



Ministry of Health
Bhutan Food and Drug Authority
CERTIFICATION SERVICES

LEGALLY ENFORCEABLE AGREEMENT FOR ORGANIC CERTIFICATION

The Bhutan Food and Drug Authority (BFDA) operates Organic Certification through Certification Services hereinafter referred to as the Certification Body makes agreement with the holder of the License, Licensee hereafter referred to as Client for the certification of the product and schemes for which the details of the licenses are given below:

SN	PRODUCT	SCHEMES	STANDARD	TRADE NAME	CERTIFICATE NO.	CERTIFICATION DATE

In order to hold and use the licence, the Client shall comply with the conditions of the agreement as follows:

Article 1: Regulations for certification and inspection

1.1 The stipulations of the general provisions for the certification system apply to this agreement specified in the Food Act of Bhutan, 2005, Food Rules and Regulations of Bhutan 2017 and also scheme requirements stipulated as per ISO/IEC 17065 and standard requirements stipulated in BOS 02:2022.

Article 2: Rights and obligations of licensee

2.1 The Client agrees that the certified products produced, manufactured and supplied by him/her as specified in the licence to this agreement complies with the requirements stated by the CB in the identified standard, certification scheme and certification requirement conditions.

2.2 The Client agrees that, in case of individual producer, regular records/documentation on farm operation shall be maintained as per the Organic Farm Diary. For group producer, in addition to the maintenance Organic Farm Diary by its members, records related to the implementation of the ICS shall be maintained as per the formats prescribed in Internal Control System (ICS) Manual Version II:2020 of the National Centre for Organic Agriculture (NCOA) Yusipang, Thimphu.

2.3 The Client agrees that the persons representing the CB will have unobstructed access without prior notification to the premises of the farm/factory covered by the license during its normal working hours. The Client also agrees to allow observers and trainee auditors with the technical audit team and observers or assessors from accreditation and regulatory bodies and also draw samples of soil, water, produce/product for laboratory testing.

Doc. No.: BFDA-CS-PR4.1-01-FM-03	ISSUE NO.: 04	Approved by: MR	Page 1 of 6
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Ministry of Health
Bhutan Food and Drug Authority
CERTIFICATION SERVICES

2.4 The Client agrees that the products for which the licence is granted will be produced as per the details submitted to the CB (as specified in the application form for organic certification).

2.5 The Client agrees to inform the CB without delay the changes that affect its ability to conform to the requirements of the standards or certification requirements.

2.6 The Client agrees to use the standard mark on the product(s) produced, processed, packed and labelled to which the licence applies and make claims regarding certification consistent with the scope of certification. The mark is non-transferable from one product to another. The mark shall not be used on the product(s) produced/processed from the farm which is under conversion to organic.

2.7 The Client shall neither use standard Mark as part of its company's name nor in any other way to identify standard marks as part of its business such as its use on the Client's stationery, business cards and website. Further, the Client shall not use the Standard Mark on laboratory test, calibration or inspection reports. The client agrees to use Organic Mark on those products if minimum of 95% (wt) of the ingredients are of organic origin.

2.8 The clients agree not to use Organic marks on the product where the ingredient of organic origin comprises less than 95% but not less than 70% (wt) and agrees to be labelled as "*made with organic ingredients*".

2.9 The Client agrees to seek approval from the Certification Body, on the design of the Standard Mark prior to the commencement of its use.

2.10 If Client provides copies of the certification documents to others, the documents shall be reproduced in their entirety or as specified in the certification scheme.

2.11 The product for which the license is granted shall be produced, processed and supplied in accordance with the standard and set certification conditions, which may be revised from time to time.

2.12 The Client shall maintain a complete record of the tests and inspection and such other data as specified in the scheme for testing and inspection, to establish to the satisfaction of the CB that the required control of production or process has been and is being satisfactorily maintained. Such records shall, on demand, be made available for inspection to CB.

2.13 The Client agrees not to use its product certification in such a manner as to bring the CB into disrepute and does not make any statement regarding its product certification that the CB may consider misleading or unauthorized.

2.14 During the period of suspension, the Client agrees to not make misleading claims and to advise relevant existing and potential purchasers regarding the status of certification, and cease to use the certification mark on the products manufactured since the date of notification of suspension.

Doc. No.: BFDA-CS-PR4.1-01-FM-03	ISSUE NO.: 04	Approved by: MR	Page 2 of 6
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Ministry of Health
Bhutan Food and Drug Authority
CERTIFICATION SERVICES

2.15 The Client agrees for its manufacturing unit to have procedures in place to ensure that a non-conforming certified product that gave rise to suspension of certification is recalled.

2.16 The Client agrees that the certification body shall withdraw the Certification, in case of misusing the Mark. The Client is liable to penal provisions under the Food Act of Bhutan, 2005 and its Regulation in the event of misuse of the standard mark.

Article 3: Surveillance

3.1 The CB carries out surveillance visit at least once in 12 months to determine continuing conformity to the Standard during the period of validity of license.

3.2 The surveillance is carried out by the auditors of the CB.

3.3 The testing of the samples taken from factory/farm or market is carried out as and when required for cases such as sample failures, consumer complaints or farm operations that would affect continued conformity to the standard.

Article 4: Information on modifications in production

4.1 The Client agrees to inform the CB, without delay, of the following changes that may affect its ability to conform to the certification requirements:

- any intended modification in the product, the process design or the manufacturing/production method or the quality management system
- any organizational and management changes (key managerial, decision-making or technical staff) which could affect the licensee's ability to continue to produce the certified product.
- changes relating to legal, commercial, organizational status or ownership
- major changes in outsourcing, production, manufacturing and testing equipment
- change of contact address and production sites, premises
- major changes in internal control measures
- any other information indicating that the product may no longer comply with the requirements of the standard and the certification mark.

4.2 The Client agrees for any verification of the above changes by the CB as and when necessary.

4.3 The Client agrees to inform BFDA-CS in case they decide to outsource parts of production/processing activities to other organic producers. In case of outsourcing, the certified client is fully responsible for overseeing the compliance of outsourced activities to the Organic Standard requirements.

4.3 The Client agrees to apply to the CB if it wishes to extend the scope of certification to additional types or models of products, to the same specified requirements as the products for which a certification is already granted.

4.4 The Client agrees to apply to the CB if it wishes to apply the certification to additional types of products, but to different specified requirements, or if the client wishes to apply for

Doc. No.: BFDA-CS-PR4.1-01-FM-03	ISSUE NO.: 04	Approved by: MR	Page 3 of 6
----------------------------------	---------------	-----------------	-------------



Ministry of Health
Bhutan Food and Drug Authority
CERTIFICATION SERVICES

an extension of the certification to cover an additional facility that is not covered by the earlier licence.

Article 5: Complaints

5.1 The Client agrees to keep a record of complaints and action taken of any complaints regarding those aspects of the products covered by the licence and to report to the CB upon request for verification.

Article 6: Publicity

6.1 The CB authorizes the Client to use the certification mark and the certificate issued by the certification body as part of publicity material. However, the client agrees to take care that certification mark and certificate used for publicity shall be used only for the certified farm/factory and specified product scope. It shall not imply that the crops/products not specified within the scope of certification and non-certified farms having common ownership are also certified.

6.2 The CB uses its official website for placing information in the public domain, about the Client, the certified product, and the status of the license for use of marks of conformity, including updates on any cancellation or suspension of the license.

Article 7: Confidentiality

7.1 The CB ensures that confidentiality is maintained by all personnel involved on its behalf concerning all confidential information with which they become acquainted as a result of their contacts with the Client.

7.2 When the CB is required by Bhutan Civil Services Rules or authorized by contractual arrangements to release confidential information, the client or person concerned is, unless prohibited by law, notified of the information provided.

Article 8: Payment

8.1 The Client agrees to pay to the CB for all expenses in relation to the certification/ surveillance, including sampling, testing, assessment and administration costs. Payment becomes due within 30 days from the date of invoices. Non-payment of invoices shall be a contractual nonconformity to suspend and/or to cancel this agreement and the certificate issued.

Article 9: Agreement period

9.1 This agreement comes into force onand remains in force untilunless withdrawn for justified reasons or cancelled by either party upon due notice given to the other party.

9.2 The validity of the license is for a period of 3 years unless it is renewed or is suspended or revoked.

Doc. No.: BFDA-CS-PR4.1-01-FM-03	ISSUE NO.: 04	Approved by: MR	Page 4 of 6
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Ministry of Health
Bhutan Food and Drug Authority
CERTIFICATION SERVICES

9.3 When the Client ceases its operation, it shall notify the CB in writing within thirty days from the date of cessation thereof.

Article 10: Termination of license

10.1 Depending on the reason for the Termination the following schedule of notice will be followed:

	Situation requiring notice that can lead to Termination	Days of notice prior to Termination
01	Producer/Manufacturers wish to terminate	Max. 60 days
02	CB determines that the product/produce is hazardous	Max. 60 days
03	Violation of the standard requirements	Max. 60 days
04	Non-payment of fees according to Article 8	Max. 30 days
05	Failure to meet other provisions of the agreement	Max. 60 days
06	Mandatory compliance with new requirements in relation to revision of standard	Max. 60 days

10.2 Upon termination, suspension or withdrawal of certification, the Client agrees to discontinue the use of standard mark in any form and all advertisement materials that contains any reference to its certification status.

10.3 In the event of a withdrawal of the right to use the Certification Mark, the certificate or the licence shall be returned to the CB. The right to use the Certification Mark expires at the same time without giving rise to any liability claim against the CB.

10.4 In the event of cancellation of license, registered letter (or equivalent means) stating the reasons and the date of termination of the certification shall be sent by the CB to the Client,

Article 11: Changes to product requirements

11.1 If the requirements applying to the produce covered by this agreement are modified, the CB shall inform the Client of changes stating on which date the modified requirements will become effective and advising the Client of any need for a supplementary examination of the produce.

11.2 Within a specified period of time after receipt of the advice described in paragraph.11.1, the Client shall inform CB whether he/she is prepared to accept the changes. If the Client gives confirmation within the specified period of his acceptance of the changes and provided the result of any supplementary examination is favourable, a supplementary licence will be issued or other modifications of the CB records.

11.3 If the Client advises the CB that he is not prepared to accept the modification within the time specified in accordance with 11.2 or if he/she allows the terms for acceptance to lapse,

Doc. No.: BFDA-CS-PR4.1-01-FM-03	ISSUE NO.: 04	Approved by: MR	Page 5 of 6
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**Ministry of Health
Bhutan Food and Drug Authority
CERTIFICATION SERVICES**

or if the result of any supplementary examination is not favourable, the licence covering the particular product shall cease to be valid on the date on which the modified specifications become effective, unless otherwise decided by the CB.

Article 12: Liability

12.1 The client has the primary responsibility to produce, process and supply products as per the Standard and certification requirements and they are liable for any non-conforming product.

12.2 All parties shall be bound by this agreement and all other legal requirements of Bhutan.

Article 13: Complaints/Appeals

13.1 All complaints and appeals that may arise in connection with this agreement are first directed to the CB to be settled in accordance with the appeal and complaints procedures of CB.

Issued in duplicate and signed by an authorized representative of the Bhutan Food and Drug Authority and the Client.

For the Certification Body:

Date.....

Management Representative

Bhutan Food and Drug Authority

(Seal and signed)

For the Client:

Date.....

Company Representative

(Seal and signed)

Doc. No.: BFDA-CS-PR4.1-01-FM-03	ISSUE NO.: 04	Approved by: MR	Page 6 of 6
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