food:

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i) Not Ready to eat food (risk score 1)

ii) Processed Ready to eat food (risk score 2)

iii) Raw Ready to eat food (risk score 3)

c) The risks associated with food processing:

i) Low (risk score 1)
ii) Medium (risk score 2)

iii) High (risk score 3)

d) The Volume of production, and product category:

i) Low volumes and low risk product category (risk score 1)

ii) Large volumes and low risk product category (risk score 1)

iii) Large volumes and high-risk product category (risk score 2)

iv) Low volumes and high-risk product category (risk score 2)

e) Food safety:

i) No cold chain required and adequate packaging (risk score 1)

ii) Presence of adequate cold chain and packaging (risk score 2)

iii) Absence of adequate cold chain and packaging (risk score 3)

f) Business compliance record (Previous Inspection):

i) Compliance with requirements of BFDA Licensing Criteria (Satisfactory) (risk score 1) ii) Minor non-compliance(s) with requirements of BFDA Licensing Criteria (risk score 2) iii) Major non-compliance(s) with requirements of BFDA Licensing Criteria (risk score 3) iv) Critical non-compliance(s) with requirements of BFDA Licensing Criteria (risk score 4)

g) Business compliance record (Previous Product testing):

i) Product Sample complies with requirements of the relevant product standard (risk score 1)

ii) Product Sample does not comply with requirements of the relevant product standard (risk score 2)

h) Business complaint received since the last inspection:

i) No complaints or illnesses reported (risk score 1)

ii) Complaints reported (risk score 2)

iii) Illnesses reported (risk score 3)

Add all the scores for each of the food business and determine the Food Business Risk. The higher the total score, the higher is the risk as illustrated in Tabled 1

S.N.	Food Business Risk (Total score of Food Business based on factor a) to g))	Risk categorization
	If score is >16	High
	If score is 10 - 15	Medium
	If score is <10	Low

This risk-based categorization shall form the basis for the development of the Tentative Work Plan for the Month, ensuring that all FB mentioned in 5.3.3 a) to d) are covered. For licensed FBOs with high scoring, surveillance inspection shall be conducted once in 3 months, for medium risk, twice in a year and for low risk, once in a year.

5.3.5 The Tentative Work Plan for the month is displayed on the Notice Board in the District Office.

5.4 The Food Act of Bhutan (2005) has stipulated the minimum requirements for education for Food Inspectors and compliance to the same is ensured. All Inspecting officials are thus competent to conduct Inspections for GHP and GMP for Licensing of food businesses. All Food Inspectors and members of BFDA Review and Licensing Committee sign the Statement of Confidentiality and non-disclosure and Impartiality at the time of joining, as per which they are amongst others bound to inform BFDA of any conflict of interest situations arising from their association with specific industry(ies) through employment, consultancy, relationships and commercial interests that could affect the impartiality of the Licensing activities.

5.5 Preparation and Planning for Inspection

5.5.1 Prior to undertaking the site inspection, the BFDA team of Food Inspectors: a) study the application and the supporting documents received;
b) prepare an Inspection Schedule in case of an announced inspection;

c) inform the FB about the scheduled Inspection along with a copy of the Inspection Schedule; and

d) study the previous inspection report as applicable and noncompliance, if any.

5.5.2 In case the FB responds indicating that the date of inspection is not suitable and requests and proposes a new date for inspection, the Officer In-charge shall consider the suitability of proposed dates and reschedule the inspection. Necessary modification to the Tentative Work Plan for the Month shall be accordingly undertaken.

5.6 Conducting Inspections

5.6.1 An opening meeting at the start of the inspection and a closing meeting at the conclusion of the inspection shall be carried out for each type of inspection conducted by BFDA.

5.6.2 Conducting the opening meeting

a) A formal opening meeting, where attendance shall be recorded, shall be held with the FBs management and, where appropriate, those responsible for the functions or processes to be inspected. The opening meeting shall be conducted by the team leader. The purpose of the opening meeting is to provide a short explanation of how the inspection activities will be undertaken and shall include the following:

i) introduction of the Inspection team, showing the official identification that provides legal authority for undertaking the inspection;
ii) introduction of the FBs participants, including an outline of their roles;

iii) confirming the purpose and type of the inspection, the Licensing Criteria against which the inspection shall be carried out;

iv) confirming the product test parameters and the relating standard against which the product as and when drawn shall be tested;

v) confirmation of the inspection plan and explaining the sequence of actions to inspect the processes;

vi) confirming the time for the closing meeting;

vii) confirmation of matters relating to confidentiality;

viii) confirmation of relevant work safety, emergency, and security procedures for the inspection team;

ix) confirmation of the availability, roles and identities of any guides and observers; x) the method of reporting, including any grading of inspection non-compliance;
xi) confirmation of the status of non-compliances of the previous inspection, if applicable; confirmation that, during the inspection, the FB shall be kept informed of inspection progress, non-compliances and concerns if any;

xii) request for Guides to be present with the Inspection team to facilitate visits to specific areas within an FB; and

xiii) opportunity for the FB to ask questions.

5.7 Collecting and verifying information

5.7.1 During the inspection, the Food Inspectors shall collect and verify the information as is relevant to the Licensing Criteria for which license has been sought. The information shall be collected by a combination of techniques that includes:

a) Observation of processes and activities which includes men, materials and products, machines and equipment, methods of work and the working environment;

b) Interviews and questioning the personnel for their understanding of their roles and responsibilities (duties) and the procedures they are following;

c) Inspection team shall collect and test water sample from the source and within the processing area to ensure its conformity to the standards;

d) Inspection team shall randomly collect and test sample of food products from the FB to ensure its conformity to the standards;

e) Inspection team shall verify the FIFO system followed by the FB for both raw materials and final products. They shall also ensure that the rejected materials/products are handled and disposed in a proper manner; and

f) Review of available documentation and records.

5.7.2 The Inspection team shall take notes of information collected through any of the means mentioned above, as they move through the facility during the inspection.

5.8 Identifying Non-compliances

5.8.1 From the information collected and notes taken the Inspection team identifies and records the non-compliances on the Inspection Checklist which is a part of the Inspection report. The Inspection team does a grading of the noncompliance in terms of the risk they pose to food safety and health, as Critical, Major or Minor. Details of how the grading shall be done are detailed in Clause 5.8.3 and this is carried out only during Factory Inspections, Surveillance Inspections and Follow Up Inspections. Observations during the Feasibility inspection that need to be improved upon by the FB are raised as Concerns.

5.8.2 The Concerns and non-compliances with their grading shall be informed in writing to the FB, discussed with them for ensuring that the findings are accurate and that they have understood the non-compliance(s).

5.8.3 **Non-Compliance Grading system** - The primary objective of the inspection (Preliminary/ Factory / Surveillance / Follow-Up) is to assess the possibility if any condition or combination of conditions could render the food unsafe or unsanitary and assess if the food business is complying with the Licensing

Criteria.

The BFDA inspection program is risk based, and the level of non-compliance observed in a food business and its linkage with the health risk it poses are as follows:

a) Minor: a low health risk

b) Major: a moderate health risk

c) Critical: a high health risk

Taking into account all the observations and findings, the non-compliances observed against each of the requirements of the Licensing Criteria shall be graded as:

a) Critical: when there is significant risk of imminent or occurring contamination that will result in contaminated food;

b) Major: when there is a high probability that the food may become contaminated during processing; and

c) Minor: when there is a low risk that the food may become contaminated but food quality may be affected.

This Noncompliance grading system shall be adopted during the Factory Inspection, Surveillance Inspection and Follow-Up Inspections.

5.8.4 Handling of non-compliances

The FB is advised to take necessary corrections and corrective action on the non- compliances within the time frame below;

For Critical non-compliances, immediate corrections and corrective action will be taken and during which FB will remain closed.

For Major non- compliances, corrections and corrective action will be taken within 15 days, otherwise action will be taken as per the food legislation.

For Minor non- compliances, corrections and corrective action will be taken within 90 days, otherwise action will be taken as per the food legislation.

The corrections and corrective actions shall be verified through a Follow-Up Inspection.

5.9 Conducting a closing meeting

5.9.1 A formal closing meeting shall be held with the FBs management and, where appropriate, with those responsible for the functions or processes inspected. The closing meeting shall be conducted by the Inspection Team Leader, with the purpose of presenting the Inspection's conclusions, including the recommendation regarding Licensing. If required, the non-compliances shall be read and discussed and the time frame for taking action and subsequent verification agreed upon. Attendance of all participating

in the Closing meeting shall be recorded.

5.9.2 The Closing meeting shall also include the following:

a) the method and timeframe of reporting, including any grading of Inspection non compliances and concerns;

b) BFDA's process for handling Concerns and non-compliances and including any consequences relating to the status of the FBs License;

c) the timeframe for the FB to take correction and corrective action for the non-compliances and concerns raised during the Inspection;

d) BFDA's post inspection activities; and

e) information about BFDA's complaint handling and appeal processes.

f) Signing of non-compliances summary report by FB and inspection team.

5.10 The Inspection Report

5.10.1 The Inspection team shall write an Inspection report for each Inspection conducted. The Inspection Report shall be written in prescribed formats and shall provide complete and accurate information, adequate details including evidence and conclusions for ensuring appropriate evaluation, review and decision in respect of grant of License or continuation of the same. The inspection reports shall preferably be submitted to Office In-charge within 3 working days of conduct of inspection.

5.11 The Feasibility Inspection

5.11.1 The Feasibility inspection is the first of the Inspections carried out before the food establishment has been set up and commissioned. The objective of the Feasibility Inspection is to determine:

a) if the location and the surroundings of the food establishment would fulfill the requirements of the Licensing Criteria;

b) if the planned structures, layout, facilities and equipment, water supply, adequacy of air and light at the proposed food establishment as evidenced onsite, or on drawings would fulfill the requirements of the Licensing Criteria;

c) conformity of the quality of water at the food establishment with those mentioned in the Licensing Criteria; and

d) availability of a Licensed Food Handler in the FB, if any.

5.11.2 The Inspection team undertakes a site tour, examines the planned structures, layout, facilities and equipment, water supply, adequacy of air and light at the proposed food establishment as evidenced on site, or on drawings for their compliance to the Licensing Criteria, and also draws samples of water for

testing at NFTL. The sample of water shall be drawn from the actual site of the FB but in case the water supply has not been commissioned then, the sample of water shall be drawn from the source from where the water would subsequently be sourced. The water samples shall be drawn in triplicate, labelled with name of product, date of sampling, name of FB, source from where sampled and sealed with a tape and signed by the Food Inspector. While one sample shall be sent to NFTL along with Food Sample Submission Form, the second sample is kept with the FB as a confirmatory sample and the third sample is brought for retention at the Dzongkhag BFDA Office under prescribed conditions of storage in terms of temperature and humidity, if any.

5.11.3 Deficiencies observed with respect to the Licensing Criteria during the Feasibility Inspection shall be discussed on site with the applicant and also informed in writing as Concerns to the applicant FB for their proposed action plan.

5.11.4 The Inspection team shall take notes during the Feasibility Inspection and that shall form the basis for preparing the Feasibility Inspection Report and making recommendations, at the end of the Inspection. The Feasibility Inspection report is prepared and submitted to the Officer In-charge of the Dzongkhag BFDA Office for their comments if any. On receipt of the test report for water from NFTL, and the response on the Concerns received from the FB, the Officer In-charge of the BFDA Dzongkhag Office will issue conditional food safety clearance based on the Feasibility Report, test report for water along with the response received from the FB.

5.11.5 The Conditional Food Safety Clearance is issued by Officer In-Charge, BFDA Dzongkhag office to the FB, with a copy to the Director, BFDA and The Department of Environment and Climate Change, Ministry of Energy and Natural Resources.

5.12 The Preliminary Inspection

5.12.1 The Preliminary Inspection of FBs is carried out once the establishment has been set up and ready for production. The Objectives of the Preliminary Inspection is to check the establishment's preparedness of licensing and to validate the information provided during the application process.

5.13 The Factory Inspection

5.13.1 The factory inspection is carried out;

a) to verify compliance with the applicable Licensing Criteria and assess their appropriateness and adequacy on a continuous basis vis-à-vis the products, processes and risk category. This would involve a detailed inspection of the facility, verification of compliance to relevant GMP/GHP and conformance to other Licensing requirements including availability of Licensed Food Handler in the FB.

b) to draw one sample of each of the products being processed at the facility. The sample of the product(s) shall be representative of normal production capability and is typical of production, for independent testing at NFTL. The samples shall be drawn in triplicate, labelled with details of name of product, date of sampling, name of FB, source from where sampled and sealed with a tape and signed by the Food

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Inspector. The Inspection team sends one sample to NFTL along with Sample Submission Form, the second sample is kept with the FB as a Confirmatory sample and the third sample is brought for retention at the District Office under prescribed conditions of storage in terms of temperature and humidity, if any; and

c) to draw a sample of water from the actual manufacturing site, in triplicate, labelled with details of name of product, date of sampling, name of FB, source from where sampled and sealed with a tape and signed by the food Inspector. The Inspection team sends one sample to NFTL along with Sample Submission Form, the second sample is kept with the FB as a confirmatory sample and the third sample is brought for retention at the District Office under prescribed conditions of storage in terms of temperature and humidity, if any.

5.13.2 The Inspection team shall take notes during the Inspection and later fill out the Inspection Checklist and grade the non-compliances as per methodology defined at Clause 5.8.3 above. The non-compliances observed during the Factory Inspection with respect to the Licensing Criteria shall be informed in writing to the applicant for taking necessary action. An acknowledgement of the non-compliances observed shall be obtained from the FB.

5.13.3 All non-compliances are required to be acted upon and closed through follow up inspections for verification of adequacy of the actions taken by the FB before the grant of License.

5.14 Independent testing of samples

5.14.1 The Inspection team shall draw product samples from the FBs site taking care of the following:

a) care shall be taken to ensure that sample is drawn in such a manner so as not to contaminate the product while sampling and packaging;

b) packing and sealing of the samples shall be such that the product integrity is maintained for its intended shelf life;

c) the samples shall be clearly identified with their name and type, batch identification and suitable identification to enable traceability to the applicant and the date and names of food inspector conducting the inspection;

d) draw samples in quantities adequate to facilitate their testing for all requirements specified in the product standards;

e) if the product is affected by the conditions of temperature, handling and storage, then care shall be taken to ensure that the sample is drawn and maintained under those conditions for testing its conformity to specified product standards; and

f) samples of food products drawn for independent testing shall be forwarded to the NFTL or any other ISO 17025 accredited laboratory or recognized laboratories for ascertaining conformance to specified product standard for each test parameter. The specified standard for each test parameter, product details

and quantity of samples shall be clearly mentioned and communicated to the testing laboratory through the Food Sample Submission Form. The sample(s) shall be so dispatched that they do not get damaged and or contaminated, undergo deterioration, and the product integrity is maintained.

5.15 Follow-Up Inspections

5.15.1 Follow- Up Inspections are conducted as and when required for verification of actions taken by FBs on the Concerns or Non-compliances observed during the previous Inspection. Follow-Up Inspections are thus carried out both before and after Licensing, that is after Feasibility Inspection, Factory Inspection or a Surveillance Inspection, as required. The Food Inspector verifies the actions taken on the Concerns or Non compliances as the case be and report their findings. If the action taken by the FB is observed to be incomplete, inadequate and compliance to Licensing Criteria has not been fulfilled, the Inspection team shall handle the non-compliances as per the clause 5.8.4.

5.16 Final Evaluation

5.16.1 The purpose of this process step is to conduct an evaluation of all the information gathered through the process steps of Feasibility Inspection, Preliminary Inspection, Factory Inspection and Follow-Up Inspections, if any, and the results of independent testing of samples of water and product (s), to ascertain if all the process steps as described in the Licensing Process leading to grant of license have been fulfilled and if the evaluation confirms that the FB has the capability and has maintained good hygienic and manufacturing practices in the establishment as per relevant Licensing Criteria and produce the relevant food product(s) that comply with the requirements of the specific product standard.

5.16.2 The final evaluation shall be carried out by the Officer In-charge of the BFDA Dzongkhag Office to ensure the following:

a) compliance to the BFDA Licensing Criteria;,

b) compliance to requirements of the BFDA Licensing Process;

c) availability of Authorized Food Handler(s);

d) evaluation regarding conformity of the product(s) with parameters/ requirements of the product standard;

e) evaluation regarding t h e conformity of the sample of water as per WHO Guidelines for Drinking Water;

f) necessary documentation for proof of legal entity and authentication of premises of manufacture where Licensing is being sought;

g) verification of implementation of corrective actions and closure of all non-compliances and concerns raised; and

h) any other requirements prescribed by BFDA.

5.16.3 Based on the evaluation as above, recommendations for proceeding to the next step (independent review and decision making) shall be made. In case the evaluation indicates that some requirements of the Licensing Criteria or the Licensing Process have not been met, then these need to be completed and evaluated before proceeding to the next step.

5.16.4 Records of final evaluation along with all supporting documents and reports shall be submitted to the BFDA Head office and also retained at the Dzongkhag office.

5.17 Review

5.17.1 An independent review is carried out by a Review and Licensing Committee set up at BFDA Head Office, having the relevant competence. The responsibility for review function, is however that of BFDA. The review is carried out within 5 working days of receipt of final evaluation report from BFDA Dzongkhag offices.

5.17.2 The review is based on the requirements specified in Licensing Criteria and the Licensing Process as stated in this document.

5.17.3 Any information on which a review and decision is based which comes from any source other than the evaluation process, for example complaints, information received from other regulators (like the Department of Environment and Climate Change, Ministry of Energy and Natural Resources), etc., is made known to the applicant along with information on the evaluation process. The applicant is given the opportunity to comment on it.

5.17.4 Concerns and non-compliances raised during any of the Inspections like Feasibility Inspection / Preliminary/Factory Inspection / Follow-Up Inspection relating to the Licensing Criteria shall be corrected and the correction verified by the Inspection team before the license is granted. The concerns and non-compliances and their resolution as indicated in subsequent inspection reports shall be documented and made available for the purpose of review.

5.17.5 The records of review are retained and provide adequate confidence that all relevant aspects were examined prior to making recommendations.

5.17.6 The recommendation for licensing decisions, whether positive or negative shall be justified and the basis for the same documented.

5.18 Licensing Decision

5.18.1 Licensing decisions are the sole responsibility of BFDA and the decisions are taken by the Committee for Review and Licensing based on the review report and inspection report submitted by the Technical Review Officer and field office respectively. The Review and Licensing Committee member shall not be involved in earlier process of FSL.

5.18.2 The Technical Food Focal appoints the Technical Reviewing Officer to review the report submitted by field offices for the grant of Food Safety License. The Technical Reviewing Officer shall not be part of the FSL process of that particular food business and shall have sufficient knowledge and experience to evaluate the report and to provide the review recommendation. The review and licensing decision is completed by the Review and Licensing Committee.

5.18.3 The roles of the Review and Licensing Committee are:

a) Review of Food Business's documents and reports

The Technical Reviewing Officer reviews and evaluates all the necessary documents and reports submitted by the BFDA field office. The Reviewing Officer ensures that application and records are completed and in compliance with GHP/GMP criteria. Finally, prepares and submits the review report of the Food Business for the Committee.

The Committee reviews the review report submitted by the Technical Reviewing Officer.

b) Recommendations for Approval

Provided recommendations for the approval or rejection of applications based on the review report by the Technical Reviewing Officer. They provide the rationale for approval or denial of FSL and ensure transparency in the licensing process in accordance with BFDA-IS-PR-22(FD).

c) Approval for FSL

The final approval for the grant of FSL is done by Director, BFDA.

5.18.4 The final evaluation is carried out by the Review and Licensing Committee for Licensing, comprising of competent personnel, duly authorized for this function. The 5-member Committee comprises of the Heads of Certification Services, Head of Laboratory Services, Chief Regulatory & Quarantine Officers of Food Quality and Safety Division, Chief Regulatory & Quarantine Officers of Plant and Animal Biosecurity Division and Technical Focal Officer of Food
Section, Focal Officer of Plant and Livestock Section, as relevant to the Application. A quorum of three is necessary for decision making.

5.18.5 BFDA grants Food Safety License after ensuring complete compliance to the requirements of the Licensing Criteria, Licensing Process and after all non-compliances and concerns have been closed. There shall be no conditional grant of License.

5.18.6 On grant of Food Safety License, the Conditional Food Safety Clearance ceases to be valid.

5.18.7 In case, based on the evaluation BFDA decides not to grant Food Safety License to the FB, then it shall notify the FB of the decision of not granting the Food Safety License along with reasons for the decision. If the FB expresses interest in continuing the Licensing Process, BFDA can resume the process for evaluation from the process as described from clause 5.14 onwards.

5.18.8 Impartiality and absence of conflict of interest shall be ensured before entrusting the task of Licensing Decision Making to the Committee for Review and Decision Making.

5.19 Licensing Documentation

5.19.1 On grant of Food Safety License, BFDA Head Office informs the FB and issues a Food Safety License, within 5 working days of decision making by the Review and Licensing Committee. The Food Safety License shall include the following information:

a) the name and address of the Licensing body (BFDA);

b) the name and address of the FB and the address of the site licensed;

c) the effective date (the date on which license is granted, which shall not precede the date on which the Licensing decision was completed);

d) the Licensing Criteria against which the license has been awarded. Reference to the Licensing Criteria document shall include issue number and/or revision, used for evaluation of the licensed FB;

e) unique identification code for the Food Safety License;

f) any other information required by the Licensing Criteria used for Licensing;

g) in the event of issuing any revised Licensing document, a means to distinguish the revised documents from any prior obsolete documents; and

h) the formal Licensing documentation shall include the signature of the authorized signatory of BFDA.

5.19.2 The Brand names of the Food products processed by the FB shall not be mentioned on the license document or any other document intimating grant of License.

5.20 Directory of Food Safety Licenses

5.20.1 BFDA shall maintain and make publicly available on its website, directory of valid Food Safety Licenses that as a minimum shall show the name, relevant Licensing Criteria (normative document), scope and geographical location (e.g. city and country) for each licensed FB. BFDA shall also display suitably on its website the names of FBs under suspension and whose Food Safety Licenses have been cancelled.

5.20.2 Apart from the information made available on its website, BFDA shall also have a provision and system for confirming validity of a Food Safety License on request.

5.20.3 BFDA shall have a mechanism for frequent updating of the information on its website.

5.21 Surveillance Inspections

5.21.1 BFDA shall conduct Surveillance Inspections of licensed FBs on a risk-based approach. For Licensed Food Business with high-risk scoring, surveillance inspection should be conducted once in 3 months, for medium risk, twice in a year and for low risk, once in a year.

5.21.2 Surveillance inspections shall be planned as per the parameters and risk-based approach described in the Tentative Work Plan for the Month described in Clause 5.3.3 above.

5.21.3 Surveillance Inspections shall be carried out for verifying on-going compliance to the Licensing Criteria and shall be carried out very much like the Factory Inspection as described in Clause 5.12 above. The Surveillance Inspection Report Shall be prepared using the Inspection Report Format.

5.21.4 The Surveillance Inspection shall preferably be conducted unannounced. If an announced Surveillance Inspection is conducted, then an inspection schedule shall be prepared in advance and forwarded to FB along with names of the Inspection team members.

5.21.5 During the Surveillance Inspection, the Inspection team shall as a minimum check and report on the following:

a) compliance to the requirements of the Licensing Criteria and other requirements of Licensing Process;

b) actions taken on non-compliances observed during the previous inspection, failure of samples if any reported shall be informed to the FB; and

c) draw samples for testing in accredited independent laboratory.

5.21.6 If any non-compliance is observed, the same shall be graded as Critical, Major or Minor as per the description given in clause 5.8.3. The noncompliance report shall be provided to the FB in writing for correction and corrective action. Details of the same shall be reported in the Inspection Report for the Surveillance Inspection.

5.21.7 Non-compliances observed during Surveillance Inspections shall be handled as per Clause 5.8.4.

5.22 Dealing with failure of samples reported in independent laboratory reports

5.22.1 Failure of sample of food product, drawn from the factory or the market, to comply with the requirements of the relevant product standards, shall be communicated to the licensed FB. FB is advised to undertake a root cause analysis and propose correction and corrective actions within 5 working days of intimation. BFDA shall respond to the proposed corrective actions within 5 working days and the FB shall implement the corrective actions within the agreed time frame from acceptance of the corrective actions by BFDA.

5.22.2 BFDA shall inform the FB and organize a Follow-Up Inspection for verification of corrective

action and draw a sample after the corrective action has been taken. If the failure was observed in a sample drawn from the market, then, the sample should preferably be drawn from the market itself.

5.22.3 When the failure of the sample is in requirements relating to microbiological parameters, adulterants, contaminants, toxins and residues BFDA shall:

a) suspend the BFDA Food Safety License till adequate and effective corrective actions are taken;
b) advise the licensed FB to;

i) stop dispatches of the failing Batch if stocks are available either at the site or in their warehouses;

ii) recall the failing Batch from the market;

iii) identify all food products manufactured with same raw material, or those manufactured during the same time under similar controls and examine their production and quality records of the failing Batch and retest the Confirmatory samples of these Batches in the custody of the FB.

5.22.4 Based on the satisfactory demonstration of root cause analysis and corrective actions to prevent such reoccurrences in future, the decision to revert to the normal operation of Licensing shall be taken by BFDA. Testing of fresh samples of the specific product manufactured after implementation of corrective actions may be one of the mechanisms of satisfactory demonstration. Based on the specific situations BFDA shall decide the appropriate actions and record the justification for the same.

5.23 Suspension

5.23.1 BFDA shall issue instructions to the licensed FB for suspension of License when:

a) the corrective actions taken by the FB on critical, major and minor non compliances within stipulated time period as defined in clause 5.8.4 above are observed to be incomplete and inadequate and do not ensure compliance to the Licensing Criteria;

b) 2 consecutive samples, from the factory or market, as determined by date of manufacture, fail to conform to the specified product requirements;

c) FB has been non-operational for a year as reported in the surveillance inspection report.

5.23.2 On receipt of instructions for suspension of License, the FB shall suspend production. The FB shall be advised to undertake a root cause analysis and identify the necessary corrective actions for resolving the same.

5.23.3 When license is suspended, BFDA requires that, during the period of suspension, the FB makes no misleading claims and should advise relevant existing and potential purchasers and consumers regarding the status of Food Safety License. BFDA shall ensure that the FB has procedures in place to ensure that

food product(s) that gave rise to suspension of Food Safety License are recalled.

5.23.4 While under suspension, BFDA advises for withholding of dispatches of Food Products.

5.23.5 The information about the suspension and withdrawal of a Food Safety License shall be made publicly available by the BFDA on its website and any other mass media.

5.23.6 BFDA shall revoke suspension only when:

a) corrective actions have been taken and verified by the BFDA inspection team;

b) reports of samples of food products manufactured after corrective actions, confirm compliance to the specific product test parameters on independent testing as given in 5.21 above.

5.23.7 Suspension shall not exceed a period of six months. The FB's inability to resolve issues relating to suspension within this period shall lead to cancellation of Food Safety License.

5.23.8 The Officer In-charge of the BFDA Dzongkhag Office reviews the status of the licensed FB once every year to assess:

a) if the inspection reports are complete and provide adequate details on compliances and non-compliances reported;

b) if the grading of the non-compliances has been done appropriately;

c) if the licensed FB has undertaken action to address the non-compliances reported within the defined time frames;

d) complaints if any received have been investigated.

5.23.9 Based on this review, the Officer In-charge of the respective BFDA office may decide upon organizing a surveillance inspection within a month by the inspection team having ***at least*** one common member from the previous inspection. The results of the review shall be shared with the Food Inspectors and the need for training if any shall be identified and shared with the BFDA Head Office for organizing the necessary training.

5.24 Cancellation

5.24.1 BFDA shall cancel the license when:

a) The FB contravenes the terms and conditions of Food Safety License and provisions of Licensing Process like suspension of license beyond the stipulated period, inadequate corrective actions, etc.,;

b) Repeated failures of food products to the specified product standard and the inability of the corrective actions taken to ensure compliance, or if the proposed plan for corrective actions is likely to take considerable time, beyond 6 months for implementation.

5.24.2 BFDA shall cancel the license at the request of the licensed FB, if the operation(s) in the licensed FB's premises can no longer be carried due to reasons of natural calamities such as flood, fire, earthquake, etc., lock out declared by the management, or closure of business operations, etc.

5.25 Changes affecting Licensing

5.25.1 When the requirements of the Licensing Criteria and Licensing Process undergo changes that affect the FB, BFDA shall ensure these changes are communicated to all FBs. BFDA shall verify the implementation of the changes by its FBs and shall take actions required under Food Safety Licensing of Food Businesses.

5.25.2 The terms and conditions of Food Safety License shall have clearly defined clauses which makes it mandatory for the licensed FB to implement the changes in their processes and product, necessitated by the changes in above requirements.

5.25.3 Following decision on the revision and publication of the revised Licensing Criteria and/or Licensing Process requirements, BFDA shall verify that each licensed FB makes any necessary adjustments within such time as, in the opinion of BFDA is reasonable, unless BFDA itself has decided the timelines. The verification would involve steps like inspections, retesting of samples in an accredited independent laboratory, evaluation, review and decision and issuance of revised formal Licensing documentation.

5.25.4 The licensed FB shall also be bound by the Licensing terms and conditions to inform BFDA about changes initiated by the FB; including changes in process and product design, changes in technology of manufacturing, etc., which have the potential to affect compliance to the Licensing Criteria. Based on the nature of changes informed, BFDA shall undertake an Inspection for verification of compliance to Licensing Criteria including testing of a sample of the product.

5.25.5 Change of location/Ownership/Name

5.25.5.1 The licensed FB shall inform BFDA of any change in its location.

5.25.5.2 On receipt of such information, BFDA shall issue instructions to the licensed FB for cancellation of Food Safety License with immediate effect and advised to seek a fresh Food Safety License for the new premises following the process steps listed above. 5.25.5.3 In the event of change of Ownership, the food business shall provide necessary documentary evidence. The new management of the organization shall submit its acceptance to the Terms and Conditions for Licensing. The same process shall be followed as and when an existing applicant undergoes a change in management. Such changes shall not call for a visit to the production site.

5.25.5.4 In case of change of Name, the manufacturer shall inform the change in the name to BFDA along

with documentary evidence, and if satisfied BFDA shall endorse the License Document in the new name.

5.26 Records

5.25.1.1 BFDA shall have a documented policy and documented procedures in respect of the retention of records to demonstrate that all Licensing Process requirements have been effectively fulfilled.

5.25.1.2 The Licensing related records shall be retained for a period of 5 years whereas the license document itself shall be retained as long as it is valid and beyond that, for a period of 5 years. BFDA shall keep records confidential. Records shall be transported, transmitted and transferred in a way that ensures confidentiality.

5.25.1.3 The Licensing records shall include records for all FBs, that submitted the application, were evaluated, licensed or with licenses suspended or withdrawn/cancelled. The records of Licensing of FBs shall include the following:

a) Application information and results of application review;

b) Inspection planning and preparation records, Inspection Schedules and other related records;

c) Records of Feasibility Inspection, Preliminary Inspection, Follow-Up Inspection and Surveillance Inspections reports and related records, Test reports from accredited independent laboratory;

d) Initial and final evaluation records, Records of verification of correction and corrective actions;

e) Records of review and Licensing decisions, committee deliberations and decisions, if applicable;

f) Licensing Documentation (Food Safety License);

g) Records of complaints and appeals, and any subsequent correction or corrective actions;

h) Related records necessary to establish the credibility of the Licensing Process, such as evidence of the competence of Food Inspectors, review and licensing committee members, etc. as relevant; and

i) Any other records as relevant to the Licensing Process, in order to provide confidence that the Licensing Process requirements were complied with.

5.27 Complaints and appeals

5.27.1 BFDA shall have a documented procedure for handling of complaints and appeals.

5.27.2 The procedure for complaint handling shall include complaints from all stake holders, especially its FBs as well as customers of its FBs.

5.27.3 The procedure for receipt and handling of complaints shall be made available to public on the

BFDA website and shall also be easily accessible on the website.

5.27.4 Upon receipt of a complaint or appeal, BFDA shall confirm whether the complaint or appeal relates to Licensing activities for which it is responsible and, if so, shall address it. BFDA shall acknowledge receipt of a formal complaint or appeal.

5.27.5 BFDA shall be responsible for gathering and verifying all necessary information (as far as possible) to progress the complaint or appeal to a decision.

5.27.6 The procedure shall include the process steps for receiving and recording, evaluating and establishing validity of the same, investigating and making decisions on complaints and appeals. The process step shall also include the activities of root cause analysis, correction and corrective actions.

5.27.7 If the complaint relates to a licensed FB and the product supplied by it, then the examination and evaluation of the complaints shall take into consideration the effectiveness and implementation of the FB's system. This would involve an inspection of the FB's premises. The decisions on complaint shall then be based on the result of this additional inspection.

5.27.8 BFDA shall record and track complaints and appeals, as well as actions undertaken to resolve them.

5.27.9 The decision resolving the complaint or appeal shall be made by, or reviewed and approved by, person(s) not involved in the Licensing activities related to the complaint or appeal. To ensure that there is no conflict of interest, personnel (including those acting in a managerial capacity) who have provided consultancy for a FB, or been employed by a FB, shall not be used by BFDA to review or approve the resolution of a complaint or appeal for that FB within two years following the end of the consultancy or employment.

5.27.10 Whenever possible, BFDA shall give formal notice of the outcome and the end of the complaint process to the complainant.

5.27.11 In respect of appeals, BFDA shall ensure that the individual(s)/committee entrusted with handling of appeal and its resolution decision shall be independent of the persons involved in Licensing related recommendations and decision and their position in the BFDA shall be such that it shall not be possible to influence their decisions with respect to the subject of the appeal.

5.27.12 The procedure shall also have provision for giving a written statement to the appellant, of the appeal findings including the reasons for the decisions reached and also communicating to the appellant about the provision for giving an opportunity to formally present their case.

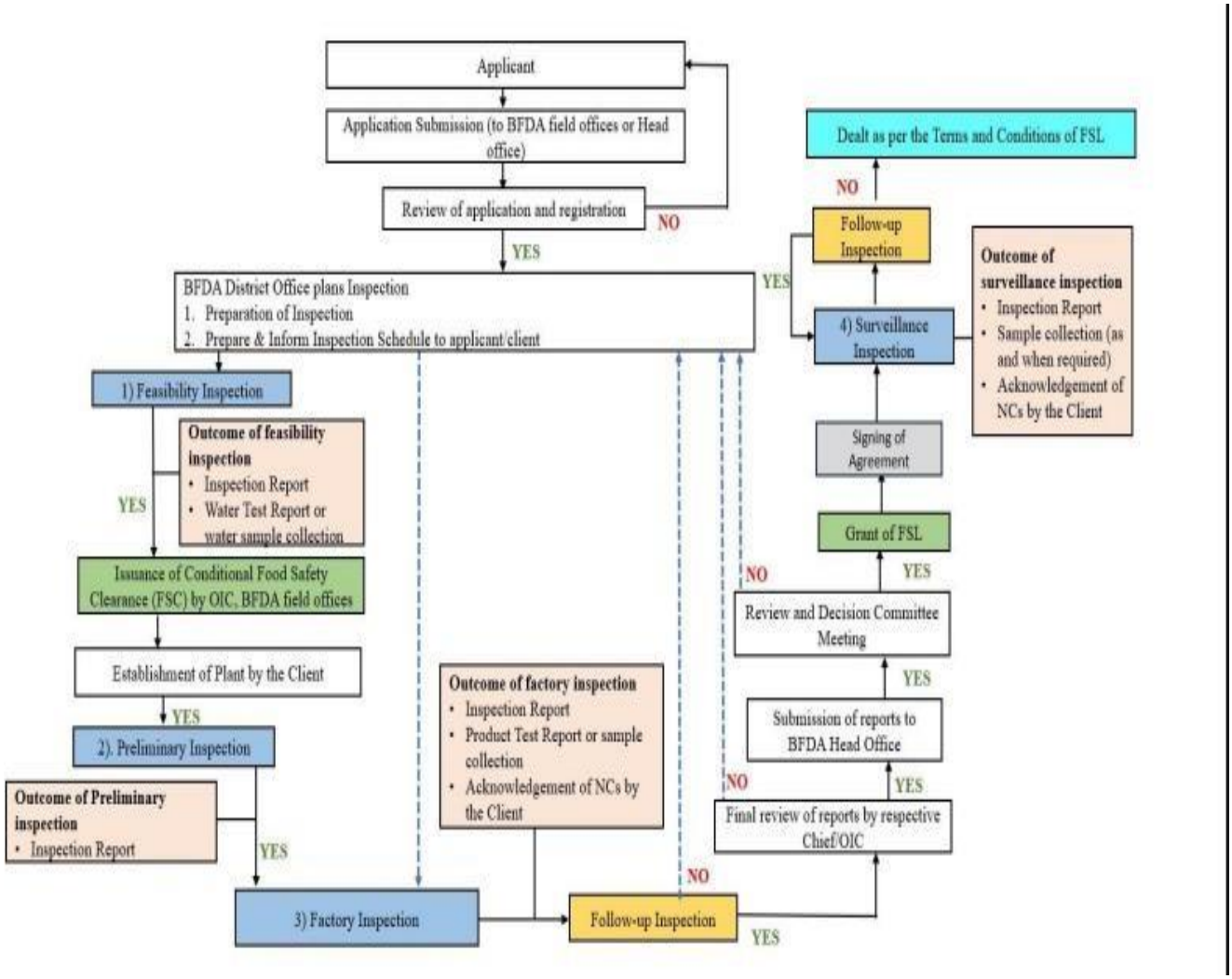
5.27.13 Based on the presentation made, the individual or a committee appointed for hearing the case shall take a final decision on the appeal and a formal notice of the outcome and the end of the appeal process shall be given to the appellant.

5.27.14 BFDA shall take any subsequent action needed to resolve the complaint or appeal.

Annexure 1

BFDA Food Businesses Licensing Process

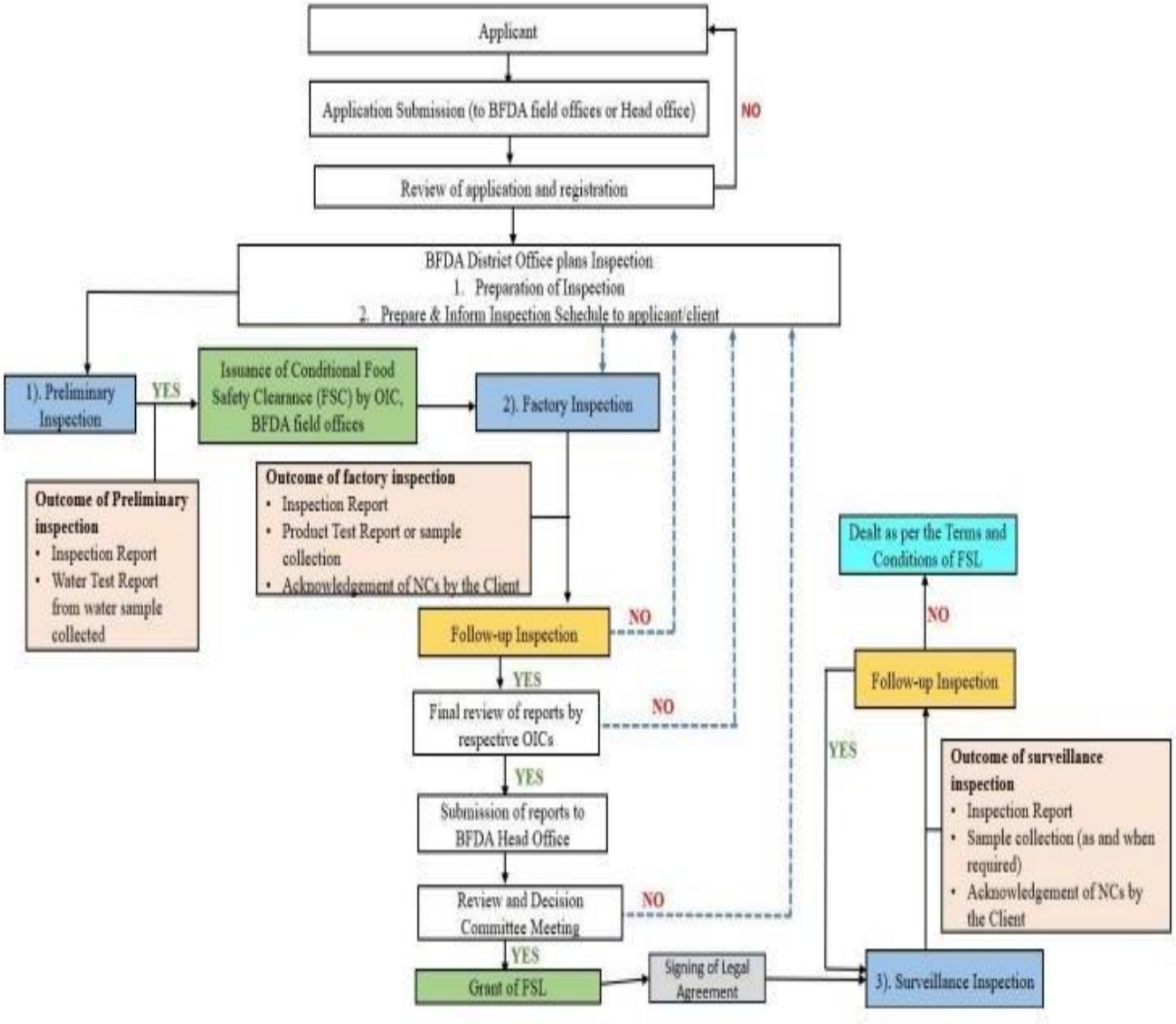
1) For new establishment at Project Stage



Note: If process is directed back to the inspection planning stage by the dotted or dashed arrow, then for the next step, it needs to follow the dotted or dashed arrow in order to continue with the licensing process.

INSPECTION PROCEDURE– Licensing Process for Food Businesses

2) For already established units with on-going production or commissioning of production



Note: If process is directed back to the inspection planning stage by the dotted or dashed arrow, then for the next step, it needs to follow the dotted or dashed arrow in order to continue with the licensing process.

INSPECTION PROCEDURE– Licensing Process for Food Businesses

Annexure 2

List of Forms and Formats

Document No	Name
BFDA-IS-FM-01	CONFIDENTIALITY STATEMENT from Committee Member (CM)
BFDA-IS-FM-02	CONFIDENTIALITY AND IMPARTIALITY STATEMENT from inspector/staff
BFDA-IS-FM-82	Application form
BFDA-IS-FM-200	Review of application
BFDA-IS-FM-83	Application acknowledgement
BFDA-IS-FM-84	Inspection Schedule
BFDA-IS-FM-85	Feasibility Report
NFTL/FORM/7.1 & 7.4/04	NFTL Food Sample Submission and Request Review Form
BFDA-IS-FM-87	Conditional Food Safety Clearance for units at project stage
BFDA-IS-FM-88	Inspection Report (Factory/ Surveillance/ Complaint Investigation)
BFDA-IS-FM-89	Follow-Up Inspection Report
BFDA-IS-FM-90	Tentative Work Plan for the Month

INSPECTION PROCEDURE– Licensing Process for Food Businesses

BFDA-IS-FM-92	Food Safety License
BFDA-IS-FM-176	Risk-Based Inspection Planning
BFDA-IS-FM-177	Final Evaluation- OICs
BFDA-IS-FM-178	Review- Decision Committee Report
BFDA-IS-FM-183	Manhours calculation work
BFDA-IS-FM-184	Preliminary Inspection Report
BFDA-IS-FM-185	Conditional Food Safety Clearance for established units
BFDA-IS-FM-186	Notesheet Approval for Grant of FSL
BFDA-IS-FM-199	Legally Enforceable Agreement for Food Safety License
BFDA-IS-FM-203	Nomination of Team Leader