

UNITED STATES  
DEPARTMENT OF  
AGRICULTURE

INSPECTION  
PROCEDURES FOR  
FOREIGN MATERIAL

AGRICULTURAL  
MARKETING  
SERVICE

FRUIT AND  
VEGETABLE  
DIVISION

PROCESSED  
PRODUCTS  
BRANCH

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## **PREFACE**

This instruction is designed for Processed Products Branch (PPB) personnel of the United States Department of Agriculture (USDA). Its purpose is to give information and guidelines to assist in the uniform application of inspection procedures for foreign material.

The information has been compiled or developed from sources available to the public as well as from technical knowledge of personnel in the USDA.

Compliance with PPB guidelines does not excuse failure to comply with the Federal Food, Drug, and Cosmetic Act or any other applicable Federal or state laws or regulations.

This issue of File Code 172-A-1, Inspection Procedures for Foreign Material, supersedes the previous edition dated September 1983, and Section III, Revised, dated July 1986.

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**SECTION I - CLASSIFICATION AND SEGREGATION**

I.	GENERAL .....	1
II.	CLASSIFICATION .....	1
	A. Foreign Material .....	1
	B. Flavor .....	2
	1. Substandard .....	2
	2. Grade Not Certified (GNC) .....	2
	C. Other Unsatisfactory Conditions .....	3
	1. Visible Mold .....	3
	2. Live Infestation .....	3
III.	ACCEPTANCE CRITERIA .....	3
	A. Foreign Material .....	3
	B. Flavor .....	5
IV.	SAMPLING RATE .....	6
	A. Foreign Material - Classes 1 and 2 .....	6
	1. Lot Inspection .....	6
	2. In-plant Inspection .....	6
	B. Foreign Material - Classes 3 and 4 .....	7
	C. Meeting Minimum Sample Unit and Poundage Criteria .....	7
V.	SEGREGATION - FAILING LOTS .....	7
	A. Class 1 and 2 Foreign Material .....	7
	B. Class 3 Foreign Material .....	8
	C. Class 4 Foreign Material .....	8
	D. Flavor .....	8

**SECTION II - CONTROL**

I.	AGREEMENT WITH FOOD & DRUG ADMINISTRATION .....	9
II.	CONTROL .....	9
A.	Under AMS Control .....	9
1.	Procedure .....	9
2.	Re-examination of Hold Lots Under AMS Control .....	10
B.	Not Under AMS Control .....	10
1.	Procedure .....	10
IV.	COMPLETION AND MAINTENANCE OF FORMS .....	11
V.	DISTRIBUTION OF FORMS .....	11
A.	FV-16, Notice of Hold for Re-Examination, Attachment II .....	11
B.	FV-16-2, Notification to Food and Drug Administration, Attachment III ....	12

**SECTION III - DEFECT ACTION LEVELS**

I.	FOOD AND DRUG ADMINISTRATION .....	13
II.	PROCESSED PRODUCTS BRANCH GUIDELINES .....	13
III.	METHOD OF ANALYSES .....	13

**ATTACHMENTS**

Attachment I	Processed Products Branch Guidelines .....	14
Attachment II	Notice For Hold For Re-Examination .....	16
Attachment III	Notification To Food and Drug Administration .....	17
Attachment IV	Letter To Applicant .....	18

## SECTION I - CLASSIFICATION AND SEGREGATION

### I. GENERAL

The limits established for foreign material in this guide are predicated upon the nature of the material, impact upon the consumer, capability of the industry to remove such material under good (acceptable) commercial practices, and possible harmful effect of such material.

The Food and Drug Administration (FDA) has set defect action levels for certain products which pose no inherent hazard to health. These limits have been established because it is economically impractical to grow, harvest, or process raw products that are totally free of non-hazardous, naturally occurring, unavoidable defects. The action levels are not intended to cover poor manufacturing practices.

Products containing foreign material which pose no inherent hazard to health (Classes 1, 2, and 3; and product that is found to contain harmful material (Class 4) are subject to regulatory action if the lot fails the criteria in Table I and is not maintained under Agricultural Marketing Service (AMS) control.

### II. CLASSIFICATION

Foreign material is not limited to the examples shown for each class nor are the examples necessarily limited to that class. Classify foreign material according to the description of each class.

#### A. Foreign Material

For ease of reference, foreign material is classified according to the following four categories:

Class 1: Not readily discernible either visually or organoleptically and generally requires microscopic examination for detection.

**Example:** Fly eggs, maggots, insects and insect fragments  
2mm or less in length, mold, rodent type hairs, and  
feather barbules.

Class 2: Generally discernible without microscopic examination, but requires careful organoleptic examination of the product for detection.

**Example:** Maggots, larvae, and insects less than 7mm in length, but more than 2mm.

Class 3: Readily discernible and/or highly objectionable from an aesthetic standpoint.

**Example:** Worms and large insects 7mm and larger in length, strands of hair, paper, excessive or coarse sand that seriously affects the eating quality.

Class 4: Readily discernible, highly objectionable, and potentially harmful.

**Example:** Machine grease, oil, stones, nails, glass, sharp metal slivers, sharp wood splinters, thorns, burrs (sharp/hard), puncture vine, barley barbs, and loose solder.

B. Flavor (See Table II)

Products found to contain an off flavor should be certified as follows:

1. Substandard

The product contains a definite off flavor, but is deemed fit for consumption.

**Example:** Fermented (winey), or musty.

2. Grade Not Certified (GNC)

The product is considered to be "out of condition" or otherwise deemed unfit for consumption.

**Example:** Putrid or flat sour.

C. Other Unsatisfactory Conditions

Poor handling and various other conditions occur that result in products being GNC but for which no defect action level (DAL) exists.

1. Visible Mold

**Example:** An appreciable growth of mold on the surface of a processed product, such as berries, indicative of the product being out of condition. Occasional moldy units are not considered in this category.

2. Live Infestation

**Example:** Presence of insects (worms) in dried fruit (not covered by other instructions).

Contact your supervisor when conditions such as these are found. FDA may not allow reconditioning of the product.

III. ACCEPTANCE CRITERIA

A. Foreign Material - Table I

When foreign material is found during examination of the product, the lot must meet the criteria in Table I for the different classes of foreign material.  
A U.S. grade cannot be assigned when a lot fails the criteria in Table I.

When more than one type of either class 3 or 4 foreign material is found in a sample unit, it is considered as only one deviant. When two different classes of foreign material are found, they are classified as two separate deviants. In examining additional product, and the (class 4) deviant is cleared, it is also permissible to clear the (class 3) deviant, **if no additional foreign material is found.**

Sample unit is defined as a container, and/or its entire contents, a portion of the contents of one or more containers, or a composite mixture of a product.

Sample is defined as the total number of sample units drawn from a lot.

**TABLE I - Acceptance Criteria (Foreign Material)**

CLASS	Acceptance Criteria	Deviants Allowed	Minimum No. Sample Units	Minimum Lbs. (Net Weight)
1	FDA-DALs (File Code 172-A-2) or PPB Guidelines (Attachment I). <u>2/</u>	0	<u>1/</u>	N/A
2	FDA-DAL's (File Code 172-A-2) or PPB Guidelines (Attachment I). <u>2/</u>	1	<u>1/</u> or 13 <u>3/</u>	N/A 26 lbs. <u>3/</u>
3	FDA-DAL's (File Code 172-A-2) or PPB Guidelines (Attachment I). <u>2/</u>	1	21 <u>4/</u>	42 lbs. <u>4/</u>
4	N/A	1	150 <u>5/</u>	300 lbs. <u>5/</u>

- 1/ Acceptance is based on sample average. When the initial sample units examined exceed the average defect action level or the PPB Guideline the lot fails unless **all** sample units are examined (at least 6 and no more than 21) and the average meets.
- 2/ If no FDA defect action level (172-A-2) or PPB Guideline (Attachment I, 172-A-1) exist, and foreign material is present, pass or fail on the number of deviants allowed, or consult your supervisor.
- 3/ Must examine a minimum of 13 sample units, which must include a minimum poundage of 26 pounds of product.
- 4/ Must examine a minimum of 21 sample units, which must include a minimum poundage of 42 pounds of product.
- 5/ Must examine a minimum of 150 sample units, which must include a minimum poundage of 300 pounds of product.

**NOTE:**        **The sample size for examination must meet the minimum number of sample units and minimum poundage shown to accept the lot.** For example, if the sample size is 13 and the net weight of the container is 12 ounces, then 35 containers must be drawn for examination.

B.     Flavor - Table II

The deviant rate for Substandard and GNC products account off flavor shall be in accordance with Table II.

**TABLE II - Acceptance Criteria (Off Flavor)**

Grade	Deviants Allowed	Minimum No. Sample Units
<u>Substandard Flavor</u> Scoreable Factor	Refer to deviant rate in File Code 109-A-1, Regulations	See applicable sampling plan in File Code 109-A-1.
<u>Substandard Flavor</u> Nonscoreable or Prerequisite Factor	1	21
<u>Grade Not Certified</u> Objectionable Flavor	1	48

IV. SAMPLING RATE 6/

The sample size for original examination for foreign material is based on the applicable lot or on-line sampling rate indicated in the Regulations (File Code 109-A-1). The sampling rates are only minimum rates and additional sample units may be examined.

A. Foreign Material - Classes 1 and 2

Visually examine each sample unit. In addition, analyze those products listed in Attachment I, and in File Code 172-A-2, for the defects(s) specified at the following rates:

1. Lot Inspection

**TABLE III**

When the number of sample units for quality determination is:	Number of sample units examined for class 1 and 2 is:
3	1
6	2
13	3
21	4
29	5
38	6

2. In-plant Inspection

A minimum of one analysis must be run on each lot, unless more than one lot can be examined at a common source.

6/ Specific instructions contain particular sampling rates. See the applicable file codes listed in File Code Section 135.

B. Foreign Material - Classes 3 and 4

Visually examine each sample unit.

For bulk containers exceeding ten (10) pounds net weight, examine approximately two pounds of product (sub-sample). On smaller containers, examine the entire contents.

C. Meeting Minimum Sample Unit and Poundage Criteria

Because of the low acceptance levels and limited number of original sample units examined, additional sample units may have to be examined to determine if the lot exceeds PPB guidelines or FDA unavoidable defect levels. The FV-16 "Hold For Re-examination" form is issued after the lot FAILS the minimum sample unit and minimum poundage acceptance criteria of Table I or Table II, as applicable.

**V. SEGREGATION - FAILING LOTS**

Inspectors should use good judgement in permitting segregation by subcode in a lot containing foreign material in excess of guides. Segregation can only be made on a lot that is separately identifiable. The low acceptance levels and limited number of sample units examined will not normally permit acceptance of remaining portions of a lot without re-inspection.

A. Class 1 and 2 Foreign Material

Examine additional sample units from the offending portion of the lot to raise the total to the number of sample units required by the single sampling plan, and if applicable, minimum poundage; and

Examine additional sample units from the remaining portion of the lot to raise the total to the number of sample units required by the single sampling plan, and if applicable, minimum poundage.

B. Class 3 Foreign Material

Examine additional sample units from the offending portion of the lot to raise the total to the number of sample units required by the single sampling plan (not less than 21 sample units and minimum poundage); and

Examine additional sample units from the remaining portion of the lot to raise the total number of sample units to (not less than 13 sample units and minimum poundage).

C. Class 4 Foreign Material

Examine additional sample units from the offending portion of the lot to raise the total number of sample units to 150 and minimum poundage; and

Examine additional sample units from the remaining portion of the lot to raise the total number of sample units to (not less than 48).

D. Flavor

Examine additional sample units from both offending and remaining portions to meet the total number of sample units required in Table II.

## SECTION II - CONTROL

### I. AGREEMENT WITH FOOD & DRUG ADMINISTRATION

The Memorandum of Understanding between AMS and the FDA requires that AMS report to FDA any product adulterated by foreign material that is found in the course of inspection and is not under control of AMS (see File Code 170-A-1, Implementation of Memorandum Agreement Between AMS and FDA). Handling and control procedures stated in File Code 170-A-1 are not applicable to the raisin inspection program in California.

## II. CONTROL

### A. Under AMS Control

Product is regarded as being "under AMS control" when the PPB inspector has specific knowledge that the **HOLD** lot is intact, can confirm the location of the **HOLD** lot, and is able to locate and identify the **HOLD** lot in storage.

Under in-plant and lot situations PPB inspectors must maintain some form of surveillance of any **HOLD** lot until such product is reconditioned to comply with FDA requirements and/or is acceptable for grade assignment; or is segregated and disposed of for nonfood use.

**NOTE: When the lot remains under AMS control, FDA is not notified.**

#### 1. Procedure

When foreign material or GNC (Grade Not Certified) flavor is found in the original sample in excess of PPB guidelines (Attachment I) or FDA defect action levels (File Code 172-A-2) the PPB inspector will notify the applicant verbally, and make arrangements with the applicant for re-examination, if desired, and complete the top part of Form FV-16.

Each **HOLD** lot must be conspicuously marked and distinguished from other lots as to code mark(s) and location when recording information on inspection documents, so that the lot may be easily found and identified.

When the applicant disposes of GNC product immediately, Form FV-16 is not issued, and inspection records are marked accordingly.

#### 2. Re-examination of Hold Lots Under AMS Control

Applicants have a number of options available, such as, segregation,

reworking, destruction, or disposal for non-food use under AMS supervision. The option taken should be reported to the PPB inspector within two weeks from the date shown on the FV-16 (adjacent to the inspector's signature).

When the applicant elects to have a re-examination after reworking or segregation, sample the lot in accordance with Branch instructions, re-inspect the product, and proceed as follows:

- a. If the product on **HOLD** meets, complete the "USDA Report Of Re-Examination" portion of the FV-16 to indicate product meets the applicable PPB guideline or FDA defect action level, date and sign. The lot is released from its "Hold" status and can be certified.
- b. If the product on **HOLD** fails, complete the bottom portion of the FV-16, informing the applicant of the options available. Lots that fail, would normally be destroyed or diverted to non-food use.

B. Not Under AMS Control

When confirmed that a **HOLD** lot is no longer under AMS control, the supervisor or inspector shall give verbal notice to the applicant of PPB's reporting responsibilities and issue applicable documents.

1. Procedure

Issue a GNC certificate and attach a letter similar to Attachment IV informing the applicant that the GNC lot will be reported to the FDA. Complete form FV-16-2, Notification to Food and Drug Administration (Attachment III). When signed by the supervisor and dated prepare sufficient copies and distribute in accordance with instructions in Section V., B.

#### IV. **COMPLETION AND MAINTENANCE OF FORMS**

A numerical filing system will be maintained for all FV-16 and FV-16-2 forms. Documents that relate to the same lot and hold numbers will be filed together. This shall include any documents concerning product disposed of for non-food use or which is

lawfully exported.

**V. DISTRIBUTION OF FORMS**

A. FV-16, Notice of Hold for Re-Examination, Attachment II

When product is placed on "HOLD," the PPB inspector will complete the top portion of the form, date and sign. Prepare sufficient copies and distribute as follows:

1. Original and one copy to the applicant (when signed and dated the original is returned to the inspector);
2. One copy for the area field office, and if applicable, a copy for the inspector's in-plant file;
3. One copy to the Regional office; and
4. One copy to the National office.

After re-examination of the product, the PPB inspector will complete the portion below the statement "USDA Report Of Re-examination" of the applicant's signed and dated FV-16. Prepare sufficient copies and distribute as follows:

1. Copy to the applicant;
2. One copy for the area field office, and if applicable, a copy for the inspector's in-plant file;
3. One copy to the Regional office; and
4. One copy to the National office.

B. FV-16-2, Notification to Food and Drug Administration, Attachment III

The PPB inspector will complete the form and forward the form to his/her supervisor for signature. When signed and dated prepare sufficient copies and distribute as follows:

1. Original to the FDA district office;
2. One copy to the applicant;
3. One copy for the area field office, and if applicable, a copy for the inspector's in-plant file;
4. One copy to the Regional office, and
5. One copy to the National office.

### **SECTION III - DEFECT ACTION LEVELS**

#### **I. FOOD AND DRUG ADMINISTRATION**

The FDA publication "Food Defect Action Levels," File Code 172-A-2, contains the action levels for natural or unavoidable defects that may be present in certain

processed fruits, vegetables, and related products that are for human use. These levels represent a specific number at which FDA will regard the food product as being adulterated and subject to enforcement action to guarantee contaminated product is removed from the market.

**II. PROCESSED PRODUCTS BRANCH GUIDELINES**

Guidelines have been established by the PPB (Attachment I) on certain defects that are not covered by an FDA action level. No U.S. grade will be assigned to a commodity that fails a PPB guideline.

**III. METHOD OF ANALYSES**

When a FDA defect action level (DAL) or an established PPB guideline is shown, review the applicable product manual or File Code 135 "Technical Inspection Procedures." Some products listed in File Code 172-A-2 show FDA's DAL's for analyses not routinely performed by PPB, and are not shown in our grading manuals or file codes. In these instances, inspectors should follow normal PPB procedures unless there is some reason to suspect adulteration. Methods of analysis referenced in File Code 172-A-2 are methods of the AOAC International (AOAC) and File Code 172-05 "FDA Technical Bulletin No. 5 - Macroanalytical Procedure Manual (MPM)." Inspectors should follow these methods and be guided by FDA DAL's when adulteration is suspected.

EXAMPLE: We do not routinely examine canned apricots for insect filth. However, if a visual examination of the apricots during grading shows evidence of insect contamination, inspectors should carry out analysis as specified in File Code 172-A-2, page 1 for canned apricots, which is MPM page v51.

NOTE: Irrespective of FDA unavoidable defects and PPB guidelines, product found to be unfit as food will be assigned Grade Not Certified (GNC) in lieu of a U.S. Grade.

**PROCESSED PRODUCTS BRANCH GUIDELINES**

PRODUCT	ANALYSES	DEFECT	PPB GUIDELINE

Beans, Green and Wax; Canned and Frozen	Visual	Worms	<p>Loose Worms: More than 1 worm (less than 20 mm in length) per 180 ounces drained weight. More than 2 worms per container or two pound sub-sample.</p> <p>Embedded Worms: More than 2 worms (less than 20 mm in length) per 180 ounces drained weight. More than 3 worms per container or two pound sub-sample.</p> <p>Combination - Loose and Embedded: More than 3 worms per 180 ounces drained weight of which no more than 2 may be loose worms per container or two pound sub-sample.</p>
Blueberries; Canned and Frozen	Visual and Sedimentation (BLACK PAN)	Maggots	Average 4 per 20 ounces-less than 7 mm.
Olives; Imported Green and Imported Black  (see 172-A-2 for other types)	Visual	Insect Damage (Maggots)	<p>Whole: An average of 5% or more by count with prominent tunneling including 1% with maggots.</p> <p>All Other Styles: 2 per 300 grams, average of 1 per 300 grams.</p>

PROCESSED RAISINS

Type of Foreign Material	Guide Accept (1)	Guide Reject (2)	Guide Avg. (3)	Column (1):
				If the first aliquot from the composite does not exceed guides in column (1), the sample unit MEETS established guides.
* 1. Striated Hairs	0	4	1.0	
2. Drosophila (Adult, Pupae and Larvae) <u>2/</u>	5	16	10.0	Column (2):
3. Insect Eggs <u>2/</u>	35	75	50.0	If any aliquot equals or exceeds guides in column (2), the composite FAILS established guides.
* 4. Feather Barbules and Barbs	5	16	10.0	Column (3):
Provided not more than: Barbs <u>1/</u>	5			The average of all three aliquots from the composite must not exceed column (3).
* 5. Insect Fragments	15	50	25.0	
* 6. Total Other Insects	5	16	10.0	<u>1/</u> Maximum per aliquot. If acceptance number is exceeded, sample fails.
Provided not more than: Saw Tooth Beetles <u>1/</u>	2			<u>2/</u> If sample unit exceeds FDA Defect Action Level, the inspection lot fails.
Dried Fruit Beetles <u>1/</u>	3			
Any other <u>single</u> insect species <u>1/</u>	5			* Processed Products Branch Guidelines
7. Sand and Grit <u>2/</u>			40 mg/100 grams	
8. Mold <u>2/</u>	5 percent by count			

Each Composite Sample Unit must stand on its own results. One to 3 aliquots of 8 ounces each are analyzed from each composite sample unit. A raisin gross composite sample unit is made up of equal amounts of raisins from different shipping cases. Several sample units may therefore make up a total sample (one or more composite samples) representing one lot. Results of 2 or more sample units may not be averaged and if one sample unit fails, the lot is reported as failing.



Attachment III

REPRODUCE LOCALLY, INCLUDE FORM NUMBER AND EDITION DATA ON ALL REPRODUCTIONS.

UNITED STATES DEPARTMENT OF AGRICULTURE  
 Agricultural Marketing Service  
 Fruit and Vegetable Division

TO: \_\_\_\_\_  
 FOOD AND DRUG ADMINISTRATION                      HOLD NUMBER

\_\_\_\_\_  
 ADDRESS (INCLUDE NUMBER, STREET,  
 CITY, STATE, AND ZIP CODE):

TELEPHONE NUMBER
------------------

PRODUCT	QUANTITY
LABEL	
CODE MARK(S)	
WAREHOUSE LOCATION	
This is to confirm our telephone report of _____, informing you that the lot above has been found by AMS, Processed Products Branch, to be Grade Not Certified Account _____.	
REMARKS	
OFFICER-IN-CHARGE, Processed Products Branch, FV, AMS	DATE
ADDRESS (Include Number, Street, City, State, and Zip Code):	TELEPHONE NUMBER (Include Area Code)
	FAX NUMBER (Include Area Code)

United States	Agriculture	Fruit and	Processed Products Branch
Department of	Marketing	Vegetable	742 E. Fond du Lac Street
Agriculture	Service	Division	Ripon, WI 54971-9555

Mr. James Smith  
Plant Manager  
Roger's Canning Company  
666 East Main Street  
Loop, Iowa 56001

Dear Mr. Smith:

Attached is Certificate No. Y-XXXXXX, that covers 400 cases, 6/No. 10 cans of whole kernel corn that was graded Grade Not Certified on June 3, 1996, account the presence of worms. This lot is designated as Hold Number RIP-002-96, on form FV-16, Notice For Hold For Re-examination. Under the Memorandum of Agreement with the Food and Drug Administration (FDA), the Processed Products Branch is required to report to the local FDA field office any GNC lot which is no longer under control of the inspection service. Since the subject lot has been shipped, the FDA will be notified.

The notification to FDA form is being prepared. You will be provided with a copy when it is completed. If you have any questions regarding this matter, please contact the area Officer-in-Charge.

Sincerely,

Alfred Bay, Inspector  
Processed Products Branch  
Fruit and Vegetable Division

cc: Officer-in-Charge  
Regional Director