COMMENTS ON FDA'S MICROBIAL SAFETY HAZARDS FOR PRODUCE GUIDE

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

RE: **Docket Number 97N-0451**

On behalf of the members of S.T.O.P. and the following members of the Safe Food Coalition,

- Consumer Federation of America
- Government Accountability Project
- National Consumers League
- Public Voice for Food & Health Policy
- United Food and Commercial Workers International Union

We are writing to comment on FDA's "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruit and Vegetables."

Safe Tables Our Priority is a nonprofit, grassroots organization consisting of victims of foodborne illness, family, friends and concerned individuals who recognize the threat pathogens pose in the U.S. food supply. Among our members are victims of contaminated produce, including: *E. coli* O157:H7 contaminated lettuce, hepatitis A contaminated strawberries, and *E. coli* O157:H7 contaminated apple juice. S.T.O.P.'s mission is to prevent unnecessary illness and loss of life from pathogenic foodborne illness.

As you will see below, S.T.O.P. has many reservations about the Guidelines in their current form. *However, of particular concern is that the Guidelines appear to be FDA's* intended solution for produce safety rather than one component of a larger strategic plan *that addresses objectives and concrete goals for reducing food poisoning associated with* raw and slightly cooked produce and its products. Beyond the research that FDA has identified, such a comprehensive plan needs to address domestic and foreign produce, on-farm and in-packing house inspections, foodborne illness surveillance of FDA regulated produce, an outbreak response program, and a long term plan to develop comprehensive water treatment, manure treatment and mandatory HACCP systems.

Dr. Fred Angulo, of the Centers for Disease Control and Prevention has stated that the key threat to public health today is not personal hygiene but animal hygiene. Emphasis must be placed on eliminating the entry of animal feces into the food supply. Recognizing this issue, the cornerstone of USDA inspection regulations ensuring the safety of meat and poultry is a zero tolerance policy for visible fecal contamination. FDA should develop a zero tolerance standard for microbial fecal contamination in produce. Science now indicates that once produce is contaminated,

there is little consumers can do to eliminate all pathogens--pathogens which can be deadly if just a few organisms remain on the fruit. Indeed, the only options for consumers are to avoid these foods altogether or cook, to temperatures that will kill pathogens, foods currently consumed raw, such as berries, sprouts, melons, and lettuce. The time has come for FDA to implement life saving standards such as zero-tolerance for microbial fecal contamination as a key component of a comprehensive foodborne illness prevention strategy for produce.

S.T.O.P.'s comments regarding the Guidelines are organized as follows:

Executive Summary

Key points of S.T.O.P.'s position on the Produce Guidelines are:

- Voluntary guidelines are insufficient to substantially improve food safety; mandatory regulations must be put in place. S.T.O.P. strongly urges mandating HACCP to produce growers and processors.
- The tone of the guidelines is too passive and repeatedly suggests that growers consider different issues. The tone must be changed to require specific actions of growers and processors.
- Food safety standards must be consistently applied across the country regardless of the size or location of the business or whether the grower considers an action feasible.

- Foods that come into direct contact with soil are more likely to be directly contaminated with soil-borne pathogens; therefore, they need to be treated differently than foods that are grown without direct contact with soil. Regulations must be developed that are "food-specific" and address hazards, harvesting practices, and post-harvest processes specific to the type of fruit or vegetable grown.
- Compost is not inherently pathogen-free, as FDA has asserted in its document, nor is the intended purpose of composting to remove pathogens.
- *E. coli* O157:H7 has been shown to survive in soil for over 18 weeks and possibly in sheep manure for a year. Therefore, applying compost or manure that is not pathogen-free up to 60 days prior to harvest is insufficient to prevent contamination of food.
- S.T.O.P. supports a single standard for all compost and manure; if it is to be used for fertilizer, it must be processed to be pathogen-free through a killstep. All water that comes into direct contact with a fruit or vegetable should be pathogen-free through a killstep.
- If an active killstep is not to be used to render compost and manure pathogen-free, compost or manure should be aged for a minimum of a year prior to planting until science proves that shorter or longer time periods are appropriate.
- FDA should develop a certification program to ensure that growers and processors have employees on site who are familiar with the Guidelines.
- Surveys are insufficient for proving the adoption of Guidance. Inspections must be used to verify whether the Guidance is being adopted.
- Water must be kept pathogen-free throughout the entire growing and processing system. Using potentially contaminated water earlier in the process is unacceptable.
- FDA must substantially improve its section on cooling and dust management.
- Containers should be sterilized between lots or daily, whichever is more frequent. Transportation vehicles should be sterilized between trips.
- Packing facilities must be enclosed. The practice of using open air barns and cowsheds for packing fresh produce must stop immediately.
- S.T.O.P. strongly supports traceback. FDA must reduce or eliminate commingling of produce from multiple sources if it hampers traceback.
- S.T.O.P. recommends labeling produce that has been grown or processed with less than pathogen-free manure, compost or water so that consumers can identify produce that has been grown under less safe conditions.

General Comments

Voluntary Guidelines are Insufficient

While S.T.O.P. recognizes that FDA is developing guidance as a first step to a longer term approach to reducing food safety hazards in fresh produce, we cannot strongly support voluntary produce guidelines. The fundamental problem with voluntary guidelines is that they preach to the choir; any grower or packer that is concerned or interested in food safety may take them into consideration; they may even implement some of the recommendations. However, growers and packers who are not so inclined neither read the guidelines nor implement them. The result is that the

average level of food safety may increase, but the minimum level of food safety stays exactly where it is: hazardous and deadly.

The purpose of federal food safety regulation should be to ensure consistent public health standards across all states. Raw and processed produce is now distributed from California to New England and from Florida to Washington state. Therefore, to maintain public health and protect our families and children, it is inappropriate for some growers to be held to different standards merely because they have a different growing season or because they find it more expensive to irrigate with pathogen-free water. FDA needs to recognize that whenever a guideline suggests a grower spend more money to make a product safer, a grower experiences a strong disincentive to increase such expenses as long as competitors exist that can legally get away without the expenditure. This type of competition very thoroughly undermines good intentions on the parts of responsible growers.

Industry, too, needs to recognize this false premise behind voluntary guidelines: voluntary guidelines are great public relations campaigns until outbreak after outbreak proves that industry has no control over its most unsafe growers, which continue to put risky food in the marketplace. What industry needs to fear is not government regulation, but the devastation that will occur after hazardous grower after hazardous grower causes more and more outbreaks. As the statistics pile up, with thousands of Americans, and children in particular, injured by tainted produce, consumers will lose confidence not only in the U.S. food industry but in government's purported interest in protecting the public health. This will be the legacy of "voluntary" guidelines.

We offer two examples in which both voluntary requests and mandatory state regulations for specific actions have been rejected or violated by the produce community. First, in August of 1997, FDA requested that all raw apple cider producers voluntarily carry a label or post warning leaflets at the point of purchase, clearly identifying the potential for hazard to at-risk consumers. The labeling request was largely ignored; S.T.O.P. was able to identify only one retail food chain and one vendor who complied with the label. While some vendors may have used leaflets, FDA should consider this experience as a bellwether for how produce growers will adopt voluntary guidelines. The labeling request was crystal clear and inexpensive to implement; yet, it was rejected by industry.

Second, a recent article in the *Wall Street Journal* (1) indicated that over the last five years, on average more than a third of inspected California growers did not comply with mandatory field sanitation regulations. These state regulations address the most basic, explicitly defined field sanitation factors, such as the availability of clean toilets, toilet paper, soap, paper towels and fresh water for drinking and handwashing. Indeed, "for farms inspected over the past five years for field sanitation, compliance with state rules has ranged from a high of 67.2% in 1995 to a low of 52% in 1996." The article indicates that industry associations, specifically the Western Growers Association and California Farm Labor Contractors Association, support reducing the fines on these violations. If California cannot get its agricultural industry to comply with the most basic field sanitation requirements, which are law, to be followed, how can FDA assume that voluntary guidelines will be implemented? It is because such state regulations are so laxly enforced that basic food and sanitation regulations must be established and enforced at a federal level.

Thus, S.T.O.P. holds that "food-specific" appropriate safety regulations should be developed and finalized, and they should be mandated for all growers. There must be no exceptions in adhering to practices that prevent produce contamination.

Tone of Guidelines Is Passive

For all the above reasons, voluntary guidelines are insufficient. S.T.O.P. strongly objects to the passive tone of many of the actions suggested in the Guidance document, such as (*italics* are our own):

"*Consider* testing water quality."

"Growers with older wells... *may* want to have their well examined by a water quality expert."

"Growers *may elect* to test their water supply for microbial contamination on a periodic basis..."

"*Consider* the use of sanitizers or antimicrobials in wash water."

"*Consider* barriers or physical containment to secure manure storage..."

"Growers *may* want to consider covering manure piles..."

"Since animal manure may contain equal of higher levels of pathogens, some of which are infectious to humans, growers *may* want to consider some of the principles behind the Part 503 requirements and consider the appropriateness of adapting these practices..."

The Webster's definition of "to consider" is "to reflect on." FDA must stop asking for reflection and begin requiring action.

When a S.T.O.P. member attended the FDA meeting held in Washington DC on May 19th, she was informed by Michelle Smith that FDA is aware it is using "soft" language throughout the document. "We are trying to raise awareness. We want operators to look around them and do what they can do. We don't know how much hazard certain things pose."

The quote that "we don't know how much hazard certain things pose" is disturbing. S.T.O.P. again asserts the need for a HACCP program in this industry. As some would define, a HACCP plan, by design, should identify and set controls for all points at which hazards, whether chemical, biological or physical, may be introduced for which a corrective action can be taken. Thus, control points are identified by:

· whether or not they may introduce a hazard and

· whether the hazard can be controlled,

not by "how much" hazard they may introduce. In the case of *E. coli* O157:H7, it is believed that less than 10 and possibly as few as a single organism has the potential to maim or kill. Therefore, we must strive to achieve zero contamination. S.T.O.P.

recognizes that a 100% safety level in a raw produce is not possible, but industry can attain a superior level of safety if HACCP is required.

S.T.O.P. also finds it disturbing that FDA actually expects operators to do "what they can do." Is FDA thinking operators will do the *minimum* they can do or the *maximum* they can do? It isn't clear. Throughout the document as well, FDA suggest operators do what is "feasible" and "adequate." This ambiguity makes it nearly impossible for an operator to understand and implement a uniform standard. We urge FDA to eliminate this conditional language, and identify specific actions and requirements that will protect public health.

One Size Does Not Fit All

The Guidelines entirely fail to differentiate between different types of produce and different types of growing and harvesting practices that are determined by the type of fruit or vegetable itself; they are therefore too general to provide concrete examples of potential hazards. Far more specific guidelines, which would be inherently easier to understand and implement, could be developed if FDA were to more closely define its target, and these would result in greater produce safety.

Pathogenic contamination can reach produce through essentially two different avenues, directly and indirectly. Direct contamination occurs when growers or packers specifically apply a liquid or solid containing pathogens to the surface of the consumable fruit or vegetable. For example, spraying a compost tea onto the fruit or vegetable bearing component of the plant would be a method of direct contamination. Dripping pathogen-contaminated water onto the ground around a fruit that grows on the ground, such as a melon, would be another method. Using an overhead spray system to irrigate an orchard with less than pathogen-free water would be a third. Floating fruit and vegetables in water that previously contained contaminated produce would be a fourth way. Growing a root vegetable, such as a carrot, in pathogen-contaminated manure or with pathogen-contaminated water, would be a fifth.

Indirect contamination can arise by people placing pathogens in the vicinity of a crop. Another step is then required to transfer the biohazard onto the fruit or vegetable. Theoretically, the wind can blow fecally contaminated dust from a local cattle farm onto produce growing nearby. A grower fertilizes a crop with pathogen-contaminated manure and flies transmit the pathogens to the fruit or vegetables growing above the ground. Deer walk through a field and leave pathogen-contaminated droppings, which harvest workers then get on their hands while stepping on the rungs of ladders. Harvest workers sit on their fruit collection bags on the ground during a break; harvested fruit is then placed into dirty bags after the break.

The Guidelines make much of the fact that not all the science is completed; yet, with respect to contamination, several "common sense" facts are asserted: treeborne fruit, for example, does not typically come into contact with mud prior to harvest. Vegetables grown directly in soil or in close contact with soil are more likely to be contaminated with soil-based pathogens such as *Listeria* than fruit grown in trees, all other factors being considered equal. Tree-borne fruit has the potential to be safer if appropriate safety standards are applied to critical hazards, such as:

- insect contamination from fertilizer on the ground
- keeping wild animals, particularly birds, to a minimum
- not using overhead spraying with water which may contain pathogens
- keeping dirt-laden dust to a minimum
- and restraining employees from contaminating the fruit

In contrast, a vegetable or melon growing on the ground is exposed to insects; wild animals, including ground-based rodents; organisms in potentially contaminated irrigation water, regardless of the mechanism of irrigation; contaminated runoff; soil-based organisms; fertilizer-based organisms, if animal fecal matter is in the fertilizer; dust-blown organisms; and contamination through harvesting. Fundamentally, produce grown on or in the ground is more vulnerable to direct contact with pathogens arriving on the ground through fertilizer or water than produce grown above ground.

Thus, based on the proximity of the fruit or vegetable to soil, S.T.O.P. urges FDA to develop additional, more specific guidelines for the growing and harvesting to address the following produce categories:

- soil-based produce, which would include subterranean produce, such as carrots, potatoes, peanuts and onions, and ground level produce, such as melons, strawberries, cabbage, and lettuce
- pole grown vine produce, such as tomatoes, kiwis, grapes and beans
- and orchard fruit.

Until industry is required to use HACCP, which would address the diversity of produce issue, FDA must be more specific in its recommendations. More extensive Good Manufacturing Practices are required for some types of produce than for other. GMPs should be appropriate to the food. One size does not fit all.

The Application of Manure, Compost and Water

As FDA has indicated in the Guidance, the use of manure, compost and water that may contain pathogens have the highest likelihood of directly contaminating produce. S.T.O.P. supports a single standard for all compost and manure; if it is to be used for fertilizer, it must be processed to be pathogen-free. All water that comes into direct contact with a fruit or vegetable should be pathogen-free. S.T.O.P. recognizes that the use of potentially contaminated water is prevalent throughout the United States today. We therefore believe that to implement a pathogen-free water system will take considerable time. In the meantime, we believe FDA should restrict the use of potentially contaminated water to irrigation situations where the water cannot come into direct contact with the fruit or vegetables being grown.

FDA Plans for Technical Education and Assistance

In the February 24, 1998 Status Report on the Initiative to Ensure the Safety of Imported and Domestic Fresh Fruits and Vegetables, the Department of HHS and USDA described plans "to promote appropriate application of the guidance and improve production and processing practices." As previously stated, S.T.O.P. feels that currently the guidelines are too general and passive in tone to effectively improve food safety and therefore are not in a condition to be used as an effective education piece.

After FDA does in fact strengthen the guideline to be clear, concrete and specific, we would suggest that FDA develop a certification process through the State Cooperative Extension Services, which, in addition to offering courses, would provide standardized, detailed testing of an individual's knowledge of the guidelines. FDA should require that at any time during the growing and harvesting process, a person should be working on site, in the field or processing site, that has successfully passed certification. Recertification would be required annually. Unless individuals in a growing or packing operation are specifically identified whose job it is to know and understand the guidelines, they cannot be effectively implemented.

FDA Focused Inspections and Verifying Application of Guidance

The February 24, 1998 Status Report also states that the government agencies plan to

"...use evaluation of risks and survey techniques to determine the extent of application of guidance... and the effectiveness of the GAP/GMP program in reducing the occurrence of pathogenic microorganisms and the incidence of produce-associated illnesses."

S.T.O.P. vehemently disagrees with the premise that surveys can validate the effectiveness of the Guidance. It is generally recognized that people complete questionnaires to reflect what they should do rather than what they actually do. Surveys are therefore particularly unacceptable as either a method for verifying:

- adoption of the guidance by industry or
- the effectiveness of the GAP/GMP program in reducing pathogenic organisms and the incidence of produce-associated illnesses.

To show reduction of pathogenic organisms, the only acceptable data would come through a carefully controlled scientific baseline study of microbial loads before implementation of GAP/GMP programs followed by a study of the same operations at a later date. Even with this data in hand, it would be challenging to correlate it with the rise or fall of produce associated illnesses because foodborne illness is so grossly underreported and incompletely tracked.

Surveys cannot produce data on pathogen reduction. S.T.O.P. believes that random, unannounced, onsite inspections must be used in conjunction with surveys to address whether or not the guidance is adequately adopted. For instance, if growers were asked on a survey whether they always have adequate toilet facilities available, many might indicate they do. Only an onsite inspection would verify whether this was, in fact, the case. Random, unannounced inspections would also be a way to verify the survey results.

Specifics

S.T.O.P. strongly supports the first principle under the Basic Principles of the guidance document, specifically, "Prevention of microbial contamination of fresh

produce is favored over reliance on corrective actions once contamination has occurred."

Once again, we remind FDA that the pathogen *E. coli* O157:H7 is considered to be potentially deadly in very small doses of fewer than 10 organisms; some experts would even say a single organism. Approximately 5% of children consuming it will develop a life-threatening condition known as Hemolytic Uremic Syndrome. Of these, 5-10% will die, and another percentage go on to develop kidney failure and other complications as a result of the injuries they sustain in the battle for their life. Senior or immune compromised adults can develop a slightly different condition, called Thrombotic Thrombocytopenic Purpura or TTP with a 75% mortality rate within 3 months (2) of onset.

In a recent study, *E. coli* O157:H7 was found to be present in 63% of cattle feedlots sampled (3). Sheep and deer have also been known to harbor the organism, with epidemiologists generally now believing that any ruminant can be a reservoir(4).

Increasingly, research is showing that once produce is contaminated with virulent pathogens (*E. coli* O157:H7, for example), old familiar techniques such as chlorine rinses recommended in the Guidance can be inadequate to kill pathogens and prevent outbreaks(5). One study has shown that while pathogenic organisms on lettuce can be reduced by washing, they are not eliminated(6). Post contamination, corrective actions are thus of dubious value unless they involve a significant, technological killstep. Even a killstep may be insufficient if the initial levels of contamination are too high.

The only steps available to consumers are rinsing produce with diluted bleach or cooking it, options that are unreasonable for many fruits and vegetables normally served raw, such as sprouts, wheat grass, mixed greens, and berries. Because consumers can be sickened by ingesting even a minute amount of microbes, it is imperative to prevent contamination issues at the farm level before produce reaches the consumer.

Manure and Compost

The use of contaminated manure and compost is one of the top two methods by which pathogens are *directly* introduced to produce during the growing process. Animal feces, unlike unpotable water, has a reasonable probability of carrying significant concentrations of organisms. The intestinal tracts of farm animal like cattle and poultry are known to harbor pathogens that cause foodborne illness. 70-90% of poultry have been found to be contaminated with Campylobacter at retail (7). Twenty to eighty percent of poultry are believed to be contaminated with *Salmonella* (8). Studies of the prevalence of *E. coli* O157:H7 are hampered by the fact that cattle shed the organisms at different times. Nevertheless, USDA's Animal and Plant Health Inspection Service found in one study that 63% of feedlots studied were shedding *E. coli* O157:H7 (9). Still, the numbers indicate that the practice of applying potentially contaminated manure or compost to the soil around crop plants has a reasonable probability of contaminating the soil, and possibly the plant itself.

Because many animal pathogens are the source of human foodborne illness, it is absolutely critical that FDA address manure and compost application correctly.

Erroneous assumptions that FDA has sprinkled throughout its manure section, such as

- describing composting as "designed to reduce possible levels of pathogens in manure," and
- minimizing manure contact "especially close to harvest," and
- supporting the National Organic Standard Board recommendation of not applying raw manure within 60 days of harvest

raise great concern within our organization that FDA is unaware of the latest science in this area and disseminating such assumptions as facts, which could result in life-threatening situations to the public.

Compost is Not Inherently Safe

In the existing Guidance, S.T.O.P. supports the definition for compost found in the definitions section: "Composting refers to a managed process in which organic materials are digested aerobically or anaerobically by microbial action."

However, in subsequent sections of the Guidance, an author has made incorrect assumptions about the purpose of compost and the safety inherent in it. These are:

Section 2.0: "Growers should follow good agricultural practices for handling manure to reduce the potential for introducing microbial hazards to produce. Such practices may include processes, such as composting, that are designed to reduce possible levels of pathogens in manure."

Section 2.1.1 Composting "Composting is a common treatment to reduce the microbial hazards of raw manure. The high temperature generated during composting can kill most pathogens in a number of days."

We have been unable to find research that supports these assertions; our sources would suggest the opposite. Indeed, compost is often created, bought and sold specifically to take advantage of different kinds of non-pathogenic bacteria that thrive in it. The "high temperature generated" would kill not only pathogens but most remaining, non-sporified bacteria, thus rendering useless the microbial value of the compost. Even if the compost did achieve a high enough temperature for a number of days, in order for it to be "safe," all of it must reach that temperature level. Yet, composts are notorious for having warm and cold spots. Such cold spots could continue to harbor pathogens.

In further support of the evidence that vague composting instructions do not render compost a pathogen-free fertilizer, a June 8, 1998 article in the Spectator (Canada) contained the following:

''Manure is often just dumped in a pile. It needs to be treated at a high temperature to kill the bacteria,'' said Wilson, also a professor at the University of Guelph. Donald Hilborn, a waste management specialist for the agriculture ministry, agreed. He said most farmers don't have the high-tech composts necessary to kill off the bacteria."

The term compost is also broadly used to encompass a form of fertilizer called a "compost tea," which is made by putting animal manure in a container, covering it with water, and stirring. After a few days, the "tea" is then sprinkled around or sprayed on food plants. In this compost, bacteria are not killed. A recent article describing how to make a compost tea indicated that it promoted "vigorous growth" in plants (10).

FDA should immediately stop referring in all documents to composting as "a treatment to reduce possible levels of pathogens" or "to reduce microbial hazards," which it is not. It is, as defined in section I, "a managed process in which organic materials are digest aerobically or anaerobically by microbial action." S.T.O.P. strongly prefers active elimination of pathogens through a killstep because of the lack of scientific evidence that the passive methods such as composting, which FDA describes and promotes in the Guidance, successfully eliminate pathogens.

Sixty Days Prior to Harvest Is Insufficient

Scientific studies have indicated that the 60 day limitation on application of raw manure is insufficient based on the survival abilities of *E. coli* O157:H7 in both feces and soil. However, in the Guidance, FDA supports the Organic Foods Production Act (OFPA) 60 day limitation on the application of raw manure prior to harvest.

In "Fate of Enterohemmorrhagic Escherichia coli O157:H7 in Bovine Feces," published in Applied and Environmental Microbiology, July 1996, authors Wang, Zhao and Doyle traced the survival rate of *E. coli* O157:H7 at 41, 71.6 and 98.6 degrees Fahrenheit. At the lowest temperature, the organism survived between 63 and 70 days in feces. The authors noted that the moisture content was highest in the lowest temperature feces, which implies that O157:H7 may be more easily cultured if kept moist. This may also suggest that the organism may survive more readily in colder climates which have shorter growing periods. Arguments by farmers in colder climates that they have shorter growing cycles and should therefore be allowed to apply raw manure with less stringent restrictions are contradicted by this data.

In "Survival Of The Verotoxigenic Strain *E. coli* O157:H7 in Laboratory-Scale Microcosms," published in the Proceedings of the International Conference sponsored by the Water Chemistry Forum of the Royal Society of Chemistry of the U.K., Dr. Maule compared survival rates of O157:H7 in cattle feces, cattle slurry, river water, and soil cores at 64.4 degrees Fahrenheit:

"It is evident that of all the model ecosystems tested, *E. coli* O157:H7 survived best in the soil cores... The current study has shown that *E. coli* O157:H7 seems to survive for long periods both in cattle faeces (sic) and in soil. Thus, it seems that once pasture land becomes contaminated with this organism, it may remain viable for several months... When enteropathogenic microorganisms are exposed to the environment they are often injured and when attempts are made to enumerate them on selective media, as in the present study, they may die or simply not grow (Singh and McPeters, 1990). This can lead to underestimation of bacterial numbers, thus the figures given for *E. coli* O157:H7 survival in laboratory ecosystems in this study may be much lower than the real situation."

Dr. Maule's latest data on O157:H7 survival in soil indicates that O157:H7 can survive **for at least 130 days in soil** containing rooted grass, e.g. over 18 weeks or

over 4.3 months. FDA itself has received information that *E. coli* O157:H7 may survive in sheep manure for more than a year, though this information only made it into the footnotes of the Guidance document (11). The Cornell Cooperative Extension brochure which FDA places in Footnote 15, indicates that *Yersinia* may survive, but not grow, in soil for up to 330 days.

The 60 day established guideline is inadequate for keeping soil-based produce from becoming contaminated. Indeed, the application of potentially contaminated manure or compost prior to harvest represents a significant risk of potential pathogenic contamination, directly for soil-based produce and indirectly for pole/vine and orchard produce. Even orchard and vine grown produce is susceptible to contamination from the flies attracted to animal fecal matter by putrefaction. While not reservoirs for the organisms, insects(12) and birds(13) have been found to be carriers. It stands to reason that birds and insects represent a threat for transporting pathogens from nearby animal feces onto fruit and vegetables.

FDA must address this science in the revised guidelines by acknowledging that based on survival rates and low infectious doses, current data suggests that aging of contaminated fecal matter for less than one year represents a food safety risk.

Manure and Compost Must Be Made Pathogen-Free

S.T.O.P. maintains that elimination of pathogens in manure is only reliably achieved through a killstep. S.T.O.P. cannot support most short term passive (14) treatments for eliminating pathogens from manure or compost until FDA can produce the science that shows that all organisms will be killed as effectively as if the manure had been processed with a killstep, which should mean *more* than a 5 log kill given the load of bacteria in manure.

S.T.O.P. generally supports the principles behind Section 3.0, which identifies ways in which nearby animal fecal matter or compost should be recognized to be a hazard. This section suggests that growers ..."assess the prevalence and likelihood of significant amounts of uncontrolled deposits of animal feces coming into contact with crops." Because even minute amounts of certain pathogens can be deadly, we would insist that FDA change the term "significant amounts" to "any amounts." FDA should mention that some studies have shown that pests and birds can transport microbes between compost or manure piles to produce. Without describing this direct link to operators, it will be challenging for farmers to justify the actions FDA recommends. We support FDA recommendations that farmers use methods to restrict access of domestic and wildlife animals to crop fields and orchards, and we support requiring the use of such methods. All the work to keep contaminated manure out of the fields as a fertilizer would do no good if deer were allowed access.

Therefore, S.T.O.P. advises that FDA require the following of growers:

1. Any compost containing animal fecal matter or any manure containing animal or human feces used on crops must be made pathogen-free. S.T.O.P. believes that if farmers continue to desire activity from "beneficial" organisms that would also be eliminated by a killstep, the farmers could contract with a laboratory to add cultures back into the fertilizer after the killstep.
2. Alternatively, if under certain exceptional circumstances, a killstep is not possible, compost containing animal fecal matter or any animal or human

feces used on crops should be aged for over one year until science shows that aging should be shorter, longer or eliminated as an option entirely. Present survival data of these organisms show no signs of a quick demise in soil. Given FDA's data on *E. coli* O157:H7's survival in sheep manure, it would seem that a year may not be long enough. In such a case, we would advocate whatever time it takes to make the fertilizer safe for direct contact.

3. Any aged animal feces treatment, composted or otherwise, must occur *prior to planting of the crop*, not prior to harvest as the industry and OFPA originally defined to ensure the maximal length of time for reduction of organisms.
4. S.T.O.P. strongly recommends that compost "teas" which contain animal or human faces be restricted from applications in which they might come into direct contact with foods. Compost teas must be subjected to the same requirements as manure and compost, as opposed to those of contaminated water.

FDA concludes the section 2.2.2. with the statement, "As more data become available on the viability of microorganisms in manure, and on treatments that most effectively reduce microbial hazards, growers and manure suppliers may need to adjust practices accordingly." Both S.T.O.P. and FDA have identified data that indicate very long survival rates of foodborne pathogens. Both S.T.O.P. and FDA know that a significant log reduction can be achieved through a killstep. Therefore, S.T.O.P. finds it remarkable that FDA is not basing its guidelines on facts. The time for FDA to take action based on fact is NOW.

Agricultural Water

This section opens with the sentence "Water quality should be adequate for its intended use." Adequate is previously defined as "that which is needed to accomplish the intended purpose in keeping with good practice."

The intended purpose must be to keep our foods from becoming contaminated with deadly pathogens, regardless of what the "best" practice may be today. Any water that can contain pathogenic microbes which comes into contact with fresh produce raises the possibility of contamination. Indeed, as S.T.O.P. understands from the public meeting FDA held in Florida, water-based pathogen uptake was described as "inherent in produce." Because it is nearly impossible to eliminate pathogens from produce "downstream," i.e. in processing or once it reaches consumers, S.T.O.P. finds unacceptable the use of water that potentially contains pathogens for any purposes related to growing or subsequent harvesting and processing of produce.

S.T.O.P. recognizes that it will be a long time before FDA will be able to implement an exclusive pathogen-free water regulation. Should FDA be unable to immediately implement this, we believe FDA should at a minimum, restrict the use of potentially contaminated water to irrigation situations where the water cannot come into direct contact with the fruit or vegetables being grown. However, we believe that FDA should use the Guidance to put industry on notice that the use of potentially contaminated water will increasingly come under scrutiny, as it has been and will continue to be, linked to multiple outbreaks (15).

In Section 1.1, first paragraph, the Guidance advises "Growers with older wells... may want to have their well examined by a water quality expert." S.T.O.P. would

suggest that if a grower has not had his well water tested in the last two years, FDA should mandate that he have his well examined. Well and *surface* water testing should be conducted semiannually in the event of no problems and at least monthly after contamination has been identified and corrected for a period of one year.

S.T.O.P. questions why information on irrigation systems and testing after filtration, included in the original draft has been omitted from this version of the Guidance. Information about when and how to test is exactly the type of information the latest draft desperately needs, and we advise FDA to put the information back into the document.

In Section 1.1, the second paragraph is entitled "Review existing practices and conditions to identify potential sources of contamination." Identifying practices and conditions should be a step prior to taking some action; yet, no actions are defined. It continues

"On-farm sources of contamination from animal waste include manure storage near crop fields, leaking or overflowing manure lagoons, uncontrolled livestock access to surface waters or pump areas, and high concentrations of wildlife. These and other potential sources of water contamination should be assessed and controlled to the extent feasible to minimize microbial food safety hazards."

S.T.O.P. urges FDA to make a list of these potential forms of contamination and others and to define the recommended solution for each. For example:

"Manure should not be stored more than 500 yards from crops. Maintain a buffer of 500 yards between crops and other animal farms or wildlife refuges. Leaking or overflowing manure lagoons must be pumped and removed from the site. Farms with the potential for wildlife contamination should enclose cropland with an 8 foot high fence."

The phrase "to the extent feasible" needs to be defined in terms of the standards needed to prevent pathogenic contamination. Does FDA consider an action feasible only if it does not cut into profits? Is an action feasible if it costs one man week of labor? Instead of this phrase, FDA should state, "if the number of potential sources of contamination prohibits correction because of high expense or the source of irrigation water is contaminated, the operator should acquire a water purification system."

The Section 1.1, third paragraph addresses water runoff obliquely. Safety demands that crop farmers be required to control runoff from neighboring animal farms. For example, near Hollister, California, cattle/dairy farms sit on hill after hill above crop fields on the valley floor just below. This type of farming no doubt arose because it was easier to plow flat cropland and let the animals live on hills. However, it also leads to contaminated runoff saturating the soil around crops and potentially contaminating wells. FDA must address the proximity issue very explicitly. Cattle in proximity to a lettuce farm in this area are implicated as the source of an outbreak that affected an identified 66 people and left at least one child with brain damage. Comments such as "Soil and water conservation practices such as grass/sod waterways, diversion berms, runoff control structures, and vegetative buffer areas may help prevent polluted runoff water from contaminating produce crops" provide

information that is too general to ensure that farmers address the real hazard produce contamination poses to consumers.

Section 1.2 Irrigation Water, first paragraph: "To the extent feasible, growers should follow good agricultural practices that minimize the potential for contaminated water contact with the edible portion of the produce." We would ask that FDA strike the phrase "to the extent feasible," which dilutes the message.

In Section 1.2, first and second paragraphs, FDA states,

"This becomes increasingly important the closer irrigation applications are made in relation to harvest."

and

"In general, as water-to-produce contact increases, microbiological water quality needs to be better, especially close to harvest."

S.T.O.P. holds that "close...to harvest" and "closer to harvest" are irrelevant when describing contamination because of how long these organisms survive. As we have previously indicated, the latest studies have shown that pathogens can survive in soil for many months. The expected survival rate on some fruit and vegetables that offer shelter from the environment could be substantially higher. Indeed, the irrigation water quality should be pathogen-free throughout the entire growing process as we indicated above. Current standard practices in which potentially contaminated water is sprayed onto fruit and vegetables must be changed to ensure the safety of our food supply, regardless of the timing of harvest.

Section 2.0 Processing Water suggests that it is acceptable to use lower quality water earlier in the process and higher quality towards the end of processing. As we have described above, contamination at any point in the process will not be rectified with further water or washing.

We question the logic FDA is using in this section and assert that in processing, only pathogen-free water should be used. Likewise, if water is expected to be reused in other processing steps, pathogenic contamination should be eliminated again before use.

Dump tanks and flumes, for which FDA apparently deems it acceptable to use low quality water, are the produce industry's equivalent of the "chill bath" for chicken, in which the pathogens on a single piece of fruit are easily spread to dozens if not hundreds or thousands of pieces of fruit. These areas must be kept clean through the use of pathogen-free water and frequent sterilization.

Section 2.2, Wash Water advises operators that "Sanitizers or antimicrobials in wash water and other processing water may be useful in reducing pathogens on the surface of produce and/or reducing pathogen build-up in water." FDA should stress that washes and rinses cannot be used to compensate for contamination. They should only be used as an additional safeguard to reduce inadvertent contamination. Data from EPA indicates that "an acceptable methodology presently does not exist for fresh produce (especially household) sanitizers."(16) We find i*t ludicro*us that FDA

suggests that operators use a swimming pool test kit to ensure the efficacy of such chlorine sanitizers when FDA admits on its own in footnote 11 of the Guidance, "Fruit and vegetable tissue components and other organic matter neutralize chlorine rendering it inactive against microorganisms." What evidence does FDA have that to show that pool quality water is free of pathogens? What evidence is there to show that water will be appropriately tested with a swimming pool kit? The best means for reducing the pathogen load in produce is preventing its application in the first place, as the principles of the Guidance suggest.

On the other hand, S.T.O.P. commends FDA for recognizing that the latest science is showing that foods with internal airspaces may be susceptible to internalization of pathogens as it indicates in Section 2.2. We urge that FDA make a clear list of produce that meets this criteria so that growers to not have to hypothesize whether guidance on water temperature differentials applies to them.

S.T.O.P. believes that Section 2.3, Cooling Operations, is better placed prior to or within Section C, Packing Facility. S.T.O.P asks that FDA closely examine the recommendations of the Western Growers Association which address many more methods of cooling, such as vacuum, pressure, HydroVac, hydrocooling, ice injection, and ice manufacturing. S.T.O.P. believes that more stringent requirements should be adopted. For example, the Western Growers Association advises that incoming ice and water must meet potable microbiological water standards "or corrective action must be taken," while FDA's Guidance does not make this obvious recommendation.

Sanitation and Hygiene

S.T.O.P. generally supports FDA's sanitation and hygiene guidelines, though we suspect that some states may have more stringent regulations. If there are states that have more stringent regulations, we would prefer those. Unfortunately, when a sick worker needs to work and be paid, and farmers need food harvested, there is a strong disincentive for either party to restrict a sick worker from working.

In Section C, Field, 2.0 Control of Potential Hazards, FDA fails to address widely different methods of harvesting. Workers may be using cloth bags, cardboard boxes, plastic cartons or conveyor belts to gather produce together. They may also sit on empty containers during their breaks. The machinery involved also can be quite varied. S.T.O.P. strongly urges FDA to be specific about standards for cleanliness and safety. In particular, we would recommend that all gathering and transporting containers, whether basket, bag or carton, be sterilized between lots which would contain the extent of contamination. Indeed, S.T.O.P. believes it would be superior to require that no container be reused at all without steam/pressure treatment.

Likewise, we would urge FDA to set standards in harvesting and processing to prohibit the placement of bags, cartons and containers on the ground, where they are highly likely to come into contact with fertilizers, chemicals, manure, compost, decomposing organic debris such as leaves or grass, mud, dirt, and insects. The combination of these two requirements would render obsolete FDA's recommendation:

"Clean muddy containers or bins before using to transport fresh produce. Clean containers for whole fruits and vegetables that are intended for hulling, husking,

peeling, or washing prior to consumption. Clean and sanitize containers used for ready-to-eat produce, such as raspberries."

As mentioned previously, washing is not considered a significant contributor to elimination of pathogens. Melons, from which the peel is never consumed, have been linked to foodborne illness outbreaks. Contamination reaches the inside of a melon from the outside when a knife slices through the peel into the interior. Therefore, presuming produce that will be washed or peeled should be treated different than ready-to-eat produce is erroneous.

We would note that if FDA were to categorize produce as we recommended (treeborne, vine-pole, soil-based) then it would be able to suggest appropriate container requirements based on how the produce is harvested.

In the Section mislabeled C, which should be D, Packing Facility, 2.2, General Considerations for Facility Maintenance, to prevent cross-contamination, we strongly support any FDA recommendations that suggest sanitizing packing equipment, dump tanks, flumes, and facilities on a lot or daily basis, whichever is more frequent, at minimum. The only way to ensure that an outbreak is constrained to a single day's or lot's production is by sanitizing between the production of each.

We also want to see that all packing facilities maintain a minimum of standards, such as they must be enclosed on sides, have a debris-free, solid floor, and have not been used to house animals, unless they have been thoroughly sterilized prior to being converted into a packing facility. The practice of using open air barns and cowsheds for packing fresh produce must stop immediately.

In Section F, Transportation, 2.2. General Transport Considerations, FDA should require that truck beds should be disinfected between shipments.

Traceback

S.T.O.P. strongly supports regulations enforcing traceback for many reasons. The produce industry should, too. First, fast, efficient traceback can effectively save lives and prevent injuries by quickly identifying the food causing an outbreak. Second, fast, efficient traceback, puts the finger on culpable producers rather than the entire industry. Third, to the extent that an outbreak is associated with a compliant grower but a GMP has failed, fast, efficient traceback will help to identify needs for improvement in FDA's Guidance. Fourth, fast, efficient traceback saves taxpayers' money by ensuring that government does not get bogged down in investigating dozens of leads trying to identify the cause (in the Odwalla outbreak, over 30 orchards were scrutinized for potential deficiencies; accurate traceback could have reduced that number to 5. Fifth, fast, efficient traceback will encourage more responsible food safety behavior by making farmers more accountable for their products.

We strongly urge FDA to strictly limit the number of pieces of produce that arrive in a package that might be purchased by consumers. In other words, berries in a single 4 ounce size should come from no more sources than FDA can readily traceback to the farm-of-origin. Packers must be made responsible to keep track of and eliminate commingling of produce from multiple sources. As long as FDA considers extensive, untraceable commingling to be acceptable, traceback will be useless. S.T.O.P.

strongly supports farm-of-origin labeling which would place the names or code numbers of the originating farms on the retail packaging itself. Of course, a traceback system is only effective if it is coupled with a recall program as well.

Additional Recommendations

FDA only briefly addresses issues with contaminated dust. Research currently conducted by Dale Hancock at Washington State University Veterinary Hospital has pointed to the potential for *E. coli* O157:H7 contamination of tree-borne fruit through windblown dust (17). We believe that the control of dust deserves its own section. Crops located next to other farms could easily be subjected to dust from tilling or plowing giving rise to a greater likelihood of contamination from Botulism spores. FDA also does not mention the possibility of dust from nearby construction.

FDA should substantially enhance its section on harvesting and address different methods and technologies involved in harvesting.

In Conclusion

S.T.O.P. feels that if FDA were really committed to food safety in produce, they would initiate HACCP rulemaking immediately. We do not believe that the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruit and Vegetables, in its April 13th form, can achieve its stated goal of minimization. It is too general for growers to adequately implement. It fails to set standards, and therefore defies reasonable verification. In fact, some growers and states have already made more stringent recommendations. Guideline suggestions and recommendations are basically only worth the paper they're written on. Operators so inclined are already doing so or are doing more.

S.T.O.P. urges a more direct and immediate approach to consumer protection. While FDA and USDA continue to edit the Guide, warn consumers about the risks posed by U.S. growing practices today. Labeling is an inexpensive, easily implementable method for informing consumers. We recommend that all produce that is grown with less than pathogen-free water or which uses potentially contaminated animal feces as a fertilizer component be labeled as such. The labels would read:

"This American produce was grown with unclean water."

and

"This American produce was fertilized with unsterilized manure/compost which could contain pathogens hazardous to your health."

We think FDA and industry do not want consumers to know that at the end of the twentieth century, U.S. food is grown with water and fertilizer that can harbor pathogens, that such practices entail significant public health risks, and that government and industry consider these practices and risks acceptable. American consumers deserve and demand a higher level of protection from their government than they are currently receiving. It is unconscionable that in this country, known

and established safety measures aren't mandated. Consumers have the right to assume that the food they feed their families is produced by the safest and most stringent methods possible and that their government is seeing to it that it is. We want and need that level of protection now. S.T.O.P. strongly urges government and industry to swiftly put mandatory controls in place, before outbreak after outbreak exposes these practices for what they are: not worth the risk.

Sincerely,

Laurie Girand
Board Member
Safe Tables Our Priority

Nancy Donley
President,
Safe Tables Our Priority

Mary Rouleau
Legislative Director,
Consumer Federation of America

Felicia Nestor,
Food Safety Project Director;
Tom Devine,
Legal Director;
Government Accountability Project

Linda Golodner
President,
National Consumers League

Art Jaeger
Executive Director,
Public Voice for Food & Health Policy

W. Gary Sauter
Executive Vice President and Director,
Legislative & Political Affairs Department;
United Food and Commercial Workers International Union

ENDNOTES

(1) March 4, 1998, California section

(2) Stein Internal Medicine, 4th Edition (1994) "Systemic necrotizing vasculitis involving small vessels."

(3) Animal Production Food Safety, An Overview for FSIS Employees, Summer 1997, page 82.

(4) Kudva, Hatfield, Hovde, "Escherichia coli O157:H7 in Microbial Flora of Sheep," Journal of Clinical Microbiology, 2/1996, p.431-433; Rice, Hancock, "Vertoxigenic *E. coli* O157 colonisation of wild deer and range cattle," Letter to the Editor of The Veterinary Record, 11/11/95; Keene, et. al "An Outbreak of Escherichia coli O157:H7 Infection Traced to Jerky Made From Deer Meat." JAMA, 4/16/97

(5) Dr. Patricia Griffin, Centers for Disease Control and Prevention, at Juice Safety Meetings, December 16, 1996; Washington, D.C.

(6) Stenson, Jacqueline, "Scientists Urge Consumers to Wash Lettuce Carefully," Medical Tribune News Service, 10/2/97

(7) U.S. News and World Report, "O is for Outbreak," mid-November, 1997, cover article, quoting Minnesota Department of Health study of Minneapolis grocery stores.

(8) Fox, Nicols, "Spoiled: The Dangerous Truth About a Food Chain Gone Haywire," BasicBooks, 1997; page 179.

(9) "Factors Associated with Escherichia coli O157 in Feces of Feedlot Cattle," USDA, Animal and Plant Health Inspection Service, Info Sheet-Veterinary Services, October 1997

(10) "Manure Tea Starter Solution, "San Jose Mercury News, Friday, May 22, 1998.

(11) Ref. 17: Bohach, C.H, Personal communication regarding survival of *E. coli* in sheep manure, December 1, 1997.

(12) "Sources of Escherichia coli O157 in feedlots and dairy farms in the Pacific Northwest," Hancock, Besser, Rice, Ebel, Herriott and Carpenter, 1997?

(13) University of Lancaster and the Central Public Health Laboratory of London, 1997 study found 3% of gull droppings were infected with *E. coli* O157:H7.

(14) "Passive treatments rely primarily on the passage of time, in conjunction with environmental factors, such as natural temperature and moisture fluctuations and UV irradiation, to reduce pathogens... To minimize microbial hazards, growers relying on passive treatments should ensure manure is well aged. Holding time for passive treatments will vary depending on seasonal climatic factors and on the type and source of manure. However, as an example, Cornell Cooperative Extension recommends that manure slurry be stored for 60 days in summer and 90 days in the winter prior to field application." Guidance document.

(15) FDA Juice Safety Meetings, December 16-17, 1996; Washington, DC; transcripts

(16) U.S. Environmental Protection Agency, Memorandum-Subject: Data Package for the September 1997 Science Advisory Panel on Fresh Fruit and Produce Sanitizing Wash", August 4, 1997.

(17) E-mail to Bert Bartleson, 12/11/96 from Dale Hancock.