Memorandum of Understanding

Between the

Food and Drug Administration
Department of Health and Human Services
of the United States of America

And

Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria
of the United Mexican States

Concerning

Entry of Mexican Cantaloupes into the United States of America

The Food and Drug Administration (FDA), Department of Health and Human Services of the United States of America (U.S.A.), and the Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA) of the United Mexican States (Mexico) (hereinafter referred to as the "Participants") have reached the following Memorandum of Understanding (MOU) concerning the entry of cantaloupes from Mexico into the U.S.A.

I. PURPOSE

The purpose of the MOU is to establish, and build confidence in, a system that increases the likelihood that cantaloupes from Mexico offered for import into the U.S.A. comply with U.S.A. law. This MOU also establishes a risk-based classification system for firms in Mexico producing cantaloupes for import into the U.S.A. to protect the public health.

II. DEFINITIONS

For the purposes of this MOU, the Participants have set out the following definitions:

A. Firms Implicated in an Outbreak of Disease -- means firms, i.e., growers, processors, packers, and importers, for which FDA or SENASICA has positive traceback information for Salmonella or other pathogenic species for cantaloupe from Mexico.

B. Category 1 Firms -- means firms that are no longer subject to the Detention without Physical Examination (DWPE) by FDA under Import Alert #22-01, Detention Without Physical Examination of Fresh, Frozen and Processed Cantaloupes from Mexico. Those firms are listed in the attachment to Import Alert #22-01.

C. Category 2 Firms -- means firms that have been directly implicated by FDA or SENASICA in an outbreak of disease or that have shipments of cantaloupes from Mexico test positive for Salmonella or other pathogenic species and are subject to Detention without Physical Examination (DWPE) by FDA under Import Alert #22-01.

D. Category 3 Firms -- means firms that have neither been directly implicated in a Salmonella or other pathogenic disease outbreak nor had shipments of cantaloupe test positive for Salmonella or other pathogenic species and are subject to Detention without Physical Examination (DWPE) by FDA under Import Alert #22-01.

III. BASIC INTENTIONS OF THE PARTIES

The parties generally intend to evaluate cantaloupe exported from Mexico and imported or offered for import into the U.S.A. in accordance with the provisions of this MOU.

A. SENASICA's INTENTIONS:

1. SENASICA intends to inspect Category 2 firms for compliance with the Federal Recognition Program (FRP), which was jointly established by SENASICA, the Comision Federal para la Proteccion Contra Riesgos Sanitarios (COFEPRIS), and the Comision Nacional del Agua (CNA) (A copy of FRP in both English and Spanish languages will be attached as Attachment A to this MOU).
2. SENASICA intends to inspect Category 3 firms for compliance with the SENASICA Good Agriculture Practice *Lineamientos* (See copy of SENASICA Good Agriculture Practice *Lineamientos* in both English and Spanish languages will be attached as Attachment B to this MOU).
3. SENASICA intends to only certify firms that are in compliance with either the FRP or the *Lineamientos* and that commit to only ship their own product and not commingle product with that of other firms.
4. SENASICA intends to allow FDA to accompany SENASICA on inspections for compliance with the FRP and the Good Agriculture Practice *Lineamientos.*
5. SENASICA intends to issue on a seasonal basis certification to Category 2 firms that comply with the FRP and to Category 3 firms that comply with the Good Agriculture Practice *Lineamientos* and to provide FDA with a list containing the names and addresses of any such firm granted certification and the type of

certification granted. SENASICA intends that any such certified firm will be classified as a Category 1 firm after certification and 5 consecutive shipments found to be negative for Salmonella as described below in the FDA Intentions section. SENASICA does not intend to certify Category 2 firms based on the Good Agriculture Practice *Lineamientos.*

6. SENASICA intends to certify and audit seasonally both Category 2 and Category 3 firms that have been reclassified as Category 1 firms under the terms of this MOU to ensure that these firms continue to be in compliance with the FRP, and SENASICA Good Agriculture Practice *Lineamientos*, respectively. If such a firm fails to maintain its certification or fails a seasonal audit, SENASICA intends to immediately notify the FDA of such results and intends for the firm to be considered as a Category 2 firm.
7. SENASICA intends that any firm classified as Category 1 whose products are found to bear or contain Salmonella or other pathogenic species or that is implicated in an outbreak of disease to be considered Category 2 and to be subject to DWPE under FDA's Import Alert #22-01.
8. SENASICA intends to provide FDA, upon request, with documentation supporting certification or denial of certification.

B. FDA's INTENTIONS:

1. For Category 1 firms, FDA intends to consider such firms to be no longer subject to DWPE under FDA Import Alert #22-01. Firms that are no longer subject to DWPE at the time of signature of this MOU are set out in an attachment to Import

Alert #22-01. FDA intends to continue to consider cantaloupes from such firms as subject to routine and random examination and testing and any other actions by FDA as authorized by the Federal Food, Drug, and Cosmetic Act (FFDCA) and any other applicable statutory authorities.

2. For Category 2 and Category 3 firms, FDA intends to accompany SENASICA on up to the first 12 inspections. After these first successful joint inspections, FDA will consider the certificate of compliance with the FRP or the Good Agriculture Practice *Lineamientos* by SENASICA alone as relevant to the appearance of adulteration.
3. For Category 2 firms, when shipments of cantaloupes are offered for import into the U.S.A., FDA intends to consider as evidence relevant to the appearance of adulteration a FRP certification issued by SENASICA and testing of the shipment of cantaloupes for Salmonella by a testing laboratory with testing and sampling methods that are acceptable to FDA.[1] If such testing is negative for Salmonella and certification has been granted, FDA intends that the particular shipment may be admitted into the U.S.A. unless it otherwise appears to be in violation of the FFDCA or any other applicable statutory provision.
4. For Category 3 firms, when shipments are offered for import into the U.S.A., FDA intends to consider as evidence relevant to the appearance of adulteration a Good Agriculture Practice *Lineamientos* certification issued by SENASICA and testing of the shipment of cantaloupes for Salmonella by a testing laboratory with testing and sampling methods acceptable to FDA. If such testing is negative for

[1] Firms should refer to Section 7 of FDA's Laboratory Procedures Manual for guidance on identifying a private laboratory. At the time of signing of this MOU, FDA's Laboratory Procedures Manual can be found at http://www.fda.gov/ora/science_ref/lm/default.htm.

Salmonella and certification has been granted, FDA intends that the particular shipment may be admitted into the U.S.A. unless it otherwise appears to be in violation of the FFDCA or any other applicable statutory provision.

5. For Category 2 and Category 3 firms, FDA alternatively intends to continue to consider as evidence relevant to the appearance of adulteration the types of information consistent with the guidance set out in Import Alert #22-01.
6. FDA intends to reclassify a Category 2 or Category 3 firm as a Category 1 firm that is no longer subject to DWPE under Import Alert #22-01 if SENASICA has certified the firm and the firm has five separate shipments that test negative for Salmonella by a testing laboratory with testing and sampling methods acceptable to FDA and the firm is not otherwise implicated in an outbreak of disease. For firms classified as Category 1, see section B.1. above.
7. For any firms that were previously categorized as Category 2 or Category 3 and were reclassifed as Category 1 under section B.6., if SENASICA advises FDA of unsatisfactory inspection and audit results or failure to maintain certification as described in section A.6., FDA intends to no longer consider the firm as Category 1 and such firm would be considered Category 2 under this MOU and again be subject to DWPE under Import Alert #22-01 unless the firm provides evidence relevant to the appearance of adulteration such as the types of information consistent with the guidance in Import Alert #22-01.
8. FDA intends that any firm classified as Category 1 whose products are offered for import into the U.S.A. and that are found to bear or contain Salmonella or other pathogenic species or any firm classified as Category 1 that is implicated in an

outbreak of disease to no longer be considered Category 1 and to be Category 2 firms under this MOU and be subject to DWPE under FDA's Import Alert #22-01.

IV. ADMINISTRATIVE PROCEDURES

Nothing in this MOU shall in any way abrogate the responsibility or authority of the FDA under section 801 of the FFDCA to examine any food product being imported or offered for import into the U.S.A. or to take any other necessary actions, under the FFDCA or any other law administered by the FDA, to protect the public health, including placing all Mexican cantaloupe firms on DWPE if warranted. All activities under this MOU are to be conducted in accordance with the laws and regulations of the U.S.A. and the United Mexican States and are subject to the availability of personnel, resources, and appropriated funds. This MOU is not intended to create binding obligations under international or other law. A list of firms in Categories 1 and 2 as of the time of the signing of this MOU will be attached to this MOU as Attachment C.

V. PERIOD OF UNDERSTANDING

Cooperation under the MOU will begin on the date of signature of both Participants and will continue for a period of five years. This MOU may be amended by mutual written consent of the Participants or terminated by either Participant upon sixty (60) calendar days' written notice to the other Participant.

Signed at Rockville for the Food and Drug Administration and the Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria, this twenty-sixth day of October, 2005.

For the
Food and Drug Administration:

Murray M. Lumpkin, M.D.
Deputy Commissioner
International and Special Programs

For the Servicio Nacional de Sanidad,
Inocuidad y Calidad Agroalimentaria:

Dr. Javier Trujillo Arriaga
Director en Jefe