DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

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Dr. Enrique Sánchez-Cruz
Director en Jefe
Servicio Nacional de Sanidad Inocuidad y Calidad Agroalimentaria
SAGARPA
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Dear Dr. Sanchez-Cruz,

I have the pleasure to write to you to propose the following amendments to the 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 signed October 26, 2005 (MOU).

1. In Section II(B), definition of "Category 1 Firms," the last sentence is amended to read, "Those firms are listed in an attachment to Import Alert #22-01."
2. In Section III, the heading is amended to read, "III. BASIC INTENTIONS OF THE PARTICIPANTS," and in the first paragraph (chapeau) of Section III, the word "parties" is amended to read "Participants."
3. In Section III, at the end of the first paragraph (chapeau) the following sentence is added: "Testing should be done in accordance with FDA methodology found in the current version of the FDA Import Produce Assignment."
4. In Section III(A)(2), the sentence inside the parentheses is amended to read, "(see copy of Good Agriculture Practice *Lineamientos* in both English and Spanish languages attached as Attachment B to this MOU)."
5. In Section III(A)(3), the provision is amended to read, "SENASICA intends to only certify firms that are in compliance with either the FRP or the Good Agriculture Practice *Lineamientos*, as appropriate, and that commit to shipping only their own product and not commingling their product with that of other firms."
6. In Section III(A)(5), in the second sentence, the words, "from that firm have been" are inserted after the words, "5 consecutive shipments".
7. In Section III(A)(6), the first sentence is amended to read, "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 or Good Agriculture Practice *Lineamientos*, as applicable."

8. In Section III(A)(7), the words "whose products are found to bear or contain Salmonella or other pathogenic species or" are deleted.
9. Section III(A)(8) is renumbered as Section III(A)(9) and a new Section III(A)(8) is added as follows:

"8. SENASICA intends that any firm classified as either:

a) Category 1 but whose products are subsequently found to bear or contain Salmonella or other pathogenic species; or
b) Category 3 after SENASICA certification but whose products are found to bear or contain Salmonella or other pathogenic species,

will be reclassified as Category 2 unless all of the following occur, in which case the firm will be classified as Category 3:

a) SENASICA inspects the firm and the inspection of the firm does not provide evidence of deviations from the Good Agriculture Practice *Lineamientos* that could have caused the contamination; and
b) SENASICA also investigates other probable non-Good Agriculture Practice *Lineamientos* cause(s) of the contamination, such as weather events, etc. including any hypothetical cause(s) specifically identified by FDA; and
c) the firm develops a corrective action plan that addresses any probable cause(s) of the contamination; and
d) SENASICA invites FDA to participate in the inspections; and
e) SENASICA verifies the implementation of the corrective action plan developed by the firm; and
f) SENASICA provides documentation of the Good Agriculture Practice *Lineamientos* and non- Good Agriculture Practice *Lineamientos* inspections, the firm's corrective action plan, and the firm's implementation of the action plan; and
g) FDA finds the inspection documentation, corrective action plan, and implementation of the action plan acceptable to address any probable cause(s) of the contamination."

10. In Section III(B)(2), the second sentence is amended to read, "After these first successful joint inspections, FDA intends to consider the certificate of compliance with the FRP or the Good Agriculture Practice *Lineamientos*, as applicable, by SENASICA alone as relevant to the appearance of adulteration."
11. In Section III(B)(3), in the last sentence the words "or regulatory" are inserted after the words "other applicable statutory."
12. In Section III(B)(4), in the last sentence the words "or regulatory" are inserted after the words "other applicable statutory."
13. In Section III(B)(8), the words "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," are deleted.

14. In Section III(B)(8) the words "Category 2 firms" are amended to read, "a Category 2 firm."
15. A new III(B)(9) is added as follows:

"9. FDA intends that any firm classified as either:

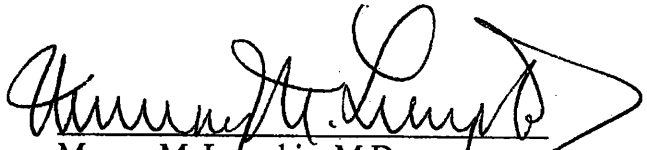
a) Category 1 but whose products are subsequently found to bear or contain Salmonella or other pathogenic species; or
b) Category 3 after SENASICA certification but whose products are found to bear or contain Salmonella or other pathogenic species;

will be reclassified as Category 2 unless all of the following occur, in which case the firm will be classified as Category 3:

a) SENASICA inspects the firm and the inspection of the firm does not provide evidence of deviations from the Good Agriculture Practice *Lineamientos* that could have caused the contamination; and
b) SENASICA also investigates other probable non-Good Agriculture Practice *Lineamientos* cause(s) of the contamination, such as weather events, etc. including any hypothetical cause(s) specifically identified by FDA; and
c) the firm develops a corrective action plan that addresses any probable cause(s) of the contamination; and
d) SENASICA invites FDA to participate in the inspections; and
e) SENASICA verifies the implementation of the corrective action plan developed by the firm; and
f) SENASICA provides documentation of the Good Agriculture Practice *Lineamientos* and non-Good Agriculture Practice *Lineamientos* inspections, the firm's corrective action plan, and the firm's implementation of the action plan; and
g) FDA finds the inspection documentation, corrective action plan, and implementation of the action plan acceptable to address any probable cause(s) of the contamination."

16. In Section IV, after the first sentence add a new sentence as follows, "FDA retains the right to conduct its own inspections of Mexican cantaloupe farms and/or processing facilities and SENASICA retains the right to accompany FDA."

If these amendments are acceptable to you, this letter and your affirmative reply will constitute an amendment to the MOU effective on the date of receipt of your reply.



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