

2323 '98 JUN 29 P4:21

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20857

Re: **Docket Number 97N-0451**
Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the Food and Drug Administration's (FDA's) voluntary guidelines for reducing microbial contamination on fresh fruits and vegetables. CSPI is a nonprofit consumer group focusing on food policy. We accept no industry or government funding and are supported almost entirely by the one million subscribers to our *Nutrition Action Healthletter*.

The guidance represents a first step in improving the safety of fresh fruits and vegetables. However, it is only a small step. It is questionable how valuable the guide as currently written will be in protecting consumers. The guide in many instances provides only very general and vague recommendations and fails to include strongly-worded, science-based guidelines, especially in the "Water" and "Manure" sections. To make the guide more useful to growers and more effective in preventing foodborne illness, FDA should incorporate the following recommendations in revising the guide.

1. The Guide Should Be More Specific and Direct

In general, the guide is not specific to particular fruit or vegetable crops. Because of this fact, recommendations in the guide are very broadly and generally stated, making them less useful and understandable to producers. There is a significant difference, for example, between the steps that should be taken to prevent contamination of cherries that are picked from a tree and those to prevent contamination of tomatoes growing near the ground. Yet the guide recognizes no such differences.

The National Advisory Committee on Microbiological Criteria for Foods recommended that Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) be

97N-0451



C75

developed based on “the risk associated with individual fruits and vegetables.”¹ FDA should heed the committee’s advice and revise the guide to apply specific recommendations to specific crops or, where they can be grouped into classes, to classes of crops. (As an example, all fruits grown on and harvested from trees could be grouped into a class.)

In addition, the guide often states recommendations so vaguely and weakly that it would be difficult for growers to comply even if they wanted to do so. This is particularly noticeable in the “Water” and “Manure” sections.

For example, Section III.2.2.1 on “Untreated Manure” states that “[g]rowers using untreated manure *may need to consider* the following good agricultural practices” (emphasis added). That section also states that growers “may want to choose” to wait longer than 60 days between applying raw manure and harvest. Setting aside the fact that scientific data justify a far more rigorous standard for raw manure (as will be discussed below), the wording of these recommendations is so vague that growers will not be able to tell whether they are in compliance.

As another example, Section II.B.2.2 states that growers should “consider the wash water temperature for certain produce.” The best available scientific data show that growers should use water for tomatoes that is hyperchlorinated and 10 degrees F warmer than the tomatoes. Such advice has been given in other contexts because research shows that tomatoes can take up contaminated water through their stem scars if the water is colder than the tomatoes. At least two outbreaks of *Salmonella* have been linked to tomatoes contaminated by wash water that was not at the proper temperature.² Although the guide mentions this information, it does not require that wash water for tomatoes be hyperchlorinated and 10 degrees F warmer than the produce. There is no excuse for the guide not to do so.

If the guide is to have any value in increasing food safety, FDA must revise the recommendations on manure and water to make them stronger and more directive, like the recommendations in other sections. For example, in the “Sanitation and Hygiene” section, the following recommendations are included: “Establish a training program” (A.2.1); “Clean muddy containers of bins before using to transport fresh produce” (C.2.1); and “Establish a pest control system” (C.2.3). The directive tone of these recommendations should be used throughout the document. The fact that compliance with the guide is voluntary should not affect the tone of the recommendations.

¹ National Advisory Committee on Microbiological Criteria for Foods, “Microbiological Safety Evaluations and Recommendations on Fresh Produce,” March 5, 1998, p. 49 [hereinafter cited as *Recommendations on Fresh Produce*].

² *Ibid.*, pp. 9-10.

2. FDA Should Make Mandatory the Parts of the Guide That Are Supported by Scientific Data

Voluntary guidelines give no assurance of safety to consumers. There is no evidence that growers will expend the resources to adopt new, safer practices when there is no real motivation for them to do so.

FDA has stated that some scientific information on reducing or eliminating pathogens in an agricultural setting is not now available.³ Thus, FDA has not promulgated the guide as a regulation, but as a set of voluntary guidelines. However, there are some areas in which available data and common sense support the promulgation of binding regulations. One such area is the application of raw manure to crops before harvesting. Another area is in the handling of compost. FDA should act promptly to issue regulations requiring grower compliance in these areas, as outlined below.

FDA has the legal authority to promulgate binding regulations regarding fresh fruits and vegetables if it wishes. Fruits and vegetables that are contaminated with pathogens are adulterated under the Federal Food, Drug and Cosmetic Act. Under the Act, a food is adulterated if it “contains any poisonous or deleterious substance which may render it injurious to health.”⁴ FDA may prescribe public health measures to reduce pathogens in food.⁵ In fact, FDA has promulgated Good Manufacturing Practices that apply to fruit and vegetable processors, although those GMPs do not include food safety practices before harvest.⁶

3. The Guide Should Include Specific Requirements for Safe Water Use

There are two key uses of water that can affect the microbial safety of fresh fruits and vegetables: irrigation and washing/processing. The guide provides inadequate standards for both. Water should be free of pathogens if it will contact produce, either during irrigation or during washing.

³ U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, “Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Draft Guidance,” April 13, 1998, pp. 3.

⁴ 21 U.S.C. § 342(a)(1).

⁵ See, e.g., U.S. v. Nova Scotia Food Products Corp., 568 F.2d 240 (2d Cir. 1977).

⁶ 21 C.F.R. § 110.

Irrigation Water

Irrigation water is a potential source of contamination of fresh produce. Irrigation water may be subject to contamination from animal manure, human sewage, or other sources of pathogens. Surface water used to irrigate leaf lettuce was identified as the possible cause of a 1995 outbreak of *E. coli* O157:H7 in Montana that sickened at least 29 people.⁷

The guide recommends that irrigation water quality be “adequate for its intended use” (II.B.1.0). Growers are told to “be aware of risk factors” and to “consider practices that will protect irrigation water quality” (II.B.1.2). These recommendations are inadequate. To protect consumers from contaminated produce, growers must do more than simply think about risks; they must take action.

Testing irrigation water, as recommended by the guide, is one way for growers to evaluate the safety of their irrigation water (II.B.1.1). However, the guide contains no standards for testing. Such standards should be included in the guide, including what indicators of fecal contamination should be used, what levels of microbial contamination are acceptable, and how often tests should be conducted.

Perhaps more importantly, however, testing is not a fail-safe way to ensure water quality, as levels of contamination may vary widely over short periods of time. Growers should not rely exclusively on testing to assure water quality, but should ensure that their irrigation water is free from environmental and other sources of contamination. This is particularly important for irrigation water that will come into contact with produce, such as water that is sprayed directly on berries.

It is vitally important that any irrigation water that comes into contact with produce that will be harvested within a few weeks and will be eaten raw is free of pathogens. That should be the standard enunciated in the guide.

Washing and Processing Water

The sanitation of water used for washing and processing is even more important than that of irrigation water, since it directly contacts fruits and vegetables immediately before they are shipped and sold to consumers. Wash water poses a known hazard to consumers. As stated above, two *Salmonella* outbreaks have been traced to tomatoes washed in contaminated water, one in 1990 that sickened 176 people, and one in 1993 that sickened 100.⁸ In addition, at least 61 people became ill in May and June 1996 from packaged pre-washed mesclun lettuce contaminated with *E. coli* O157:H7. The lettuce had been washed and processed at a farm in

⁷ *Recommendations on Fresh Produce*, p. 12.

⁸ *Recommendations on Fresh Produce*, p. 9.

California. Epidemiologists believe the wash water became contaminated from cattle manure next to the processing area.⁹

The guide fails to require that growers use water that is free of pathogens for washing and processing purposes. This is a significant omission. It is difficult to imagine how the guide can be taken seriously as a food safety measure if it does not require at least this minimum step. Using only pathogen-free water on all food for human consumption should not be unduly burdensome on growers and processors of fresh fruits and vegetables. Meat and poultry processors have long complied with an identical requirement.¹⁰

Growers must do more than “consider the use of sanitizers or antimicrobials in wash water,” as stated in the guide (II.B.2.2). They must actually use such substances or ensure in some other way that washing and processing water is free of pathogens that could contaminate fresh produce. The guide should be revised to clearly state that growers cannot be considered in compliance with the guide unless they do so.

4. The Guide Should Include Specific Requirements for Safe Manure Use

The use and management of animal manure in food production raises significant public health concerns. Human pathogens that may be present in manure include *E. coli* O157:H7, *Salmonella*, *Campylobacter*, *Yersinia*, *Listeria*, *Cryptosporidium*, *Giardia*, mycobacterium, and viruses.¹¹ Many foodborne illnesses have been linked in recent years to pathogens found in animal manure, most notably *E. coli* O157:H7. An increasing number of these illnesses have been traced to fresh fruits and vegetables, rather than the ground beef typically responsible for such illnesses. For example, in the *E. coli* O157:H7 outbreak from packaged lettuce described above, investigators believe the contamination came from the manure of cattle kept in a pen near a barn where the lettuce was rinsed and packaged.¹²

The use of manure as fertilizer on land used to grow crops for human consumption poses a major public health concern. The problem is especially acute in the case of lettuce, seeds for

⁹ Pam Belluck and Christopher Drew, “Tracing Bout of Illness to Small Lettuce Farm,” *The New York Times*, Jan. 5, 1998, p. A1

¹⁰ U.S. Department of Agriculture, Food Safety and Inspection Service, “Sanitation Requirements for Official Meat and Poultry Establishments,” *Federal Register*, Vol. 62, No. 164 (1997), p. 45056 (to be codified at 9 C.F.R. § 416.2(g)).

¹¹ Statement of Ronald Fayer, U.S. Department of Agriculture, Agricultural Research Service, at USDA/EPA public meeting on manure, March 11, 1998.

¹² Pam Belluck and Christopher Drew, “Tracing Bout of Illness to Small Lettuce Farm,” *The New York Times*, Jan. 5, 1998, p. A1.

sprouts, and other low-growing fruits and vegetables that come into contact with the soil in which they are grown and that are typically consumed raw.

The guidance recommends that raw manure be applied to crops no sooner than 60 days before harvest. The guidance states that FDA is relying on the recommendation of the National Organic Standards Board (NOSB) in establishing the 60-day time period. The NOSB in turn relied upon the provisions of the Organic Food Production Act, which provides that raw manure may be used on crops for human consumption if the crops are not harvested until after “a reasonable period of time . . . to ensure the safety of such crop,” and in no event less than 60 days.¹³

Reliance upon the 60-day time period is utterly misplaced. First, the organic program is not a safety program, and there is no evidence that safety concerns entered into the decision of Congress or the NOSB to set the time period at 60 days. Second, scientific knowledge about the safety of bovine manure has increased significantly since the OFPA was enacted. One study found that *E. coli* O157:H7 survived for up to 70 days in cattle manure under certain conditions.¹⁴ One scientist’s research showed that the pathogen could live in soil for up to 130 days.¹⁵ Yet another study found that *E. coli* O157:H7 may survive in sheep manure for more than a year.¹⁶

Although much more research in this area is needed, it seems clear that a standard of 60 days is not sufficiently protective of public health. Until specific data are available on safe animal-manure application, the guidance should incorporate requirements at least as stringent as those in the regulations on the use of sewage sludge promulgated by the Environmental Protection Agency.¹⁷

Animal manure should be required to meet stringent pathogen reduction controls and to undergo composting, pasteurization, or other method before it is applied on agricultural lands. The sewage-sludge regulation requires fecal coliform to be less than 1,000 Most Probable Number per gram of biosolids, or less than three *Salmonella* bacteria per four grams of

¹³ 7 U.S.C. § 6513(b)(2).

¹⁴ G. Wang, et al., “Fate of Enterohemorrhagic *Escherichia coli* O157:H7 in Bovine Feces,” *Applied and Environmental Microbiology*, Vol. 62, No. 7 (1996), pp. 2567-2570.

¹⁵ Letter from Andrew Maule, Center for Applied Microbiology and Research, to Laurie Girand, Safe Tables Our Priority, April 24, 1998.

¹⁶ U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Working Draft,” Nov. 25, 1997, (III)(B)(2.2.1), available at <<http://vm.cfsan.fda.gov/~dms/proddrft.htm>> INTERNET.

¹⁷ 40 C.F.R. § 503.32.

biosolids.¹⁸ In the alternative, manure should be required to meet less stringent pathogen-reduction standards, and to be applied a significant amount of time before harvest of food crops. The EPA sewage-sludge regulation requires that sludge be applied at least 14 months before harvest of a food crop totally above the land surface but with harvested parts that touch the soil and 20 to 38 months before harvest of food crops with harvested parts below the land surface.¹⁹

5. The Guide Should Include More Specific Requirements for the Safe Composting of Manure

The guide states that research on pathogen survival in manure is at the beginning stages and that growers and manure suppliers may have to adjust their practices as new information becomes available. Even though there is a need for additional research, FDA should make stronger recommendations on composting guidelines based on existing scientific data and on common sense.

As stated previously, the regulations for the use of biosolids on food crops should be adapted to the use of composted manure on food crops.²⁰ The guidance document should require that composting of manure follow the time, temperature, and pH requirements outlined in the regulations governing biosolids, unless the current science on composting supports different requirements.²¹ As new science on manure composting becomes available, the requirements for manure should be adjusted based on this new data. Consumers cannot wait for additional research on composting to be completed, especially when there are regulations on a similar substance, biosolids, that are designed to address similar pathogens and that can be applied to manure management.

The guide states that composting may not eliminate pathogens, but gives growers only general guidance on how to minimize the risks from composted manure. The guidance document should require a Hazard Analysis and Critical Control Point (HACCP) system to minimize the risk of contaminating produce through composted manure use. The HACCP plan should cover all aspects of composting, including minimizing the hazards associated with transporting the manure from the supplier to the growers. To ensure that a HACCP plan is working, strong verification steps must be included. Manure should be tested to be sure it has reached sufficient time, temperature, and pH requirements. The manure must also be tested for pathogens to ensure that they have been minimized or eliminated.

¹⁸ 40 C.F.R. § 503.32(a).

¹⁹ 40 C.F.R. § 503.32(b).

²⁰ 40 C.F.R. § 503.

²¹ 40 C.F.R. § 503.32.

Detailed model HACCP plans, such as those provided by USDA for the meat and poultry industries, should be developed to help growers and manure suppliers implement their own HACCP systems.²² Model plans can be designed for different farm sizes and types of produce and for all methods of composting, including those methods outlined in Section III.B2.1 of the guide.

6. The Guide Should Include More Stringent Traceback Requirements

CSPI strongly supports practices that ensure that successful tracebacks can take place. The guide's direction that growers should develop traceback procedures is highly appropriate. However, the minimum suggested documentation appears to be incomplete. The only items listed are (1) date of harvest; (2) farm identification; and (3) who handled the produce from cooler to receiver (V). The third item is confusing. It is unclear who "the receiver" is in any given situation. In addition, it is incomplete. Some produce may not go to the cooler, or may not go directly from the cooler to the receiver. All handlers should be included. In addition, the name and address of the purchaser of the produce from the grower or processor should be documented.

Respectfully Submitted,



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²² See, e.g., United States Department of Agriculture, Food Safety and Inspection Service, *Generic HACCP Model for Poultry Slaughter*, (United States Department of Agriculture, April 1997).