



J & K FRESH, LLC

A CUSTOMHOUSE BROKERAGE FIRM

ROSS JONES
LYNNETTE KEFFER

December 22, 2003

Food & Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane Room 1061
Rockville, MD 20852

RE: **Comments on Proposed Notice of Rulemaking:
21 CFR Part 1, Docket No. 02N-0278
FDA Prior Notice Proposal, Interim Final Rule**

To Whom it May Concern:

This letter contains our comments for the above referenced regulation. J & K Fresh is a Customhouse Brokerage firm specializing in the clearance of imported fresh produce. As Americans and consumers, we are extremely concerned with the security of the supply chain for imported food. The continued success of our business (as well as our clients') is dependent upon it.

The Public Health Security and Bioterrorism Preparedness and Response act of 2002 (BTA) is intended to protect the health and safety of the people of the United States. In that context and in order to make examination decisions, Section 307c was amended.¹ This *Prior Notice* regulation requires that information must be submitted and confirmed electronically as factually complete by FDA **before** the food arrives at the port of arrival. (Times vary according to the mode of transportation.) For fresh produce, one of the requirements is the transmission of the growers (although many are exempt from registration). This requirement is turning a one or two line entry into a 1 to 200-line entry. (A good example is weekly break-bulk vessel shipments of bananas controlled by one exporter, but obtained from several farms.) In addition, some farms utilize packing or storage facilities (which are required to register) and others

¹. "(m)(1) In the case of an article of food that is being imported or offered for import into the United States, the secretary, after consultation with the Secretary of the Treasury, shall by regulation require, for the purpose of enabling such article to be inspected at port of entry into the United States, the submission to the Secretary of a notice providing the identity of each of the following:"

2002N.0278

EMC151

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are exempt, which requires a more complicated sort. In addition some growers may pack in more than one size box, which is a further breakout. The number of cases and value for each line need to be totaled and input for each grower. This additional work has vastly increased our cost of doing business. We have increased our fees 20% (to our clients, which will be passed down the line all the way to the consumer level). There will be further increases, as the 20% is not covering our increased costs.

The point I want to make is that this requirement (prior notification for review for the purpose of deciding whether or not an inspection is necessary) is redundant as inspection is a mandatory condition of entry. Quarantine is addressed in 7CFR319.56-6, (a-f), which requires that all importations of fresh fruit and vegetables be placed on an automatic hold upon arrival by USDA/CBP. Item (d) specifically addresses "*Release for movement. No person shall move from the port of first arrival any imported fruit or vegetable unless and until the inspector notifies the person.....*" It should be noted that the responsibility for these required inspectional functions was transferred from the U.S. Department of Agriculture to Customs Border Protection on March 1, 2003.

Fresh produce shipments are subject to inspection upon arrival. The regulations require that the USDA/CBP officer do the inspection at the first port of arrival. Fresh produce cannot enter the commerce without going through the inspection and review process. There is protocol in place for some produce for pre-clearance inspections and/or treatments. These programs are conducted under the direct supervision of qualified USDA officers stationed at the foreign site and in accordance with the protocol in place (similar to the CBP Container Security Initiative). For your information I have attached copies of certificates that are attached to the pallets, a bill of lading listing the USDA container seal, and sample PPQ203 Foreign Site Certificate of Inspection and/or Treatment. It should be noted that even this pre-cleared produce is subject to quarantine (automatic hold upon arrival) until the original documents are presented to USDA/CBP for verification. The reviewing officer may accept the documents or may opt for another inspection. The shipment will remain "on hold" at the terminal until USDA/CBP releases the shipment. Produce shipments are not allowed to enter commerce without being released from quarantine.

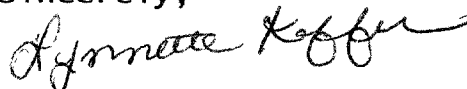
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I do not believe Section 315, Rule of Construction, to be relevant to this particular case of point. The point is:

- ✓ The Department of Homeland Security was created to better protect the United States against terrorist attacks, including biological attacks on the food supply.
- ✓ Fresh produce shipments are placed on a quarantine (automatic USDA/CBP hold) status upon arrival, subject to a mandatory review and inspection process.
- ✓ As of March 1, 2003, this responsibility was transferred to Customs Border Protection under the jurisdiction of the Department of Homeland Security.
- ✓ CBP Agriculture Specialist Officers are on the frontline reviewing and inspecting all fresh produce shipments before they are released to enter commerce. CBP's Fact Sheet states: The establishment of this new position will help CBP protect the American public from agro-terrorism and bio-terrorism."

We are not arguing the issue of jurisdiction; we are arguing the issue of redundancy. Redundancy creates excessive costs for both the government and the private sector. Redundancy is particularly oppressive to the small business. Our resources (man-power, computer equipment, programs, etc.) are much more limited than those of the larger company. It seems pointless to notify FDA (who is implementing this act in conjunction with CBP) for the purpose of a *possible inspection* when an **inspection (by a CBP Agriculture Specialist) is a mandatory condition of entry**. We ask after careful review of the facts, FDA exempt importations of fresh produce (subject to 7CFR19.56-6, a-f) from the requirement of Section 307, Prior Notice.

Sincerely,



Lynnette Keffer
President

Enclosures

SAMPLE OF PRE-INSPECTION CERTIFICATE

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
PLANT PROTECTION AND QUARANTINE

1. CERTIFICATE NO.

2. COUNTRY OF ORIGIN

ECVADOR

FOREIGN SITE CERTIFICATE OF INSPECTION
AND/OR TREATMENT

3. DATE LOADED

12-11-03

4. FOREIGN PORT OF EXPORT

GVAYAQUIL

5. CARRIER IDENTIFICATION

6. U. S. PORT OF ENTRY

LOS ANGELES

7. SHIPPER (Name & Address)

8. CONSIGNEE (Name & Address - Include Zip Code)

9. COMMODITY

10. NO. CONTAINERS
(Identify as box, sack,
½ Bruce box, flat, card-
board box, etc.)

11. CONTAINER
IDENTIFICATION MARKS

FRESH MANGOES (4.0 KG/BOX)
TOMMY VAR.

BOXES

CONTAINER #

7 PALLETS OF 240 BXS EACH ONE
HADEN VAR.

1680

MWCU-6697768

7 PALLETS OF 240 BXS EACH ONE
TOMMY VAR.

1680

4 PALLETS OF 228 BXS EACH ONE
HADEN VAR.

912

4 PALLETS OF 228 BXS EACH ONE

912

TOTAL = 22 PALLETS

5184

IDENTY MARK OF
BOXES: SABRINA

WEIGHT

20734 KG.

USDA-APHIS SEAL#

00053

12. LOCATION OF INSPECTION AND/OR TREATMENT

DUREXPORTA S.A. GVAYAQUIL, ECVADOR

13. DATE

12-09,10-03

This certifies that the shipment described above has been inspected and/or treated in accordance with agricultural requirements for entry into the United States.

14. SIGNATURE OF PLANT PROTECTION AND QUARANTINE OFFICER

Camilo Becerra

15. DATE ISSUED

12-11-03

Shipper

**SAMPLE OF BILL OF LADING FOR
FRUIT WHICH WAS PRE-INSPECTED.
PLEASE NOTE THAT THE USDA SEAL NUMBER
IS SHOWN AND MATCHES THE 203 FORM.**

FAA

Consignee (negotiable only if consigned "to order", "to order of" a named Person or "to order of bearer")

Booking No.
002020659

Export references

Forwarder's name & address

Notify Party (see clause 22)
J&K FRESH
9911 INGLEWOOD AVE. SUITE 200
INGLEWOOD, CA. 90301
TEL. (310) 4199770 FAX (310) 4199790
SR. ROBERT O LUPITA

Onward inland routing (Not part of Carriage as defined in clause 1. For account and risk of Merchant)

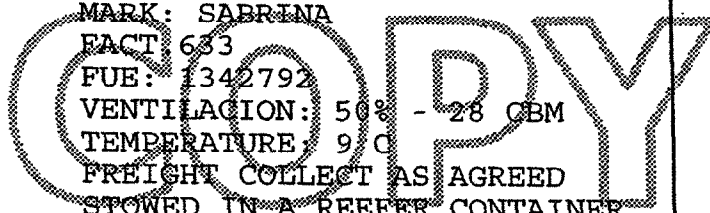
Place of Receipt. Applicable only when document used as Multimodal Transport B/L. (see clause 1)
PASCUALES - GUAYA

Vessel (see clause 1 + 19) MAERSK SAN JUAN	Voyage No. 0350
Port of Loading GUAYAQUIL	Port of Discharge LOS ANGELES

Place of Delivery. Applicable only when document used as Multimodal Transport B/L. (see clause 1)

PARTICULARS FURNISHED BY SHIPPER - CARRIER NOT RESPONSIBLE

Kind of packages; Description of goods; Marks and Numbers; Container No./Seal No.	Gross Weight	Measurement
MWCU6697768 ML-SA1236416 00053 MWCU6700012 ML-SA1236415 00054 MWCU6545106 ML-SA1236478 25034 00056 MWCU6020000 ML-SA1236470 25034 00061 MWCU6027447	40HREF SAID TO CONTAIN 26088 BOXES CY / CY FRESH MANGOES MARK: SABRINA FACT: 633 FUE: 1342792 VENTILACION: 50% - 28 CBM TEMPERATURE: 9 C FREIGHT COLLECT AS AGREED STOWED IN A REEFER CONTAINER SET AT SHIPPERS REQUESTED CARRIAGE TEMPERATURE OF 48 DEGREES FAHRENHEIT	KGS 109570.000 CB 170.00



Above particulars as declared by Shipper, but without responsibility of or representation by Carrier (see clause 14)

Freight & Charges	Rate	Unit	Currency	Prepaid	Collect

RECEIVED ON BOARD ON DEC 16 2003

Carrier's Receipt (see clauses 1 and 14)
Total number of containers or packages received by Carrier.

5 CONTAINER (S)
Number & Sequence of Original B(s)/L
3 / THREE

Declared Value (see clause 7.3)

Place of Issue of B/L
GUAYAQUIL

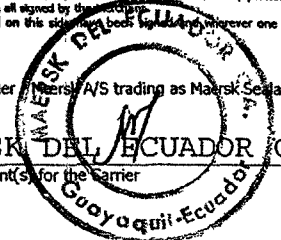
Date of Issue of B/L
DEC 17 03

SHIPPED, as far as ascertained by reasonable means of checking in apparent good order and condition unless otherwise stated herein the total number or quantity of Containers or other packages or units indicated in the box opposite entitled "Carrier's Receipt" for carriage from the Port of Loading (or the Place of Receipt, if mentioned above) to the Port of Discharge (or the Place of Delivery, if mentioned above), such carriage being always subject to the terms, rights, defences, provisions, conditions, exceptions, limitations, and liberties hereof (INCLUDING ALL THOSE TERMS AND CONDITIONS ON THE FACE HEREOF NUMBERED 1-25 AND THOSE TERMS AND CONDITIONS IN THE CARRIER'S APPLICABLE TARIFF) and the Merchant's attention is drawn in particular to the Carrier's liberties in respect of on deck stowage (see clause 15) and the carrying vessel (see clause 19). Where the bill of lading is non-negotiable the Carrier may give delivery of the Goods to the named consignee upon reasonable proof of identity and without requiring surrender of an original bill of lading. Where the bill of lading is negotiable, the Carrier will be entitled to give delivery of the Goods against what he reasonably believes to be a genuine original bill of lading. Delivery as aforesaid is authorized and shall constitute due delivery hereunder and the Merchant shall have no claim for loss or non-delivery. In accepting this bill of lading, any local customs or privileges to the contrary notwithstanding, the Merchant agrees to be bound by all Terms and Conditions stated herein whether written, printed, stamped or incorporated on the face or reverse side hereof, as fully as if they were all signed by the Merchant.

In WITNESS WHEREOF the number of original Bills of Lading stated on this side have been signed and wherever one original Bill of Lading has been surrendered any others shall be void.

Signed for the Carrier A.P. Møller / Maersk A/S trading as Maersk Sealand

MAERSK DEL ECUADOR C.A.
As Agent(s) for the Carrier



ATTACHMENT: SAMPLE OF ONE OF ANOTHER TAG ATTACHED TO PALLETS OF FRESH FRUIT WHICH WAS "PRE-INSPECTED" PRIOR TO IMORTATION.

FRUPCO EXPEDITING

13108335668

UNITED STATES DEPARTMENT OF AGRICULTURE

PLANT INDUSTRY AND PROTECTION SERVICE

CERTIFICATE OF PRESAMPLING
FOR USDA/SAG INSPECTION

COMMODITY Pineapples
LOT NUMBER 15
DATE 7-11-03

ATTACHMENT: SAMPLE OF 1 OF THE TAGS ATTACHED TO PALLETS OF FRESH FRUIT WHICH WERE "PRE-INSPECTED" PRIOR TO IMPORTATION.

UNITED STATES DEPARTMENT OF AGRICULTURE

ANIMAL AND PLANT HEALTH INSPECTION SERVICE
PLANT PROTECTION AND QUARANTINE

CERTIFICATE OF INSPECTION

NUMBER OF CASES

109

CERTIFICATE N°. D 321445

PPQ FORM 531 (SEP. 2002)

