

SALMONELLA SAMPLING PLAN

PURPOSE:

To determine the presence of Salmonella in processed foods intended for human consumption.

APPLICABILITY:

This sampling plan is applicable to the inspection of either a continuing series of production lots or to isolated lots consisting of an identifiable collection of process units (cans, bags, packages, or similar units). This plan is for use by FDA for regulatory purposes.

FOOD CATEGORIES:

Foods are listed in three categories based on the number of Salmonella hazards and whether a food is to be consumed by infants, the aged, or infirm.

The three defined Salmonella Hazards of foods are:

1. The food or an ingredient of the food is a significant potential source of Salmonella;
2. The manufacturing process does not include a controlled step that destroys Salmonella; and
3. The food has significant potential for microbiological growth if "abused" in distribution or by consumers.

Classification of Foods:

Foods have been classified into three food Categories for regulatory sampling purposes. The foods are listed in the Categories by Product Code sequence.

NOTE: For products not listed, check with your supervisor. The District will request categorization from the Office of Field Programs/Center for Food Safety and Applied Nutrition (HFS-600), or, when time is of essence, the District will make the categorization and obtain later concurrence from CFSAN.

Category I

This includes all foods that would normally be in Category II except that they are intended for consumption by the aged, the infirm, and infants.

Category II

This includes the foods that would not normally be subjected to a process lethal to Salmonella between the time of sampling and consumption. Examples are as follows:

PRODUCT CODE	FOOD ITEM
03	Bread, rolls, buns, sugared breads, crackers, custard and cream filled sweet goods
05	Breakfast cereals, ready to eat
07	Pretzels, chips and specialty items

09	Butter and butter products; pasteurized milk and raw fluid milk and fluid milk products for consumption; pasteurized and unpasteurized concentrated liquid milk products for consumption; dried milk and dried milk products for consumption
12	Cheese and Cheese products
13	Ice cream from pasteurized milk and related products that have been pasteurized; raw ice cream mix and related unpasteurized products for consumption.
14	Pasteurized and unpasteurized imitation dairy products for consumption
15	Pasteurized eggs, egg products from pasteurized eggs; unpasteurized eggs and egg products from unpasteurized eggs for consumption without further cooking
16	Canned and cured fish, vertebrates; other fish products; fresh and frozen raw oysters and raw clams, shellfish and crustacean products; smoked fish, shellfish and crustaceans for consumption
17	Unflavored gelatin
20-22	Fresh, frozen and canned fruits and juices, concentrates and nectars ; dried fruit for consumption; jams, jellies, preserves and butters
23	Nuts and nut products for consumption
26	Oils consumed directly without further processing and oleomargarine
27	Dressings and condiments (including mayonnaise) salad dressing and vinegar
28	Spices including salt; flavors and extracts
29	Soft drinks and water
30	Beverage bases
31	Coffee and tea
33	Chewing gum and candy
34	Chocolate and cocoa products
35	Pudding mixes not cooked prior to consumption, gelatin products
36	Syrups, sugars and honey
38	Soups
39	Prepared salads

Category III

This includes the following foods that would normally be subjected to a process lethal to Salmonella between the time of sampling and consumption. Examples are as follows:

PRODUCT CODE	FOOD ITEM
02	Whole grain, processed grain and starch products for human use
04	Macaroni and noodle products
16	Fresh and frozen fish; vertebrates (except that eaten raw); fresh and frozen shellfish and crustaceans (except raw oysters and raw clams for consumption); other aquatic animals (including frog legs)
24	Fresh vegetables, frozen vegetables, dried vegetables, cured and processed vegetable products

- normally cooked before consumption
- 26 Vegetable oils, oil stock and vegetable shortening
- 35 Dry dessert and pudding mixes that are cooked prior to consumption
- 37 Frozen dinners, multiple food dinners
- 45-46 Food chemicals (direct additives)

SAMPLE COLLECTION

Each sub will consist of a minimum of 100 gm (approx 3.53 oz). The usual subsample is a consumer size container of a product. Subsamples should be obtained at random to insure that the total sample is representative of the lot. When a lot consists of identifiable subdivisions (e.g., different codes), sub samples should be obtained from subdivisions in the proportion that the subdivisions are to the whole lot.

More than one subsample may be collected from large institutional or bulk containers when the number of sub samples required exceeds the number of containers in the lot. A subsample will consist of more that one container when the lot consists of containers smaller than 100 gm (e.g., 4 - 25 gm containers is a subsample).

When a sample is collected by transferring it to sample containers, a sample control must be submitted which consists of an empty sample container that is exposed to the same conditions under which the sample is collected. See IOM 4.3.6.2 and 4.3.6.4 on controls. Use aseptic technique when sampling from bulk containers.

SAMPLE SIZE

The following sample sizes also apply to the finished product portion of in-line samples when analyzed for Salmonella. Each subsample will consist of at least 100 gm (approx 3.5 oz).

The 702(b) [21 U.S.C. 372(b)] portion is included in these subsamples, however all subs must be collected for proper analysis. Do not reduce the number of subsamples when collecting import samples.

<u>FOOD CATEGORY</u>	<u>NUMBER OF SAMPLE UNITS (SUBS)</u>
I	60
II	30
III	15

SAMPLE SUBMISSION

Submit all samples collected to your district's microbiological servicing laboratory unless directed otherwise by your supervisor or assignment. See IOM 4.5.5.2.

SAMPLING SCHEDULE FOR CANNED AND ACIDIFIED FOODS

Canned Foods

Field Examination

1. At the beginning of the inspection, conduct visual exams of warehouse stock for evidence of abnormal cans including swollen and leaking cans, wet cases, swarms of fruit flies around isolated pallets, etc.
2. If the visual exam or inspectional evidence indicates possible problems, such as under processed lots, lots with questionable seam integrity, or abnormal cans, exam the affected lots. Preferably field examine lots that have been warehoused at least 14 days.
3. A lot to be examined will be one production code.
4. Follow the chart below for the field examination. If abnormal containers are found, always collect an official sample of the lot, if possible. For lots with abnormal cans collect an investigational sample ONLY when there is not enough product available to collect an official sample. In all cases, include on the collection report: the lot size, the number of containers examined, and the number of abnormal containers found by type (e.g., hard swells).
5. The chart provides instructions on the number of cans/cases to examine depending on the size of the lot. **When the maximum number of containers / cases have been examined for the specified lot size, collect a sample if one or more abnormal containers are found.** The exam can be discontinued early based on the number of abnormal containers found. For example, if examining a lot consisting of 3409 or more cans, if 11 abnormal cans are found after examining 1000 cans, discontinue the exam and collect a sample
 - a. Flippers. Only one end is slack or slightly bulged and the end remains flat if pressed in. Cans which bulge when sharply and squarely struck end-down on a flat surface are flippers, provided that the bulged end remains flat when pressed. Flippers result from a lack of vacuum.

- b. Springers. One end of a can bulges. Manual pressure on the bulged end forces the opposite end out or the same end will spring out with release of pressure. If both ends bulge, but only one will remain flat when pressed, the can is a springer. Springers result from moderate positive pressure in the can. Buckling or extensive denting of the side wall may produce a springer.
- c. Swells. Both ends of the can are bulged. Neither end will remain flat without pressure. Soft swells yield to manual pressure, but no impression can be made manually on hard swells. Swells result from positive pressure in the can usually because of spoilage of the contents. Some swells, especially in acid products, may result from chemical reaction between the contents and the container.

NOTE: Other abnormalities or defects, such as visibly leaking cans, severe dents around seams, gross seam defects, severely rusted containers should be reported on C/R, (with numbers of cans defective cans observed) but not counted as "abnormal containers" for the purposes of the sequential field examination. Do not collect leakers, but report the number observed. It may be necessary to collect samples of other defects (e.g. seam defects) to support observations and document the severity of the defects. In some cases photographs may be a suitable substitute for collection of physical samples.

If a sample is collected, identify on the C/R, by sub-sample number, the condition of each container in the sample (e.g., sub-sample 1 - flipper; sub-sample 2 - hard swell; - sub-sample x - normal). Report the results of the warehouse stock examination in the EIR and in FACTs. See IOM 5.1.5.3

Special Sample Handling: If you are shipping swollen cans, double bag and ground ship the sample. If the cans are moderately swollen or worse you should ship the sample with ice packs.

Lot Size Contain	Number to Examine	PACKED 48/CASE		PACKED 24/CASE		PACKED 12/CASE		PACKED 6/CASE		*Number Abnormal Containers to Discontinue Examination Early
		Lot Size (Cases)	Cases to Examine	Lot Size (Cases)	Cases to Examine	Lot Size (Cases)	Cases to Examine	Lot Size (Cases)	Cases to Examine	
192 or less	All	1 - 4	all	1 - 8	All	1 - 16	All	1 - 32	all	3
193 - 288	192	4 - 6	4	8 - 12	8	16 - 24	16	32 - 48	32	5
289 - 384	all for ≤ 298 298 if greater	6 - 8	6	12 - 16	12	24 - 32	25	48 - 64	all ≤ 50 50 if greater	6
385 - 576	363	8 - 12	8	16 - 24	15	32 - 48	30	64 - 96	61	7
577 - 912	433	12 - 19	9	24 - 38	18	48 - 76	36	96 - 152	72	8
913 - 1488	480	19 - 31	10	38 - 62	20	76 - 124	40	152 - 248	80	9
1489 - 3408	529	31 - 71	11	62 - 142	22	124 - 284	44	248 - 568	88	10
3409 or more	576	71 or more	12	142 or more	24	284 or more	48	568 or more	96	11

1. Sample Size for Samples Collected as a Result of a Field Exam:

a. Official Sample

The sample will consist of all abnormal containers and the number of normal cans specified under "2. Official Samples" below (e.g., if 8 abnormal containers are observed during the examination of a lot containing 696/ 2 lb. cans the sample will consist of the 8 abnormal cans and 48 normal cans, collected 2 cans from each of 24 cases). Open additional cases, if necessary to meet this requirement. This will provide enough product for complete analysis, including: can seam, incubation, aerobic and anaerobic growth, pH and water. Note that the sample size given for normal cans includes the 702(b) portion.

b. Investigational Sample

Samples for laboratory examination will consist of all abnormal and 12 normal containers.

2. Other Sampling

Official Samples

- a. Filth, Micro, etc. (Includes 702(b) [21U.S.C.372 (b) portion])

Collect each subdivision to duplicate from a separate case, if possible. Mark subs 1a, 1b, 2a, 2b, etc. Collect as follows:

NET WEIGHT	SIZE OF LOT	MIN TOTAL CANS	CANS/CASE
906 gm (2 lbs.) and smaller	Up to 50 cases	48	2 from 24
	More than 50 cases	96	2 from 48
Over 906 gm (2 lbs)	Up to 600 cases	48	2 from 24
	More than 600 cases	72	2 from 36

b. Standards Assay (Includes 702(b) portion)

NOTE: Sample sizes listed below are based upon the requirements of the Standards (21 CFR 145.3)When sampling products which are likely to be non-uniform throughout the lot because of variations from standards of quality, identity, fill-of-container, grade, etc., collect each subdivision in triplicate from a separate case. Mark subs 1a, 1b, 1c, 2a, 2b, 2c, etc. Collect as follows:

NET WEIGHT	NUMBER OF CANS OR PACKAGES	MIN TOTAL CANS	CANS/CASE
1 kg (2.2 lbs) or less	4800 or less	48	3 from 16
	4801 to 24,000	72	3 from 24
	24,001 to 48,000	96	3 from 32
	48,001 to 84,000	144	3 from 48
	84,001 to 144,000	264	3 from 88
	144,001 to 240,000	384	3 from 128
Greater than	Over 240,000	600	3 from 200
	2400 or less	48	3 from 16

1 kg (2.2lbs), but less than 4.5 kg (10 lbs.)	2401 to 15000	72	3 from 24
	15001 to 24000	96	3 from 32
	24001 to 42000	144	3 from 48
	42001 to 72000	252	3 from 88
	72001 to 120,000	384	3 from 128
	Over 120,000	600	3 from 200
Greater than 4.5 kg (10 lbs)	600 or less	48	3 from 16
	601 to 2000	72	3 from 24
	2001 to 7200	96	3 from 32
	7201 to 15000	144	3 from 48
	15001 to 24000	252	3 from 88
	24001 to 42000	384	3 from 128
	Over 42000	600	3 from 200

Acidified Foods (Metal or Glass)

A lot is defined as one production code.

Samples must be collected randomly from the entire lot.

Sample size does not include 702(b) portion.

- 1. # 10 size containers - Randomly select 1 normal container from each of 12 randomly selected cases (if available) in the lot.
- 2. # 2 and smaller - Randomly select 2 normal containers from each of 12 randomly selected cases (if available) in the lot. Sample size is 24 containers.

For acidified products, the equilibrium pH determines whether the product will support organisms of public health significance. Spoilage in such products is usually due to inadequate heat treatment to kill spoilage organisms. Spoilage may be significant because high numbers of microorganisms may affect the adequacy of the thermal process. Molds and some bacteria can grow in an acid environment and actually utilize acid as one of their nutrients; and thus, raise the pH to a level above 4.6 where *Clostridium botulinum* or other toxin-producing microorganisms can grow.

Microbial spoilage can be detected by observing swollen lids on jars or swollen can ends. The liquid may be turbid and a whitish deposit may be visible on the product or in the bottom of the jar. See DFI Guide to Inspection of Acidified Food Manufacturers for additional information: http://www.fda.gov/ora/inspect_ref/igs/iglist.html

If you observe abnormal containers conduct an examination following the sequential plan provided for canned foods. Collect all abnormal containers (up to a maximum of 24) in addition to the normal containers collected for pH determination referenced in the table above. Indicate on the C/R the total number of containers examined and the number of each type of abnormality and defect observed. Also indicate the estimated percentage of abnormal containers in the lot.

PESTICIDE SAMPLES

(includes 702(b) portion)

DO NOT FUMIGATE PESTICIDE SAMPLES

INTRODUCTION

The objectives of FDA's pesticide monitoring program are to gather information on levels and incidence of pesticide residues in the nation's food supply and to initiate enforcement action against shipments of food and feed found to contain illegal pesticide residues. To meet both objectives, it is necessary to collect samples of food and feed for pesticide residue analysis. These instructions describe procedures for collecting samples of raw agricultural commodities and processed commodities. The procedures apply to domestic and import shipments. The instructions include a separate set of procedures for collecting samples for special investigations such as determining levels of pesticide residues in soil, water, and growing crops.

For pesticide samples, the laboratory will maintain a portion of the composited sample as the 702(b) [21U.S.C.372(b)] portion.

Pesticide sample sizes no longer differentiate between Surveillance and Compliance Samples. All pesticide samples will be collected as directed below. Remember to include the state and county or country of origin in the Flag. See IOM 4.4.10.1.

For appraisal purposes, you must Flag each Domestic as to the basis for sampling in accordance with the definitions below.

Pesticide Compliance Sample. Collected on a selective basis as a result of inspectional or other evidence of suspected misuse of a pesticide on a food or feed commodity or as a follow-up to a "Pesticide Surveillance Sample" that was found to contain actionable levels of pesticide residues. Flag "Pesticide Compliance".

Pesticide Surveillance Sample. Collected on an objective basis where there is no evidence or suspicion of pesticide misuse on a food or feed commodity. Flag "Pesticide Surveillance".

Districts have the option to collect 1 intact shipping case of fresh produce from packing sheds or large produce warehouses. The one case must meet the minimum sample size specified below. This "one case" option may be used on any import sample or on domestic Pesticide Surveillance Samples, if the collector can be assured that the "one case" collected is representative of the lot or field. If the collector is not assured of this, collect the samples according to the instructions below. This "one case" sampling does not apply to large items such as melons.

NOTE: If "one case" option is used for surveillance samples of domestic produce, describe in the Remarks Section of the CR, the basis for determining that the sample is representative of the lot or field.

Plant products: description of primary samples and minimum size of laboratory samples (total weight of all subs or units collected).

Commodity classification	Examples	Nature of primary samples to be taken	Minimum size of each laboratory sample
Primary Food Commodities of Plant Origin			
1 All fresh fruits, All fresh vegetables, Frozen bulk produce (not retail) except dry pulses			
1.1 small sized products			
units generally < 25 g	berries peas olives	whole units, or packages, or units taken with sampling device	1 kg (2.2 lbs)
1.2 medium sized products			
units generally 25 - 250 g	apples oranges corn on the cob potatoes	whole units, or units taken with sampling device	1 kg (2.2 lbs) (at least 10 units)
1.3 large sized products			
units generally > 250 g	cabbages lettuce cucumbers grapes (bunches, except for sulfites) sweet potatoes	whole units, units taken with sampling device	2 kg(4.4 lbs) (at least 5 units)
2 Pulses, Cereal grains,			
Tree nuts,	soy beans, peas, lentils rice, wheat (except from rail carloads) (except coconuts) coconuts		1 kg (2.2 lbs) 1 kg (2.2 lbs) 1 kg (2.2 lbs) 5 units
Oilseeds,	peanuts		0.5 kg (1.1 lb)
Seeds for beverages and sweets	coffee beans		0.5 kg (1.1 lb)
3 Herbs(for dried herbs see section 5 of this Table)			
Spices	fresh parsley others, fresh dried	whole units or units taken with sampling device whole units or units taken with sampling device	0.5 kg (1.1 lb) 0.2 kg (0.5 lb) 0.1 kg (0.25 lb)

Commodity classification	Examples	Nature of primary samples to be taken	Minimum size of each laboratory sample
Primary Animal Feed Commodities			
4. Primary feed commodities of plant origin			
4.1 Legume animal feeds, and other forages and fodders		whole units, or units taken with sampling device	1 kg (2.2 lbs) (from least 10 units)
4.2 Straw, hay and other dried products		whole units, or units taken with sampling device	0.5 kg(1.1 lbs) (at least 10 units)
See IOM Sample Schedule Chart 4, Wheat Carload Sampling for guidance in the collection of samples by trier from railcars and trucks.			
Processed Foods of Plant Origin			
5. Secondary food commodities of plant origin , dried fruits, vegetables, herbs, milled cereal products Derived products of plant origin , teas, vegetable oils, juices, by-products for animal feed and miscellaneous products Manufactured foods (single ingredient) of plant origin , Manufactured foods (multi-ingredient) of plant origin , including products with ingredients of animal origin where the ingredient(s) of plant origin predominate(s), and breads			
5.1 Products of high unit value		packages or units taken with a sampling device	0.1 kg* (0.25 lb)
5.2 Solid products of low bulk density	Hops, Tea	packaged units, or units taken with a sampling device	0.2 kg(0.5 lbs)
5.3 Other solid products	bread, flour, apple pomace, dried fruit	packages or other whole units, or units taken with a sampling device	0.5 kg (1.1 lbs)
5.4 Liquid products	vegetable oils, juices	packaged units, or units taken with a sampling device	0.5 L or 0.5 kg
* A smaller laboratory sample may be taken from a product of exceptionally high value but the reason for doing so should be noted in the collection report.			
Eggs and Dairy Products			
6. Poultry eggs			
6.1 Eggs, except quail and similar		whole eggs	12 whole chicken eggs, 6 whole goose or duck eggs
6.2 Eggs, quail and similar		whole eggs	24 whole eggs
7 Milks		whole unit(s), or unit(s) taken with a sampling device	0.5 L
Processed Foods of Animal Origin			
8. Secondary food commodities of animal origin , skimmed milks, evaporated milks and milk powders Derived edible products of animal origin , milk fats, butters, butter oils, creams, cream powders, caseins, etc. Manufactured food (single ingredient) of animal origin , Manufactured food (multi-ingredient) of animal origin , (including products with ingredients of plant origin where the ingredient(s) of animal origin predominates(s))			
8.1 Liquid milk, milk powders, evaporated milk and cream, cream, dairy ice cream, yogurt		packaged unit(s), or unit(s) taken with a sampling device	0.5 L (liquid) or 0.5 kg (solid)
<i>Notes. (i) Evaporated milks and evaporated cream in bulk must be mixed thoroughly before sampling aseptically. (ii) Milk powder in bulk should be sampled aseptically, passing a dry borer tube through the powder at an even rate. (iii) Creams in bulk should be mixed thoroughly with a plunger before sampling but foaming, whipping and churning must be avoided.</i>			
8.2 Butter and butter oils (butter, whey butter, low fat spreads containing butter fat, anhydrous butter oil, anhydrous milk fat)		whole or parts of packaged unit(s), or unit(s) taken with a sampling device	0.2 kg or 0.2 L
8.3 Cheeses, including processed cheeses	units 0.3 kg or greater	Whole unit(s) or units taken aseptically with a sampling device	0.5 kg
	units < 0.3 kg	whole unit(s)	0.3 kg
<i>Note. Cheeses with a circular base should be sampled by making two cuts radiating from the center. Cheeses with a rectangular base should be sampled by making two cuts parallel to the sides.</i>			
8.4 Liquid, frozen or dried egg products	unit(s) taken aseptically	with a sampling device	0.5 kg

9. GRAPES FOR SULFITES

Collect approximately 900 - 1800 g (2 - 4 lbs) of grapes [10/100 - 200 g (1/4 to 1/2 lb) subs]. Each subsample will consist of individual grapes, not bunches, and will be collected from different lugs (cases) on as many different pallets in the lot as possible. No grapes that are damaged during the sampling procedure should be included in the sample. However, grapes with damage prior to sampling may be included in the sample.

If sulfiting pads are present, grapes sampled should be selected from areas closest to and directly under the pad.

Monitoring activities should be focused upon lots of grapes with the highest potential for violative sulfite residues.

Direct efforts to lots of grapes sulfited through fumigation or to lots with multiple fumigations especially towards the end of the harvesting season and also to lots with significant numbers of damaged grapes (split, crushed, or unusually wet, if such damage is apparent).

Sample lots of grapes sulfited through use of sulfiting pads, with or without additional fumigation. If at all possible, sample lots subjected to the following conditions, which could cause high sulfite residues:

Lots subjected to un-refrigerated storage of 2 or more hours during warm weather.

Unusual shipping conditions (ships at sea during heavy storms).

Lots with significant numbers of damaged grapes.

Lots containing evidence of sulfite pad damage sufficient to cause spilling of sulfiting agent onto grapes.

Special Sample Handling

Place sample in tightly closed airtight glass mason jar(s) or sealed plastic bag(s). Although no effort should be made to commingle subsamples, more than one subsample may be placed in the same container for shipping convenience.

Appropriate cooling procedures are:

Place samples in shipping container or cooler with sufficient ice or other refrigerant to keep sample refrigerated until arrival at the laboratory. Sample should be placed immediately in a refrigerator at or below 7 degrees C. If sample is not to be analyzed within a few hours, the sample should be placed in a freezer, which is maintained at or below -20 degrees C.

or

Place sample in container with sufficient dry ice to keep sample frozen until arrival at the lab, sample should be placed in freezer upon arrival at laboratory.

1. FISH AND SHELLFISH PRODUCTS

NOTE: THIS SAMPLE SIZE FURNISHES SUFFICIENT FISH FOR HEAVY METAL ANALYSIS.

Packaged Fish, fresh, frozen, smoked, cured, or shellfish (except oysters)

Collect 12 subs - minimum sub size is 453 g (1 lb)

Bulk Fish - .453 - 1.35 kg (1 - 3 lb)/fish

Collect 12 subs, each sub to consist of 453 g (1 lb) of edible fish

Bulk Shellfish (except oysters)

Collect 12 - 453 g (1 lb) subs

Canned Fish and Shellfish Products (except oysters)

Collect 12 subs - 5 cans per sub

Other Fish and Shellfish Products

Oysters - Collect 12 1 pint subs

Fish Flour and Meal

Follow the guidance in section 5 above.

SWORDFISH FOR HEAVY METALS

These sample sizes must be used whenever sampling swordfish, either for audit, surveillance, or compliance purposes.

Whole Fish (dressed, head removed)

Characterize lot in terms of fish sizes, i.e., small, medium, and large. The following dressed weight ranges are used for classification:

Small Fish - Weighs less than 36.4 kg (80 lbs)

Medium Fish - Weighs 36.4 - 54.5 kg (80 - 120 lbs)

Large Fish - Weighs more than 54.5 kg (120 lbs)

For lots consisting of 12 or more fish, the representative sample to be collected will be determined by the following formula:

$$ns = (n) (Ns)/N$$

ns = the number of fish in a given weight range from which subsamples must be taken

n = total number of subsamples to be collected from the lot. (In using this formula n will always equal 12)

Ns = the number of fish in a given weight range in the lot

N = the total number of fish in the lot

Example: If a lot consists of 25 fish and is characterized as: 5 small fish [less than 36.4 kg(80 lbs)], 15 medium fish [36.4 - 54.5 kg (80 - 120 lbs)], and 5 large fish [greater than 54.5 kg (129 lbs)], the sample should be collected as follows:

$$\text{small fish } \frac{(12)(5)}{25} = 2.4 = 2$$

$$\text{medium fish } \frac{(12)(15)}{25} = 7.2 = 7$$

$$\text{large fish } \frac{(12)(5)}{25} = 2.4 = 2$$

TOTAL SAMPLE: 11 sub samples

Usually, the total sample will consist of 12 subsamples. However, due to rounding numbers of subsamples determined by the formula may be 11 or 13 in some instances. The total sample should consist of the specific number of sub samples determined by the formula in all cases.

Each sub sample should consist of approximately a 0.5 kg (1 lb) steak cut from just below the nape of the fish. Care should be taken to avoid mutilation of fish. The sub must consist of edible flesh. If a private laboratory is conducting the analysis, individual fish from which the sub sample is taken should be identified with a tag or other suitable method. This will permit FDA to take audit samples from the same fish sampled by the private laboratories.

For lots consisting of 12 or less fish, collect 1 sub from each fish.

Swordfish Loins (slabs or sides cut from dressed whole fish which has been boned or trimmed).

Use the same formula stipulated for whole fish, with the exception that the following weight ranges should be used to characterize the lot:

- Small fish loins = weighs 9.1 - 18.2 kg (20 - 40 lbs)
- Medium fish loins) = weighs 18.2 - 36.4 kg (40 - 80 lbs)
- Large fish loins = weighs over 36.4 kg (80 lbs)

Swordfish Steaks

Collect 12 sub samples, i.e., 12 steaks, at random from different containers in the lot (as many as possible)

Canned Swordfish

Collect 12/453 g (1 lb) sub samples at random

11. RETAIL CONTAINERS CANNED, FROZEN AND DRIED FOODS

Collect retail containers equal to the number of primary units specified above.

12. SPECIAL INVESTIGATIONS

Growing Crops

Superimpose an imaginary grid on the field dividing it into approximately 100 areas. Randomly select 10 areas to form a representative sample of the field. Collect one pound subs from each area. Combine to form a composite. If a sample is being collected to document drift, etc. DO NOT composite subs. In addition, diagram the field in the Remarks Section of the C/R and indicate sub number where each sub was collected.

For leafy vegetables, such as lettuce, cabbage, etc. INV Samples collected in the growing field should be representative of local commercial harvesting practices If

the local practice is to strip outer leaves at the time of harvest, this practice should be followed when collecting field samples. In head lettuce, for example, the lettuce may be packed directly into shipping cartons in the field, in which case 6 or 8 outer leaves are left on the head to be removed at the retail outlet. In other instances, each head is stripped of 2 or 3 outer leaves and individually wrapped in plastic, placed in shipping cartons, and the consumer receives the produce in this condition. Describe sampling method on C/R and describe how packing shed handles produce prior to shipping (e.g., washing, waxing, stripping, etc.).

Soil Samples

Collect soil samples from fields according to the following 3x3 grid diagram:

	a	b	c
1	o	o	o
2	o	o	o
3	o	o	o

Sample at the 9 locations indicated by the "o". If the field being sampled is very large, you may have to sample it using a 4x4, 5x5, or even larger grid pattern.

Subs are to be placed in clean quart glass jars, which have been washed in water, rinsed in methanol, and air dried. If methanol is not available, use washed, air dried jars and submit an empty jar as a control. Note on CR that jars were or were not rinsed with methanol.

Obtain two "6 in" deep plugs (1-2 in. in diameter from each sampling location. Place two plugs from each location in cleaned glass jars, place clean aluminum foil over top of jar and seal with screw cap.

Soil samples should be submitted to the lab at 4 degrees C (39 degrees F) or below.

Water Samples - Collect 3 quarts of water from the same sampling source (e.g., faucet, stream, lake, etc.) and place in cleaned, washed and methanol rinsed jars as described under "Soil Samples".

Submit water samples to lab at 4 degrees C (39 degrees F) or below.

GENERAL

Official Samples shall be collected whenever feasible unless they are not required to accomplish the objective of the assignment. Investigational Samples shall be collected only when Official Samples are not readily available.

Consult with your supervisor in cases of doubt as to sample cost, size, or collection technique. When collecting samples in glass jars, line the lids with aluminum foil which has been certified by the laboratory as contaminant free or use teflon lined lids.

If shipment of shell eggs is required and breakage may result during transit, subs may be broken, shells discarded, and liquid magma collected in clean glass jars. Each sub jar should be properly identified.

Samples collected at Packing Sheds should be representative of the produce as shipped in commerce. DO NOT strip outer leaves from subs collected at packing sheds from bulk lots, shipping cartons ready for shipment, in-transit lots or at final destination. If the packing shed practice is to strip outer leaves prior to shipment, follow this practice when collecting the samples. Describe the sampling method on the C/R.

DO NOT USE magic markers, etc. to identify sub bags, because the ink may affect assay results. Use stick on labels to identify sub bags.

Collect samples in the container in which the dealer is packaging the product. If the dealer is packaging the

product in plastic bags, collect sample in these bags. If the firm is not packing the product, collect the samples in paper bags, cardboard cartons, etc. Do not use plastic bags as this may interfere with the analysis, unless the bags are certified as contaminant free by your district laboratory.

Samples must be delivered as promptly as possible to the laboratory if regulatory action is to be taken against actionable lots.

Hold samples in cold storage until ready to be shipped or delivered to the laboratory. If the sample is of a hard fruit or vegetable (such as apples, pears, butternut squash), and is shipped overnight delivery, it can be shipped to the laboratory unrefrigerated, but the FDA 525 should direct refrigeration upon receipt.

Use aseptic technique, where applicable, when collecting samples of finished products from bulk containers.

WHEAT CARLOAD SAMPLING

I. SAMPLING NORMALCARS

CAUTION: WHEN USING A GRAIN PROBE, BE CAREFUL NOT TO CLOSE THE TRIER COMPARTMENT DOORS ON YOUR FINGERS. Collect samples only of specific assignment.

A. Equipment

1. Double tube compartmented trier, 60 in. long
2. Sampling cloth at least 60 in. long
3. 1000 ml plastic graduate
4. Paper bags or other suitable containers capable of holding more than one quart of sample and do not use canvas bags.
5. FDA Metal Car Seals for resealing railroad cars
6. Aluminum ladder
7. Block and tackle to open railcar door

B. Drawing Sample

Principal sources of grain samples are railcars, barges, and trucks. Draw 5 probes (in duplicate) for each sample taken as described below. However, if the sample is to be Field Examined, an initial sample of 5 probes drawn as indicated below will be sufficient.

Probe samples from railcars and trucks as follows:

Probe #1 - From Center of car

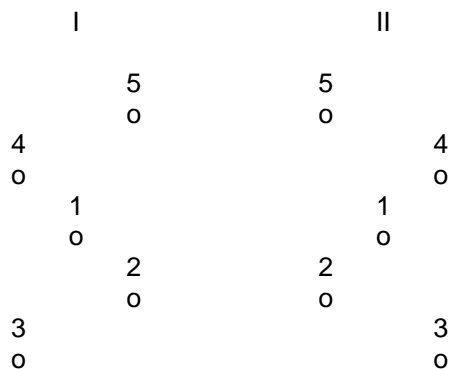
Probe #2 - From 3-5 feet back from door post toward end of the car and approximately 2 feet from the side of the car.

Probe #3 - From 3-5 feet from the same end of the car, but approximately 2 feet from the opposite side of car as Probe #2.

Probe #4 - Same as Probe #2, but opposite end of car.

Probe #5 - Same as Probe #3, but opposite end of car.

Sketches I and II below are alternatives showing the approximate sampling locations.



Insert trier in the grain at an angle of about 10° from the vertical, with the slot up and closed. Open slots, give trier 2 or 3 short up and down motions, so that the openings will fill. Close slots (SEE CAUTION AT BEGINNING OF

SCHEDULE), withdraw trier and carefully empty over sampling cloth. The cloth should be long enough to catch product from each compartment separately when you open the trier compartment doors; e.g. about 6 feet long.

C. Field Examination

Examine each pocket of the probe separately, looking for evidence of pink wheat, rodent pellets, insect damage and uneven loading or plugging. Note any insect infestation and record types of insects and whether live or dead. Count and report for each probe the number of rodent pellets, or rodent pellet fragments. Follow procedure in I.C.2 below. Count as pellets any that are sufficiently large to be readily identified by size, shape, surface coating, and/or presence of rodent hairs. Report the number of rodent pellets per sub. Measure the volume of each sub (probe) in quarts and calculate the average number of pellets per quart per I.C.2.a below. Place pellets from each sub in separate vials and submit with each wheat sub. Place each of the wheat subs in clean, paper bags.

Do not use canvas bags or take glass jars into railcars.

Substantially larger loads will require additional probing or larger samples taken from falling grain during loading or unloading operations.

Submit all suspect samples to laboratory for confirmatory analysis.

1. **Non-Violative Samples.** When field examination shows sample as non-violative, return grain to the car, unless collected for pesticide analysis. Report results in the Remarks Section of the C/R.

2. **Violative Samples**

a. **Rodent Pellet Contamination.** The guideline for determining whether wheat is violative due to rodent contamination is: "9 mg or more rodent excreta pellets and/or fragments of rodent excreta pellets per kg of wheat."

NOTE: Since it is impractical to weigh rodent pellets and wheat in the field, the following estimations can be used. Mouse pellets average approximately 8.7 mg each and a kilogram of wheat about 2.35 pints. This translates roughly as 1 pellet per quart of wheat or 1/2 pellet per pint.

Where your field examination reveals one or more rodent pellets (or you can estimate that sufficient fragments of rodent pellets exist to equal one pellet) in a quart of wheat, take duplicate probes to furnish the claimants portion. Take the duplicate probes from the same locations as the original probes. Place the duplicates in separate containers and identify these to correspond with the original probes.

b. **Pink Wheat.** Where evidence of pink wheat or other fungicide treated wheat is found, collect 15 probe samples. Take 5 probes from each end of the car and 5 probes from the center of the car. Submit the three 5-probe portions separately, using new clean containers.

c. **Insect Damaged Kernels.** The violative status of these samples should be established by laboratory analysis. When any evidence of insect damage is

revealed by cursory examination, collect duplicate samples and submit for laboratory analysis.

3. **Resealing Cars** See IOM 4.3.4.
4. **Procedures for Actionable Cars.** If field examination reveals an average of one or more rodent pellets per quart or gross evidence of insect-damaged kernels, evidence of plugging, or "pink wheat" contamination, determine any movement of the car or other disposition of the grain and notify your supervisor immediately.
5. **Preparation of Sample for Laboratory Analysis.** If a sample can be delivered to the laboratory promptly and confirmatory analysis handled expeditiously, freezing of the FDA subsamples is not necessary. The claimant's (702(b)) portion of the sample, however, must be frozen. It is preferable to freeze the subsamples in paper bags. If a freezer is not available, the subsamples (in paper bags) can be placed in a cooler box with dry ice. Do not use glass jars with dry ice. Officially seal all subsamples. If dry ice is used, you must label the shipping container as described in IOM 4.5.5.8.6 no. 6. See Exhibit 4-19. Indicate frozen storage on the FDA 525.

D. Special Reporting

Submit an Analyst Worksheet (FDA-431) for each sample analyzed and found in compliance. See IOM 4.3.7.1. If field examination shows the sample is possibly actionable, report analytical results in Remarks Section of the C/R.

II. SAMPLING PLUGGED CAR

If uneven loading, layering or "plugging" is suspected, contact your supervisor as to whether to sample or not. A 'plugged' car is a railcar, truck, or barge load of grain where the contamination is suspected of being in only one portion or layer of grain. Plugging is usually the deliberate mixing of violative grain below the surface or in isolated pockets of grain.

- A. Equipment**
 Equipment needed is the same as in 1.A. above except:

1. Double tube grain probe must have individual compartments permanently separated.
2. Small containers of sufficient size to hold the contents of each compartment of each grain probe.

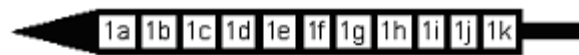
B. Procedure

1. In the Remarks Section of the C/R, draw a diagram showing actual "plugging" pattern suspected.
2. Each sample consists of thirty probes of grain with each probe compartment maintained as a separate sub. Each sample thus consists of 300-330 subs depending on whether a 10 or 11 compartment probe is used and if grain depth is sufficient to insert the probe to fully cover all compartments of the probe.
3. Probe each load and number the probes as follows:

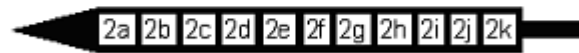
1 4 7 10 13 16 19 22 25 28
 2 5 8 11 14 17 20 23 26 29
 3 6 9 12 15 18 21 24 27 30

4. Identify the subs by probe number plus compartment letter starting with small "a" as the compartment nearest the tip of the probe.

Example:



Probe #1



Probe #2

5. Submit sample to your district's servicing laboratory. See IOM 4.5.5.2.

IMPORTED WHITEFISH SAMPLING SCHEDULE

GENERAL

This Sample Schedule objective is to maintain import lot integrity from time of importation thru FDA inspection or examination and final action.

Shipments will be special manifested from non-lab ports to DO cities and other cities designated by the DD as FDA inspection points. These shipments will arrive in Customs bonded trucks under seal applied by Customs at the port of entry. Customs Entry documents and commercial invoice will accompany each shipment. The commercial invoice contains a description of the lots in the shipment and will serve as a guide in the selection of the lots to be sampled.

1. Special Manifested Shipments:
 - a. Determine if seals are intact and record seal number.
 - b. FDA metal seals may be broken and lots checked against invoice.
 - c. Customs seals may be broken only if authorized by Customs.
 - d. Lots which are not to be examined will be released by completing the "MAY PROCEED" block of the FDA-701.
 - e. Sample lots to be examined by using either the Single or Sequential Sampling Plan depending on whether examination is made at the DO Lab or at the dock. The Sequential Plan can only be used where additional fish are immediately available for cutting.
2. Definition of a Lot & Selection for Examination.
 - a. A lot is defined as "Each group of fish of a distinct size, listed in the invoice as from a distinct lake, will be considered as a separate lot. Where an invoice does not list lakes of origin of boxes of fish in a shipment, fish of the same size and kind will be considered to comprise a single lot. When the size of the fish or lakes of origin in a shipment are not specified, the shipment will be treated as a single lot."
 - b. Limit sampling to lots containing 5 or more boxes unless deliberate splitting up of lots is suspected.
 - c. Basis for Sampling. Select lots for sampling on either a "selective" or "objective" (random) basis. The criteria in selective sampling may be prior knowledge or suspicion that fish listed as from a given lake are likely to have excess cysts; that the shipper has been known to manipulate shipments; etc. Regardless of the reason for selective sampling, record the basis for sampling each lot in your examination report. Simply list the basis as "selective" or "objective" next to the results of each lot sampled.

- d. Normally, select boxes in a lot for sampling at random. However, where there's evidence of layering, selectively sample the suspect boxes.
3. Sampling Schedule.
 - a. Imported samples of whitefish & related fish for parasites. The sampling schedules estimate lot quality more precisely, thereby reducing the likelihood of passing a lot which should be detained, or vice versa, due to an inadequate sample. SCHEDULE A below is a single sample plan for use in collecting samples for examination in the district lab or other location where it is impossible or undesirable to return and obtain additional fish. SCHEDULE B below contains sequential sampling plans for use when the exam is made at a customs office or a carrier's dock where you have immediate access to the lot and can obtain additional fish, if necessary. The sequential plan for lots of 20 to 100 boxes is presented in tabular form. the sequential sample plan for lots of 100 or more boxes is presented in a sampling chart. For small lots of 5-20 boxes, a sequential sample plan is not feasible. All import sampling plans are based on lot size and the sizes of the fish in the lot. When lots are very good or very poor quality, in terms of cyst infestation, double sample plans require a smaller sample size on the average than single sampling plans, to reach a decision.
 - b. Domestic Samples for Parasites.
 - i. For Laboratory Examination. Lots of 11 or more boxes; Collect at least 25 fish from a representative number of boxes. For small lots, under 11 boxes; Collect 12 fish from a representative number of boxes.
 - ii. For Examination in Other Than Laboratory. Cut a preliminary sample in accordance with the appropriate double sampling plan, Schedule B. Cut the additional sample where indicated or bring the additional sample to the laboratory for examination.

SCHEDULE A - SINGLE SAMPLE PLAN

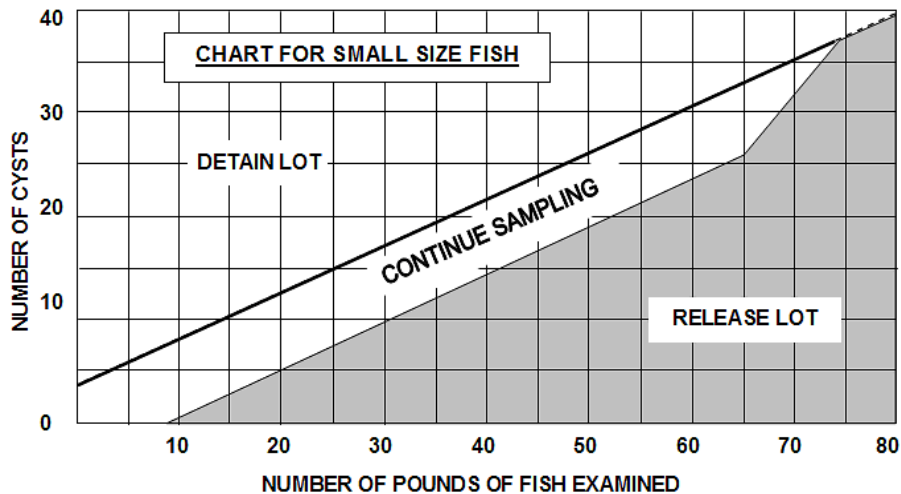
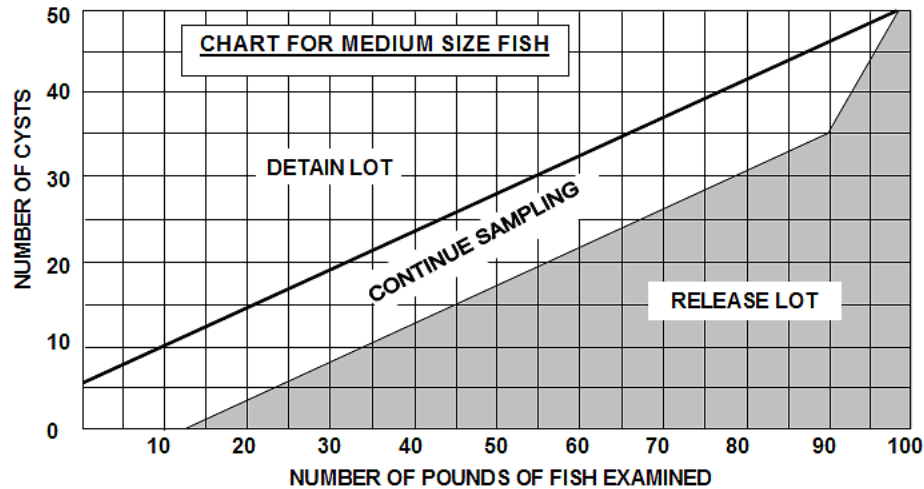
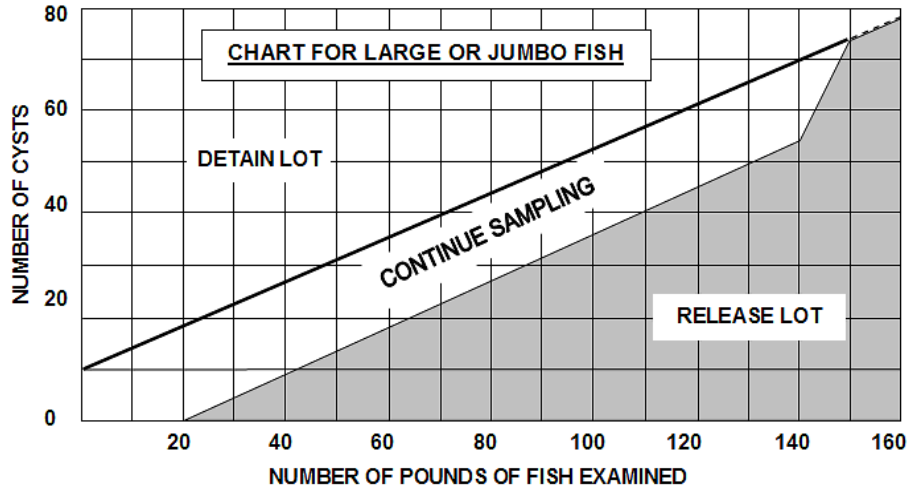
Number of Boxes in Lots	NUMBER OF KG'S (POUNDS) IN A SAMPLE ^{1/}		
	Jumbo or Large ^{2/}	Medium ^{2/}	Small ^{2/}
5 - 19 boxes	12.7 Kg (28lbs)	10.5 Kg (23lbs)	7.3 Kg (16lbs)
20 - 100 boxes	24 Kg (73lbs)	20.5 Kg (45lbs)	15 Kg (33lbs)
100 or over	32 Kg (70lbs)	25.5 Kg (56lbs)	17.8 Kg (39lbs)

- 1/ When an invoice does not designate the size of the fish in the shipment and inspection reveals more than one size in the lot, use sampling plan for medium fish.
- 2/ RANGE OF WEIGHT OF FISH IN EACH SIZE CLASS:
 - SMALL Under 675 gm (1 1/2lbs)
 - MEDIUM 675 gm (1 1/2lbs) & under 1.4 Kg (3lbs)
 - LARGE 1.4 Kg (3lbs) & under 1.8 Kg (4lbs)
 - JUMBO Over 1.8 Kg (4lbs)

SCHEDULE B - SEQUENTIAL SAMPLE PLAN							
1. Limited to lots of 20 - 100 boxes. 454 Kg (1000lbs) to 2272 Kg (5000lbs)							
Size of Fish 1/	Size of preliminary Sample	Cysts/45.5 Kg (100lbs) in Preliminary Sample			Size of ADD'L SMPL	Cysts/45.5 Kg (100lbs) in sample	
		PASS	DETAIN	TAKE ADD'L SMPL		PASS	DETAIN
Large & Jumbo	16 Kg (35lbs)	30 or less	70 or more	31-69	28.6Kg (63lbs)	49 or less	50 or more
Medium	12.3 Kg (27lbs)	26 or less	67 or more	27-66	19.5 Kg (43lbs)	49 or less	50 or more
Small	8.2 Kg (18lbs)	38 or less	61 or more	39-61	11.8Kg (26lbs)	49 or less	50 or more

1/ When an invoice does not designate the size of the fish in the shipment and inspection reveals more than one size in the lot, use sampling plan for medium fish.
 2/ For lots of 100 boxes or over, use the Sequential Sampling Chart for the particular size fish in the lot.

WHITEFISH SEQUENTIAL SAMPLING PLAN (WHEN LOT SIZE EXCEEDS 100 BOX)



AFLATOXIN SAMPLE SIZES

Sample sizes for all other mycotoxins can be found in CP7307.001 Domestic & Import Mycotoxin Compliance Program

PRODUCT SAMPLE SIZES FOR AFLATOXIN ANALYSIS

(Includes 702(b) [21U.S.C. 372(b)] portion - each sample unit, contains product for the reserve portion, no duplicate subs are necessary)

NOTE: COMPLIANCE SAMPLE SIZES MAY DIFFER FROM SURVEILLANCE SAMPLE SIZES.

PRODUCT	PACKAGE TYPE	LOT SIZE	NUMBER OF SAMPLE UNITS*	UNIT SIZE (minimum)	TOTAL SAMPLE SIZE (minimum)
Peanut Butter (smooth)	Consumer or bulk	NA	24	225 gm (8 oz)	5.4 Kg (12 lbs)
			12	454 gm (1 lb)	5.4 kg (12 lbs)
Peanut Butter (Crunchy) Peanuts shelled roasted, or unroasted, Peanuts ground for topping	Consumer or bulk	NA	SURVEILLANCE SAMPLE		
			10	454 gm (1 lb)	4.5 kg (10 lb)
			COMPLIANCE SAMPLE		
Peanuts, roasted in shell (only for domestic runner variety)	Consumer or bulk	NA	SURVEILLANCE SAMPLE		
			15	454 gm (1 lb)	6.8 kg (15 lbs)
			COMPLIANCE SAMPLE		
Tree nuts (except in-shell Brazil Nuts and all pistachio nuts in import status) shelled, in-shell slices, pieces, or flour	Consumer or bulk	NA	SURVEILLANCE SAMPLE		
			10	454 gm (1 lb)	4.5 kg (10 lb)
			COMPLIANCE SAMPLE		
Tree nuts - paste			12	454 gm (1 lb)	5.4 kg (12 lbs)
			50	454 gm (1 lb)	22.7 kg (50 lbs)
Brazil Nuts in-shell (in import status)	Bulk	< 200 bags 201-800" 801-2000"	20	454 gm (1 lb)	9 kg(20 lbs)
			40		18 kg (40 lbs)
			60		27 kg (60 lbs)
Pistachio nuts in-shell (in import status)	Bulk	multiples of 34,100 kg (75,000 lbs)	20 % of units	---	50 lbs for each multiple of 34,100 kg (75,000 lbs) or less
Pistachio nuts shelled (in import status)		SAME	SAME	---	25 lbs for each multiple of 34,100 kg (75,000 lbs) or less
Corn - shelled, meal flour or grits	Consumer or bulk	NA	10	454 gm (1 lb)	4.5 kg (10 lbs)
Oil seed meals - Peanut meal, cottonseed meal	Bulk	NA	20	454 gm (1 lb)	9 kg (20 lbs)
Edible seeds** melon pumpkin, sesame, etc	Bulk	NA	SURVEILLANCE SAMPLE		
			10	454 gm (1 lb)	4.5 kg (10 lb)
			COMPLIANCE SAMPLE		
Ginger Root dried whole ground	Bulk	"n" units	Sq root "n"	---	6.8 kg (15 lbs)
			Consumer	NA	16
Milk - whole, skim low fat	Consumer	NA	10	454 gm (1 lb)	4.5 kg (10 lbs)
	Bulk	NA	---	---	4.5 kg (10 lbs)
Small grains - wheat sorghum, barley, etc	Bulk	NA	10	454 gm (1 lb)	4.5 kg (10 lbs)
Dried fruit** - e.g.: Figs	Consumer or bulk	NA	SURVEILLANCE SAMPLE		
			10	454 gm (1 lb)	4.5 kg (10 lb)
			COMPLIANCE SAMPLE		
Mixtures containing commodities susceptible to mycotoxin contamination	Consumer	NA	SURVEILLANCE SAMPLE		
			50	454 gm (1 lb)	22.7 kg (50 lbs)
			10	454 gm (1 lb)	4.5 kg (10 lbs)

NOTE: Containers for samples of unprocessed, intact nuts, seeds, or grains must be sufficiently porous to provide for dissipation of moisture produced by respiration of the nut, seed, or grain.

* To be collected from as many random sites in the lot as possible. For surveillance samples, you may combine

subs prior to shipping to the laboratory. For compliance samples, you must maintain sub integrity.

** Optional sampling program for seeds or dried fruit with a low incidence of contamination. Take initial 10 x 454 gm (1 lb) sample. If any aflatoxin is detected, resample 50 x 454 gm (1 lb) sample for determination of contamination level on which to base regulatory judgment.

CANNED FRUIT - FILL OF CONTAINER - AUTHENTIC PACK

Collect samples only on a specific assignment or during inspections when it appears that the firm is not filling the containers to capacity.

1. INVESTIGATIONAL SAMPLES: Authentic Pack Preparation . Procedure for preparing authentic factory packs.
 - a. Remove 72 cans, 3 at a time, from packing line after fruit has been added and before syruling.
 - b. Mark 24 cans with the sub numbers A-1, A-2, A-3, etc.; 24 cans with sub numbers B-1, B-2, B-3; and 24 cans with sub numbers C-1, C-2, C-3, etc. See IOM 4.5.2.3.
 - c. Drain water from the "B" subs by inverting each can for 10 seconds, holding the fruit so it doesn't fall out.
 - d. Obtain gross weight of each can and record data for each series of sub on 3 separate FDA-485 - Field Weight Sheets.
 - e. Add additional fruit of the same kind and style to the "C" subs until the cans are filled to capacity. Do not tamp the contents or crush the fruit.
 - f. Record the number of fruit pieces added where the size of the fruit makes the procedure reasonable. Do not make time consuming counts of small pieces of fruit or berries.
 - g. Obtain the gross weight of the "C" subs after additional fruit is added and record on "C" series Field Weight Sheet.
 2. OFFICIAL SAMPLES
See Sample Schedule Chart 2 for sample size.
 3. SPECIAL REPORTING AND PRECAUTIONS
 - a. Report coding of cans and shipping cases.
 - b. Obtain label specimen(s) for the slack filled products.
 - c. Report shipments made before the inspection or since previous inspection in the same canning season.
 - d. Do not prepare Authentic Factory Samples when the cannery is packing for USDA fill-of-container certification unless:
 - i. USDA inspection is not continuous.
 - ii. USDA Certification is for quality only.
 - iii. USDA recommendations for weights are not being followed.
 4. SAMPLE SUBMISSION
Submit samples to your district's designated workplan servicing laboratory
- h. Return all 72 cans to the filling line for syruling, exhausting, sealing, etc. in normal cannery operation.
 - i. Remove cans after cooking and cooling.
 - j. Identify cans with a single INV Sample number.
 - k. Attach FDA-485 - Field Weight Sheets to C/R.

IMPORTS - COFFEE, DATES AND DATE MATERIAL

1. Coffee - Import Field Examination - Note: Examine a minimum of six bags of coffee beans regardless of lot size. If a significant number of defective beans or significant contamination is found during the examination of these six bags, continue the examination using the following schedule, which applies for both Import Field Examination and samples for laboratory analysis:

LOT SIZE	NO. BAGS TO BE SAMPLED
100 or less	6 bags
101 - 200	10 bags
201 - 1000	15 bags
over 1000	20 bags

- a. Sample each bag with a trier, collecting 1/2 pt. of beans from the top and 1/2 pt. from the bottom of the bag. The total quantity of beans taken from each bag must be the same, since both wharf and laboratory examinations are to be performed on a composite sample of all beans collected. Shake each sub on a #8 sieve nested in a pan. Dump the sifted beans from each sub into a bag of sufficient size to hold and permit mixing all of the subs collected from the lot. Composite the subs. Do not maintain individually.
- b. Macroscopic Filth Examine the siftings for macroscopic filth (live and dead whole insects, excreta pellets, extraneous material and sweepings), reporting findings for each sub separately. See IOM 4.3.7.4. Transfer macroscopic filth, including all sifted material to a second bag and submit to the laboratory for confirmation. If live insect infestation is encountered, freeze the filth portion containing the insects and the composite coffee bean sample. The lot will be detained if a live insect infestation is encountered, however, proceed with the defect bean examination since the reconditioning process will depend on the results.
- c. Defect Bean Examination Thoroughly mix the composite sample of coffee beans and remove three-hundred beans at random. Examine each individual bean visually (or at a 5X magnification) for insect tunneling and mold damage. Count as moldy only those beans with 1/4 or more of the surface being moldy. Note: Each district office has examples of the various types of reject beans. Accept the lot if twenty or less rejects are found and discard the sample. Report your wharf examination into FACTS or OASIS, depending on your assignment; no Sample Collection Report is necessary.
- d. If twenty-one or more rejects are detected, return beans examined to the composite and submit to the laboratory. You may discontinue the examination when twenty-one rejects are detected. When a sample is submitted to the laboratory, all import field examination time is reported as a field exam in FACTS and the sample collection time is reported

as an import sample collection. All necessary documents for an import sample collection must be completed.

2. Dates & Date Material - Filth

In the laboratory, dates, like in-shell nuts are sampled in accordance with a sequential sampling program, i.e. all subsamples are composited, and 100 dates are sampled at a time, repetitively, until such time they either exceed or fall under certain reject numbers. It is not uncommon to have to examine 3 to 6 (100 date) repetitions. It is therefore important for each subsample to contain at least 200-300 dates or 2 lbs of date material. Sample according to the following schedule:

NUMBER OF SUBSAMPLES REQUIRED

NO. CONTAINERS IN LOT*	WHOLE DATES	DATE MATERIAL
100 or less	3	4
101 - 600	8	6
601 - 1200	14	8
1201 - 2000	26	10
2001 - 2800	36	12
2801 - 6000	44	14
6001 - 9600	56	16
9601 - 15000	68	18
Over 15000	82	22

* Schedule is based upon unit containers weighing between twenty and one-hundred pounds. For containers exceeding one-hundred pounds each, consider as two or more containers. For example, a one-hundred and fifty pound container is considered as two containers; a three-hundred pound container as three containers, etc.

- a. Identify each subsample separately.
- b. Each lot will be a separate sample. Reconditioning, if possible, will be based on lot numbers.
- c. Jujube sampling – collect according to the above schedule for dates and date material. Do not identify jujube samples as dates, *Phoenix dactylifera*. Jujubes, *Zizphus jujube*, are usually labeled as Chinese Red Dates, Dried Red Dates, or Honey Dates and are not misbranded when labeled as such due to long standing use of these names.
- d. If live insects are noted, include these as part of the sample collected and report on the C.R. which subs contained the insects and how many insects, adult or larvae, were noted. If live infestation is noted, place all subs from the lot sampled in large plastic whirlpak bags and freeze or place in a cooler on dry ice.

SAMPLING SCHEDULE FOR COLOR CONTAINING PRODUCTS & COLOR ADDITIVES

The following schedule provides general guidance for collecting samples of foods and cosmetics to determine whether non-permitted colors are present, rather than to determine the actual level of a particular color. This schedule was developed with the assumption that color distribution in the lot will be homogeneous. In the case of heterogeneous products, your supervisor should contact Center for Food Safety and Applied Nutrition, Office of Field Programs, Division of Enforcement (HFS-605) to determine sample size.

INDUSTRY CODE SAMPLE SIZE (DO NOT COMMINGLE CODES) (Min. 225 gm (8 oz)/pkg Unless otherwise specified)

GRAIN AND BAKING

02	Whole grains, Milled Grain Products and Starch	2 retail packages
03	Bakery Products, Doughs, Bakery Mixes, and Icings	2 retail packages
04	Macaroni and Noodle Products	2 retail packages
05	Cereal Preparations Breakfast Foods	2 retail packages
07	Snack Food Items (Flour, Meal, or Vegetable Base)	2 retail packages

DAIRY

09	Milk, Butter, and Dried Milk Pdts	Liquid Pdts: 2 pts where possible Solid: 2 packages
12	Cheese and Cheese Products	2 retail packages
13	Ice Cream and Related Products	6 items per sample (If item is single serving; i.e., cup, popsicle, bar, etc.) 2 pt containers where possible, or 1 quart or 1/2 gal
14	Filled Milk and Imitation Milk Products	2 pints

EGGS

15	Egg and Egg Pdts	2 dozen whole eggs (e.g. colored hard boiled Easter eggs) 2 retail pkg of egg pdts
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FISH

16	Fishery/Seafood Pdts	2 retail packages. Any collection of smoked salmon should be selective, based on inspectional evidence
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MEAT & SIMULATED MEAT PRODUCTS

17	Meat, Meat Products and Poultry	2 retail packages
18	Vegetable Protein Pdts	2 retail packages

FRUIT, NUT AND VEGETABLE PRODUCTS

20-22	Fruit & Fruit Pdts	2 retail packages canned or glazed. 12 fresh fruit (e.g., oranges, etc.).
23	Nuts & Edible Seeds	2 retail packages
24-25	Vegetable & Vegetable Products	2 retail packages
26	Vegetable Oils & Olive Oil	Liquids - 2 pints Solids - 2 retail packages

DRESSINGS AND SPICES

27	Dressings & Condiments	2 retail packages
28	Spices, Flavors, & Salts	Extracts - 2 pints Solids - 2 retail packages

BEVERAGES

29	Soft Drinks & Waters	6 Retail Units (Cans, Bottles, Packets)
30	Beverage Bases, Concentrates, and Nectars	Liquids - 1 pint Solids (Powder mix, packets) - 6 Consumer Pkg Solids - 2/225 gm (8 oz) or larger containers
31	Coffee and Tea	2 retail packages
32	Alcoholic Beverages	2 pints or 1 quart

CONFECTIONS AND DESSERTS

33	Candy w/o chocolate, Candy Specialties, and Chewing Gum	2 retail packages
34	Chocolate & Cocoa Pdts	2 retail packages
35	Gelatin, Rennet, Pudding Mixes, & Pie Fillings	6 pkgs - smallest consumer size
36	Food Sweeteners (Nutritive)	2 pints

MULTIPLE FOODS, SOUPS, SALADS, BABY FOOD AND DIETARY

37	Multiple Food	Single Serving Dinners,
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	Dinners	etc - 4 pkgs
	Gravies, Sauces and Specialties (Total)	Two Consumer Pkgs when 1 pkg serves more than 2
38	Soups	Same as 37 Above
39	Prepared Salad Products	Same as 37 Above
40	Baby (Infant and Junior) Food Pdts	Sufficient retail pkgs to total at least 454 gm (1 lb) of food
41	Dietary Conventional Foods and Meal Replacements	Same as 37 Above

COLORS AND COSMETICS

		1. Straight Color 28 gm (1 oz) powder.
		2. Color Mixtures 110 gm (4 oz) Liq, paste or powder.
50	Color Additives for Foods Drugs, and Cosmetics	If mixture contains over 50% pure dye, 55 gm (2 oz) is sufficient Four retail packages of the same lot code for each shade (color) in the product line, if the product is strongly colored. (e.g., Lipsticks, hair coloring products, eye mascara, eye liners, make up pencils of all types)
53	Cosmetics	Sufficient number of retail packages to equal 1 lb or 1 pt of sample if the product is lightly colored. (e.g., creams, lotions, shampoos, bath products, shaving preparations, and perfumes.) Note: Always collect a minimum of two retail units of each product.

MISCELLANEOUS

Bulk Items (Any bulk food or cosmetic)	Dry - 454 gm (1 lb) Liquid - Min 36 fl oz
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DRUG SAMPLING SCHEDULES
(Does not include Antibiotic Preparations)

STERILITY TESTING VITAMINS, DEVICES, & DRUGS

Type of Product	Sample Size ¹	
	INV Sample ²	Official [702(b) & Check] ³
DRUGS	36	86
DEVICES	46	106

LEGEND:

¹Double sample size requirements when individual containers are 2 ml (2 gm) or smaller.

²INV sample includes units (30 for Drugs & 40 for devices) for examination and 6 units for bacteriostasis.

³Official Sample includes units (30 for drugs & 40 for devices) for examination, units (30-40) for check, 20 units for 702(b) [21 U.S.C. 372(b)] and 6 for bacteriostasis.

Note: If a lot is aseptically filled into 200 finished units or less, sample no less than 10% of lot.

DISSOLUTION TEST - USP & NF

Unless directed otherwise by your assignment or supervisor, submit samples to your normal servicing laboratory.

SAMPLE SIZE

Collect a 200 tablet portion for drug potency analysis by the collecting district lab, plus a separate 100 tab portion to be split for dissolution testing.

MICROBIOLOGICAL EXAMINATION OF DRUGS (Other than for Sterility)

PRODUCT	<u>MINIMUM SAMPLE SIZE (Includes 702(b) portion)</u>	
	<u>Sub Size</u>	<u>Nos. of Subdivisions</u>
Dosage Form Drugs (See #1 below), Bulk Drugs, or Raw Materials for Manufacturing	90 gm or 90 ml	10

SAMPLING INSTRUCTIONS

1. Contact the laboratory (which has microbiological testing capabilities) serving your district for sample size requirements before sampling dosage form drugs containing less than 3 grains, 200 mg, or 25% of the suspect ingredient.
2. Use aseptic technique when collecting samples from raw materials or bulk containers. Implements and sample containers used must be sterile. Submit controls. See IOM 4.3.6 through 4.3.6.5.
3. Submit samples to the laboratory with microbiological testing capabilities which serves your district unless directed otherwise.

VETERINARY PRODUCTS, FEEDS, & BY- PRODUCTS FOR ANIMAL FEEDS

1. GENERAL

This sampling schedule may be used as a guide in the collection of surveillance or compliance samples resulting from district assignments or as a follow-up to violative inspections and/or investigations. Before collecting follow-up samples to violative inspections or investigations, contact your supervisor since it may be necessary for your district to consult with the Atlanta Center for Nutrient Analysis (HFR-SE680) when unscheduled compliance sampling is contemplated.

2. SAMPLE PRODUCT, SIZE, & SPECIAL INSTRUCTIONS

Vitamin-mineral testing, sampling instructions and information. Sample size includes 702(b) portion.

Unless excessive cost is a factor, collect at least 3 intact containers from each lot or control number. When sampling from bulk lots, collect appropriate subs from a minimum of 3 different bulk containers in the lot.

DOSAGE FORM VITAMIN-MINERAL PREPARATIONS (Single/Multiple Ingredients)

PRODUCT	NO. SUBSAMPLES	MINIMUM TOTAL SAMPLE SIZE	REMARKS
Injectables	3 vials/amps	30 ml	Split samples for sterility testing (60 vials/amps)
Tabs/Caps	3 retail units	300 Tabs/Caps	Split sample for micro tests (10/50 tab/cap subs)
Liquids	3 retail units	4 fl. oz.	Split sample for micro tests (10/2 fl. oz. subs)
Powders	3 retail units	112 gm (4 oz)	Same as above

FEEDS & BY-PRODUCTS FOR ANIMAL FEEDS (Vitamin-Mineral Claims)

Vitamin A & D Concentrates, Supplements & (A&D feeding	3 retail units(1/2 gal or less)	3 lbs (1.4 kg) 3 pints	Limit samples to those products containing at least 800 units/g Vit A and/or 80 Feeds units/g Vit D
Vitamin B2 (Riboflavin) Concentrates, Supplements, & feeds	Same	Same	Limit samples to those products containing at least 20 mg/lb
Vitamin B12 (Cyanocobalamin) Concentrates, Supplements& feeds	Same	Same	Limit samples to those products containing at least 1 mg/lb
Multiple Vitamins Concentrates, Supplements, & feeds.	Same	Same	Limit samples to those products meeting vitamin levels listed above.

3. SAMPLE SUBMISSION

Submit all samples for Vitamin Potency analysis to the Atlanta Center for Nutrient Analysis (HFR-SE680).

Submit samples for filth analysis, microbiological examination, sterility, etc. to your district servicing laboratory.

MEDICATED ANIMAL FEEDS SAMPLING

provide warning and/or withdrawal statements which could present danger to animals or man, or gross evidence of false and misleading therapeutic claims, are factors for consideration.

Medicated Premixes**1. Investigational Samples (INV Samples)**

To demonstrate suspected drug carryover or other chemical contamination during manufacturing, collect 1-900 gm (2 lbs) of static residual material in the equipment, and the finished product premixes.

2. Official Physical Samples 702(b) [21U.S.C.372(b)] Portion Included

For expensive premixes or components, collect a total of 3/170 gm(6 oz) subs; One sub from each of 3 containers. In the case of premixes packaged in plastic; e.g., mini-packs, follow instructions under bagged premixes.

a. Bagged Premixes

Collect 10 - 454 gm (1 lb) subs from each lot. Sample all bags in lots under 10 bags, for a total of 10 subs from the lot.

Collect 454 gm (1 lb) subs from at least 10 different bags selected at random in lots of more than 10 bags.

b. Bulk Premixes

Collect at least 10 - 454 gm (1 lb) subs, from different locations in the lot providing a minimum total sample of 4.5 Kg (10 lbs).

3. Documentary Samples (DOC Sample) - Refer to IOM 4.1.4.2 for guidance on the collection of DOC Samples.**Sampling Precautions (See IOM Sample Schedule Chart 4)**

1. Insert the trier the full length of the bag when sampling bagged premixes, or complete feeds.
2. Clean trier between sampling the different lots of premixes or complete feeds.
3. Place subs in clean airtight container, preferably clean glass jars.
4. DO not fumigate samples intended for potency analysis, drug carryover or cross-contamination.

Sample Submission

Submit samples to your district's servicing laboratory or as directed by your assignment or supervisor. See IOM 4.5.5.2.

Medicated Feeds**1. Investigational Samples (INV Sample)**

Collect 1 - 900 gm (2 lb) of static residual material in the equipment and correlate with finished feed samples to show that residues are being carried over into the finished product.

2. Official Samples (Includes 702(b) portion)**a. Bagged Complete Feed**

Collect a total sample of not less than 2.3 Kg (5 lbs) from each lot. Collect 454 gm (1 lb) subs sampling all available bags from lots of 10 bags or less. If lot size is greater than 10 bags, collect 454 gm (1 lb) from each of 10 bags selected at random.

b. Bulk Complete Feed

Collect at least 10 - 454 (1lb) subs from different points in the bulk lot to obtain a minimum total sample of 4.5 kg (10 lbs).

c. Concentrates/Supplements

If the concentrate or supplement is relatively inexpensive, follow the sampling procedures for complete feeds. Limit sampling of more expensive drug materials, concentrates, or supplements to no more than 3 containers taking a 170 gm (6 oz) or 6 fl. oz. sub from each of the 3 containers.

3. Documentary Samples (DOC Sample)

a. Feed Subject to MFA Approval - Collect DOC Samples of products processed without required MFA approval. Where the plant does not ship in IS commerce, but ingredients are received from IS sources, document the IS nature of drug ingredients and the "Held For Sale" status of the finished feed. Labeling of drug ingredients must be submitted.

b. Misbranded Products - Collect a DOC Sample for misbranding or labeling deficiencies. The failure to

SAMPLE SIZES WITH APPLICATION TO FOOD PRODUCTS FOR ALLERGENS^a

(Listed below is the sample size needed for lab analysis. Collect all samples in duplicate, with the duplicate serving as the 702 (b) reserve sample)

Product	Package type	Number of sample units	Unit size	Total sample
Non-liquefied foods, i.e., cereals, cookies	Consumer	20	1 lb	20 lbs
Pre-liquefied foods, i.e., ice cream, chocolates	Consumer	10	1 lb	10 lbs
Paste or slurry type	Consumer	24	8 oz	12 lbs
		12	1 lb	12 lbs
Fluid, i.e., beverages	Consumer	10	16 fl. oz	160 fl. oz

IMPORTANT! WHEN TO SAMPLE: At the time of submission of this table to the IOM, only “for cause” allergen samples for peanut contamination should be collected. Test methods for additional allergens are under development and the field will be notified when they are available for regulatory purposes. The allergen compliance program, when issued, will provide additional sampling guidance. “For cause” sampling should be limited to instances where a consumer, medically determined to have a food allergy, experiences an adverse event believed due to the allergenic food, and the labeling of the suspect product does not indicate the presence of the allergen.

^a See Laboratory Information Bulletin (LIB) # 4341, Application of Validated, Multiple Laboratory *Performance Test Methods*SM for the Detection of Peanuts in Food, Vol 21(2) 2005 for details regarding the analysis and quantitation of analytical samples.

Note: To be collected from random sites. May combine subs or maintain sub integrity depending on purpose of sampling

Note: Prepare composite following proper grinding and mixing procedures. Separate four 1-lb portions from composite.

Adapted from U.S. Food and Drug Administration, Office of Regulatory Affairs, Investigations Operations Manual, Chapter 4, Sample Schedule 6, Mycotoxin Sample Sizes, http://www.fda.gov/ora/inspect_ref/iom/ChapterText/sschedule6.html

