



J & K FRESH, LLC

A CUSTOMHOUSE BROKERAGE FIRM

ROSS JONES
LYNNETTE KEFFER

December 23, 2003

TO: All Produce Importers

RE: FDA Bio-terrorism Regulations

Tomorrow is the last day to make comments on the new FDA Bio-terrorism Regulations. I have attached my comments for your review. Unfortunately, with the early season and trying to cope with these massive changes, I was not able to get these finished any earlier. This is a very important issue; and I am asking for your support. If you agree with my comments, please forward a message (by email to www.fda.gov/dockets/ecomments). You may forward a copy of my comments and state that you are in agreement with them. Feel free to add any additional statements as to how the FDA BTA will affect your business when it is fully implemented. This needs to be done before Christmas (12-24-03 is the last day).

The second thing I am asking is for you to contact your Congressional leaders and plead our case. I attended a meeting where the lobbyist for the Pacific Coast Customs Brokers Association spoke. He said that the agriculture constituency is one of the strongest on the hill. So use your power. You have a little more time for this, as Congress will not reconvene until after the first of the year. If you would like a copy of one of my political letters on this issue, let me know and I will be happy to send you one.

The industry has not felt the effects of this new law because of the implementation plan. We are in Phase 1, which is "*education and communication*." However, there is no doubt that when full implementation is in effect, these regulations are going to be very costly to the produce industry (both monetarily and with delivery delays). We cannot afford to ignore the issue.

Thank you and happy holidays,

Lynnette Keffer
President

Enclosure

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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:"

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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.

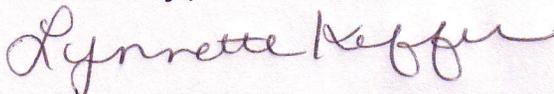
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I do not believe Section 315, Rule of Construction, to be relevant to this particular case of point. The point is:

- ✓ 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