Foreign Material Manual

United States Department of Agriculture

Marketing and Regulatory Programs

Agricultural Marketing Service

Fruit and Vegetable Programs

Processed Products Branch

AIM Instructional System

Inspection Series

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Foreign Material Manual
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INTRODUCTION

This manual is designed for Processed Products Branch (PPB) employees of the U.S. Department of Agriculture (USDA). Its purpose is to assist in the uniform evaluation of foreign material in processed fruit and vegetable commodities. This involves application of Food and Drug (FDA) guidelines and procedures, which form an integral part of Branch services. If needed, contact your immediate supervisor for any situation not addressed in this manual.

This manual contains links to various internal and external sources of information. For inspection personnel without internet or intranet access, please contact your immediate supervisor to obtain hard copies of documents as needed.

GUIDE FOR ELECTRONIC USAGE

The Administrative, Inspection, and Management (AIM) System of instructional manuals is available electronically in Adobe Acrobat Portable Document Format (PDF) at the following intranet address: http://agnis/sites/FV/PPB/default.aspx.

When accessed electronically, AIM materials have hyperlinks and hypertext (visible as underlined blue text) available to the PDF user. Clicking on a hyperlink takes the reader to a web site with information relating to the subject. Hypertext will link the reader to a different page within the current manual - or even a different manual - with information relating to the subject. For example, the hypertext in the Table of Contents allows a reader to go directly to the section of interest in the manual by clicking on the section title within the Table of Contents.

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FDA AND PPB GUIDELINES

Title 21, Code of Federal Regulations (CFR), Part 110.110 which may be found at the following internet address: http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1 allows the Food and Drug Administration (FDA) to establish maximum levels of natural or unavoidable defects in foods for human use that present no inherent hazards to health.

The FDA publication "Defect Levels Handbook – The Food Defect Action Levels," contains the action levels for natural or unavoidable defects that may be present in certain processed fruits, vegetables, and related products intended for human use. This publication may also be found on the FDA website at the following internet address: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Sanitation/ucm056174.htm.

Poor manufacturing practices and/or products that are harmful to consumers may result in enforcement or regulatory action without regard to the end product defect level. Likewise, the mixing or blending of food with a defect at or above the current defect action level with another lot of the same or another food is not permitted. Such a practice would render the final food unlawful regardless of the defect level of the finished food.

FDA has set a defect action level (DAL) for certain defects 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. The DAL represents a specific number at which FDA will regard the food product as being adulterated and subject to enforcement action to ensure that contaminated product does not reach the consumer.

Classification and Segregation

The limits established for foreign material in this guide are based upon the nature of the material, the impact upon the consumer, the capability of the industry to remove such material under good (acceptable) commercial practices, and the possible harmful effect of such material. The FDA recognizes that three factors must be taken into account in evaluating the presence of an adulterant in food:

1. Significance to public health;
2. Origin (e.g., field pest vs. stored product pest); and
3. Concentration (how many or how much was found in a known amount of food).

Products that are not covered by the FDA DALs that contain foreign material are subject to regulatory action if a lot fails the criteria in Table I, and it is not maintained under Agricultural

Marketing Service (AMS) control. For products with foreign material which poses no inherent hazard to health, use Classes 1, 2, and 3 in Table I. For products containing harmful material, use Class 4 and Grade Not Certified (GNC) in Table I

PPB Guidelines

Guidelines have been established by PPB for certain defects that are not covered by an FDA DAL, and the table is shown on page 12 (PPB Guideline). No U.S. grade will be assigned to a commodity that fails a PPB guideline. Additionally, all items bearing ”Official Marks” as described in the regulations must be examined for wholesomeness according to the applicable table in this instruction. Honey and maple syrup are exempt from this requirement.

Methods of Analysis

When an FDA DAL or an established PPB Guideline exists, review the applicable product grading manual or the AIM Inspection Series, Technical Procedures Manual. Some products listed in this Foreign Material manual show FDA DALs for analyses not routinely performed by PPB, and not covered in PPB grading manuals or the AIM Inspection Series instructional manuals. In these instances, inspectors should follow normal PPB procedures unless there is some reason to suspect adulteration. Methods of analysis referenced in this manual include methods of the Association of Official Analytical Chemists International (AOAC) and the "FDA Technical Bulletin No. 5 - Macroanalytical Procedure Manual (MPM)." This FDA manual may be found on the FDA internet site at the following address: http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/MacroanalyticalProceduresManualMPM/default.htm. Inspectors should follow the methods referenced in this manual and be guided by FDA DALs when adulteration is suspected.

Example: PPB does 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 the MPM, procedure V51 and determine compliance with the FDA DAL for canned apricots contained in the FDA Defect Levels Handbook.

Note: **Regardless of FDA DAL and PPB guidelines, product found to be unfit as food will be assigned GNC in lieu of a U.S. grade.**

Classification

Foreign material is not limited to the examples shown below for each class, nor are the examples necessarily limited to that class. **Classify foreign material according to the <u>description</u> of each class.**

A. <u>Foreign Material</u>

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

Class 1: Not readily discernible in the product, visually or organoleptically, and generally requires microscopic examination for detection.

Examples: Fly eggs, maggots, worms, larvae, insects and insect fragments, or other material 2 mm or less in length; mold, hairs (any), feather barbules, and barbs.

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

Examples: Maggots, larvae, worms, insects, or other material more than 2 mm, but less than 7 mm in length.

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

Examples: Larvae, worms and large insects 7 mm and larger in length, paper, excessive or coarse sand that seriously affects the eating quality.

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

Examples: Machine (non-petroleum based) grease, stones, metal machine parts (nuts, bolts), belting material, paint chips, rubber gloves, or any other protective equipment.

GNC: Readily discernible, highly objectionable, harmful, unfit for consumption, and/or exceeds tolerances in Table I.

Examples: Matter contributed by insects, rodents, and birds. Animal excreta, animal parts, or whole animals such as, but not limited to mice, snakes, houseflies,

cockroaches, frogs, or parts thereof. Sharp objects that are potentially harmful or may cause injury. Nails, glass, sharp metal slivers or filings, hard or sharp plastic, wood splinters, thorns, burrs, puncture vines, and barley barbs. Petroleum based products such as diesel fuel, gasoline, or motor oil.

B. Other Unsatisfactory Conditions

Poor handling and various other conditions occur that result in products being **GNC** but for which no DAL or PPB Guideline exists. The following are two examples:

1. Visible Mold

Example: An appreciable growth of mold on the surface of a processed product, such as berries, is 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, or larvae 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.

C. Off 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 human consumption.

Example: Fermented (winey), or musty.

2. GNC

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

Example: Putrid or flat sour.

Acceptance Criteria

A "sample unit" is defined as either a container and its entire contents; a portion of the contents of one or more containers; or a composite mixture of a product. A "sample" is defined as the total number of sample units drawn from a lot.

A. Foreign Material

1. **If an FDA DAL or PPB Guideline exists for the product and type of foreign material found:**

   Base acceptance according to the DALs or PPB Guidelines **based on the average** of all sample units examined, or a predetermined amount of sample. The DAL represents limits at which FDA will regard the food product as "adulterated" and subject to enforcement action under the Food, Drug, and Cosmetics Act. When the initial sample units examined for foreign material exceed the DAL or the PPB Guideline, the lot is considered adulterated, and fails.

2. **Samples not Officially drawn by USDA:**

   Any FDA DAL or PPB Guideline applicable to officially drawn sample units shall also be applied to sample units submitted by an applicant. **Since sample units submitted by an applicant do not officially represent any lot, lot acceptance criteria based on officially drawn samples shall not apply.** If foreign material is found in sample units not officially drawn by USDA, the sample units fail.

   Notify the applicant of the finding of foreign material. The applicant has an obligation to report the incident through the FDA Reportable Food Registry when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals. **Notify the FDA district office** where the product is located. Request guidance from your supervisor whenever this occurs.

3. **If no FDA DAL or PPB Guideline exists for the product and type of foreign material found, use Table I.**

   A lot in which foreign material is found during examination of the product is considered failing until all sample units are examined for foreign material. To qualify for a grade, the lot must be examined for the different classes of foreign material in accordance with criteria in Table I. Failure to meet these criteria will result in the product being GNC, and no U.S. grade can be assigned to the lot.

For example, the acceptance criteria for class 3 foreign material is 1 in 21 samples/42 lbs. If two class 3 worms were found in a 21 sample lot, the lot would fail on foreign material.

If different classes of foreign material are found in a sample unit, they are classified as separate deviants. When additional samples are examined in accordance with Table I and no additional foreign material is found, the deviant in the less severe class is generally cleared if the deviant in the more severe class is cleared.

For example, in a 13 sample lot, you find one 8 mm worm (class 3), and one machine bolt (class 4). Additional samples are pulled to meet the most severe deviant involved - in this case, the class 4 deviant (1 in 150 samples/300 lbs.).

In these additional samples, two class 3 and zero class 4 deviants are found, bringing the lot total to 3 class 3 and 1 class 4 deviants. The class 4 deviant meets the 1 out of 150 samples/300 lbs. rate shown in Table I. The class 3 acceptance rate is expressed as 1 out of 21 samples/42 lbs. Considerably more product than this was actually examined, so the allowable deviant number is adjusted accordingly. To do so, divide the number of samples and pounds examined by the corresponding numbers shown in Table I. In this case:

$$\frac{150 \text{ samples}}{21 \text{ samples}} \quad \text{or} \quad \frac{300 \text{ lbs.}}{42 \text{ lbs.}} = \mathbf{7.14} \text{ (round to } \mathbf{7}\text{)}$$

So when examined at the class 4 rate of 150 samples/300 lbs., **up to seven** class 3 deviants would be allowable. In this case, a total of 3 class 3 deviants and 1 class 4 deviant were found in the lot, therefore it MEETS criteria for both class 3 and class 4 foreign material.

TABLE I - Acceptance Criteria - Foreign Material (No FDA or PPB Guidelines)

CLASS	Acceptance Criteria	Deviants Allowed	Minimum # Sample Units	Minimum lbs. (net wt.)
1	No FDA-DAL or PPB Guideline	**See below**	6	N/A
2	No FDA-DAL or PPB Guideline	1	13	26 lbs.
3	No FDA-DAL or PPB Guideline	1	21	42 lbs.
4	N/A	1	150	300 lbs.
GNC	**None – no deviants or acceptance criteria**	0	N/A	N/A

For Class 1, examine a minimum of 6 sample units and apply the following limits. If you have questions about tolerances for Class I foreign material, consult your supervisor.

Fly eggs, maggots, worms, larvae, insects and insect fragments 2 mm or less:

In readily separable products, the lot fails if the average is greater than 25.0 units in 100 grams **(an average of 25.1 in 100 grams would FAIL**).

In comminuted, fluid, or homogeneous product, the lot fails if the average is greater than 5.0 units in 250 ml, or if one individual subsample exceeds 5.0 in 250 ml.

Hairs and/or feather barbules/barbs:

Less than 7 mm, product fails if 4 or more are found in 2 or more samples, or if the average number of hairs found in 6 samples is greater than 2.0 in 100 grams.

7 mm or longer, product fails if **any** are found in 2 of 6 subsamples

Other foreign material 2 mm or less, or mold:

Use deviant and acceptance criteria for Class 2

Note: **The sample size for examination must meet the minimum number of sample units and minimum poundage shown in Table I to accept the lot.** For example, in class 2, if the sample size is 13, and the container net weight is 12 ounces, additional samples must be drawn to meet the minimum of 26 lbs. This example would require that a total of 35 containers be examined for class 2 material.

26 lbs. = 416 oz; 1 sample unit = 12 oz. 416 ÷ 12 = 34.67 or **35** containers

B. Off 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
When Substandard Flavor is found, and Flavor is a Scoreable Factor:	Refer to acceptance number in the AIM Inspection Series, Sampling Manual, and the Regulations	See applicable sampling plan in the AIM Inspection Series, Sampling Manual.
When Substandard Flavor is found, and Flavor is a Non-scoreable or a Prerequisite Factor:	1	21
When Objectionable Flavor is found that would render the product Grade Not Certified:	1	48

Sampling Rates

The sample size for examination for foreign material is based on the applicable lot or on-line sampling rate indicated in the Regulations, and the AIM Inspection Series, Sampling Manual. The sampling rates are only minimum rates; additional sample units may be examined.

Under 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. Instructions may contain specific sampling rates. See the applicable instructions listed in the AIM Inspection Series, Sampling Manual

A. Foreign Material - Classes 1 and 2

For products listed in the PPB Guideline or FDA DAL, examine for class 1 and 2 material according to Table III.

If the product does not have a PPB Guideline or Food Defect Action Levels, visually examine every sample unit for class 1 and 2 material.

B. Foreign Material - Classes 3 and 4

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

TABLE III – Lot Inspection Sampling Rates

Number of quality samples	Number of samples examined for Classes 1 & 2*	Number of samples **visually examined** for Classes 3 & 4
3	1	3
6	2	6
13	3	13
21	4	21
29	5	29
38	6	38

*** Visually examine all samples** for Class 1 and 2 foreign material if there is no established FDA DAL or PPB Guideline for the product

C. Meeting Minimum Sample Unit and Poundage Criteria

If a lot fails inspection due to the presence of foreign material, and the product and defect is not covered by FDA DALs or PPB Guidelines, additional sample units may have to be examined to determine if the lot can be accepted.

The FV-16 "Hold for Re-examination" form is issued if/when a lot FAILS the minimum sample unit and minimum poundage acceptance criteria of Table I or Table II, as applicable.

Segregation - Failing Lots

Inspectors should use good judgment in permitting segregation by sub code in a lot containing foreign material which exceeds original inspection guidelines. 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.

Lot segregation procedures for:

A. Class 1 and 2 Foreign Material

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

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

B. Class 3 Foreign Material

Examine additional sample units from the offending portion of the lot to raise the total sample units drawn from the offending portion to the number of sample units required by the single sampling plan (not less than 21 sample units and minimum poundage from Table 1); and

Examine additional sample units from the remaining portion of the lot to raise the total sample units drawn from the remaining portion to the number of sample units required by the single sampling plan (not less than 13 sample units and minimum poundage from Table 1).

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 from Table 1; 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. Off Flavor

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

Established PPB Guidelines

The charts below summarize PPB Guidelines for Canned and Frozen Green and Wax Beans, Canned and Frozen Blueberries, Imported Olives and Processed Raisins.

PROCESSED PRODUCTS BRANCH FOREIGN MATERIAL GUIDELINES
(for certain products NOT covered by an FDA DAL)

PRODUCT	ANALYSIS	DEFECT	PPB GUIDELINE (compelling lot failure)
Beans, Green and Wax: Canned and Frozen	Visual	Worms	Loose Worms (less than 20 mm in length): More than 1 worm per 180 ounces drained weight. More than 2 worms per container or two pound sub-sample. Embedded Worms (less than 20 mm in length): More than 2 worms per 180 ounces drained weight. More than 3 worms per container or two pound sub-sample. 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.
Blueberries; Canned and Frozen	Visual and Sedimentation (Black pan)	Maggots	Maggots (less than 7 mm): Average 4 per 20 ounces.
Olives; Imported Green and Imported Black (see Defect Level Handbook for other types of Olives)	Visual	Insect Damage (Maggots)	Whole Style: An average of 5% or more by count with prominent tunneling, including 1% with maggots. All Other Styles: 2 per 300 grams, average of 1 per 300 grams.

PROCESSED RAISINS

Type of Foreign Material	Column 1 Guide Accept	Column 2 Guide Reject	Column 3 Guide Average
* 1. Striated Hairs	0	4	1.0
2. Drosophila (Adult, Pupae and Larvae) 2/3/	5	16	10.0
3. Insect Eggs 2/3/	35	75	50.0
* 4. Feather Barbules and Barbs	5	16	10.0
Provided not more than: Barbs 1/	5		
* 5. Insect Fragments	15	50	25.0
* 6. Total Other Insects	5	16	10.0
Provided not more than: Saw Tooth Beetles 1/	2		
Dried Fruit Beetles 1/	3		
Any other single insect species 1/	5		
7. Sand and Grit 2/			Avg. of 40 mg or more per 100 g
8. Mold 2/	Avg. of 10 subsamples is 5 % or more by count		

Column 1:

If the first aliquot from the composite does not exceed guides in Column 1, the sample unit MEETS established guides.

Column 2:

If any aliquot equals or exceeds guides in Column 2, the composite FAILS established guides.

Column 3:

The average of all three aliquots from the composite must not exceed Column 3.

* Processed Products Branch Guidelines

1/ Maximum per aliquot. If acceptance number is exceeded, sample fails.
2/ If sample unit exceeds FDA Defect Action Level, the inspection lot fails.
3/ Golden Raisins.

Each Composite Sample Unit must stand on its own results. One to three aliquots of eight 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 two or more sample units may not be averaged, and if one sample unit fails, the lot is reported as failing.

RECORDING RESULTS

Record all types of infestation and contamination by size and number on Form FV-140, which may be found on the AMS Forms Catalog at the following intranet address: http://agnis/AMSFormsCatalog/Forms/AllItems.aspx. Complete the fields as applicable for the product being inspected. Examples of completed forms are shown below and on the following page.

FOREIGN MATERIAL RECORD — U.S. DEPARTMENT OF AGRICULTURE, AGRICULTURAL MARKETING SERVICE, FRUIT AND VEGETABLE PROGRAMS — **MOLD COUNT RECORD**

DATE *January 31, 2011* | CONT. NO./P.O. NO./LOT NO *011711.* | PRODUCT *Orange Juice from Concentrate* | OFFICIAL USDA INSPECTOR Matthew King *Matthew King*

METHOD OF ANALYSIS AND IDENTIFICATION: ☐ Gasoline extraction ☐ Water floatation ☐ Visual examination ☒ Wide field scope

ACCEPTANCE LEVEL: < 10%

FOREIGN MATERIAL	SAMPLE NO. OR CODE 1	7	13
FLY EGGS	0	0	0
MAGGOTS < 2 mm	0	0	0
> 2 mm	0	0	0
LARVAE < 2 mm	0	0	0
2 mm to 6 mm	0	0	0
> 6 mm (¼")	0	0	0
WEEVILS < 2 mm			
2 mm to 6 mm			
> 6 mm (¼")			
WHOLE INSECTS ( )	0	0	0
INSECT PARTS ( )	0	0	0
INSECT FRAGMENTS	0	0	0
APHIDS			
THRIPS			
MITES			
SPRINGTAILS			
LEAF MINERS < 2 mm			
2 mm to 6 mm			
> 6 mm (¼")			
RODENT PELLETS			
HAIR (type)			
Length to			
Length to			
PEBBLES			
Size to			
Size to			
MUD BALLS			
Size to			
Size to			
OTHER MATERIAL( )	0	0	0
Size to			

Sample No. or Code	Record by Fields	Acc.	Rej.
1	- - - - -		
	+ - - - -		
	- - - - -		
	- - - - -		
	- - - - -	✓	
	- - - - -		
	- - - - -		
2/50 = 4%	- - - + -		
	- - - - -		
7	- - - - -		
	- - - - -		
	- - - - -		
	- - - - -		
	- - - - -		
	- - - + -	✓	
	+ - - - -		
3/50 = 6%	- - - - -		
	- - - - +		
	- - - - -		
13	- - - - -		
	- - - + -		
	+ - - - -		
	- - - - -		
	- - - - -		
	- - - - -		
	- - - - -	✓	
2/50 = 4%	- - - - -		
	- - - - -		

Sample No. or Code	Record by Fields	Acc.	Rej.

FV-140 EXAMPLE

FOREIGN MATERIAL RECORD

U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
FRUIT AND VEGETABLE PROGRAMS

MOLD COUNT RECORD

DATE *January 31, 2011*	CONT. NO./P.O. NO./LOT NO *572185.*	PRODUCT *Frozen Broccoli - Spears*	OFFICIAL USDA INSPECTOR Matthew King *Matthew King*

METHOD OF ANALYSIS AND IDENTIFICATION
- ☐ Gasoline extraction
- ☐ Water floatation
- ☐ Visual examination
- ☒ Wide field scope

ACCEPTANCE LEVEL Average less than **60** aphids, thrips and/or mites per **100** grams

Sample No. or Code	Record by Fields	Acc.	Rej.	Sample No. or Code	Record by Fields	Acc.	Rej.
				N/A			

FOREIGN MATERIAL	SAMPLE NO. OR CODE 1	7	13	21			
FLY EGGS	0	0	0	0			
MAGGOTS < 2 mm	0	0	0	0			
> 2 mm	0	0	0	0			
LARVAE < 2 mm	0	0	0	0			
2 mm to 6 mm	0	0	0	0			
> 6 mm (¼")	0	0	0	0			
WEEVILS < 2 mm	0	0	0	0			
2 mm to 6 mm	0	0	0	0			
> 6 mm (¼")	0	0	0	0			
WHOLE INSECTS ( )	0	0	0	0			
INSECT PARTS ( )	0	0	0	0			
INSECT FRAGMENTS	0	0	0	0			
APHIDS	7	3	7	6			
THRIPS	2	3	4	3			
MITES	0	0	0	0			
SPRINGTAILS	0	0	0	0			
LEAF MINERS < 2 mm	0	0	0	0			
2 mm to 6 mm	0	0	0	0			
> 6 mm (¼")	0	0	0	0			
RODENT PELLETS	0	0	0	0			
HAIR (type)	0	0	0	0			
Length to	0	0	0	0			
Length to	0	0	0	0			
PEBBLES	0	0	0	0			
Size to	0	0	0	0			
Size to	0	0	0	0			
MUD BALLS	0	0	0	0			
Size to	0	0	0	0			
Size to	0	0	0	0			
OTHER MATERIAL( ) Size to	0	0	0	0			

FV-140 EXAMPLE

AGREEMENT WITH FOOD & DRUG ADMINISTRATION

The Memorandum of Understanding between AMS and FDA requires that AMS report to FDA any product found to be adulterated by foreign material that is not under control of AMS. See the Memorandum Agreement between AMS and FDA, MOU 225-72-2009 at the following internet address: http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs).

Additional information on handling and control procedures is available on the AIM Management site on AGNIS under Regulations/MOU.

Control

A. Under AMS Control

Product is considered "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 flavor is in excess of PPB Guidelines or at or above FDA DALs is found in the original sample, the PPB inspector will notify the applicant verbally, and place the lot on **HOLD**. The inspector will make arrangements with the applicant for re-examination, if desired, and complete the top part of Form FV-16, (which may be found on the AMS Forms Catalog at the following intranet address: http://agnis/AMSFormsCatalog/Forms/AllItems.aspx.

Each **HOLD** lot must be conspicuously marked and distinguished from other lots by code mark(s) and location when recording information on inspection documents so that the lot may be easily found and identified. At this stage the lot is considered GNC.

When the applicant disposes of such 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, including this manual, 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 the 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 are normally destroyed or diverted to non-food use.

B. Not under AMS Control

When it has been confirmed that a **HOLD** lot is no longer under AMS control, the supervisor or inspector shall notify the applicant verbally of PPB's reporting responsibilities and issue applicable documents.

Procedure: Issue a GNC certificate and attach a letter similar to the one shown here informing the applicant that the GNC lot will be reported to the FDA. Complete form FV-16-2, Notification to Food and Drug Administration. After the FV-16-2 has been dated and signed by the supervisor, prepare copies and distribute in accordance with instructions.

All imports (including 8e) which fail the tolerances in Table I, PPB Guidelines, or FDA defect action level are considered as **Not under AMS Control.** Do not complete and distribute form FV-16 or FV-16-2. Forward a copy of the failing certificate directly to the local FDA district office.

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.

Distribution of Forms

A. FV-16, Notice for Hold for Re-Examination

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

1. Original and one copy to the applicant. When signed and dated by the applicant, 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" on the applicant's signed and dated FV-16. Prepare copies and distribute as follows:

1. Copy to the applicant;

1. One copy for the area field office, and if applicable, a copy for the inspector's in-plant file;

2. One copy to the Regional office; and

4. One copy to the National office.

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

The PPB inspector will complete and forward the form to his/her supervisor for signature. After the form is signed and dated, the PPB inspector will 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.

REPRODUCE LOCALLY *Include form number and edition data on all reproductions.* **OMB XXXXXXXX**

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

NOTICE FOR HOLD FOR RE-EXAMINATION

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is XXXX-XXXX. The time required to complete this information collection is estimated to average X minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or part of an individual's income is derived from any public assistance program. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD). To file a complaint of discrimination, write to USDA, Director, Office of Civil Rights, 1400 Independence Avenue, S.W., Washington, D.C. 20260-9410, or call (800) 795-3272 (voice) or (202) 720-6382 (TDD). USDA is an equal opportunity provider and employer.

Applicant _____ Hold Number _____

Address (Include Number, Street, City, State, and Zip Code) _____

	QUANTITY	CODE MARK(S)
LABEL		WAREHOUSE LOCATION

REASON FOR HOLD

We require that the above lot not be shipped pending further examination. The code mark(s) have been marked "hold" on inspection records pending further action. Control of this product must be maintained. If the product with the above code mark(s) is shipped prior to re-examination or prior to corrective action taken under USDA observation, it will be necessary to notify the Food and Drug Administration.

DATE	USDA INSPECTOR (Signature)

Mark an "X" in the block that indicates the course of action that will be taken. Sign, date, and return a copy to the inspection or to the USDA office address by _____.

- ☐ **Re-examination of code mark(s)**
- ☐ **Re-examination after segregation**
- ☐ **Re-examination after reworking**
- ☐ **Dispose for nonfood use**
- ☐ **Other action (specify)** _____

DATE	PLANT OFFICIAL (Title and Signature)

USDA REPORT OF RE-EXAMINATION

We have completed the re-examination of the above merchandise. Re-examination results indicate the product is _____.

DATE	USDA INSPECTOR (Signature)

Control must be maintained on Grade Not Certified (GNC) products in order to preclude reporting to the Food and Drug Administration. On GNC product, please indicate the appropriate steps that will be taken. Sign, date, and return a copy to the inspector or to the USDA office address by _____.

APPLICANT - Complete by marking an "X" in appropriate block(s) and return: ☐ **SEGREGATION** ☐ **RECONDITIONING**

☐ **DISPOSAL of (product) by** _____ ☐ **OTHER ACTION (Specify)**

DATE	PLANT OFFICIAL (Title and Signature)

FV-16 (X-XX) (Previous editions are to be destroyed)

EXAMPLE

UNITED STATES OF DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
FRUIT AND VEGETABLE PROGRAMS
PROCESSED PRODUCTS BRANCH

NOTIFICATION TO FOOD AND DRUG ADMINISTRATION

TO: _____ _____
FOOD AND DRUG ADMINISTRATION HOLD NUMBER

_____
ADDRESS (INCLUDE NUMBER, STREET, CITY, STATE AND ZIP CODE)

_____

TELEPHONE NUMBER: _____

PRODUCT	QUANTITY

LABEL

CODE MARKS

_____
WAREHOUSE LOCATION

This is to confirm our telephone report of _____, informing you that the above lot 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)

FV-16-2 EXAMPLE

EXAMPLE

Sample Letter informing Applicant of FDA notification after lot failure

USE CURRENT LETTERHEAD LOGO AND FORMAT

Mr. James Smith
Plant Manager
Roger's Canning Company
417 East Main Street
Charles, 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 January 31, 2011, account presence of worms. This lot is designated as Hold Number RIP-002-11, 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.

We are preparing the form for notifying FDA. We will provide you with a copy when it is completed. If you have any questions regarding this matter, please contact the area Officer-in-Charge.

Sincerely,

Zachery Conner, Inspector
Processed Products Branch
Fruit and Vegetable Programs

CC: Officer-in-Charge
Regional Director

DROSOPHILA EGG AND LARVA DETERMINATION – TOMATO PRODUCTS

Canned tomatoes and tomato products are susceptible to contamination by eggs and maggots of the Drosophila fly (fruit fly). The extraction method described in these instructions is used to determine the extent of fly egg and larvae infestation in these products.

Counting and Recording Infestation

The extraction method results in a clear separation of the tomato component on top, and any fly eggs and larvae present on the bottom. These are then drained into a beaker. This material is filtered, and the filter papers examined for the presence of eggs and maggots using a 20x to 30x wide-field microscope. An optional 60x lens should be available for verification. Inspectors must use a teasing needle to probe any large pieces of product that may conceal eggs or larvae.

Use Form FV-140 to record results. The form may be found on the AMS Forms Catalog at the following intranet address: http://agnis/AMSFormsCatalog/Forms/AllItems.aspx

Sampling Rate/Frequency

A. Lot inspection

1. Domestic - Examine at the rate of one analysis per inspection lot.

   If any eggs or larva are found, examine the lot at the rate indicated in Table III of this Manual

2. Imported - Examine at the rate indicated in Table III of this Manual

B. On Line Inspection

Examine at the rate of one analysis every 24 hours, for each product. A common source beyond which no further product contamination can occur may be used.

If any eggs or larva are found, examine at the rate of one analysis every 8 hours, with a minimum of one analysis for each shift or period, on each lot.

Return to the lower rate when no eggs or larva have been found for the past 24 hours of production.

If any other foreign material is found, consult your supervisor.

C. Special Agreement Lot Inspection

With the approval of the regional director, the on-line sampling rate may be used for egg and larva determination of products covered by Special Agreement Lot

Inspection Service. These types of agreements provide for inspection of all products of a single type or can size. The applicant establishes a history of production reliability through a series of continuous inspection lots. This history forms a basis for granting the on-line rate.

Sample Size

Use the amount of sample for drosophila egg and larva counting as shown in the following table.

Product 4/	Canned Tomatoes, any style	Tomato Juice	Conc. Tomato Juice	Tomato Sauce	
Sample Size	500 g 1/	100 g 2/			
Product 4/	Tomato Puree	Tomato Paste	Tomato Catsup 3/	Chili Sauce	Pizza Sauce
Sample Size	100 g 2/				

1/ Multiples of 100 g may be used. From cumulative results, determine the average number of eggs and larva for each 500 g increment.

2/ If the filtered trapping contains excessive pulp the amount of product may be reduced to 75 g, or 25 g. Calculate and record the equivalent number of eggs and larva per 100 g of product.

3/ Egg and larva determination are not routinely performed on Tomato Catsup, unless requested by the applicant.

4/ See additional special procedures in this manual as applicable.

At the discretion of the inspector in an in-plant inspection situation, the point of sampling for egg and larva may be a common source (single product or multiple products), or warehouse sample (tomatoes and "associated" drained packing medium from individual containers). If a common source sample exceeds the defect action level, all affected products must be held until the extent of contamination is determined by individually sampling the finished products.

A. Preparation

1. Canned Tomatoes (any packing medium), Stewed Tomatoes, Tomatoes and Okra, and Other Similar Products:

Use 500 g. Multiples of 100 g may be used. From cumulative results, determine the average number of eggs and larva for each 500 g increment.

a. Place a large funnel into a large container, such as an empty No. 10 can. Rest an 8-mesh sieve inside the cone of the funnel.

b. Place the 500 g aliquot (tomatoes and "associated" packing medium) on the sieve.

c. Rinse the container that was used to transfer the aliquot to the funnel. Add the rinse water to the funnel.

d. Wash the tomatoes with a fine spray of warm water (approximately 125 degrees F). Use as little water as possible.

e. Repeat and completely wash all material on the screen.

Use the procedure outlined under "Method of Extraction" on the following page.

If the volume of washings and juice is ½ to ¾ the volume of a No. 10 can, one separatory funnel is probably sufficient to make a good, clean separation of pulpy material in the juice. If the washing and juice volume exceeds this amount, or if multiples of 500 g aliquots are used, more than one separatory funnel may be needed.

Note: Select the 500 g aliquot and add washings to it. Do not select the 500 g aliquot from diluted packing medium.

2. All Products Other Than Canned Tomatoes and Other Similar Products.

Use 100 g of product without dilution. If the filtered trapping contains excessive pulp, the amount of product may be reduced to 75 g, or 25 g. Calculate and record the equivalent number of eggs and larva per 100 g of product.

For pizza sauce and chili sauce, wash the aliquot with warm water (approximately 125 degrees F) through a 10-mesh sieve, using the funnel and large container as above. Transfer the residue left on the screen to a black bottom pan and examine for the presence of larva. See the Macroscopic Examination section of this manual for guidance on this

procedure. The drained portion is transferred to a separatory funnel for extraction.

Note: Unless requested by the applicant, egg and larva determination are not routinely performed on Tomato Catsup.

Preparation of Pectolytic Enzyme Solution

1. Prepare the solution fresh daily.

2. Add 1 level teaspoon of pectolytic enzyme (Pectinol AC) for every 300 ml of warm water (approximately 125 degrees F). Stir well for 2 minutes.

3. Let settle. Pour off the clear solution and discard the sediment.

4. Optionally, use 0.5 g of potassium oxalate in the above solution to break up gelation of material in the separatory funnel.

Method of Extraction

1. Wash the sample into the separatory funnel. Rinse the transfer container.

2. Add about 15 ml of pectolytic enzyme solution, shake, and let stand 15 minutes or longer.

3. Add about 30 ml of white gasoline. Stopper, invert with the stem up (and not pointing at anyone), and immediately open the stopcock to release excess pressure. Close the stopcock and briefly shake the separatory funnel. Invert the funnel and release excess pressure through the stopcock again. Repeat until only a small amount of pressure is released when vented. Hold the funnel horizontally (stopcock closed) and shake vigorously for one minute. Invert and open the stopper to release pressure as necessary; <u>be sure to close the stopper before resuming shaking</u>.

CAUTION: White gasoline should be stored in a safety can, and appropriate safe handling measures should be observed.

4. Add warm water (125 degrees F) and bring the level of the contents to the wide portion of the funnel. Swirl and invert the funnel several times.

5. Let stand 15 minutes or longer, and drain about 20 ml into a 400 ml beaker.

6. Filter the trapped liquid in the 400 ml beaker through black 10XX bolting cloth (or alternate filter cloth that provides equivalent results) or ruled (if

available) black filter paper with vacuum (aspirator or vacuum pump).

7. Examine the bolting cloth or filter paper under 20X magnification.

8. If no eggs or larva are found at this point, the sample is considered negative and can be discarded.

9. If one or more egg or larva are found, repeat swirling, standing for 15 minutes, and draining 2 more times. The last time, remove about 200 ml of the bottom liquid for a total of approximately 240 ml).

10. Filter and examine, compare results with the tolerance in this Manual.

LIGHT FILTH

The term "light filth" refers to materials such as insects, insect fragments, and rodent hairs in processed fruit and vegetables. The two general methods of extraction described in these instructions are for determining the extent of aphid, thrip and similar insect infestation or other light filth that can be recovered in the upper layer or kerosene fraction of the Wildman trap flask.

Supervisors will guide inspectors in determining the method of analysis used for the particular type and style of product. Generally, the Wildman Method is the most effective on products that disintegrate on agitation or under strong spray, or products that are finely chopped. The Rapid Jar Method is effective on coarsely chopped products that do not tend to disintegrate upon agitation. To guide inspectors, supervisors will use specific commodity instructions to determine the sample rate for these extractions as well as the extent of permissible infestation.

Counting and Recording Infestation

Use Form FV-140 for recording results obtained from light filth examinations. This form may be found in the AMS Forms Catalog at the following intranet address: http://agnis/AMSFormsCatalog/Forms/AllItems.aspx. Record all types of infestation and contamination by size as well as by count.

A 20x to 30x wide-field microscope should be used to examine filter paper. An optional 60x lens should be available for verification. Inspectors must use a teasing needle to probe any large pieces of product that may conceal insect fragments or other filth.

Wildman Extraction Method

Equipment:

Wildman trap flask (2000 ml.) and plunger
50 and 100 ml. graduated cylinders
Buchner funnel (8 cm inside diameter) and screen
Filtering flask, heavy walled
Filter pump or vacuum pump
Ruled filter paper, 9 cm diameter
Petri dish
Stirring rods
Wash bottles
Sharp probe
Gram scale
20x-30x Wide-field microscope
250 and 400 ml beakers

Reagents:

Lead acetate solution – Dissolve 350 g Lead Acetate in approximately 850 ml. boiling water. Add Glacial Acetate Acid slowly until mixture becomes clear and stays clear; then add 5 additional ml.
Glacial Acetic Acid. Dilute w/water to 1 liter mark.

Kerosene, refined if available; if not use commercial Heptane
Deaerated water
Glycerin Solution (½ glycerin and ½ water)
Mineral Oil (for tomato products)

General Procedures:

A. Preparation of Sample

1. Thawed Frozen Products:

   Boil 200 g (7 oz) of proportional amounts of product and packing media for 30 minutes with 20 ml of lead acetate solution. Boil in a 1000 ml beaker or a 2000 ml Erlenmeyer flask with the plunger held up by a clothespin or similar clasp. To control foaming during heating of the sample, add a small amount of anti-foam agent.

2. Canned Products:

   As above, except boil for only 10 minutes.

Add additional water periodically while boiling to maintain a consistent level in the flask. Units of product may be chopped up or mashed while boiling or prior to this step.

Determine proportional amounts of products and packing media as follows:

$$\text{Weight of product ingredient} = \frac{\text{Drained Weight}}{\text{Net Weight}} \times 200 \text{ g}$$

Example:

Net weight of sample	- 106 ozs.
Drained weight of sample	- 70 ozs.
Required weight of material	- 200 g

$$\text{Product} = \frac{\text{dr. wt. (oz)}}{\text{net wt. (oz)}} \times (200)$$

$$= \frac{70}{106} \times (200)$$

$$= 132.08 \text{ g}$$

Therefore, a 200 gram proportionate subsample will require 132 g of product and 68 g of packing media.

B. Extraction of Prepared Sample

1. If an Erlenmeyer flask was not used for initial cooking, transfer cooled solution of product and water to a 2000 ml Erlenmeyer flask. Be careful to remove all product and packing media by thoroughly rinsing during the transfer. Add 5-10 drops of wetting agent.

2. Add 35 ml kerosene (or light mineral oil for tomato products). Tilt the flask at a 45 degree angle and move the plunger disc below the surface of the liquid. Mix with a plunger for two or three minutes, using short up and down strokes to drive the oil or kerosene down into the sample. Avoid beating in any air or churning the mixture. If this occurs, the emulsified oil and entrapped air can prevent a good oil/water separation, and cause vegetable material to rise to the oil level with the potential to be trapped off in the fraction for filtering. This would materially increase the time and effort required for filtering and searching the filter paper.

3. Add sufficient deaereated water to bring the solution level up to the neck of the flask. Water can be siphoned from a source into the flask through a tube introduced below the level of liquid in the flask, which will not introduce air bubbles into the flask.

4. Allow to stand for about 30 minutes.

5. Prior to trapping off the kerosene fraction, rotate the plunger slightly to produce a "swishing" action to clear any vegetative debris that may be floating at the interface of water and kerosene layers. This technique helps to disperse the concentration of material which tends to accumulate there. Without this step, the material may be trapped off in the fraction for filtering, and interfere with observing and identifying insect specimens.

6. After gently swishing away vegetative material, raise the plunger disc slowly into position below the oil level and pull it up tight. Wash the oil off the plunger rod into the flask with hot water from the wash bottle.

7. Decant the trapped oil layer into a beaker. Wash out the neck of the flask with hot water while the flask is held at a reclined angle over the beaker.

8. Return the flask to the upright position. Gently work the plunger disc loose with a stirring rod and lower into the flask.

9. Add 20 ml of kerosene and mix with plunger as above. Add enough water to bring the level up to the neck of the flask. Let stand 10 minutes. Decant again into the same beaker.

10. Filter the trapped off oil-water solution using a Buchner funnel lined with ruled filter paper. If the solution contains too much material to produce fairly clean filter papers, re-extract as above with a clean Wildman Trap Flask.

11. Place filter paper in Petri dish and add several drops of glycerin to prevent dehydration. Additional drops may be placed on filter paper as needed.

12. Using 20x to 30x wide-field scope and adequate light, search paper and count insects and other filth. Use a teasing needle to separate any large pieces of material on the filter paper for positive identification.

13. Verify suspect particles by 60x or higher magnification. This step may be particularly necessary to identify nymph thrips, which are practically transparent except for dark or red eyes.

As needed, consult entomological references such as the FDA Training Manual for Analytical Entomology in the Food Industry, and Microscopic-Analytical Methods in Food and Drug Control to assist in identifying small insects and other infestations. Record all types of infestation and contamination by size as well as by number on Form FV-140, found on the AMS Forms Catalog at the following intranet address: http://agnis/AMSFormsCatalog/Forms/AllItems.aspx).

Wildman Extraction for Canned and Frozen Berries

Cane berries (raspberries, blackberries, loganberries, boysenberries, etc.), are subject to various types of infestation, including thrip, ants, stink bugs, mites, larvae of various types, orange tortrix and raspberry worm. Some types of infestation are of such size and character as to be readily observed by visual examination of the product. However, infestations such as thrip are too small to be identified and counted by macroscopic (visual) examination, and insects may be imbedded in the drupelets of the berry. Insects must therefore be extracted and examined by microanalytical methods (Wildman Extraction) to estimate any light filth present.

Procedure for Canned and Frozen Berries

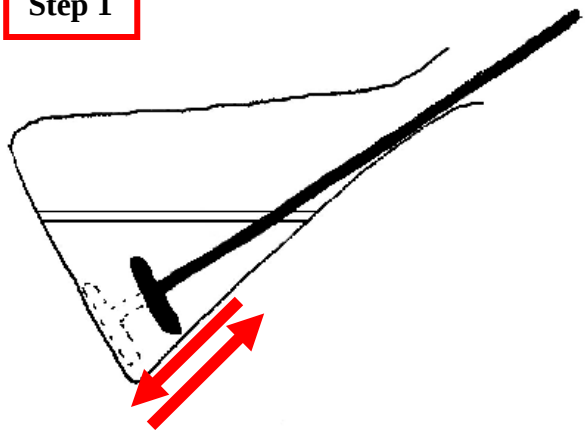
Proceed with Wildman Extraction Method, Preparation of Sample and Extraction of Prepared Sample as above, EXCEPT add an additional extraction step after Step 9 as follows.

Gently work the plunger disc loose with a stirring rod and lower into the flask. Stir vigorously for approximately 30 seconds, and allow to stand 10 minutes with an occasional gentle stir. Trap off any additional kerosene which may have risen, and decant to the same 250 ml beaker, washing neck of flask thoroughly. Follow with extraction Steps 10-13 as referenced above.

Do not rush the process. The times shown in all of the steps are the minimum needed for good results. Small drupelet berries such as loganberries can take a few minutes less boiling time than large drupelet berries, such as boysenberries. However it is unwise to reduce the boiling time since this is the step that releases the insects from the berries, allowing for adequate separation
.

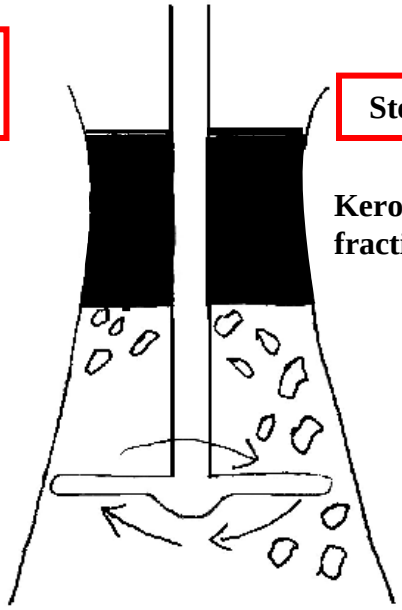
Steps in Wildman Trap Extraction

Step 1



Step 3

Kerosene fraction



<u>Step 1 - mix kerosene with sample:</u>
Using short strokes, thoroughly mix kerosene with sample. Avoid a "churning" or "thrashing" action that will emulsify the mixture or incorporate air with the sample

<u>Step 3 - eliminate excess extraneous matter in trapping off kerosene fraction:</u>
Gradually raise plunger to neck of flask. As rubber stopper on plunger approaches kerosene fraction, carefully rotate plunger to make a circular "swishing" action that will clear debris without agitating kerosene layer.

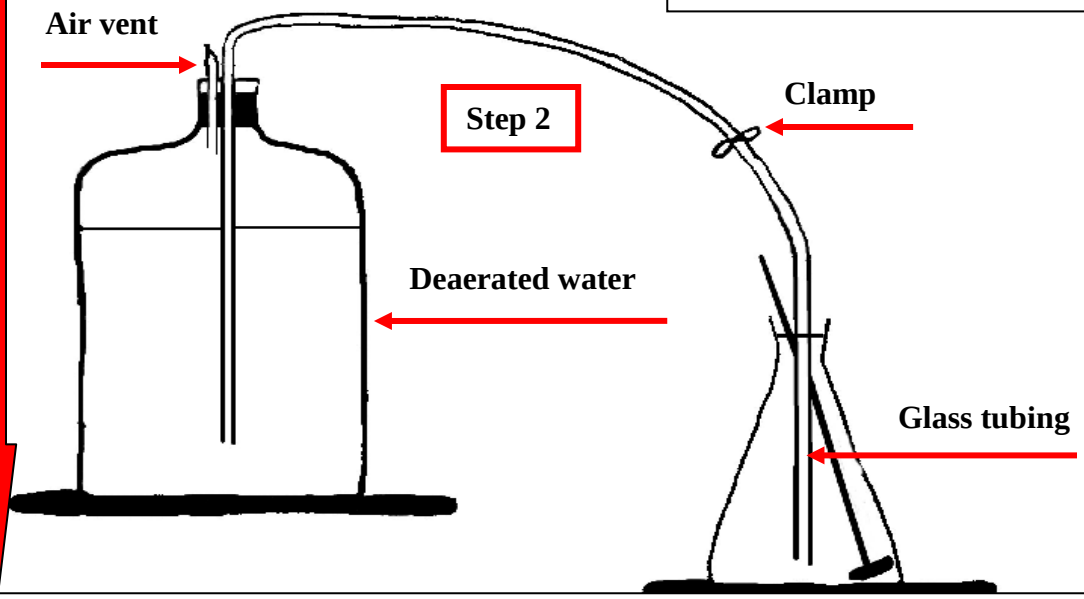
Air vent

Step 2

Clamp

Deaerated water

Glass tubing



<u>Step 2 – add deaereated water up to the neck of flask</u>
One method to add water without adding air bubbles: insert a siphon tube to bottom of flask and allow water to flow into sample. Be sure the tube is <u>underneath</u> the surface of the liquid. As water level approaches neck of flask, stop the flow of water and withdraw the tube. Wash sides of tube into flask with wash bottle. Allow a few additional drops of water to flow through the tube to remove any remaining oil. Bring water level in flask to trapping position in neck.

RAPID JAR METHOD

The Wildman Method is used on products that disintegrate on agitation or under strong spray, or products that are finely chopped. The Rapid Jar Method is used on coarsely chopped products that do not tend to disintegrate upon agitation. This method is described below.

Equipment:

- Large wide mouth glass or plastic jar with smooth inside wall (2 qt capacity is adequate, except for spinach use a 1 gal. container with 3 ¼" minimum opening is recommended).
- Two caps with seals to fit above jar. One cap should have center portion removed with an approximately 12-mesh screen soldered into the opening.
- Liquid detergent.
- 2000 ml beaker or a large container.
- Gram scale.
- 250 ml beaker for weighing sample.
- Wash bottle.
- Filtering equipment - same as for Wildman extraction method.

A. <u>Preparation of Sample</u>

1. On gram scale, weigh 200 g of product to be checked for infestation (except weigh 100 g for spinach).

2. Cut product into very coarse pieces (approximately 2" squares for spinach) and place into jar.

3. Add tap water to contents of jar. Use about 500 ml for most products in 2 quart jar, and 2000 ml for spinach in 1 gallon jar. Add ½ to 1 teaspoon of liquid detergent to water and product in jar.

4. Place solid cap on jar and shake vigorously for one minute. Remove cap, and wash any material or insects adhering to cap into jar using wash bottle. Place screened cap on jar and quickly pour liquid contents into large container. After pouring liquid, remove cap and wash any adhering insects into the container with spray from wash bottle.

5. Add the same amount of tap water (without detergent) to contents in the jar and shake vigorously for one minute, preferably with the addition of an anti-foaming agent. Drain liquid into large container as above.

6. Repeat step 5 again, making a total of three washings.

7. Carefully filter the drained water collected in steps 4, 5, and 6 through bolting cloth or ruled filter paper using the same equipment as for the Wildman extraction method. Use the wash bottle to rinse beaker thoroughly to remove any adhering insects.

8. Place filter paper under 20x to 30x wide field microscope and count any aphids, thrips, and mites that are present. Normally cast skins or insect parts that do not have the heads attached are not counted. However, instructions for certain products may specifically require that they be part of the count. Consult your supervisor as needed.

Record all types of infestation and contamination by size and number on Form FV-140, which may be found on the AMS Forms Catalog at the following intranet address: http://agnis/AMSFormsCatalog/Forms/AllItems.aspx).

MACROSCOPIC EXAMINATION

Macroscopic examination refers to a visual examination of product without the aid of a microscope. It includes certain sedimentation procedures, such as maggot recovery in blueberries and cherries, and also flotation procedures without the use of a Wildman trap flask. There are distinct advantages in using macroscopic procedures. A large quantity of product can be examined in a relatively short time, and the larger, more objectionable types of foreign material can be readily seen and evaluated in relation to the entire sample. Various techniques are employed in macroscopic procedures.

A. Procedure

Products such as cane berries can be mashed by hand and submerged in water in a deep enameled tray. With the addition of a little mineral oil stirred into the solution, light filth will separate out on top of the water in the oil layer where it can be easily seen and counted. This is a rapid method which can be run on many samples as a guide to the overall infestation throughout the lot. This procedure will supplement (but is not intended to replace) the Wildman extraction procedure as outlined in this instruction.

Maggots are checked in blueberries and cherries according to the following procedures:

1. Select a representative 20 ounce sample, add approximately 100 ml of water, and boil 5 minutes.

2. Transfer prepared aliquot to a No. 6 sieve immersed in a pan of water.

4. Mash fruit carefully under water, rubbing the material through sieve.

5. Rinse and discard any pulp and seeds.

6. Repeat process with another portion of fruit.

7. After all fruit has been screened, transfer water, pulp, and maggots to a black-bottomed pan.

8. Slowly decant water and pulp from pan.

9. Add more water and repeat decantation.

10. Maggots will be evident on bottom of black pan. By swirling the water, maggots and heavy material will collect near the center of the pan.

11. Record the number and size of any maggots recovered by size as well as by number on Form FV-140, which may be found on the AMS Forms Catalog at the following intranet address: http://agnis/AMSFormsCatalog/Forms/AllItems.aspx).

For products such as fruit butters, preserves (jams) and cranberry sauce, macroscopic examinations are made with the aid of a light box. This piece of equipment should be available wherever these products are graded. A suitable light box can be made by simply putting a piece of frosted glass measuring approximately 12 by 12 inches on top of a wooden box, and installing a strong light inside. The product should be spread evenly on the glass in a layer thin enough that the light will readily penetrate the product and permit the grader to observe any foreign material in the product.

Some berries, chiefly strawberries, are especially susceptible to embedded sand and grit and occasionally may contain rather large pebbles or mud balls. This can be attributed in part to inadequate washing procedures, and in some instances to abnormal contours of the berries, i.e., "monkey faces," etc. If there is reason to suspect the presence of larva, the tips of the berries should be cut and examined for them.

Occasionally lots have had objectionable amounts of sand, grit and pebbles found at the bottom of bulk containers of frozen strawberries. The inspector should be alert during all phases of inspection for material of this nature. When the berries are washed for light filth, the bottom of the pan should be examined for heavy material. Normally, sand and grit would be noted in organoleptic checks for flavor, but this method cannot be relied upon because of its limitations in sample size.

MAGGOTS IN CANNED MUSHROOMS

Maggots may be present in canned mushrooms under certain conditions. They are more likely to be found in stems and pieces style, and in product having a poor appearance such as external or internal dark brown or black spots, or pathological injury.

A. Sampling Rates

All lots of mushrooms offered for inspection should be examined for maggots. The number of samples checked for maggots should be as follows:

Drawn for Quality	Examine for Maggots
3	1
6	1
13 and up	same as the deviant number

If appropriate for the history established by an individual plant, the frequency of maggot determination may be reduced. For example, if 10 consecutive lots are free of maggots, the frequency of analysis may be reduced to one lot in each four lots examined.

Method

A. Reagents and Apparatus

1. Crystal Violet -- saturated aqueous solution or crystal
2. Sodium Hypochlorite solution (NaOC1), commercial 5.25 percent bleach product in wash bottle
3. Wash bottle with tap water
4. High-speed blender
5. Buchner funnel
6. Vacuum source
7. Ruled filter paper
8. 20, 40, and 140 mesh sieves
9. 600 ml beaker

B. Sample Preparation

The standard analytical sample is 100 g of drained product, plus 100 g of the packing media. For container sizes smaller than 4 oz. mushroom can, combine the contents of enough cans to make 100 g. The entire drained contents of a 4 oz can should be taken for the sample.

Designate samples for microanalysis, saving a portion of the packing liquid from the designated samples. Weigh 100 g drained mushrooms into large beaker and add packing liquid up to 200 g net weight. Pour the product and drained liquid onto an 8 mesh screen. The drained liquid and any material passing through the screen should be dyed, filtered, and examined separately. Any maggots or mites found in this examination should be included in the total count.

C. Extraction and Examination

1. Place 100 g drained mushrooms into high speed blender cup.

2. Add 300 ml H_2O and blend contents briefly to obtain mushroom fragments no larger than 3-5 mm long. Avoid over-pulping the product. If this occurs, excessive plant material will accumulate on the filter papers making it difficult to observe any maggots. Some mushrooms, particularly soft broken pieces, require a minimum of blending while larger, firm, whole units may require longer. Through experience, the analyst will learn when the blending step is complete.

3. Pour mixture into a 600 ml beaker and add 15 ml saturated aqueous crystal violet or approximately 100 mg of powdered crystal violet, stir and heat to boiling.

4. Pour stained mixture into a nested set of 8 inch Nos. 20, 40, and 140 sieves, with the 140 sieve on the bottom and the No. 20 on the top.

5. Rinse tissue 2-3 minutes with spray of tap water, and discard material on the No. 20 sieve.

6. Wash material on the No. 40 and 140 sieves to edge of sieve and remove excess stain with tap water.

7. Using wash bottle containing NaOC1 solution and a gentle spray of tap water, alternately spray tissue with water and NaOC1 solution until stain has been removed from mushroom tissue.

8. Rest the 40 sieve in a forward-tilted position on the beaker. Wash the material into the beaker by directing a spray of water through the back side of the sieve. Avoid spilling any material in the transfer.

9. Repeat Step 8 with the 140 mesh sieve. Several small washings are desirable, resulting in a total accumulation of about 300 ml of liquid from both sieves in the beaker

10. Transfer contents of beaker to ruled filter paper with suction. Avoid obscuring maggots and/or mites with mushroom tissue. Use as many filter papers as necessary to avoid piling up too much material on a single paper.

11. Examine papers for maggots and mites at 10-30X. Insects will retain a dark violet stain from the crystal violet.

12. Determine number of maggots in 100 g drained mushrooms and add to this the number any insects found in the drained packing liquid. Calculate as follows: 100/total grams drained mushrooms x total number maggots in liquid.

The FDA Defect Action Level Handbook is available at the following internet address: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Sanitation/ucm056174.htm.

MOLD COUNT

These instructions cover the procedures used to estimate the amount of mold that may be present in various processed fruits and vegetables.

Characteristics of Mold

To recognize mold, it's helpful to briefly focus on its cellular structure. Mold is considered a fungus. It belongs to the plant kingdom, and is characterized by growing in irregular masses without the differentiation of roots, stems, and leaves found in higher plants. Molds lack chlorophyll and cannot manufacture their own food; they must obtain food from external sources such as living and dead plants.

Molds can reproduce in two ways, by means of a tiny specialized cell called a spore, or by means of vegetative multiplication in which broken-off-pieces of the plant grow and form new plants. A long, tubular filament grows out of the germinating spore or the broken-off-piece much like a sprout grows out of a bean seed. This filament is called a hypha. As the hypha continues to grow, it starts to branch and rebranch until a whole system or body of fine intertwining, branching hyphae is formed. These break down the plant cells upon which they feed as they spread across the surface or throughout the food source.

Although a mass of hyphae can grow large enough to be visible to the naked eye, the individual hypha is visible only under a microscope. Mold evaluation is largely a microscopic technique to determine compliance with FDA applicable Food Defect Action Levels; see FDA, PPB Guidelines section of this Manual.

Classification of Mold

The hyphae eventually divide into two types with separate functions:

A. Vegetative type, which grows underneath the surface to digest and absorb the material on which the mold is growing. There are no distinctive differences between the vegetative hyphae of one species of mold and another.

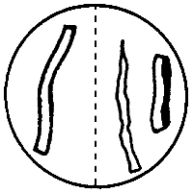
B. Fertile type, which grows out from the mass like branches of a plant, with spores growing on the ends of the branches like seeds. The spores of each mold species are distinctive, and serve as a means of classifying the species.

Inspectors don't need to identify mold by species, but they must be able to distinguish mold filaments from non-mold material that resembles mold.

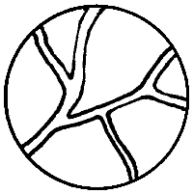
Mold's fertile hyphae and spores are located on or above a product's surface, and can be easily removed by washing and soaking the item that the mold is growing on. Therefore very little of this type of hypha typically remains on processed fruits or vegetables after the canning or freezing process. However submerged vegetative hyphae can be removed only by careful trimming and sorting. This type is more frequently found in processed fruits and vegetables.

The following illustrations show characteristics of mold and non-mold materials to aid in differentiating between the two. Rarely are all mold characteristics shown below present at one time. **Only filaments which have at least one of the following six characteristics** shall be classed as mold hyphae:

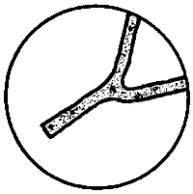
1. Parallel walls of even intensity with both ends definitely blunt.

This  Not This

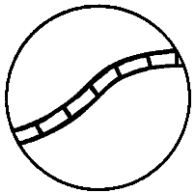
2. Parallel walls of even intensity with characteristic branching.



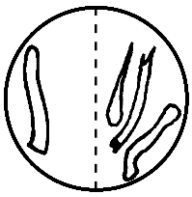
3. Parallel walls of even intensity with characteristic granulation.



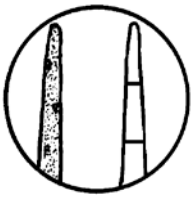
4. Parallel walls of even intensity divided into segments or sections by cross walls (septation).



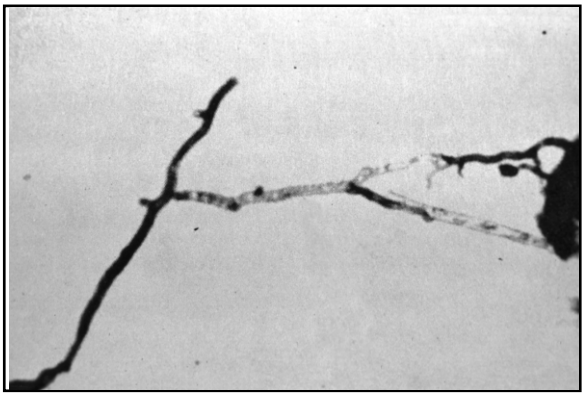
5. Occasionally encountered, parallel walls of even intensity with one end blunt and the other end rounded.

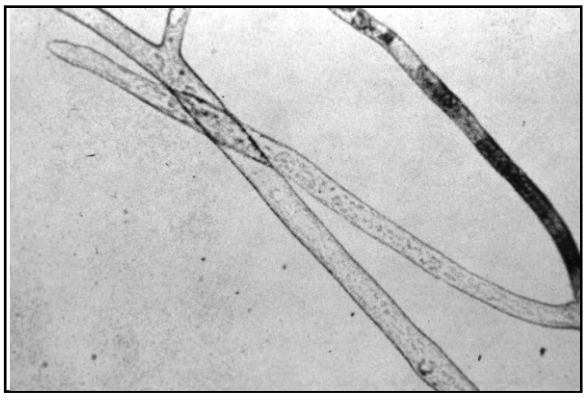
This  Not This

6. Occasionally encountered, slowly tapering walls of even intensity with one end with characteristic granulation or septation.

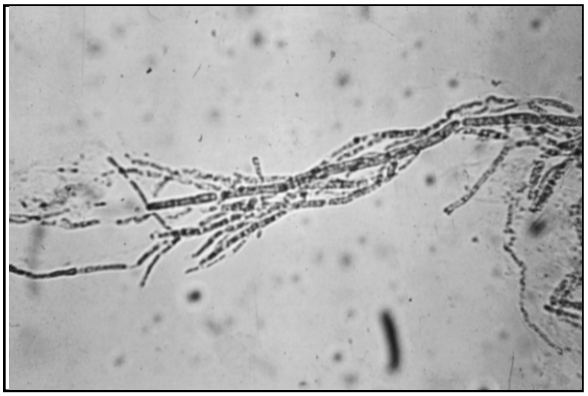


Illustrating blunt end of broken filament, granulation and branching.

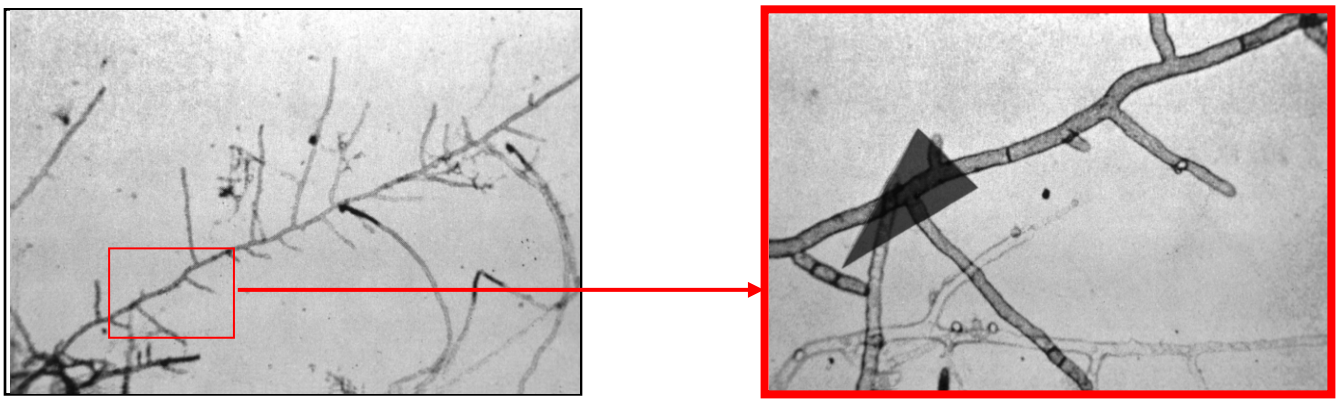


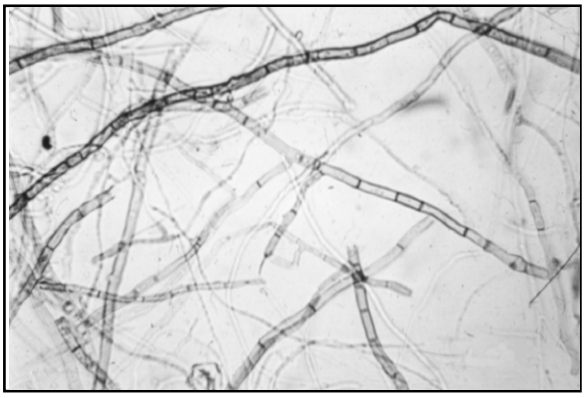


Illustrating "broken" mold.

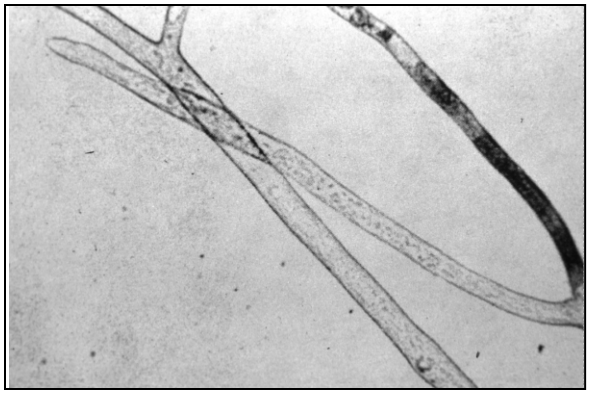


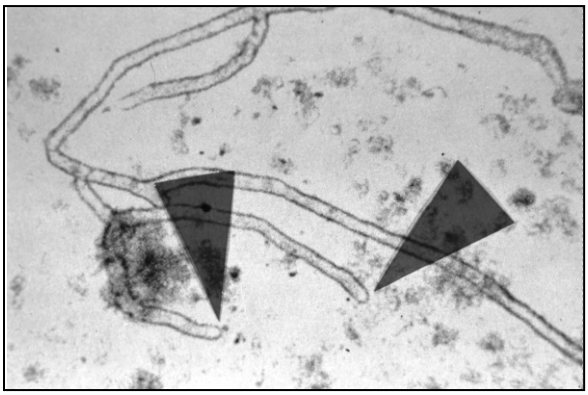
"Fine" mold hyphae illustrating parallel walls of even intensity, septa (cross walls), and branching.



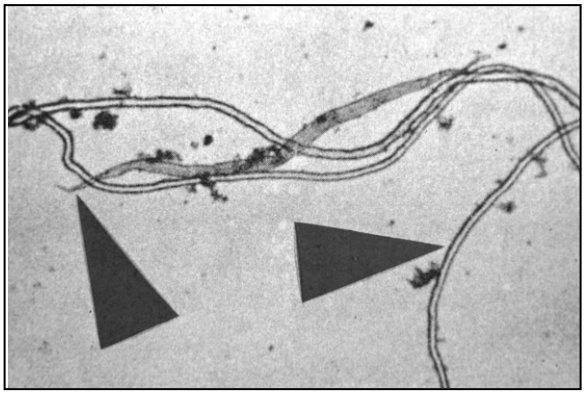


Branched mold filaments showing granulation and parallel walls of even intensity, and slightly rounded growing ends of branched mold hypha.





Illustrating structures easily confused with mold.
Note frayed, pointed ends, and walls of uneven intensity.

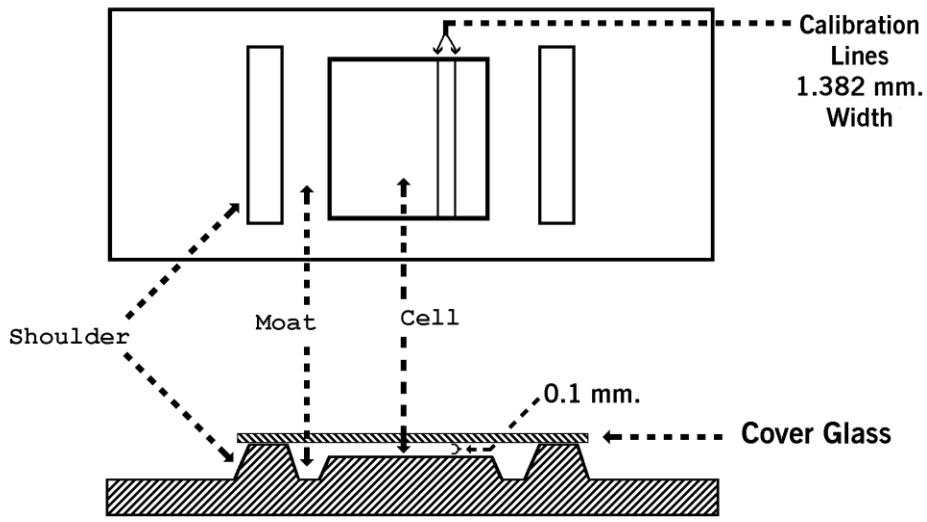


HOWARD MOLD COUNTING METHOD

The Howard Mold counting technique is recognized internationally as a standard procedure for estimating the extent to which a product is contaminated with mold. The "Howard Count" in turn can be related to the condition of the raw material as well as effectiveness of plant sanitation, particularly when such contamination is due to fungus decay. The Howard Count method is the procedure used by the Branch to determine compliance with FDA applicable Food Defect Action Levels.

In performing a Howard Mold Count, all details of sample preparation, slide preparation, and counting techniques must be carefully followed. The inspector must also have considerable practice in proper slide preparation and proper identification of mold filaments to obtain consistent and reliable results

A. <u>The Howard Mold Counting Chamber</u>



Area of circle = $\pi r^2 = \frac{1}{4} \pi d^2 = 0.7854d^2$

Area of Howard mold count microscopic field = Diameter$^2 \times 0.7854$
= 1.382^2 mm x 0.7854
= 1.5 sq. mm

Volume of material in microscopic field = Area $\times$ Height

= 1.5 sq. mm $\times$ 0.1 mm
= 0.15 cu. mm

B. <u>Preparation of the Mount</u>

1. Preparation of the Sample

Most products require specific preparation before a subsample may be transferred to the mold chamber for counting. Refer to the applicable

instruction in this Manual for Canned and Frozen Berries, Fruit Nectars, Purees, and Pastes, Pineapple and Citrus Products, and Canned Tomatoes and Tomato Products. For Florida Citrus Products, see the Citrus Handbook.

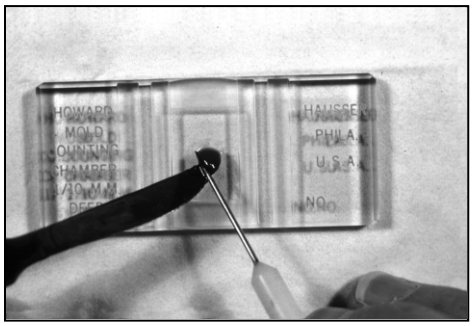
2. Cleaning the Chamber

Wash the chamber and cover glass with soapy water. Dry with a lint free cloth. Test for cleanliness by placing the cover glass in position and pressing it firmly against the shoulders of the slide. Then hold the chamber at an angle so that light is reflected from the cover glass. If a rainbow effect is visible between the shoulders and the cover glass, the chamber is considered properly clean. The rainbow effect is called "Newton's Rings" and is caused by interference between light beams reflected at the juncture of the two glass surfaces. Their absence indicates that dirt is preventing proper seating of the cover glass on the shoulders of the chamber.

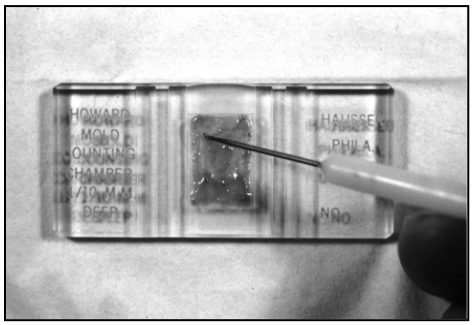
Newer Howard Mold counting chambers are constructed with a Teflon coating on the shoulders, and will not show "Newton's Rings."

3. Transferring Sample to Cell

Dip the blade of a clean scalpel, spatula or rubber policeman into the prepared, <u>thoroughly mixed</u> sample with a scooping motion. Pick up just enough sample to cover the cell to the edge. This will prevent excess spilling over the moat and onto the shoulders of the chamber when the cover glass is in place. Spread the drop evenly over the surface of the cell. If there is too much or too little material on the slide, clean and dry the slide and prepare another one. Do not add more sample to the material already on the cell, or try to remove some of the material already there. An inexperienced inspector is likely to need some practice before becoming proficient in judging the proper amount of sample to use.



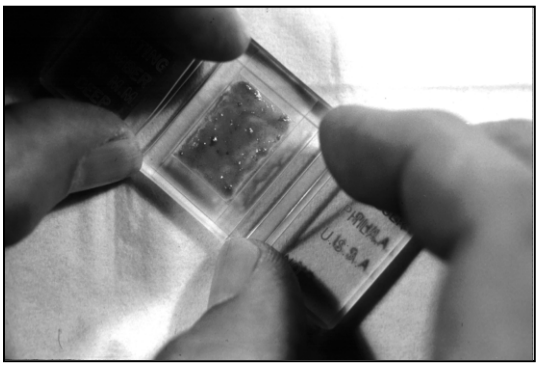
Transfer sample to mold chamber



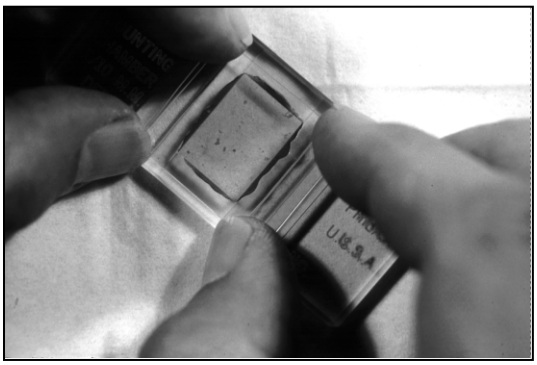
Spread sample across cell

4. The Cover Glass

Next position the cover glass at an approximately 45 degree angle, with one edge resting along the shoulder~~s~~ of the chamber. Alternatively, suspend the glass entirely above the cell. Then lower the glass in place. Take care to prevent air bubbles in the prepared mount. Lowering the glass too fast may splash the material onto the shoulder of the slide; and lowering too slowly may result in uneven distribution of sample material on the cell. Practice will be needed to master the proper technique.



Position cover glass on slide shoulder



Lower cover glass into place

5. Examine the Prepared Mount before Counting

The test material examined under each microscopic field is a very small amount (1/250 of a drop). A well prepared slide is essential to obtain reliable results. Before counting the mount, check for:

a. Newton's Rings:

Newton’s rings should be visible on the shoulders of the prepared slide. If they are not, don’t count the mount, unless it is the type of chamber manufactured with a Teflon coating as mentioned above.

The presence of Newton’s rings signifies that that there is a uniform thickness of test material present between the cell and cover glass, yielding the correct sample volume of 0.1 mm. Their absence indicates that either the slide was not thoroughly cleaned and dried, or excessive product is holding the cover glass above the designated height, so the slide holds too much product to count.

b. Uneven Distribution:

Do not count a mount where distribution of the insoluble material on the cell is visibly uneven. An even distribution of test material is required to evaluate any mold present.

c. Test Material in Moat or on Shoulders:

Do not count the mount when there is material on the shoulders or an excessive amount in the moat. This will prevent the cover glass from fitting properly, and is also indicative of uneven distribution. Test material on the shoulder will also prevent the appearance of Newton's Rings.

d. Air Bubbles:

A field with air bubbles may be counted as positive. However, it must never be recorded as negative, because technically the slide contains insufficient sample, and the field must be skipped. If too many fields are skipped, not all sections of the mount will be represented. If in doubt about a slide containing air bubbles, clean the slide and prepare another one.

C. Standardization of the Microscope

The microscope field must be checked against calibration marks etched on the mold counting slide before counting begins. The calibration marks are usually in the form of a circle or two parallel lines etched on one shoulder or on the cell portion of the slide (See Howard Mold Counting illustration). When properly adjusted, the field of vision will fall just within the outside lines of the calibration device and will measure 1.382 mm as specified in the official method. The proper drop-in micrometer disk inserted in the ocular of the microscope can be used to divide the field into squares. Each side of each square equals 1/6 of the diameter of the field. This calibration device is used to measure the length of the mold filaments (see paragraph G. of this section). Unless equipped with a stage micrometer, monocular microscopes are not recommended for use in the Howard Mold Count because of the difficulty of adjusting the draw tube to assure that the diameter of the field is 1.382 mm.

D. Illumination

Proper illumination is very important. It is often necessary to change the intensity of the light while the sample is being examined. This adjustment should be made at the light source by adding or removing filters, manipulating the diaphragm on the lamp, or by using a rheostat. Too much light will conceal fine mold, and too little light will not penetrate a mass of insoluble material sufficiently to identify any mold present.

E. Focusing

Improper focusing techniques can often lead to damage to the objective of the microscope or to the counting chamber. To prevent this, proceed as follows:

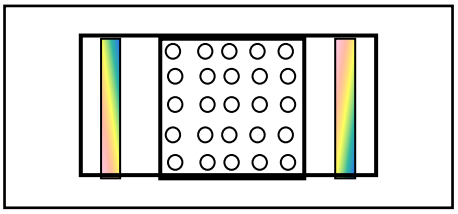
1. Place the slide in position on the stage of the microscope

2. Observing both the slide and the objective of the microscope simultaneously, SLOWLY bring the objective down until just before it touches the cover glass of the slide

3. Look through the ocular tube and bring the field into view by focusing the microscope tube UPWARD.

F. Counting Patterns

The AOAC handbook requires that mold analysis consist of examination of at least 25 fields per mount, representing all sections of that mount. Skipping every other field as the mount is moved horizontally across the entire cell will result in the examination of the recommended 25 representative fields. See below.



When counting fields on a mount, it is important not to lose your place in the sequence, as this could result in miscounting a field. To prevent this, always count from left to right the same way that you read. The process then becomes more automatic and makes any interruption less likely to result in error.

It is essential that the fields be selected systematically and that the slide is never moved to include or exclude mold filaments.

G. Examination of the Field

When counting mold, a field is either **positive** or **negative**. A field is considered positive when the aggregate length of not more than three filaments exceeds 1/6 of the diameter of the field. If mold filaments are present that do not meet this minimum, the field is considered **negative**.

It can save time to give each field a quick "once over." Observe each field in the counting pattern, noting the presence (positive) or absence (negative) of mold filaments. If there is enough mold in the field to make it positive, record it. If there is not enough mold, examine all parts of the field thoroughly to verify that

the field is negative. This includes continual use of the fine adjustment on the microscope, and varying the intensity of the light occasionally. In some cases, increased magnification may be necessary to positively identify mold filaments. Observe the suspect material at 200X magnification. Once a determination is made, return to 100X for classifying length and routine counting.

H. Use of Howard Method

The Howard Method requires a minimum of 25 fields per mount, and 50 fields per subsample.

The average percent mold is calculated by:

$$\frac{\text{Total number of positive fields}}{\text{Total number of fields examined}} \times 100 = \text{Average percent mold}$$

SAMPLING/INSPECTION PROCEDURES

Use the procedure in this manual for inspection of processed fruits and vegetables that require acceptance for specified lot average mold limits.

Inspection Procedure

A. Products Examined

Examine only those products listed in FDA's Food Defect Action Levels publication that have a specific mold defect action level.

B. Sampling Rate

1. Lot Inspection

Count 50 fields for each subsample. Examine subsamples for mold at a rate of the deviant rate for the lot PLUS one. For example, examine one subsample for a lot of 3, 2 subsamples for a lot of 6, 3 subsamples for a lot of 13, etc.

2. On-line Inspection

Count 50 fields for each subsample. Examine production at the following minimum rates:

a. Normal: 1 mold count every 4 hours.

b. Reduced: 1 mold count every 8 hours

c. Tightened: 1 mold count every 2 hours.

3. Special Agreement Lot Inspection Service

When approved by the Regional Director, the on-line sampling rate may be used for mold counting of products covered by Special Agreement Lot Inspection Service. This type of service provides for inspection of all products of a single type or can size. The applicant establishes a history of production reliability through series of continuous inspection lots. This history forms a basis for granting the on-line rate. Examine production at the rates shown above for Normal, Reduced and Tightened.

C. Number of Fields to Examine

The Howard Method requires counting a minimum of 50 fields (2 mounts) per subsample.

Acceptance Criteria

A. Lot Inspection

Based on lot size, determine the appropriate number of mold subsamples to examine (deviant rate + 1). Count 50 fields per subsample. Accept the lot if the percentage of positive fields does not exceed the mold defect action level for the product, based on the average of the total fields counted.

Example: You have a 13 sample lot of product with a defect action level of 12 percent. You must examine at least 3 subsamples for mold (deviant rate + 1). For each subsample, you properly prepare and count 2 mounts at 25 fields each.

Sample 1: The first mount contained 3 positive fields; the second contained 1 positive field.

Sample 2: The first mount contained 2 positive fields; the second contained 1 positive field.

Sample 3: The first mount contained 3 positive fields; the second contained 3 positive fields.

Total positive out of 150 fields = 13

13 ÷ 150 = 0.087 x 100 = 8.7%; less than DAL of 12%, so the lot is acceptable on mold count.

B. On-line Inspection

1. Examine production at the appropriate rate shown in B. 2., page 49, (Normal, Reduced or Tightened). Count 50 fields per subsample, and calculate the percentage of mold found. Accept production if the percentage of mold found does not exceed the acceptance number for the product's DAL.

2. Reinspect rejected production only as an appeal lot inspection.

3. If rejected production is packed so that containers are separately identifiable (totes, barrels, etc.), count 50 fields per subsample and treat each container as a separate lot inspection.

CERTIFICATION

Refer to the AIM Inspection Series, Certification Manual for appropriate certification statements. Mold count results are certified only when requested by the applicant.

COMMODITY SPECIFIC PROCEDURES

This instruction describes the preparation of various products for mold counting in the Howard Mold Method.

MOLD ANALYSIS - CANNED AND FROZEN FRUIT AND BERRIES

A. Care and Operation of Pulper

The cyclone pulping machine is used in the preparation of certain products for mold counting. It contains spinning blades which force the pulp through a fine wire mesh to separate the seeds and skin from the material to be examined.

Products that should be well mixed, but need not be put through a cyclone:

Fruit Purees
Fruit Butters
Cranberry Sauce, Jellied

The cyclone should be washed and cleaned after running each sample. This is done by dismantling the machine and removing the parts for washing. Reassemble the cyclone as follows:

1. Slide cylinder with hopper on motor and tighten set screw.

2. Place threaded end of screw shaft through opening in end of cylindrical sieve and twist on knurled screw.

3. Grasp screw assembly by knurled screw and slide into cylinder until slotted shaft fits into motor coupling.

4. Tighten set screws.

5. Be sure the screen fits snugly in the recessed areas within the cylinder at both ends to prevent leakage of fibrous matter and seeds into the pulped material. If a tight fit is not possible, have the cylinder wall machined down until a close seal can be achieved.

B. Preparation of Sample

In selecting the subsamples to analyze, choose those that are most suspicious looking or which have the appearance of decay.

1. Sample Size

Retail size containers - use the entire container.

Bulk containers - use an approximate 2 pound core, or a 2 pound representative portion of the sample.

2. Draining Berries

a. Canned or frozen strawberries, blueberries, blackberries, raspberries, and other drupelet berries with water or syrup packing media:

Drain these products two minutes on a No. 20 sieve and pulp the drained material only. Discard the packing media.

b. Frozen strawberries, blackberries, raspberries, and other drupelet berries with dry sugar or no packing media:

Pulp these products as they are. Do not drain.

3. Pulping

a. Be sure the outlet tube is pointing upwards and is plugged with a stopper.

b. Add the berries or fruit and juice to the cyclone hopper.

c. Pulp the entire subsample and collect the material emerging from the cyclone in a large evaporating type dish or similar receptacle.

d. Dismantle the pulper and scrape any material adhering to the outside of the screen, adding it to the sample in the dish.

e. Mix the pulped material well.

f. Check the appearance of the residue inside the cylindrical screen. It should be quite dry and consist mainly of seedy and fibrous material.

4. Deaeration

Transfer approximately 100 g of the well mixed pulped material to a beaker. Add about 15 drops (1/2 ml) of 2 octanol and stir the mixture carefully to dissipate air bubbles.

Note: The 2 octanol may be added to the entire sample in the evaporating dish to deaereate the whole sample if desired.

For fruit preserves, the following optional method may be used:

Place approximately 100 g of the well mixed sample in 400 to 600 ml size beaker and boil vigorously for about 1 minute. Stir the sample while cooling. Do not place hot material on Howard Mold Count cell, as it may crack the glass.

5. Dilution with Stabilizer

Any one of the following three stabilizers may be prepared and used:

a. 0.5 percent Na Carboxymethylcellulose

Preparation: Place 500 ml of boiling water in high speed blender. With blender running, slowly add 2.5 g of the cellulose gum (CMC) and blend for one minute. Treat the solution with heat or vacuum to remove air bubbles. After the solution has cooled, add 2 ml of formaldehyde for each 100 ml of solution as a preservative, mix well, and store in a closed container. Larger volumes of CMC solution may be prepared ahead of the season. Label the solution: "POISON - FORMALIN ADDED." Small "Poison" decals may be available from your local pharmacy.

3-5 percent pectin solution.

Follow the same procedure as the CMC solution procedure, except use 15 g to 25 g of pectin instead of cellulose gum.

1 percent algin solution. As a preservative, formaldehyde may be added (2 ml per 100 ml stabilizer).

Follow the same procedure as the CMC solution procedure, except use 5 g of algin instead of cellulose gum.

b. Do not add stabilizer to the following products:

Strawberries
Light Colored Fruit Preserves
Fruit Butters

c. Count the following products after diluting 100 g of the sample with 100 g of stabilizer:

Light Colored Cane Berries - pulped in cyclone pulper

Cranberry Sauce - does not need to be pulped. Immerse unopened can in boiling water 30-45 minutes. Open can carefully and transfer a portion of the contents to a beaker. Stir or use an electric mixer at slow speed to break the gel.

d. Count the following products after first diluting 100 g of the pulped sample with 200 g of stabilizer:

Dark Colored Cane Berries
Dark Colored Fruit Preserves

C. Howard Mold Count

Proceed with mold counting according to the instructions in this Manual.

MOLD ANALYSIS - FRUIT NECTARS, PUREES, AND PASTES

A. Sample Preparation

1. Fruit Nectars:

   Measure well mixed sample into a 50 ml graduated conical centrifuge tube.

2. Fruit purees with no added starch:

   Dilute sample with an equal volume of water, and measure well mixed sample into a 50 ml graduated conical centrifuge tube.

3. Fruit purees with added starch:

   Weigh 50 g of fruit puree into a 250 ml beaker and add 50 ml hydrochloric acid solution (5 ml HCL and 45 ml water). Mix well and heat on a steam bath or in a pot with water on the stove for 15 minutes. Measure well-mixed, hydrolyzed sample into a 50 ml graduated conical centrifuge tube.

4. Fruit pastes:

   Combine 1 part paste in 3 parts water. If necessary, warm gently to break the gel. Measure well mixed sample into a 50 ml graduated conical centrifuge tube.

B. Centrifuge Computations

Centrifuge the samples for 10 minutes at a Relative Centrifugal Force (RCF) of 1060 g. This value is computed from the following formula:

RCF max = $1.118 \times 10^{-5} N^2 r g$

Where N = revolutions per minute (rpm),

r = radius of centrifuge arm in cm (distance from the center of the centrifuge head to the bottom of the centrifuge tube when in the horizontal position), and

g = a gravitational constant.

The AOAC references a specific International type centrifuge which has a radius of 19.6 cm and attains RCF of 1060 g at a speed of 2200 rpm. Since many of the centrifuges used in plants and field offices differ from this reference centrifuge, the following equation may be used to calculate the speed at which a given centrifuge must run to attain RCF of 1060 g.

$N_1^2 \times r_1 = N_2^2 \times r_2$

Where N_1 = 2200 rpm
r_1 = 19.6 cm
N_2 = speed of centrifuge
r_2 = radius of centrifuge arm

For a centrifuge with a radius of 14.1 cm, determine the speed (N_2) as follows:

$N_1^2 \times r_1 = N_2^2 \times r_2$

$$\frac{N_1^2 \; r_1}{r_2} = N_2^2$$

$$N_2^2 = \frac{(2200)^2 \; (19.6)}{(14.1)}$$

$$N_2^2 = (2594)^2$$

$$N_2 = 2594 \text{ rpm}$$

Rounding to the nearest 100 rpm would result in a speed of 2600 rpm – the speed necessary to run the centrifuge to attain the proper RCF of 1060 g.

Consult the manufacturer's instructions for the radius of the centrifuge arm. Be certain that the measurement is taken to the bottom of the centrifuge tube when it is positioned horizontally. Strobe type tachometers are not as accurate as a tachometer that reads by direct contact when setting the speed of the centrifuge.

C. Procedure

1. After centrifuging for 10 minutes, allow the centrifuge to come to a stop gradually. Do not use the centrifuge brake. Do not open the cover until the centrifuge comes to a complete stop.

2. Remove the tubes and decant supernatant liquid without disturbing the sediment. Using the graduations on the centrifuge tube, dilute the sediment with stabilizer solution as follows.

   a. Peach, apricot, mango, and papaya — 1 + 1

   b. Pear and guava — 1 + 3

   c. Strawberries, blackberries, raspberries, and blueberries — 1 + 6

   Use the same stabilizer solutions as referenced in Canned and Frozen

Fruits and Berries section of this instruction. Mix by pouring back and forth between beaker and centrifuge tube several times. Stir mixture thoroughly in beaker and proceed with mold counting according to instructions in this Manual. For products diluted 1 + 1, divide the number of positive fields by 2 before calculating the percent mold count.

MOLD ANALYSIS - PINEAPPLE AND CITRUS PRODUCTS

A. Sample Preparation

1. For single strength juices: use the product as it is with no further dilution.

2. For other than crushed style canned pineapple: drain the pineapple on an 8 mesh sieve of suitable diameter for two minutes; for crushed style, drain on a 12 mesh sieve. Prepare sample from the drained juice.

3. For concentrated pineapple juice: reconstitute sample to single strength.

4. For concentrated citrus juices: follow the instructions in the Citrus Products Technical Manual, Reconstitution of Concentrates.

B. Procedure

Use distilled water for all dilutions. Thoroughly mix sample by pouring between two containers several times. After mixing, pour into 50 ml graduated conical centrifuge tube. Centrifuge according to instructions in Fruit Nectars, Purees and Pastes, Section C. of this instruction. After centrifuging, decant the supernatant liquid without disturbing the sediment. Add distilled water to the centrifuge tube to bring the level to the 10 ml mark. Add 5 ml stabilizing solution. For pineapple juice, also add 0.5 ml hydrochloric acid to the sediment to dissolve oxalate crystals.

The stabilizing solution may be any one of the following. See Canned and Frozen Fruits and Berries Section B. 5 of this instruction for solution preparation.

1. 0.5 percent Sodium Carboxymethylcellulose

2. 3 to 5 percent Pectin Solution

3. 1 percent Algin Solution

Thoroughly mix sediment, water, and stabilizing solution and pour into a small beaker. Mix by pouring back and forth between beaker and centrifuge tube several times. Stir mixture thoroughly in beaker and proceed with mold counting according to the instructions in this Manual.

MOLD ANALYSIS – CANNED TOMATOES AND TOMATO PRODUCTS

A. Sample Preparation

Prepare the sample for mold counting as outlined in the Table below.

Product	Canned Tomatoes and Stewed Tomatoes all styles	Tomato Juice	Tomato Sauce	Tomato Paste	Tomato Puree	Conc. Tomato Juice
Preparation	Canned Tomatoes - drain product and use packing medium; use Tomato Juice and Tomato Sauce without dilution. 2/			Dilute with water to 7.9% to 8.8% Tomato Soluble Solids		
Product	Tomato Catsup	Chili Sauce	Pizza Sauce, Crushed Tomatoes, Salsa, & other similar products	Tomato Powder	Specialty Products (canned dried beans in tomato sauce, pork and beans, soup, spaghetti, etc.)	
Preparation	Mix 1:1 with stabilizer 1/		Dilute with water to 6% total solids 1/	Mix 17 g with 200 ml water	Follow AOAC procedure.	

1/ See Canned and Frozen Fruits and Berries Section B. 5 of this instruction for preparation of stabilizer solution.

2/ In the event of an appeal inspection of a failing lot for mold count, follow the AOAC procedure for Canned Whole Tomatoes.

B. Canned Tomatoes-all styles (any packing medium), Stewed Tomatoes, Tomatoes and Okra, and Other Similar Products

Drain whole tomatoes on a number 2 sieve for two minutes; use a number 8 sieve for sliced and diced styles of canned and stewed tomatoes. Collect and use the packing medium for the Howard Mold count.

At the discretion of the inspector under in-plant inspection, the point of sampling for mold counting may be any of the following:

1. Common source (single or multiple products; or

2. Filler bowl (topping medium); or

3. Warehouse sample.

C. Tomato Juice and Tomato Sauce

Under in-plant inspection, at the discretion of the inspector the point of sampling for mold counting may be any of the following:

1. Common source (single product or multiple products); or

2. Warehouse sample (individual containers).

D. Tomato Paste, Tomato Puree, and Concentrated Tomato Juice

$$\frac{(8.5)\ (100)}{\text{Tomato Soluble Solids (\%) of Paste, Puree; or Juice}} = \text{Grams of Product}$$

Mix the grams of product indicated above with water until 100 g is reached (product + water). Use this sample unit for color, defects, and mold counting.

Under in-plant inspection, the point of sampling may be as in B above.

E. Pizza Sauce, Crushed Tomatoes, Salsa, and other similar products.

Under in-plant inspection, the point of sampling may be as B above.

Use the entire contents of the individual container; or a suitable aliquot from a well mixed container; and

Pass the product through an approved laboratory pulper to remove seeds and large particles. See Canned and Frozen Fruits and Berries Section B. 3 of this instruction for guidelines on use of the pulper.

F. Tomato Catsup and Chili Sauce

Use one of the following stabilizing solutions for counting mold (1:1 dilution).

1. 0.5% Sodium Carboxyl Methyl Cellulose

2. 3% to 5% Pectin Solution

3. 1% Algin Solution

Caution: Check all stabilizer solutions for mold growth if formaldehyde has not been added, or the solution has been stored from the previous season.

Use the following method for mixing the product with the stabilizing solution:

- Place 50 ml of the stabilizing solution in a 100 ml graduated cylinder;
- Add 50 ml of well mixed product sample to the cylinder by displacement. Drop catsup or chili sauce directly into the solution and mix thoroughly in the cylinder (if the product is allowed to run down the side of the cylinder, the graduations are difficult to read); and
- Transfer the mixture to a suitable beaker. Use a few drops of 2 octonal and stir the mixture if air bubbles are a problem. Determine the mold count.

Alternate method:

- Tare a beaker;
- Add 50 ml of the stabilizing solution and weigh (use this reference weight for any subsequent samples); and
- Add 50 ml of product (use this 2nd reference weight for any subsequent samples); and
- Mix thoroughly. Use a few drops of 2 octonal if air bubbles are a problem. Determine the mold count.

Caution: If the total solids of the product should change, such as from 33% to 29%, make a new determination for the weight of 50 ml of product.

TECHNICAL INSPECTION PROCEDURES FOR MICROANALYSIS OF PROCESSED RAISINS

Raisins are subject to the same general requirements as other food for human consumption. They must be packed under sanitary conditions and must not be adulterated or contaminated with decay, insects, filth, or any harmful substance

Action levels have been established for processed raisins and are incorporated into the PPB guidelines. (See the Processed Raisins Table on page 13.) No grade will be assigned to processed raisins that exceed the guidelines, nor are they allowed into the marketing system. They must be successfully reconditioned or used for other than human consumption. Raisins with contamination exceeding PPB guidelines that reach the market place are subject to regulatory action.

For Sand, Soil or Similar Inorganic Material

If observed organoleptically while evaluating the product, the presence and amount of sand or gritty substance in processed raisins may be verified by the following objective method. This method requires the use of a standardized sand tube.

Procedure

1. Mix representative sample thoroughly.

2. Weigh out 250 grams of the thoroughly mixed sample and place in a 3-quart saucepan with 1½ quarts of water. Heat to boiling and simmer for 20 minutes or reconstitute overnight.

3. Pour about ⅓ of the raisins into an 8-mesh screen nested on a 150-mesh screen. Use a spray hose or wash bottle to wash all the raisins, turning each berry by hand. Rub or press moldy and decomposed berries through the top screen to remove any embedded dirt and sand.

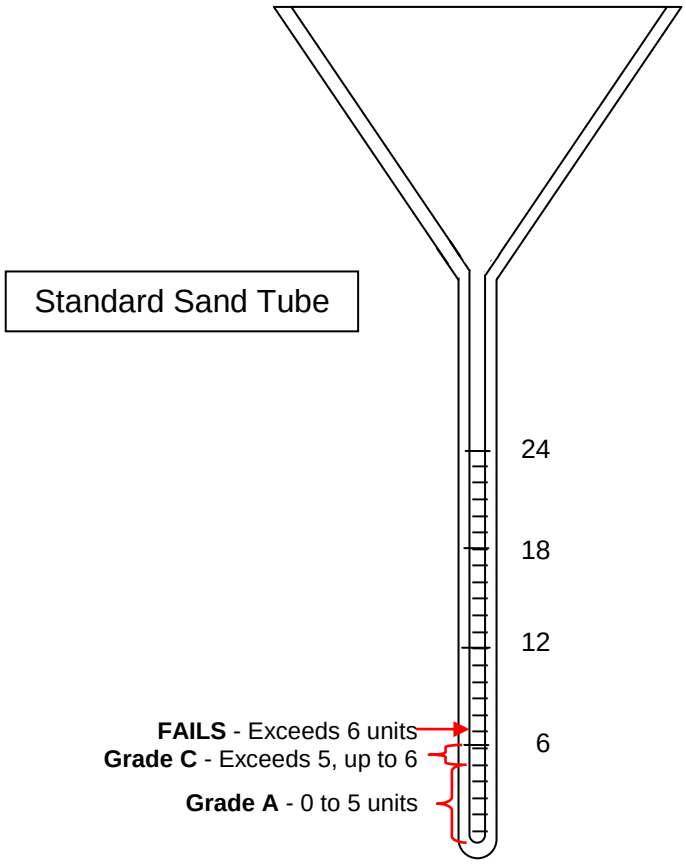
4. Use enough pressure to thoroughly wash the fruit, but not so much that large drops of water splash out. After washing this portion of the sample, remove the 8-mesh screen from the 150-mesh screen and dump the washed and rinsed raisins into a discard container.

5. Repeat the process until all of the raisins in the sample are washed. After pouring the final third of the raisins onto the screen, thoroughly wash the cooking pan and rinse the water through the screen. After the last portion of the sample has been washed and discarded, thoroughly rinse the 8-mesh screen onto the 150-mesh screen, making sure the bottom rim is also rinsed.

6. Use the spray to wash down the sides of the 150-mesh screen. Tilt the screen at a 45-60 degree angle. Starting at the top, direct a stream of water into the screen using a side-to-side motion of the stream, and wash the sand and raisin material into a container.

7. Decant all raisin material and most of the water. Place a white tray underneath during the process to catch any sand that might be washed from the container. After the decanting process is complete, use a wash bottle to direct the sand from the container (as well as any sand in the grading tray) into the standard measuring tube. Jar the tube slightly to settle the sand. Record the results as follows:

Grade A	0-5 units of sand
Grade C	Exceeds 5 units, up to 6 units of sand
Failing Sand	Exceeds 6 units of sand



Each calibration mark represents 1 unit of sand. A unit of sand equals the volume of 133.4 mg. of mercury

For insects, hairs, and feather barbs/barbules, use the following procedures to perform microanalysis:

1. Place 227 g (8 ounces) of raisins into a 2000 ml Erlenmeyer flask. Add one-sixth teaspoon of powdered detergent and fill with about three inches of tap water. Soak raisins overnight, or heat the flask until the water starts to bubble, then remove from the heat and let set for 45 minutes or more until rehydrated. Rehydrated raisins look like grapes.

2. After rehydrating, agitate the flask on a Yankee rotator for 30 seconds or rotate by hand for 1 minute. Nest an 8 mesh sieve on top of a No. 140 mesh sieve. Fill a 10"x14"x2" plastic pan half full of warm water. Pour about one-third of the agitated sample into the 8 mesh sieve and wash all raisins with a spray hose, turning each berry by hand at least once.

3. DO NOT rub the berries because too much raisin material will be pressed through the sieve and make the sample difficult to read. Adjust water pressure to thoroughly wash fruit without splashing water out of the sieve.

4. After washing this portion of the sample, separate the sieves and move the 8 mesh up and down in the plastic pan of water. This will remove any additional loose material adhering to the raisins. The washed and rinsed raisins are then dumped into a discard container. The entire process is repeated until all raisins in the sample have been washed.

5. Rinse the flask into the sieve two times to clean thoroughly.

6. After the last portion of the sample has been washed, replace the empty 8 mesh sieve on the 140 mesh sieve, and pour the rinse water from the plastic pan through it. Carefully spray down the sides and bottom of the plastic pan into the sieve. Wash the 8 mesh sieve and remove from 140 mesh sieve after it is clean.

7. Spray and wash the sides of the 140 mesh sieve. Tilt the sieve at a 45 degree to 60 degree angle. Starting at the top, wash the screen with a side-to-side motion, rinsing the raisin material into an 800 ml plastic beaker.

   Thoroughly clean all equipment before using again, including washing the sieves from the underside.

Filtering

Filtering equipment consists of a vacuum pump or water aspirator with a suction hose connected to a 1000 ml filter flask, a Coors porcelain filter funnel with a small piece of copper or brass screen, ruled 7 cm filter paper, a stirring rod with a rubber policeman, a squeeze bottle, and tweezers.

1. Prepare clean Petri dishes to receive the filter papers by squirting a bit of water from the squeeze bottle into each dish. This will help the paper to adhere to the dish and delay drying.

2. Turn on the vacuum pump, and lay the filter paper in the funnel. Wet it with squeeze bottle, making a seal between the filter paper and the funnel with the stirring rod. When sealed, the surface of the paper will make a hissing sound.

3. Stir the sample in the beaker with the stirring rod and slowly pour evenly over the filter paper. Avoid overloading the filter paper, as this will make it difficult to read.

4. With tweezers lift the filter paper out and lay it in the Petri dish, being careful not to trap air between the filter paper and the dish.

5. Repeat this process with additional filter papers until the beaker is empty. Use the policeman to scrape down the sides of the beaker. Use the squeeze bottle to wash both the beaker and the policeman onto the last filter paper. Be careful not to spill any of the sample material or contaminate the sample.

6. Empty the filtering flask before it gets too full. Drain the vacuum pump water trap several times a day, depending on how much filtering has been done.

Examining Filter Papers

Establish a regular viewing pattern when examining the filter papers. Stay between the green lines and cover all areas of the filter paper. Use the probe to investigate suspicious objects or to turn large pieces of raisin material that may be covering filth. Use 20x for general reading and higher magnification for more specific identification.

Analysis of Results

Apply the AMS guidelines to determine if the sample meets, fails or requires additional analysis. If first aliquot falls between meeting and failing guidelines, a draw two is taken. This means two additional 227 g (8 ounce) aliquots of the same original gross sample are analyzed. The sample will meet or fail according to the three aliquot average.

Attachments

Version Date
(Printed for distribution)

☐ **21 CFR 101.110, :** _____
http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1.

☐ **FDA Defect Levels Handbook:** _____
http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Sanitation/ucm056174.htm.

☐ **FDA AMS MOU 225-72-2009:** _____
http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/default.htm.

☐ **FDA Macroanalytical Procedures Manual:** _____
http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/MacroanalyticalProceduresManualMPM/default.htm.

☐ **Form FV-16, Notice for Hold for Re-Examination:** _____
http://agnis/AMSFormsCatalog/Forms/AllItems.aspx.

☐ **Form FV-16-2CG, Notification to Food and Drug Administration:** _____
http://agnis/AMSFormsCatalog/Forms/AllItems.aspx.

☐ **Form FV-140, Foreign Material Record:** _____
http://agnis/AMSFormsCatalog/Forms/AllItems.aspx.

Checked Materials have been printed from the links in this Manual and included for reference.