

CPG Sec. 550.300 Dates and Date Material; Imported and Domestic - Adulteration Involving Mold, Insect Excreta, Sour, Dirty, Worthless and Pits

REGULATORY ACTION GUIDANCE:

The following represents the criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN*, direct reference citation requests, and detention of imported products by the appropriate *Field Office within the Human and Animal Food Program*:

- A. Dates - (Whole or Pitted) - Mold, dead insects, insect excreta, sour, dirty and worthless (e.g., mite infested, immature, grossly fibrous or woody, etc.) dates.

The sample (collected according to criteria in Table II), examined in accordance with the sequential analysis plan of Table I, shows a number of reject dates that meets or exceeds the indicated reject number.

See FDA Technical Bulletin Number 5, Macroanalytical Procedures Manual, pages V-53 through V-58 for (1) definitions of reject dates, (2) methodology for determining rejects, and (3) reporting requirements (including findings chart).

- B. Pitted Dates - Pits

The dates contain an average of 2 or more pits and/or pit fragments 2 mm or longer measured in the longest dimension per 100 dates.

- C. Date Material (Chopped, Sliced or Macerated) - Dead Insects, Pits

Examination of 100 gram representative portions from each subsample collected according to procedures in Table II, shows the following:

1. One or more subs contain 10 or more dead insects (whole or equivalent);

or

2. The dates contain an average of 5 or more dead insects (whole or equivalent) per 100 grams;

or

3. The dates contain an average of 2 or more pits and/or pit fragments 2 mm or longer measured in the longest dimension per 900 grams.

REMARKS:

1. Methodology

FDA Technical Bulletin Number 5, Macroanalytical Procedures Manual, is published and distributed by an organization outside of FDA. As a result, simultaneous revision of both the manual and this Compliance Policy Guide cannot always be arranged and there may be times when the manual contains an outdated plan. Therefore, if the manual plan (on page V-56, section (4)(b)) differs from the plan in Table II of this guide use the plan in this guide in lieu of the manual plan.

2. Imports

According to the current agreement *(MOU, FDA 225-72-2001,* signed 11/19/85) with USDA, FDA will examine date material, dates declared for processing, and those dates that are packaged or declared for packaging in lots of 70 lbs. or less. USDA will examine packaged dates or dates declared for packaging in lots of over 70 lbs.

Notify the appropriate USDA field office when:

1. USDA findings on a lot are not accepted by FDA.
2. A lot of dates, previously declared for processing and subsequently detained by FDA, might be reentered for packaging or other purposes.

SPECIMEN CHARGE:

1. Pits:

Article adulterated when introduced into and while in interstate commerce within the meaning of *21 U.S.C. 342(b)(2),* in that a substance, namely pits, has been substituted in part for pitted dates.

2. Insects, Moldy, Sour, Decomposed, Worthless:

Article adulterated (when introduced into and while in interstate commerce) (while held for sale after shipment in interstate commerce), within the meaning of 21 U.S.C. 342(a)(3), in that it consists in part of a (filthy) (decomposed) substance by reason of the presence therein of (insects/insect fragments/insect excreta) (moldy/sour/decomposed/worthless dates).

NOTE: Only use direct reference citation authority when prosecution is anticipated and evidence to support a prosecution is included with the adulteration charge. Evidence necessary to support a prosecution is specified in existing regulatory procedures issuances.

TABLE I**Sequential Analysis Plan for Dates****Number of Defective Dates**

Number of Dates Examined¹	Accept (at or below)	Continue Analysis	Reject (at or above)
100	1	2-7	8
200	5	6-12	13
300	10	11-17	18
400	14	15-21	22
500	18	19-25	26
600	23	24-30	31
700	27	28-34	35
800	34	-	35

¹Product is to be selected at random and as nearly equal in number as practical from each subsample in the sample.

Sequential Analysis Plan for Dates

Number of Defective Dates

**Number of
Dates Examined¹**

Accept (at or below)

Continue Analysis

Reject (at or above)

TABLE II

SAMPLE COLLECTION CRITERIA

A. Random sample all lots of:

1. Whole Dates, 70 pounds or less, or declared for use in processing.
2. Date Material (chopped, sliced and macerated dates) being submitted for entry.
NOTE: See Investigations Operations Manual, Subsection *427.04(c) and 536.01* for examining and reporting on live insect infestation.

B. Determine number of subsamples to collect on the basis of lot size from the following chart:

NUMBER OF CONTAINERS¹ IN THE LOT

Number of Containers In the Lot	Number of Subsamples Required	
	Whole Dates	Date Material
100 or less	3	4
101-600	8	6
601-1200	14	8
1201-2000	26	10
2001-2800	36	12
2801-6000	44	14
6001-9600	56	16
9601-15000	68	18
Over 15000	82	22

¹ NOTE: Chart is based upon unit containers weighing between 20 pounds and 100 pounds. Should containers exceed 100 pounds, consider as 2 or more containers. For example, a 150-pound container would be 2 containers and a 300-pound container, 3 containers.

C. Each subsample should consist of 300-400 dates or a 3-pound chunk. Bag subs separately and identify.

* Material between asterisks is new or revised*

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