FOOD AND DRUG ADMINISTRATION COMPLIANCE POLICY GUIDES

GUIDE

7155a.05

CHAPTER 55a - MOUS and IAGS - FEDERAL

SUBJECT: MOU with Food Safety and Quality Service regarding Imported Dates and Date Material (FDA-225-72-2001)

MEMORANDUM OF UNDERSTANDING

Between The

U. S. DEPARIMENT OF AGRICULTURE FOOD SAFETY AND QUALITY SERVICE

And The

U.S. DEPARIMENT OF HEALTH, EDUCATION & WELFARE FOOD AND DRUG ADMINISTRATION

The Food Safety and Quality Service and the Food and Drug Administration hereby jointly agree to the following terms and conditions as described herein.

I. PURPOSE:

To set forth the working arrangements being followed or adopted to enable each agency to discharge, as effectively as possible, its responsibilities relating to the inspection, sampling, and examination of imported dates and date material.

II. STATUTES RELATING TO THE AGREEMENT:

A. The Food and Drug Administration of the Department of Health, Education, and Welfare is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act. The Food and Drug Administration inspects, samples, and examines imported dates and date products intended for processing for the purpose of determining their status under the statute. One provision of the Act deems a food to be adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance.

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ISSUING OFFICE:

B. The Food Safety and Quality Service of the U.S. Department of Agriculture is responsible for certifying that imported retail packages of dates or bulk dates interded for packaging meet the minimum grade and condition standards as outlined in Section 608e of the Agricultural Marketing Agreement Act of 1937, as amended. These requirements recognize insect infested, filthy, and decomposed dates as defects which may prohibit importation.

Nothing in this agreement shall lessen the responsibilities of the Food Safety and Quality Service under the Agricultural Marketing Agreement Act of 1937; nor of the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

III. BACKGROUND:

So that the responsibilities of both agencies could be efficiently carried out, an agreement concerning the inspection, sampling, and examination of whole dates, packaged or intended for packaging was executed May 29, 1953. The agreement was subsequently amended October 7, 1963, and September 27, 1971.

IV. SUBSTANCE OF AGREEMENT:

A. In addition to evaluating dates for the grade condition requirements, the Food Safety and Quality Service will:

- Sample and examine at time and place of entry all lots (except those of 70 pounds or less, or lots that are so denatured as to render them unfit for human consumption) of imported packaged dates or bulk dates that are declared for packaging. For the purpose of this agreement, a "lot" shall be considered that portion of an offering for import bearing a single identifying number or mark.
- Examine the dates for insect infestation, filth, decomposition, and (if pitted) for pit or pit fragments by the method mutually agreed upon.

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- 3. Accept or reject lots of dates according to the guidelines covering filth, decomposition or insect infestation using the statistical sampling plan 1/ and the sequential analysis plan 1/ made a part of this agreement.
- 4. Upon completion of the examination, promptly notify the appropriate Food and Drug District Office:
 - a. of any lots found not to meet minimum acceptance criteria of this agreement because of pit or pit fragments, insect infestation, filthy or decomposed dates, and
 - b. any cases about which there is any question regarding the laboratory examination results.
- 5. Upon request, provide the Food and Drug Administration with a copy of each examination report which will contain information such as required in FD 1575, a copy of which is made a part of this agreement. 1/
- 6. Inform the Division of Microbiology, Bureau of Foods, Food and Drug Administration of any requests for reclassification and action taken with respect to dates imported as dates for processing to dates for packaging.

B. The Food and Drug Administration will:

 Sample and examine lots of dates or date material that are declared for use in processing.

^{1/} Filed as part of the original document

- Deny entry to any lots of packaged dates or bulk dates intended for other than processing to be reentered for processing when such lots have been sampled and examined by the Food Safety and Quality Service and found to exceed the mutually agreed upon administrative working tolerance.
- 3. Unless the Food Safety and Quality Service is notified to the contrary:
 - a. accept the findings of the Food Safety and Quality Service on any lot of dates sampled and inspected by them.
 - b. cause detention of any lot of dates rejected by the Food Safety and Quality Service because it contains excess pit, or pit fragments, insect infestation and/or filthy and decomposed dates if offered for reentry by the importer for processing.
 - permit entry as dates for processing without resampling any lot of whole dates certified by the Food Safety and Quality Service as failing to meet the minimum grade and condition requirements as outlined in Section 608e of the Agricultural Marketing Agreement Act of 1937, as amended, but which lot does not exceed the administrative working tolerance for insect infestation or filthy and decomposed dates, further provided that such lot is not othewise in violation of the Federal Food, Drug, and Cosmetic Act.
- 4. To inform the appropriate Food Safety and Quality Service field office of any detention of dates that might be offered for entry for other than processing purposes.

V. NAME AND ADDRESS OF PARTICIPATING AGENCIES:

Food and Drug Administration 5600 Fishers Lane Rockville, Maryland 20857

Food Safety and Quality Service U.S. Department of Agriculture 12th and Independence Avenue, S.W. Washington, DC 20250

VI LIAISON OFFICERS:

- A. Charles W. Luxford, Head
 Grading Section
 Processed Products Branch
 Fruit and Vegetable Quality Division
 Food Safety and Quality Service
 U.S. Department of Agriculture
 12th and Independence Avenue, S.W.
 Washington, DC 20250
 Telephone: 447-5021
- B. Paris M. Brickey, Jr., Acting Chief Microanalytical Branch (HFF-127)
 Division of Microbiology
 Bureau of Foods
 Food and Drug Administration
 200 "C" Street, S.W.
 Washington, DC 20204
 Telephone: 245-1564

VII. PERIOD OF AGREEMENT:

This agreement, when accepted by both parties, covers an indefinite period of time and may be modified by mutual consent of both agencies or terminated by either agency upon thirty (30) days written notice.



APPROVED AND ACCEPTED FOR THE FOOD SAFETY AND QUALITY SERVICE

s/Robert Angelotti, Ph.D. Administrator

Date: October 28, 1977.

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

s/Joseph P. Hile
Associate Commissioner
for Compliance

Date: November 21, 1977.



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. FD FORM 1575 (M/72)

Date:

Imported Datos and Dato Haterial <u>SEQUENTIAL AIMLYSIS PLAN</u>

SEQUENTIAL PLAN FOR SUBSAMPLE EXAMINATIONS

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[&]quot;a" - Accept when the number of Class II subsamples equals or is less than the acceptance number.

[&]quot;d" - Detain when the number of Class II subsamples equals or exceeds the detention number.

Imported Dates and Date Material STATISTICAL SAMPLING PLAN

SAMPLE EXAMINATION AND CLASSIFICATION TABLES

TABLE 1
MUMBER OF DEFECTIVE DATES

| TOTAL DATES EXAMINED | CLASS I | NO DECISION | DISQUALIFIED AS CLASS I |
|----------------------------|-----------|----------------|-------------------------|
| 25 | • | 0-3 | 4 or more |
| 50 | I or less | 2-4 | 5 or more |
| 75 | 2 or less | 3-5 | 6 or more |
| 100 | 4 or less | 5-6 | 7 or more |
| 125 | 6 or less | 400 | 7 or sore |

^{*}Sample size of 25 does not allow for acceptance, only rejection.

For Use on Subs Disqualified as Class I MADMBER OF DEFECTIVE DATES

| TOTAL DATES XAMINED | CLASS II | NO DECISION | CLASS III |
|---------------------------|------------|----------------|------------|
| 25 | | 4-6 | 7 or more |
| 50 | 5 or Tess | 6-10 | ll or more |
| 75 | 8 or less | 9-14 | 15 or more |
| 100 | 12 or less | 13-18 | 19 or more |
| 125 | 18 or less | 000 | 19 or more |

^{*}Sample size of 25 does not allow for acceptance, only rejection.