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Final Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce

I. Introduction and Scope

Eating fruits and vegetables is an important part of a healthy diet[209]. FDA is responsible for ensuring the safety of all domestic and imported fruits and vegetables consumed in the United States. We place a high priority on identifying and implementing measures that can reduce the incidence of foodborne illness associated with produce.

This document provides a scientific evaluation of potential adverse health effects resulting from human exposure to microbiological hazards in produce, with a focus on public health risk associated with the on-farm contamination of produce. The qualitative assessment of risk (QAR) includes: (1) Hazard Identification, (2) Hazard Characterization, (3) Exposure Assessment, and (4) Risk Characterization (CAC, 1999).

Section 419 of the FD&C Act directs FDA to establish science-based minimum standards for the safe production and harvesting of those types of fruit and vegetable raw agricultural commodities (RACs) for which we determine that such standards minimize the risk of serious adverse health consequences or death (section 419(a)(1)(A) of the Food, Drug and Cosmetic Act (FD&C Act)). The statute directs us to base these standards on known safety risks and to include procedures, processes, and practices that we determine to be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards into fruit and vegetable RACs and to provide reasonable assurances that produce will not be adulterated under section 402 of the FD&C Act (section 419(b)(1) and 419(c)(1)(A) of the FD&C Act).

To inform the development of produce safety standards, we conducted a qualitative assessment of risk associated with growing, harvesting, packing, and holding of produce. We published our tentative findings of this assessment in a report titled, "Draft Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce" (hereafter referred to as "the Draft QAR") (Ref. X), which accompanied the proposed rule titled, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (78 FR 3504; January 16, 2013; hereafter referred to as "the proposed Produce Safety rule"). In the proposed Produce Safety rule, we asked for public comment on the Draft QAR and conclusions drawn from that assessment (78 FR 3504 at 3618). In addition, we noted that the Draft QAR was being peer reviewed and changes can be reasonably anticipated based on the peer review. We also indicated that we would consider peer reviewers' and public comments in finalizing the qualitative assessment of risk (78 FR 3504 at 3522).

The Draft QAR was peer reviewed in April 2013 (See peer review plan online at: http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm). We considered peer reviewers' comments as well as public comments received in response to the proposed Produce Safety rule in finalizing the assessment and conclusions drawn from that assessment. We provide a summary of these comments and respond to the comments in an accompanying document: "Memorandum to the File – Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce – FDA Responses to Public and Peer Reviewer Comments, October 2015." This report provides the final Qualitative Assessment of Risk and its conclusions.

This QAR is intended to inform the development of minimum science-based standards for the growing, harvesting, packing, and holding of produce for human consumption, established in 21 CFR part 112 (see the Produce Safety final rule).This assessment is limited in scope to biological hazards and focuses on (but is not limited to) those biological hazards that present a risk of serious adverse health consequences or death to the consumer.[1] In particular, it is intended to explore the following questions, which are important from a risk management perspective:

- Q1 What are the biological hazards of concern for produce that can lead to serious adverse health consequences or death?
- Q2 How does produce become contaminated (i.e., routes of contamination) during on-farm growth, harvesting, and postharvest operations[2]?
- Q3 Does the likelihood of contamination vary among produce commodity types?
- Q4 Does the likelihood of illness attributable to produce consumption vary among produce commodity types?
- Q5 What is the impact of postharvest practices on the level of contamination at consumption?
- Q6 What on-farm interventions are available to reduce the likelihood of contamination?

Several specific sections of this assessment involved analyses for which detailed and specific citations may not be available. For these decision points, FDA staff with subject matter expertise analyzed the data and other available information. Each section herein notes when data from these analyses were used.

II. Hazard Identification

The Hazard Identification provides an overview of the biological agents capable of causing adverse health effects that may be present in produce. Hazards are identified from relevant sources, including the scientific literature, outbreak data, and other sources such as the Reportable Food Registry (RFR)[3] [92].

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[1] This assessment was carried out specifically to inform regulatory actions implementing section 419 of the FD&C Act and, consistent with section 419, the assessment focuses in particular on those hazards that present a risk of serious adverse health consequences or death to the consumer. In addition, our qualitative assessment of risk described in this document focuses on biological hazards only; the agency's considerations related to chemical (including radiological) and physical hazards are outside the scope of this assessment.

[2] For the purposes of this assessment, we use the term "harvest" to refer only to the activity of removing a crop from the growing area, and the term "postharvest operations" to refer to activities that take place on farms after harvest.

[3] The FDA Reportable Food Registry (RFR) was created by the Food and Drug Administration Amendments Act of 2007 (FDAAA) by adding section 417 to the FD&C Act (21 USC 350f). FDAAA mandated that we establish an electronic portal to which facilities required to register with FDA (responsible parties) must report instances when there is a reasonable probability that an article of human food or animal food/feed will cause serious adverse health consequences or death to humans or animals (reportable food). Federal, State, and local public health officials may also use the portal voluntarily to report information that may come to them about reportable foods. The RFR covers all human and animal food/feed regulated by FDA except infant formula and dietary supplements. Submissions to the RFR electronic portal provide early warning to FDA about potential public health risks from reportable foods and increase the speed with which the agency and its partners at the State and local levels can

A. Biological Hazards

1. CDC Data

Historical data reported to the U.S. Centers for Disease Control and Prevention (CDC) indicate that, in the 25 year span between 1973 and 1997, outbreaks of foodborne illness in the United States associated with produce increased both in absolute numbers and in proportion to all reported foodborne outbreaks [189]. By "outbreak," we mean the occurrence of two or more cases of a similar illness likely resulting from the ingestion of a common food. Between 1973 and 1997, CDC reports that 190 produce-associated outbreaks occurred, 16,058 people became ill from these outbreaks, 598 people were hospitalized, and eight died [189].More recently, in the 11 year span between 1998 and 2008, CDC reports that 455 total produce-associated outbreaks occurred [48], more than twice that reported in the prior 25 year span between 1973 and 1997. These outbreaks were caused by a wide variety of pathogens, including bacteria (e.g., *Salmonella*, *Escherichia coli* (*E. coli*) O157:H7, non O157:H7 Shiga toxin-producing *E. coli* (STEC), viruses (e.g., Hepatitis A and Norovirus), and parasites (e.g., *Cyclospora cayetanensis*) [48, 189]. The pathogen-commodity pairs responsible for the most illnesses during the 1998-2008 reporting period were norovirus and leafy vegetables (4,011 illnesses) and *Salmonella* and vine-stalk vegetables (3,216 illnesses). The pathogen-commodity pairs responsible for the most hospitalizations and deaths were *Salmonella* and fruits/nuts (452 hospitalizations, 14 deaths), *Salmonella* and vine-stalk vegetables (441 hospitalizations) and STEC and leafy vegetables (301 hospitalizations, 7 deaths) [48]. Among outbreaks occurring in a single year, in 2006, that were likely caused by a single food vehicle (n = 243), 17 percent of cases were attributed to leafy greens (including mixed salads) and 16 percent were attributed to fruits (including juice) and nuts[42]. Produce constituted the single largest category of foodborne illness cases attributed to a single food vehicle in 2006 [42]. Among outbreaks occurring in 2013 reported to be attributed to a single food vehicle (n = 210), the most illnesses were attributed to produce: 5% of which were associated with leafy greens and 11 % associated with fruits [49].

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investigate the reports and take appropriate follow-up action, including ensuring that the reportable foods are removed from commerce when necessary. At the date of this writing, there have been four year-long reporting periods since the RFR began operating. In the first period (September 2009 - September 2010), there were 2,240 total entries, of which 229 were primary entries (i.e., initial, rather than subsequent, reports about a safety concern). Of the 229 primary entries, 6 percent (14 entries) were reports related to produce RACs, all reported to be contaminated with Salmonella. In the second period (September 2010 – September 2011), there were 882 total entries, of which 225 were primary entries. Of the primary entries, 12 percent (27 entries) were reports related to produce RACs, 25 of which were reported to be contaminated with *Salmonella* and 2 of which were reported to be contaminated with *Listeria monocytogenes*. In the third period (September 2011 – September 2012), there were 1095 total entries, of which 224 were primary entries. Of the primary entries, 15 percent (33 entries) were reports related to produce RACs, 22 of which were reported to be contaminated with *Salmonella*, 10 of which were reported to be contaminated with *Listeria monocytogenes*, and 1 of which was reported to be contaminated with *E. coli* O157:H7. In the fourth reporting period (September 2012-September 2013) there were 1,269 total entries, of which 202 were primary entries. Of the 202 primary entries, 5 percent (10 entries) were reports related to produce RACs, 7 of which were reported to be contaminated with *Salmonella*, and 3 of which were reported to be contaminated with *Listeria monocytogenes*. The annual RFR reports can be downloaded from http://www.fda.gov/Food/ComplianceEnforcement/RFR/ucm200958.htm.

For attribution purposes, CDC has described "produce" as a group of foods including fresh fruits and vegetables, mixed salads, nuts and juice. The CDC category for produce includes a number of foods, such as juice, that FDA has not traditionally included in our definition of produce. In addition, CDC data represent outbreaks where contamination could have occurred at any point along the chain between the farm and the point of preparation by consumers or service at retail.

2. FDA Data

FDA has looked specifically at outbreaks where the point of contamination is likely to have happened early in the production chain, during growing, harvesting, manufacturing, processing, packing, holding, or transportation. FDA outbreak surveillance data from 1996 to 2014 [59, 150] is derived from CDC data; however, unlike the CDC data, the FDA data do not include intrastate outbreaks, illnesses likely associated with person-to-person transmission, or where the source of contamination was likely in the home or at a retail setting.

The FDA outbreak surveillance data show that between 1996 and 2014 the majority of produce-related outbreaks and illnesses were associated with bacterial agents (86%), followed by parasites (12%) and viruses (2%) [59, 150] (Table 1 and Table 2). Both domestic produce and imported produce were identified as vehicles in these outbreaks. From 1996 to 2014, approximately 173 produce-related reported outbreaks occurred, resulting in 17,212 outbreak-related illnesses, 2,083 hospitalizations and 69 deaths. These outbreaks were associated with approximately 20 different produce commodities[59, 150]. Of the total produce-associated outbreaks, sprouts, leafy greens, melons, tomatoes, berries, herbs, cucumbers and green onions accounted for 85 percent of the implicated commodities (see Table 4 for more details).

In the FDA database, fresh-cut leafy greens, fresh-cut tomatoes and fresh-cut melons accounted for 46 percent (n=79) of the total produce-related outbreaks between 1996 and 2014[59, 150][4]. Based on outbreak investigations by FDA and its federal and state partners, it appears that, in several cases, the most likely point of original contamination for the fresh-cut-related outbreaks occurred during growing, harvest, packing or holding, while the commodity was still in its RAC form, rather than during manufacturing/processing of the fresh-cut product[31, 32]. In a few instances, such as unwashed, field packed tomatoes being removed from a warm ripening room and placed in cold water to firm for slicing (which may have promoted infiltration of pathogens)[40], it is possible that practices or conditions at

[4] While we are not counting these illnesses for purposes of the Regulatory Impact Analysis (RIA) for the Produce Safety final rule, we are otherwise considering them in our assessment in this QAR and in establishing the Produce Safety final rule. We have determined that it is most appropriate to attribute the benefits of avoiding fresh-cut produce related illnesses to the Preventive Controls for Human Food (PCHF) regulation for purpose of economic analysis to avoid double counting such benefits, however, we note that it appears that in several cases, the most likely point of original contamination for the fresh-cut-related outbreaks occurred on the farm rather than at the fresh-cut facility. Both farms and fresh-cut manufacturing/processing operations provide routes of contamination that may contribute to adulteration of fresh-cut produce, and the integrated system of preventive controls we are establishing under FSMA is intended to address these risks at multiple stages in the farm-to-table continuum. Thus, illnesses attributable to fresh-cut produce are relevant to both the produce rule (and this QAR, which informs the development of the produce rule) and the PCHF rule even though the economic benefits of avoiding illnesses attributable to such products are being estimated only in the PCHF RIA.

the fresh-cut facility contributed to the contamination event. It is possible that the way product is handled during processing, including mixing large batches of fresh-cut product and washing in water without maintaining effective disinfectant concentration may cross-contaminate a large volume of product, thereby impacting the size and scope of an outbreak associated with fresh-cut produce[29, 30, 142].

3. Data Limitations

Both CDC and FDA foodborne illness data, especially data for outbreaks associated with produce, reflect certain challenges, including: (1) Most cases of foodborne illness are sporadic and/or unreported and some outbreaks are undetected; (2) Some outbreaks are recognized by State or local health departments but never reported to CDC; (3) Even when an outbreak is recognized, the food vehicle for the outbreak remains undetected in approximately half of reported outbreaks[42]; and (4) The short shelf-life of produce, lack of available package labeling and complex distribution systems can hinder efforts to trace an outbreak to its source. Also, the more time that elapses between (1) a contamination event and the identification of the source of product and (2) conducting an investigation, the more difficult it is to determine the likely means by which the produce was contaminated. In many cases, it has not been possible to trace product back to a single source. Perhaps the most critical component to any successful outbreak investigation is the data collection period, which begins with a survey of any and all potential foods that may have caused illness, and which is dependent mainly on accurate patient recollection of foods consumed. If convergence on a common route or commodity of concern is reached as a result of these case-control studies, a traceback effort may attempt to locate and confirm the source of the contaminated product. For every successful outbreak investigation reported in this QAR, there are many more epidemiological case-control studies that have not been able to converge on a common commodity of concern. Inconclusive or unconfirmed outbreak case studies were not deemed appropriate for incorporating into the QAR.

Further, the extent of illness and death associated with microbiological hazards in produce is likely much higher than these statistics represent, because the illness data represent only the number of illnesses reported to CDC, FDA, and state/local health departments in association with an outbreak. The data do not include illnesses that may have occurred but were not reported, sporadic cases of illness (i.e., not associated with an outbreak), and illnesses for which the food vehicle was not identified. FDA also recognizes the likelihood that many sporadic foodborne illnesses due to the consumption of contaminated produce are unreported, and that these illnesses may or may not be associated with an outbreak (i.e. two or more illnesses associated with a common pathogen). These data would not be captured in either CDC or FDA datasets, which may contribute to the underestimation of foodborne illness due to the consumption of contaminated produce.

Table 1. Pathogens Associated with Produce Outbreaks, 1973-2014 [59, 150, 189]

Group	Specific pathogen
Bacteria	*Escherichia coli* (*E. coli*) O157:H7, non O157 Shiga toxin-producing *E. coli* (STECs) (e.g., O145, O111, O104:H4); *Salmonella* spp.; *Listeria monocytogenes* (*L. monocytogenes*); *Shigella sonnei*
Viruses	Hepatitis A; Norovirus
Parasites	*Cryptosporidium parvum*; *Cyclospora cayetanesis* and *Giardia lamblia*

Table 2. FDA Outbreak Surveillance Data, Outbreaks Linked to Produce (attributed to biological hazards), by Pathogen Types, 1996-2014[59, 150].

Pathogen Type	No. of Outbreaks (% of total)	Agent		No. ill (% of total)	No. Hosp. (% of total)	No. Deaths
		Organism	Ranking[2]			
Bacterial	148 (85.55)	*Salmonella* Pathogenic *E. coli* *Shigella*	#1 #2 #5	11,422 (66.36)	1,859 (89.25)	66
Parasitic	21 (12.14)	*Cyclospora*	#3	4789 (27.82)	68 (3.26)	0
Viral	3 (1.73)	Hepatitis A	#4	993 (5.77)	156 (7.49)	3
Total[1]	**173**			**17,212**	**2,083**	**69**

[1] Includes chemical hazards (e.g. toxins) not identified in this table.

[2] Comparative ranking based on number of outbreaks linked with produce.

In our final Regulatory Impact Analysis, FDA has also estimated the total number of all foodborne illnesses caused by microbial contamination of produce commodities where the contamination occurred on farms. During the time span between 2003 and 2012, we estimate a total of 194,751 (per annum) illnesses were attributed to FDA-regulated produce RACs, including sprouts.[5] The calculations used in deriving these estimates make adjustments for under-reporting and under-identification of a foodborne illness, and for unidentified pathogens potentially attributable to FDA-regulated RACs. (For additional details about the derivation of these estimates, see Regulatory Impact Analysis for the Produce Safety final rule).

[5] See footnote 4 regarding illnesses attributable to fresh-cut produce.

B. Conclusions on Hazard Identification

We conclude that microbiological hazards are a significant and reoccurring risk in fruits and vegetables, which we expect to be of continued concern for the production of safe produce.

III. Hazard Characterization

Hazard characterization provides a qualitative description of the nature, severity and duration of adverse effects of microbiological hazards that may result from ingestion of contaminated produce[127]. In characterizing the human health effects, information relevant to the frequency or incidence of the disease such as severity (morbidity, mortality), duration of illness, and/or other clinical effects are provided.

A. Biological Hazards

Biological (specifically, microbiological) hazards can pose a risk of serious adverse health consequences or death. The primary agents associated with produce-related outbreaks, most of which are identified in the Hazard Identification section of this document, include bacteria, viruses, and parasites. We will use the following foodborne pathogens to represent the biological hazards of concern for produce: for bacterial foodborne pathogens we will use *E. coli* O157:H7, *L. monocytogenes*, and *Salmonella*; and for viral foodborne pathogens we will use hepatitis A virus. We focus on these pathogens because *Listeria* has been linked to a major produce outbreak in 2011 and in 2014 (see section IV.B.6.c. of this document) and the others have consistently and historically been associated with produce outbreaks (see Table 2). In addition, these selected pathogens are representative of the diverse spectrum of virulence factors (genetic components associated with the ability to cause infection and disease) and mechanisms for environmental persistence associated with foodborne pathogens in general. Furthermore, the successful implementation of controls designed to prevent or eliminate these pathogens would likely prevent or eliminate all other microbial pathogens in the growing, harvesting, packing and/or holding environment. Adverse effects associated with biological hazards may occur as a result of consumption of a contaminated food during a single eating occasion, however, we also acknowledge that several servings might also need to be consumed over time to ingest a sufficient number of organisms to cause illness (e.g. consider the growth potential of *L. monocytogenes* in contaminated cantaloupe during refrigerated storage). A common measure of the frequency of a hazard is the number of reported illnesses. Two common measures of the severity of illness are hospitalizations and deaths.

Table 3 provides an estimate of the annual number of illnesses, hospitalizations, and deaths associated with major foodborne pathogens, using a model that attempts to account for unreported outbreaks and sporadic illnesses (see Scallan et al.[184]). Scallan reported major pathogens; we report numbers here for selected pathogens, relevant to produce. Note that these data represent public health impacts associated with all foods, rather than with produce consumption alone. Whereas information about the number of hospitalizations and deaths illustrates the likely frequency of serious foodborne illness associated with these foodborne pathogens, the rates (i.e., percentage) of hospitalization and deaths give an indication of the severity of the foodborne illnesses. For example, although Table 3 estimates a large number of illnesses, hospitalizations, and deaths from norovirus, Table 3 shows that norovirus has the lowest hospitalization rate and has one of the lowest death rates. Thus, the relatively large numbers of hospitalizations and death estimated to be associated with norovirus reflect the frequency, rather than the severity, of the illness.

Table 3. Modeled estimates of Illness, Hospitalization, and Death for Selected Foodborne Pathogens Identified in the Hazard Identification, all foods [184]

Pathogen	Mean Number of Annual Episodes of Foodborne Illness*	Mean Number of Annual Hospitalizations	Hospitalization Rate (%)**	Mean Number of Annual Deaths**	Death Rate (%)**
E. coli O157:H7	63,153	2,138	46.2	20	0.5
Hepatitis A Virus	1,566	99	31.5	7	2.4
L. monocytogenes	1,591	1,455	94	255	15.9
Norovirus	5,461,731	14,663	0.03	149	<0.1
Salmonella (non-typhoidal)	1,027,561	19,336	27.2	378	0.5
Shigella	131,254	1,456	20.2	10	0.1
Cyclospora cayetanesis	11,407	11	6.5	0	0.0
Cryptosporidium parvum	57,616	210	25.0	4	0.3
Giardia lamblia	76,840	225	8.8	2	0.1

* Based on laboratory surveillance adjusted for under-reporting and under-diagnosis[184].

** Based on unadjusted laboratory-confirmed illnesses[184].

1. *Escherichia coli* O157:H7

Escherichia coli (*E. coli*) O157:H7 is a bacterium that causes an intestinal illness [91] and has been linked to outbreaks associated with spinach, lettuce, walnuts and sprouts. The infectious dose is low (fewer than 100 cells)[149]. Symptoms include severe cramping (abdominal pain) and diarrhea, which often becomes bloody (hemorrhagic colitis) after 1 to 2 days [149]. Occasionally vomiting occurs. The illness is usually self-limiting and lasts for an average of 8 days [91]. Some hemorrhagic colitis victims, particularly the very young (up to 15 percent in children under 10), develop hemolytic uremic syndrome (HUS), characterized by renal failure and hemolytic anemia [149]. The disease can lead to permanent loss of kidney function and death (the case fatality rate is less than 1 percent)[91, 149]. In addition, non-O157 STEC, such as O145[56], and O104 [75], are increasingly being recognized as pathogens of concern in foodborne disease outbreaks associated with produce.

2. Hepatitis A virus

Infection with hepatitis A virus (HAV) may or may not result in clinical disease[91], and it can take 15-50 days for symptoms to manifest themselves[78]. Outbreaks of HAV have been linked to consumption of produce such as green onions[223]., frozen strawberries[160], and frozen raspberries[175]. Symptoms of HAV infection include fever, malaise, nausea, vomiting, diarrhea, anorexia, and abdominal discomfort, followed in several days by jaundice[78, 91]. Many persons (particularly children) infected with HAV do not experience clinical disease or, if they do experience clinical disease, do not experience jaundice[78, 91]. When disease does occur, symptoms are usually mild and recovery is complete in 1-2 weeks. Occasionally, the symptoms are severe and convalescence can take several months. Patients who experience severe symptoms suffer from feeling chronically tired during convalescence, and their inability to work can cause financial loss. The illness can be fatal (estimated to be as high as 2.4 percent based on laboratory-confirmed cases of those who are sick enough to see a doctor and be tested)[184]. Deaths usually occur in the elderly and in persons with underlying chronic liver disease[78]. The infectious dose is unknown but has been assumed to be 10-100 virus particles. Persons who are exposed to HAV generally develop immunity to the virus, and vaccination against the virus has increased. Consequently, in the United States the percentage of adults with immunity increases with age (i.e., 10 percent of adults aged 18-19 years show signs of immunity whereas 65 percent of adults over 50 years show signs of immunity)[91]. Viruses may be excreted in large numbers by infected individuals and can be transferred to crops either directly by handling or indirectly via contaminated water[13, 183, 221].

3. *Listeria monocytogenes*

Listeria monocytogenes (*L. monocytogenes*) is a bacterium that can cause a mild, non-invasive intestinal illness (called listerial gastroenteritis) or a severe, sometimes life-threatening illness (called invasive listeriosis). Most healthy persons who are infected with *L. monocytogenes* either show no symptoms or experience mild listerial gastroenteritis [91]. Symptoms of listerial gastroenteritis include diarrhea, fever and fatigue [167]. Persons at higher risk for severe, invasive listeriosis include the elderly, individuals who have a deficient immune system, pregnant women, and fetuses and neonates who are infected after the mother is exposed to *L. monocytogenes* during pregnancy [91, 167]. Symptoms and manifestations of invasive listeriosis include septicemia, meningitis, encephalitis, or intrauterine or cervical infections in pregnant women, which may result in spontaneous abortion or stillbirth [91, 167]. Serious, invasive listeriosis is usually preceded by influenza-like symptoms (including persistent fever) or gastrointestinal symptoms such as nausea, vomiting, and diarrhea[81, 104]. The infective dose of *L. monocytogenes* is unknown but is believed to vary with the strain and susceptibility of the victim[91]. In 2003, FDA and the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA), in consultation with CDC, released a quantitative assessment of relative risk associated with consumption of 23 categories of ready-to-eat (RTE) foods that had a history of contamination with *L. monocytogenes*, or that were implicated epidemiologically with an outbreak or a sporadic case of listeriosis [94, 95]. The FDA/FSIS *L. monocytogenes* Risk Assessment (RA) showed that the risk of illness from *L. monocytogenes* increases with the number of cells ingested and that there is greater risk of illness from RTE foods that support growth of *L. monocytogenes* than from those that do not. A key finding of the 2004 FAO/WHO risk assessment on *L. monocytogenes* in RTE foods was that the models developed predict that nearly all cases of listeriosis result from the consumption of high numbers of the pathogen [81]. Refrigerated foods present a greater risk from *L. monocytogenes* because some refrigerated foods that support growth may be held for an extended period of time, thus increasing the risk if *L. monocytogenes* is present in a food. Growth of *L. monocytogenes* does not occur if the food is frozen, but the organism may survive. If a frozen food contaminated with *L. monocytogenes* is thawed and held at temperatures that support growth, e.g., under refrigeration, the risk of illness from *L. monocytogenes* in that food increases.

4. Norovirus

Norovirus causes an intestinal illness [91]. Symptoms of infection usually include acute-onset vomiting, watery non-bloody diarrhea with abdominal cramps, and nausea. Low-grade fever also occasionally occurs, and diarrhea is more common than vomiting in children. Dehydration is the most common complication, especially among the young and elderly, and may require medical attention. Symptoms usually persist 24 to 72 hours. Recovery is usually complete and there is no evidence of any serious long-term sequelae (i.e., chronic conditions resulting from the illness)[47].

5. *Salmonella* species

Salmonella enterica, - the bacterium that causes the illness salmonellosis[91], is composed of six subspecies containing over 2,700 serotypes, all of which are presumed to be pathogenic, and has been linked to cantaloupe, sprouts, raw almonds, mangos, peppers and tomato-related outbreaks[59, 76, 150]. Symptoms of salmonellosis include diarrhea, fever, abdominal cramps, headache, nausea, and vomiting[91]. Acute symptoms may persist for 1 to 2 days or may be prolonged, depending on host factors, ingested dose, and characteristics of the specific bacterial strain [91]. Most healthy people recover, but the infection can spread to the bloodstream, and then to other areas of the body, leading to severe and fatal illness, which is more likely to occur in children, the elderly, and persons with weakened immune systems [91]. The infective dose can be as few as 15-20 cells, depending on age and health of the victim and strain differences among the members of the genus [91]. *S. enterica subsp. enterica (serovar Typhi* and *Paratyphi* A, B, and C) produce typhoid and typhoid-like fever in humans, infecting various organs and leading to lesions. The fatality rate for most forms of salmonellosis is less than 1 percent, although it is usually higher for typhoid fever (≤10% mortality)[91]. However, a number of strains can cause severe disease, e.g., the fatality rate of *S. enterica subsp. enterica* serovar Dublin is 15 percent when accompanied by septicemia in the elderly, and the fatality rate of *S. enterica subsp. enterica (*serovar *En*teritidis) is approximately 3.6 percent in hospital/nursing home outbreaks, with the elderly being particularly affected [91]. Reactive arthritis may occur in about 2 percent of culture-confirmed cases[91]. Septic arthritis, subsequent to or coincident with septicemia, also occurs and can be difficult to treat [91].

6. *Shigella*

Shigella is a bacterium that can be transmitted only to humans through the consumption of contaminated food and water [43], and has been linked to several large outbreaks associated with the consumption of raw fruits and vegetables. *Shigella* is also known to have a low infectious dose, 10-200 cells, similar to that of *E. coli* O157:H7 [91]. Certain strains produce enterotoxins and Shiga toxin which is similar to toxins produced by *E. coli* O157:H7. Past outbreaks involving lettuce, parsley, and honeydew melon have been linked to *Shigella* contamination. This bacterium causes the illness shigellosis with symptoms such as fever, stomach cramps and bloody diarrhea that can range from watery stools to severe, life-threatening dysentery. Disease onset ranges from 8-50 hours after exposure and majority of uncomplicated cases resolve in 5 to 7 days [43, 91].

7. *Cryptosporidium parvum, Cyclospora cayetanesis, Giardia lamblia*

Cryptosporidium parvum, *Cyclospora cayetanesis* and *Giardia lamblia* are parasites that have been associated with past produce outbreaks[44, 45, 91]. Past outbreaks involving parasites have been linked to raspberries, mesclun lettuce, basil, and snow peas[45]. Produce can be contaminated with *Cryptosporidium parvum* via the usage of untreated soil amendments of animal origin (i.e. manure). Cryptosporidiosis has an onset time of 7 to 10 days after exposure, and is self-limiting in otherwise healthy individuals. Some cases are asymptomatic while others may experience a range of diarrhea from mild to severe. However, immunocompromised individuals are at a higher risk for complications. Illness onset after infection with *Cyclospora* is usually 7-10 days after ingestion, and can persist for days to months with a possibility of relapse. Symptoms include watery diarrhea, loss of appetite, weight loss, abdominal cramping and bloating, nausea and fatigue. In certain cases, severe flu-like symptoms are observed[91]. Giardiasis is most frequently associated with the consumption of contaminated water which may also come in contact with produce[44]. Cases of giardiasis can be asymptomatic, but when symptoms are present they include diarrhea, malaise, abdominal cramps, flatulence and weight loss. Onset of illness ranges from 1-2 weeks after exposure, and can last from 2-6 weeks. Mortality from infection by these parasites is low in the United States[91]. For a comprehensive review of pathogens, including a discussion of the diseases they cause, see FDA's Bad Bug Book[91].

B. Outbreaks Associated with Commodities

One of the risk management questions that this analysis is designed to explore is, "Does the likelihood of illness attributable to produce consumption vary among produce commodity types?" (Q4) The following discussion is intended to synthesize the available information on this topic. Data below were obtained from the FDA outbreak surveillance database described in section II.A.2.

Table 4. ++ FDA Data on Reported Outbreaks Linked to Produce Where Contamination was Likely prior to Retail, by Commodity, 1996-2014[59, 108, 150].

Commodity	No. Outbreaks (%)	No. Illnesses (%)	No. Hospitalized (%)	No. Deaths
Sprouts	43 (24.86)	2,405 (13.96)	171 (8.21)	3
Leafy greens	44 (25.43)	1,742 (10.11)	456 (21.90)	9
Melons (Cantaloupe and Honeydew)	17 (9.83)	997 (5.79)	334 (16.04)	41
Tomatoes	18 (10.40)	2,329 (13.52)	268 (12.87)	3
Berries*	10 (5.78)	2,753 (15.98)	12 (0.58)	0
Herbs (Basil, Parsley, Cilantro)	8 (4.62)	2,022 (11.74)	14 (0.67)	0
Cucumbers	4 (2.31)	178 (1.03)	40 (1.92)	0
Green onions	3 (1.73)	993 (5.76)	156 (7.49)	3
Mangos	3 (1.73)	234 (1.36)	34 (1.63)	0
Almonds	2 (1.16)	210 (1.22)	10 (0.48)	1
Grapes	2 (1.16)	45 (0.26)	12 (0.58)	0
Papaya	2 (1.16)	129 (0.75)	15 (0.72)	0
Multiple**	2 (1.16)	94 (0.55)	0 (0.00)	0
Other***	7 (4.05)	1,869 (10.85)	330 (15.85)	7
Unknown+	8 (4.62)	1,226 (7.12)	230 (11.05)	1
Total	**173**	**17,226**	**2,082**	**68**

* One outbreak of *Cyclospora* associated with raspberries in 1997 accounts for 1,012 illnesses, with no information on hospitalizations and deaths.

** Two outbreaks in 2004 were associated with mesclun lettuce and/or basil.

*** "Other" includes one outbreak associated with each of the following commodities: celery, hazelnuts, hot peppers, pine nuts, pistachios, snow peas, and squash. The single *Salmonella* Saintpaul outbreak associated with hot peppers accounts for 1,535 illnesses, 308 hospitalizations, and 2 deaths.

[+] Five outbreaks during this time period were associated with unknown produce; while no specific produce item was identified as the vehicle for these outbreaks, various produce items were found to be epidemiologically associated with illness.

[++]Other Notes:

- These data do not contain information on outbreaks/illnesses where the point of contamination is the retail food setting or home.
- These data do not include illnesses transmitted from person-to-person.
- Illness data represents only the number of illnesses reported to CDC, FDA, and state/local health departments in association with an outbreak. These data do not include illnesses that may have occurred but were not reported, sporadic cases of illness, and illnesses not associated with a food vehicle.
- Information on outbreaks/illness reported prior to 2004 has been compiled from paper records; information on outbreaks/illnesses since 2004 has been obtained from the CFSAN Outbreak Surveillance Database.
- The outbreaks tracked by FDA are a subset of all the outbreaks tracked by CDC. CDC also tracks outbreaks/illnesses where the point of contamination is the retail food setting or the home. Due to lags in reporting of illnesses, some differences in numerical tallies may exist between FDA and CDC data.

The number of outbreaks attributed to individual commodities can be an important epidemiological statistic to help understand underlying hazards, but should not be the only consideration of risk. For example, while melons accounted for only approximately 10 percent of all produce-related outbreaks and approximately 6 percent of illnesses from 1996-2014, they accounted for 16 percent of hospitalizations and over 60 percent of deaths. In contrast, in the same timeframe, sprouts and leafy greens together accounted for over 50 percent of produce-related illnesses and over 30 percent of produce-related hospitalizations, but only approximately 18 percent of deaths.

We have examined the characteristics of crops associated with outbreaks. Even though the majority of outbreaks have been associated with a relatively small number of commodities, we have seen one or more outbreaks over the last 20 years in a crop that can be characterized by one of the following characteristics:

- **Crops where a portion of the harvestable portion grows in the ground, such as green onions;**
- **Row crops where the harvestable portion grows on or near the ground, such as lettuce, spinach, basil, parsley, and cantaloupe;**
- **Crops where the harvestable portion grows above the ground, such as tomatoes, chili peppers, raspberries, and blueberries;**
- **Crops where the harvestable portion grows on trees, high above the ground, such as mangos, and almonds; and**
- **Crops generally grown without soil, such as sprouts.**

Even within a commodity group, physical characteristics of the produce that could alter the potential for contamination and, therefore, association with an outbreak, do not always appear to do so. For example, within the melon group, cantaloupe has a netted rind, whereas honeydew and watermelon have a smooth rind, which is physically less likely to harbor pathogens (i.e. easier to clean). However, FDA data show that of the 15 outbreaks between 1996 and 2014 associated with whole melons (2 outbreaks were associated with fresh-cut melons), 13 were specifically linked to the consumption of whole cantaloupes and two were linked to honeydew.[59, 150]. In a Meta-analysis of CDC-reported outbreaks associated with melons from 1973-2011, cantaloupes were the most commonly reported melon type (19 outbreaks, 56%), followed by watermelons (13 outbreaks, 38%) and honeydews (2 outbreaks, 6%)[220]. Further, among those outbreaks with available information, the most common source of contamination was on farm (65%)[220]. Tomatoes and apples have waxy (hydrophobic) surfaces and some degree of porosity, particularly near the stem-end, yet both whole (RAC) tomatoes and apples have been linked to outbreaks. Similarly, cucumbers have a waxy surface, little porosity at the stem or blossom end, and are not likely to be subject to water infiltration, yet there have been outbreaks linked to cucumbers. In conclusion, using crop physical characteristics **alone** seems to be a poor indicator of which commodities are at a **greater or lesser** likelihood of contamination that may lead to a foodborne outbreak.

Our data show that the patterns of outbreaks associated with produce commodities change over time. Occasionally, a produce commodity is associated with an outbreak that had not been previously linked to foodborne illness. For example, prior to the 2008 *Salmonella* Saintpaul outbreak [41], jalapeño and Serrano peppers had not been identified as vehicles in a foodborne illness outbreak. On the other hand, some commodities have a continuing and repeated pattern of association with outbreaks, over multiple years, such as sprouts, tomatoes and leafy greens. This phenomenon is further illustrated in Table 5.

Table 5. Annual Pattern of Reported Outbreaks by Commodity, FDA Database, 1996-2014[6]

Commodity	1996	97	98	99	2000	01	02	03	04	05	06	07	08	09	10	11	12	13	14
Almond						1		1											
Berries	1	1		1	2	1							1	2	1				
Celery															1				
Cucumber																	1	2	1
Grapes						1													1
Green Onions			1		1			1											
Hazelnuts															1				
Herbs (Basil, Parsley, Cilantro)		1	1	1						3								1	1
Leafy Greens	2	1	2	6		1	2	3	2	1	3		4	1	2	2	6	4	2
Mango				1		1											1		
Melons (Cantaloupe and Honeydew)		1			1	2	1	3			1	1	1	1		3	2		
Papaya																1	1		
Peppers (hot)													1						
Pistachio																		1	
Pine nuts																1			
Snow Peas									1										
Sprouts	2	3	2	6	1	3	2	5	2				2	3	3	4	1		4
Squash									1										
Tomato			1		1		3		2	3	2	1	1	1	2			1	

[6] Table 5 has been introduced in the Final QAR in response to peer review comment in efforts to facilitate comparison of the number of outbreaks associated with each commodity, as was previously presented in the draft QAR as individual bar graphs for each commodity.

Within some commodity groups, outbreaks have been associated with relatively few types of produce, such as cantaloupe and honeydew melons within the melon group. In other groups, outbreaks have occurred more broadly, such as Roma, red round, plum, and grape tomatoes within the tomato group[59].

C. Conclusions on Hazard Characterization

Available data and information establish that human pathogens constitute a biological hazard with the potential to cause serious adverse health consequences or death and result in the vast majority of foodborne illness known to be associated with produce consumption.

Some produce types are repeatedly associated with reported foodborne illness whereas other produce types are only intermittently associated with foodborne illness. Still other produce commodities have not been associated with reported foodborne illness. Using crop physical characteristics alone seems to be a poor indicator of which commodities are at a greater or lesser likelihood of contamination.

IV. Exposure Assessment

For this Exposure Assessment, FDA analyzed data from the published literature and surveys. Exposure is a function of the level of contamination in the food and the quantity of the food consumed [80, 82]. A variety of factors were taken into account in evaluating exposure, including the likelihood of contamination of produce from five key routes or pathways: water; soil amendments; animals; workers; and equipment and buildings. For selected commodity-pathway pairs, an analysis was conducted to qualitatively estimate the likelihood of contamination up to the point when the produce leaves the farm and the likelihood that the contamination remains at the point of consumption, which can be influenced by certain consumer practices such as cooking for produce that is rarely consumed raw. The frequency of consumption was also considered in qualitatively estimating the likelihood of exposure to the hazards of concern from a selected group of representative commodities.

A. Sources of Contamination

Pathogens may be of human and animal origin[61, 145, 235]. On-farm contamination can be direct (such as contact with feces from domestic or wild animals) or indirect (such as contamination that may be moved from a manure storage area to crops via water runoff)[225].

1. Survival of Pathogens in the Environment

The presence of pathogens in the environment is largely dependent upon two factors: input (load) and survival[147]. Sources of contamination events are typically traced to either point sources (e.g., any discernable, discrete or confined event that can include sewage effluent spills, runoff from on-farm manure stockpiles, etc.) and nonpoint sources (many diffuse or sporadic events that can include wildlife and/or livestock fecal droppings). Both point source and non-point source contamination events can contribute to the total environmental pathogen load where their persistence in the environment, including in soil and water, increases the potential for food contamination. Survival of pathogens in the environment is influenced by complex physical, chemical, and biological interactions. Some pathogens are widely distributed and naturally capable of long-term survival under a wide range of natural conditions (e.g., *L. monocytogenes*) while the distribution of others (e.g., *Salmonella, E. coli* H7:O157) may be more narrowly defined by temperature, sunlight (UV exposure), moisture level, pH, available nutrients and related factors, each of which may limit survival to some degree[147]. Even slight variations in any one of these environmental parameters can have a large effect on pathogen persistence [164, 165, 186]. Movement among various environments is also possible; for example, fecal bacteria were reported to be found in surface waters through particle attachment, suspension, and deposition[225]. In addition, predation, competition with native microorganisms, metabolic diversity, and biofilm and spore formation are key determinants of pathogen survival and environmental distribution[225].

Under favorable conditions, pathogens may survive for extended periods of time and even thrive in the environment. Various sites in production areas may provide safe harborage for pathogens and act as reservoirs from which food contamination may occur. When manure-based composts that were inoculated with *Salmonella* and *E. coli* O157:H7 were applied in fields, significant survival times of > 215 days were reported in soil. In these same fields, *Salmonella* and *E. coli* O157:H7 were detected on parsley samples up to 231 days and 177 days, respectively, and on lettuce samples up to 63 days and 77 days, respectively[120, 121]. Despite well-defined studies, the complexity of interactions between crops, pathogens, and environmental factors in a given agricultural setting makes predicting specific pathogen survival rates difficult.

2. Transfer of Pathogens into or onto Produce

Produce is subject to both direct (e.g., insanitary hand or equipment contact, application of agricultural water) and indirect (e.g., contact with articles that have previously contacted manure piles or effluent from broken sewer lines) pathogen contamination. Produce outbreak investigations are frequently more conclusive in cases where direct transfer by infected workers is implicated and especially so when humans are the exclusive pathogen reservoir (e.g., *Shigella*, hepatitis A)[35, 67, 130]. Often, however, the same cannot be said for outbreaks tied to pathogen introduction by indirect routes. In these cases, identifying the pathogen source can be complicated by the practices and production methods associated with the commodity and its storage and distribution patterns, which may vary by region and operation. Despite these differences, it is likely that most farms share commonalities in fundamental activities such as planting, use of soil amendments, irrigation and other water use, removing the edible portion of the crop from the growing area (i.e., harvesting), and subsequent activities (such as washing, trimming outer leaves, cooling, and packing), all of which may serve as possible routes of contamination and cross-contamination from one produce commodity to another.

Workers who fail to practice good personal hygiene are recognized as increasing the likelihood of contaminating food during handling [22]. The magnitude of worker-associated contamination of food is illustrated in a retrospective study conducted by Greig and colleagues [106]who reviewed outbreak data from 1927 to 2006 and collected a total of 816 reports (80,682 cases) where workers were reported to be instrumental in or contributory to the outbreak. Fourteen causative agents were identified in these outbreaks led primarily by norovirus, *Salmonella*, hepatitis A, *Staphylococcus*, *Shigella*, and parasites (*Cyclospora*, *Giardia*, and *Cryptosporidium*). In a related report, the most frequently identified contributing factor in these outbreaks was reported to be bare hand-to-food contact, with the second being improper hand-washing methods[203]. Similar reasons were cited during an investigation of a *Vibrio cholera* outbreak in sliced melon[1].

Pathogens may be transferred to produce either by fecal shedding or by direct contact of animals with produce[224]. In 2006 alone, feces were cited as a potential contributing factor in three separate outbreaks involving fresh spinach, lettuce, and tomatoes[40, 86, 87]. Follow-up environmental investigations further identified proximity of irrigation wells and surface water sources with potential exposure to cattle and wildlife feces, wildlife droppings in growing fields, and use of soil amendments made from incompletely composted animal manure[67].

In addition, soil amendments containing manure are clearly capable of acting as a vehicle in the fecal-oral route of human disease transmission. Survival times for pathogens in soil, if present, may vary with conditions but have been reported as less than 30 days to more than 12 months[6, 236]. There are a limited number of conclusive reports linking improper use and application of soil amendments to foodborne illness in produce. Known examples include an occurrence of *E. coli* O157:H7 in rural Maine linked to a home garden amended with on-site raw cattle manure[52], and a Canadian outbreak of listeriosis linked to coleslaw made from cabbage grown using manure from sheep shedding *Listeria[185]*.

Water can be a route of pathogen contamination in the field and after harvest. While produce outbreaks citing contaminated water as a suspect vehicle in foodborne disease are plentiful, conclusive evidence is rare [192, 232] due to time and resource constraints related to field evaluations, collections, and analytical work coupled with the often-transient nature of circumstances leading to contamination. Potential contributing factors cited in produce-associated outbreaks where water was identified as the likely source of contamination include run-off from nearby animal pastures and feed lots, cracked or damaged wells, floods, raw sewage, and surface waters contaminated with feces[14]. One study demonstrated that pathogens can be transferred from contaminated water to produce[117]. The presence of bacteria in irrigation surface waters is dynamic, often showing seasonal variation due to changes in temperature, precipitation, and animal carriage rates that may ultimately influence human exposure to waterborne pathogens. For example, one research paper correlated the number and diversity of *Salmonella* serotypes isolated from a mixed use watershed (irrigation, swimming, fishing) in southern Georgia to summer seasonal temperature/rainfall patterns and coincident with salmonellosis case reports[109]. Pathogen survival rates in water are affected by many of the same parameters affecting survival rates in soil, i.e., UV exposure, temperature, nutrient availability, competition, and pH among others. However, some pathogens (e.g., *Salmonella*) appear to be better adapted for long term aquatic survival than others (e.g., *Shigella*)[147].

Ground water has been historically viewed as less likely to be contaminated with human pathogens than surface water because of the natural filtering capacity of soil and the depth pathogens would have to travel to compromise its source. As a general rule, deeper wells filter out more pathogens than shallower counterparts given similarly structured soils and other geological properties. However, ground water can be contaminated with pathogens by infusion of wastewater, failed septic tanks, landfill leaks, and improper management of animal wastes. Although wells that are properly constructed, adequately maintained, and appropriately situated are generally less vulnerable to contamination compared to surface water sources, private wells are an additional concern as routine monitoring and regular treatment are rare[178]. Studies have found that (1) 11 percent of US ground water sites from 20 states are reported to have tested positive for *Cryptosporidium*, *Giardia* or both[155]; and (2) in a 12 year (1991-2002) survey of waterborne diseases, of 183 documented outbreaks associated with drinking water, 76 percent were from a ground water source[178]. Moreover, direct leaching of *E. coli* and *Campylobacter* into shallow ground water sources has been demonstrated[53].

In addition to water source and quality, the type of irrigation system or method of use may influence the likelihood of pathogen contamination of produce. For instance, Mitra et al. (2009) [152]showed that *E. coli* O157:H7 survived longer, in a growth-chamber study, on leaf surfaces of spinach when introduced via water droplets than on roots when introduced by soil infiltration.[152] However, the opposite relationship was demonstrated in the case of *Campylobacter jejuni* in growth-chamber grown spinach and radish, where survival rates in root systems were significantly higher than on leaves[24]. In one study, no viral or bacterial pathogen surrogates were recovered from bell pepper when irrigated by subsurface drip or furrow [194] These findings suggest that pathogen survival rates may be dependent not only on mode of introduction (in this case, type of irrigation system – see section IV.B.2.b.), but also on specific pathogen-commodity interactions.

Equipment and tools can become contaminated if not properly maintained, and may serve as vehicles for microbial contamination into or onto produce[137, 166]. A study by Kusumaningrum et al. (2003) [136]showed that pathogens can remain viable on dry stainless steel surfaces and present a contamination hazard, with survival for up to 4 days dependent on the contamination levels and type of pathogen. Specifically, *Salmonella* Enteritidis, *Staphylococcus aureus*, and *Campylobacter jejuni* were readily transmitted from wet sponges to stainless steel and from steel surfaces to cucumber and chicken fillet slices at transfer rates ranging from 20 to 100 percent[136]. Contaminated tools that are used repeatedly or continuously can quickly contaminate a large volume of product.[239].

Although current scientific literature indicates that transfer of pathogens to produce can occur from soil, application of soil amendments and water, handling, etc., there are limited data on the rates of transfer (i.e. transfer coefficients) or factors influencing these rates.

3. Survival and Persistence Factors

Pathogen survival may be extended if the pathogen successfully colonizes plant surfaces[208]. Recent studies show that some pathogenic strains may be better adapted for survival on certain plants or plant structures than non-pathogenic strains [10, 171], and indicate that these pathogens may use plants as intermediates in the disease cycle prior to ingestion by herbivores [208]. Passive adhesion may adequately explain the initial attachment process in some plant-microbe interactions [191], while others may be mediated by active processes often involving multiple strategies [10, 11, 171]. For example, in a study of the interaction of *E. coli* O157:H7 with leafy green produce, pathogenic *E. coli* O157:H7 was found to attach to leaf surfaces of lettuce and baby spinach in large numbers through flagella and a protein export system. In contrast, non-pathogenic *E. coli* that lack similar mechanisms exhibited poor attachment[233]. Similarly, *Salmonella enterica* appears to use adhesive proteins, polysaccharides, and cell appendages to securely attach to alfalfa sprouts[9]. Colonization studies using different *Salmonella enterica* serovars and commercially available lettuce cultivars showed significantly different degrees of serovar-cultivar colonization (epiphytic and endophytic) suggesting different colonization mechanisms and levels of risk to human health[133]. In each of these cases, pathogens that successfully and securely attach to plants, especially to the edible portion, increase the likelihood of human exposure, and potentially the likelihood of foodborne illness. In a surface inoculation study, pathogens (*Shigella, E. coli*

O157:H7, HAV, *Salmonella*) survived significantly longer on cantaloupe than on lettuce or green pepper[194]. *Salmonella* Thompson (which was linked to an outbreak associated with cilantro consumption) has significant tolerance to environmental conditions on cilantro, and its competitiveness with native bacterial plant colonizers is enhanced at high temperature and relative humidity[25]. In all of these studies, researchers attributed findings, in part, to surface texture (i.e. roughness) of the commodity.

For some pathogens, colonization of plants begins by attachment to the exterior surface of leaves, stems, or roots, and by gaining access to internal plant structures. Access to the internal plant spaces may be gained through natural breaks in the plant cuticle; through openings in flowers, stomata, or lenticels; or through abrasions or other damage incurred during production or harvest. Internal colonization of produce may increase the risk of foodborne outbreaks because the pathogens may be protected from mitigation steps (e.g., washing) and perhaps even benefit from available plant nutrients[143]. When pathogen colonization of the edible portion or internalization occurs, a potential hazard exists to the consumer.

Furthermore, pathogen colonization of post-harvest fruit has been shown to occur at rapid rates and is frequently dependent on storage temperature. For example, *Salmonella enterica* can outgrow other bacteria on cilantro leaves at warm temperatures (85 °F), reaching densities of up to 80 percent of the total bacteria population in as few as 3 days[25]. Similarly, in surface-inoculated tomatoes, numbers of *Salmonella* Montevideo can increase rapidly with storage time, reaching maximum density in only 1 day when stored at 85 °F[238].

B. Routes of Contamination

Produce commodities are susceptible to exposure to hazards before, during and after harvest. Although the likelihood of exposure to such hazards varies by commodity and by other factors such as cultivation and production systems, the supply chain infrastructure, and environmental considerations, the sources of potential contamination during growing, harvesting, packing, and holding are common across commodities (for example, see the FAO/WHO meeting report on fresh leafy vegetables and herbs[84]).

Over the years, FDA has obtained information that can provide insight regarding the routes of contamination during growing, harvesting, packing, and holding of produce on farms. Based on our observations during domestic and foreign inspections, investigations, and surveillance activities and other available information[57, 84, 110, 128, 169, 218], we have grouped the possible routes of contamination into five pathways: (1) Water, (2) Soil amendments, (3) Animals, (4) Worker health and hygiene, and (5) Equipment and buildings. Each is considered separately below.

One of the risk management questions that this analysis is designed to answer is, “How does produce become contaminated (i.e., what are the routes of contamination) during on-farm growth, harvesting, and postharvest operations?” The following discussion is intended to provide information that may be useful in answering this question.

1. General Data about Routes of Contamination

We have conducted a number of inspections and investigations that have provided useful information about the routes of contamination. It is important to note that the type of inspection or investigation impacts how the information informs us. For example, when we conduct a routine inspection, we review records and make observations to determine if an operation's conditions and practices appear to be consistent with the requirements of the FD&C Act and any applicable regulations. We are looking at the "adequacy" of practices and conditions at an operation compared to a set of applicable standards. In contrast, investigations conducted in response to a foodborne illness outbreak or contamination event (i.e., "for cause" investigations) still involve considering the adequacy of practices and conditions against applicable standards, but are also likely to be more focused on identifying practices and conditions at an operation, and in the environment nearby, that may have contributed to the contamination event or outbreak. We have traditionally visited farms in a "for cause" investigational capacity and not for routine inspections. Therefore, our observations are reflective of conditions and practices at operations where a contamination event likely occurred, and are not necessarily representative of conditions and practices across the entire industry. Our inspections, investigations, and surveillance sampling activities are described in more detail in accompanying documents[57, 118, 169, 218].

From 2005 to 2014 FDA conducted over 30 farm investigations (domestic and foreign) in response to produce-associated outbreaks. Some investigations involved visiting multiple field locations and packing operations. The commodities of concern included tomatoes, lettuce and leafy greens (lettuce, basil, parsley, cilantro, and salad mix), melons (honeydew and cantaloupe), pistachios, papaya, berries, hot peppers, and sprouts. The causative agents identified were bacterial, viral, and parasitic pathogens. There were over 39 observations made during the course of these investigations that revealed practices associated with the growing, harvesting, packing and/or holding of the implicated produce commodity that were possible routes of contamination in the outbreaks[57, 118]. These observations, listed in Table 6, were recorded during the investigations and are, for the most part, the kinds of concerns that can be detected visually, collected through interviews, or via sampling and laboratory analysis. Moreover, our observations are reflective of conditions and practices observed at a point in time that may be distant from the actual contamination event. For example, the presence of animal droppings can be detected visually, even some time after the animals have left. On the other hand, contaminated water generally cannot be detected visually and is often transient, although certain defects that can lead to contaminated water, such as an improperly maintained wellhead, can be detected visually. Further, it should be recognized that there is interplay among the routes of contamination. For example, animals in or near water sources can contaminate the water. In addition, a limited number of contamination events are investigated for potential routes of contamination. This table is best thought of as a list of possible contributing factors noted during the investigations.

Table 6. Possible Routes of Contamination Based on FDA Farm Investigations [57, 118]

Area	No. of Observations
Water	**7**
Soil amendments	**2**
Animals	**8**
Worker health and hygiene	**9**
Equipment and buildings	**13**

Limitations of this information about routes of contamination include: 1) our observations are reflective of conditions and practices at operations where a contamination event likely occurred, and they are not necessarily representative of conditions and practices across the entire industry; 2) observations recorded during the investigations are, for the most part, limited to the kinds of concerns that can be detected visually, collected through interviews, or via sampling and laboratory analysis; 3) our observations are reflective of conditions and practices observed at a point in time that may be distant from the actual contamination event; 4) a limited number of contamination events are investigated for potential routes of contamination; and 5) observations do not necessarily indicate the actual routes of contamination of produce but rather suggest possible routes of contamination, based in some cases on very limited investigational data..

We acknowledge that there may be other, as yet unidentified, routes of contamination that may contribute to produce contamination. Note, however, that our focus on these potential routes of contamination is consistent with conclusions of other relevant reports, (such as Codex Guidelines, NACMCF review, WHO/FAO report), which identified the following potential routes for pathogenic contamination or cross contamination during growing, harvesting, packing, and holding: water; manure (including soil amendments and manure deposits from wild and domestic animals); workers; and buildings and food contact surfaces[83, 110, 128, 157].

2. Water

Water is used extensively in produce growing (e.g. irrigation, frost protection, direct application of pesticides) and harvesting (e.g., hydration, washing, rinsing, and cooling) operations. Water can be a carrier of many different microorganisms of public health concern including pathogenic strains of *E. coli*, *Salmonella, Shigella, Cryptosporidium parvum*, and *Giardia lamblia* and viruses, such as hepatitis A virus. If present, pathogens can potentially enter a water system anywhere along its continuum from its source to distribution and use.

Some farms have a variety of water sources available to them for performing various activities. These include public or municipal water, ground water (wells or springs), surface water sources, including natural rivers, and reservoirs or man-made containment structures such as ponds, catches, and storage tanks. Other farms may be more limited in availability of source water, relying, for example, on untreated surface water for all irrigation and crop protection sprays and treated water for postharvest operations. Although different water sources may share vulnerabilities to contamination, each may differ with respect to the degree and magnitude to which they are susceptible to those vulnerabilities.

a. Water Sources and Factors that Affect their Quality

Public water systems provide water with the lowest likelihood of being contaminated with pathogens. In the U.S., public water systems are required to meet national standards for safe, clean water suitable for drinking, set by the U.S. EPA National Primary Drinking Water Regulations (NPDWR) in 40 CFR 141, under the authority granted to the agency by the Safe Drinking Water Act (SDWA). The microbiological standards of the NPDWR are based upon the maximum contaminant level (MCL) for microbiological contaminants, as determined by the presence or absence of total coliforms in a sample. For any public water system, sampling frequency is determined as a function of the size of the population it serves. Water systems that are required to collect at least 40 samples per month are in compliance with the MCL for total coliforms if no more than 5.0 percent of the samples collected during a month are total coliform-positive (40 CFR 141.63(a)(1)), while systems that are required to collect fewer than 40 samples per month are considered in compliance if no more than one sample is total coliform-positive (40 CFR 141.63(a)(1)). Under such sampling, testing and reporting, water supplied by a public system is not reasonably likely to be a source of pathogen contamination to produce, as long as it is not contaminated after delivery to the farm. For example, during 2007-2008, 16 outbreaks were associated with drinking water supplied by public water systems (drinking water systems under the jurisdiction of EPA regulations and water utility management). These outbreaks represent only a small fraction of the water delivered by the estimated 153,530 public water systems operating in the US during this period[28]. It should be noted that water testing alone does not ensure safety or reduce the likelihood of contamination of a water supply, rather, water test results provide information on the quality of water and inform appropriate use of the water under control systems such as the NPDWR.

Generally, ground water sources, such as properly designed, located, and constructed wells, provide high quality water and show little variability due to the natural filtering capacity of soils[53, 102]. Water obtained from deep underground aquifers is also considered fairly constant in composition because it is not expected to be subject to rapid fluctuations due to environmental factors (such as runoff, precipitation, erosion) that may adversely affect the quality of surface waters. However, ground water from wells can be compromised and their water quality degraded if the wells are poorly constructed, in disrepair, or improperly located (e.g., near septic systems, areas of livestock production, fields where manure is applied), or the ground water is under the direct influence of surface water[114, 123]. In these cases, wells have been found to contain fecal pathogens[114, 123]. Such contamination is more likely to occur in shallow wells, where conditions and practices occurring on the surface have a greater influence on water quality [53]. Cracked casings, landfill leaks, and failed septic tanks may directly impact ground water quality of the well, although the extent to which water quality may be affected is not fully known because of the general absence of routine monitoring, testing, and treatment[178].

Despite the protections inherent in ground water sources, contamination of this water source has been reported. A survey of 183 drinking water outbreaks (1991-2002) found 76 percent were associated with groundwater sources[178]. In another survey reported across 20 states, 19 of 166 (11%) groundwater survey sites were positive for *Cryptosporidium*, *Giardia*, or both[155]. A more recent survey found among 21 drinking water outbreaks (2007-8), 13 (61.9%) were due to untreated groundwater that was under the influence of surface water[28]. Ground water under the influence of surface water remains a significant concern to public health. Close et al., 2008, reported that in wells located near fields where border strip irrigation was used to irrigate dairy farm pasture *E. coli* and

Campylobacter were detected in 75 percent and 12 percent, respectively, of groundwater samples. It was estimated that drinking water from those wells would result in a 60-75 percent probability of *Campylobacter* contamination over the period of time in which border strip irrigation was practiced [53].

Environmental factors have an even greater influence on surface waters than they do on ground water. Examples of agricultural surface waters include natural flowing rivers and streams, man-made irrigation ditches and open canals. Other surface water sources include natural ponds, reservoirs, lakes, and on-farm containment structures such as ponds, and holding impoundments. By their nature, surface waters are open systems, subject to the influence of various environmental factors that can impact and change the system continually. For example, increased precipitation or storm events may result in a spike in water turbidity due to redistribution of sediments, which is readily observable over a brief period of time[102, 145]. Habitat and flow alterations, oxygen depletion, and high levels of nutrients also adversely affect the water quality of surface waters[215, 216]. The potential for human pathogen contamination, as indicated by the presence of indicator organisms, is the leading cause for impairment of US rivers and streams, affecting approximately one third of all impaired miles or approximately 70,000 miles over the most recent EPA reporting period [216]. The potential for human pathogen contamination is less acute in US lakes, ponds, and reservoirs, which was the 8th ranking cause of impairment in these water bodies. Pathogen contamination in lakes, ponds and reservoirs was the cause of impairment for only 5 percent, or approximately 528,000 acres of all impaired lakes, ponds and reservoirs that were reported [216]. In general, surface water is always more susceptible to contamination than groundwater because of the potential for direct discharge of sewage and input of runoff from rainfall events[102, 166, 197]. On-farm surface water held in impoundments, catches, and ponds allows farms to exercise a greater degree of control over discharge and runoff into those sources compared to flowing surface waters, such as rivers and canals. For example, walls or earthen berms may minimize the influence of runoff into a water source. Natural flowing waters are not only exposed to the same types of factors as ponds, reservoirs, and on-farm water containment structures, but their composition and chemistry can be expected to be largely influenced by their course through land used for purposes that may lead to their contamination and, potentially, to the contamination of produce exposed to those waters. Further, surface water quality can be greatly and rapidly influenced by natural occurrences such as seasonal changes in rainfall, bird migration patterns, changes in prevailing wind, blowing dust, erosion, sediment suspension, and similar events – all of which add a significant degree of uncertainty as to the quality and reliability of surface water sources, requiring an understanding of the quality of water used from surface water sources.

In 2010, we conducted an environmental assessment in response to a foodborne illness outbreak involving 33 cases of STEC O145 infection in five States. An epidemiologic investigation found that illnesses were associated with consumption of shredded romaine lettuce processed at a single firm in Ohio. Our investigation at the fresh-cut processor did not identify a likely source of contamination at the firm, suggesting that the initial contamination probably originated on the farm. It was hypothesized that this initial contamination was likely spread to many bags of product during commercial processing. We traced product back from the processor to a farm in Arizona. This outbreak was the first produce-associated outbreak of *E. coli* O145, and was the first outbreak associated with produce grown in this region. An environmental assessment at the farm identified six potential sources of STEC: three concentrated animal feeding operations (CAFOs); one housing development with a co-located sewage treatment facility; seasonal grazing of sheep on harvested wheat and alfalfa fields in the area; and, one recreational vehicle (R.V.) park with multiple septic leach systems. Based upon the R.V. park's location above the lateral canal; the direct drainage into the canal from the R.V. park property; the multiple septic systems on the property and subterranean moisture in the area that drains into the lateral canal; soil survey findings; positive STEC samples (though non-outbreak strain) from the lateral canal at the R.V. park and at the farm; and the fact that water from this canal section services the suspect farm and only one other farm, we determined that this R.V. park was the most likely source of contamination. On December 29, 2010, we posted a report, entitled "Environmental Assessment: Non-O157 Shiga Toxin-Producing *E. coli* (STEC): Findings and Potential Preventive Control Strategies"[56], outlining the environmental assessment approach used in this investigation, our observations and tentative conclusions.

b. Application Method during Growing

Reducing the likelihood of contamination from water requires that consideration be given not only to the microbial quality of the water but the intended use and application of the water. The combination of these factors (quality, when and how water is applied) are controllable in that changes in one or more of them may lower the likelihood of produce contamination. For example, using a single contaminated water source, Stine et al. (2005) [194]reported significantly lower amounts of contamination in lettuce when the water was applied by subsurface drip irrigation than by overhead spray. They also reported that furrow irrigation can increase contamination by up to 2 log over subsurface drip irrigation[193, 194]. Solomon et al., reported higher *E. coli* transfer rates to lettuce when irrigation water was applied via overhead spray compared to subsurface drip irrigation[192]. They reported *E. coli* O157:H7 transferred to 90 percent of lettuce plants by overhead spray compared to 18 percent for subsurface irrigation[192]. The location of the harvestable or edible portion of the plant in relation to the water applied also can affect the potential for pathogen contamination. Pathogen transfer onto low-growing crops (e.g., root crops, lettuce) was reduced by up to 2 log through use of drip irrigation as compared to overhead spraying; a 4 log reduction occurred for higher-growing crops (e.g., tomatoes)[232]. Stine et al. (2005) also reported the location of the harvestable portion of a plant in relation to irrigation water plays a significant role in contamination in studies of lettuce, cantaloupe, and bell pepper[194].

c. Timing of Application

The timing of water application can affect the potential for produce contamination. Water that is adequate for use weeks before harvest may not automatically be considered adequate for the same use the day prior to harvest. Generally, bacteria or pathogens in water that is applied early in the growing cycle are subject to die-off from several environmental forces (UV exposure, temperature, humidity, presence of competitive organisms)[232]. In contrast, pathogens present in water that is applied to the harvestable portion of plants shortly before harvest may not be exposed to the same environmental conditions for sufficient time to provide a similar magnitude of die-off. The WHO (2006) estimated pathogen die-off from crop surfaces post-irrigation (0.5-2.0 log per day) is dependent upon climate (temp, UV exposure, humidity), time, and crop type [232]. Stine et al estimated the population densities of *Salmonella* and HAV in irrigation water that would result in a risk of infection from waterborne pathogens greater than 1:10,000 per year[194]. They reported that over a 3-log decrease in the density of *Salmonella* and 2-log decrease in the density of HAV-contaminated irrigation water is required to meet the benchmark annual risk of infection when cantaloupe and lettuce plants are irrigated 1 day prior to harvest, compared to densities calculated when plants are watered 14 days prior to harvest [194]. Crop protection sprays also can be utilized during periods shortly prior to harvest. Crop protection sprays utilize chemistry that is usually specific to targeted pests or plant pathogens, and cannot be expected to eliminate human pathogens[107]. Water used for crop protection that harbors pathogens can contaminate produce (e.g., raspberry) [111]. Postharvest water (e.g., for washing) is also a potential source of contamination. As water used in postharvest practices is frequently the last application of agricultural water before packing, storage, and transportation, it is often disinfected to minimize the potential for contamination. However, sanitizers used in postharvest wash water to minimize cross-contamination during washing do not effectively eliminate *E. coli* (< 1 log reduction) from previously contaminated lettuce [140]. Maintaining an effective sanitizer concentration in wash water is critical to reducing the potential for pathogen cross-contamination through the water as demonstrated by one study, where the *E. coli* population on un-inoculated lettuce increased from 0 to 3.4 log colony forming units (CFU)/gram (g) after 1 minute wash in unsanitized wash water previously contaminated by lettuce inoculated at 5.4 log CFU/g [140].

d. Water Quality during Specific Farm Activities and Practices

The quality of water affects the likelihood of contamination and the risk of illness. A study performed by Wood et al. (2010) on spinach found that the contamination level of plants was greatly influenced by the amount of *E. coli* present in the irrigation water [231]. They found that water quality (loading rate) accounted for 77 percent of the variation in initial *E. coli* colonization densities on spinach [231]. In studies of lettuce irrigated by wastewater, it is estimated that a 2-log increase in water quality (from 3 log to 1 log *E. coli* per 100 ml) would result in a 3-log reduction in median risk (per person per year) of rotavirus, *Campylobacter* and *Cryptosporidium* infection [232].

The World Health Organization (WHO) has developed a recommended framework for the safe use of reclaimed wastewater in agriculture [232]. The WHO presents several illustrations for reducing risks associated with consuming raw crops irrigated by wastewater. However, these are only examples of how to apply the guidelines to reach the health-based target and do not represent specific water quality criteria for particular commodities. The guidelines recommend several health protection measures, each of which can be used alone or in combination to achieve a specific microbial log reduction or range of microbial reductions necessary to meet the desired ($\leq 10^{-6}$ DALY) health outcome. In the absence of full wastewater disinfection, the WHO approach rests on a multi-step process, each with incremental microbial reductions, in order to meet the overall necessary microbial reductions. The initial step of the multi-barrier process begins with wastewater treatment, which is followed by subsequent protection measures to achieve the final health-based target of $\leq 10^{-6}$ DALY per person, per year. For example, for use of domestic sewage effluents during the growing of produce to be consumed raw, a total 7 log microbial reduction is recommended for root crops, which can be achieved either through a tertiary (multi-step) treatment and disinfection of the wastewater (7 log reduction); or through combinations of primary treatment of the wastewater (e.g., solids separation) and secondary treatment of the wastewater (e.g., activated sludge), followed by other protective measures such as application of the treated wastewater through drip irrigation (2-4 log reduction), pre-harvest intervals allowing for in-field microbial die-off after irrigation (0.5-2 log reduction per day), and consumer washing of produce (1 log reduction) [232].

Specific farm activities and personal sanitation practices present an even greater need for care with regard to the adequacy of water quality. These include: washing hands; sprout irrigation; harvest, packing and holding activities where direct contact with produce occurs (e.g., washing, cooling) or direct contact with food contact surfaces occurs; making treated agricultural tea; (IV.B.3.b); and making ice that will contact produce or food-contact surfaces.

Waterborne pathogens can be easily transferred to produce if contaminated water is used for hand washing or in harvest, packing or holding activities where it directly contacts produce or surfaces that contact produce. It is reasonably likely that pathogens could survive in the water until such time as they find harborage on plant surfaces during these activities[166]. These events occur most often, and are of greatest concern, during harvest, packing, and holding activities (e.g., cooling and packing), leaving little opportunity or time for pathogen die-off that occurs in the course of field exposure (e.g., irrigation, some crop protection sprays). The presence of pathogens in water used for sprouting seeds and in the production of treated agricultural teas compromises food safety because the high nutrient, high moisture conditions in these situations not only support pathogen survival but are conducive to their propagation [119].

It is a common practice to re-circulate or re-use water during on-farm activities that involve the use of water (except for sprouting operations which typically use water only once per batch of sprouts). Steps where water is frequently used on multiple batches of produce include dump tanks, washing, water-mediated transport (flumes), and cooling. In the interest of energy and water conservation, farms may also capture water used in one operation (such as the final rinse before packing) and re-use or re-circulate that water for use in an earlier postharvest process step, such as a hydro-cooling, dump tank or flume transport[182, 196, 198].

Water removes excess dirt and debris, which also should reduce the population of loosely-attached pathogens that may be present on easily accessible commodity surfaces. However, postharvest water may also serve as a vehicle for pathogen transmission (if present) if measures are not taken to reduce the likelihood of contamination, particularly if water is re-circulated or re-used for multiple batches of produce when high organic loads are present in the system with an inadequate concentration of sanitizer. Research has shown that re-circulated water used in postharvest activities, in the absence of adequate disinfectant, can accumulate both human and plant-disease-causing microorganisms which may be transmitted to produce from water and from one produce item to another[195, 198]. Gagliardi et. al. demonstrated this significance for cantaloupe operations in 1999 when the researchers found significantly higher populations of coliforms, fecal coliforms and enterococci on washed and hydro-cooled melon rinds than on field-match controls [98].

Processes that use water in a single use (or single pass) are less likely to contaminate produce than those involving water re-circulation or re-use because the water contacts a limited amount of produce and has less opportunity to accumulate dirt, debris, and pathogens (if present). Sprouting operations, although most involve single-use irrigation systems, present a unique situation in that any level of foodborne pathogen contamination (from seed, water or equipment) can exponentially increase to contaminate the entire batch of sprouts within 24hrs (see discussion in Section IV.C.1). Because of the higher costs associated with single use water, it is most often used for processes toward the end of the produce production cycle, before sale to consumers. Examples include the final spray wash on cantaloupe or citrus fruits prior to packing.

The use of water, without adequate concentration of disinfectant, that contacts multiple produce units or food contact surfaces increases the likelihood that the water will cross-contaminate other produce with which it comes into contact[195]. Physical force generated by spray washing and hydro-cooling may aerosolize water or form droplets that may carry pathogens, thereby facilitating cross contamination to other produce and from food contact surfaces or the packing environment to other produce lots over time. The use of adequate disinfectant greatly reduces the likelihood of cross contamination during these handling steps and increases the likelihood that produce will be microbiologically safe for consumption[198].

e. Conclusions about Water Use

- **Agricultural water can be a source of contamination of produce.**
- **Public Drinking Water Systems (domestically regulated by the EPA) have the lowest relative likelihood of contamination due to existing standards and routine analytical testing.**
- **Though less likely to be contaminated than surface water, groundwater continues to pose a public health risk, despite the regulation of many U.S. public wells under the Ground Water Regulation.**
- **There is a significant likelihood that U.S. surface waters will contain human pathogens, and surface waters pose the highest potential for contamination and the greatest variability in quality of the agricultural water sources.**
- **Susceptibility to runoff significantly increases the variability of surface water quality.**
- **Water that is applied directly to the harvestable portion of the plant is more likely to contaminate produce than water applied by indirect methods that are not intended to, or not likely to, contact produce.**
- **Proximity of the harvestable portion of produce to water is a factor in the likelihood of contamination during indirect application.**
- **Timing of water application in produce production before consumption is an important factor in determining likelihood of contamination.**
- **Commodity type (growth characteristics, e.g. near to ground) and surface properties (e.g., porosity) affect the probability and degree of contamination.**
- **Microbial quality of source waters, method of application, and timing of application are key determinants in assessing relative likelihood of contamination attributable to agricultural water use practices.**

The following table considers the data citations and conclusions drawn above to present a relative comparison of the likelihood of contamination attributable to practices related to water. Factors are listed in the heading column on the left, and variables in how these factors may impact produce safety are listed in the row, with practices increasing in relative likelihood of contamination to that factor (only) as read left to right. Relative likelihood is read only left and right (across columns within individual rows); no implied comparison is made within columns (up and down). We provide a similar table for soil amendments in the section that follows.

Table 7. Relative Likelihood of Produce Becoming Contaminated with Pathogens of Public Health Concern from Agricultural Water

	Least ⟷			Most
Source	Public Drinking Water	Ground water	Surface water protected from runoff	Surface water unprotected from runoff
And where contamination is known to exist, the likelihood of contamination is a function of the following factors:				
Contact with commodity	Indirect contact		Direct contact	
Commodity effects	Unlikely infiltration		Susceptible to infiltration	
	Surface not conducive to adhesion		Surface conducive to adhesion	
Application timing	Early in crop growth	Late in crop growth	During harvest	Postharvest

3. Soil Amendments

It has long been recognized that pathogens can be introduced to fruit and vegetable production systems by the application of manures or sewage sludges as soil amendments[185]. Fecal material has been shown to contain human pathogens[126, 135, 172, 232, 236], and the use of manure-containing soil amendments as an agricultural input increases the likelihood that produce may become contaminated[126]. Soil amendments, such as partially composted manure, raw manures or agricultural teas made from such materials, are potentially significant reservoirs of human pathogens.

a. Use and Utility of Soil Amendments

Soil amendments include those additives intended to facilitate plant health, production and growth, and improve soil tilth by altering soil pH, increasing organic matter, decreasing compaction, or increasing water-holding capacity. Such amendments allow crops to be grown in soils that otherwise would be un-arable or may be nutrient depleted due to repetitive cropping cycles and also enhance the growth and production of plants. Manure, a widely used crop soil amendment, is estimated to be used on 5 percent of all US cropland[211]. Commercial fertilizers most commonly consisting of nitrogen, phosphorous, and potassium are commonly used, and generally consist of synthetically refined nutrients, often originating from fossil fuels or mined minerals. In recent years, the price of commercial fertilizers has increased dramatically, largely due to increasing fuel costs. For example, the price of nitrogen increased by 100 percent and that of phosphate rose by 115 percent between 2000 and 2007[213]. Such price hikes have made manure-containing amendments more attractive to growers.

As the number and size of animal production facilities continue to increase, land acres available for animal production and grazing continue to decrease[212]. In addition, as manures are concentrated around livestock production areas requiring the disposal of this waste, it can be expected that manure-containing soil amendments will continue to be used in food production. However, use of manures as soil amendments can pose environmental and human health risks when stockpiled or applied to fields, as they may transmit human pathogens from croplands to surface water, ground water, or the crops to which they have been applied. However, there are limited data directly linking produce-associated foodborne outbreaks to the use or improper handling of soil amendments. Known examples include an occurrence of *E. coli* O157:H7 in rural Maine linked to a home garden amended with on-site cattle manure [52] and a Canadian outbreak of *L. monocytogenes* linked to coleslaw made from cabbage grown with contaminated sheep manure[185].

b. Types of Soil Amendments

Soil amendments can be divided into two very broad categories: chemical or physical soil amendments (inorganic) and biological soil amendments (organic). Chemical or physical soil amendments include elemental fertilizers (e.g., potash, aqueous nitrates), soil stabilizers (e.g., sand or crushed rock), and other, often commercially available products typically made of mined or synthetic materials. Such soil amendments have not been shown to be sources of microbial contamination. Biological soil amendments include any material that originates from living organisms, such as animals (e.g., waste such as manure, carcasses, bedding litter, feathers, egg shells) or plants, and are applied to a growing field for the purposes of enhancing the soil's tilth, to provide proper structure, microbiota and nutrients to enhance the growth of produce in the amended soil.

Agricultural teas are a type of biological soil amendment that originates from other biological soil amendments (e.g., composted animal waste and/or plant material). Agricultural teas are made by steeping biological materials in water to create an emulsion (i.e. extract) of nutrients and beneficial microorganisms from the biological feedstock in a concentrated and aqueous form, allowing for easy and directed application that does not increase the mass of the soil to which it is applied. Agricultural teas that contain "amendments," such as molasses intended to enhance the growth of beneficial microorganisms, have been shown to increase the populations of foodborne pathogens compared to teas that do not have such amendments, even when the initial population of pathogens was at very low levels in the biological materials (approximating 10 cfu/g dry weight) [119]. In some studies, agricultural teas have shown efficacy as bactericides [2] and fungicides [181] when applied directly to the phyllosphere (the above ground surfaces of plants). To the extent agricultural teas are being used as pesticides, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (7 U.S.C. 136 et seq.) provides for federal regulation of their distribution, sale, and use. All pesticides distributed or sold in the United States must be registered (licensed) by the U.S. Environmental Protection Agency.

c. Pathogens in Soil Amendments

Biological soil amendments can be further subcategorized as those that contain animal waste (e.g., biosolids or raw sewage, mortalities, manure, and animal excreta), and those that do not contain animal waste (e.g., yard trimmings or other greenwaste). Animal wastes, such as animal carcasses, manure and excreta, are well-documented sources of numerous human pathogens, as are live animals, including those that only sporadically show symptoms [179] or that may be asymptomatic shedders[149, 236], including cattle that may harbor and shed, but not be ill or show outward signs of *E. coli* O157:H7 infection. Animal waste has been shown to harbor many bacterial pathogens (e.g., *Campylobacter*, *Salmonella* spp., enterohemorrhagic *E. coli*) and various other pathogens such as parasites (e.g., *Cryptosporidium parvum*, helminthes), which may infect humans. The type of pathogen that may be present and its population density are dependent on the source of the manure (e.g., *E. coli* O157:H7 is more common in ruminants such as cattle, whereas *Salmonella* is more common in fowl such as chickens) and the rearing practices of the source animals (e.g., animals from densely populated farms or farms with a high population of immature animals have an increased likelihood of harboring various pathogens)[177]. Other factors may also impact fecal excretion of pathogens, including species of animals, age, health status, diets, seasonal effect, and farm practices[62, 131]. Wastes from some animals, such as animals from domestic production [177] or wild animals closely associated with human activities (e.g., rats[159]), present a greater likelihood of harboring pathogens, of harboring a greater diversity of pathogens, and of harboring human pathogens of higher virulence. A biological soil amendment of animal origin can spread pathogens to produce by either directly or indirectly contacting the produce [66, 176].

Most enteric (or gastrointestinal) pathogens are not generally considered to be associated with plants, and are more commonly expected to be derived (and in higher populations) from a human or animal source (e.g, through feces, mortalities, blood, spittle, etc.)[234]. Material that does not contain any animal or human waste is far less likely to harbor these food safety hazards at microbial populations that can reasonably be expected to lead to severe adverse health consequences or death[54].

While some, but not all, pathogens of animals are zoonotic (i.e., capable of also infecting humans), pathogens originating from humans and found in human waste can all potentially infect new human hosts[214]. Human waste has the highest probability of containing multiple human pathogens[214], including bacteria, parasites and viruses, at potentially very large populations (e.g. ≥ 8 log cfu/g) [214, 232]and is likely to contaminate produce if used as an untreated soil amendment[214]. Agricultural land use of these materials is subject to regulations established by EPA (40 CFR part 503).

Mortality composting (composting of dead animals) is used as an agricultural soil amendment and presents a potential source of human pathogens in the farm environment[71]. The likelihood of contamination associated with the use of composted mortalities in the growing of produce is not well documented. Some states have adopted regulations or provided guidance to address mortality composting (e.g., Iowa State Department of Natural Resources http://www3.abe.iastate.edu/PigsGone/Regs.htm; Colorado State University http://www.cvmbs.colostate.edu/ilm/proinfo/necropsy/notes/composting.htm). We expect that mortality compost can present a similar likelihood of contamination as presented by other composted manure-containing feedstocks[71].

Animal excreta, primarily manure, are the most commonly used biological soil amendment of animal origin in the production of produce. The likelihood of contamination from animal excreta is considered to be relatively high due to its potential to harbor zoonotic pathogens at potentially high population levels [225] (populations of *Salmonella* spp., e.g., have been detected in amounts up to 7 log CFU/g in feces of healthy animals [112, 116, 126, 172]. Also, biological soil amendments of animal origin are expected to have a high content of available nutrients and minerals, including those expected to support rapid and prolific microbial population growth, provided that sufficient moisture is available[132]. However, unlike in the case of biosolids, not all of the microorganisms present in animal excreta are expected to be zoonotic (i.e. human pathogens). Moreover, some human pathogens would not be expected to be found in non-human excreta (e.g., *Shigella* and HAV) [8, 35, 43, 78].

Biological soil amendments consisting of plant material (i.e., greenwaste), such as yard trimmings, are a common component of compost. Plant debris from yard waste may be contaminated with any pathogens contained in feces from wild or domesticated animals. Material that does not contain any animal waste is far less likely to harbor these food safety hazards at microbial populations that can reasonably be expected to lead to severe adverse health consequences or death[227]. We conclude that biological, chemical or physical soil amendments that do not contain animal waste or human waste (e.g. yard trimmings, pre-consumer vegetative waste, lime, vermiculite, potash, aqueous nitrates, and sand or crushed rock), have a low likelihood of containing a biological hazard, such as human pathogens. Moreover, we are unaware of a situation in which these soil amendments have served as sources of microbial contamination. We consider the likelihood that a biological soil amendment of mixed plant and animal origin may harbor and spread various microbiological hazards to be equivalent to the likelihood that a biological soil amendment of animal origin may harbor and spread microbiological hazards. Post-consumer waste, or table waste (such as plate scrapings), also has the potential for containing human pathogens due to its unknown content (e.g., animal products, vegetable products, etc.) and its greater likelihood of containing human fluids or waste (e.g., spittle, vomitus, etc)[70].

d. Treated Biological Soil Amendments

Materials intended for use as biological soil amendments can be treated to reduce the population of microbial human pathogens that may be present. Biological, chemical, or physical treatments can be used to reduce the likelihood of contamination associated with using biological soil amendments [214] in the production of produce. Composting, which is the most common treatment, involves the biological degradation of feedstocks through many successive stages of breakdown by various microbiological populations which alter the chemical and physical nature of the feedstocks into a humus-like, chemically stabilized and homogenous product. The composting process is considered to be a biological treatment because the metabolic activity of certain microorganisms can dramatically and rapidly reduce pathogen populations through thermal inactivation, competition or predation [214]. However, due to its variable nature and lack of a standardized process, composting cannot be assumed to be a complete kill step [27, 226]. Physical or chemical treatments other than those due to composting, alone or in combination, can also be effective at significantly reducing or eliminating human pathogens in soil amendments, in some studies up to 8 log CFU per gram[112, 222]. Physical and chemical treatments that are commonly used include heat, pH adjustment, and ammonia saturation [112, 126, 214]. However, improperly controlled treatment steps may instead enhance the survival of human pathogens in biological soil amendments[187]. Similarly, cross-contamination of treated biological soil amendments of animal origin with sources of human pathogens (e.g., untreated biological soil amendments of animal origin, raw animal feces) can lead to growth of pathogens in the previously treated biological soil amendment of animal origin[188].

Application methods, too, can affect likelihood of contamination from soil amendments. In general, human pathogens in biological soil amendments applied to a field decrease in population over time, but the rate of decline and the overall survival of pathogens is highly variable depending on multiple factors (e.g., source of manure, temperature of soil, UV exposure, moisture level, pathogen in question, ecological diversity of the soil) [123, 225]. Any microbial pathogen in the soil amendment will survive for a longer period of time if the amendment is incorporated into the soil, but run-off and spread of any microbial contaminant present in a soil amendment is greatly increased if the amendment is allowed to remain unincorporated on the surface of the soil [115]. In produce production, the most common practice is to incorporate the amendment into the soil soon after (or during) application. If an amendment is not thoroughly mixed into the soil or left on the surface of the soil during the growing of produce, its efficacy as a soil amendment is greatly reduced may interfere with water movement and reduce root growth potential.

Use of adequate time intervals between the application of a soil amendment and the harvest of produce can also affect the likelihood of human pathogen persistence in the amendment. Increasing this time interval, coupled with unfavorable environmental conditions for the pathogens that may be present (e.g., lack of nutrients and water and a high UV index), has been shown to reduce, although not necessarily eliminate, the likelihood of human pathogen persistence[126]. The survival time of microbes in field-applied soil amendments can vary greatly from days, months, or years [115, 125, 126, 214, 228, 235]. Similarly, the efficacy of time intervals can be greatly influenced by numerous factors such as crop, production practices, initial pathogen load, soil type, and agronomic growing conditions. Equally, application methods may impact the likelihood of contamination of produce by applied soil amendments. For example, overhead spreading while the above-ground harvestable portion of produce is present in the field is likely to lead to produce contamination via direct contact [176]; conversely, subsurface application, or a surface application followed by turning the soil prior to planting, is less likely to contaminate produce[115].

e. Conclusions about Soil Amendment Use

- **Soil amendments can be a source of produce contamination.**
- **Biological soil amendments of animal origin have a greater likelihood of containing human pathogens than do chemical or physical soil amendments or those biological soil amendments that do not contain animal waste (e.g., plant-based soil amendments).**
- **Human waste is the most likely waste to contain human pathogens.**
- **Animal waste subject to treatments, such as chemical and physical treatments and composting, has relatively lower levels of human pathogens than untreated animal waste.**
- **Composting is less likely than controlled chemical or physical treatments to fully eliminate human pathogens from animal waste.**
- **Incompletely treated, or re-contaminated, biological soil amendments of animal origin may also contain human pathogens.**
- **Human pathogens in untreated or composted biological soil amendments, once introduced to the growing environment, will eventually die off, but the rate of die-off is dependent upon a number of environmental, regional, and other agro-ecological factors.**
- **Among application methods, application of soil amendments in a manner in which they contact the harvestable portion of the crop presents the greatest likelihood of contamination, especially when applied close to harvest.**

The following table considers the data citations and conclusions drawn above to present a relative comparison of the likelihood of contamination attributable to practices related to soil amendments.

Table 8. Relative Likelihood of Produce Becoming Contaminated with Pathogens of Public Health Concern from Soil Amendments

<table>
<tr><th></th><th colspan="12">Least ⟷ Most</th></tr>
<tr><td>Type</td><td colspan="3">Non-Biological (e.g., elemental)</td><td colspan="3">Non-Animal Origin</td><td colspan="3">Animal Origin</td><td colspan="3">Human waste</td></tr>
<tr><td colspan="13">And where contamination is known to exist, the likelihood of contamination is a function of the following factors:</td></tr>
<tr><td>Treatment</td><td colspan="4">Pasteurized (heat, chemical, physical)</td><td colspan="4">Composted</td><td colspan="4">Untreated/Raw; Partially treated; Re-contaminated</td></tr>
<tr><td>Application timing</td><td colspan="6">Further from harvest</td><td colspan="6">Close to harvest</td></tr>
<tr><td>Application method</td><td colspan="4">No contact with harvestable portion</td><td colspan="4">Effort made to minimize contact</td><td colspan="4">Contact with harvestable portion</td></tr>
</table>

4. Animals

Feces from warm-blooded mammals, birds, and reptiles are considered to be a primary source of many pathogens that may affect the safety of produce[96]. Animals are a likely source of contamination of produce with human pathogens, and have been identified as a likely cause of illness [36, 85-87, 96, 124]. Many species of domestic and wild animals are potential carriers of human pathogens, with both the incidence and concentration of human pathogens varying widely depending upon the animal species [69, 70, 97, 137, 145, 159, 162, 177].

a. Animals as Carriers of Pathogens

It is well-established that animal excreta are a source of pathogens [126, 135, 149, 172, 177, 179, 185, 232, 236], sometimes containing them at very high populations (such as *Salmonella* spp. up to 7 log (10^7 CFU/g) [112, 116, 126, 172] and *E. coli* O157:H7 up to 5 log (10^5 CFU/g) [236] that, when present on farms, can introduce pathogens into fruit and vegetable production systems[85]. Transmission of pathogens from animal excreta to produce and, subsequently, to humans through consumption is reasonably likely in cases where the presence of animal excreta can be visually confirmed [57, 84, 85]. The potential for animals to act as vectors of human pathogens is determined by several factors, including the commodity, the species of the animal, and the animal's association with human or domesticated animal activity or waste[141].

Pathogens may be transferred to produce either by fecal shedding or by direct contact of animals with the produce[224]. For example, fecal material deposited in close proximity to a water supply, such as a well or pond used for irrigation of produce or on the soil near produce, may result in contamination of these agricultural inputs [53, 56, 102, 117, 123, 124, 192-194, 197]. Exposure of produce to animal feces may occur directly through wildlife and domestic animal droppings, or through runoff that enters the growing area, contaminated agricultural water, flood waters, and soil amendments among other means[143]. While illnesses associated with animal intrusion into produce production areas were linked to animals defecating directly on produce (e.g., spinach)[124], animals can also serve as vectors carrying pathogens on their fur or feet[51].

b. Wild and Domesticated Animals on Farm

The number and type of pathogens detected in animal feces varies with the animal species. For example, the predominant source of pathogenic *E. coli* O157:H7 from animal feces is cattle, and the predominant source of *Salmonella* spp. from animal feces is poultry [112, 126]. Cattle are also well-known carriers of different types of pathogens, including strains of *Salmonella enterica*, *C. jejuni* and other (non-O157:H7) pathogenic *E. coli* [116, 126, 235, 236]. Beyond cattle and poultry, other domesticated animals such as sheep, goats, and swine are also potential carriers of pathogenic microorganisms [180, 235]. Wild animals, including pests, can also act as carriers of human pathogens[79, 124]. Pathogenic *E. coli* have been isolated from deer, feral swine, pigeons and seagulls[79, 124, 159], and Dunn and colleagues reported that the prevalence of *E. coli* O157:H7 in white-tailed deer ranged from undetectable levels to 2.4 percent[69].

Domesticated animals [97, 177] and pests (e.g., rats[159]) are generally more likely to harbor zoonotic pathogens than are wild animals, due to their closer proximity to and interaction with humans. As wild animals interact more with humans or domesticated animals, they are more likely to become carriers of human pathogens[159].

The likelihood of contaminating produce with human pathogens from excreta from grazing and working animals or from wild animals is determined by numerous factors, including but not limited to the species of the animal, the number of animals per unit area of land, agro-ecological conditions, location of the excrement, frequency of grazing, and the time period between animal exposure in fields and the harvest of produce[6, 122, 135, 177, 224]. Domesticated companion animals such as dogs and cats can carry many zoonotic pathogens [51], including *Salmonella* spp. [7, 201]and pathogenic strains of *E. coli[18, 154]*, potentially resulting in contamination of produce or food contact surfaces if they are allowed to access these areas.

For example, on September 14, 2006, we issued a news release alerting consumers about an outbreak of *E. coli* O157:H7 in multiple states and advising the public not to eat bagged fresh spinach because it had been implicated in the outbreak[88]. During the course of this outbreak, approximately 200 illnesses were reported to the CDC, including more than 30 cases of hemolytic uremic syndrome (HUS, a condition that occurs mainly in children and can result in kidney failure), more than 100 hospitalizations, and three deaths[39]. With partner agencies, we conducted a traceback investigation using product codes from bags of fresh baby spinach, collected at case households, that led to four fields that provided product for the implicated production lot of bagged fresh baby spinach. *E. coli* O157:H7 with a pulsed-field gel electrophoresis pattern indistinguishable from the outbreak strain was found in environmental samples, including stream water, and cattle and wild pig fecal samples collected at one of the ranches. Potential contributing factors identified during this investigation included the presence of wild pigs in and around spinach fields and exposure of surface waterways to cattle and wildlife feces[124].

c. Conclusions about Wild and Domesticated Animals

- **Animals can be a source of contamination to produce.**

- **Animal excreta poses a high likelihood of contamination of produce.**
- **Excreta from domesticated animals poses a greater likelihood of contamination of produce than does excreta of wild animals. However, domesticated animals can be expected to be more readily controlled (i.e., kept apart from produce growing, harvesting, and postharvest areas).**
- **Human pathogens from animal excreta, once introduced to the growing environment, can be expected to eventually die off; but the rate of die-off is dependent upon a number of environmental, regional, and other agro-ecological factors.**

5. Worker Health and Hygiene

Human workers and visitors are potential carriers of pathogens, such as Norovirus, hepatitis A virus, *Salmonella*, *E. coli* O157:H7, *Shigella*, *Cyclospora*, and *Cryptosporidium* [106]. Bacteria, viruses, and parasites are frequently transmitted from person to person and from person to food, particularly through the fecal-oral route[4, 20, 50, 105, 151, 223]. Workers with communicable diseases who touch produce, such as lettuce, tomatoes, or cut melon, can transfer human pathogens to the produce[204].

a. Hygienic Practices and Personal Cleanliness

Hygienic practices can prevent the introduction of microbial (such as bacteria and viruses that could be present in saliva or on skin) contamination of produce[190]. Inadequate hygienic practices among workers have been associated with outbreaks transmitted by various produce commodities, including strawberries, green onions, mamey, leaf lettuce, and basil[151]. Poor hygiene may contribute to contamination of produce[151].

Jewelry that is not effectively cleaned could serve as a harborage for pathogens [207] and could contaminate produce under conditions where it comes into direct contact with produce. Eating, chewing gum (and potentially spitting the gum out), and using tobacco products (and potentially dropping cigarette or cigar butts or spitting tobacco juice) all constitute potential avenues for the dissemination of enteric foodborne pathogens[5, 190].

b. Animal Contact

Pathogens can be directly transmitted from animals to people when persons touch, pet, feed, or are licked by animals because animal hair, fur, saliva and skin can harbor pathogens[46, 58, 173]. For example, transmission of the pathogen *Giardia lamblia* from animals to humans was linked in an outbreak of foodborne illness associated with the consumption of mixed fruit salad [173]. The National Association of State Public Health Veterinarians has associated washing hands after touching animals with protection against outbreaks of *E. coli* O157:H7, *Salmonella* spp., *Cryptosporidium parvum*, non-O157 STEC, and *Campylobacter jejuni* [158].

c. Hand-Washing

Proper washing and drying of hands are fundamental practices demonstrated to be effective in breaking the fecal-oral route of contamination by reducing the number of transient pathogenic bacteria on the hands of a worker[151]. Lack of hand-washing can lead to contamination of produce[206], in particular through the fecal-oral route [4, 17, 20, 47, 105, 106, 163].

The effectiveness of hand-washing is determined by multiple factors, including whether or not soap is used, the quality of water used, the duration of scrubbing and rinsing, and whether hands are dried. Soap serves as an emulsifier that enables dirt and oil to be suspended and washed off[206]. Washing hands without the use of soap, which may reduce the duration of exposure of the hands to running water, and not drying hands after washing can promote the spread of microorganisms. For example, rinsing hands without using soap and for a shorter duration can loosen microorganisms without removing them, leaving the microorganisms more readily transferable to the next surface touched[206].

The use of potable water in hand-washing reduces the likelihood of hands becoming contaminated during hand-washing from human pathogens that may be present in non-potable water[174]. Drying hands is important because wet skin is more likely to transmit microorganisms than dry skin[206]. Cloth towels can become contaminated through use by multiple persons, and can transfer pathogens from one user to another[206].

The effectiveness of hand sanitizers has been shown to be highly dependent upon the removal of organic material from the hands prior to their use, as the presence of dirt, grease, or soil significantly reduces their effectiveness in eliminating bacteria on hands[151]. Hand sanitizer use on dirty hands is not as effective as hand washing with soap and water and should not be considered a comparable alternative [163].

d. Glove Use

The use of dirty or damaged gloves can be a source of contamination to produce [105] . While gloves also provide a barrier that can reduce the potential for pathogens on workers' hands to contaminate produce, gloves themselves, whether re-usable or disposable, can transfer pathogens to produce if the gloves become contaminated[105]. It has been reported that glove use can foster a "false sense of security" that can lead to less sanitary practices such as wearing the same pair of gloves for extended periods of time without cleaning or changing them, or washing hands infrequently[205].

e. Sanitation Issues

Inadequate or inaccessible toilet facilities can lead to contamination of produce[105]. Workers are more likely to use toilet facilities that are clean, well-stocked, accessible, and in good condition[19].

f. Conclusions about Worker Health and Hygiene

- **Humans (i.e., workers and visitors) are potential carriers of foodborne pathogens and can be a source of produce contamination.**
- **Individuals with communicable diseases that can be spread via food who are engaged in activities in which they contact produce or food contact surfaces can contaminate produce or food-contact surfaces with human pathogens.**
- **Hand-washing reduces the potential for contamination of produce. Its efficacy varies depending upon the use of soap, the quality of the water, duration of scrub under running water, and whether or not hands are dried after washing.**
- **Dirty and damaged gloves may contaminate produce.**
- **Workers or visitors that touch animals can contaminate produce or food contact surfaces.**
- **Poor hygienic practices, e.g. lack of hand washing, can lead to the contamination of produce.**
- **The presence of adequate toilet facilities in reasonable proximity to areas where relevant activities take place, including growing areas, can reduce produce contamination.**

6. Equipment and Buildings

a. Food Contact Surfaces

Food contact surfaces that become contaminated can contaminate produce (e.g., stone fruit, cantaloupe, oranges, parsley, romaine lettuce, and iceberg lettuce) [50, 66, 68, 129, 153, 168, 199, 229]. For example, it has been documented that *E. coli* O157:H7 can be transferred to Iceberg lettuce from contaminated coring devices used in simulated field coring[199]. Moreover, transfer of pathogens from stainless steel tools to lettuce has been demonstrated to various extents, depending on the amount of water on the leaf surface[153]. Relatively high numbers of bacteria may be transferred to a food from food contact surfaces, even 1 to 2 hours after surface contamination of the food contact surface occurred[153]. In addition, routine cleaning is important to prevent formation of biofilms, which have been shown to persist once established, even when later cleaning efforts are made. For example, inspection of conveyor belts used for moving intact citrus fruit on which biofilms were allowed to form have been shown to harbor a high population of fecal coliforms (> Log 3 MPN/unit) even after daily cleaning and disinfection operations [168].

Using tools that are designed to minimize the potential for pathogen transfer from soil to the produce and/or that allows for mechanical polishing to facilitate cleaning and sanitizing would enhance food safety[237].

b. Pests

Pests such as rodents[38], snakes[37], lizards[37], turtles[37], iguanas[37], and birds [36] are known to carry human pathogens, such as *Salmonella* spp. and, if not controlled, can cause the contamination of produce, food contact surfaces or food-packing materials. Pests (e.g., opossums) that enter into buildings in which produce is being grown can contaminate produce (e.g., tomatoes) with human pathogens (e.g., *Salmonella* Montevideo)[162].

Partially-enclosed buildings are less likely to restrict the entry of pests than fully-enclosed buildings[148]. Farm equipment or tools that are stored outside, or in a partially-enclosed building, may attract or harbor pests[55]. Trash and litter can provide food and shelter to pests, and thus serve as pest attractants[148].

c. Buildings

Buildings and equipment that are not easily accessible and cleanable are less likely to be properly maintained and may therefore become a source or route of contamination[90]. Also, cross contamination can occur in buildings in which multiple activities are conducted [113] (e.g., spray washing field equipment can contaminate a produce handling line if they are not adequately separated).

In 2011, we conducted an environmental assessment in response to a foodborne illness outbreak involving a total of 139 persons infected with any of four outbreak-associated strains of *L. monocytogenes*, including 30 deaths, in 28 States (as of December 8, 2011). In addition, one woman pregnant at the time of illness had a miscarriage. An epidemiologic investigation found that illnesses were associated with consumption of cantaloupe packed at a single firm in Colorado. The environmental assessment followed an inspection of the firm on September 10, 2011, by FDA along with Colorado state officials, during which we also collected multiple samples, including whole cantaloupes and environmental (non-product) samples from within the packing facility. Of the 39 environmental samples collected, 13 were confirmed positive for *L. monocytogenes* with pulsed-field gel electrophoresis (PFGE) pattern combinations that were indistinguishable from three of the four outbreak strains collected from affected patients. Cantaloupe collected from the firm's cold storage during the inspection was also confirmed positive for *L. monocytogenes* with PFGE pattern combinations that were indistinguishable from two of the four outbreak strains.

As a result of the positive sample findings and the fact that this was the first documented listeriosis outbreak associated with fresh, whole cantaloupe in the U.S., we initiated the larger environmental assessment in conjunction with Colorado state and local officials on September 22-23, 2011. The environmental assessment involved a multi-disciplinary team and included an in-depth interview with the firm's management regarding their food safety practices and procedures, as well as on-site visits to the farm, packing facility, and cold storage. We also conducted environmental and finished product sampling. Because the samples collected in the growing fields were negative for *L. monocytogenes*, whereas the environmental samples collected in the packing facility and cantaloupe collected in cold storage were positive for *L. monocytogenes*, the growing fields are not a likely source of contamination for this outbreak. However, low-level sporadic *L. monocytogenes* contamination from the agricultural environment and incoming cantaloupes may have allowed for establishment of a harborage or niche for *L. monocytogenes* in the packing facility and cold storage. In addition, we identified a number of factors that may have contributed to the introduction, growth, and spread of *L. monocytogenes* contamination within the facility, including: facility and equipment design and postharvest practices. Specific observations of potential contributing factors included: (1) a truck used to haul culled cantaloupe to a cattle operation was parked adjacent to the packing facility and could have introduced contamination into the facility; (2) facility design allowed for the pooling of water on the packing facility floor adjacent to equipment and an employee walkway to grading stations; (3) the packing facility floor was constructed in a manner that was not easily cleanable; (4) the packing equipment was not easily cleaned and sanitized; (5) washing and drying equipment used for cantaloupe packing was previously used for postharvest handling of another raw agricultural commodity; and (6) there was no pre-cooling step to remove field heat from the cantaloupes before cold storage.

On October 19, 2011, we posted a report, entitled "Environmental Assessment: Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Listeriosis," providing an overview of the assessment process, potential contributing factors in this outbreak, and recommended measures firms should employ to prevent similar contamination [90].

d. Waste and Wastewater

Improperly contained waste or wastewater may be a source of bacterial contamination leading to an outbreak [232], or may encourage harborage by animals that may be a source of bacterial contamination[90]. Cross-contamination of clean water and wastewater has been implicated in outbreak investigations [31, 32, 57, 118].

Human feces may contain pathogens in relatively high concentrations[34]. Runoff from a portable toilet facility that leaks or a fixed toilet facility that lacks proper drainage or backflow devices has the potential to directly contaminate produce, while contamination of soil and irrigation water from such runoff can have longer-lasting impact[56, 102, 145]. The importance of sanitary facilities in the safe elimination of human waste is highlighted in scientific literature[19, 105].

e. Domesticated Animals

Domesticated animals such as dogs and cats can carry pathogens, such as *Salmonella* spp. [7, 201]and pathogenic strains of *E. coli* [18, 154], potentially resulting in contamination of produce or food contact surfaces.

Studies have shown that farm animals are one of the major sources of fecal bacteria in agricultural watersheds[134, 219]. Pathogens inhabit the gut of a variety of warm-blooded animal species and have been shown to be shed in feces in high populations (such as *Salmonella* spp. up to 7 log CFU/g [172]and *E. coli* O157:H7 up to 5 log CFU/g [236]. Levels of *E. coli* O157:H7 in fresh cattle manures averaged 6 log CFU/g and as high as 8 log CFU/g wet weight in a study involving British livestock[116]. Pathogens detected in animal feces vary depending on the animal species. For example, the predominant source of pathogenic *E. coli* O157:H7 from animal feces is cattle and the predominant source of *Salmonella* spp. from animal feces is poultry[112, 235]. Pathogens such as *E. coli* O157:H7 and *Salmonella* spp. have been implicated in a number of outbreaks involving produce[59]. Domestic animal wastes may be controlled, for example, by not locating manure piles adjacent to packing sheds or growing areas in a manner such that produce may be exposed. If not effectively controlled, pathogens from domesticated animal waste may contaminate nearby production operations, persist in the environment for long periods of time, pose a threat to water quality from runoff and leaching. In addition, uncontrolled domesticated animal wastes can attract pest animal vectors [180], creating multiple opportunities for these pathogens to contaminate produce and/or food contact surfaces.

f. Transport

Improperly packed shipping vessels may lead to cross-contamination of produce, e.g., raw meats or poultry dripping on vegetables[230]. Equipment used in transporting tomatoes has tested positive for *Salmonella* at a rate of 20 percent in a study at one greenhouse[162].

g. Conclusions about Equipment and Buildings

- **Food contact surfaces are potential routes of contamination of produce.**
- **Equipment and tools that contact produce and that are designed and constructed to be cleanable minimize the potential for contamination of produce.**
- **Pests in buildings used to grow, harvest, pack, or hold produce can be a source of contamination of produce.**
- **Waste material can be a source of contamination, or may become an attractant for pests and thereby act as a source of contamination to produce, if not properly contained, stored and conveyed.**

C. Likelihood of Contamination during Growing, Harvest, and Postharvest

The risk assessment question that this analysis is designed to inform is, "Does the likelihood of contamination vary among produce commodity types?" The following discussion is intended to provide information that may be useful in understanding various factors related to this question.

1. Relative Likelihood of Contamination On-Farm

FDA performed an analysis to estimate the relative likelihood of contamination through the above described potential routes of contamination for a selected group of produce commodities. The results are presented in Table 9 and the methods are described below. Commodities included in the analysis were selected to be representative across the spectrum of produce commodities, considering their physical characteristics, agricultural practices, consumer use and consumption rates, and history of associated outbreaks.

Commodities selected for this analysis were: Almonds, Apples, Artichoke, Asparagus, Bananas, Basil, Blackberries, Blueberries, Broccoli, Cabbage, Cantaloupe (field-packed), Cantaloupe (shed-packed), Carrots, Celery, Cilantro, Coconuts, Cranberries, Cucumbers, Grapefruit, Grapes, Green onions, Honeydew, Lemons, Lettuce, Mango, Mushrooms, Onions, Oranges, Papaya, Parsley, Peaches, Pears, Peas, Peppers (hot), Pineapple, Potatoes, Raspberries, Spinach, Sprouts, Strawberries, Summer Squash, Tomatoes (field-packed), Tomatoes(shed-packed), Walnuts, Watercress, Watermelon. Where the form in which a commodity is consumed was relevant to this analysis, these commodities were considered in their raw state of consumption except for asparagus, cranberries and potatoes which were considered as processed with a “kill step” (cooked). These commodities were considered likely to be cooked before consumption based on FDA’s analysis of data from CDC’s National Health and Nutrition Examination Survey (NHANES) indicating that the percentage of the population consuming the produce commodity in fresh form as well as the percentage of eating occasions on which the produce commodity is eaten uncooked are less than 0.1% , and consumption (in any form – raw, processed, or other) was reported by at least 0.01% of total survey respondents [202].

To craft an assessment of the potential routes of contamination, stages of production were used as the first organizational level, i.e., 1) growing, 2) harvesting, and 3) postharvest). Then, potential routes of contamination were listed for each of these production stages. The potential routes of contamination considered for growing were: Seed; Water (direct application through irrigation and/or protective sprays, indirect application); Biological soil amendments of animal origin; Worker health and hygiene; Animals; and Equipment. The potential routes of contamination considered for harvesting were: Water (direct application for hydration and lubrication); Worker health and hygiene; and equipment. The potential routes of contamination considered for postharvest were: Water (direct application); Worker health and hygiene; and Equipment and buildings.

We discuss seeds as a potential route of contamination here because this route has not been demonstrated to be relevant to produce other than sprouts. We are aware of outbreaks associated with multiple sprout farms using the same lot of seed[26, 75, 156]. In addition, pathogens, such as *Salmonella* and *E. coli* O157:H7, can survive for an extended period of time on seeds and beans, as evidenced by outbreaks linked to seed that is a year or two old, so setting aside a potentially contaminated seed lot for later use does not appear to reduce the likelihood of producing contaminated sprouts from that lot of seeds or beans[77, 156]. Although the likely source of contamination in outbreaks associated with sprouts has most often been incoming seeds or beans, pathogens can also be introduced during sprout growing, harvesting, packing, and holding[156]. The sprouting process represents a unique bacterial amplification step that suggests a need for a higher level of care compared to the growing, harvesting, packing, and holding of other produce[156, 200]. In fact, in several recent investigations the most likely source of contamination has been identified as unsanitary conditions at the sprout farm[89, 144]. Introduction of even low numbers of pathogens, even intermittently, into the sprout growing, harvesting, packing and holding environment presents a likelihood that they will increase to significant numbers by the time that the sprouts are packed and refrigerated, resulting in a significantly heightened risk of serious adverse health consequences or death. Introduction of pathogens can occur, for example, when sprout growing, harvesting, packing or holding takes place in uncontrolled outside conditions.

Operations that are conducted in a building that is not fully enclosed have an increased potential for exposure to airborne contamination and a greater likelihood of exposure to pests[100]. Introduction of pathogens can also occur when contaminated equipment is rinsed but not sanitized before contact with the sprouts because, while washing serves to physically remove the majority of microorganisms, including pathogens, from properly designed food contact surfaces, often some are left behind[239].

We characterized the relative likelihood of contamination by each potential route of contamination for each commodity, using the designations of "higher," "medium," or "lower." Note that ranking for each commodity/route combination was relative to other commodities in the same column for that route, i.e., while one may have a "higher" or "lower" likelihood of contamination than another, this is not to say that any one commodity/route combination categorically has a "high likelihood" or that the other has a "low likelihood." Also note that our rankings of likelihood of contamination are based, in part, on our understanding of current common practices related to different commodities and associated risks. Changes in common practices (for example, employing new practices or implementing practices commonly used in one commodity for a different commodity) may change the likelihood of contamination such that rankings characterized for the particular commodity/route combination in Table 9 would not be applicable. The rankings used for the likelihood of contamination are defined below:

- Relatively Higher – Defined as those commodity/route combinations that have been linked to at least one outbreak where the specific route was cited as a potential contributing factor of contamination in that outbreak. We did not account for differences in the numbers of outbreaks associated with the specific commodity-route of contamination combinations (i.e., single versus multiple outbreaks associated with a specific commodity-route of contamination combination). Each of the "higher" blocks include a citation to the reference for the outbreak(s) discussing the likely route of contamination.

- Medium – Defined as a reasonably likely route of contamination for that commodity. No specific outbreaks are currently known to be linked to these commodity/route combinations. However, in some cases, this route of contamination may have been identified as a potential contributing factor in an outbreak associated with a crop with similar characteristics, agricultural practices or environmental conditions. For example, direct application of irrigation water has been identified as a potential contributing factor in an outbreak from the consumption of lettuce. While no known outbreaks from the consumption of spinach have been linked to direct application of irrigation water, it seems intuitive that the same potential exists for spinach because the commodity characteristics and agricultural practices are similar to those for lettuce.

- Relatively Lower – Defined as a possible route of contamination for the commodity-given the right environmental conditions, though there is generally less evidence of the possibility of contamination for the commodity/route combination than there is for the same route applied to other commodities ranked "medium".

- Not Applicable (N/A) – Defined as a potential route of contamination that does not exist because the practice or event necessary for the route to arise does not occur, or is not expected to occur to any significant degree, for the specific commodity. For example, direct contact irrigation is unlikely to be used in growing most tree fruit commodities (such as apples, pears, or oranges), and strawberries are highly perishable and the use of postharvest water for cooling or washing them would greatly reduce shelf-life and marketability, so is not commonly practiced.

In order for us to obtain a total "route score" for each commodity/route, we assigned values to each relative likelihood as follows: N/A = 0; Lower = 1; Medium = 3; and Higher = 6. The scores were assigned based on an assumption that a potential route of contamination designated as "medium" is 3 times more likely to cause contamination than one with a "lower" designation; and a route of contamination designated as "higher" is 6 times more likely to cause contamination than one with a "lower" designation. A variety of alternative assumptions are possible, and a sensitivity analysis was performed using several different scales to determine that the scale used produced the most logical and practical outcome in terms of assigning both the relative risk of 'on-farm' contamination as well as the risk of illness based on consumption rates and consumer practices. Using an 'unweighted' scale of 0-1-2-3 would have effectively assigned similar risk to all commodities for all the possible routes of on-farm contamination (table 9). We consider that this approach would insufficiently emphasize routes of contamination that have past associations with a commodity/outbreak combination, and also would have resulted in more reliance on the values for rate of consumption and consumer practices (e.g. cooking, peeling)(Table 11) to assess the risk of illness for each commodity (table 13). Similarly, using an extreme log-scale (e.g. 0-1-10-100) produced similar results to the chosen scale, but would have elevated the 'likelihood of contamination' score for five commodities (oranges, field-packed cantaloupes, green onions, basil and cabbage). We determined that the 0-1-3-6 scaling appropriately captured the risk-based goal of this QAR which emphasizes each potential route of on-farm contamination and gives weight to each route that has past association with an outbreak.

We acknowledge that applying such an ordinal scale implies that we think that all cells labeled as "higher" have an equal likelihood of contamination. This is likely not the case. For each commodity, we added up the relative rankings for each potential route of contamination to arrive at a total "route score" for that commodity/route. We also acknowledge that not all potential routes of contamination contribute equally to the likelihood of contamination attributed to a commodity and that there are differences in the extent to which different routes of contamination likely contribute to contamination on-farm. However, for the purposes of this qualitative assessment, we did not weight the routes of contamination (i.e. in some situations, irrigation water and/or soil amendments may have a larger impact on the microbiological quality of produce than animal intrusion), and we therefore calculated the route score assuming no difference in the potential routes of contamination as factors contributing to the likelihood of contamination on-farm.[7]

Table 9 displays the likelihood of produce contamination for each commodity/route combination, as well as the "route score" for each commodity. We then calculated a "percent of maximum score" for each commodity by dividing the route score for each commodity by 84, which would be the highest possible score if all 14 potential routes of contamination in the chart were given a score of 6 (representing a theoretical highest likelihood of contamination on-farm). The mean ($\overline{X}$) "percentage of

[7] Such weighting of potential routes of contamination was considered in FDA's Regulatory Impact Analysis (available online at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm).

maximum score" for all commodities was 35.8%, with a standard deviation (s) of 7.2%. To derive the relative likelihood of contamination on-farm, we assigned a relative rank of "higher" for those commodities with a "percent of maximum score" above one standard deviation of the mean of all commodities ($\overline{X}$ + 1s = 43 %); "lower" for those commodities with a "percent of maximum score" at or less than one standard deviation below the mean of all commodities ($\overline{X}$ – 1s = 28.6%); and "medium" for those commodities between 28.6% and 43%. Commodities with higher, medium, and lower relative likelihoods of contamination on-farm are identified with different shades of grey in Table 9 (see key at bottom of Table 9).

Interaction between practices and potential mitigation steps has not been considered at this stage in the analysis. Table 10 (a,b and c), provides further information about how the definitions were applied to each of the potential routes of contamination.

We then tested the construct validity of our resulting route scores by comparing them with whether or not pathogens had been detected on any commodity for which there were data from USDA's Microbiological Data Program (MDP). In Table 9, an asterisk (*) by the number in the "route score" column indicates commodities for which at least one positive sample finding was identified in the MDP program. The MDP data are only available for a small number of commodities, and the data only indicate the presence or absence of certain pathogens (see Appendix 1).

Table 9. Assessment of Potential Routes of Contamination and Likelihood of Contamination On-Farm

Commodity			Growing								Harvest			Postharvest				
				Water														
Group	Sub	E.g.	Seed	Direct (Irr.)	Direct (Prot.)	Indirect	BSAAO	Workers	Animals [a]	Equipment	Water (direct) [b]	Workers	Equipment	Water (Direct)	Workers	Equipment/ Buildings [c]	Route Score	% of Maximum Score
Pome		Apple		N/A							N/A						26	31.0%
		Pears		N/A							N/A						26	31.0%
Stone		Peach		N/A							N/A						26	31.0%
Small		Strawberries		N/A					iii		N/A	i		N/A			31	36.9%
		Blackberries		N/A							N/A			N/A			25	29.8%
		Raspberries		N/A	i						N/A	i		N/A			31	36.9%
		Blueberries		N/A							N/A			N/A			25	29.8%
		Cranberries				N/A											33	39.3%
		Grapes		N/A							N/A			N/A			25	29.8%
Sub-tropical	citrus	Grapefruit		N/A							N/A						24	28.6%
		Oranges		N/A							N/A						24	28.6%
		Lemons		N/A							N/A						24	28.6%
Tropical		Mango		N/A							N/A			v			29	34.5%
		Papaya		N/A							N/A			xi		xi	32	38.0%
		Bananas									N/A						25	29.8%
		Coconuts		N/A	N/A						N/A						21	25.0%
		Pineapple		N/A							N/A						26	31.0%
Vegetable	Flower	Broccoli									N/A						31	36.9%
	Leafy	Cabbage			i		i				N/A			N/A			34	40.5%

Commodity			Growing								Harvest			Postharvest				
				Water														
Group	Sub	E.g.	Seed	Direct (Irr.)	Direct (Prot.)	Indirect	BSAAO	Workers	Animals [a]	Equipment	Water (direct) [b]	Workers	Equipment	Water (Direct)	Workers	Equipment/ Buildings [c]	Route Score	% of Maximum Score
Vegetable	Leafy	Watercress		i			N/A				N/A						31	36.9%
		Artichoke									N/A						29	34.5%
		Lettuce		i			i		i					N/A			40*	47.6%
		Spinach							i				i				40*	47.6%
	Stem	*Asparagus*									N/A						31	36.9%
		Celery									N/A						31*	36.9%
	Fruiting	Tomato (field-pack)									N/A			N/A			30*	35.7%
		Tomato (shed-pack)			i						N/A			i		i	42*	50.0%
		Pepper (hot)									N/A						31*	36.9%
		Watermelon									N/A			N/A			28	33.3%
		Cantaloupe (field-pack)									N/A			N/A	N/A	N/A	24*	28.6%
		Cantaloupe (shed-pack)									N/A		vii	vii		vii	42*	50.0%
		Honeydew									N/A						31	36.9%
		Summer Squash									N/A			N/A			28	33.3%
		Peas							ii		N/A			ii			37	44.0%
		Cucumbers									N/A						31	36.9%

Commodity			Growing								Harvest			Postharvest				
				Water														
Group	Sub	E.g.	Seed	Direct (Irr.)	Direct (Prot.)	Indirect	BSAAO	Workers	Animals [a]	Equipment	Water (direct) [b]	Workers	Equipment	Water (Direct)	Workers	Equipment/ Buildings [c]	Route Score	% of Maximum Score
Under-Ground Vegetable	Roots	Carrot				N/A					N/A						28	33.3%
	Tubers	*Potatoes*				N/A					N/A						28	33.3%
	Bulbs	Green onion				N/A					N/A	iv		iv			36*	42.9%
		Onion				N/A					N/A			N/A			25	29.8%
Herbs		Cilantro						x			N/A	x		x	x	x	48*	57.1%
		Parsley									N/A	ix		ix	ix		40*	47.6%
		Basil									N/A	vi		N/A	vi		34	40.5%
Sprouts		Sprouts	i		N/A	N/A				i			i			i	48*	57.1%
Fungi		Mushroom		N/A	N/A				N/A		N/A			N/A			17	20.2%
Tree Nuts		Walnuts		N/A							N/A						28	33.3%
		Almonds		N/A			viii				N/A			N/A			30	35.7%

Higher (6 points)	Route of contamination identified as a potential contributing factor of contamination in an outbreak in specified commodity
Medium (3 points)	Route of contamination reasonably likely to occur
Lower (1 point)	Possible route of contamination
N/A (0 points)	Practice not generally applied to commodity

* Represents a commodity where a positive sample finding was identified in the U.S. Department of Agriculture's Microbiological Data Program (as discussed in Appendix 1). The USDA AMS MDP was discontinued in 2012 and FDA is evaluating options for any future collection of similar microbiological data.

[a] May be exacerbated at harvest

[b] For Hydration and lubrication

[c] Includes pest control and storage

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Table 10a. **GROWING**: Supporting information for commodity/practice ranking pair decisions in Table 9.

Route	Commodity	Considerations
Seed	Sprouts	Seeds for sprouting have repeatedly tested positive with outbreak strains of pathogens and have been identified as possible contributing factors in outbreaks associated with multiple sprout operations. No other commodity is currently suspected as being contaminated by this route.
Water (Direct Irrigation)	General	Direct contact of water with any commodity has the potential to deposit any pathogens in the water on the commodity. Some commodities are not irrigated by direct application for quality, agronomic, or economic reasons. Some commodities are direct-irrigated early in the irrigation cycle and, thus, have a lower ranking.
	Underground Crops	All applications of irrigation water are considered direct
Water (Direct Protection)	General	Includes water used as a carrier for crop protectants (e.g., pesticide sprays), water used for frost protection, or similar purposes. To be effective, such applications must be made directly in contact with the produce item. Few commodities are grown without the use of some form of crop protectant.
Water (Indirect)	General	Indirect water application has not been identified as a likely contributing factor in any known outbreaks. Since there is no direct contact with produce, there is no direct route of contamination.
	Tree Crops	For tree crops, we assumed that indirectly applied irrigation water is applied to the soil (e.g., through drip or furrow irrigation). Produce grown on trees is expected to be far removed from the soil, such that it is unlikely for any pathogens the water may introduce to the soil to transfer to the fruit. Low branches (e.g., trellised) or harvest methods involving dropped produce (e.g., almonds, walnuts) may raise the potential for contamination.
Soil Amendments	General	Use of soil amendments of animal origin in a manner where there is reasonable possibility of contact with the harvestable portion of the crop and the soil amendment has not been treated in a way to eliminate human pathogens has the potential to deposit any pathogens in the soil amendment on the commodity. Soil amendments of animal origin are not used on some crops.
	Tree Crops	Produce grown on trees is expected to be far removed from the soil, such that it is unlikely for any pathogens in the soil to transfer to the fruit. Low branches (e.g., trellised) or harvest methods involving dropped produce (e.g., almonds, walnuts) may raise the potential for contamination.
	Mushroom	Manure is not known to be used as an amendment to existing soil in mushroom growth, but rather as a growth medium (similar to use of potting soil). This might suggest a high likelihood of contamination due to extensive contact. However, the nature of mushroom production is such that the media must be pasteurized or the crop yield is unmarketable. Pasteurized growth media is unlikely to harbor human pathogens and so is considered to present a low potential for contamination.
Worker Health and Hygiene	General	Most produce is not hand manipulated by workers during growing such that a significant potential for contamination exists. However, some notable exceptions include stringing tomato plants, bagging bananas, turning melons (such as cantaloupe and honeydew), and manipulating sprouts and some greenhouse-grown commodities.
Animals	General	Several outbreaks from the consumption of produce implicated animal intrusion during the growing of the commodity as a possible contributing factor. Produce items contaminated by animals can then serve to contaminate other produce items during harvesting and postharvest.

Route	Commodity	Considerations
Animals	Tree Crops	Land animals implicated as possible contributing factors in past outbreaks (e.g., feral hogs, deer) have limited or no access to arboreal fruit, limiting the potential for contamination. On the other hand, birds have been shown to carry pathogens and may contaminate produce, as was believed to be the case in an outbreak associated with snow peas. Birds and rats are attracted to plants that bear edible food; they may be more attracted to fruit that is accessible for them to consume (e.g. apples, bananas, pears, peaches, and mangos, rather than grapefruit, lemons or oranges).
	Root Crops	Crops such as potatoes and carrots are generally inaccessible to most animals. Animals that dig up root crops most likely will damage those items dug up, rendering them unmarketable, while not coming in contact with items not dug up. Pathogen concerns for these crops are likely to be limited to cross-contamination during harvest, and not direct contact with animal waste.
	Crops that resist animal feeding	Pineapple and artichoke present a lower likelihood of being contaminated by animals because they are highly resistant to animal feeding. Both have thick outer layers, and have firm leaves with thorns that discourage animal feeding.
Equipment	General	Few commodities are manipulated with any equipment during growing such that there is a reasonable likelihood of contamination. Notable exceptions to this include sprouts and possibly some greenhouse-grown commodities.

Table 10b. **HARVESTING**: Supporting information for commodity/practice ranking pair decisions in Table 9.

Route	Commodity	Considerations
Water (Direct)	General	Water is not commonly used as a part of harvesting. Notable exceptions include: cranberries (harvested by flooding a field and collecting floating berries); leafy greens and herbs (water may be sprayed into bags during field-harvest for lubrication or quality purposes); and sprouts (hydroponically grown and in contact with water for the entire production chain).
Workers	General	Direct contact by harvest workers using poor hygienic practices has been identified as a possible contributing factor in a number of produce outbreak investigations. Even for commodities that are most often mechanically harvested, some segments of the industry still rely on hand harvesting, making this a possible route of contamination for all commodities.
Equipment	General	Some form of equipment (e.g. harvest bins, harvest knives) is utilized in the harvesting of all commodities. Unsanitary food contact surfaces on such equipment pose a possible route of contamination for all commodities.

Table 10c. **POSTHARVEST**: Supporting information for commodity/practice ranking pair decisions in Table 9.

Route	Commodity	Considerations
Water (Direct)	General	Direct use of water during postharvest operations is most commonly associated with washing produce (e.g., washing sooty mold off of citrus for quality purposes), use as a means to transport produce (e.g., water flumes for tomatoes or green beans), or for hydrating and cooling produce (e.g., top icing carrots, keeping lettuce from wilting). Direct contact of water with any commodity has the potential to deposit any pathogens in the water on the commodity, or to spread pathogens from one item to others (cross-contamination).

Route	Commodity	Considerations
Water (Direct)	Walnuts	Water used during the handling of walnuts is limited to water used to bleach the shell for cosmetic purposes. Unlike water used in a flume, if the chlorination level decreases, the water does not serve its purpose and is likely to be immediately visible and noted and corrected by attending employees. For this reason, this route of contamination presents a lower potential for contamination.
Workers	General	Direct contact by postharvest workers using poor hygienic practices has been identified as a possible contributing factor in a number of produce outbreak investigations. At this stage of production there is little time for die-off of human pathogens that may be contributed by the workers. Commodities with extensive handling, grading, and sorting practices (e.g., green onions, herbs, and tomatoes) are likely to be most vulnerable to contamination due to the high number of touch-points and therefore the high number of opportunities for contamination. Some commodities may be removed from packaging and re-packed (e.g., tomatoes) or packaged (e.g., for quality control or to build mixed-product consumer or retail packs). This practice increases the number of touch points and therefore increases the number of opportunities for contamination.
Equipment	General	Includes any food contact surfaces during postharvest operations. All produce commodities are placed in some kind of container for storage or shipping (e.g., “clam-shell” for field-packed berries, truck bed for watermelons, or crates or bins for many others). Other food contact surfaces include sorting tables, flumes and dump bins. Unsanitary food contact surfaces of such equipment pose a possible route of contamination to all commodities. Some commodities may be removed from packaging and re-packed (e.g., tomatoes) or packaged (e.g., for quality control or to build mixed-product consumer or retail packs). This practice increases the number of touch points and therefore increases the number of opportunities for contamination.

2. Qualitative Patterns of the Likelihood of Contamination during Growing, Harvest, and Postharvest

The assessment of likelihood of contamination in Table 9 shows that produce commodities are generally susceptible to hazards during and after harvest, although the likelihood of such hazards occurring varies by commodity depending upon the agricultural practices employed, the environmental conditions during growth, and the characteristics of the commodity. The analysis also shows that the likelihood of hazards occurring during growth of the crop varies more widely than does the likelihood of hazards occurring during and after harvest. For example, Table 9 shows a likelihood of contamination ranging from “lower” to “higher” during “growing” across all routes of contamination whereas during “harvest” and “postharvest” the likelihood of contamination ranges from “medium” to “higher”. The variability in likelihood of contamination during growing may be due to a wide range of agricultural practices and environmental conditions during growth which can vary from crop to crop, and within the same crop across different producers. Commodities with lower route scores are those that are exposed to fewer potential routes of contamination and/or exhibit a lower likelihood of contamination through those routes. We acknowledge that there may be other routes of contamination that may contribute to produce contamination.

The assessment of the degree of commonality between our relative likelihood of contamination determinations and the MDP data show that all but one of the commodities that are ranked as having a relatively “higher” likelihood of contamination on-farm in our assessment also are identified with a positive sample finding in the MDP database. As noted above, however, the MDP database presents significant limitations in that it only provides data on the presence or absence of pathogens (not levels of pathogens) and data are available for a relatively small number of commodities (mainly those that have been associated with outbreaks) that were collected at retail. Therefore, any patterns of commonality should be interpreted within the context of these limitations.

D. Likelihood of Consuming Contaminated Produce

FDA continued its analysis of the commodities selected and analyzed in Table 9 to determine the relative likelihood that the commodity would expose a consumer to a pathogen. Specifically, to the relative likelihoods generated in Table 9 we added consideration of: (1) consumer or retail handling practices, such as cooking and peeling and their influence on produce contamination (see section D.1. below); and (2) relative rates of consumption among the selected commodities (see section D.2. below). Applying these two factors, we qualitatively assess the likelihood of exposure using a decision key (see section D.3. below). The results of the analysis are presented in Table 11 and explained in the discussion that follows. Effective analysis and understanding of the information in Table 11 will be facilitated by first reading through the supporting discussions found below in sections D.1 (Consideration of Consumer or Retail Handling Practices), D.2 (Consumption Rates) and D.3 (Likelihood of Exposure).

Table 11. Assessment of Likelihood of Exposure for Produce Commodities (Raw unless otherwise *noted*)

Group	Sub	E.g.	Likelihood of Contamination: On-farm[1]	Likelihood of Contamination: @ Consumption[2]	Rate of Consumption[3]	Likelihood of Exposure[4]
Pome		Apple				
		Pears				
Stone		Peach				
Small		Strawberries				
		Blackberries				
		Raspberries				
		Blueberries				
		Cranberries		Cooked		
		Grapes				
Subtropical	Citrus	Grapefruit				
		Oranges				
		Lemons				
Tropical		Mango				
		Papaya				
		Bananas				
		Coconuts				
		Pineapple				
Vegetable	Flower	Broccoli				
	Leafy	Cabbage				
		Watercress				
		Artichoke				
		Lettuce				
		Spinach				
	Stem	*Asparagus*		Cooked		
		Celery				
Fruiting Vegetable		Tomato (field-pack)				
		Tomato (shed-pack)				
		Pepper (hot)				
		Watermelon				
		Cantaloupe (field-pack)				
		Cantaloupe (shed-pack)				
		Honeydew				
		Summer Squash				
		Peas				

Group	Sub	E.g.	Likelihood of Contamination: On-farm[1]	Likelihood of Contamination: @ Consumption[2]	Rate of Consumption[3]	Likelihood of Exposure[4]
Fruiting Vegetable		Cucumbers				
Under-ground	Roots	Carrot				
	Tubers	*Potatoes*		Cooked		
	Bulbs	Green onion				
		Onion				
Herbs		Cilantro				
		Parsley				
		Basil				
Sprouts		Sprouts				
Fungi		Mushroom				
Tree Nuts		Walnuts				
		Almonds				

[1] The relative likelihood of contamination while on the farm is the value generated from the far right column of Table 9 ("% of maximum score").

[2] The likelihood of contamination at consumption considers the expected likelihood of contamination on-farm, modified based on consumer or retail practices likely to significantly impact the likelihood of contamination at the time of consumption. Consumer or retail handling practices considered were: washing; cutting and peeling; and cooking. In short, cooking and certain peeling are the only activities assumed to mitigate the risk if the commodity were to be contaminated in the field. For the purposes of this qualitative assessment, the ranking in this column does not account for changes to the prevalence or levels of pathogens from on-farm to the point of consumption, for example due to die-off, growth, washing, or cross-contamination. See section D.1. of the document for a discussion of the rankings in this column.

[3] The relative rate of consumption for each commodity was calculated using the number of eating occasions per day for that commodity reported in NHANES. The relative rankings for rate of consumption are based on the proportion of total number of eating occasions for the commodity compared to the sum total of number of eating occasions for all commodities included in this assessment. See section D.2. of the document for a discussion of the rankings in this column.

[4] The relative likelihood of exposure was determined based on the rankings of relative "rate of consumption" and "likelihood of contamination at consumption" and applying the decision key in Table 12. See section D.3. of the document for a discussion of the rankings in this column

1. Consideration of Consumer or Retail Handling Practices

The likelihood of contamination at consumption considers the expected likelihood of contamination on-farm, modified based on consumer or retail practices likely to significantly impact the likelihood of contamination at the time of consumption. Consumer or retail handling practices considered were 1) washing, 2) cutting and peeling, and 3) cooking.

a. Washing

Once established in or on produce, pathogens cannot reliably be completely removed by washing with or without a disinfectant[17]. Washing with water containing a disinfectant can have up to a 2 log reduction of pathogens on the surfaces of some produce. Washing in clean water alone can have up to a 1 log reduction[232]. Viruses and protozoan cysts on fruits and vegetables generally exhibit higher resistance to disinfectants than do bacteria or fungi.

The effectiveness of washing in removing pathogens varies greatly with the type and pH of disinfectant, contact time, organic load, temperature and the chemical and physical properties of the fruit or vegetable surface. Little is known about the efficacy of disinfectants in relation to the roughness of fruit and vegetable surfaces, although factors such as the amounts of cuticle material on the produce may have an impact[16]. In one study, low levels of *E. coli* O157:H7 inoculum, when applied to lettuce using bovine feces as a carrier and stored under commercial and home refrigeration conditions, survived and were not removed by washing with water or treating with 200 ppm chlorine solution[15].

Further, consumers wash fruits and vegetables for a variety of reasons, including the removal of soil, waxes, and pesticides. However, some consumers do not routinely wash produce at all[138]. For these reasons, washing cannot be relied upon to eliminate pathogens on the edible portion.

b. Cutting and Peeling

Cutting and peeling affect the microbiota and safety of produce in several ways. Peeling, by its very nature, can potentially remove a contaminated exterior surface of a produce item. If done in a manner that does not contaminate the interior edible portion, this seems likely to protect the safety of the produce prior to consumption (e.g., banana, coconut). However, FDA is not aware of any scientific studies demonstrating such an effect. In the draft QAR, we had included in our analysis a protective effect for peeling of bananas and coconuts; however, upon further reflection and review of comments, we do not believe we can rely on such peeling to be done in a manner that does not contaminate the interior edible portion of the commodity. As a result, we consider such peeling as providing a potential, but uncertain, contribution to safety. For many fresh fruits and vegetables, cutting or peeling exposes the nutrient-containing internal fluids to microorganisms and thereby may accelerate pathogen growth, if present. Secondly, cutting and peeling provides more surface area on which microorganisms can propagate[23]. One study showed a significant reduction in levels of both HAV and murine Norovirus on contaminated produce (carrots and celery) was achieved through peeling the produce after scrubbing it under running water with a nylon brush or scouring pad; however, the utensils then provided a mechanism for cross-contamination [221]. One study demonstrated the potential for *Salmonella* Miami to be transferred to the interior edible surface of a watermelon after the watermelon rind was artificially inoculated and then cut with a clean knife[101]. Another study demonstrated the potential for *Salmonella* Poona to be transferred to the interior edible portion of cantaloupes during slicing with a sterile knife, even after washing the rinds of inoculated melons thoroughly with either tap water or subjecting to a 200ppm chlorine submersion [217]. Similarly, Erickson et al. determined that contaminated knives may lead to subsequent contamination of at least 7 produce items sliced with the same contaminated knife[73].

Many produce commodities (e.g., mangos, oranges, carrots, and melons) are usually peeled in such a way (e.g., using a knife or peeler) that contamination on the surface can be carried to the edible portion of the produce as well as the utensil used to peel the commodity, which may lead to further cross-contamination[74]. Other commodities (e.g., apples, melons, cucumbers) are sometimes peeled or brushed, and other times not. In these latter two cases, peeling and/or brushing performed by the end user may not be a reliable risk mitigation step[74]. In other cases (e.g., tomatoes), pathogens may become internalized, rendering peeling ineffective in eliminating pathogens even if done hygienically.

Thus, cutting and peeling may enhance, reduce, or have no effect on the level of pathogens on the edible portion. In addition, there is limited data on the effect of cutting and peeling on the levels of pathogens across the range of commodities.

c. Cooking

Cooking practices generally significantly reduce the level of microbiological hazards in produce. Thermal inactivation studies of pathogens in produce are relatively few, since cooking of produce (including blanching) typically is done for palatability and enzyme inactivation, rather than for pathogen elimination. A number of studies have examined the effects of heat on eliminating *L. monocytogenes* from various types of vegetables[65]. *L. monocytogenes* is subject to thermal inactivation(decimal reduction or D-Values) under the following conditions, for the following lengths of time, in the following vegetables: at 154^{o}F for 18 seconds in carrot homogenate; at 140 ^{o}F for 30 seconds in potato slices ; at 144 ^{o}F for 6 seconds in onions; at 144 ^{o}F for 23 seconds in broccoli; at 144 ^{o}F for 19 seconds in green peppers; at 144 ^{o}F for 18 seconds in mushrooms; and at 144 ^{o}F for 25 seconds in peas[65]. For most vegetables, blanching to inactivate 5 logs of *L. monocytogenes* can be accomplished through heating the vegetables at 167 ^{o}F for at least 10 seconds or at 180 ^{o}F instantaneously (less than 1 second)[146].

With respect to *Salmonella*, water blanching at 190 ^{o} F for 4 minutes reportedly reduced *Salmonella* spp. by >5.4 log CFU/g in potato slices [63]and by 4.6-5.1 log CFU/g in carrots [64]. Also, a study has shown that mung bean seeds that were inoculated with 5-6 log (10^5 to 10^6) CFU/g *E. coli* O157:H7 and/or *Salmonella,* then treated with hot water at 194 ^{o}F for 90 seconds, and then dipped in chilled water for 30 seconds, were not found to have any viable pathogens after the treatment[12].

In addition, seven different Shiga toxin-producing *E. coli* serotypes in apple juice were thermally inactivated in less than 1 minute when held at a 144 ^{o}F[72]. Therefore, cooking of produce can be considered to result in significant reductions of pathogens.

d. Conclusions on Consumer and Retail Handling Practices

Foods that are generally eaten cooked have a low probability of being contaminated at consumption. Some produce commodities have an inedible rind that is generally removed in such a way that minimizes the potential for any surface contamination to come in contact with the edible portion of the fruit. In such commodities, for example bananas and coconuts, peeling before consumption may reduce the potential for contamination, although this is a potential, but uncertain, contribution to safety. Other produce commodities (e.g., mangos, oranges, carrots) are usually peeled in such a way (e.g., using a knife) that contamination on the surface can be carried to the edible portion of the produce. Slicing a watermelon, too, would not be expected to reduce the likelihood of contamination of the edible portion of that commodity. Therefore, we do not consider commodities that are peeled or sliced to have a low probability of being contaminated at consumption based on the peeling or slicing. We also do not consider commodities to have a low probability of being contaminated at consumption based on washing before consumption because washing of produce cannot be relied upon to eliminate pathogens on produce.

Changes in consumer practices (for example, changes in washing, cutting, or peeling practices) may change the likelihood of contamination such that our qualitative assessment for the particular commodity/postharvest practice may not be applicable. In addition, there is limited data on the effect of cutting and peeling on the levels of pathogens across the range of commodities.

Based on these conclusions, and using the rankings obtained in Table 9 on likelihood of contamination on-farm (shown as column 4 of Table 11), we assign a low likelihood of contamination at consumption (column 5 of Table 11) ranking to commodities that are generally cooked before consumption (cranberries, asparagus, potatoes).

2. Consumption Rates

Consumption estimates were derived from the results of the What We Eat in America (WWEIA)/National Health and Nutrition Examination Survey (NHANES). The NHANES is a program of studies designed to assess the health and nutritional status of adults and children in the United States, and the sample is selected to represent all ages of the U.S. population. For the final QAR, the datasets used were those available from the 2003-2010 NHANES/WWEIA surveys for 2-day dietary intakes (Data accessible at http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm). FARE™ (Foods Analysis and Residue Evaluation Program), a proprietary software program leased by CFSAN, was used to analyze data from the 2003-2010 WWEIA/NHANES (updated from the 1999-2006 database used for the draft QAR). For estimating consumption of commodities, it was necessary to convert the survey foods to their constituent ingredients or commodities. The software made these conversions by creating "recipes" for each food reported in WWEIA/NHANES; ingredients in these recipes are raw agricultural commodities (RACs). In the recipes, food forms (e.g., raw, boiled, baked, freeze-dried) are also specified for each commodity ingredient, where possible, to indicate the form in which the ingredient was consumed.

An eating occasion is each time the commodity is eaten in raw form (unless otherwise noted in Appendix 2) or otherwise consumed in a prepared dish in which the commodity remains uncooked (for example, tomatoes used in salsa). To get the total number of eating occasions per day, we used the number of eating occasions for the commodity reported for two days. The reported numbers of eating occasions per day in the NHANES database for the selected commodities are provided in Appendix 2, including information on the commodity rankings that changed from the draft QAR with the use of the updated datasets in the final QAR.

To account for relative rates of consumption in our estimation of the relative likelihood of exposure, we used the number of eating occasions per day for each commodity to obtain a relative ranking for the rate of consumption of that commodity. Note that the list of commodities we selected for our analysis represents a limited number of the full spectrum of produce commodities. To derive the relative ranking of rates of consumption, we calculated the sum total of number of eating occasions per day for all commodities included in this assessment. We then calculated the rate of consumption for each commodity as a proportion of this sum total number of eating occasions per day for all commodities included in the assessment. Finally, we assigned a relative rank of "higher" for those commodities with a percentage of eating occasions above 5%; "medium" for those commodities with a percentage between 1 and 5%; and "lower" for those commodities with a percentage below 1 % (Appendix 2).

In column 6 of Table 11, commodities with higher, medium, and lower relative consumption rates are identified with different shades of grey. Note that our ranking of "higher," "medium," and "lower" represent rates of consumption of commodities relative to each other within the selected group of commodities analyzed. As such, the rankings should not be interpreted as representative of absolute consumption.

3. Likelihood of Exposure

The relative likelihood that a commodity would expose a consumer to a pathogen (column 7 in Table 11) was determined based on the relative consumption rates and the likelihood of contamination at consumption using the decision key in Table 12. The assumption in this key is that the likelihood of contamination is the primary driving factor, although significant differences in the rate of consumption can magnify or mitigate a given likelihood. We believe this assumption is appropriate given that, for example, sprouts have a relatively low rate of consumption but have been associated with a number of outbreaks because they have a relatively higher likelihood of contamination. Under these assumptions, we see that a low likelihood of contamination coupled with a higher consumption rate has a relatively lower likelihood of exposure than a commodity with a higher likelihood of contamination, but lower consumption rate.

Table 12. Likelihood of Exposure Decision Key[1]

		Rate of Consumption		
		L	M	H
Likelihood of contamination at consumption	L	Low	Low	Low
	M	Low	Medium	Medium
	H	Medium	High	High

[1] This decision key was used to apply the rankings for likelihood of contamination at consumption (column 5 of Table 11) and rate of consumption (column 6 of Table 11) to obtain the rankings for likelihood of exposure (column 7 of Table 11).

4. Conclusions about Likelihood of Consuming Contaminated Produce

Subsequent to any contamination on-farm, consumer and retail handling practices and produce consumption rates affect the likelihood of exposure to contamination. Postharvest practices such as cooking (and possibly certain peeling) before consumption may have an impact on the likelihood of contamination of the edible portion and, thus, may decrease the likelihood of exposure of consumers to contamination.

V. Risk Characterization

Risk Characterization integrates information from hazard identification, hazard characterization, and exposure assessment to qualitatively estimate the adverse effects likely to occur in the population[80, 82]. Risk characterization links the qualitative assessment of the likelihood of exposure to pathogens from consumption of produce contaminated by on-farm pathways with potential adverse health outcomes, likelihood of illness.

FDA conducted the analysis concerning the routes of contamination, described in section IV, to determine the outcomes and relative likelihood of illness for each commodity, focusing on illnesses that can cause serious adverse health consequences or death. For that reason, severity, which is normally an element of risk, had no impact on our estimation of likelihood of illness in Table 13. Where severity of the hazard is limited to those illnesses that cause serious adverse health consequences or death, the risk of illness is directly proportional to the likelihood of exposure.

For the purposes of this assessment, we make the assumption that the risk of illness is directly proportional to the likelihood of exposure, meaning that we assume that there is not a dose-response relationship and any amount of contamination would be expected to cause illness. We also assume that any contamination that may occur while on farm will carry through to the point of consumption, and that the level of contamination neither increases nor decreases unless contamination is minimized through consumer or retail handling practices, as described in section IV.D.1., above. We acknowledge that this may not always be the case. We also acknowledge there is also generally an under-reporting of illnesses related to foods and only a limited proportion of reported food-borne illnesses have been attributed to an identifiable vehicle.

The results of the analysis of risk of illness are presented in Table 13. Note that the likelihood of exposure identified in this table is derived from Table 11. For a comparison of this analysis to the FDA-RTI risk ranking model, see Appendix 3.

Table 13. Assessment of Risk of Illness for Produce Commodities (Raw unless otherwise *noted*)

Group	Sub	E.g.	Likelihood of Exposure[1]	Severity of Hazard[2]	Risk of Illness
Pome		Apple			
		Pears			
Stone		Peach			
		Strawberries			
		Blackberries			
Small		Raspberries			
		Blueberries			
		Cranberries (cooked)			
		Grapes			
		Grapefruit			
Subtropical	Citrus	Oranges			
		Lemons			
		Mango			
		Papaya			
Tropical		Bananas			
		Coconuts			
		Pineapple			
	Flower	Broccoli			
		Cabbage			
		Watercress			
Vegetable	Leafy	Artichoke			
		Lettuce			
		Spinach			
	Stem	*Asparagus (cooked)*			
		Celery			
		Tomato (field-pack)			
		Tomato (shed-pack)			
		Pepper (hot)			
		Watermelon			
Fruiting Vegetables		Cantaloupe (field-pack)			
		Cantaloupe (shed-pack)			
		Honeydew			
		Summer Squash			
		Peas			
		Cucumbers			
	Roots	Carrot			
Under-ground	Tubers	*Potatoes (cooked)*			
	Bulbs	Green onion			
		Onion			

Group	Sub	E.g.	Likelihood of Exposure[1]	Severity of Hazard[2]	Risk of Illness
Herbs		Cilantro			
		Parsley			
		Basil			
Sprouts		Sprouts			
Fungi		Mushroom			
Tree Nuts		Walnuts			
		Almonds			

[1] Rankings in this column are derived from the "Likelihood of exposure" rankings in Table 11

[2] Severity of hazard covered in this assessment is limited to those illnesses that can cause serious adverse health consequences or death

VI. Conclusions

FDA conducted this qualitative assessment of risk to provide a foundation for understanding the hazards of concern in produce and the likely routes of contamination that could cause foodborne illnesses and outbreaks. In conducting this assessment, published scientific literature, government surveys and expert opinion were collected and considered. Gaps in current knowledge were identified and resulting research needs are provided below.

Key conclusions from this assessment are:

1) **Produce can be contaminated with biological hazards, and the vast majority of produce-related illnesses are associated with biological hazards.**

2) **The known routes of contamination from growing, harvesting, and on-farm postharvest activities are associated with seed (for sprouts), water, soil amendments, animals, worker health and hygiene, and buildings/equipment.**

3) **Although some types of produce have been repeatedly associated with outbreaks, all types of produce commodities have the potential to become contaminated through one or more of these potential routes of contamination.**

4) **The specific growing, harvesting, and on-farm postharvest conditions and practices associated with a produce commodity influence the potential routes of contamination and the likelihood that the given route could lead to contamination and illness. Use of poor agricultural practices could lead to contamination and illness, even for produce commodities where the potential for contamination is considered to be relatively low.**

5) **Postharvest practices such as cooking (and possibly certain peeling) before consumption may have an impact on the likelihood of contamination of the edible portion and, thus, may decrease the likelihood of exposure of consumers to contamination.**

<u>Hazards of concern in produce</u> -- The scientific evidence from outbreaks, surveys and published literature establishes that human pathogens (e.g., *Salmonella*, pathogenic *E.coli*, *Shigella*, *Cyclospora*) constitute a biological hazard with the potential to cause serious adverse health consequences or death and result in the vast majority of foodborne illness known to be associated with produce consumption.

<u>Potential routes of contamination</u> -- Based on our observations during inspections, investigations, and surveillance activities and other available information, we have grouped the possible routes of contamination into five major pathways: Water, Soil amendments, Animals, Worker health and hygiene, and Equipment and buildings. Seed is an additional route of contamination for sprouts.

<u>Likelihood of contamination</u> -- All produce commodities can be contaminated before, during, and/or after harvest through one or more of the potential routes of contamination. Although the likelihood of contamination varies by commodity, it appears to be dependent on the practices employed

and, to a lesser extent, on the characteristics of the commodity. There appears to be greater variability in the likelihood of contamination among commodities during growing than during harvest or after harvest.

Likelihood of exposure -- Subsequent to any contamination on-farm, consumer and retail handling practices and produce consumption rates affect the likelihood that consumers will be exposed to contamination. Postharvest practices such as cooking (and possibly certain peeling) before consumption may have an impact on the likelihood of exposure if indeed the produce is contaminated.

Risk of illness – Contaminated produce has the potential to cause illness. However, there are differences among commodities in the risk of illness, primarily based on the routes of contamination associated with the commodity.

Produce commodities that are ranked as “higher” risk of illness and those ranked as “lower” risk of illness share some of the same characteristics. Both categories include:

- Crops where the harvestable portion grows in the ground;
- Row crops where the harvestable portion grows on or in close proximity to the ground;
- Crops where the harvestable portion grows above the ground;
- Crops where the harvestable portion grows on trees, high above the ground; and
- Crops that are generally grown without soil.

Such diversity suggests that sorting commodities for risk based only on the manner in which commodities grow would be inappropriate. This diversity also characterizes commodities associated with outbreaks. Even within a commodity group, physical characteristics (such as texture of the fruit) of the commodity that could alter the potential for contamination and, therefore, association with an outbreak, do not always appear to do so.

In summary, some produce types are repeatedly associated with reported foodborne illness whereas other produce types are only intermittently associated with foodborne illness. Still other produce commodities have not been associated with reported foodborne illness. Likely factors contributing to the likelihood of contamination, exposure, and illness include: agricultural practices used during growing, harvesting, and postharvest; physical characteristics of the crop; consumer and retail handling practices (such as cooking and possibly some peeling); and rates of consumption. However, use of poor agricultural practices could lead to contamination and illness, even where the potential for contamination is relatively low.

Data Gaps and Research Needs -- Produce safety involves complex and variable interactions of factors to prevent or minimize contamination leading to illnesses. Below are key areas of research needs that would reduce our uncertainty in understanding how produce becomes contaminated and how that contributes to risk during growing, harvesting, and postharvest activities:

- Origins of pathogens in the farm environment;
- Survival and distribution of pathogens in the farm environment, specifically in animals, soils, water, and post-harvest operations;
- Transfer of pathogens to produce;
- Survival and growth of pathogens on produce;
- On-farm practices that mitigate potential contamination; and
- Prevalence and levels of pathogens in produce that cause illness.

This assessment of risk advances our ability to describe, in a systematic manner, the current state of our knowledge about the likelihood of illness associated with produce and the likely routes of contamination from on-farm activities. It provides a framework for integrating and evaluating the scientific knowledge related to public health and can be used in support of regulatory decisions in the implementation of section 419 of the FD&C Act.

VII. List of Tables

VIII. References

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IX. List of Appendices

Appendix 1. Consideration of Microbiological Data Program (MDP) Sampling Data

Contamination data are generally available only for those commodities for which outbreaks have occurred, as contamination surveys are costly and those costs are generally supportable only in such cases. Expanded surveys to include more commodities, in particular those that had not been linked to previous outbreaks, would provide for a more robust and accurate baseline data set that could be utilized to assess exposure for the range of commodities that are covered in this qualitative assessment. Further, generally the only data that are available are data on the presence or absence for selected pathogens (particularly *Salmonella* spp. and *E. coli* O157:H7), and do not include quantification when pathogens are found. Some commodities with a relatively low rate of positive sample findings (e.g., tomatoes) have been associated with many outbreaks, while others associated with a relatively high rate of contamination (e.g., cilantro) only rarely have been associated with outbreaks[33]. We considered sampling data from the U.S. Department of Agriculture's Microbiological Data Program (MDP) [210]to identify whether commodities evaluated in our assessment of likelihood of contamination on-farm (Table 9) were associated with positive sample findings in the MDP database.

The MDP database is statistically designed to be representative of the commodities collected. It is also the largest database of microbiological contamination of produce available for U.S. produce, both in numbers of commodities included and in the numbers of samples per commodity. We considered but rejected other databases, i.e., the FDA domestic and imported produce regulatory databases and a database produced under an FDA contract for collection of produce samples. The FDA regulatory databases are not designed to be statistically representative of product in U.S. commerce and are often targeted for regulatory purposes. As such, they may not be an ideal data set from which to extrapolate overall pathogen prevalence. Further, MDP averages over 8,000 samples per commodity per year, while FDA surveillance sampling averages 230 samples per commodity per year. The FDA contract sampling is limited to leafy greens and has numbers of samples per commodity between those of the FDA regulatory sample databases and the MDP database. We considered merging the databases, but rejected the idea because we were concerned that the targeted FDA data might compromise the representative data in the other databases and because the different databases represent samples collected at different points in the supply chain.

The MDP database for the years 2002-2009 includes the following commodities: spinach, cilantro, parsley, hot peppers, lettuce, alfalfa sprouts, green onions, cantaloupe, tomato and celery. The samples were collected from warehouses and distribution centers. The samples were analyzed for enterohemorrhagic *E. coli* (EHEC), Shiga toxin-producing *E. coli* (STEC), and *Salmonella*. It should be noted that, while the MDP database was selected as the best for the purposes of this qualitative analysis, it presents significant challenges in that it only provides data on the presence or absence of pathogens (not levels of pathogens) and is limited to a relatively small number of commodities, requiring extrapolation of the data to other commodities. The data that are available do not adequately allow us to predict the frequency of contamination in produce commodities that have not been previously associated with an outbreak because the MDP database largely focuses on commodities that have been associated with outbreaks.

The table below contains a summary of the MDP data for 2002 to 2009. The third column in the table signifies the number of samples for that commodity that tested positive for any one of these pathogens. The last column in the table signifies the percentage of total samples for that commodity that tested positive for any one of these pathogens.

Commodity	Number of Samples	Number of Positive Samples	% Positive Samples
Spinach	4433	33	0.74%
Cilantro	2510	16	0.64%
Parsley	1706	8	0.47%
Hot Peppers	1995	6	0.30%
Lettuce	13947	34	0.24%
Sprouts, alfalfa	7055	12	0.17%
Green Onions	7342	7	0.10%
Cantaloupe	13264	11	0.08%
Tomatoes	19017	6	0.03%
Celery	5478	1	0.02%

Appendix 2. 2003-2010 Consumption Data Obtained from NHANES

Commodity (uncooked, unless otherwise noted)	**# of eating occasions using 2-day survey**	**% relative to all eating occasions for analyzed commodities**
Potato, uncooked and COOKED	692,155,457	31.64%
Lettuce (leaf, head)	229,110,230	10.47%
Tomato	161,063,308	7.36%
Onion, bulb	148,940,100	6.81%
Banana	142,153,762	6.50%
Apple	76,332,440	3.49%
Strawberry	68,428,071	3.13%
Carrot	65,130,314	2.98%
Peach^	54,780,015	2.50%
Celery	53,852,295	2.46%
Blueberry^	50,318,102	2.30%
Cucumber	50,233,216	2.30%
Pepper, non-bell	43,930,228	2.01%
Raspberry^	42,061,047	1.92%
Grape	40,473,666	1.85%
Orange	29,188,247	1.33%
Spinach	26,605,102	1.22%
Cilantro^	25,585,518	1.17%
Lemons^	25,075,973	1.15%
Cabbage*	19,925,278	0.91%
Cantaloupe*	17,860,422	0.82%
Watermelon	15,971,687	0.73%
Cranberry, uncooked and COOKED	14,588,714	0.67%
Pineapple	13,597,075	0.62%
Pear	13,358,042	0.61%
Walnut	10,798,907	0.49%
Broccoli	8,117,765	0.37%
Mushroom	8,020,669	0.37%
Asparagus, uncooked and COOKED	6,424,951	0.29%
Grapefruit	6,031,493	0.28%
Mango	4,259,655	0.19%
Pea, snow and green	3,761,721	0.17%
Honeydew	3,183,026	0.15%
Blackberry	2,610,914	0.12%

Onion, green	2,539,808	0.12%
Artichoke, globe-type (cooked)	1,855,983	0.08%
Sprouts (mung bean, alfalfa)	1,778,917	0.08%
Squash, summer	1,654,244	0.08%
Basil	1,347,469	0.06%
Coconut	1,081,148	0.05%
Parsley	1,033,292	0.05%
Papaya	947,986	0.04%
Almond	945,069	0.04%
Watercress	759,666	0.03%

* Cabbage and cantaloupe were in the "medium" consumption (medium gray) category in the draft QAR based on NHANES data from 1999-2006.

^ Peach, blueberry, raspberry, lemons and cilantro were in the "lower" consumption (light gray) category in the draft QAR based on NHANES data from 1999-2006.

Appendix 3. Comparison of Assessment to the FDA-RTI Risk Ranking Model

Description of the FDA-RTI Risk Ranking Model

FDA worked with other experts to produce a semi-quantitative risk ranking for produce commodities that have been associated with foodborne illness, based on CDC data, as described above[3]. The risk ranking tool is available at: <http://www.foodrisk.org/exclusives/RRT/>. The general criteria used for modeling took into account several factors: strength of epidemiological association; severity of disease; pathogen characteristics that affect disease risk; and commodity characteristics that affect pathogen prevalence, and likelihood of exposure by the consuming public (e.g., potential to support growth, shelf life, prevalence of contamination, consumption). Risk scores are calculated for the various commodities based on available data and analysis of these characteristics. Since publication of this methodology, we used the risk ranking tool to include other commonly consumed commodities [209]. Commodities added to the original list are indicated in the table below with an asterisk.

General Category	Specific Commodity Categories
Berries	Strawberries, raspberries, blackberries, blueberries, grapes
Crucifers	Cabbage, broccoli
Citrus	Grapefruit*, lemons*
Green onions	Green onions, scallions
Herbs	Basil, parsley, cilantro
Leafy greens	Lettuce, mesclun, spinach, romaine, leaf, iceberg
Mango	Mango
Melons	Watermelon, cantaloupe, honeydew, muskmelon
Mixed produce	Salad (lettuce, vegetable or fruit based, garden, green, house, chef, cucumber); mixed vegetables, mixed fruit
Mushrooms	Mushrooms
Nuts	Walnuts*
Peppers (hot)	Jalapeño and Serrano peppers
Pineapple	Pineapple
Pomme fruit	Pears*
Root vegetables	Carrots
Sprouts	Sprouts*
Tomatoes	Tomatoes, Roma, cherry, grape

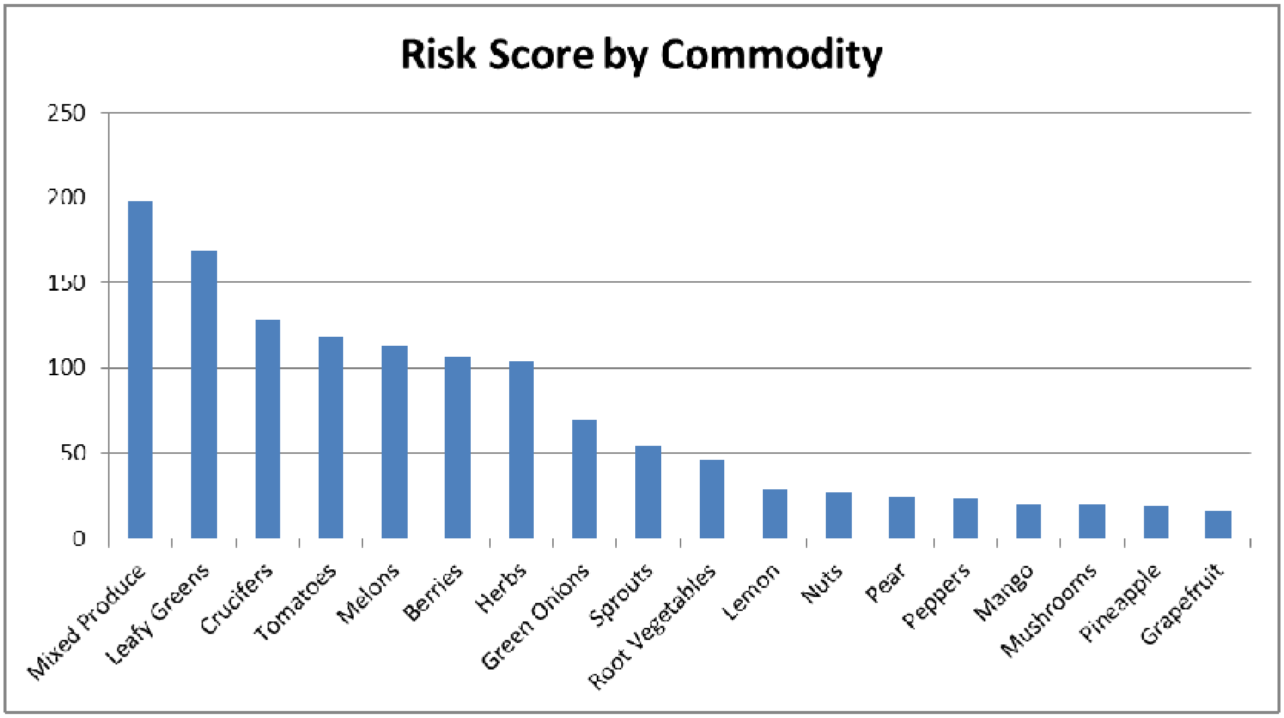

Figure 1- RTI Risk Ranking Model – Commodity Scores

When risk scores for the various commodities are computed, their risk ranking appears as shown in the graph above. The higher the number, the greater the risk.

Comparison of Assessment to the FDA-RTI Risk Ranking Model

Here we provide a comparison of the results of this assessment to the results of the FDA-RTI produce risk ranking model. Limitations of this comparison include the different methodology used for these two assessments, different data sources, and different commodities/grouping of commodities. For example, these two methods use different scoring systems. In determining the total risk score, the FDA-RTI method considers all pathogens linked to reported illnesses associated with outbreaks, whereas the qualitative risk assessment only considers those pathogens that can cause serious adverse health consequences or death. The FDA-RTI risk ranking only included foods associated with outbreaks, whereas the current qualitative risk assessment is more inclusive. A comparison of the rankings from the two assessments is presented below.

Group	Commodity	FDA 2015 qualitative risk assessment[1]	FDA-RTI 2011 semi-quantitative risk assessment[2]
Pome	Apple	Moderate	NA
	Pears	Lower	Lower (<50)
Stone	Peach	Moderate	NA
Small	Strawberries	Moderate	Higher (>100)
	Blackberries	Lower	Higher (>100)
	Raspberries	Moderate	Higher (>100)
	Blueberries	Moderate	Higher (>100)
	Cranberries	Lower	NA
	Grapes	Moderate	Higher (>100)
Subtropical	Grapefruit	Lower	Lower (<50)
	Oranges	Lower	NA
	Lemons	Lower	Lower (<50)
Tropical	Mango	Lower	Lower (<50)
	Papaya	Lower	NA
	Bananas	Moderate	NA
	Coconuts	Lower	NA
	Pineapple	Lower	Lower (<50)
Vegetable (flower)	Broccoli	Lower	Higher (>100)
Vegetable (Leafy)	Cabbage	Lower	Higher (>100)
	Watercress	Lower	NA
	Artichoke	Lower	NA
	Lettuce	Higher	Higher (>150)
	Spinach	Higher	Higher (>150)
Vegetable (stem)	Asparagus	Lower	NA
	Celery	Moderate	NA
Fruiting Vegetables (Mature)	Tomato (field)	Moderate	*(Undifferentiated from "shed")*
	Tomato (shed)	Higher	Higher (>100)
	Pepper	Moderate	Lower (<50)
	Watermelon	Lower	Higher (>100)
	Cantaloupe (field)	Lower	*(Undifferentiated from "shed")*
	Cantaloupe (shed)	Moderate	Higher (>100)
	Honeydew	Lower	Higher (>100)
Fruiting Vegetables (immature)	Summer Squash	Lower	NA
	Peas	Moderate	NA
	Cucumbers	Moderate	NA
Roots	Carrot	Moderate	Lower (<50)
Tuber	Potato	Lower	NA
Bulbs	Green onion	Lower	Moderate (>50, <100)
	Onion	Moderate	NA
Herbs	Cilantro	Higher	Higher (>100)
	Parsley	Moderate	Higher (>100)
	Basil	Lower	Higher (>100)
Sprouts	Sprouts	Moderate	Moderate (>50, <100)

Fungi	Mushrooms	Lower	Lower (<50)
Tree Nuts	Walnuts	Lower	Lower (<50)
	Almonds	Lower	NA

[1] Data from this assessment, see table 13.
[2] See Risk Score by Commodity chart above; values in parentheses are the commodity risk scores. To allow comparison, the scoring was grouped into Higher (risk score > 100), Moderate (risk score >50 but <100), and Lower (risk score <50).

This comparison shows that of the total 44 commodities evaluated in this assessment, there were 27 commodities that were also evaluated in the FDA-RTI assessment. Of these 27 commodities, approximately 44% (12/27) scored similarly. Among the 15 commodities that did not have the same qualitative score, 13 received higher scores using the FDA-RTI semi-quantitative method and 2 received a higher score using the FDA qualitative risk assessment method. It should be noted that the differences in rankings attributed for 15 of the commodities is not surprising considering the different criterion used by each tool to attribute risk. For example, the RTI Fresh Produce Risk Ranking Tool focuses more on the strength of epidemiological evidence and severity of illness or deaths associated with each pathogen/commodity pair which is largely associated with the pathogen of concern (e.g. prevalence and consumption rates) as well as commodity characteristics that may affect pathogen prevalence (and perhaps growth). In general, the RTI rankings were higher than that of the FDA Qualitative Assessment of Risk (QAR) due to the incorporation of this epidemiological data which increased the rankings for commodities that have been associated with one or more outbreaks. The FDA QAR did not integrate data associated with the amount of epidemiological evidence nor severity of illness associated with each commodity/pathogen pairs linked to outbreaks, but attributed risk for each commodity by focusing mainly on the common growing practices that may be likely to contribute to the on-farm contamination of that produce item, as well as consumption patterns and consumer behaviors associated with the consumption of each commodity.