GUIDELINES FOR DRAWL, CODING, SEALING AND DISPATCH OF SAMPLES

1. PURPOSE

To provide guidelines for drawl, coding, sealing and dispatch of samples drawn from farm/factory as well as from market.

2. SCOPE

This Guideline covers all types of samples drawn for the following Product Certification Schemes operated by BFDA-CS:

a) product certification scheme covering general food products;
b) product certification scheme covering organic products; and
c) product certification scheme covering GAP products.

3. RESPONSIBILITIES

3.1 Certification Manager is responsible for developing this guideline and ensuring its implementation.

3.2 Certification Officer is responsible for making necessary arrangements for for drawl and dispatch of samples to the laboratory for testing.

3.3 Technical Auditor is responsible for drawl, coding, sealing and dispatch of samples to the CS for further submission to the laboratory having facility for testing.

4. GUIDELINES

4.1 Guidelines for Drawl of samples for raw materials of products**.**

4.1.1 For uniformity in operation with respect to drawl of samples for raw materials of products under Certification, the following guidelines have been formulated:

a) During factory/farm audit, samples of raw materials/components are drawn following random sampling for independent testing where ensuring conformity of raw materials is the requirement of the product standard being considered for Certification. In case of audits for inclusion of new varieties, samples of only additional raw materials/components, if any, shall be drawn.

b) Samples of raw materials/components are drawn following random sampling, even if they are BFDA-CS Marked. However, they are treated only as Market sample(s) of the concerned licensee(s). If BFDA-CS marked raw material/component is found failing, it is taken as a failure of market sample and does not affect the grant of license. It should however, be ensured that the markings on the raw material/component are genuine, and the firm has the appropriate records of purchase.

c) Samples of raw materials / components may also be drawn following random sampling during surveillance visits by rotation so as to test all raw materials during a period of two years.

d) In case of unsatisfactory conditions or other non-conforming evidences observed while inspecting, the Auditors shall draw samples following selective sampling. This may be done at the farm/factory/manufacturing premises, wholesale level and at the market.

e) Where Bhutan standards for raw materials are referred to in the product Standard for guidance or reference only, raw material samples should not be drawn. However, suitable declaration may be taken from the applicant/ licensee depending on the stipulation in the standard.

f) Separate raw material samples are not to be drawn where the requirements of a raw material can be tested from the product itself.

4.1.2 Test certificates of the conformity of raw material/components provided by the applicant/ licensee is not accepted in general. However, if Test Certificates are from an accredited Laboratory, they are accepted. Where general statements are made in Bhutan Standards that raw materials should conform to 'relevant Standards' without indicating the specific Bhutan Standard, raw material samples is not to be drawn. In case of such statement being in the standards pertaining to products of direct human consumption/application, an undertaking with regard to safety of the raw material in use may be obtained from the manufacturer.

Selecting a representative sample

For the sampling of bulk commodities, the Auditor shall select the items at random – select items from throughout the consignment (or lot/batch) from top, bottom, middle, front and back. Do not just select items from the product first seen when accessing the consignment.

Sampling technique for ensuring a random, representative sample from a single lot, five replicates are needed to get a representative sample. Sample randomly from different parts of the lot, from top, bottom, middle, front and back.

When the consignment consists of multiple lots (packages, bags, boxes) of the same product, to ensure inspection of a representative sample, the simple approach is to use the rule of cubes that sets out the minimum of lots needed to be examined based on the number of lots in the consignment. This rule requires that the minimum number of lots to be examined is the largest whole number of the cube root of the total number of lots in the consignment.

Sampling technique – Sterile technique for microbiological analysis

- When sterile samples are needed for microbiological analysis, you must use sterile technique.
- Five replicate samples are needed and each should be kept separate.
- Use protective clothing, gloves.

- Sample with clean and sterile equipment and wash equipment with 70% alcohol between each sample collection.
- Place sample in sterile sample container (or medium as required) and place into cold storage to maintain temperature.
- Do not focus sample collection from the surface of the lot, but collect samples from within the lot.
- Do not breathe, sneeze or cough on the sample when it is collected.
- Maintain the integrity and condition of the sample at all times.

Sampling technique – non-sterile samples

- For non-sterile samples, five replicates are needed but these may be combined into a composite sample.
- Protect consignment and samples from contamination during sampling
- Transport in bags or containers to prevent contamination or cross contamination

4.2 Sampling of products applied for or under certification

4.2.1 For Food product and BhutanGAP produce certification, it is necessary that sample is drawn at random from sufficient quantity of the material which is representative of production level. The quantity representing one control unit or batch is considered adequate. In case of products that are discrete items, a lot of about 10 items is considered adequate. The samples of each type and grade which the applicant wants to be included in the license are drawn.

4.2.2 For organic products, the auditors shall take and analyze samples in each case if the auditors suspect possible contamination through the use of products or techniques not authorized for organic production. Refer Table 1-3 for the details on the MRLs established by the NCOA, MoAL.

4.2.3 The technical auditors should also note down the test results of the particular control unit from which samples are drawn as recorded by the licensee. The technical auditors should invariably ensure that, at the time of drawl of the sample whether the particular type /grade /size /brand/variety of the sample drawn is the one which is included in the standard and for which the license has been granted.

4.3 Sampling during Surveillance Visits

4.3.1 Draw samples of the material with the Mark and test it in the factory for the important requirements of the specification. The test results obtained should be compared with the results recorded by the licensee. Another sample with the Mark preferably of different type/size/ grade/ lot/ control unit should be drawn for independent testing. One sample properly sealed and labeled is also left with the licensee as counter sample. Where conformity of raw materials is specified, samples of raw materials may be drawn by rotation during surveillance visits.

4.3.2 The technical auditors should also note down the test results of the particular control unit from which samples are drawn as recorded by the licensee. The technical auditors should invariably ensure that at the time of drawl of the sample whether the particular type/ grade/ size/brand/variety of the sample drawn is the one which is included in the standard and for which the license has been granted.

4.3.3 Technical auditor while reporting any result should employ the symbols and units given in the relevant standard in reports and correspondence and the suitable abbreviations (See 4.5.3). The observations noted by the technical auditor in the record of licensee/applicant are also reproduced in the inspection report.

4.3.4 Where the license covers a number of sizes, types, grades, etc., it should be ensured that the sample(s) is (are) not of the same size/grade/type as the ones that had been drawn earlier. Every effort should be made to cover the entire or maximum possible range in one year of operative period of the license. Normally, one sample of a size/type/grade should be drawn.

4.4 Size of the Sample to be drawn

4.4.1 It shall be ensured that the size of the sample is adequate for testing (and retesting wherever needed) the requirements for which it is desired to be tested. The technical auditor should anticipate all requirements of the laboratory on the basis of' the relevant Bhutan Standards and STI, and draw the required size of the sample. Counter samples of identical size shall be drawn and left with the applicant/licensee. The identical sample left with the applicant/licensee shall be retained with them until the time they receive test report copy from BFDA for the particular case. Based on the test report, the applicant/licensee should dispose the retained counter samples as deemed fit or may consult BFDA for any technical advice regarding the disposal of the retained sample if they are not confident to do so. At the time of taking sample, a sample retention form shall be signed between the auditor and the client (BFDA-CS-GL 7.4-01-FM 01).

4.4.2 For products where complete testing facilities are not available in the BFDA and where the sample is required to be tested in another lab for some requirements, one more set of samples should be drawn and sent simultaneously to the relevant laboratory indicating clearly the tests to be carried out. Similarly, appropriate number of samples should be drawn when separate tests are required for chemical, physical, microbiological characteristics etc. for expeditious testing.

The Sample size depends on the sample type, number if tests and the laboratory requirements, For instance, the National Food Testing Laboratory protocol document outlines what types of sample and the size of sample that may be needed (noting that sample size may need to be increased if multiple tests are required. The recommended sample sizes are outlined in Table below:

4.4.6 Type/Grade/Size of the Material - These should be ascertained and indicated on the sample and test request. In case any other information is required for testing of the sample, information on the same should also be obtained and indicated.

4.5 Requirements for handling and storage of microbiological samples

4.5.1 The sampling for microbiological analysis shall be adequately collected, stored and handled to preserve the integrity of the sample to obtain accurate results. The tools and containers used for sampling for microbiological analysis shall be sterilized before use and also follow the manufacturer's instructions for the use of sampling devices.

4.5.2 All samples collected should be transported to the laboratory at the earliest possible.

4.5.3 Chilled samples shall be transported to the laboratory for testing as quickly as possible at the temperature (2-8 °C, but not frozen). Frozen or refrigerated products shall be transported in insulated containers of rigid construction under frozen conditions and prescribed temperature of the products. Samples which were not frozen before sampling shall not be frozen after sampling. Dehydrated and dry foods may be shipped and stored without refrigeration and should not be allowed to absorb any atmospheric moisture. These shall be stored in a clean, cool and dust free place. The samples should be protected from direct sunlight or other sources of heat. Meat and meat products, poultry and fish should preferably be transferred under wet ice refrigeration to avoid dehydration at the surface of the sample. Samples having different storage temperature shall be transported in separate transport

container. The packaged water sample shall be stored and transported to the laboratory under the ambient conditions avoiding any kind of physical damage and cross contamination.

4.6 Packing, Labeling, Coding, Sealing and Signing of Samples

4.6.1 Packing - The technical auditor should take every precaution or suitably instruct the licensee to ensure that the sample is packed in a durable packing material to withstand hazards during handling and transportation. Wherever feasible, all original markings indicating the origin of the product would be removed / defaced from the sample with the objective of concealing the identity of the origin from the testing laboratory.

4.6.2 Labeling - The sample should be labeled to indicate:

a) name of the product;
b) the relevant Bhutan Standard with its year;
c) grade/type/size of the product
d) quantity of sample;
e) batch No./Control Unit No./date of production;
f) declared values, if any.

4.6.3 Coding - A code number should be given to the sample/label in the following manner:

Initials of the technical auditor/Date of drawl of sample (DD-MM-YYYY)/Type of Sample/Nature of sample/Application registration number issued by BFDA-CS (UID of farmers in the farm group, incase of group certification)

For example,

Sample Code = *DC/07-03-2023/FS/Buckwheat Flour/BFDA-CS-52*

Where, DC = initials of technical auditor
07-03-2023 = date of sample drawl
FS = factory sample
Buckwheat flour = nature of sample
BFDA-CS-52 = registration number issued by BFDA-CS

The abbreviation to be used for different type of samples is given below:

AS- Applicant Sample
CP-Complaint Sample
MS-Market Sample
FS-Factory Sample (Normal Licensee Sample)
CS-Counter Sample

The type of the sample may also be prominently indicated on the test request so that the concerned laboratory is able to give priority to the testing depending on the type of the sample.

4.6.4 Sealing - The sample should be properly sealed with official seal and signed by technical auditor and the representative of applicant/licensee (if he demands*)* so that no substitution or tampering with the contents is possible subsequently. For the purpose of sealing, the technical auditor should always carry the official self-inking stamp.

4.6.5 Receipt for Samples - For any sample(s) drawn for testing including counter samples, complaint samples etc. receipt should be issued by the technical auditor. The receipt should be countersigned by representative of the firm.

4.6.6 Dispatch of Samples and test request

4.6.6.1 Dispatch of Samples

As far as possible, samples should be brought to office personally by the technical auditor or the transportation to the laboratory should be arranged through the officially appointed courier. Where samples are bulky, delicate or very expensive, they may be left with the firm along with instructions as to where the samples are to be dispatched; it should also be impressed upon the licensee/applicant that the sample should be dispatched quickly and that contact or correspondence directly or indirectly with the concerned testing laboratory should be done. Till the sample is received by the concerned laboratory, the office should keep track and follow up actively. During the next visit the technical auditor should invariably check whether or not previous sample(s) had been dispatched.

4.6.6.2 Test Requests

A copy of test request should accompany the sample being sent to the laboratory for testing. In the test request, the date by which the test report is required should be mentioned. Proper attention should be given to indicate the version of standard/ Amendment Number to which the sample is to be tested, grade, type, size and other details about the sample in the test request so as to avoid unnecessary delays in completion of tests by the laboratory. It should also be verified whether the particular type, grade or size is included in the Standard. In case of licensee's sample, it should also be ensured that the particular type, grade or size is included in the license.

4.6.7 Guidelines for Choosing Laboratories for Dispatch of Samples

4.6.7.1 Selection of Laboratory

Technical Auditors should send the samples to BFDA-CS or its approved laboratories, the primary objective of expeditious testing of samples may be kept in view and the following guidelines may be followed:

a) the applicant and complaint samples may preferably be tested at National laboratories, if testing facility exists;

b) other surveillance visit samples and market samples may be tested at BFDA Approved or ISO/IEC 17025 accredited laboratories keeping in view that sending samples of one particular licensee repeatedly to the same laboratory is avoided.

4.6.7.2 Follow up of movement of sample

In order to follow up the movement of sample and to ensure that test reports are received in time; Office should maintain a record of samples procured both from the market and the factory in appropriate format. BFDA-CS should ensure that sample has been deposited with the concerned laboratory and also follow up with laboratory to provide the test report by the date stipulated in test request.

4.6.7.3 Return of Tested Factory Samples

The returnable samples which are not consumed during testing or remnants of samples should be returned to the applicants/licensees if they so desire after the testing is over. In such a case, BFDA-CS should ensure that firms are intimated about the collection of samples. A copy of the letter sent to the firm may also be sent to the concerned laboratory to facilitate handing over the samples to the firms' representatives as and when they approach the laboratories.

4.7 Omission of Sampling and Testing

Sampling and testing may be waived in specific situations, provided the following conditions are met:

- The product has already undergone testing and certification to a recognized equivalent or higher standard, with supporting verifiable documentation.
- A risk assessment concludes that sampling and testing do not play a critical role in verifying compliance with the specified requirements.
- The product is consistently produced under a certified and accredited quality management system, ensuring reliable conformity to standards.
- The decision to waive sampling and testing is supported by clear, documented objective evidence from the auditors, confirming that the farm complies fully with the standard and shows no deviations.

5. REFERENCES

BFDA-CS-PR7.4-01 Procedure for Processing of Application for Certification
ISO 10576-1:2003 Statistical methods - Guidelines for the evaluation of conformity with specified requirements - Part 1: General principles
ISO 2859-10: 2006 Sampling procedures for inspection by attributes - Part 10: Introduction to the ISO 2859 series of standards for sampling for inspection by attributes
ISO 3951-1:2013 Sampling procedures for inspection by variables - Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL
ISO 22514-1:2009 Statistical methods in process management - Capability and performance - Part 1: General principles and concepts
https://www.ivtnetwork.com/article/sampling-microbiological-analysis-collection-storage-and-handling

1. LABORATORY

In the field conditions the contamination can be from the neighboring agricultural or non-agricultural activities, off-farm inputs and in many cases are non-intentional. The general measure that is adopted for pesticide residues are maximum residue levels (MRL). Following are the details of the some applicable MRL and appropriate action that needs to be taken for certification incase laboratory testing is deemed necessary.

TABLE 1: Maximum Residue Limits (MRL) for Agriculture Produce

Maximum Residue Limits (MRL) as fresh matter of the product/crop	Action
Detection level (DL) of 0.01 mg/kg of the produce	Certified as Organic
0.01 to 0.025 mg/kg for harvested products 0.01 to 0.05 mg/kg for harvested products	Improvement actions need to be taken by identifying the potential source of contamination and taking appropriate measures. The product shall be certified as organic.
0.025 to 0.1 mg/kg for harvested products 0.05 to 0.1 mg/kg for harvested products	Suspension of Organic Certification

TABLE 2: Maximum Residue Levels (MRL) for heavy metals present in soil, irrigation water and food

Sl.No.	Heavy Metals	Maximum permissible limit		
		Soil	Irrigation Water	Food
1	Nickel	75-150 mg/kg	NA	1-5 mg/kg
2	Chromium	NA	0.05 mg/L	20 mg/kg
3	Lead	250-500 mg/kg	0.1 mg/L	2.5 mg/kg
4	Cadmium	3-6 mg/kg	5 mg/L	1.5 mg/kg
5	Zinc	300-500 mg/kg	0.05 mg/L	50 mg/kg
6	Copper	135-270 mg/kg	0.05 mg/L	30 mg/kg

TABLE 3: Maxmum Residue Levels (MRL) for pesticides present in soil and irrigation water

Pesticides	MRL (Soil), PPM	MRL (Water), µg/L
2,4,-D	0.05	0.25
2,4,-DB	0.05	0.25

2,4,5,-T	0.05	0.13
Dalapon	0.05	0.50
Dicamba	0.10	0.13
Dichloroprop	0.05	0.13
Dinoseb	0.05	0.13
Aldicarb (Temik)	0.05	0.50
Aldicarb Sulfone	0.03	0.50
Aldicarb Sulfoxide	0.03	0.50
Carbary (Sevin)	0.03	0.50
Carbofuran	0.03	0.70
3-OH Carbofuran	0.05	0.70
Methomy	0.05	0.70
O – Phenylphenol	0.05	0.50
Oxamyl (Vydate)	0.03	0.50
Ametryn	0.03	0.70
Atrazine	0.05	0.50
Prometryne	0.05	0.50
Propazine	0.05	0.50
Simazine	0.05	0.50
Terbutryn	0.05	0.50
Diuron	0.05	5
Fenuron	0.05	5
Linuron	0.05	5
Monuron	0.05	5
Siduron	0.05	5