



**Ministry of Health  
Bhutan Food and Drug Authority  
CERTIFICATION SERVICES**

**INITIAL QUESTIONNAIRE FOR FARM OR FACTORY ASSESSMENT FOR ORGANIC  
CERTIFICATION**

(Annex to Application -BFDA-CS-PR7.2-01-FM-05)

- This questionnaire should be completed and returned together with the application. It is intended to provide preliminary information relevant to the applicant and his capability to practice organic farming and/or processing and continuous conformance of the farm/processing unit to the specified requirements of the relevant standard.
- This document will be used by BFDA's inspection/audit staff during preliminary visit to the farm unit as part of the initial inspection.
- Supplements may be included when it is necessary to expand any statement. A separate document should be completed for each farm unit involved, or variation between farm units clearly indicated.
- The statements should relate to the facilities available at the date of completion of this form.
- The information given in this document will be treated in the strictest confidence.
- Please answer every question. A response 'Yes' or 'No' is accepted for most of the sections. Negative responses do not disqualify the client's application. If the question is not applicable mark N/A.
- Whenever supplements are attached as annexure, indicate clearly the annexure number and title.

**Note:**

1. *Part A- Preliminary Information on Application* needs to be mandatorily filled by all applicants.
2. *Part B – Information on Basic Farm System* needs to be filled if the application is for primary production only.
3. *Part C – Information on Processing of Organic Products* needs to be filled if the application is for organic processing only.
4. *Part B – Information on Basic Farm System and Part C – Information on Processing of Organic Products* needs to be filled if the application is for primary production and organic processing.

**A. PRELIMINARY INFORMATION ON APPLICATION**

Information on the following subjects will be used to assess the completeness of your application. Please tick the appropriate response, where indicated.

1. Indicate the date when your produce/product is available for inspection :
2. Standard for which you wish to become certified :
3. Do you have a copy of the standard according to which you request certification? Please tick. a) Hardcopy <input type="checkbox"/> b) Access through internet <input type="checkbox"/> c) No copy <input type="checkbox"/>



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4. Scheme for which you wish to be certified:
5. Do you have a copy of the Scheme for which you wish to be certified? Please tick.  a) Hardcopy <input type="checkbox"/> b) Access through internet <input type="checkbox"/> c) No copy <input type="checkbox"/>
6. Is the mentioned produce cultivated/processed as per the requirement of relevant standard? Please Tick  a) Yes <input type="checkbox"/> b) No <input type="checkbox"/>
7. Have the mentioned produce/product in the application form ever been inspected and/or certified before? Please tick.  a) Yes <input type="checkbox"/> b) No <input type="checkbox"/>  If Yes, please enclose all the information regarding the inspection(s) and/or certification(s), including report of findings, etc.
8. Legal status of the farm/factory. Please tick.  a) Sole proprietorship <input type="checkbox"/> b) Partnership <input type="checkbox"/> c) Farmers Cooperative <input type="checkbox"/> d) Farmers Group <input type="checkbox"/>  e) Others (please specify):  Where applicable, please attach copies of the following: - Lease agreement - Lag Thram - Registration certificate from the Department of Agricultural Marketing and Cooperatives - Any other relevant documents to support the legal status of the farm/factory.

**B. INFORMATION ON BASIC FARM SYSTEM (If applicable)**

- Section 1 - Production Details
- Section 2 - Farm Group Management Plan
- Section 3 - Farm Equipment Record

**SECTION 1: PRODUCTION DETAILS**

Please give the following information on basic farm system.

1.1 Did you conduct land/site assessment of mentioned area of your farm? Please tick.  a) Yes <input type="checkbox"/> b) No <input type="checkbox"/>
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1.2 Do you have any parallel or split production of the mentioned crops/products? Please tick.

- a) Yes                       b) No

If Yes, specify the crops cultivated under parallel or split production.

1.3 Provide a farm map/layout clearly showing organic production/harvesting areas for the identified produce/product and conventional areas? (Attach a map if readily available).

1.4 What types of production practice do you follow? Please tick.

- a) Open field cultivation
- b) Protective cultivation

If protective cultivation is followed, do you meet the requirements of protective house? Please describe briefly.

1.5 Is the biomass or manure produced at farm sufficient for soil nutrient and fertility management? Please tick.

- a) Yes                       b) No

If No, what types of nutrient do you procure and from where? Please tick.

- a) Bio Fertilizer
- b) Organic Manure

c) Others (please specify below):



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Please specify the dealer's address:

1.6 What is the source of water used to irrigate your farm? Please tick.

- a) Rain-fed       b) Irrigation channel       c) Neighbour's water source   
d) Other (please specify below):

If the water source is from neighboring farm, what is their source?

1.7 How do you manage weed problems? Please tick.

- a) Bio-pesticides (bio-weedicides)       b) Cultural Method   
c) Other (please specify below):

1.8 Any history of pests or diseases outbreak in the farm? Please tick.

- a) Yes       b) No

1.9 If yes, provide details of the pests and diseases outbreak and the year of outbreak.

1.10 How do you manage the pests and disease outbreaks on the farm? Please tick.

- a) Cultural method       b) Bio-pesticides   
c) Other (please specify below):

1.11 Do you have separate storage facilities for storing organic products and non-organic products/agrochemicals/bio-inputs/equipment?

- a) Yes       b) No

If No, please describe briefly how you prevent cross-contamination or mixing of those with organic products.



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1.12 Are you aware of prohibited and restricted lists of inputs/additives as per the Standard? Please tick.

a) Yes                       b) No

1.13 Does your neighbour apply chemical sprays and fertilizers on their farm? Please tick.

a) Yes                       b) No

If Yes, what type of buffers do you maintain to prevent cross-contamination of your farm?

1.14 Do you use clean (not contaminated) and safe packing materials to pack your produce? Please tick.

a) Yes                       b) No

If yes, please specify the type of packing material used.

1.15 Do you maintain Farmer's Diary? Please tick.

a) Yes                       b) No

If Yes, please attach a copy.

1.16 Do you hire labour from outside? Please tick.

a) Yes                       b) No

If yes, for what farm activities do you hire labour? Please provide details.

1.17 Do you have a system to allot identification number for each lot of produce? Please Tick.

a) Yes                       b) No

If Yes, please write the sample ID number in use and how do you ensure product traceability.

If No, how do you segregate the doubtful produce to ensure product integrity? Describe briefly.



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1.18 Do you have a packing house?

- a) Yes                       b) No

If No, where do you carry out the segregation, grading and packing of produce? Please describe briefly.

1.19 Do you outsource any activity and processes such as repackaging, storage, processing, etc? Please tick.

- a) Yes                       b) No

If Yes, please provide the following details:

- a) Name and address of the unit:
- b) Process or activity outsourced:
- c) Name and contact details of the person responsible:

1.20 Do you have a technical manager to provide necessary guidance on organic farm/processing unit operations?

- a) Yes                       b) No

If Yes, please provide the following details:

- a) Name of Technical Manager :
- b) Contact No :
- c) Email Address :

1.21 Do you have an Organic System Management (OSM) plan or an internal plan of your farm/processing unit for organic activities?

- a) Yes                       b) No

If Yes, please attach the document(s).

1.22 Do you have a document(s) that allows to trace the flow of product from purchase to processing and sales of organic products, which are mentioned below:



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S.N	Activities	Yes	No
1.	All incoming and outgoing invoices.		
2.	Processing ratios at each processing step.		
3.	Daily records at each processing step.		
4.	Purchase information of supplier.		
5.	Inventory and book keeping records.		

If Yes, please attach the document(s).

**SECTION 2 - FARMER GROUP MANAGEMENT PLAN (If applicable).**

Please give the following information on management practices of the farmer group.

2.1 Do you maintain Internal Control System (ICS)? Please tick.

a) Yes       b) No

If Yes, please attach copies of documents.

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2.2 Do you have internal inspector(s)? Please tick.

a) Yes       b) No

Please provide the name(s) and organization(s) of the internal inspector(s).

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2.3 Are internal farm audit checks carried out as per the ICS? Please tick.

a) Yes       b) No

If Yes, by whom and how frequently is the internal farm audit check carried out?

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2.4 Do you assign any identification number to the member farmers of the group? Please tick.

a) Yes       b) No

If Yes, please write the sample ID number in use:

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2.5 Do you have a designated common pack house? Please tick.

a) Yes       b) No



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If No, where do you carry out the segregation, grading and packing of produce? Please describe briefly.

**SECTION 3 - FARM EQUIPMENT RECORD**

3.1 Please list the equipment and farm machineries used on your farm.

3.2 Attach calibration test report, if any.





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1.1.7 Please give any other relevant information on basic system.

## 1.2 Quality Control / Inspection Staff

Please give the following information on factory quality control structure .

1.2.1 Total Number of Staff in Quality Control Unit:
1.2.2 Head of Quality Assurance (Name and Designation):
1.2.3 Reporting to? (Name and Designation):
1.2.4 Is there a separate Quality Control and/or Inspection Department? Please tick.  a) Yes <input type="checkbox"/> b) No <input type="checkbox"/>
1.2.5 If Yes, indicate the followings:  1.2.5.1 Name of Chief Inspector (Head), if different from 1.2.2:  1.2.5.2 Are inspection staff aware of the tests in the relevant standard(s)? Please tick.  a) Yes <input type="checkbox"/> b) No <input type="checkbox"/>
1.2.6 Does the quality control personnel inspect:  1.2.6.1      Materials? Please tick.                      a) Yes <input type="checkbox"/> b) No <input type="checkbox"/> 1.2.6.2      In-process operations? Please tick.                      a) Yes <input type="checkbox"/> b) No <input type="checkbox"/> 1.2.6.3      Final product? Please tick.                      a) Yes <input type="checkbox"/> b) No <input type="checkbox"/>
1.2.7 If yes to any of the above under 1.2.6, are these inspectors monitored by Quality Control staff? Please tick.  a) Yes <input type="checkbox"/> b) No <input type="checkbox"/>



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1.2.8 Are quality audit checks carried out? Please tick.

a) Yes                       b) No

If Yes, by whom?

1.2.9 How is training on hygienic food handling provided to all relevant staff? Please attach evidence(s).

1.2.10 Do employment terms & conditions meet regulatory requirements?

a) Yes                       b) No

If Yes, please provide details.

1.2.11 Please provide any other additional information on staff working for Quality Control Unit.

**SECTION 2: MATERIALS, COMPONENTS & SERVICES**

2.1 Purchase specifications and materials quality assurance

2.1.1 Is a signed contract available for all contract units (farms & facilities) in organic operation?

a) Yes     b) No

If yes, attach evidence.



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2.2 Are all Supplier / Producer certificates (and approved product lists) for purchased ingredients and products valid at the time of purchase?

a) Yes

b) No

If yes, please attach evidence.

2.3 Is any ingredient used in an organic product made up of both organic and non-organic status?

a) Yes

b) No

2.4 If Yes for 2.3, how is the separation of organic and non-organic production implemented?

2.5 Are all multi-ingredient product formula declared?

a) Yes

b) No

If Yes, please attach evidence.

2.6 Are all ingredients of organic origin as per the standard and does not contain GMO and Nanotechnology sources? Attach evidence for inputs.

2.7 Describe measures taken to prevent contamination of organic production from non-organic production.



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2.8 Is water used in processing of drinking water quality?

a) Yes

b) No

If Yes, please attach evidence.

2.9 Describe how organic status of in-coming goods is verified.

2.10 How are organic produce/product identified in all stages of handling?

2.11 Are organic labelled packaging material re-used for keeping substances prohibited for use in organic production?

a) Yes

b) No

2.12 Describe measures taken to ensure correct use of packaging/label for final organic produce/products.

2.13 Are other containers/packaging materials re-used for packing organic produce/products?

2.14 Describe traceability (lot/batch) code used for produce/products handled and how it facilitates trace back to batch(es) of harvests/purchases of ingredients and suppliers.

2.15 Describe storage method and substances used.



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2.16 How is transportation of organic produce/products carried out?

2.17 Described the Quality checks and when and how are Sampling & Testing for contaminants done, if applicable.

2.18 Please give an overview of the quality assurance methods adopted on receipt of materials, components including actions taken on rejects.

2.19 Do pest control record specify date, time of application, areas applied, pest control method & agent used, and responsible person?

a) Yes

b) No

If Yes, please attach evidence.



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**SECTION 3: MANUFACTURE**

**3.1 SYSTEM**

3.1.1 Please attach the details of the various steps in manufacture. (A production processes and / or supplement in chart form showing stages may be advantageous).

3.1.2 How are waste material from handling/processing managed or disposed to minimise impact to environment? Attach Standard Operating Procedure (SOP), if available.

**3.2 EQUIPMENT MAINTENANCE SYSTEM**

3.2.1 How are equipment and machinery used cleaned before every organic production run?



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3.2.2 How do you determine that adequate amount of organic flushing material is used?

3.2.3 Describe measures to keep facility, equipment & containers clean and hygienic.

3.2.4 Do cleaning record specify date, time of cleaning, equipment, cleaning agent used & responsible person?

a) Yes

b) No

If Yes, please attach evidence.

3.2.5 Describe the maintenance system in operation.



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**SECTION 4: QUALITY CONTROL & TESTING**

**4.1 QUALITY CONTROL SYSTEM**

Please give details of the Quality Control System, including sampling plan followed, with particular reference to test in the relevant standard. (A quality control schedule or any supplement cross-reference in 3.1.1 is advantageous)

S.N	Name	Quality control check	Sampling plan	Method

**4.2 LIST: TEST EQUIPMENT / INSTRUMENT, GAUGES AND TOOLS FOR QUALITY CONTROL**

S.N	Name of the test equipment	Manufacturer's name	Calibration frequency	Calibration certificate number



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**SECTION 5: QUALITY CONTROL & DOCUMENTATION**

**5.1 GENERAL**

5.1.1 Please indicate the form of master specification in use (i.e drawing, product or part schedule, or a reference sample etc.). Please do also indicate the general records available.

5.1.2 Please indicate the system used to amend design or specification.

**5.2 COMPLIANCE WITH SPECIFICATION**

5.2.1 Please indicate the level of defectives found in the last three batches of production. If test in accordance with relevant standards have already been carried out, attach copies of summary of test result if available.

5.2.2 Please indicate the level of claims or complaints made under warranty and/or otherwise. Give this as a percentage of total output (Numbers as well).

5.2.3 Have independent test (apart from the in-house testing) been made on the product against the standard? Please tick.

a) Yes

b) No

5.2.4 If yes, by whom ? .....

Please attach copies of test reports if available.