NATIONAL FOOD PROCESSORS ASSOCIATION

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

RE: Docket No. 97N-0451 ***Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (63*** Federal Register, 18029, April 13, 1998)

Dear Sir or Madam:

The National Food Processors Association (NFPA) appreciates this opportunity to provide comments on the above referenced public notice regarding draft guidance to minimize microbial food safety hazards for fresh fruits and vegetables. **NFPA commends the Food and Drug Administration (FDA) for its critical thinking in developing this guidance and recognizing the crucial role it will provide for microbial food safety of imported and domestic fruits and vegetables.**

NFPA is the voice of the $430 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three laboratory centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international members who produce processed and packaged foods, drinks, and juices. Food safety is our members' highest priority. NFPA members export and import food products globally and have an interest in international trade policy. In addition, NFPA members are strongly supportive of the international harmonization efforts of Codex Alimentarius, and NFPA staff and members serve actively on the delegations for several Codex committees.

INTERNATIONAL CONSIDERATIONS

NFPA commends FDA for developing this guidance and recognizing the importance of enhancing global food safety through improved production practices. NFPA strongly supports equivalent standards for both domestic and i reported products, and supports international solutions to address food safety concerns. In October 1997, NFPA filed comments to support FDA's efforts to develop criteria for the judgment of equivalence, NFPA believes that food safety standards globally will be improved through efforts to develop equivalence agreements and enable better allocation of limited resources based on risk

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assessment within the U.S. government and other nations. The "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (Guide) may be a useful tool towards that end.

While it is not clear to NFPA how FDA intends to implement the "Guide" either domestically or internationally, the U. S. must consider commitments under the World Trade Organization (wTO) and political sensitivities of our trading partners. The "Guide" cannot be used as a technical barrier to trade or perceived as protection of domestic markets. It must not inadvertently invite retaliation towards U.S. exports. The WTO Agreement on Sanitary and Phytosanitary measures (SPS Agreement) requires WTO member countries to accept as equivalent measures from other nations (even if different) if the exporting member objectively demonstrates that its measures will achieve the importing members' appropriate level of sanitary or phytosanitary protection. The SPS agreement also obligates member countries to base SPS measures on risk assessment and sound science, and prohibits unjustifiable discrimination against products from other nations. Without strict adherence to these equitable trade principles, the U.S. risks a WTO dispute challenge and disruption in trade.

Considering those concerns, NFPA believes that the "Guide" would be more universally supported, and thus more effectively achieve its stated goals, if it were to become accepted by Codex Alimentarius. Because Codex is an international standard setting organization and a reference for the WTO with respect to food trade, Codex standards become the "baseline" requiring nations to justify more restrictive standards by risk assessment. As a Codex document, the "Guide" could be used by the U.S. and other nations to evaluate equivalency without risking a WTO challenge or alienation of trading partners. It would also be accepted for educational and training material for the Food and Agriculture Organization (FAO). The Codex Committee on Food Hygiene (CCFH) is currently drafting a discussion paper on a proposed "Draft Code of Hygienic Practice for Primary Production, Harvesting and Packaging" intended to be introduced at the October 1998 session. As Chairman of CCFH, the U. S. is in a key position to influence the development of the document and to build a consensus of support. NFPA strongly urges the U.S. delegation to CCFH to provide the leadership to ensure that the food safety principles in the "Guide" are incorporated into the CCFH document and to encourage accelerating the Codex step process toward international acceptance. NFPA agrees that the "Guide" includes valuable food safety principles that should be endorsed globally. NFPA staff serves on the U.S. delegation for CCFH and welcomes the opportunity to work with you on this important issue.

TECHNICAL CONSIDERATIONS

NFPA is pleased that FDA recognizes that specialty produce items (e.g., cut and packaged fresh produce) already subject to specific good manufacturing practices are beyond the scope of the present document. FDA has correctly recognized the need for more research on possible sources of contamination in pre- and post-harvesting and processing of fruits and vegetables. Other research foci must include improved testing procedures for pathogens and improved technologies to eliminate or reduce pathogen levels. But NFPA expresses its concern that in its zeal to improve the safety of produce, FDA may urge a change unjustified by the current knowledge base. Examples follow:

Water

. In Part 1.0, the "Guide" suggests drip irrigation to ensure adequate water quality. However, there are positive and negative aspects to drip versus spray irrigation water in terms of safet y, efficiency, and cost, and thus recommending one over the other is not appropriate. Airborne and dust transmitted pathogens can be washed away with sprinklers while they remain on the plant with drip irrigation.

. In Part 1.1, reference is made to inspection of older wells. NFPA is aware of older well inspection using cameras that let cracks go unseen. And cracks may not always indicate contamination.

. In the same section as above, we recommend strengthening the comments on manure and livestock to say that manure cannot be stored near/adjacent to maturing crops.

. Further to the comments on water quality testing in 1.1, the "Guide" should note that when water used for agricultural purposes comes from public agencies in the U. S., information on the microbiological quality of the water is available and additional testing should not be necessary. However, when information on water quality is not available, appropriate testing or knowledge should be used to prevent avoidable or known hazards. Historical information can be a supplement for some water quality issues. For example, the Yuma, AZ water supply is difficult to control because it travels great distances in an open channel. Vegetables have been grown in the Yuma area and irrigated with the canal water for decades with no indication of a public health issue.

. Part 1.1 discusses "polluted runoff' but gives no guidance as to how land surrounding the crop field should be evaluated for potential for polluted runoff.

. A further comment to Part 1.2 concerning wildlife entry of wells: Typically the pump is placed above the hole, which prevents entry of livestock and wildlife.

. In Part 2,2, FDA encourages washing produce with warm water to reduce the potential for microbial food safety hazards. Warm water may not be readily available in the field, especially after a cold night. Secondly, many crops such as celery and lettuce are treated with water to remove field heat or,

occasionally, to remove mud. Key to field washing for heat reduction is to use potable water to minimize contamination and cross-contamination.

. Because produce for commodity sale is generally not subjected to wash steps, the use of chemicals in water should be directed toward keeping the water (used to cool the product, not wash it) sanitary.

. In Part 2.2, FDA suggests a number of chemicals that are possible sanitizers or antimicrobial for produce. However, some important comments are omitted. Trisodium phosphate (TSP) and organic acids have not been sufficiently assessed for microbial efficacy on produce. Ozone may hold promise as a sanitizer in processing water, but at this time little published information is available on microbial efficacy of ozone applied to foods under production conditions, including fruits and vegetables. While use of novel antimicrobial may prove efficacious, urging changes to their use may not be in the best interest of the industry until science has documented their utility.

. In Part 2.2, FDA notes that alternative non-aqueous disinfectants such as *W,* low dose ionizing radiation, ozone, and gas-based disinfectants are "under study." FDA should further note that these treatments have not been researched sufficiently for application to fruits and vegetables.

. The draft fails to duly note the safety issues surrounding generation of ozonated or chlorinated water and use of *W* light, etc.

Manure and Municipal Solids

. Given the great risk of using untreated manure on food crops (Part 1.0, Part 2.1, Part 2.2. 1), the document should have a specially highlighted box recommending against use of raw manure and biosolids until more is known about survival of pathogens in manure.

. Part 2.2: Manure should not be stacked adjacent to growing crops.

. Part 3.0: The category of domestic animals should be expanded to include pets.

. In the same section as above, high concentrations of wildlife in an area will almost certainly ensure no crops to harvest.

Sanitation and Hygiene

. Section IV focuses on some difficult-to-control issues that, in some cases, may not be realistic risk to food safety.

  . Training: The "Guide" does not address the difficult issue of effective training of a transient population of field workers.

  . The "Guide" recommends excusing workers who are diagnosed with cases of *Salmonella, Shigella, E. coli O* 157:H7, or hepatitis A and should not be harvesting crops. It is also well established that some people maybe transient carriers of such pathogenic organisms without showing any visible symptoms of infection. When faced with loss of wages, a worker is

not likely to report to sick call. The "Guide" should provide clear guidance on identifying employees infected with transmittable diseases.

. Supplying warm water to the field for handwashing is not practical.

- Recommending handwashing prior to harvesting crops dug out of the soil (e.g., potatoes) seems a measure with doubtful benefit, although we would agree that handwashing after using the toilet is important.
- Storage of lunches and tools on crop harvesting equipment is not a serious food safety risk. Even so, the "Guide" might encourage storage areas for lunches, tools, etc.

. The "Guide" notes that "gloves can be an important hygienic practice in combination with handwashing. . . " This is more intuitive than scientifically y proven fact. In fact, the use of gloves in food handling is a hotly debated issue that is yet to be resolved. Improper use of gloves may increase risk of microbial contamination.

. A general note that packing houses and storage facilities should be maintained in clean condition is warranted.

. Part D has a guide on Pest Control, but no mention is made of Integrated Pest Management, a commonly used system in industry, both pre- and post-harvest.

. Part F encourages attention to temperature conditions from the farm to retail outlets. Temperature conditions may be under the control of a contract hauler, not the grower, so it is important to work with all parts of the transportation system to insure adequate control. The draft document makes no mention of the issue of loading patterns on trucks which impact proper refrigerated air circulation.

TRACEBACK

. Traceback procedures are reviewed far more extensively in the document presented at the Association of Food and Drug Officials (AFDO) Workshop on Outbreak Response Coordination on June 6. The AFDO document recognizes the difficulties of traceback for fresh fruits and vegetables and addresses alternatives when the lot numbers/grower identifications are not used or recorded. NFPA is in the process of reviewing this document. Finalized concepts from the latter should be incorporated into the "Guide." At the present time, tracing individual components outside their original shipping container through bar codes, tags, etc., as suggested in the "Guide," is a huge expense to the produce industry requiring packaging, documentation, and record keeping with no certainty of added safety benefits.

GENERAL COMMENT

. NFPA wishes to emphasize the need to regard the document as a general guideline only. A generic document to cover all produce types is a laudable

but optimistic undertaking. In implementing the document, flexibility with regard to practices on specific types of produce is a necessity. We look forward to working with industry, government, and universities to enhance our mutual understanding of the variables that affect the safety of fresh produce from the farm to the table.

. The document defines *facility as:* "the sites and buildings used for, or in connection with, the harvesting, storage, processing, packaging, labeling, or holding of fruits and vegetables." The "Guide" recommends that the facilities should be kept clean and refers to cGMP, 21CFR$~110.35 and 110.37, for sanitation. Generally the site used for, or in connection with, harvesting of vegetables and fruits are crop lands, and sanitation of the facilit y as referenced in cGMPs cannot be implemented. Where GMP guidelines can be followed in the field and are appropriate, they should be employed.

- The "Guide" should contain a Table of Contents as in the November 1997 draft.

SUMMARY

NFPA commends the Food and Drug Administration (FDA) for its critical thinking in developing this guidance and recognizing the crucial role it will provide for microbial food safety of domestic and imported fruits and vegetables.

In summary, NFPA offers the following comments:

- NFPA strongly supports equivalent requirements for both domestic and imported products. The "Guide" may be a useful tool towards outlining appropriate requirements.
- Implementation of the document must consider WTO commitments and sensitivities of our trading partners.
- The "Guide" document would be more widely supported internationally if it were to become accepted by Codex Alimentarius. The "Guide" should be consistent with the work of the Codex Committee on Food Hygiene.
- Drip versus spray irrigation is not a clear-cut issue. There are positives and negatives to both in terms of safety, efficiency, and cost.
- Warm water washing for microbial efficacy must be considered separately from cool water used to reduce field heat from produce, Produce for commodity sale is generally not given a rigorous wash at all. Water used for cooling must be potable, however.
- The "Guide" implies that a number of chemical sanitizers (ozone, TSP, and organic acids) and non-aqueous disinfectants such as *W* light, low dose ionizing radiation, ozone, and gas-based disinfectants are well-researched for their application to fruits and vegetables. As discussed in our comments, this is not the case. Much work is still needed to understand conditions for microbial efficacy. Chlorine dioxide has been well researched, but FDA has

not yet approved the chemical for use on fruits and vegetables other than those intended for further processing (e.g., peeling, cutting, slicing, dicing). The Agency should expedite approval of such use in the interest of food safety.

- The "Guide" should recommend against use of raw manure and biosolids on fields used to grow crops until more is known about survival of pathogens in manure. The recommendation should be emphasized in the document. Manure should not be stacked adjacent to growing crops.
- The "Guide" focuses on ideas in sanitation and hygiene that need further thinking:
  - training of the transient worker,
  - judging a worker's physical health for field work, and
  - use of gloves.
- The "Guide" recommends some costly procedures of limited benefit to food safety:
  - supplying warm water to field workers for handwashing,
  - handwashing prior to harvesting *all* crops, even those which must be dug out of the soil, and
  - sanitizing tools defined as food contact surfaces even though they will be used in contact with the soil.
- The "Guide" should include comment on loading patterns on trucks which impact proper refrigerated air circulation.
- Tracing individual produce items outside their original shipping container through bar codes, tags, etc. is a huge expense to the industry with no certainty of added safety benefits.
- In implementing the document, flexibility with regard to practices on specific types-of produce is a necessity.

Thank you for the opportunist y to comment and your consideration of the information contained herein. NFPA staff is available to provide additional information and to work with FDA at their convenience to advance the completion of the "Guide."

Sincerely,

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Executive Vice-President
Scientific and Regulatory Affairs