

## 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.

When the 'Reason for Collection' on the Collection Report includes can seam analysis, the CSO shall collect the can seam specifications for the cans in the sample. This is specific to the can manufacturer and can size collected in the sample. The can seam specifications will be submitted in the FD-525 along with the Collection Report for the servicing laboratory.

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 $\leq$ 298 298 if greater	6 - 8	6	12 - 16	12	24 - 32	25	48 - 64	all $\leq$ 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 subsample 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 subsample 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
	Over 240,000	600	3 from 200
Greater than 1 kg (2.2lbs), but less than 4.5 kg (10 lbs.)	2400 or less	48	3 from 16
	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
Greater than 4.5 kg (10 lbs)	Over 120,000	600	3 from 200
	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.**

- # 10 size containers - Randomly select 1 normal container from each of 12 randomly selected cases (if available) in the lot.
- # 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 the Guide to Inspection of Acidified Food Manufacturers for additional information: [http://www.fda.gov/ora/inspect\\_ref/igs/iglist.html](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.