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Divisions of Document Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 2004N-0258, Produce Safety from Production to Consumption: An Action Plan to Minimize Foodborne Illness Associated with Fresh Produce

Safe Tables Our Priority (S.T.O.P.) 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. S.T.O.P.'s mission is to prevent unnecessary illness and loss of life from pathogenic foodborne illness. We count among our members victims of *E. coli* O157:H7-contaminated lettuce and apple juice; hepatitis A- contaminated strawberries and green onions; and *Salmonella*-contaminated orange juice, almonds, spices like cilantro and tomatoes. In all of these cases, government knew the dangers of potentially contaminated produce. And in all of these cases, inadequate efforts by government to warn consumers failed to protect them from life threatening illnesses. We appreciate this opportunity to comment on Produce Safety from Production to Consumption.

S.T.O.P. has previously submitted comments on similar topics to both state and federal regulatory agencies. The following is a list of those comments:

- 11/8/99 – State of California's Water Recycling Criteria
- 3/25/99 – Microbial Safety Evaluation of Sprouts
- 4/30/98 – National Organic Program Proposed Rule
- 6/26/98 - Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruit and Vegetables.”

These comments are included with this set by reference to their publication on S.T.O.P.'s website at:

http://www.safetables.org/Policy_&_Outreach/Public_Comments/pc_recycled_water_11_1999.html

http://www.safetables.org/Policy_&_Outreach/Public_Comments/ltr_nacmcf_sprouts_3_1999.html

http://www.safetables.org/Policy_&_Outreach/Public_Comments/pc_tmd94002_organic_4_1998.html

http://www.stop-usa.org/Policy_&_Outreach/Public_Comments/pc_97n0451_prodcom_06_1998.html

Recommendations in this document supersede some of the recommendations in previous documents.

Preface

The Federal Register Notice of FDA's meeting on Produce Safety indicates that FDA asks very important questions about produce safety and seeks input for potential actions; this is to be commended. However, the subsequent publication of "Produce Safety From Production to Consumption: A Proposed Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption" on June 18, 2004 indicates that FDA's plans for prevention almost strictly emphasize guidance and not regulation. S.T.O.P. cannot support the use of guidance documents as a primary method of preventing foodborne illness.

Since the publications of FDA's Guidance for Industry (Minimizing Microbial Food Hazards) in 1998 and its Guidance for Sprouts, outbreaks from domestically grown produce continue apace, proving that guidance does not result in the types of changes required to make produce safer. Leaving alone the fact that much of the guidance proposed in these documents by CFSAN was insufficient in the first place to prevent contamination, CFSAN must also come to recognize that guidance documents are only read by a subset of producers. Thus, while aware producers might attempt to follow the guidance and still cause outbreaks because of weaknesses in the guidance, others remain unaware and cause outbreaks out of sheer ignorance. 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 safety of the least safe producers can only be raised with regulations and on-farm inspections for compliance.

Beyond the spotty implementation, commodity produce industries remain in a state of denial about the shared practices of producers which aggravate food hazards. With each "first" identified outbreak in a specific produce industry, growers and other aggregators blame the individual producer and distance themselves from shared responsibility. If FDA is ever to make progress in this area, the agency must find a way to break through the entrenched "it's not us" mindset.

One component of breaking through the mindset is that FDA must aggressively seek and maintain outbreak information with respect to produce. The data FDA must collect at minimum from CDC and/or other sources, is:

- ?? produce product and source produce implicated
- ?? organism causing outbreak
- ?? food growers, aggregators, distributors, retailers involved in the outbreak
- ?? suspected cause(s) of contamination
- ?? number of cases identified

- ?? ages of victims clustered by every 5 years (ages 0-5, 6-10, etc.)
- ?? number died

Without this data, FDA presents a very weak case for the need for regulation. Relying on the CDC to produce this information as is currently done not only delays response but also does not give specific commodity growers the opportunity to see how their produce commodity has or has not been involved in food safety breakdowns.

Another component of breaking through this mindset would be for FDA to develop a DVD that could be distributed to food producers. The purpose of such a video would not be to tell producers what to do but to inspire them to believe that food safety IS a problem worth addressing. It should include the following:

- data on outbreaks
- stories of the experiences of victims
- examples of what has happened to producers that have done the wrong thing
- interviews with attorneys who sue on behalf of victims
- interviews with domestic producers that are leading in food safety, detailing what they how food safety improvements have helped them deliver better quality product
- interviews with retail customers that want to see safer food
- examples of food safety practices in foreign countries that surpass practices in the United States, with interviews of producers explaining their beliefs in the need for stricter standards.

S.T.O.P. points out that by the time FDA produces such a DVD, most producers will be capable of downloading it electronically, which could limit the expense to production.

Our document today is divided into the following sections:

- Executive Summary
- Emphasis Must Be On Prevention
- Categorization of Produce
- Need for Regulations, Not More Guidance
- Practices Contributing to Contamination of Produce
 - On-Farm Control Points
 - Post-Farm Control Points
- Need for Interventions
- Measuring Success Through Outbreak Minimization and Rapid Traceback
- Accountability Helps to Minimize Outbreaks
- In Conclusion

Executive Summary

Because much of produce in the United States is consumed raw or minimally cooked, and because there are no killsteps that render such produce pathogen free, it is imperative that FDA emphasize prevention of contamination on the farm, in transport and in processing. Because guidance has failed to reduce outbreaks, it is imperative that FDA move to

national regulations that prevent contamination, coupling them with onsite inspections. With rising pressure from two sources:

- high concentration animal farming
 - municipal sewage companies wanting to dispose of biosolids and fluids,
- our nation's crop farms are poised to become the recipients of massive quantities of pathogens which will find their way into our food supply.

The emphasis of FDA's action plan must be on prevention because there is only one effective method for eliminating contamination from produce, cooking, and many forms of produce are served raw or undercooked. S.T.O.P. holds that FDA must develop immediate, commodity-neutral regulations addressing produce in four categories: tray-grown, in and on-ground grown, pole/vine/bush grown, and tree grown produce. In addition, specific regulations must be brought to bear on "chopped, mixed" produce products.

On-farm contamination stems from contaminated seeds/seedlings, intentional and unintentional contact with feces, proximity of animals, contact with contaminated water, and insufficient sanitation facilities, training and oversight of workers. Mandatory standards and restrictions in these areas would prevent significant contamination. Post-farm contamination can come initially through contamination in transport or human contact but is amplified subsequently through the use of shared water and large batches. S.T.O.P. recommends many interventions in these areas.

To assist in measuring FDA's success, a rigorous traceback system must be instituted, of which there should be three components: registration of produce companies, tracking records, and batching. Holding producers accountable through country and farm-of-origin labeling, certification, and industry-wide warning labeling will reduce outbreaks.

Emphasis Must Be On Prevention

FDA now has copies of studies that indicate that pathogens can be absorbed internally to produce. Science has also proven that once *E. coli* forms a biofilm on the exterior of produce, it is protected to withstand rinsing and washing.¹ One study has shown that while pathogenic organisms on lettuce can be reduced by washing, they are not eliminated.² In a study conducted by USDA ARS, the only effective way to remove *E. coli* from the exterior of contaminated apples was with both heat and chlorine, not just one or the other. Indeed, the summary concludes: "*E. coli*... cannot be rinsed off with water," which is presently the advice given by government as a consumer reduction

¹ September, 28-29, 1998 Sprout Meetings held in Washington, D.C. before the NACMCF.

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

method.³ The only effective consumer method for preventing illness against fecally-contaminated fruit and vegetables is heating to high temperatures. Therefore, the time has come for government and industry to make a sincere effort to prevent contamination in the first place.

Categorization of Produce

FDA has asked how it should define “produce” and segment the produce industry in order to introduce interventions for segments. In terms of definitions, FDA must come to recognize that consumers view “produce” as raw foods that are found in the “produce” section of a grocery store. This definition includes nuts, dried fruit, grasses (wheat grass), herbs and spices, and fungi in addition to FDA’s rather narrowly defined fruits and vegetables. If FDA chooses to ignore these foods in the current action plan, it is beholden to address these forms of produce in a separate plan because, like the foods in FDA’s present narrow definition of produce, these foods are often eaten raw or undercooked.

Certainly, the current method of writing a separate plan for each commodity that causes repeated outbreaks is a tedious, slow, inefficient one, so it is appropriate that FDA attempt to leverage rulemaking across common segments. In the Federal Register notice, FDA has asked, “There is a broad variation within food operations including variations in size of establishments, the nature of the commodity produced, the practices used in production, and the vulnerability of a particular commodity to microbial hazards. How, if at all, should the produce action plan be structured to take into account such variation?”

S.T.O.P. trusts that FDA understands and supports the evidence that much initial contamination occurs on the farm. Indeed, the farm offers the most opportunity for contamination along the produce delivery chain because produce so often grows outside, exposed to insects, animals, amphibians, runoff from rainwater, irrigation with well or river water, harvesters and their equipment, etc. Multiple outbreaks traced to the same pathogen affiliated with a specific type of produce suggest

- 1) initial contamination is the result of an early growing/processing step shared by multiple farmers and selects for a particular pathogen over other pathogens,
- 2) initial contamination grows and spreads subsequently, aggravated by post-growing activities, also shared by multiple farmers and processors.

If these conditions hold to be true for produce that repeatedly cause outbreaks, as they have been for juice and sprouts, it is probable that the source contamination causing detected outbreaks is also occurring in other produce grown similarly. Even though that other produce might be contaminated initially, because it is processed differently, cross-

³ Saper, Gerald, “Research on Decontamination of Apples by Washing with Detergents and Sanitizing Agents,” Apple Cider Food Safety Control Workshop, July 15-16, 1999; <http://vm.cfsan.fda.gov/~comm/cidwsape.html>

contamination and amplification have been reduced, and illnesses remain unassociated with these types of produce. Hence, if FDA applies regulations to produce groups grown or processed under similar conditions, it can successfully address the proverbial seven flies with one swat.

Therefore, the action plan must address the following categories of produce:

- tray-grown produce
- in- and on-ground grown, soil based produce
- vine-, bush- and pole-grown produce
- tree-grown produce.

Although many of the foods within these categories have slightly different growing and harvesting practices, the reality is that these categories define the likelihood that produce comes into contact with contamination from fecal and water sources. Regulations should address each category specifically. Ground- and tray-grown produce should receive the highest priority amongst these categories.

Specific commodity industries (e.g. artichokes) may claim that they have never been the source of an outbreak because their produce is always served cooked, and therefore, the regulations should not apply to them. However, these foods still represent a risk to consumers for four reasons. First, any killstep, even cooking, can be overwhelmed by a high microbial load. Second, contaminated foods are a vehicle for toxins which can also be involved in cross-contamination; the emphasis should be on keeping these toxins out of the kitchen environment. Third, consumers do not want their foods contaminated with feces even when it has been rendered sterile. Lastly, the raw food movement has begun to adopt plants that previously have not been consumed at all or not previously been consumed raw, so that it is not necessarily true that a food is “always” cooked prior to eating.

FDA must also recognize a fifth category of produce products, which we will refer to as “combined, mixed,” in which the consumer encounters multiple pieces of produce from more than one source fruit or vegetable. Examples of these categories are: unpasteurized juices, sprouts (in which each sprouted seed is mixed or shares water with other sprouts), chopped and bagged lettuces and lettuce mixes, raw salsa mixes, and cole slaw. In the last 10 years, produce products that are combined/mixed have caused more produce outbreaks than any single type of produce.⁴ The category of “combined, mixed” produce demands very specific regulations which will reduce outbreaks and illnesses from these food products.

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

⁴ Outbreaks of combined mixed products would include juice, sprouts, and chopped lettuce and coleslaw and salsa.

because they find it more expensive to irrigate with higher quality 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. In addition, it is absolutely unacceptable for FDA or OMB to modify requirements based on farm size. Many, serious outbreaks have been caused by small farmers.⁵ Therefore, all players in delivering food to the consumer should be required to produce equally safe products, regardless of size or location.

Need for Regulations, Not More Guidance

FDA's produce guidance of the late 1990's was a welcome direction setting for the produce industry, but it is grossly deficient in terms of its indirect method of advice and the fact that it is strictly voluntary. It is a testament to the failure of voluntary guidelines that FDA continues to see major outbreaks in industries such as sprouts and lettuce more than 5 years after the guidance was first published. Indeed, at the FDA meeting held June 29, 2004 on the 2004 Action Plan, a food science professor from Cornell indicated that in a survey of New York state produce growers, 30% were unaware of guidance.⁶ As there are no penalties for ignoring the guidance and only a few more if a business causes an outbreak, there is little penalization of bad producers. The upshot is that while some members of industry attempt to implement the vague GAPs and GMPs, the remaining are left in a state of "Catch Me If You Can!" and "What, me worry?"

Even when regulations are mandatory, compliance is low. A 1998 article in the *Wall Street Journal*⁷ indicated that over the previous 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."

Food safety regulations and standards must be specific and measurable. Foreign growers know that FDA has not set specific standards and requirements for U.S. growers. According to NAFTA, foreign producers are supposed to meet or exceed U.S. "standards," which is an ambiguous requirement because the U.S. does not have

⁵ The October, 1999, *E. coli* O157:H7 apple juice outbreak in Oklahoma, the 1996 spring mix lettuce outbreak originating in Hollister, CA; and numerous sprout outbreaks are just a few examples of outbreaks caused by "small" growers.

⁶ Comment by Robert B. Gravani, Ph.D., GAPs Program Director, Professor of Food Science, Dept of Food Science of Cornell University at FDA Meeting on the 2004 Produce Action Plan on June 29, 2004, College Park, Maryland.

⁷ Front page of California section, *Wall Street Journal*, March 4, 1998

“standards.” Following the advice of FDA’s Guidance, foreign producers may “consider” all sorts of issues, “implement” little, and still have met FDA’s requirements.

FDA must create a common set of mandatory regulations that address general categories of produce. S.T.O.P. strongly believes that real, mandatory interventions must be coupled with strong enforcement.

Practices Contributing to Contamination of Produce

On-Farm Control Points

E. coli O157:H7 is a human pathogen commonly found in the intestines of mammals (*E. coli* O157:H7), particularly ruminants such as cattle and deer. *Salmonella* is a pathogen commonly found in the intestines of birds. As a result, both pathogens subsequently reside in the feces of the respective animal. Other pathogens, such as hepatitis A found recurring in outbreaks can be traced to human reservoirs. Thus, the predominance of produce outbreaks involving these pathogens indicates that the single largest source of contamination of produce is feces.

Under a Hazards Analysis and Critical Control Points (HACCP) system, potential weaknesses in a system that might be exploited by contamination must be identified in advance. For all produce farms, regardless of the food, there are at minimum six control points where fecal contamination may first be introduced:

- 1) the seedling or seed,
- 2) the intentional application of animal feces as an “amendment” to the growing soil, whether in prior years to that of a given crop, immediately prior to the crop or while the crop is in the field,
- 3) the application of potentially pathogenically contaminated water, whether intentionally for irrigation or unintentionally through runoff,
- 4) contact with infected workers,
- 5) the unintentional application of animal feces in the growing area by ruminants and amphibians allowed to penetrate the farm, and
- 6) the proximity of ruminant carriers to the crop farm.

Seedling or Seed

Studies of alfalfa seed have demonstrated that contaminated seed can yield contaminated sprouts;⁸ Safe Tables believes that more research must be conducted on other kinds of seed and seedlings, for example, lettuce or tomato, to examine the possibility that this factor may play a role in produce outbreaks.

⁸ NACMCF's 1999 Draft on "Microbiological Safety Evaluations and Recommendations on Sprouted Seeds"

Intentional Application of Feces

In a recent study by Mukherjee⁹, et al. the *direct* application of animal feces as a soil “amendment” was significantly implicated in contamination of produce with *E. coli*, which is considered an indicator organism for *E. coli* O157:H7:

“Among organic practices, the prevalence of E. coli was 2.4 times greater in produce grown on farms using cattle manure than in produce from farms using other types of manure...Applying manure or compost in the spring or fall did not appear to be related with increased numbers of E. coli positive samples. However, organic samples from farms that used materials aged 6 to 12 months had 19 times greater (OR = 23.8) prevalence than those from farms that used material more than 1 year old.”

While FDA might argue that it has yet to traceback an outbreak to the intentional application of animal feces, such a lack of evidence says more about FDA’s current inability to do rapid traceback and pathogenic soil sampling than it says about the hazards of applying undertreated animal feces to crops. Indeed, often, the pathogenic organism is not found at the source of an outbreak. Instead only the likely contamination practices are left behind like the footprints of a thief in the night.

The study continues:

“... among the various types of manure, the use of cattle manure alone or in combination with other animal manures appeared to be related to an increased number of E.coli positive samples as compared to other types of manure.”

Science has demonstrated that *E. coli* can survive for months in soil¹⁰, and up to a year in sheep manure¹¹, so the intentional application of manure results in

⁹ Mukherjee, Speh, Dyck and Diez-Gonzalez, “Preharvest Evaluation of Coliforms, Escherichia coli, *Salmonella* and Escherichia coli O157:H7 in Organic and Conventional Produce Grown by Minnesota Farmers,” Journal of Food Protection, Vol. 67, No. 5, 2004, page 898.

¹⁰ Maule, A. 1997. Survival of the verotoxigenic strain *Escherichia coli* O157:H7 in laboratory-scale microcosms, p. 61-65. In D. Kay and C. Fricker (ed.), Coliforms and *E. coli*: problem or solution? Royal Society of Chemistry, London, England.. 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 and in soil. Thus, it seems that once pasture land becomes contaminated with this organism, it may remain viable for

long term contamination of the growing environment. This study was conducted in a relatively cold-climate, northern state, Minnesota. S.T.O.P. suggests that had this study been conducted in a state with a largely warmer climate, *Salmonella* may well have played a larger role in the outcome of the study, which is reflected in the presence of *Salmonella* contamination seen in produce products that come from warmer climates, such as oranges and cantaloupe.

In addition, no national regulations prevent the use of human excrement, a significant potential source for the hepatitis A outbreaks, composted or otherwise as an “amendment” on crops. Although human excrement, biosolids and sewer water have not been identified as a source of an outbreak in the U.S. yet, the lack of regulations in this area suggests that if it were to occur, no food safety protection regulations would have been broken despite the fact that the success of a hundred years of public sanitation argues that sewage not be applied to food or soil for growing food. Current regulations of human excrement on the farm are minimal and are designed to protect workers and not the food; most toileting sanitation regulations fall under OSHA. In addition, it is important to note that under NAFTA, the rules that FDA sets are supposed to be met by countries providing produce to the U.S., and sewage sanitation in the vicinity of crops is not equal in all countries.¹²

Contact with Contaminated Water

On-farm irrigation water contaminated with parasites or pathogens has been implicated in outbreaks. Science conducted in the study of sprouts has indicated that once pathogens are present in a sprout’s water supply, pathogens are taken up by the root system and are then conducted internally to

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 give for *E. coli* O157:H7 survival in laboratory ecosystems in this study may be much lower than the real situation.”

Dr. Maule’s data on O157:H7 survival in soil indicated that O157:H7 can survive **for at least 130 days in soil**, e.g. over 18 weeks or over 4.3 months. Additional data on suggesting survival rates of pathogens up to 231 days in amended soil can be found in: Jiang, X., Morgan, J., Doyle, M. “Fate of Escherichia coli O157:H7 in Manure-Amended Soil”, Applied and Environmental Microbiology, November, 2001; <http://aem.asm.org/cgi/content/full/68/5/2605>

¹¹ Bohach, C.H, Personal communication with FDA regarding survival of *E. coli* in sheep manure, December 1, 1997.

¹² In the April, 1997 hepatitis A/strawberries outbreak, farms in Mexico were determined to have open latrines within 10 feet of growing crops.

the top of the sprouts.¹³ Science has proven that pathogens exposed to lettuce are attracted to and absorbed at the broken edges of lettuce.¹⁴ Thus, the use of pathogenically contaminated water of any form is a potential hazard.

Contact with Sick Workers

While outbreaks have yet to be traced to sick workers at a farm level, this is more likely evidence of the inadequacy of outbreak investigations than a lack of casuality. Certainly outbreaks traced to sick workers at retail demonstrate the ability of human contact to contaminate produce.¹⁵ Farm workers can contaminate produce via direct skin-to-produce contact or other routes of infectious transmission. This likelihood is multiplied by inadequate health resources for farm workers, inadequate sanitation facilities for field workers and processors, and lack of adequate safeguards and government oversight for on-farm food handlers.¹⁶

Unintentional Contact with Feces

The presence of deer and cattle in orchards has been hypothesized as a source of multiple juice outbreaks.¹⁷ Produce can come into contact with animal feces if it falls or is lying on the ground or open packing grates may be set on the ground and unintentionally come into contact with the feces. Feces left on an orchard floor can be tracked via shoes onto ladder rungs; when workers climb the rungs to pick fruit, their hands may transfer pathogens to the fruit. Hence, unintentional contact of foods with animal feces is highly suspect as a source of contamination and represents a potential, controllable hazard.

Proximity

Indirect contamination of feces by proximity of animals to crop farms or wells has been definitively implicated as well in outbreaks. In outbreaks, runoff onto produce or into well water subsequently used on produce has been

¹³ September 28-29, 1998 Sprout Meetings, held in Washington D.C. before the NACMCF.

¹⁴ Tauxe, R., H. Kruse, C. Hedberg, M. Potter, J. Madden, and K. Wachsmuth 1997. Microbial Hazards and Emerging Issues Associated with Produce: A Preliminary Report to the National Advisory Committee on the Microbial Criteria for Foods, *Journal of Food Protection*, Volume 60, pages 1400-1408.

¹⁵ October, 1989 unpasteurized orange juice outbreak was believed to have been caused by a sick worker; the viral suspected agent was not determined.

¹⁶ *Ibid.*, Wall Street Journal, March 4, 1998.

¹⁷ In the 1996 Odwalla outbreak, deer feces was found in orchards that supplied apples to Odwalla. The 1991 Massachusetts cider outbreak also implicated deer in the orchards. Although less common, it has been admitted that cattle are not precluded from orchards in Florida at citrus juice meetings, Dr. Mohamed Ismail, Florida Department of Citrus.

implicated.¹⁸ Flies and birds have been proven to carry fecal germs.¹⁹ Windblown dust can harbor pathogens.²⁰ Therefore, the proximity of wildlife preserves and animal farms to crop farms represents a controllable hazard. The lack of control over the on-farm, open air environment also strongly argues that processing produce beyond simple harvesting in the fields could exacerbate the opportunities for transfer of pathogens in these indirect manners, where harvesting storage units might come into contact with the ground and where insects and birds might be attracted to produce that is more broken or open to the environment than would be necessary in covered, enclosed post harvest processing.

In short, the crop farm is ripe with opportunities for pathogens via water and fecal vectors, which are then aggravated if any processing other than harvesting takes place in an open-air farm space.

Post Farm Control Points (Production and Food Preparation)

A basic requirement should be for post-farm processing to take place in a controlled, enclosed environment. Under these conditions then, initial contamination post-farm would likely be introduced from two sources: human contact and transportation.

- 1) Human contact in subsequent off-farm processing introduces still further opportunity for human viral and fecal contamination. Much reasonable guidance has already been proposed in the context of reducing worker hand-to-produce contact, including the possibility of keeping sick workers home and wearing gloves.
- 2) Transportation is a key area in the post-harvest process which affords opportunities for direct contamination and the growth of organisms. Trucks that have been used to haul manure are then used to haul produce.²¹ In addition, the temperatures at which fruit and vegetables in warm climates are transported encourage the growth of organisms such as *Salmonella*, which in colder temperatures is less likely to grow to dangerous levels.

¹⁸ The 1996 lettuce outbreak caused by a Hollister, California grower was downhill from a cattle farm; water used in washing the lettuce came from a nearby well. The 1993 Cryptosporidium outbreak in unpasteurized apple juice was traced to spray irrigation water. In addition, an *E. coli* O157:H7 outbreak at a state fair in New York in 199x was traced to well water which was subjected to runoff in the vicinity of animals.

¹⁹ Flies: Wojciech Janisiewicz, Applied and Environmental Microbiology, 1/99; Seagulls: 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.

²⁰ Hancock, D., Description of study entitled "Possible Escherichia coli contamination of apples via airborne dust from feedlots." in e-mail to Bert Bartleson, 12/11/96

²¹ Conversation with Jeff Farrar, California Department of Health, Food Safety.

Given government's woeful traceback abilities, any single piece of contaminated fruit or vegetable would not by itself cause a presently identifiable outbreak, unless contamination were enabled to spread to multiple fruit and vegetables. Though S.T.O.P. deplures any contaminated fruit or vegetables, it decries outbreaks that sicken an identified dozens of people and potentially hundreds more that go unidentified. Therefore, while there are many, many potential control points in post farm production and processing, S.T.O.P. considers the most critical post-farm control points to be those associated with cross contamination.

There are two key areas of cross contamination that result in dramatic amplification of pathogens. The first is the use of low quality water, and the second is chopping and mixing of produce into large batches of food.

- 1) Lower quality water in a combination of cooling, cleaning and packing processes (and in the growing process for wheat grass and sprouts) is a contamination bomb ready to explode. Science has also proven that produce such as tomatoes and apples²² floating in contaminated water can uptake pathogens through the stem or flower end. So, once contamination is present, the fruit or vegetable can become internally contaminated. Occasionally, growers use well water, which may be subject to runoff contamination after storms. Just as the water in which sprouts are growing spreads pathogens from contaminated sprouts to others, water can spread pathogens from some fruit to others floating in the tank. As FDA well knows, the buildup of microscopic debris reduces the effectiveness of chlorine and other sanitizing components in the water because the microbial load can overwhelm reduction steps. Industry has complained since the late 1990's that FDA guidance about ongoing water quality in packing and processing conflicts with EPA and state regulations about recycling water, which mandate that water must be reused.
- 2) Chopping and/or mixing of produce into large batches of food has already played a significant amplifying role in both juice and sprout outbreaks. Salsa made of untreated fruit and vegetables, spring lettuce mixes, cole slaw, unpasteurized juices – all share a common denominator. In the process of creating a final produce product, dozens or hundreds of pieces of produce become involved. In the chopping of one contaminated tomato into a hundred gallon "batch" of salsa, or a few contaminated apples into a 1000 gallon batch of apple juice, organisms have the opportunity to spread and grow. Lax cleaning standards for processing equipment (including chopping and grinding equipment and water tanks) coupled with large batches dramatically exacerbate the potential for outbreaks.

Need for Interventions

The interventions/controls required to address the above hazards are as follows.

²² Potential for Infiltration, Survival and Growth of Human Pathogens within Fruit and Vegetables, Center for Food Safety and Applied Nutrition, November, 1999; <http://vm.cfsan.fda.gov/~comm/juicback.html>

To eliminate direct and indirect contact of produce crops with fecal contamination:

- 1) The application of human waste, and undertreated human sewage (“municipal biosolids”) and sewage water should be strictly prohibited from application to crops for human consumption or fallow crop soil in order to prevent the spread of human disease by food.
- 2) The practice of applying undertreated animal fecal wastes (manure or animal feces), or undertreated waste lagoon fluids to crops for human consumption or fallow crop soil should be ended, owing to the extended survival of *E. coli* O157:H7 in soil²³ and feces²⁴ and its ease in escaping detection.
- 3) Either:
 - animal fecal products (including mammalian and poultry) used for “amendment” should be aged for a minimum of **two years prior to application to unplanted soil**. S.T.O.P. has chosen two years because of the high likelihood of contamination of produce demonstrated in the Mukherjee study. Though the discrepancy in that study is between feces aged 6 to 12 and more than 12 months, S.T.O.P. feels that an additional year beyond the 12 months gives a greater margin of safety. In addition, the study did not reveal how many MORE months than 12 months the manure in the study was aged. Any animal-fecal amendment must be applied prior to planting of the crop to reduce the likelihood of direct contact from any remaining pathogens.

or

- animal fecal products used for “amendment” should be composted **prior to application to unplanted soil**. Time and temperatures for composting must be scientifically determined to eliminate pathogens. Fecal coliform quantification and testing for the presence of *E. coli* and *Salmonella* should be conducted. Compost testing should be audited by an outside firm. Any animal-fecal amendment must be applied prior to planting of the crop to reduce the likelihood of direct contact from any remaining pathogens, as when the compost might be insufficiently composted.
- 4) The FDA must set soil quality, manure aging, and composting standards for levels of biological activity. We encourage FDA to consider *E. coli* and *Salmonella* as indicator organisms. The success of composting and aging to render amendments pathogen-free should be verified by testing.

²³ Ibid., Maule A.

²⁴ Ibid., Bohach.

- 5) FDA must regulate the distribution and proper treatment of animal wastes with respect to their potential for application to crops, their potential for contaminating crops via runoff, and their potential for contaminating irrigation water of crops. Presently, there appears to be no government oversight of the sale and transfer of animal waste which becomes involved in food production.
- 6) Seed that is produced to create foods for human consumption should be grown under the same hazard control conditions as those of human crops. Contaminated seed has been traced to multiple sprout outbreaks.²⁵ Thus, the controls for pathogens in the production of produce seed whose sprout, fruit or vegetable is destined for humans should be more stringent than the controls for seed raised for animal products. For example, alfalfa seed destined to become sprouts for human consumption should be farmed without application of manure as soil amendment or undertreated manure lagoon fluids as a form of irrigation.
- 7) Restrict in-field/orchard processing strictly to harvest procedures in order to reduce the likelihood of field environmental contamination in the form of insects, dust, human waste from workers and potentially less-than-potable irrigation water. Any additional cutting, chopping or mixing should only be done in enclosed, sanitary areas.
- 8) Identify further harvesting critical control points. For example, eliminate the practice of setting packing crates and boxes on the ground. Mandate plastic crates, which can be steam or pressure treated. We HIGHLY recommend that FDA visit Mark McAfee's McAfee Farms in Fresno, California. McAfee has instituted on-farm HACCP improvements in his orchards, which he indicates not only make his product safer but actually have reduced some of his costs.²⁶ McAfee makes an excellent example of why on-farm standards programs such as HACCP not only benefit the public but also the producer.
- 9) Worker handling guidance, which reduces direct physical contact with produce and cross-contaminating contact between produce and soil, must be made mandatory. Human sanitation regulations must reflect restrictions to prevent contamination of food and not just better standards to protect workers' health.
- 10) Periodic soil testing by FDA should be mandated if a crop farm is adjacent to an animal farm or wildlife refuge or downhill from either. A positive identification of *E. coli* or *Salmonella* in crop soil or animal feces found in the crop field/orchard should result in crop tissue testing prior to harvest. Crops harboring pathogens should not be sold for human consumption.

²⁵ September, 28-29, 1998 Sprout Meetings held in Washington, D.C. before the NACMCF.

²⁶ Mark McAfee, McAfee Farms; mark@mcafeefarms.com.

- 11) The proximity of livestock and animal farms to crop farms should be restricted. Crops should not be grown close to animal farms, and in particular, downhill from them, to reduce the risk of contamination by runoff, insect transmission^a, and dust²⁷.

To reduce on-farm fecal contamination via water:

- 1) Set irrigation water quality standards and mandate them. For the present, water should be divided into two categories: potable, and potentially contaminated.
- 2) Only potable (drinking) water should be allowed as spray irrigation of crops and fallow crop fields.
- 3) Only pathogen-free water should be allowed in nonspray, above ground irrigation. Using potentially lower quality water earlier in the growing process is unacceptable owing to the extended survival of pathogens in soil.
- 4) Water from uncertified(non municipal) sources, including wells and surface water, must be tested semiannually to determine whether the water is pathogen-free and at least weekly after contamination has been identified until a period of one year of clear tests. Produce from farms with positive water tests for organisms must submit to tissue testing.
- 5) For produce farms within potential drainage pathways of higher risk neighboring properties, berms and gutters should be mandated around the perimeter of crop farms to direct the flow of runoff water from adjacent properties away from the crop.
- 6) On farm inspections must ensure that basic water and feces hygiene and sanitation regulations are followed. To quote one farmer: “You get what you inspect, not what you expect.”

To reduce initial contamination post-farm:

- 1) Worker handling guidance which eliminates direct physical contact with produce must be made mandatory. Human sanitation regulations must reflect restrictions to prevent contamination of food and not just better standards to protect workers' health.
- 2) Vehicles used for the transfer of animals or animal byproducts should be prohibited from transporting produce or produce products. Truck beds should be steam power washed to sanitize between crop loads.

To reduce cross contamination in processing in general:

²⁷ Ibid., Hancock, D.

- 1) FDA must phase-in a retooling of produce processing away from continuous processing and in favor of batching. It must mandate “small” succinct batches and an elimination of commingling of products from different, distant fields and farms in receiving, packing, transportation, distribution, and retail. A “succinct” batch, by S.T.O.P.’s definition, is a finite quantity of produce or produce product in which all the produce within shares a single source farm (multiple farm sources only if multiple types of produce are involved, as in tomatoes, onions and peppers going into salsa) and goes through processing, contemporaneously and contiguously, at a particular location. S.T.O.P. defines “small” to be on the order of hundreds of servings of a type of produce or of a mixed produce product. Batches must be separated by a significant sanitation killstep at each point of processing. Thus, after batch 1 of fruit A comes through a soaking flume, the soaking flume is emptied and the water and flume are sanitized prior to beginning batch 2 of fruit A. A single batch should then be packed and shipped to a specific geographic area, and ideally, to one store, not commingled with similar fruit from other sources. Thus, the cross contamination possibility in the United States would be reduced to hundreds of servings, not the limitless possibility that is currently in place.

To reduce cross contamination in processing with respect to water:

- 1) FDA must set water quality standards for specific steps throughout processing. These standards should not be subordinate to EPA requirements, but should be designed to address EPA’s concerns as well so that processors do not receive conflicting requirements. The purpose of water quality standards in processing is to determine the point at which potable water is in need of recycling, filtering and cleaning.
- 2) All water used in post-harvest processing must be potable (drinking quality) water at first introduction to the process.
- 3) Lower quality water should be prohibited from re-use at another point in the process; all spent water must be filtered and treated to be pathogen-free before being reintroduced.
- 4) Either
 - eliminate dunking and floating of all fruit and vegetables in water and replace soaking tanks with “shower” systems that recycle, filter and clean the water

OR

- replace processing water between batches to reduce cross contamination between batches. Water quality must be tested whenever the water is recycled.

Measuring Success Through Outbreak Minimization and Rapid Traceback

The greatest measure of progress toward minimizing illness would be to see declines in the following:

- ?? total number of outbreaks (which could rise initially, as traceback improves)
- ?? number of cases in outbreaks
- ?? number of states involved in outbreaks
- ?? frequency of certain organisms associated with outbreaks
- ?? frequency of the same type of produce associated with outbreaks
- ?? contamination of produce through post- and on- farm studies.
- ?? the time between when the food arrives at retail and the implementation of a recall

Correspondingly, there should be an increase in:

- ?? rapid traceback of outbreaks to actual farm of origin
- ?? on-farm inspections
- ?? penalties to producers that operate under hazardous conditions.

In order to know whether FDA is successful, it must have a rigorous traceback system, of which there should be three components:

- registration of produce companies,
- tracking records,
- batching.

It is imperative that FDA develop quick, efficient and twenty-first century methods of communicating directly with growers, in particular, and also packers, processors and distributors, and not just their trade associations. S.T.O.P. strongly urges FDA to develop a mandatory, national registry of all food producers, not just processors, indicating where the farms are, what foods they produce, and an updated fax and email contact. This national database should be shared with both the state food officials and trade associations to ensure that all growers are in the “flow” of communication on food safety, meetings, training, and outbreaks. All food producers should be required to become accessible electronically and FDA should implement a program to encourage and fund such access. Information could then be transmitted nearly immediately, electronically, at very low cost. Registration information should be required to be updated whenever the information changes.

With each grower, packer, etc. having a unique registration number, FDA must mandate that food companies track food batches as they move from the farm to retail. Each business in the chain from farm to retail should be required to keep track of its supplier (seed, plant, water and fertilizer suppliers, in the case of farms) and its food recipient, the date on which the batch of produce moved from one “owner” to another, and a lot or batch number.

The amplification of outbreaks is dramatically aggravated when a few pieces of contaminated fruit or vegetables are combined in water or in processing with uncontaminated fruit or vegetables. The three components of batching, mentioned above:

- 1) single farm source of produce,
- 2) limited batch size separated by sanitation steps,
- 3) limited distribution

would dramatically reduce the total number of illnesses due to outbreaks. In addition, an elimination of the widespread distribution of the produce from a particular farm mingled with fruit or vegetables from many other sources, would reduce the geographic scope of outbreak investigation, facilitating quicker identification of an outbreak and quicker investigation of the sources of contamination. Coupled with mandatory traceback identification data, source farms could be quickly identified and recalls could be quickly implemented.

Accountability Helps to Minimize Outbreaks

At present, the U.S. utterly lacks any true accountability system for food producers. Government's inability to quickly identify outbreaks and the sources of outbreaks leaves thousands of consumers and whole industries exposed when consumers are only informed that a form of produce has been implicated again. To save lives, government **MUST** also give **CONSUMERS** the tools, specifically farm and country of origin labeling, to protect themselves as outbreaks occur. When consumers receive the message: "don't eat cantaloupe from Farm A this month," they can both cease to buy the product **AND** they can throw out product they might still have at home. Without such information, outbreaks will continue and even after contaminated produce is identified and recalled, consumers who have already purchased the product will continue to be poisoned.

A coalition of retail companies in Europe and South Africa are in the process of implementing an audit system for identifying whether companies have met basic, commodity-neutral GAPs and GMPs, which they call "EuroGAP."²⁸ If there is any violation of the most basic requirements, companies would not receive certification. The earliest opportunity to recertify is in three months. FDA should introduce such a certification system here in the U.S., indicating adherence to food safety GAPs and GMPs, including strong enforcement and imposing penalties and fines on those that fail to comply, and when necessary, shutting down badly run enterprises.

To ensure education is successful, FDA must establish a mandatory certification system that shows that growers, packers, processors, transporters, distributors have read and implemented GAPs and GMPs appropriate to the foods they handle. Present methods of ensuring that producers are educated about GAPs are hampered by both government's inability to identify producers, and a lack of requirements that producers be educated. With a certification system, each legitimate business in the food system would have an

²⁸ More information on this system can be found at www.eurep.org

identification number indicating they had reviewed materials about food safety, and without which they would not be allowed to sell or distribute produce in the United States. S.T.O.P. begs the question: if consumers must have driver's licenses to prove they know the rules of the road, why are food producers allowed to grow food without knowing how to do it safely?

When a given company is identified as the source of an outbreak, substantial penalties should be levied. In addition, the offending company should be required to pay for onsite daily inspection and testing until FDA has determined that underlying practices have been corrected.

Commodity growers whose industry visits repeated outbreaks upon unwitting consumers need to recognize their shared culpability. The repeated outbreaks since FDA first published Guidance demonstrate that while industry trade associations are capable of jumping on the "education" bandwagon, either they cannot identify and educate hazardous producers or their education is falling on deaf ears. Even if all the players in a commodity industry are not sure what the source of their repeated outbreaks is, they need to ensure that every producer is delivering on all GAPs and GMPs appropriate to their food. Once registration and certification are required, it is no longer sufficient to say, "We didn't know he was producing food hazardously" or "We sent him all the educational brochures."

Safe Tables believes that when a given food product causes multiple, detected outbreaks in a year, industry-wide education and guidance have clearly failed. Therefore, when a food proves to be a repeated hazard, all such foods should also be required to carry labels indicating to consumers that they are "high-risk;" labeling must inform consumers of the health risks inherent in consuming these foods.

With traceback and accountability, FDA must acquire recall authority in order to be able to take quick action; public health interests should have priority in determining a recall and not the economic interest of the producer.

In Conclusion

Feces is the source of many of today's lifethreatening foodborne illnesses. Typically, fecal organisms come into contact with crops in one of six ways, through a contaminated seed or seedling, intentional application to soil, unintentional application to soil, contaminated water, proximity or workers. Post-harvest, key hazards are most likely to be introduced via transportation and worker handling, and through cross-contamination in water and chopping/mixing. Many interventions are available today that would reduce contamination in produce before it arrives at the consumer. To support traditional practices without modifying them to exclude pathogens is to ignore the evidence of more than a 100 years of public sanitation; employing these practices in the twenty first century represents an unnecessary hazard to food safety. It is time for FDA to act on the science available to it.

Laurie Girand
Produce Programs Manager

A handwritten signature in black ink that reads "Nancy Donley". The signature is written in a cursive, flowing style with a large initial 'N' and 'D'.

Nancy Donley
President