



AMERICAN FARM BUREAU FEDERATION®

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December 15, 1977

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, Maryland 20857

Re: Docket No. 97N-0451; Microbial Safety of Produce; Grassroots and International Meetings

Dear Sir/Madam:

The American Farm Bureau Federation is the nation's largest general farm organization with over 4.7 million member families. Our members produce virtually every commodity grown in the United States. The safety and wholesomeness of the nation's food supply is one of our highest concerns and priorities. For this reason, we appreciate the opportunity to comment on the President's recently announced initiative to ensure the safety of imported and domestic fruits and vegetables and the Food and Drug Administration's (FDA) general draft guide entitled "Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruit and Vegetables."

Farm Bureau has three general concerns regarding the President's initiative as well as several specific comments on the draft guide, which are outlined below.

First, Farm Bureau believes the manner in which FDA announced the public meetings and released the draft guide will not at all contribute to a full and complete discussion of these issues and to participatory government. FDA formally announced grassroots and international meetings to discuss the general draft guide on minimizing safety hazards before releasing the guide itself. FDA formally announced the meetings on November 28, the day after Thanksgiving, and released the guide on December 1, the day of the very first meeting. It is unreasonable to expect growers and farm groups to adequately discuss this proposal without having seen it or to prepare and arrange to attend a meeting during the extended Thanksgiving holiday weekend. Because of this, Farm Bureau is concerned that FDA will not gain from the proceedings of these meetings all viewpoints regarding the draft guide and of the President's initiative. While the November 17 public meeting provided details on the guide, not enough specifics were made available from that meeting to make informed decisions. Also, FDA formally announced the November 17 meeting on November 10, with a meeting registration deadline of November 12. Since November 11 was a federal holiday, if stakeholders wanted to register for the November 17 meeting, they must have done so with just one day's notice.

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Second, Farm Bureau is concerned with the pace which FDA is moving to establish new guidelines when FDA readily admits the difficulty in identifying the source of potential microbial contamination. In the 1995 outbreak associated with unpasteurized orange juice, FDA admits that the "cause of the contamination was not identified." The outbreak of *Shigella sonnei* associated with iceberg lettuce "was thought to have resulted from the use of fecally contaminated water." Packing imported green onions in ice made from nearby river water was the "likely cause" of a 1994 outbreak of shigellosis. In each of these instances and in others, the cause of food contamination has never been precisely identified. As a result, before embarking on a costly new regulatory initiative, FDA and the U.S. Department of Agriculture (USDA) should work jointly to positively identify the causes of past contamination problems. Since the cause and reasons for past cases have not been clearly identified, there exists a knowledge gap which prevents an accurate analysis of the problem. This would be valuable information to know prior to establishment of risk mitigation measures and guidelines. Plus, establishing guidance based on inaccurate information may not prevent problems at all.

As FDA points out in the guide, "despite the best efforts by food industry operators, food will never be completely free of microbial hazards." Farm Bureau agrees with that assessment and strongly urges FDA to focus its efforts on education. As FDA points out in the guidance document, the ultimate source of contamination from most enteric pathogens is human or animal feces. Proper sanitation, therefore, is critically important in the field and in packing houses. Creating regulations to mandate specific hygienic practices will likely have little more effect than proper education. Requiring workers to employ proper sanitation techniques doesn't mean that workers will accomplish those tasks successfully all the time. Some workers may neglect, either willfully or inadvertently, to do so. Others will fail to notify supervisors when they are ill and work anyway. Requiring workers to do something that they may not always want to do or forget to do, means growers are penalized for the willful or accidental actions of employees. In this regard, education will reach the same goals as does a regulatory program without creating another layer of unnecessary and costly regulations -- costs that farmers must absorb.

Third, farmers have little control in controlling wild animal populations. For example, in some parts of the country there are serious deer overpopulation problems. FDA identified deer feces as the likely cause of the recent *E. coli* outbreak in apple cider. FDA's suggested options for growers to "include visual, auditory, or physical deterrents and border crops or buffer areas," simply haven't worked. This means that despite growers best efforts, there will still be factors and potential sources of contamination that farmers have little or no control over.

Farm Bureau has the following specific concerns with the FDA guidance document and the President' initiative.

Farm Bureau Supports Voluntary Efforts to Reduce the Risk of Microbial Contamination

Farmers clearly understand the importance preventing pathogens in their operation and are already voluntarily adopting new practices which prevent and reduce the incidence of microbial contamination. The FDA guidance provides additional information on good agricultural practices.

Farmers share the concern over microbial contamination. It is critical that we make every effort to ensure the safety of our food supply. As mentioned before, FDA seems to be rushing to regulation even before its own advisory committee -- the National Advisory Committee on Microbiological Criteria on Food -- has issued its white paper and recommendations on what should be done. Farm Bureau supports using the best science before making policy decisions and developing educational programs affecting every U.S. fruit and vegetable producer based on the best available science.

USDA Should Serve as the Lead Agency

USDA has primary jurisdiction for all other food safety inspection programs through the Food Safety Inspection Service (FSIS) of USDA. FSIS is developing similar safety procedures through the development of Hazard Analysis and Critical Control Point Programs (HACCP) for other commodities. USDA has offices throughout the United States which could potentially be used to administer grower education programs. FDA does not. For these reasons, Farm Bureau urges that USDA serve as the lead agency in any effort.

Guidance Document Concerns

Farm Bureau has the following concerns regarding the FDA guidance document.

1. Disposable gloves

Farm Bureau believes the use of disposable rubber or similar gloves or other corrective measures for personnel who have contact with produce is sometimes counterproductive and in other cases unnecessary. There are some situations where gloves may be effective and appropriate. However, there are other situations where they are not. For example, rubber gloves tear easily and can just as easily be sources of contamination as bare hands. Plus, rubber gloves are hot and can cause hands to perspire, which is a better media for contamination than dry hands if rubber gloves rip or tear. FDA points out that persons who scratch their head or place their fingers in or about the mouth can create microbial hazards. Glove wearers who do the same thing are also a source of potential contamination.

Gloves also hamper the ability to harvest some crops. Some crops, including raspberries, sweet cherries and apples bruise easily and require careful handling or they can be damaged during harvest. Gloves lessen manual dexterity and the ability of workers to feel how hard they may be

grasping certain crops while removing them from plants and trees. Squeezing fruits too hard can cause bruising, and in some cases, the skin of fruits can crack or tear, which creates an opening for contamination to occur.

Requiring only rubber gloves creates other problems. Workers who harvest citrus fruits typically wear cloth gloves to protect their hands from thorns and sharp twigs. Without proper protection, hands easily cut and bleed. Rubber gloves do not provide the same level of protection.

2. Wash water

Farm Bureau agrees with FDA on the importance of wash water in preventing microbial contamination. However, as FDA notes, some products cannot tolerate exposure to water. FDA suggests alternative treatments including irradiation, ozone, or gas-based disinfectants. However, there are problems with each of these treatments that make these alternatives unacceptable. It appears that many consumers will simply not accept irradiation as an acceptable treatment. Ozone treatments affect produce quality for some crops and the major gas-based disinfectant, methyl bromide, is being phased out by EPA. FDA, working with USDA should examine other treatments for crops that cannot tolerate exposure to water.

FDA also suggests that the risk of cross contamination may be reduced by segregating, or discarding, poorer quality produce before washing. For many produce items this is impractical and places the food safety burden on harvest workers who must, according to FDA's guidance, grade and rate produce during harvest and discard items that may or may not be contaminated. While harvest workers often do discard damaged items, asking them to carefully examine everything they harvest is unreasonable and unworkable.

3. Untreated manure

FDA identifies untreated manure as a source of contamination. Apparently, USDA is close to issuing Organic Standards under the Organic Food Production Act of 1990. Has FDA consulted with USDA regarding how untreated manure will be addressed under the new organic standards? The guidance document states that the new organic standards under review at USDA will prevent untreated manure from being applied to fields within 60 days of harvest. Yet, FDA states that *E. Coli* 0157:H7 may survive in dairy cattle manure for at least 70 days and in sheep manure for more than one year. Has FDA suggested to USDA the need to readdress the untreated manure regulations under the proposed organic standards? If not, organic food seems to carry a higher risk of microbiological contamination, which consumers should be made aware of, similar to other FDA microbial food safety labeling initiatives.

4. Personal health

Farm Bureau agrees with FDA's assessment on the importance of personal health and good hygienic practices by all personnel who handle fresh produce. Good hygiene and proper sanitation are important in minimizing microbial hazards. FDA's recommendation that growers place toilet facilities and hand washing stations in the field are important factors in reducing risks. However, we would urge FDA to work cooperatively with the Occupational Safety and Health Administration (OSHA) and EPA. OSHA, under its field sanitation regulations, already has a hand washing requirement that includes washing stations. EPA, under the Worker Protection Standard, has separate grower requirements for hand washing and decontamination kits. FDA guidance should take these requirements into consideration to ensure they do not conflict with one another.

Farm Bureau also urges FDA to focus its efforts, not only on farm and packing house workers, but on other workers in the farm to consumer chain. Of particular importance, and an area FDA largely ignores in the guidance document, are practices at the retail level. How fresh produce is handled, stored, displayed and the length fresh produce stays on shelves at retail level are critically important in reducing hazards. How consumers handle and prepare produce is also important. Consumers who fail to wash their hands during food preparation or who prepare food on surfaces where other food has been prepared, particularly meat products, can also contaminate produce. These sources of potential contamination should not be ignored.

5. Harvesting precautions

FDA recommends that harvest crews remove as much dirt and mud as possible from the produce before it leaves the field. Many on-farm situations make this recommendation impractical and unworkable. When fruits and vegetables are ripe, they must be harvested. If field conditions are wet and muddy, harvest must continue anyway. Unlike grain and cereal crops, which can be stored in the field for extended periods of time, fresh produce cannot wait for ideal conditions. It is highly likely in muddy fields for all individual fruits and vegetables to have some soil or water on them. Working in these conditions means harvest workers will also have mud on their hands and gloves. Requiring harvest workers to remove all mud from crops or waiting for the weather to improve are simply not feasible options. Even under good conditions workers, when harvesting row crop vegetables like lettuce or cabbage, will still likely come into contact with soil and mud and transfer that to harvested crops.

6. Equipment maintenance

FDA suggests that growers remove diesel, grease, and oil from harvesting and processing equipment daily. There are several practical problems with this recommendation. First, it is not clear why FDA is making this recommendation. Are diesel, grease and oil potential media for pathogens or is this a concern that produce will come into contact with lubricants? Most equipment requires periodic, usually daily lubrication. Growers are already very careful to

prevent produce from coming into contact with lubricants because grease and oil are not typically washed off by water or other measures. Contaminated produce must be discarded. Farm Bureau requests that FDA clarify why they are making this recommendation.

The President's Initiative - Imported Produce

The President's initiative will give FDA expanded authority to refuse shipments of imported fruits and vegetables which do not meet U.S. standards for food safety. Farm Bureau supports more extensive testing and inspection of imports to prevent contaminated produce from reaching U.S. consumers. However, it is not clear how this inspection will be conducted and again, why FDA is the lead agency in this effort. USDA, through the Animal and Plant Health Inspection Service's Plant Protection and Quarantine (APHIS/PPQ), already conducts phytosanitary inspections at all U.S. ports of entry. FDA conducts limited pesticide residue monitoring programs at ports, but APHIS/PPQ has extensive personnel better equipped and capable of conducting inspections. USDA is better prepared and staffed to conduct these inspections and should serve as the lead agency for inspecting imported fresh produce.

While we support increased inspections, it is not clear whether inspections can be conducted quickly and effectively. For example, will a visual inspection reveal microbiological contamination or is there some other rapid detection method to reveal hazards? Without a rapid detection method, impounding produce for extended periods of time will likely result in other countries treating our exports in a similar manner.

The President's proposal will also seek additional funding of \$20-25 million for inspection and enforcement of imported produce. It appears that FDA will actually inspect foreign farms, packing plants and processors that export food into the United States. What FDA will do if they find violations is not clear, but should be identified soon. Will certain farms that do not meet FDA standards be barred from sending food to the United States? Or, will they have the ability to correct violations before sanctions are imposed? Also, the scope and extent of this inspection effort is suspect, when only \$20-25 million was allocated. Trying to inspect hundreds, or perhaps thousands of foreign farms and packing plants will likely be a larger effort than anticipated.

Inspection of foreign farms also raises alarm bells for U.S. producers for two reasons. First, if the U.S. inspects foreign farms to ensure they meet specific safety guidelines, under trade equivalency rules, the inspection of domestic farms by our competitors is a likely outcome. If foreign farms must meet specific safety standards and pass an inspection, U.S. growers will likely face the same scrutiny. Second, if the FDA prevents food from entering the United States, what will prevent other countries from raising the same barriers to U.S. products? For example, Japan already restricts U.S. apples due to questionable phytosanitary and pest concerns. Japan allows apple imports from Washington only after certifying orchards that follow certain procedures for

codling moth control. The European Union also restricts U.S. food products for similar concerns. What will prevent other countries from insisting on inspections of U.S. farms if we assert that we are the world's food police and all farms must meet our guidelines? This proposal opens the door for a new round of potential phytosanitary wars between our competitors and customers in world markets. FDA needs to seriously consider these concerns in light of the international trade implications.

Farm Bureau is concerned that any proposal that places regulatory requirements on growers in other countries will be interpreted by them as a nontariff trade barrier. Inspections at the border will be interpreted similarly. If the United States imposes requirements on growers in other countries, then other countries will likely place the same type of requirements on U.S. growers.

Public Policy Goals

The FDA proposal has no clear policy goals. When all this is implemented, what are the public health benefits? As FDA states, "despite the best efforts by food industry operators, food will never be completely free of microbial hazards." What FDA hopes to accomplish with this proposal and by what magnitude microbial contamination will be reduced is not clear. This proposal, as FDA points out, will not eliminate all sources and incidents of contamination. Unfortunately, no regulatory scheme or guidance will prevent contamination from willful misconduct, which current law already covers. It doesn't matter what type of regulatory apparatus anyone builds if someone is willing to skirt the law or if accidents occur.

The one-size-fits-all approach will not work.

The U.S. produce industry raises and handles hundreds of different commodities grown under a wide variety of conditions. Developing a single regulatory scheme may work for some commodities, but not for others. The guidance document does not recognize certain farming practices and the uniqueness of the U.S. fresh produce industry. Conversely, trying to develop a commodity-by-commodity program means farmers who raise many crops may face a conflicting maze of regulatory requirements. Again, Farm Bureau urges FDA to focus on grower education on the most important and likely causes of microbial contamination.

Summary

FDA accurately points out in the guidance document that consumers should increase their consumption of fruits and vegetables to at least five servings a day to reduce the risk of chronic disease. To facilitate this, consumers need to have confidence in the safety of fruits and vegetables. Farm Bureau recognizes that periodic microbiological outbreaks damage the reputation of fruits and vegetables and will discourage increased consumption. We also agree with FDA that "the ultimate source of contamination for produce is human or animal feces." Based on this, FDA and USDA should focus on education from farm to consumer, for fecal

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contamination can occur at any point in this chain. Ignoring food preparation education is a mistake and suggests to consumers that contamination can only occur before fresh produce reaches them. This is dangerous and unfair and diverts attention from other likely sources. We encourage any effort to have as its foundation education of all handlers of fresh produce.

Thank you for the opportunity to comment.

Sincerely,

A handwritten signature in cursive script, appearing to read "Richard Newpher".

Richard Newpher
Executive Director
Washington Office



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