



J & K FRESH, LLC

A CUSTOMHOUSE BROKERAGE FIRM

ROSS JONES
LYNNETTE KEFFER

April 28, 2004

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

RE: Comments on Proposed Notice of Rulemaking:
Docket No. 2002N-0278), Interim Final Rule

To Whom It May Concern:

In accordance with Volume 69, Number 72 (Federal Register) we are submitting our comments on the FDA BTA, specifically Section 307 of the IFR, which pertains to Prior Notice. We will limit our comments to the issues discussed in the publication that directly affect our business.

J & K Fresh is a Customhouse Brokerage Firm specializing in the clearance of fresh produce at the ports of Los Angeles-Long Beach and San Diego. We process shipments arriving by sea, air, and rail (for land-bridge movements only). J & K Fresh is a member of the Customs-Trade Partnership Against Terrorism. We realize that in this era a portion of our resources must be devoted to security programs.

FDA OUTREACH AND EDUCATION (BTA):

In the fall of 2003 (prior to the initial implementation), FDA conducted outreach programs (such as the Satellite Broadcast and outreach seminars conducted at various ports of entry). These programs provided the basic information of the law and its implementation. There were no "nuts and bolts" sessions. There have been no outreach programs since implementation to discuss specific operational problems and/or inadequacies (although FDA's statistics state that 50% of the data transmissions are inaccurate or incomplete). We received ABI Administrative Message 04-0982 stating that full edits go into effect on May 13, 2004. The same message states: "Receipt of a PNC number does not indicate that the submission is error free for FDA Prior Notice purposes....." In other words, we have had the understanding that we were transmitting properly because we received the PNC number. Now we learn that is not the case! How do we know what adjustments in our operations, programming and databases need to be made; and when do we make them (without experiencing delays in processing our daily arrivals)? We encourage FDA to schedule additional training and outreach programs prior to full implementation of the BTA.

C-TPAT:

As noted, participants of this program have conducted comprehensive self-assessment programs and documented in detail the security of their entire supply chain. These documents are reviewed and kept on

02N-0278

C295

file with The Bureau of Customs and Border Protection (CBP). In addition, CBP follows-up with a validation. (CBP sends personnel to visit and verify the participating company's documented profile.) Definitely a participant of C-TPAT would be a lower security risk.

I believe this subject needs to be further explored and addressed by FDA and CBP. Importers that show the initiative and willingness to cooperate in this manner should receive benefits equal to their investment (time as well as monetary). FDA could possibly consider implementing a more lenient timeframe for C-PAT members.

I would suggest that the C-TPAT Importer Profile be amended for importers of food to add the FDA Registration information for the food facilities listed in their profile.

FLEXIBLE ALTERNATIVES:

As stated in my comments of December 22, 2003, I firmly believe that importations of fresh produce are already meeting the requirements of the FDA BTA. Following are the basic points. (There is more detail in the attached copy of my December comments.)

- The purpose of the prior notification to FDA is to provide FDA with the information necessary to make a decision (prior to arrival) for a *possible* physical inspection.
- Fresh produce already is subject to *mandatory* quarantine at the first port of arrival by USDA/CBP.
- The CBP Agriculture Specialist performs the physical inspection (or reviews original documentation than confirms pre-inspection).

Produce should be exempt form the requirement of prior notice. It is already carefully monitored by CBP. As it is placed on automatic quarantine for a mandatory inspection, it meets the requirement of the BTA.

Security is of the utmost concern to those of us involved in the international food industry. Our livelihood depends upon the free flow of legitimate trade. We want to comply and cooperate all in all programs that promote border security and food safety. However, we also believe that the government (CBP, USDA, FDA) should be able to consolidate this process and share information.

Sincerely,



Lynnette Keffer
President

Enclosures



J & K FRESH, LLC

A CUSTOMHOUSE BROKERAGE FIRM

ROSS JOI
LYNNETTE KEF

December 22, 2003

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

Copy org
Comments sent
12-22-2003

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

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:"

Page 2

storage facilities (which are required to register) and others 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.

Page 3

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

UNITED STATES DEPARTMENT OF AGRICULTURE

ANIMAL AND PLANT HEALTH INSPECTION SERVICE
PLANT PROTECTION AND QUARANTINE

OFFICE OF INSPECTION

NUMBER OF CASES

109

1445

Attached to Pallets
When Pre-Inspected

Shipper
EXPORTACIONES DUREXPORTA S.A.
 KM. 14,5 VIA DAULE
 R.U.C. 0991149406001
 TEL. (593 4) 2893651
 FAX (593 4) 2893648

Booking No.
002020659

Export references

Forwarder's name & address
FDI C/O CAP SUN PRODUCE 511
MOUNTAIN VIEW AVE OXNARD, CA.93031
TEL:8059858887/4871464 ATT:MORGAN

Consignee (negotiable only if consigned "to order", "to order of" a named Person or "to order of bearer")
FRESH DIRECTIONS INTERNATIONAL INC.
 10195 TELEPHONE ROAD
 VENTURA. CA. 93004

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

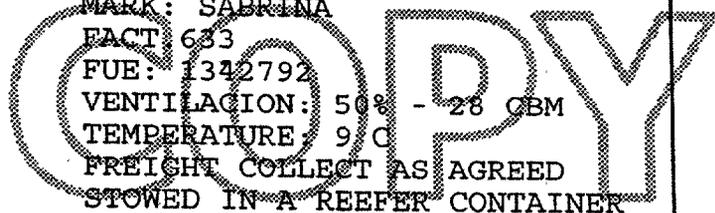
Place of Delivery. Applicable only when document used as Multimodal Transport B/L (see clause 1)

Port of Loading
GUAYAQUIL

Port of Discharge
LOS ANGELES

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 EACT: 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 109570.000 170.00



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 the total number or quantity of Containers or other packages or units indicated in the box opposite entitled "Carrier's Receipt" for c 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, defenses, provisions, conditions, exceptions, limitations, and liabilities hereof (INCLUDING ALL THOSE TERMS AND CONDITIONS ON THE FACE HEREOF NUMBERED 1-26 AND THOSE TERMS AND CONDITIONS IN THE CARRIER'S APPLICABLE TARIFF) and the Merchant's attention is drawn in particular to the Carrier's liability respect of on deck stowage (see clause 18) and the carrying vessel (see clause 19). Where the bill of lading is non-negotiable 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 otherwise 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 of this book has been signed and delivered and one original bill of lading has been surrendered any others shall be void.

Signed for the Carrier A.P. Møller
MAERSK DEL ECUADOR C.S.A.
 AS AGENTS FOR THE CARRIER
 Guayaquil-Ecuador

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

FOREIGN SITE CERTIFICATE OF INSPECTION
AND/OR TREATMENT

1. CERTIFICATE NO.

DVREX-0301

2. COUNTRY OF ORIGIN

ECVADOR

3. DATE LOADED

12-11-03

4. FOREIGN PORT OF EXPORT

GUAYAQUIL

5. CARRIER IDENTIFICATION

SAN JUAN 0350

6. U.S. PORT OF ENTRY

LOS ANGELES

7. SHIPPER (Name & Address)

EXPORTACIONES DVREXPORTA S.A.

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

FRESH DIRECTIONS INTERNATIONAL

KM. 14.5 VIA A DAVLE

10195 TELEPHONE ROAD

GUAYAQUIL, ECVADOR

VENTURA, CA. 93004

9. COMMODITY

FRESH MANGOES (4.0 KG/BOX)
TOMMY VAR.

10. NO. CONTAINERS
(Identify as box, sack,
1/2 Bruce box, flat, card,
board box, etc.)

BOXES

11. CONTAINER
IDENTIFICATION MARKS

CONTAINER #

7 PALLETS OF 240 BXS EACH ONE
HADEN VAR.

1680

MWCV-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

DVREXPORTA S.A. GUAYAQUIL, 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