



J & K FRESH, LLC

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ROSS JONES
LYNNETTE KEFFER

April 1, 2003

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

RE: **Comments on Proposed Notices of Rulemaking:
Docket Numbers 02N-0276 and 02N-0278**

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 last thing any food importer (or associated business) would want is contaminated food (for obvious reasons). We believe that the Food and Drug Administration and the importing public have the same goal: to comply with The Public Health Security and Bioterrorism Preparedness and Response Act of 2002. We also want to remain in business! As a small company with more than 85% of our income coming from imported produce, it is questionable if we will be able to operate (with a profit) under the guidelines of the proposed regulations. These proposed regulations are far-reaching and quite frankly, overwhelming. Rather than address all issues, I will address those that affect our business the most.

21 CFR Part 1 (Docket No. 02N-0276) Registration of Food Facilities

COMMENTS:

The proposed rule states that all foreign and domestic facilities with operations that have an affect or impact on food must register unless subject to specific exemptions. This is vague and not specific for imported shipments, especially fresh produce. This would indicate that all parties having any contact with the produce would be required to register. In the supply chain there are the farms, packinghouse, trucking companies, inspection stations, and cold storage facilities. It is redundant and a misappropriation of the government's and the private sector's resources to require all of these facilities to register.

02N-0278

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9911 INGLEWOOD AVENUE, SUITE 200 • INGLEWOOD, CALIFORNIA 90301-3600
P.O. BOX 92815 • LOS ANGELES, CALIFORNIA 90009-2815
TEL (310) 419-8770 • FAX (310) 419-8790



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The party required registering with FDA for produce shipments should be the exporter. Following are the reasons.

- **Documentation:** Both U. S. Customs and USDA require the exporter (complete name and address) be listed on the commercial invoice and the Phytosanitary Certificate. Please note that grower's lists most often only contain the grower name (which may not be complete) and/or a grower code. We never receive packinghouse information.
- **Validation:** The exporter and importer have sales contracts in place. Payments are made in accordance with the terms of the contract. There is a paper trail.
- **Control:** Shippers have a set of protocol of standards in place for the fruit they procure for shipment to the United States. A *bar-code system* is utilized to identify the boxes. The name of the shipper along with the *bar-code* enables the produce to be tracked (through the shipper) all the way back to the packinghouse and farm it came from. I would also like to point out that about 80% of the produce we receive is from shippers operating within the guidelines of HACCP (Hazard Analysis and Critical Control Points) Program.

A combination of HACCP and registration of the exporter will accomplish the goal of the FDA Bioterrorism Preparedness Response Act of 2002. This process has one party take ownership of the security process and it enables any given box of fruit to be tracked all the way back to where it was grown. This is the most efficient way to implement the registration process for produce.

21 CFR Part 1 (Docket No. 02N-0278) FDA PRIOR NOTICE PROPOSAL

COMMENTS:

- **Availability of Information:** FDA believes that information is available at the time the product is ordered. This is not true with the produce industry. Seasonal contracts are made (between the importer and the shipper). The contracts are filled, as produce becomes available for shipment during the season. There are different factors that figure into when the produce will be shipped. Of course, the weather plays a part as to when the produce is ripe enough for harvest; and when it rains, the



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produce cannot be picked. A good percentage of our produce is "Pre-inspected" by USDA officers stationed in the foreign country. If USDA finds a pest, it is not shipped. During the peak of the season, the vessels and/or airplanes may be over-booked and produce has been known not to make the scheduled sailing or flight.

- **Documentation:** It appears that FDA believes that there should be no problem in having the documentation (for ocean arrivals) in time to meet all the requirements of the proposed regulations. This is not true. Our ocean arrivals take from as little as 5 days and up to 22 days to arrive. However, we very seldom have documents more than 3 days in advance, and many times we receive documents the day before arrival. In addition on a chartered Chilean Produce vessel, we may have over 30 entries; and in the peak of the season we may have two vessels on one day. If we received all of those documents a day prior to arrival and the day of arrival, it would be impossible to meet the proposed requirements. (It is not uncommon for this to happen, especially during the holidays.)
- **Arrival Time:** Of our produce business, about 20% is air and 80% ocean. During the produce season (winter months), over half of our ocean arrivals arrive on chartered break-bulk vessels. In addition, we clear weekly arrivals of break-bulk banana vessels (year round). I mention this because the charter vessels come direct and arrival times are always varying. (It could be the age of the vessel and engine, storms at sea, delays in loading, etc.) I don't know why. But it is a fact of life we must deal with. In addition, arrival times of air flights from South America are not always accurate. There would be cases (due to circumstances beyond control) where we would not be able to meet the deadline of noon the calendar day before arrival. In addition, to meet these requirements would require a 24-hour day, year-round operation. We (as most small brokers) cannot afford to operate 24-hours a day. This gives large companies an unfair advantage.
- **Notification Process:** At the present time, FDA is receiving all the information required through the OASIS system except for the registration information. FDA is now proposing to have the notification made through a web-based system. The proposal will require filers to re-input the same information that is in OASIS through the web. The web transmission will include registration information. However, FDA is not only requiring the registration number to be transmitted, but also the address, phone number, etc. must be re-keyed in. This is not only a waste of resources; it increases the chances of error. A simple typographical error would cause a mismatch. FDA will have a database developed from the registration information. The registration number with the supplier's name should be sufficient. It is **not** logical to transmit the complete information time and time again. If filers are required to do that, what is the purpose of advance registration? This requirement would



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more than double my office's workload, not to mention FDA's workload (as they will be reviewing **all** transmissions).

- **Grower Information:** We are not required to transmit actual grower information at this time. We transmit the seller/shipper information through OASIS. When FDA elects to sample, we supply complete grower information. Our produce shipments have 1 to 200 growers, the average being about 50. However, please note that the weekly banana shipments have over 100 growers each. If we are required to transmit grower information (twice, once through OASIS and once through the web), our workload will increase 100%. For the reasons stated in our comments on Docket 02N-0276, we believe that the registration and transmission of the seller/shipper would meet FDA's requirements.
- **Refusal of Admission:** There are so many areas that are unclear. First of all, we will transmit through the web. We will not receive a validation that the transmission has been accepted. If there is a problem, entry is refused. It appears that a simple clerical error could be cause for refusal. And, of course, failure to notify timely is cause for refusal. It is unclear as to how these refusals will be handled and how long it will take. The quality and condition of fresh produce is greatly affected by time delays. Will there be a fast track for fresh products? Another concern, is the lack of bonded cold storage facilities. Has FDA researched this? During the produce season, the break-bulk produce is off loaded (at the ports of Los Angeles-Long Beach) at a warehouse with **no** refrigeration. We get it cleared and moved as soon as possible. If FDA will recall with the Chilean grape incident (in 1988) the cold storage facilities in Southern California filled to capacity in a little over two weeks (and these were not bonded facilities).

If implemented (in the present form) these proposed regulations as described in Docket No. 02N-0276, would require us to double our staff, invest in additional computers (and upgrades), move to larger quarters, and change from an 8-hour workday to a 24-hour, 7 days a week work situation. Of course this would result in a large rate increase which I would have to pass on to my clients. These proposed regulations would have a devastating affect on our business and our client's as well. It will trigger price increases of imported produce (like a domino effect) all the way to the consumer level.

We would ask that in writing the final regulations, FDA consider the following:

- **Customs Manifest:** Customs receives manifest information for inbound cargo 24 hours in advance of sailing. The manifest lists the complete name and address of



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- the shipper and importer. A complete and accurate description of the contents is required by Customs. We suggest that FDA access that information.
- **OASIS System:** We ask that FDA re-address this issue. We believe the OASIS system could work. The registration number could be listed as an Affirmation of Compliance Code. This way FDA would have more time to develop a web-based system to be operational in conjunction with Customs' system in 2005. This would solve the immediate problem as well as meet budget constraints.
 - **C-TPAT:** J & K Fresh as well as many of our clients are participants of CTPAT (Customs-Trade Partnership Against Terrorism). To be a participant, the member must have processes in place that insures the security of the supply chain. I think to recognize C-TPAT Certified Members, as being secure and low-risk would allow FDA to better target inspections and intercept contaminated products (of importers with no programs). Some importers are asking, "How many ways do I have to validate my operation to the government?"
 - **HACCP (Hazard Analysis and Critical Control Points) Program:** Again importers and shippers participating in this program are low-risk. There should be a way to identify these participants. Perhaps a different series of numbers could be used for those importers and/or exporters that have programs in place.

I reiterate, we want to comply with the Bioterrorism Preparedness and Response Act of 2002. However, the regulations need to be implemented in manner that will allow good, honest companies to comply and remain in business.

Sincerely,

Lynnette Keffer
President