FRESH PRODUCE ASSOCIATION OF THE AMERICAS

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To Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr. Room 1-23
Rockville, MD 20857

From Al Yamada, Washington Representative

Date January 7, 1998

Subject Docket No. 97N-0451

We hereby submit written comments on Microbial Safety of Produce to Docket No. 97N-0451.

If you have any questions or if I can provide additional information or materials, please call me at (202) 296-4484 or fax at (202) 293-3060.

Attachment

97N-0451

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Docket No. 97N-0451
Food and Drug Administration
Department of Health and Human Services

Written submission
Fresh Produce Association of the Americas
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Microbial Safety of Produce
(Guide to Minimizing Microbial Food Safety Hazards
for Fresh Fruits and Vegetables)

December 29, 1997

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Summary of FPAA Statement

--Voluntary "Guide" inevitably will become codified into regulations.
FDA admits guidance might become regulations.
Guidance, therefore, should be based on science.
FDA has no proof guidance represents existing US level of cleanliness.
Foreign governments will not accept guidance without scientific proof.

--Guide shows lack of familiarity with agricultural practices and science.
Proposed guidance is not realistic.
Farmers do not have exact control over operations or environment.
Farming operations should not be compared to factory production.
Guide is unduly influenced by FDA's past experience with manufacturers.
Specific scientific reasons are needed to justify the proposed guidance.
FDA should not be final arbitrator of acceptable farming practices.
More farming industry input and participation are needed.

--Guide must apply to all farming operations in the US.
Guide lacks provisions for oversight of small and local farms.
National standard must apply to every farming operation.
Guide must not regulate only large farms and imports.
Other countries will not accept discriminatory regulations.

--Regional and locality differences should be taken into consideration.

Guidance needs to incorporate local and regional differences.
International differences are not included.
Provisions are needed to approve regional or special growing areas, as well as individual operations.
Mexican farms growing for export are different from local-market farms.
Regions, therefore, rather than entire countries, should be evaluated.

--International agricultural practices should be taken into consideration.
Proposed guidance assumes US already has all the answers.
Established foreign practices should be included for approval.
Negative foreign reaction to guidance can be significant.
FDA should not become committed to certain practices.
Guide should be flexible and open to changes.

--Not enough attention is paid to non-farm microbial contamination.
Guidance assumes contamination occurs mostly on farms.
Microbial contamination occurs more frequently away from the farm.
More attention should be paid to entire seed to table system.
Similar guides, therefore, are needed for transportation, food handlers, etc.
Contamination takes place most frequently in the kitchen.
Outreach and educational programs are needed.

--Specific fruits and vegetables should not be identified for guidance.
It is unfair and unwarranted to write commodity specific guides.
Commodities would be "tainted" by association to past outbreaks.
Consumers will be needlessly frightened.

--Government efforts should focus on better science.
Better and faster ways to detect contamination should be found.
Prevention does not eliminate, or replace, need for better detection.
Clean farm produce does become contaminated through handling later.

--Availability of sanitation facilities, etc. do not assure cleanliness.
Workers must be given opportunity to actually use the facilities.
Diarrhea by itself does not indicate communicable disease.
Farmers cannot diagnose infectious disease.

--Traceback is possible but off-farm commingling negates benefits.
Technology is available for detailed traceback, but at high costs.
After-farm commingling can seriously hinder traceback effectiveness.

--Farm visits and hearings in growing areas are needed.
FDA, in contrast to USDA, lacks field crop knowledge.
Before finalizing Guide, FDA must visit farms and growing areas.
More farmers should express their opinions.

Statement of FPAA Position

The Fresh Produce Association of the Americas (FPAA) is a trade association primarily representing the interests of American firms involved in the importation and distribution of fresh produce from Mexico. The FPAA already has commented and offered its views on the subject of microbial safety of produce at several of the public meetings held on the subject by FDA and USDA. FPAA offers further and additional comments as follows:

The voluntary "guide" inevitably will become codified into regulations.

FDA repeatedly has said that it has not ruled out the possibility of turning the guidance into mandatory regulations some day, even though the FDA also has repeatedly assured attendees of public meetings that the guidance will be voluntary.

Consequently, if even the most remote possibility exists that the guide will become codified into regulations, every aspect of the guidance should be based on science. The idea that science will be found later to back up a requirement in the guidance is not only unsettling and disturbing, it is frightening. American--and foreign--farmers should not have to volunteer to use agricultural practices that have no scientific basis.

FDA indicated at its "international meeting" that a standard for American agriculture must be established before the US government can tell foreign farmers to meet an equivalent level of safety. That "equivalent level" is not yet defined and apparently does not exist, judging by comments expressed by American agricultural interests at the public meetings.

FDA, therefore, should not create an arbitrary standard and then impose it on American farmers in hopes of imposing a similar standard on imports. If the situation were reversed, and a foreign government were to suggest imposing a vague and newly created standard on American agricultural exports, the US government would consider that to be a non-tariff barrier and protest vigorously.

The US, therefore, must not rush into creating an arbitrary standard which American farmers do not meet today--and probably cannot meet soon, and which other nations would consider to be a non-tariff barrier to trade.

The "guide" shows lack of familiarity with agricultural practices and science.

Guidance fails to take into consideration the realities of farms--ranging from the inevitable presence of wildlife in fields to a farmer's inability to control neighboring activities, such as ranching that result in cattle wading through streams, hog feeding operations, and chicken farms.

For example, exact control of animal life on farms is not possible. Witnesses at public hearings repeatedly stated the obvious--wildlife cannot be kept out of fields. Witnesses have referred to birds that nest in plants, bears in watermelon fields, and various rats, mice, raccoons, and deer that inhabit or roam through fields. They also have mentioned federal laws that prohibit disturbing certain wildlife, e.g., protected migratory birds.

Guidance appears to be unduly influenced by the past experiences of the FDA which is familiar with highly controlled production processes, e.g. factories, but is obviously unfamiliar with farming operations. Greater input from USDA is needed in order to make the guidance more in line with the realities and practices of American (and foreign) farming operations.

To make the guidance more "do-able" (as FDA has professed at public meetings), a greater involvement of USDA in its writing is necessary.

It is absolutely necessary to avoid fixating on the FDA as the ultimate arbitrator and judge of what is safe and what is acceptable on the farm. Existing industry practices have provided safe foods and continue to do so. There are continuing industry attempts to improve and better their already exemplary record. Therefore, the guidance should rely more heavily on past industry experience and knowledge, and make provisions for the involvement of the produce industry in the creation of an acceptable and usable guidance.

A major problem with the guidance is its lack of specific scientific reasons, lack of expected quantifiable reductions in pathogen counts or types, and lack of stated scientific basis for its various provisions. Additional scientific data, therefore, must be included in order to create credibility within the American farming community and also to gain acceptability within the international community of trading nations.

Guide must apply to all farming operations regardless of size and locality.

Another major concern is the inclusion of smaller and local growers who are now apparently unregulated. Between May and September, small and local growers (that range in size from 20 to 50 acres per farm) ship considerable volume of produce to the market. In many instances, they are the predominant supplier of fresh produce. (In fact, one witness testified that there is a current movement that advocates increased use of local farm markets because of the belief that food is safer when grown and consumed as close to the point of production as possible.)

Small and local farmers do not usually come under the scrutiny of the FDA for microbial or pesticide contamination. There is very little control or regulatory action. Most small farmers (e.g. in Tennessee, the Carolinas, Virginia, Georgia, Alabama) use river water for irrigation and do not have access to wells with potable water for irrigation. Rivers east of the Mississippi are often polluted with runoff from pig and chicken farms and ranching operations. Florida is among the top cattle producing states in the nation, and is also one of the top producers of vegetables.

Some farmers even reuse boxes to ship produce, a practice that is both illegal and unsanitary. Small farmers also do not have sanitary facilities in the field. Small farmers also store produce in sheds and barns where the produce would be exposed to rodent and bird fecal matter. Vegetables are often field packed without any washing or cooling.

Smaller farms also rotate crops by using fields on which cattle grazed the year before. Fields are put in and out of production depending on market conditions so that cattle might graze on them for years before they are used for growing vegetables, including in-ground crops such as carrots.

If the guidance is to establish a national level of cleanliness, the guidance must be applicable to all farming operations, not just to large farmers or to imported produce.

The guidance is not clear on how it will be applied to small and local farms. FDA also has not been clear on how it intends to make sure the guidance is followed. Unless the guidance is applicable to small and local farmers (which seldom seem to be under the scrutiny of the FDA or any other government agency--Federal, state, or local), the guidance cannot be designated as a document that establishes a national standard of cleanliness which will be enforced against imports.

Regional and locality differences should be taken into consideration.

FDA claims the guidance is not "one-size-fits-all," yet it has created very broad guidelines that ignore varying farming practices due to regional, climatic, soil, and water availability differences.

In case of internationally traded commodities, regional differences in agricultural practices could be significant. For example, fruits and vegetables grown for export may come from farms that plan from beginning to end for international trade and, therefore, the level of sanitation may be different.

In Mexico, fruits and vegetables shipped to the US are grown in specific regions on farms that grow for export. Farming practices are equivalent to, or better than, existing US practices. The same might not be true for other Mexican farms growing vegetables for the local market. The proposed guidance, therefore, must take those special factors into consideration. In view of the fact the FDA has said the guidance eventually will be used to establish a US standard against which other countries will be evaluated, there must be provisions to differentiate groups of farms, regions, or localities for purposes of establishing import acceptability.

International agricultural practices should be taken into consideration.

It is arrogant for the US to assume that US agricultural practices are the most sanitary or hygienic in the world. Other countries may have differing practices and systems that are equivalent or better. The proposed guidance should reflect, or include, the best practices in the world, rather than only the perceived best practice in the US.

It is also highly unfair to subject foreign growers to US agricultural standards unless there is incontrovertible scientific evidence in favor of the US standard. So far, there is no proof that the proposed guidance contains such evidence.

Failure to accommodate foreign practices could result in retaliation against US agricultural exports which are highly successful in the world market. US agricultural exports should not be jeopardized through failure to take into consideration equitable treatment of foreign agricultural imports in the US.

It is important not to become too committed to the process of mandating a guidance that is too specific or fixed in its allowable practices. The process, as well as the guidance document itself, should be sufficiently flexible to allow for changes and modifications. As new knowledge, technology, and scientific information become available, the guidance should be changed and revised. That process should happen easily, frequently, and without bureaucratic intervention.

Not enough attention is paid to off-the-farm microbial contamination.

The proposed guidance assumes--without much evidence--that the most likely source of microbial contamination is the farm. In fact, the Center for Disease Control says most of the microbial contaminations of food occur away from the farm.

There should be more emphasis on examining the entire food delivery system.

Microbial contamination of fruits and vegetables can occur in transit, at terminal markets, during repackaging, at retail, or in the kitchen. Without sufficient controls on the handling of produce after it leaves the farm, food safety cannot be assured by the grower.

It is inherently unfair to burden the farmer by placing so much emphasis on farming operations to eliminate microbial contamination unless similarly complex guidances are imposed on those responsible for fruits and vegetables after they leave the control of the farmer, i.e., transportation, storage, retail, food preparation, etc.

Vigorous outreach and educational programs, equivalent to the proposed guidance, are necessary to make sure consumers become involved in safe food handling practices at home and in food service establishments.

An informal survey by a national organization reportedly shows that eight out of ten Americans do not wash their hands after using toilet facilities. Obviously, such lack of personal hygiene can lead to contamination of foods, including those fruits and vegetables with thick skin that are peeled. Dirty hands can result in contaminated foods.

Specific fruits and vegetables should not be identified for guidance.

It is one thing to create guidelines that are so broad as to be vague and it is another to write one so specific as to be inapplicable without a lot of exceptions.

It is inherently unfair and against the best interests of both farmers and consumers to create specific guidances for specific fruits and vegetables.

"Commodity specific guidances" will unnecessarily focus negative attention on selected fruits and vegetables. Those commodities will be disadvantaged in the market place because they will be "tainted" by association to past, and unrelated, outbreaks.

The very fact that a commodity is singled out for specific guidance will convey to the consumer a negative image. Consumers will see the commodities as possible carriers of microbial contamination and, therefore, as commodities that should be avoided. In other words, consumers would be misinformed and misled.

Neither past histories of outbreaks nor frequency of apparent consumption are reasons good enough to create commodity specific guidances. FDA data (see "Bad Bug Book") repeatedly and clearly show that mishandling of produce beyond the farm is a more likely cause of microbial contamination than agricultural practices. FDA data show that microbial contamination is more likely to occur after the fruit or vegetable has left the farm.

Lack of a "kill step" for microbial contamination also is not a good criteria because the range of produce for inclusion would be needlessly large, e.g. carrots, celery, lettuce, spinach, fresh mushrooms, broccoli, cauliflower, apples, virtually all berries, and melons.

Commodity specific guidance will frighten consumers and potentially cause them to avoid fruits and vegetables that are important sources of nutrition.

Government efforts should focus on better science.

To have a workable guidance, government efforts should focus on research to find better and faster ways to detect contamination. Current methodology is slow and cumbersome. In some instances, there apparently is no known way to detect contamination, e.g. cyclospora. FDA and USDA must focus more attention on research for better detection methods.

FDA has stated that prevention is better than detection because current technology is lacking. FDA justifies its approach by saying many other countries are also turning to prevention of contamination rather than detection at the border. There can be no argument with the idea of prevention. However, foods that leave the farm in clean condition, can become contaminated in route or during preparation for consumption. That means quick, easy, and inexpensive detection methods will continue to be necessary. FDA and USDA, therefore, must not abandon research on detection methods, and must not assume that clean foods will always stay clean. Past experience and existing evidence show that fruits and vegetables get contaminated away from the farm. Detection of microbial contamination, therefore, will continue to be absolutely necessary.

Availability of sanitation facilities, etc. do not assure cleanliness.

Availability of sanitary facilities for use by farm workers, packing shed workers, etc. are obviously necessary. Testimony has been given, however, that in the United States workers often cannot use the facilities which are technically available to them. Lack of time, distance, poor maintenance, or sufficient number of facilities prevent workers from using them.

Furthermore, diarrhea alone is not a sufficient indication of communicable disease. Diarrhea can be caused for a number of reasons, including allergic reactions. A non-medical person cannot make judgments as to the cause. It is, therefore, unfair and unreasonable to expect workers to report each and every case of diarrhea, and *it is also unreasonable to require a supervisor to make a diagnosis as to the cause of the reported case of diarrhea.*

Traceback is possible but repacker, wholesaler, retailer can commingle.

Traceback, or positive lot identification, is possible and highly desirable for various reasons. It does, however, add costs and complications to farming, packing, shipping, and selling operations. Tracebacks add costs not only at the farming level but to all subsequent operations, and imposes recordkeeping burdens. With existing technology, boxes can be specifically identified as to field of origin, date of packing, etc., but at considerable additional costs which would be passed on to consumers.

Traceback benefits, however, are lost when produce is repacked, as in the case of gassed green tomatoes.

Commingling of produce from various boxes or suppliers at the retail level will negate traceback benefits.

Farm visits and hearings in growing areas are needed.

If FDA is to be the lead agency in the preparation of the proposed guidance, FDA must know more about farm operations. To learn more about day-to-day farming

operations, practices, and systems, FDA must visit farming operations both in the US and in foreign countries.

To get more practical and realistic input from farmers, hearings must be held in growing regions where farmers can attend the meetings and give their comments and ideas.

FPAA has in place a five-point program to educate growers to assure clean produce. FPAA does not dispute the good intentions of the FDA or the need for better programs to avoid microbial contamination of produce. FPAA, however, does question the validity of the proposed guide. FPAA, therefore, asks for more science and technical information from the FDA to substantiate the proposed guidance before proceeding further to a final version.

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