

MANUAL ON

GENERAL GUIDELINES ON SAMPLING





FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
GOVERNMENT OF INDIA
NEW DELHI
2016

GENERAL GUIDELINES ON SAMPLING TABLE OF CONTENTS

S.No.	TITLE	Pg.No.
1.0	Introduction	2
1.1	Scope of Sampling	2
1.2	Purpose of Sampling	2
1.3	Category of analysis	4
2.0	Sampling Plan	4
2.1	Purpose	4
2.2	Target audience of the guidelines	4
2.3	Users of sampling plans recommended by the guidelines	5
2.4	Basic recommendations for the selection of sampling plans	5
2.5	Statistical design for sampling	8
3.0	Sampling Procedure	10
3.1	General Information	10
3.2	Employment of Food Safety officer or Sampling personnel	10
3.3	Material to be sampled	10
3.4	Representative sampling	10
3.5	Types of single sampling plans	12
3.6	Two and three class attributes plans for microbiological	15
	assessments	
4.0	Manner of collecting the sample	17
4.1	Sample taking and despatching	23
4.2	Time for Sample delivery to the Public Analyst/ Accredited lab/	26
	Referral lab	
4.3	Time for Sample Analysis and reporting by the Lab	26
4.4	Suitable container	26
4.5	Quantity of sample to be drawn as sufficient for analysis	27
4.6	Important Points to consider	28
5.0	Sample Preparation	30
5.1	Preparation of Samples	31
6.0	Other points of consideration	32
6.1	Sampling Report	32
6.2	Sample preservation/storage during transport	32
6.3	Define time	32
6.4	Frequency of sampling	33
6.5	Tolerance criteria with reference to sampling	33
7.0	Documentation	34
	■ Sampling form (Refer Rule 3.3.2.(1))	34
	■ Sampling form (Refer Rule 3.4.1.(3))	35
	■ Sampling form (Refer Rule 3.4.3.(7))	36
8.0	References	37
9.0	Annexure:	
	Annexure I:Commonly Used Terms And Notions	38
	Annexure II: Quantity of Sample To Collect For Each Commodity	42

GENERAL GUIDELINES ON SAMPLING

1. INTRODUCTION

The Food Standards are aimed at protecting consumers' health and ensuring fair practices in the food trade. The prescribed method of sampling are designed to ensure that fair and valid sampling procedures are used when food is being tested for compliance with a particular commodity standard. The sampling methods are intended for use as methods designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to sampling and by diverging interpretation of results of analysis in relation to lots or consignments of foods, in the light of the relevant provision(s) of the applicable standard. A lot is a definite quantity of some commodity manufactured or produced under conditions, which are presumed uniform for the purpose of these Guidelines.

The present guidelines have been elaborated to facilitate the implementation of these goals by FSSA Food Safety officers, government and other users.

1.1 SCOPE OF SAMPLING

These Guidelines can be used by FSSA Food Safety Officers, government and other users who can select from the recommended sampling plan the best suited for the inspection to be made depending on the purpose of sampling.

1.2 PURPOSE OF SAMPLING

Label should mention purpose of drawing / collecting the sample i.e. whether it's for regulatory purpose or for monitoring only.

I. Regulatory:

Regulatory samples are picked for evaluation in case of certain concerns, issues. The reports of these analyses are filed for legal actions. Keeping this in mind, the sample integrity, homogeneity, and representativeness is vital for a fair and meaningful inference and subsequent actions.

Formal samples will be taken where formal enforcement action may result if an adverse report is received following examination or analysis. Hence formal samples have to be purchased or procurred by suitably trained, qualified and experienced authorised officers. The officer should strictly use the procedure for statistical sampling. The objective of the sampling procedures is to ensure that any sample procured is a 'fair sample' that accurately reflects the constituents of the bulk material being sampled. Regulatory samples should be collected in two sets and divided into four subsets.

II. Monitoring:

For samples to be drawn for the monitoring purpose, the notified institutions/labs should be involved as per approved protocol based on susceptibility of the product.

Monitoring activity is an ongoing process and samples picked for this activity are large in size. The sample number should be preferably in the range of 5 to 8 samples per location/product. The reports of these monitoring samples help the system to review quality, safety, freshness and preferencesin market place. It also helps in ascertaining consumption pattern and exposures to food additives and unintended contaminants and residues.

Routine sampling will take place to monitor the quality and safety of foods manufactured, distributed and retailed. All routine samples will be purchased and procurred anonymously by an authorised officer and should be analysed or examined in an informal manner by the appointed Public Analyst or Food Examiner.

The label should also specify the nature of analysis to be conducted (Qualitative/ Quantitative/Microbiological / Chemical).

1.3 CATEGORY OF ANALYSIS

The category of analysis for foods should be defined according to the requirement for regulatory or monitoring purpose.

- > Chemical analysis: Required chemical tests to prove the safety of the product. Nutritional tests required if product exhibits a claim
- Microbial analysis: Test for Absence of pathogens and safety in microbial counts
- Physical analysis: Test for extraneous matter, damaged product
- > Sensory analysis: Test for retention of original characteristics including flavour, texture etc. and other expected characteristics

2. SAMPLING PLAN

2.1 PURPOSE

Sampling plans are required which ensure that fair and valid procedures are used when food is being controlled for compliance with a particular commodity standard. Since numerous, yet often complex, sampling plans are available it is the purpose of these guidelines to help those responsible for sampling to select sampling plans that are appropriate for statistical inspections under specifications laid down in standards. No sampling plan can ensure that every item in a lot conforms. These sampling plans are nevertheless useful for guaranteeing an acceptable quality level. These guidelines contain the elementary principles of statistical control at reception, which complete the basic recommendations mentioned above.

2.2 TARGET AUDIENCE OF THE GUIDELINES

These Guidelines are above all aimed at FSSA Food Safety Officers, government and other users who can select from the recommended plans those which appear to them best suited for the inspection to be made. These Guidelines can also be used, if applicable, by governments in case of international trade disputes.

2.3 USERS OF SAMPLING PLANS RECOMMENDED BY THE GUIDELINES

The sampling plans described in these Guidelines may be implemented either by Governmental food control authorities, or by professionals themselves (self-inspection performed by producers and/or traders). In the latter case, these Guidelines enable the governmental authorities to check the appropriateness of the sampling plans implemented by the professionals. It is recommended that the different parties concerned with sampling come to an agreement on the implementation of the same sampling plan for the respective controls.

2.4 BASIC RECOMMENDATIONS FOR THE SELECTION OF SAMPLING PLANS

The present clause represents a pre-requisite to the use of these Guidelines and is intended to facilitate the selection of sampling plans, as well as to follow a systematic approach for this selection. The following enumerates the essential points that the relevant FSSA Food Safety Officers, Governments and other users should address for the selection of appropriate sampling plans, when setting-up specifications.

1) Nature of the control

- Characteristic applicable to each individual item of the lot
- Characteristic applicable to the whole lot (statistical approach)

2) Nature of the characteristic to control

- Qualitative characteristic (characteristic measured on a pass/failed or similar basis, i.e. presence of a pathogen micro-organism)
- Quantitative characteristic (characteristic measured on a continuous scale, for example a compositional characteristic)

3) Choice of the quality level (AQL or LQ)

• In accordance with the principles laid down in the FSSA Manual and with the type of risk: critical/non-critical non-conformities.

The Acceptable Quality Level (AQL) for a given sampling plan is the rate of nonconforming items at which a lot will be rejected with a low probability, usually 5 %. The Acceptable Quality Level (AQL) is used as an indexing criterion applied to a continuous series of lots which corresponds to a maximum rate of acceptable defective items in lots (or the maximum number of defective items per hundred items). This does not mean that all the lots having a rate of defective items greater than the AQL will be rejected at the control, but this means that the higher the rate of defective items exceeds the AQL, the greater is the probability of rejection of a lot.

4) Nature of the lot

- Bulk or pre-packed commodities
- Size, homogeneity and distribution concerning the characteristic to control

5) Composition of the sample

- Sample composed of a single sampling unit
- Sample composed of more than one unit (including the composite sample)

6) Choice of the type of sampling plan

Sampling plan needs to be specified. Single sampling plans for inspections of percent non-conforming items by attributes can be used. Sampling should be done considering the no. and nature of parameters to be assessed. Attribute sampling plan can be used when evaluating isolated lots. Variable method can be used if less no. of parameters is to be assessed. Sampling plan for lots moving in international trade are to be selected by attributes indexed by limiting quality level. For microbiological assessment, inspection by two or three class attributes is to be done:

- acceptance sampling plans for statistical quality control
- for the control of the *average* of the characteristic
- for the control of per-cent non-conforming items in the lot
- Definition and enumeration of non-conforming items in the sample (attribute plans)
- Comparison of the mean value of the items forming the sample with regards to an algebraic formula (variable plans)
- Convenience (or pragmatic, empirical) sampling plans

The two flow-charts in the following pages sum up a systematic approach for the selection of a sampling plan and reference to the appropriate sections in the document, which does not cover sampling of heterogeneous bulk lots.

FLOW-CHART FOR CHEMICAL AND PHYSICAL CHARACTERISTICS

Qualitative Characteristics (e.g. commoditydefects)

Inspection of isolated lots

E.g., inspection of the aspects of a piece of fruit, or of a can in isolated lots To be sampled by **attribute sampling** plan for isolated lots,

Inspection of a **continuous** series of

E.g., inspection of the aspects of a piece offruit, or of a can in continuous lots To be sampled by **attribute sampling** plans

for continuous lots, see section 4.2

Quantitative characteristics (e.g. compositional characteristics)

Inspection of isolated lots

Inspection of a **continuous** series of lots

bulk

E.g. : fat content of milk in a tank To be sampled by variable sampling plans for a isolated lots

item

E.g.: sodium content of a dietary cheese Sampling by attributes,

bulk

E.g.: fat content of milk in a tank. To be sampled by variable sampling plans for a continuous series of lots sections

item

E.g.: sodium content of a dietary cheese To be sampled by attribute sampling plans

Ref. CAC/GL 50-2004 Page 5 of 69

FLOW-CHART FOR MICROBIOLOGICAL CHARACTERISTICS

Micro-organisms with severe hazard or withmoderate direct health hazard of potentially extensive spread in food.

E.g., pathogenic *E. coli, Salmonella* spp, Shigella, Clostridium botulinum, Listeriamonocytogenes (risk groups)

Sampling by two-class attributes plans,

Micro-organisms with no or low direct health hazard (spoilage, shelf-life and indicator organisms) or with moderate direct health hazard (limited spread). E.g., aerobic microorganisms, psychrotrophic microorganisms lactic acid bacteria, yeasts, moulds (exceptfor Mycotoxins), coliform, thermotolerantcoliforms

Sampling by three-class attributes plans

Ref. CAC/GL 50-2004 Page 5 of 69

7) Decision rules for the lot acceptance/rejection: Ref. CAC/GL 50-2004

2.5 STATISTICAL DESIGN FOR SAMPLING (Applicable for monitoring and not for regulatory samples)

Sampling should be done as per Section 47 defined in the FSSA act. Food inspectors should buy samples from vendors/owners in presence of external witnesses. These samples are appropriately divided, packed, sealed. A sample pick up report, with other observations and comments is prepared and signed by the inspector, vendor/owner and the witness. As only one sample is picked up randomly, no statistical inferences can be concluded. However, based on findings for one sample test, it would be relevant to have at least 5 to 8 samples randomly picked up for reconfirmation and have some statistical inferences.

For packed foods it is necessary to decide the number of samples to be sampled. The generic formula used is:

i) For number of packages < 100, minimum of 10 samples has to be sampled

- ii) For number of samples > 100 in a batch, root of total number of samples need to be sampled
- After deciding the number of packages to be sampled, the numbers of packages are to be selected from the bulk consignment in a random manner so that each package in a lot has an equal chance of being selected.
- For package weight less than 5 kg the entire contents can be taken as incremental sample. For > 5kg the samples are transferred to a clean surface and mixed before sampling v) The incremental samples are mixed together, the size of the sample is then reduced by either riffling, or conning and quartering
- Final laboratory samples must be prepared and transmitted to the laboratory for testing without delay.

Based on the vendor being inspected the location for pick up or shop should be one that is handling a large volume of business for that vendor. The generic formula should be used:

- i) For number packages < 100, minimum of samples has to be sampled
- ii) For number samples > 100 in a batch, root of total number of samples need to be sampled

The number of units that comprise a representative sample from a designated lot of a food product must be statistically significant. The composition and nature of each lot affects the homogeneity and uniformity of the total sample mass. The proper statistical sampling procedure, according to whether the food is solid, semisolid, viscous, or liquid, must be determined by the collector at the time of sampling. [Refer Microorganisms in Foods: Sampling for Microbiological Analysis: Principles and Specific Applications, 2nd ed. University of Toronto Press, Toronto, Ontario, Canada]. Sampling should be done with a proper statistical design which will help cover the regulatory and monitoring issues for safe food production and maintain the transparency in the sample selection procedure. Samples should be despatched to the Public Analyst as soon as practically possible to avoid any discrepancies in testing.

3. SAMPLING PROCEDURE

3.1 GENERAL

Sampling procedures should be performed in accordance with appropriate Standards related to the commodity of concern (for example ISO 707 for sampling of milk and milk products, other official methods of sampling like BIS etc).

3.2 EMPLOYMENT OF FOOD SAFETY OFFICER OR SAMPLING PERSONNEL'S

Sampling should be performed by persons trained in the techniques of sample collection by the importing country.

3.3 MATERIAL TO BE SAMPLED

Each lot that is to be examined must be clearly defined. The appropriate regulatory body should stipulate how a consignment should be handled in instances where no lot designation exists.

3.4 REPRESENTATIVE SAMPLING

The representative sampling is a procedure used for drawing or forming a representative sample. The requirements of this clause shall be, if needed, completed by procedures (such as how to collect and to prepare a sample). Random sampling involves the collection of *n* items from a lot of *N* items in such a way that all possible combinations of *n* items have the same probability of being collected. The randomness can be obtained by use of table of random number which can be generated by using computer software.In order to avoid any dispute over the representativeness of the sample, a random sampling procedure should be chosen, whenever possible, alone, or in combination with other sampling techniques. Assuming the items can be numbered or ordered, even virtually when it is not possible to have individual items (e.g., in the case of a tank of milk or of a silo of grains), the choice of the items or of the increments entering into the sample should be done as follows:

- 1. To number all the items or increments of the lot (true or virtual)
- 2. The numbers of the items or increments to be sampled are determined randomly.

The collection of samples is to be performed in a random manner, whenever possible during the loading or unloading of the lot. If the lot is heterogeneous, a random sample may not be representative of the lot. In such cases, stratifiedsampling may be a solution. Stratified sampling consists of dividing the lot into different strata or zones, each stratum being more homogenous than the original lot. Then a random sample is drawn from each ofthese strata, following specified instructions which may be drafted by relevant regulatory body (for ex. APEDA has given guidelines for sampling of peanuts specifically to detect Aflatoxin levels). . Each stratum can then be inspected by random sampling which usually includes from 2 to 20 items or increments per sample. When it is not possible to sample at random, for example in a very large store where the goods are badlytidied or when the production process includes a periodic phenomenon (e.g. a contaminant which isspecifically located in a particular area of the silo or a regulator detuned every each k seconds, such as every k seconds the products packaged by this regulator have defaults), it is mandatory:

- 1. To avoid preferentially choosing items which are more easily accessible or which can be differentiated by a visible characteristic.
- 2. In the case of periodic phenomena, to avoid sampling every k seconds or every kth package, orevery kth centimetres, to take a unit from every nth palette, pre-package.

	Lots consisting of individualisable bulk material	Lots consisting of <u>individual</u> ⁴ <u>items</u>			
	Quantitative Measurements	Qualitative Measurements ⁵	Quantitative Measurements		
Isolated lots	Inspection by Variables of Bulk Materials for Percentage Non- conforming -Section 5.1 Example: check tank of milk for added water	Inspection by Attributes for percentage non- conforming - Section 2.5.1.1 Example: inspection of pieces of fruit for defects Microbiological inspection of product - Section 3.1, 3.2 Example: testing uncooked vegetables for mesophilic aerobic micro-organisms.(see ICMSF standards)	Inspection by Variables for percentage non-conforming - Section 4.3.2 (s method) Example: to check whether fat content of a skimmed milk powder complies with Codex limit	Average Content – Sections 3.3 and 4.4 Example: to check that average weight of items in a lot complies with label declaration (see also ISO 2854-1976, 3494-1976)	
Continuous series of lots	Inspection by Variables of Bulk Materials for Percentage Non- conforming - Section 5.1 Example: check a tank of milk for added water	Inspection by Attributes for percentage non- conforming - Section 2.5.1.1 Example: inspection of pieces of fruit for defects Microbiological inspection of product - Section 3.1, 3.2 Example: testing uncooked vegetables for mesophilic aerobic micro-organisms (see ICMSF)	Inspection by Variables for percentage non-conforming - Section 4.3.3 (σ method) Example: to check whether fat content of a skimmed milk powder complies with Codex limit	not exceed prescribed level	

³ Assuming for quantitative measurements, that measurement error is negligible in relation to process variation (see Section 2.4)

Table I: Selection of Sampling Plan

3.5 TYPES OF SINGLE SAMPLING PLANS

3.5.1 Single sampling plans for inspections of percent non-conforming items

3.5.1.1 Principles of inspection by attributes of percent non-conforming items

The following text and curves present simply the principles of inspection by single sampling plans byattributes and by variables of percent nonconforming as well as their efficacy.

⁴ Or individualisable.

Qualitative data includes quantitative data classified as attributes, for example with respect to a limit.

A sampling plan for inspection by attributes is a method for evaluating the quality of a lot which operates by classifying each increment of the sample as a conforming or nonconforming characteristic or attribute, depending on whether the standard specification is complied with or not. This characteristic is either qualitative (for example the presence of a blemish on fruit) or quantitative (for example the sodium contentof a dietary food, classified as conforming or non-conforming in relation to a limit noted). The number ofincrements having the nonconforming attribute are then counted and if the acceptance number set by the planis not exceeded the lot is accepted, otherwise it is refused.

3.5.1.2 Comparative advantages and disadvantages of attribute plans and variable plans

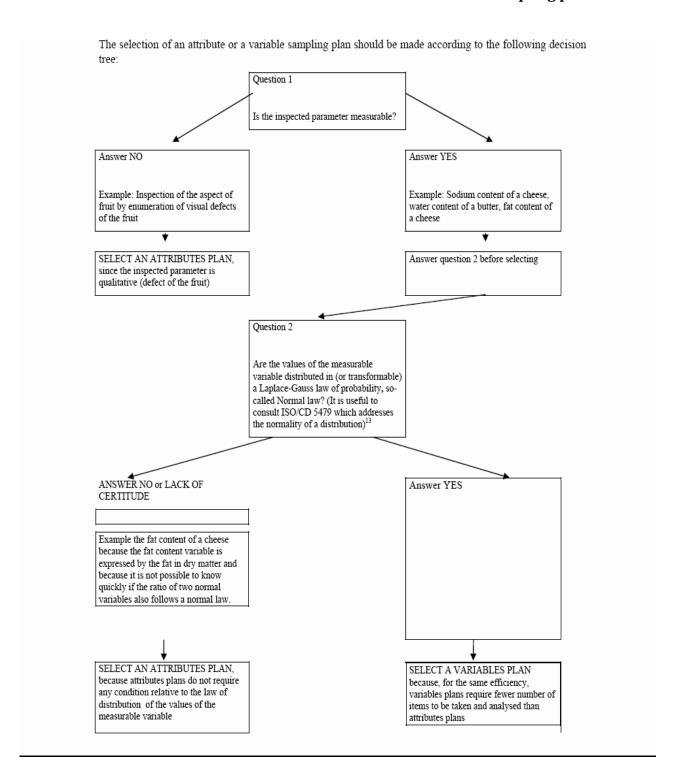
When it is possible to implement either an attributes plan or a variables plan, for example for the inspection of the sodium content of a dietary cheese, the selection must be made after having consulted in particular the following Table on the comparative advantages and disadvantages of the plans.

Table: Comparison of attribute and variable sampling plans

	ADVANTAGES	DISADVANTAGES		
ATTRIBUTES	No condition on the mathematical	Less effective than variables plans		
PLANS	law of distribution of the variable	for a same sample size of n		
	inspected	increments (the LQ is higher);		
	Greater simplicity of processing	more costly than variables plans		
	the results on the sample	because the collected sample		
		requires more increments than		
		those required, for the same		
		efficacy, by a variables plan		
VARIABLES	More effective than attributes	They cannot be used in all cases		
PLANS	plans for the same sample size of	because to validate the calculation		
	n increments (the LQ is lower); for	formulas the mathematical law of		
	the same AQL they are less	distribution of the inspected		
	expensive than attributes plans	variable must necessarily follow or		

because the s	sample collected	approximately follow a normal law
requires fewer	increments than	
those required, fo	or a same efficacy,	
by attributes plar	ns	

Decision tree for the selection of an attributes or a variables sampling plan



3.6 TWO AND THREE CLASS ATTRIBUTES PLANS FOR MICROBIOLOGICAL ASSESSMENTS

3.6.1 Two-class Attributes Plans

Two-class attributes plans provide a simple means of inspection *where the sampling plan is defined by twovalues, n and c.* The value of n defines the sample size in terms of the number of items; and the value cdenotes the maximum number of nonconforming items permitted in the sample. When undertaking amicrobiological assessment, a maximum concentration of micro-organisms permitted in any item is denotedby m; any item contaminated at a concentration greater than m is considered to be nonconforming.

For a given value of c, the stringency (probability of rejection) of the plan will increase as n increases.

The application of a two-class attributes plan can be summarized as follows:

Set the value of m, n and c

 Ψ

Collect the sample with n items

 \downarrow

Inspect each item in the sample



Accept the lot if: number of defective items $\leq c$

3.6.2 Three-class Attributes Plans

Three class attributes plans are defined by the values n, c, m and M (see below); and are applied to situationswhere the *quality of the product can be divided into three attribute classes* depending upon the concentration of micro-organisms within the sample:

- Unacceptable quality, with a concentration of micro-organisms above the value, M (which must not be exceeded by any items in the sample).
- Good quality, where the concentration must not exceed the value, m.
- Marginally acceptable quality. Marginal items have a concentration which exceeds m, but which isless than M (such concentrations are undesirable but some can be accepted, the maximum numberacceptable being denoted by c).

The value m is the concentration of the micro-organism which is acceptable and attainable in the food underinspection, as reflected by Good Commercial Practice (GCP). For 3-class plans, m will be assigned a non zero value.

The value M is a hazardous or unacceptable level of contamination caused by poor hygienic practice, including improper storage. There are several approaches to choosing the value of M:

- (i) As a 'utility' (spoilage or shelf-life) index, relating levels of contamination to detectable spoilage (odour, flavour) or to an unacceptably short shelf-life;
- (ii) As a general hygiene indicator, relating levels of the indicator contaminant to a clearlyunacceptable condition of hygiene;
- (iii) As a health hazard, relating contamination levels to illness. A variety of data may be used forthis purpose including, for example, epidemiological, experimental animal feeding and human feeding data.

The values m and M may be independent of each other. The choice of values for n and c varies with the desired stringency (probability of rejection). For stringent'cases', n is high and c is low; for lenient 'cases' n is low and c is high. The choice of n is usually acompromise between what is an ideal probability of assurance of consumer safety and the work load thelaboratory can handle. If the concentration of micro-organisms in any item of the sample is greater than M, the lot is directly rejected.

The application of a three-class attributes sampling plan may be summarized as follows:

Set the values of m, M, n, c Collect the sample with n items Inspect each item in the sample

Accept the lot if: number of marginally defective items (i.e. a concentration of microorganismsbetween m and M) \leq c

Immediately reject the lot if the concentration of micro-organisms in any item >M and/or the number of marginally defective items > c

3.6.3 The Application of Two and Three-class Attributes Plans

Two and three-class attributes plans are ideally suited for regulatory, port-ofentry, and other consumerorientedsituations where little information is available concerning the microbiological history of the lot. The plans are independent of lot size if the lot is large in comparison to sample size. The relationship between sample size and lot size only becomes significant when the sample size approaches one tenth of thelot size, a situation rarely occurring in the bacteriological inspection of foods. When choosing a plan one must consider:

- (i) The type and seriousness of hazards implied by the microorganisms, and
- (ii) The conditions under which the food is expected to be handled and consumed after sampling.

4. MANNER OF COLLECTING THE SAMPLE

The current practice of sample collection should be modified to include more transperancy, confidence and involvement of vendor/owner.

Information concerning the powers of the officer making an investigation, the legal rights of the occupier of a food premises and the Food Authority's Enforcement Policy should be included in any post inspection report.

A formal sample for analysis should as soon as possible, be carefully divided into four representative parts, preferably on the premises of the seller/owner of the food and giving the owner the opportunity to witness the sampling taking place. Each part must then be labelled and sealed to ensure that any evidence of tempering can be identified.

One part of the formal sample must be given to the owner, his agent or employee incharge of the food with notice that the sample will be analysed. The second final part of the sample must be submitted for analysis to the Public Analyst of the Food Authority concerned. The third final part must be retained by the authority for possible future analysis by the referee analyst (Govt. Chemist). In the event of any dispute over the composition or other alleged defect in the sample, as decided by the court, or by mutual agreement of the authorised officer and the owner of the food. For sealed containers wherein opening of the container could impede analysis the unopened containers might make the actual sample to be sent to the analyst. Also, cases where it is not practically possible to have a uniform mixing of samples from the three containers then the single part sample is to be submitted for analysis.

Samples to be taken, as far as possible, using sterile techniques (wherever microbiological tests are applicable) i.e., sampling personnel should use sterile gloves, sealed sterilised bags or sterile bottles. To avoid contamination from lot to lot, the sampling equipment has to be clean, dry and free from foreign odours. Using sharp objects should be avoided to prevent the possibility of damage to the surface of the equipment. BIS documents (wherever applicable) can also be considered for guidance purpose [Refer IS 5404-1984 (RA 2013)].

Samples to be taken for microbial analysis should be collected in sterile containers.

The adequacy and condition of the sample or specimen received for examination are of primary importance. If samples are improperly collected and mishandled or are not

representative of the sampled lot, the laboratory results will be meaningless. Because interpretations about a large consignment of food are based on a relatively small sample of the lot, established sampling procedures must be applied uniformly. A representative sample is essential when pathogens or toxins are sparsely distributed within the food or when disposal of a food shipment depends on the demonstrated bacterial content in relation to a legal standard.

The number of units that comprise a representative sample from a designated lot of a food product must be statistically significant. The composition and nature of each lot affects the homogeneity and uniformity of the total sample mass. The proper statistical sampling procedure, according to whether the food is solid, semisolid, viscous, or liquid, must be determined by the collector at the time of sampling.

Whenever possible, submit samples to the laboratory in the original unopened containers. If products are in bulk or in containers too large for submission to the laboratory, transfer representative portions to sterile containers under aseptic conditions. There can be no compromise in the use of sterile sampling equipment and the use of aseptic technique. Sterilize one-piece stainless steel spoons, forceps, spatulas, and scissors in an autoclave or dry-heat oven. Use of a propane torch or dipping the instrument in alcohol and igniting is dangerous and may be inadequate for sterilizing equipment.

Use containers that are clean, dry, leak-proof, wide-mouthed, sterile, and of a size suitable for samples of the product. Containers such as plastic jars or metal cans that are leak-proof may be hermetically sealed. Whenever possible, avoid glass containers, which may break and contaminate the food product. For dry materials, use sterile metal boxes, cans, bags, or packets with suitable closures. Sterile plastic bags (for materials only) or plastic bottles are useful containers for line samples. Take care not to overfill bags or permit puncture by wire closure. Identify each sample unit (defined later) with a properly marked strip of masking tape. Do not use a felt pen on plastic because the ink might penetrate the container. Whenever possible, obtain at least 100 gm for each sample unit. Submit open and closed controls of sterile containers with the sample.

Deliver samples to the laboratory promptly with the original storage conditions maintained as nearly as possible. When collecting liquid samples, take an additional sample as a temperature control. Check the temperature of the control sample at the time of collection and on receipt at the laboratory. Make a record for all samples of the times and dates of collection and of arrival at the laboratory. Dry or canned foods that are not perishable and are collected at ambient temperatures need not be refrigerated. Transport frozen or refrigerated products in approved insulated containers of rigid construction so that they will arrive at the laboratory unchanged. Collect frozen samples in pre-chilled containers.

Place containers in a freezer long enough to chill them thoroughly. Keep frozen samples solidly frozen at all times. Cool refrigerated samples, except shellfish and shell stock, in ice at 0-4°C and transport them in a sample chest with suitable refrigerant capable of maintaining the sample at 0-4°C until arrival at the laboratory. Do not freeze refrigerated products. Unless otherwise specified, refrigerated samples should not be analyzed more than 36 h after collection. Special conditions apply to the collection and storage of shucked, unfrozen shellfish and shell stock (1). Pack samples of shucked shellfish immediately in crushed ice (no temperature specified) until analyzed; keep shell stock above freezing but below 10C. Examine refrigerated shellfish and shell stock within 6 h of collection but in no case more than 24 h after collection.

Sample amount collected should be sufficient enough for the required analysis. Public analyst consent should be taken in case of doubt. The officer needs to consider what analysis needs to be requested and whether opening the sealed container would prevent the analysis. Examples were the analysis may be affected include the following:

- a) Foods containing evanescent ingredients e.g. soft drinks containing vitamin C, dried fruit containing sulphur dioxide;
- b) Foods containing or suspected of containing, volatile substances ex. solvent, alcohol; foods packed in modified atmospheres where gas analysis is required or loss of the protective atmosphere could alter preservative levels;
- c) Foods packaged in aerosols
- d) 'Aerated' foods e.g. carbonated soft drinks

- e) Products where it is necessary to have an unopened container in order to carry out a particular test e.g.condensed milk where there is a statement that the contents are equivalent to a quantity of whole milk;
- f) Products which are difficult to extract from the container and where there is possibility of a considerable quantity of the food remaining in the container e.g., salad cream, sauces, treacle.

For microbiological analysis, different sampling plans may be implemented considering the nature of microorganism/microorganisms to be tested. Sampling is followed according to the food category. Aseptic sampling should be done for microbiological analysis. General procedure for aseptic sample follows the use of sterile equipments; care should be taken while using propane torch or other flame while sterilizing the equipments on site. On site conditions should be evaluated for explosive vapours, dusty air, flame restricted area, firm's policy or management wishes. All flammable liquids should be kept in metal safety cans and not in breakable containers. Handle the item being sampled using sterile gloves [rubber, vinyl, plastic, etc. surgeon's gloves are good]. Use fresh glove for each sub sample and submit an unopened pair of glove as a control.

Sterile sampling containers should be opened with care. Open it only to introduce the sample and close immediately. Do not touch the inside of the containers, lip or lid. Submit one empty sterile container opened and closed in the same manner as a control. Do not collect the sample in dusty areas. Dried powders like dried yeast, dried milk powder, dried eggs, and similar products are packed in multi layered poly bags or containers so care should be taken to dust the bag by brushing, wipe it with alcohol using a cloth, remove the seam and open the bag enough to withdraw the sample. Water samples should be collected in sterile bottles. Decholrination if necessary should be done by placing 100mg/L of sodium thiosulphate in bottles before sterilization. Carefully inspect the faucet. Do not collect from the faucet which leak. Clean and dry the outside of faucet allow the water to run for 1/2 a min or 2-3 min if the pipeline is too long. Partially close the faucet to collect the sample without splashing the water. Take care while opening and closing the bottle. Rodent contaminated, Insect contaminated and Bird contaminated samples should be taken as given in relevant compliance policy guide.

Sample amount collected should be sufficient enough for the required analysis. Public analysts consent should be taken in of doubt. case The officer needs to consider what analysis needs to be requested and whether opening the sealed container would prevent the analysis. Examples where the analysis may be affected include the following: (a) foods containing evanescent ingredients e.g. soft drinks containing Vitamin C, dried fruit containing sulphur dioxide; (b) foods containing, or suspected of containing, volatile substances, e.g. solvent, alcohol; (c) foods packaged in modified atmospheres where gas analysis is required or loss of the protective atmosphere could alter preservative levels; (d) foods packed in aerosols; (e) "aerated" foods, e.g. carbonated soft drinks; (f) products where it is necessary to have an unopened containerin order to carry out a particular test e.g. condensed milk where there is a statement that the contents are equivalent to quantity of whole milk; (g) products which are difficult to extract from the container and where there is a possibility of a considerable quantity of the food remaining in the container e.g. salad cream, sauces, treacle.

If the product is perishable and fresh or thawed, cool samples to 32-38°F (0-3.3°C) and transport them in a protective insulated container. Pack samples with layers of frozen gel packs in sufficient quantity to maintain the product at a temperature not to exceed 38°F (3.3°C) for the duration of transportation to the lab. Any excess space should be filled so that the samples and gel packs cannot shift and separate from one another. Crunched up newspaper is recommended for filling up excess space because it is also a good insulator and will help keep samples cold. The container should be marked "Perishable Product" and shipped the same day of collection.

If the product is perishable and frozen, maintain samples in the frozen state -20 to 0°F (-28.9 to -17.8°C) and transport them in a protective insulated container. Pack the samples with layers of frozen gel packs or dry ice in sufficient quantity to maintain the product at a temperature not to exceed 0°F (-17.8°C) for the duration of transportation to the lab. Any excess space should be filled so that the samples and gel packs cannot shift and separate from one another. Crunched up newspaper is recommended for filling up excess space because it is also a good insulator and will help keep samples cold. The container should be marked "Perishable, Frozen Product".

If a lot inspection office or a company ships packages with dry ice, ensure that whoever signs the shipping document has completed the DOT Hazardous Shipper Training and has a copy of his or her current training certificate. Use dry ice (solid carbon dioxide) as the refrigerant if the time spent in transport may lead to thawing. Any excess space should be filled so that the samples and dry ice cannot shift and separate from one another. Crunched up newspaper is recommended for filling up excess space because it is also a good insulator and will help keep samples cold. Dry ice weighing approximately ½ the sample weight is sufficient for this purpose provided the container is insulated with 1 ½-2 inches of a foamtype material, and is tightly sealed. The container should be marked "Perishable, Frozen Product".

If the container is to be shipped to the laboratory by a common carrier, i.e. Federal Express, it is imperative to send it "FedEx Priority Overnight (next business morning), and indicate the total number of packages and weight on the label. Also, if dry ice is used, the words "dry ice" and weight of dry ice must be declared on package and label.

Please make sure to weigh the container and to round it to the nearest pound / kgs. In order to avoid excessive shipping charges, DO NOT estimate the weight or ship a container without indicating the actual weight. Include the sample information form in a sealable plastic bag to avoid it from becoming wet and illegible. Include any reusable supplies inside the shipping container on top of samples.

Preservatives like formalin (which is added to the milk to extend its shelf life) if added to the sample the amount needs to be specified alongwith the purpose. In case the purpose of sample collection is detecting the presence/absence of adulterants or microbial analysis such preservatives are not recommended to be used.

4.1 SAMPLE TAKING AND DESPATCHING

Sampling should be random and without prior intimation to the food business operator. Sample should be despatched in a manner that does not alter the character of the product. Sample integrity should be maintained. Sampling can be done while inspecting the premises itself. The owner need not be informed in advance. Samples should be taken in the right manner to maintain the integrity and homogeneity of the sample. Sample can be taken while conducting inspection of the premises. Prior notice is not mandatory. Receipt to be given to the owner, in-charge, operator on completion of inspection and prior to leaving the premises.

Sample taken should be divided into 4 parts immediately. There are exceptions where the division of sample might not be possible:-

- Sample is insufficient
- Sample is unopened
- Sample is non-homogenous

Where practicable, the division should be carried out on the premises of the seller/owner of the food, who, ifpresent, should be given the opportunity to observe the sampling and division before being invited to choose one of the parts for retention.Care should be taken to prevent contamination of samples and instruments and containers used should be clean and dry. The use of cleaning and sterilising methods should be avoided as it may leave residues on the instruments and containers which could affect the results of the analysis (e.g. alcohol).

Samples which Present Difficulties in Dividing into Parts where there is insufficient product available, where there is no way of storing a final part for further analysis as with tests for previously frozen meat, where foods are not pre-packed and are not homogenous and it is difficult to divide the food into three parts so that each part contains the same proportion of each ingredient e.g. meat products with lumps of meat, pies where it is difficult to divide the pastry and the filling into three, fruit cocktail/yogurts with fruit where an ingredient is to be quantified. When food is pre-packed, where the sample consists of unopened containers and opening them would, in the opinion of the authorised officer, impede proper analysis. In these circumstances the authorised officer should divide the sample into parts by putting containers into three lots, and each lot should be treated as a final part.

A sampling kit should be designed based on the nature of sample and the purpose of sampling. Below enlisted are the basic requirements that are to be fulfilled by a sampling kit:

- Carrying case
- Notebook
- White coats
- White hats
- Chill packs
- Lockable or secure freezer (-18 °C)
- Insulated boxes
- Adequate supply of hard frozen ice blocks
- Food grade sampling bags
- Sample Labels
- Seals
- Hair nets
- Disposable paper towels
- Measuring jug(s)
- Funnel(s)
- Scissors
- Knives
- Spoons
- Can Opener
- Sample containers (various sizes)
- Glass bottles
- Thermometer (Calibrated)
- Disinfectant wipes
- Sterile sample jars (various sizes)
- Sterile knives and spoons as necessary
- Swabbing equipment
- Water sampling bottles
- Latex gloves
- Isopropanol (70%)

4.2 TIME FOR SAMPLE DELIVERY TO THE PUBLIC ANALYST/ACCREDITED LAB/REFERRAL LAB

Samples should be despatched to the Public Analyst as soon as practically possible to avoid any discrepancies in testing. Perishable samples, samples for micro-testing and samples which change with time should be considered on urgent basis for delivery to the analytical lab. Water samples should be delivered for analysis within 24 hours.

Sample be transmitted as soon as practicable after sampling, particularly where tests are to be made for substances which may deteriorate or change with time (e.g. certain pesticides, sulphur dioxide, etc). In any case where doubt exists about suitable storage or transport arrangements for samples for analysis, the public analyst should be consulted. Since retained final parts may need to be stored for several months prior to submission to the Government Chemist, it is important that they are appropriately stored.

4.3 TIME FOR SAMPLE ANALYSIS AND REPORTING BY THE LAB

Sample Analysis should be considered as per the urgency basis. Minimum time should be taken to analyse and report the findings of the disputed sample. In either case the sample should be analysed and reported within 7 - 14 working days from the date of receipt of samples by the Public Analyst. Sample reporting should report the results in terms of: -CONFORMS/DOES NOT CONFORM. The analysis report should be submitted as per the format prescribed in Form B of FSS (Laboratory and Sampling) Regulations, 2011.

4.4 SUITABLE CONTAINERS

The laboratory sample must be placed in a clean, inert container which provides secure protection from contamination, damage and leakage. The container should be sealed, the sampling record must be attached and the sample delivered to the laboratory as soon as practicable.

Solids: For packaged consumer packs, the samples should be collected as is without opening the packs. This is true for solids and liquid packaged products. For open and loose food products, the containers should be of appropriate size, clean, sterile incase of microbiological testing and should have tamper evident closures and seals. Sterile and clean sampling gadgets, seals, and containers should be used. Aseptic sampling procedure should be followed.

Liquids: Containers liquid/semi-solid products should preferably be of inert materials, glass or plastic. The containers should preferably be of appropriate size, capable of air-tight closure and preferably dark-coloured so as to prevent light-based degradation

4.4.1 Type of containers

Material of the container should be inert. Containers used for sampling should be air tight for chemical analysis and sterile for microbiological analysis. Preferable type of container used for chemical and microbiological analysis should be the same for ease.

Samples of food which are not pre-packed or opened cans or packets of foods should first be placed in clean, dry leak-proof containers such as wide-mouth glass or food quality plastic jars, stainless metal cans or disposable food quality plastic bags. Jars, bottles or cans should be suitably closed. Disposable food quality plastic bags should be sealed securely after filling so that they cannot leak or become contaminated during normal handling. Samples of alcoholic drinks should be placed in glass bottles. Samples for microbiological examination should be taken and handled in a manner that eliminates the risk of contamination during the sampling process.

Food Safety officer or Sampling personnel's should have regard to any advice provided by the food examiner on the need to observe aseptic sampling techniques. The owner of the food should be given the opportunity if present to observe the sampling procedure.

4.5 QUANTITY OF SAMPLE TO BE DRAWN AS SUFFICIENT FOR ANALYSIS

Quantity of sample to be drawn which will be sufficient for the required analysis. This should be as per the FSSA for most samples. Odd expensive items can be given due consideration. Quantity will vary according to product and type of analysis. It will also depend on the purpose for which the analysis is undertaken. Twice the amount of samples required for analysis should be taken. In case of large consignment of imported food, modified protocol would be necessary. Minimum 100gm of sample must be sent for analysis Samples for examination are not required to be divided into three parts since the non-homogeneous distribution of bacterial contaminantsmeans that no two samples will be the same. It is not appropriate to retain a part for examination later in the event of a dispute, as bacteria may not survive prolonged storage or conversely, may greatly multiply.

4.6 IMPORTANT POINTS TO CONSIDER

- a. No.of batches/ lot: A representative statistical sampling strategy should be made for batches and lots based on the volume of material available on-site.
- b. No. of batches or lot are decided as per the Investigations Operations Manual Sample Plan.
- c. Each lot that is to be examined must be clearly defined. In case of random sampling the items are collected in such a way that all possible combinations have same probability of being collected. If the lot is heterogeneous, stratified sampling may be a solution.
- d. Protocol for labelling and sealing: Labelling and sealing should be appropriate to maintain integrity and traceability of the sample. The identity of the sample should be evident from the reference stated on the drawn sample container.
- e. Representative number of subsamples should be made with the sample number, collection date and your written initials. Similarly identify any outer packaging, labels or circulars.
- f. Transparent tape such as Scotch Magic Transparent tape accepts ball point ink and may be used on glossy items such as glass, plastic, tin, etc. Glass, such as bottles, vials and ampules, may be identified by using a very fine pointed felt or nylon marking pen and identification covering the with transparent tape for protection. Do not use tape on very small containers such as ampoules, which must be snapped or

broken to remove the contents for analysis. Tape wrapped around the container may interfere with assay. Do not use permanent type markers when identifying subs in absorbent containers if the ink may penetrate into the product thus contaminating the sample. Diamond or carbide tipped stylus pencils may be used to mark tin, glass, etc. Do not use diamond or carbide tipped stylus to mark products in glass under pressure (i.e., carbonated beverages).

g. The contained final parts should each be secured with a tamper evident seal, and labelled specifying the name of the food, the name of the officer, the name of the authority, the place, date and time of sampling and an identification number. Where necessary, it should then be placed in a second container, such as a plastic bag, which should be sealed in such a way as to ensure that the sample cannot be tampered with. A copy of the food label if available and any other relevant details should be submitted to the public analyst with a final part.

- h. Sealing the edges: All the samples should be sealed immediately post sampling. A tamper evident seal should be used like wax, adhesives etc.
- i. Thread: Maybe used to identify any tampering taking place.
- j. Seal of the owner Required.
- k. Signature/Thumb impression of the owner/witness: Required.
- l. Name and Address of the owner: Required on the container.
- m. Batch No. /Lot No. Required.
- n. Code No. and serial no. of Local authority: Code/License of Local Authority is required.
- o. Date and place of collection: Required.
- p. Nature of article submitted: Required.

- q. Nature and qty. of preservative added: Preservative should be added in amounts which do not interfere with the chemical and microbial analysis. In case of doubt Public Analyst should be consulted.
- r. For Agmark sealed containers:-Grade, Agmark Label No. /Batch no., Name of packaging station required.
- s. Manner of packing: Packing of the sample should be done taking care to maintain the integrity and homogeneity of the sample. Packing should avoid pilferage and should be tamper evident. Clean inert container should be used offering adequate protection from external contamination and protection against damage to the sample in transit. The container should be sealed in such a manner that unauthorised opening is detectable and sent to lab as soon as possible. Precautions should be taken against leakage and spoilage. Storage conditions should also be maintained.
- t. Define category of analysis: The category of analysis for foods should be done according to the requirement for regulatory or monitoring purpose. Category of analysis to be chosen should be done in sync with the Public Analyst.
 - i. Chemical
 - ii. Microbiological
 - iii. Physical
 - iv. Sensory

Final parts of food which are perishable should be kept refrigerated or in a frozen state, as necessary. The method of storage used will differ depending on whether the final part is to be submitted to the public analyst or retained for possible submission to the government chemist.

5. SAMPLE PREPARATION

The preparation varies depending on the nature of sample. Primary sample/Composite sample or Final sample. For detailed sample preparation test procedure refer manual for Guidelines on Sample Preparation.

5.1 PREPARATION OF SAMPLES

5.1.1 Primary Samples

A **primary sample** is the 'portion of product' collected from a lot during the first stage of the sampling process, and will normally be in the form of an item (if collected from a lot of prepacked products) or of an increment (if collected from a bulk lot). (However, an 'increment' may be considered to be an 'item' if measurements are made on individual increments.) As far as is practicable, primary samples should be taken throughout the lot and departures from this requirement should be recorded. Sufficient primary samples of similar size should be collected to facilitate laboratory analysis. In the course of taking the primary samples (items or increments), and in all subsequent procedures, precautions must be taken to maintain sample integrity (i.e., to avoid contamination of the samples or any other changes which would adversely affect the amount of residues or the analytical determinations, or make the laboratory sample not representative of the composite sample from the lot).

5.1.2 Composite Sample

When required by the sampling plan, a **composite sample** is produced by carefully mixing the primary samples (items) from a lot of pre-packaged products; or by carefully mixing the primary samples (increments) from a bulk (not pre-packaged) lot. Except for economical reasons, this sampling technique is not to be recommended given the loss of information on sample-to-sample variation due to the combination of primary samples.

5.1.3 Final Sample

The bulk or bulked sample should, if possible, constitute the final sample and be submitted to the laboratory for analysis. If the bulk/bulked sample is too large, the final sample may be prepared from it by a suitable *method of reduction*. In this process, however, individual items must not be cut or divided.

6. OTHER POINTS OF CONSIDERATION

6.1 SAMPLING REPORT

The sampling report should include the reason for sampling, the origin of sample, the sampling method and the date and place of sampling together with any additional information like transport time and conditions. Any deviation from the specified sampling procedure to be reflected in report.

6.2 SAMPLE PRESERVATION/STORAGE DURING TRANSPORT

The storage condition will be determined by the temperature control required for individual products.

- i. Perishable. Sample storage under chilled or frozen condition as the product demands. Ice packs can be used during transportation and temperature is to be maintained between $4-6^{\circ}$ C.
- ii. Non-perishable: Storage of non-perishables should maintain the originality of the sample as is during the sampling conditions. Transportation should be done at temperatures not more than 4°C. Care should be taken to provide maximum protection from pilferage.

6.3 DEFINE TIME

For microbiological samples analysis should initiate within 24 hours of sample being drawn. For chemical tests analysis has to be initiated within 48 to 72 hours.

Samples should be transported and stored under conditionswhich inhibit changes in microbial numbers and be delivered to the laboratory without undue delay. The final part to be submitted to the public analyst should be transmitted as soon as practicable after sampling, particularly where tests are to be made for substances which may deteriorate or change with time (e.g. certain pesticides, sulphur dioxide, etc). In any case where doubt exists about suitable storage or transport arrangements for samples for analysis, the public analyst should be consulted. Since retained final parts may need to be stored for several months prior to submission to the Government Chemist, it is important that they are appropriately stored.

6.4 FREQUENCY OF SAMPLING

4 representative samples yearly for monitoring issues. For regulatory issues it should be taken as and when required.

6.5 TOLERANCE CRITERIA WITH REFERENCE TO SAMPLING

Acceptable specifications for chemical tests are available in the PFA, need to be reviewed. Once all the specifications are finalized, tolerance limits needs to be defined.

7. DOCUMENTATION

FORM III

[Refer rule 3.3.2.(1)]

(To keep any article of food in safe custody of the vendor)

10
(Name and address of the vendor)

Whereas *intended for food which is in your possession appears to me to be adulterated/misbranded:
Now therefore under clause (c) of sub-section (1) of section 38 of the Food Safety and Standards Act, 2006 (34 of 2006), I hereby direct you to keep in your safe custody the said sealed stock subject to such orders as may be issued subsequently in relation thereto.
Food Safety Officer
Area
Place:
Date:
*Here give the name of article of food.

$FORM\ V$

(Refer rule 3.4.1. (3))

То		
Dear Sir/s/ Madam:		
I have this day taken frosamples of food specific for		athe Food Analyst
Details of food: Code number:		
Place:		
Date:		
	(Sd/-) Foo	od Safety Officer
	Address:	

FORM VI

(Refer rule 3.4.3 (7))

Memorandum to Food Analyst

·
From:
Date:
To
Food Analyst
MEMORANDUM
(Refer rule (v)a of 3.4.1(8))
1. The sample described below is sent herewith for analysis under of o section of Food Safety and Standards Act, 2006
I. Code Number
II. Date and place of collection
III. Nature of articles submitted for analysis
IV. Nature and quantity of preservative, if any, added to the sample.
2. A copy of this memo and specimen impression, of the seal used to seal the packer of sample are being sent separately by post/courier/hand delivery (strike out whichever is not applicable)
(Sd/) Food Analyst
Address

8. REFERENCES

- 1. Food Safety and Standards Act, 2006, Rules 2011, Regulations 2011, 7th Edition
- 2. CAC/GL 50-2004; General Guidelines on Sampling by Codex Alimentarius Commission, Pages 1-69
- 3. Microorganisms in Foods: Sampling for Microbiological Analysis: Principles and Specific Applications, 2nd ed. University of Toronto Press, Toronto, Ontario, Canada
- 4. IS 5404-1984 (RA 2013)

ANNEXURE I

COMMONLY USED TERMS AND NOTIONS

Some of the more commonly used terms in acceptance sampling are described in this section.

2.2.1 Lot

A lot is a definite quantity of some commodity manufactured or produced under conditions, which are presumed uniform for the purpose of these Guidelines. For the goods presumed heterogeneous, sampling can only be achieved on each homogeneous part of this heterogeneous lot. In that case, the final sample is called a stratified sample.

NOTE: A continuous series of lots is a series of lots produced, manufactured or commercialised on a continuous manner, under conditions presumed uniform. The inspection of a continuous series of lots can only be achieved at the production or processing stage.

2.2.2 Consignment

A consignment is a quantity of some commodity delivered at one time. It may consist in either a portion of a lot, either a set of several lots. However, in the case of statistical inspection, the consignment shall be considered as a new lot for the interpretation of the results.

- If the consignment is a portion of a lot, each portion is considered as a lot for the inspection.
- If the consignment is a set of several lots, before any inspection, care shall be given to the homogeneity of the consignment. If not homogeneous, a stratified sampling may be used.

2.2.3 Sample (representative sample)

Set composed of one or several items (or a portion of matter) selected by different means in a population (or in an important quantity of matter). It is intended to provide information on a given characteristic of the studied population (or matter), and to form a basis for a decision concerning the population or the matter or the process, which has produced it.

A representative sample is a sample in which the characteristics of the lot from which it is drawn are maintained. It is in particular the case of a simple random sample where each of the items or increments of the lot has been given the same probability of entering the sample.

2.2.4 Sampling

Procedure used to draw or constitute a sample. Empirical or punctual sampling procedures are sampling procedures, which are not statistical-based procedures that are used to make a decision on the inspected lot.

Item or increment of individualisable goods

- a) Individualisable goods: Goods which can be individualised as items (see b) or in increments (see c), for example:
- a pre-package,
- a flask or a spoon containing a quantity of goods determined by the sampling plan, and taken from a lot, for example:
 - a volume of milk or of wine stored in a tank,
 - a quantity of goods taken from a conveyor belt,...
- b) Item: An actual or conventional object on which a set of observations may be made, and which is drawn to form a sample.

Note: The terms "individual" and "unit" are synonymous with "item"

c) Increment: Quantity of material drawn at one time from a larger quantity of material to form a sample.

2.2.8 Sampling plan

Planned procedure which enables one to choose, or draw separate samples from a lot, in order to get the information needed, such as a decision on compliance status of the lot.

More precisely, a sampling plan is a scheme defining the number of items to collect and the number of nonconforming items required in a sample to evaluate the compliance status of a lot.

2.2.9 The Characteristic

A characteristic is a property, which helps to identify, or differentiate between, items within a given lot. The characteristic may be either quantitative (a specific measured amount, plan by variables) or qualitative (meets or does not meet a specification, plan by attributes). Three types of characteristic and associated types of sampling plan are illustrated in Table below.

Table: Sampling plans to be associated with the type of characteristic

Type of Characteristic	Type of Sampling Plan		
Commodity defects: characteristics that may	By'Attributes'		
be expressed by two excluding situations as			
passed/notpassed, yes/not, integer/not integer,			
spoiled/not spoiled (e.g. as applied to visual			
defects such as loss of colour, mis-grading,			
extraneous matter etc)			
Compositional characteristics: Characteristic	'Variables with unknown		
that may be expressed by continuous variables.	standard deviation' for		
They maybe normally distributed (e.g. most	normally distributed		
analytically determined compositional characteristics			
characteristics such as moisture content) or	'attributes'for characteristics		
they may be non-normallydistributed.	whose distributions deviate		
	significantly from normal		
Health-related properties (e.g. in the	ne Specified sampling plans to be		
assessment of microbial spoilage, microbial	al proposed appropriate to each		
hazards, irregularly occurring chemical	cal individual situation. Plans to		
contaminants etc.)	determine incidence rates in a		
	population may be used.		

2.2.10 Homogeneity

A lot is **homogenous** relative to a given characteristic if the characteristic is uniformly distributed according to a given probability law throughout the lot.

NOTE: A lot being homogeneous for a given characteristic does not mean that the value of the characteristic is the same throughout the lot.

A lot is **heterogeneous** relative to a given characteristic if the characteristic is **not** uniformly distributed throughout the lot. Items in a lot may be homogenous on one characteristic whilst heterogeneous on another characteristic.

2.2.11 Defects (Nonconformities) and Critical Nonconformities

A defect (nonconformity) occurs within an item when one or more, quality characteristic does not meet its established quality specification. A defective item contains one or more defects. Lot quality may be judged in terms of the acceptable percentage of defective items or the maximum number of defects (nonconformities) per hundred items, in respect of any type of defects.

Most acceptance sampling involves the evaluation of more than one quality characteristic, which may differ in importance with respect to quality and/or economic considerations.

ANNEXURE II

Quantity of Sample to Collect For Each Commodity

Quantity of sample to be sent to the public analyst:- The quantity of sample of food to be sent to the public analyst / Director for analysis shall be as specified in the Table below:

While defining these please bear in mind microbiological and chemical tests Should you feel that fixed sample weights can be applied for dry, nonperishable and perishable foods, please categorize in general and not for individual categories.

Sr. No	Article of food	Approximate	
		quantity	
		recommended in	
		FSSA	
1	Milk	500 ml	
2	Sterilized Milk/UHT Milk	250 ml	
3	Malai/Dahi.	200 g	
4	Yoghurt/Sweetened Dahi	300 gms.	
5	Chhana/Paneer/Khoya/Shrikhand	240 gms.	
6	Cheese/Cheese spread	200 gms.	
7	Evaporated Milk/Condensed Milk	200 gms.	
8	Ice-cream /Softy/Kulfi/Ice Candy/Ice lolly	300 gms.	
9	Milk Powder /Skimmed Milk Powder	250 gms.	
10	Infant Food /Weaning Food	500 gms.	
11	Malt Food/ Malted Milk Food	300 gms.	
12	Butter/ButterOil/Ghee/Margarine/Cream/	200 gms.	
	Bakery Shortening		
13	Vanaspati, Edible Oils/Fats	250 gms.	
14	Carbonated Water	600 ml.	
15	Baking Powder	100 gms	
16	Arrow root/Sago	250 gms.	

17	Corn flakes /Macaroni Products/ Corn	200 gms.
	Flour/Custard Powder	
18	Spices, Condiments and Mixed Masala(Whole)	200 gms.
19	Spices, Condiments and Mixed Masala (Powder)	250 gms.
20	Nutmeg/Mace	150 gms.
21	Asafoetida	100 gms.
22	Compounded Asafoetida	150 gms.
23	Saffron	20 gm.
24	Gur/jaggery, Icing Sugar, Honey, Synthetic Syrup, Bura	250 gms.
25	Cane sugar/Cube sugar /Refined sugar /Dextrose/ misri/dried glucose syrup	200 gms
26	Artificial Sweetener	100 gms
27	Fruit Juice/Fruit Drink/Fruit Squash	400 ml
28	Tomato Sauce /Ketch up /Tomato Paste, Jam/ Jelly/Marmalade/Tomato Puree/Vegetable Sauce	300 gms.
29	Non Fruit Jellies	200 gms.
30	Pickles and Chutneys	250 gms.
31	Oilseeds/Nuts/ Dry Fruits	250 gms.
32	Tea/Roasted Coffee/RoastedChicory	200 gms.
33	Instant Tea /Instant Coffee /Instant Coffee Chicory Mixture.	100 gms
34	Sugar Confectionery /Chewing Gum/Bubble Gum	200 gms.
35	Chocolates	200 gms
36	Edible Salt.	200 gms
37	Iodised Salt/ Iron Fortified Salt	200 gms.
38	Food Grains and Pulses (Whole and Split)	500 gms.
39	Atta/Maida/Suji/Besan/Other Milled Product	500 gms.
	/Paushtik and Fortified Atta/Maida	
40	Biscuits and Rusks	200 gms.

41	Bread/Cakes/Pastries	250 gms.
42	Gelatin	150 gms.
43	Catechu	150 gms.
44	Vinegar/ Synthetic Vinegar	300 gms.
45	Food colour	25 gms.
46	Food colour preparation (Solid/Liquid)	25 gms
		Solid/100 ml
		liquid
47	Natural Mineral water/Packaged Drinking water	4000 ml in
		three minimum
		original sealed
		packs.
48	Silver Leafs	1 gm
49	Prepared Food	500 gms.
50	Proprietary Food, (Non-Standardised Foods)	300 gms.
51	Canned Foods	6 sealed cans
52	Food not specified	300 gms.

Contents of one or more similar sealed containers having identical labels to constitute the quantity of food sample:-

Where food is sold or stocked for sale or for distribution in sealed containershaving identical label declaration, the contents of one or more of such containers as may be required to satisfy the quantity prescribed in Rule 22shall be treated to be part of the sample.

pick multiple means samples if pack size is small, must be of same batch etc.

Quantity of sample to be sent considered as sufficient:-

Notwithstanding anything contained in Rule 22	unless	report	ed by	the
and rule 22C, the quantity of sample sent for	lab,	sam	ple	is
analysis shall be considered as sufficientunless	underst	ood	to	be

the public analyst or the Director reports to the enough contrary.

Quantity of samples of food packaging material to be sent to the public analyst:-

8x1000x9 surface sq.cm. area

The quantity of sample of food packaging material to be sent to Public Analyst / Director for analysis shall be as specified

Note: In case of if any additional tests are required, additional amount of sample (than the one specified above) can be collected



Food Safety and Standards Authority of India (Ministry of Health and Family Welfare)
FDA Bhawan, Kotla Road,
New Delhi-110002
www.fssai.gov.in